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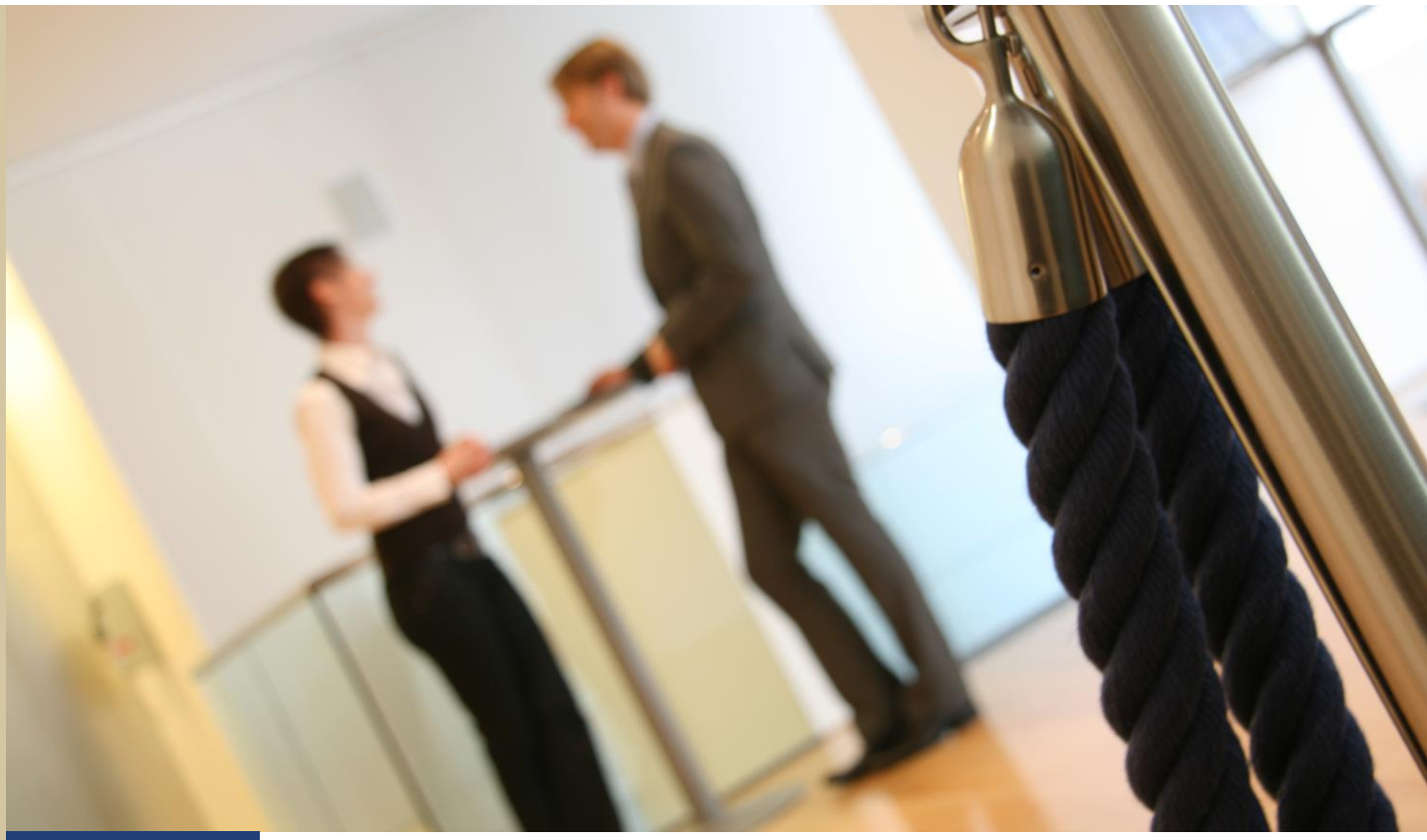
DOCUMENTATION

ENHANCING LAW ENFORCEMENT COOPERATION TO REDUCE DRUG SUPPLY



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I

(Resolutions, recommendations and opinions)

RECOMMENDATIONS

COUNCIL

EU Drugs Strategy (2013-20)

(2012/C 402/01)

PREFACE

1. This EU Drugs Strategy provides the overarching political framework and priorities for EU drugs policy identified by Member States and EU institutions, for the period 2013-20. The framework, aim and objectives of this Strategy will serve as a basis for two consecutive 4-year EU Drugs Action plans.

2. This Drugs Strategy is based first and foremost on the fundamental principles of EU law and, in every regard, upholds the founding values of the Union: respect for human dignity, liberty, democracy, equality, solidarity, the rule of law and human rights. It aims to protect and improve the well-being of society and of the individual, to protect public health, to offer a high level of security for the general public and to take a balanced, integrated and evidence-based approach to the drugs phenomenon.

3. The Strategy is also based on international law, the relevant UN Conventions [1] which provide the international legal framework for addressing the illicit drugs phenomenon and the Universal Declaration on Human Rights. This EU Drugs Strategy takes into account relevant UN political documents, including the UN Political Declaration and Action Plan on International Cooperation towards an Integrated and Balanced Strategy to Counter the World Drug Problem, adopted in 2009, which states that drug demand reduction and drug supply reduction are mutually reinforcing elements in illicit drugs policy and the UN Political Declaration on HIV/AIDS. The Strategy has been drafted on the basis of the principles set out in the Lisbon Treaty and on the respective competences of the Union and individual Member States. Due regard is given to subsidiarity and proportionality, as this EU Strategy intends to add value to national strategies. The Strategy shall be implemented in accordance with these principles and competencies. Furthermore, the Strategy respects fully the European Convention on Human Rights and the EU Charter of Fundamental Rights.

4. By 2020, the priorities and actions in the field of illicit drugs, encouraged and coordinated through this EU Drugs Strategy, should have achieved an overall impact on key aspects of the EU drug situation. They shall ensure a high level of human health protection, social stability and security, through a coherent, effective and efficient implementation of measures, interventions and approaches in drug demand and drug supply reduction at national, EU and international level, and by minimising potential unintended negative consequences associated with the implementation of these actions.

5. The drugs phenomenon is a national and international issue that needs to be addressed in a global context. In this regard, coordinated action carried out at EU level plays an important role. This EU Drugs

[1] The UN Single Convention on Narcotic Drugs of 1961 as amended by the 1972 protocol, the Convention on Psychotropic Substances (1971) and the Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances (1988).

Strategy provides a common and evidence-based framework for responding to the drugs phenomenon within and outside the EU. By providing a framework for joint and complementary actions, the Strategy ensures that resources invested in this area are used effectively and efficiently, whilst taking into account the institutional and financial constraints and capacities of Member States and of the EU institutions.

6. The Strategy aims to contribute to a reduction in drug demand and drug supply within the EU, as well as a reduction as regards the health and social risks and harms caused by drugs through a strategic approach that supports and complements national policies, that provides a framework for coordinated and joint actions and that forms the basis and political framework for EU external cooperation in this field. This will be achieved through an integrated, balanced and evidence-based approach.

7. Finally, this Strategy builds on the lessons learned from the implementation of previous EU Drugs Strategies and associated Action Plans, including the findings and recommendations from the external evaluation of the EU Drugs Strategy 2005-12, while taking into account other relevant policy developments and actions at EU level and international level in the field of drugs.

I. **Introduction**

8. The Strategy takes on board new approaches and addresses new challenges which have been identified in recent years, including:

— the increasing trend towards poly-substance use, including the combination of licit substances, such as alcohol and prescribed controlled medication, and illicit substances;

— the trends towards non-opioid drug use as well as the emergence and spread of new psychoactive substances;

— the need to ensure and improve access to prescribed controlled medications;

— the need to improve the quality, coverage and diversification of drug demand reduction services;

— the continued high incidence of blood-borne diseases, especially hepatitis C virus, among injecting drug users and potential risks of new outbreaks of HIV infections and other blood-borne diseases related to injecting drugs use;

— the continuing high prevalence of numbers of drug-related deaths within the EU;

— the need to target drug use through an integrated health care approach addressing — inter alia — psychiatric co-morbidity;

— the dynamics in the illicit drug markets, including shifting drug trafficking routes, cross-border organised crime and the use of new communication technologies as a facilitator for the distribution of illicit drugs and new psychoactive substances;

— the need to prevent diversion of precursors, pre-precursors and other essential chemicals used in the illicit manufacture of drugs from legal trade to the illicit market and the diversion of certain chemicals used as cutting agents.

9. The objectives of the EU Drugs Strategy are:

— to contribute to a measurable reduction of the demand for drugs, of drug dependence and of drug-related health and social risks and harms;

— to contribute to a disruption of the illicit drugs market and a measurable reduction of the availability of illicit drugs;

— to encourage coordination through active discourse and analysis of developments and challenges in the field of drugs at EU and international level;

— to further strengthen dialogue and cooperation between the EU and third countries and international organisations on drug issues;

— to contribute to a better dissemination of monitoring, research and evaluation results and a better understanding of all aspects of the drugs phenomenon and of the impact of interventions in order to provide sound and comprehensive evidence-base for policies and actions.

10. The Strategy builds upon the achievements [1] made by the EU in the field of illicit drugs and is informed by an ongoing, comprehensive assessment of the current drug situation in particular that provided by the EMCDDA, while recognising the need to proactively respond to developments and challenges.

11. The Strategy is structured around two policy areas; drug demand reduction and drug supply reduction, and three cross-cutting themes: (a) coordination, (b) international cooperation and (c) research, information, monitoring and evaluation. Its two consecutive Action Plans, drafted by corresponding Presidencies in 2013 and 2017, will provide a list of specific actions with a timetable, responsible parties, indicators and assessment tools.

12. Taking due account of the current drugs situation and the implementation needs of the Strategy, a limited number of targeted actions will be selected on each of the two policy areas and three cross-cutting themes, for inclusion in the Action Plans based on criteria which include the following:

(a) actions must be evidence-based, scientifically sound and cost-effective, and aim for realistic and measurable results that can be evaluated;

(b) actions will be time-bound, have associated benchmarks, performance indicators and identify responsible parties for their implementation, reporting and evaluation;

(c) actions must have a clear EU relevance and added value.

13. To safeguard a continued focus on the implementation of the Strategy and of its accompanying Action Plans, each Presidency, with the support of the Commission and the technical input from EMCDDA and Europol shall address priorities and actions that require follow up in the HDG during its term and shall monitor progress. The Commission, taking into account information provided by the Member States, the European External Action Service (EEAS), and available from the EMCDDA, Europol and other EU bodies, as well as from the civil society, shall provide biannual progress reports, with the purpose of assessing the implementation of objectives and priorities of the EU Drugs Strategy and its Action Plan(s).

14. The Commission, taking into account information provided by the Member States and available from the EMCDDA, Europol, other relevant EU institutions and bodies and civil society, will initiate an external midterm assessment of the Strategy by 2016, in view of preparing a second Action Plan for the period 2017-20. Upon conclusion of the Drugs Strategy and its Action Plans by 2020, the Commission will initiate an overall external evaluation of their implementation. This evaluation should also take into account information gathered from the Member States, the EMCDDA, Europol, other relevant EU institutions and bodies, civil society, and previous evaluations in order to provide input and recommendations for the future development of EU drugs policy.

15. To reach its objectives and to ensure efficiency, the EU Drugs Strategy 2013-20 will use, wherever possible, existing instruments and bodies operating in the drug field, within the respective mandate, or that have relevance for key aspects of it, both within the EU (in particular the EMCDDA, Europol, Eurojust, the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) and collaboration with bodies outside the EU (such as UNODC, WCO, WHO and the Pompidou Group). The Commission, the High Representative, the Council, the European Parliament will ensure that the EU's activities in the field of illicit drugs are coordinated and that they complement each other.

[1] Report on the independent assessment of the EU Drugs Strategy 2005-12 and its action plans (http://ec.europa.eu/justice/anti-drugs/files/rand_final_report_eu_drug_strategy_2005-2012_en.pdf)

16. Appropriate and targeted resources should be allocated for the implementation of the objectives of this EU Drugs Strategy at both EU and national level.

II. **Policy field: drug demand reduction**

17. Drug demand reduction consists of a range of equally important and mutually reinforcing measures, including prevention (environmental, universal, selective and indicated), early detection and intervention, risk and harm reduction, treatment, rehabilitation, social reintegration and recovery.

18. In the field of drug demand reduction, the objective of the EU Drugs Strategy 2013-20 is to contribute to the measurable reduction of the use of illicit drugs, to delay the age of onset, to prevent and reduce problem drug use, drug dependence and drug-related health and social risks and harms through an integrated, multidisciplinary and evidence-based approach, and by promoting and safeguarding coherence between health, social and justice policies.

19. In the field of drug demand reduction, the following priorities (not listed in the order of priority) are identified.

19.1. Improve the availability, accessibility and coverage of effective and diversified drug demand reduction measures, promote the use and exchange of best practices and develop and implement quality standards in prevention (environmental, universal, selective and indicated), early detection and intervention, risk and harm reduction, treatment, rehabilitation, social reintegration and recovery.

19.2. Improve the availability and effectiveness of prevention programmes (from initial impact to long-term sustainability), and raise awareness about the risk of the use of illicit drugs and other psycho-active substances and related consequences. To this end, prevention measures should include early detection and intervention, promotion of healthy lifestyles and targeted prevention (i.e. selective and indicated) directed also at families and communities.

19.3. Scale up and develop effective demand reduction measures to respond to challenges such as: polydrug use including the combined use of licit and illicit substances, misuse of prescribed controlled medications and the use of new psychoactive substances.

19.4. Invest in and further research on effective risk and harm reduction measures aimed at substantially reducing the number of direct and indirect drug-related deaths and infectious blood-borne diseases, associated with drug use, but not limited to, HIV and viral hepatitis as well as sexually transmittable diseases and tuberculosis.

19.5. Expand the availability, accessibility and coverage of effective and diversified drug treatment across the EU to problem and dependent drug users including non-opioids users, so that all those who wish to enter drug treatment can do so, according to relevant needs.

19.6. Scale up the development, availability and coverage of drug demand reduction measures in prison settings, as appropriate and based on a proper assessment of the health situation and the needs of prisoners, with the aim of achieving a quality of care equivalent to that provided in the community and in accordance with the right to health care and human dignity as enshrined in the European Convention on Human Rights and the EU Charter of Fundamental Rights. Continuity of care should be ensured at all stages of the criminal justice system and after release.

19.7. Develop and expand integrated models of care, covering needs related to mental and/or physical health-related problems, rehabilitation and social support in order to improve and increase the health and social situation, social reintegration and recovery of problem and dependent drug users, including those affected by co-morbidity.

19.8. Develop effective and differentiated drug demand reduction measures that aim to reduce and/or delay the onset of drug use and that are appropriate to the needs of specific groups, patterns of drug use and settings, with particular attention to be paid to vulnerable and marginalised groups.

19.9. Prevent local and regional drug use epidemics, which may threaten the public health within the EU by ensuring coordinated and effective common approaches.

19.10. Drug demand reduction priorities need to take into account the specific characteristics, needs and challenges posed by the drug phenomenon at national and EU level. It is imperative that an appropriate level of resources is provided for that purpose at local, national and EU level.

III. **Policy field: drug supply reduction**

20. Drug supply reduction includes the prevention and dissuasion and disruption of drug-related, in particular organised, crime, through judicial and law enforcement cooperation, interdiction, confiscation of criminal assets, investigations and border management.

21. In the field of drug supply reduction, the objective of the EU Drugs Strategy 2013-20 is to contribute to a measurable reduction of the availability of illicit drugs, through the disruption of illicit drug trafficking, the dismantling of organised crime groups that are involved in drug production and trafficking, efficient use of the criminal justice system, effective intelligence-led law enforcement and increased intelligence sharing. At EU level, emphasis will be placed on large-scale, cross-border and organised drug-related crime.

22. In the field of drug supply reduction, the following priorities (not listed in the order of priority) are identified.

22.1. Strengthen the cooperation and coordination between law enforcement agencies at strategic and operational level. This should include, but not be limited to, improving cross-border exchange of information (and intelligence) in real time, best practices and knowledge, as well as conducting joint operations and investigations. Cooperation with third countries as regards tackling drug-related organised crime operating towards and within the EU should be seen as important in this respect.

22.2. Reduce intra-EU and cross-border production, smuggling, trafficking, distribution and sale of illicit drugs and the facilitation of such activities, as well as reduce the diversion of drug precursors, pre-precursors and other essential chemicals used in the illicit manufacture of drugs.

22.3. Respond effectively to the evolving trends, such as the diversion of certain chemicals utilised as cutting agents for illicit drugs and the supply of drugs through the use of new technology.

22.4. Special attention must be given to new communication technologies as having a significant role as a facilitation for the production, marketing, trafficking and distribution of drugs (including controlled new psychoactive substances).

22.5. Member States shall continue to cooperate, and coordinate — where appropriate — their actions at EU level, together with relevant EU and international bodies and agencies, such as Europol, Eurojust, EMCDDA and fully exploit existing instruments and methods provided in the field of judicial and law enforcement cooperation, such as intelligence-led policing, drug profiling, Joint Investigation Teams, Joint Customs and Police Operations and relevant initiatives such as the EMPACT projects, Liaison Officer Platforms and through the use of regional platforms.

22.6. At EU level, emphasis shall be placed on intelligence-led law enforcement aimed at targeting large-scale drug production and trafficking. Closer coordination and cooperation between law enforcement agencies within and between Member States as well as with Europol should be further strengthened.

22.7. Where necessary, when such tasks are not initiated or implemented through Europol, ad hoc regional collaboration initiatives or platforms may be created within the EU, to counter emerging threats from shifting drug trafficking routes and emerging organised crime hubs. This shall be done by means of coordinated operation responses. Such actions need to be compatible with and complementary to existing legal and operational arrangements at EU level and shall be based on threat assessments and analysis. Such cooperation structures should be flexible, may have a temporary lifespan depending on the future development of the specific threat that they address and work in close cooperation with all relevant EU agencies and platforms, in particular with Europol.

22.8. Strengthen, where deemed necessary, the EU drug-related judicial and law enforcement cooperation and the use of existing practices by establishing faster and more accurate responses. Support judicial and law enforcement cooperation activities and exchange of information and intelligence.

22.9. Reinforce the European Union's legislative framework in a targeted way as deemed necessary so as to strengthen the EU response in dealing with new trends, ensure that collaborative efforts complement each other with a view to dismantle cross-border organised crime groups, confiscate the proceeds of drug-related crime by fully utilising the EU network of asset recovery offices and thus ensure a more effective response to drug trafficking. The further development of relevant law enforcement instruments can be explored.

22.10. The EU shall work towards more effective policies in the field of drug supply reduction, by reinforcing policy evaluation and analysis to improve the understanding of drug-markets, drug-related crimes and the effectiveness of drug-related law enforcement responses.

22.11. In order to prevent crime, avoid recidivism and enhance the efficiency and effectiveness of the criminal justice system while ensuring proportionality, the EU shall encourage, where appropriate, the use, monitoring and effective implementation of drug policies and programmes including arrest referral and appropriate alternatives to coercive sanctions (such as education, treatment, rehabilitation, aftercare and social reintegration) for drug-using offenders.

IV. **Cross-cutting theme: coordination**

23. In the field of EU drugs policy, the objective of coordination is twofold, namely to ensure synergies, communication and an effective exchange of information and views in support of the policy objectives, while at the same time encouraging an active political discourse and analysis of developments and challenges in the field of drugs at EU and international levels.

Coordination is required within and among EU institutions, Member States, other relevant European bodies and civil society on the one hand, and between the EU, international bodies and third countries on the other hand.

24. In the field of coordination, the following priorities (not listed in the order of priority) are identified.

24.1. Ensure synergies, coherence and effective working practices among relevant Member States, EU institutions, bodies and initiatives, based on the principle of sincere cooperation ([1]), avoiding duplication of efforts, securing efficient exchange of information, using resources effectively and guaranteeing continuity of actions across Presidencies.

24.2. Given the role of the HDG as the main drugs coordinating body within the Council, its coordinating efforts need to be further strengthened to take account of the work of the various bodies, that include a drugs component such as the Standing Committee on Operational Cooperation on Internal Security (COSI) and the Working Party on Public Health. In addition, the balanced approach to the drugs

([1]) TEU article 4.

problem, targeting with equal vigour the demand for and the supply of drugs, requires close cooperation, interaction and information exchange with relevant other Council preparatory bodies including those in the area of external action and other relevant EU initiatives, in the areas of judicial and criminal matters, law enforcement, public health, social affairs.

24.3. Ensure that the EU and Member States further develop and implement working methods and best practices for multidisciplinary cooperation in support of the objectives of the Strategy and that these are promoted at national level.

24.4. Provide opportunities under each Presidency to discuss, monitor and evaluate issues of coordination, cooperation, emerging trends, effective interventions and other policy developments of added value to the EU Drugs Strategy for instance during the National Drugs Coordinators' Meetings.

24.5. Promote and encourage the active and meaningful participation and involvement of civil society, including non-governmental organisations as well as young people, drug users and clients of drug-related services, in the development and implementation of drug policies, at national, EU and international level. Also to ensure the engagement with the EU Civil Society Forum on Drugs at EU and international level.

24.6. Ensure that the EU speaks with one strong voice in international forums such as the Commission on Narcotic Drugs (CND) and in dialogues with third countries, promoting the integrated, balanced and evidence-based EU approach to drugs. In this framework, the EU Delegations can play a useful role in promoting such approach in the field of drugs and in facilitating a coherent discourse on drugs policy.

V. **Cross-cutting theme: international cooperation**

25. International cooperation is a key area where the EU adds value to Member States efforts in coordinating drug policies and addressing challenges. The EU external relations in the field of drugs are based on the principles of shared responsibility, multilateralism, an integrated, balanced and evidence-based approach, the mainstreaming of development, respect for human rights and human dignity and respect for international conventions.

26. The objective of the EU Drugs Strategy 2013-20 in the field of international cooperation, is to further strengthen dialogue and cooperation between the EU and third countries and international organisations on drug issues in a comprehensive and balanced manner.

27. The EU Drugs Strategy is part of an overall approach that enables the EU to speak with one voice in the international arena and with the partner countries. The EU will remain committed to international cooperation and debate on the fundamentals of drug policy, and actively share the achievements of the EU approach in drug policy that is balanced between drug demand reduction and drug supply reduction, based on scientific evidence and intelligence as well as respecting human rights.

This requires coherence between policies and actions at the EU level, including external cooperation on drug demand reduction, including risk and harm reduction, drug supply reduction, alternative development, the exchange and transfer of knowledge and the involvement of both state and non-state actors.

28. The EU and its Member States should guarantee the integration of the EU Drugs Strategy and its objectives within the EU's overall foreign policy framework as part of a comprehensive approach that makes full use of the variety of policies and diplomatic, political and financial instruments at the EU's disposal in a coherent and coordinated manner. The High Representative supported by the EEAS should facilitate this process.

29. The EU external action approach in the field of drugs aims to further strengthen and support third countries' efforts to deal with the challenges to public health, safety and security. This will be done through the implementation of initiatives set out in this Strategy and subsequent action plans, including alternative development, drug demand reduction, drug supply reduction, the promotion and protection of human rights and also taking into account regional initiatives. Given the impact of drug production and trafficking on the internal stability and security situation in source and transit countries, actions will also target corruption, money laundering and the proceeds of drug-related crime.

30. In the field of international cooperation, the following priorities (not listed in the order of priority) are identified.

30.1. Improve coherence between the internal and external aspects of the EU drugs policies and responses towards third countries in the field of drugs.

30.2. Increase the EU's engagement and coordination in the international drug policy discourse, both in respect of negotiations with international organisations and structures including the UN, G8 and the Council of Europe and relations with third countries by achieving common EU positions, and ensure an effective role within the UN drug policy process.

30.3. Ensure that international cooperation in the field of drugs is integrated within the overall political relations and framework agreements between the EU and its partners, both at national and/or regional level. It should reflect the integrated, balanced and evidence-based EU approach and include: political dialogue, drug coordination, demand reduction (including risk and harm reduction), supply reduction including alternative development and law enforcement, integration of drug policies within the broader development cooperation agenda, information, research, monitoring and evaluation.

30.4. Ensure that the EU international response and actions in priority third countries and regions around the world are comprehensive taking into account every dimension of the drug phenomenon, and address the development, stability and security of these countries and regions through enhanced partnership.

30.5. Ensure that the EU international drug response is evidence-based and includes a monitoring process on the situation and progress involving different information tools from the Commission, EEAS, including the EU Delegations, Member States, EMCDDA, Europol, Eurojust and the European Centre for Disease Prevention and Control in close cooperation with UNODC.

30.6. Ensure that support to the candidate and potential candidate countries, and the countries of the European Neighbourhood Policy, focuses on capacity-building on both supply and demand reduction and evidence-based, effective and balanced drug policies, through strengthened cooperation including sharing of EU best practices and participation, where appropriate, in EU agencies, such as the EMCDDA, Europol and Eurojust.

30.7. Ensure a sustainable level of policy dialogue and information sharing on the strategies, aims and relevant initiatives through the dialogues on drugs with international partners, both at regional and bilateral level. Key partners are identified on the basis of their status of cooperation with the EU and their relevance in addressing the global illicit drug phenomenon while taking account of partners emerging as a result of developments in the drug situation. The Political Dialogues should be complementary to and coherent with other external cooperation structures and their impact and, where appropriate, provide a forum for discussing priorities on cooperation and progress on EU-funded projects.

30.8. Ensure an appropriate level of funding and expertise (provided for by the EU and its Member States) including by reinforcing coordination, monitoring and evaluation of financial and technical support,

while striving for synergies and by continuously balancing the transparent allocation of cooperation, resources, financial and technical assistance, between drug demand and drug supply reduction measures reflecting the EU approach. The EU should work towards providing relevant expertise in EU Delegations to support the implementation of measures targeting third countries in the field of drugs. The midterm review and final assessment of this EU Drugs Strategy should reflect on the impact of EU spending in third countries and the Commission and the EEAS should provide updates on priorities and progress on the EU spending overseas to Member States when appropriate.

30.9. When providing financial and technical support to source countries, the EU and Member States shall ensure, in particular, that alternative development programmes:

— are non-conditional, non-discriminating and, if eradication is scheduled, properly sequenced,

— set realistic rural development-related objectives and indicators for success, ensuring ownership among target communities and

— support local development, while considering interactions with factors such as human security, governance, violence, human rights, development and food security.

30.10. Ensure that the protection of human rights is fully integrated in political dialogues and in the implementation and delivery of relevant programs and projects in the field of drugs.

VI. **Cross-cutting theme: information, research, monitoring and evaluation**

31. The objective of the EU Drugs Strategy 2013-20 in the field of information, research, monitoring and evaluation is to contribute to a better understanding of all aspects of the drugs phenomenon and of the impact of measures in order to provide sound and comprehensive evidence for policies and actions. Furthermore, the EU Drugs Strategy 2013-20 aims to contribute to a better dissemination of monitoring, research and evaluation results at EU and national level ensuring the strengthening of synergies, a balanced allocation of financial resources and avoiding duplication of efforts. This can be achieved through harmonisation of methodologies, networking and closer cooperation.

32. In the field of information, research, monitoring and evaluation the following priorities (not listed in the order of priority) are identified.

32.1. The EU and its Member States should continue to invest in information exchange, data collection and monitoring, and in research and evaluation of the drug situation and responses to it at national and EU level. This should cover all relevant aspects of the drug phenomenon, including drug demand and drug supply. Particular emphasis should be placed on maintaining and further enhancing data collection and reporting through the EMCDDA key indicators in drug demand reduction.

32.2. The EMCDDA should, within its mandate, further enhance the knowledge infrastructure and should continue to play a key role as the central facilitator, supporter and provider of information, research, monitoring and evaluation of illicit drugs across the EU. It should continue to provide a timely, holistic and comprehensive analysis of the European drugs situation and of responses to it, and collaborate with other relevant agencies, including, when relevant and appropriate, the European Centre for Disease Control (ECDC) and the European Medicines Agency (EMA) and WHO.

32.3. Europol should continue its efforts as regards information gathering and analysis in the area of drug-related organised crime, while Member States should deliver relevant information to the Agency. The Agency should continue the regular delivery of threat assessment reports (e.g. EU SOCTA) on EU drug-related organised crime.

32.4. Member States, EU institutions and agencies should enhance information and data collection on all aspects of drug supply, including on drug markets, drug-related crimes and drug supply reduction with the aim to improve analysis and informed decision making. Member States, the Commission, EMCDDA, Europol and — where appropriate — other EU agencies should work together to improve data collection and the development of policy-relevant and scientifically sound indicators.

32.5. The EU institutions, bodies and Member States should improve the capacity to detect, assess and respond rapidly and effectively to the emergence of new psychoactive substances, to behavioural changes in drugs consumption and epidemic outbreaks and to other emerging trends that pose risks to public health and safety. This can be achieved, inter alia, through the strengthening of existing EU legislation, the exchange of information, intelligence, knowledge and best practices.

32.6. Member States, EU institutions and agencies should promote and support research, including applied research, into new psychoactive substances and ensure cooperation and coordination between networks at national and EU level in order to strengthen the understanding of the phenomenon. Monitoring in this area should be scaled up in close coordination with the EMCDDA. In particular, emphasis should be placed on developing forensic and toxicological capacity as well as on improving the availability of epidemiological information.

32.7. Member States should continue efforts to maintain the achievements made within the EU in terms of monitoring and information exchange, including through the Reitox Network of National Focal Points, while supporting the further development of EU standardised data collection and analysis in the areas of drug demand and drug supply.

32.8. Ensure adequate financing for drug-related research and development projects at EU and national level, according to financial resources including through the EU financial programmes covering the period 2014-20. Projects supported at EU level should take into account the priorities of the Strategy and its Action Plans and deliver a clear EU added value, ensuring coherence and synergies while avoiding duplication within programmes and with EU bodies.

32.9. EU institutions, bodies and Member States should recognise the role of scientific evaluation of policies and interventions (with a focus on outcomes achieved) as a key element in strengthening of the EU approach to drugs, and should promote its use both at national, EU and international level.

32.10. Ensure and reinforce training of professionals involved with drug-related issues, both in the drug demand as well as the drug supply reduction field.

IV

(Notices)

NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

COUNCIL

EU ACTION PLAN ON DRUGS 2013-2016

(2013/C 351/01)

CONTENTS

Introduction

The use of illicit drugs and the misuse of drugs generally, is a major problem for individuals, families and communities across Europe. Apart from the health and social implications of drug misuse, the illicit drugs market constitutes a major element of criminal activity across European society and, indeed, on a global level.

In December 2012, the Council adopted the EU Drugs Strategy for 2013-2020. The Strategy aims to contribute to a reduction in drug demand and drug supply within the EU. It also aims to reduce the health and social risks and harms caused by drugs through a strategic approach that supports and complements national policies, that provides a framework for coordinated and joint actions and that forms the basis and political framework for EU external cooperation in this field. This will be achieved through an integrated, balanced and evidence-based approach.

The objectives of the Strategy are:

— to contribute to a measurable reduction of the use of drugs, of drug dependence and of drug-related health and social risks and harms,

— to contribute to a disruption of the illicit drugs market and a measurable reduction of the availability of illicit drugs,

— to encourage coordination through active discourse and analysis of developments and challenges in the field of drugs at EU and international level,

— to further strengthen dialogue and cooperation between the EU and third countries, international organisations and fora on drug issues,

— to contribute to a better understanding of all aspects of the drugs phenomenon and of the impact of interventions in order to provide a sound and comprehensive evidence-base for policies and actions.

This EU Drugs Action Plan, like the EU Drugs Strategy, is based on the fundamental principles of EU law and it upholds the founding values of the Union — respect for human dignity, liberty, democracy, equality, solidarity, the rule of law and human rights. It is also based on the UN conventions that provide the international legal framework to address, inter alia, the use of illicit drugs, as well as on the Universal Declaration on Human Rights.

The Plan sets out the actions that will be implemented to achieve the objectives of the Strategy. Actions are set out under the two policy areas of the Strategy:

— drug demand reduction, and

— drug supply reduction;

and the three cross-cutting themes of the Strategy:

— coordination,

— international cooperation, and

— information, research, monitoring and evaluation.

Actions are aligned to objectives of the EU Drugs Strategy 2013-2020. In drawing up the actions, account was taken of the need to be evidence-based, scientifically sound, realistic, time-bound and measurable with a clear EU relevance and added value. This Action Plan indicates timetables, responsible parties, indicators and data collection/assessment mechanisms.

Based on existing reporting mechanisms, a number of over-arching indicators are set out in Annex 1. These facilitate the measurement of the overall effectiveness of this EU Drugs Action Plan and do not involve an additional reporting burden. A number of these are referenced, as appropriate, across the Plan. Furthermore, throughout the Plan, indicators are set out that draw on programme, evaluative and other data sources. Utilisation of these indicators is dependent on data collection processes in each Member State or at EU institution level.

In line with the Strategy stipulation that its detailed implementation should be set out in two consecutive Action Plans, this Action Plan covers the four years from 2013 until 2016. A second Action Plan for the period 2017-2020 will be prepared following an external mid-term assessment of the EU Drugs Strategy by 2016 and taking account of any other relevant strategies and evaluations.

1. **Drug demand reduction**

Contribute to a measurable reduction in the use of illicit drugs, in problem drug use, in drug dependence and in drug-related health and social harms as well as contributing to a delay in the onset of drug use

Objective	Action	Timetable	Responsible party	Indicator(s)	Data collection/assessment mechanisms
1. Prevent drug use and, secondly, delay the onset of drug use	1. Improve the availability and effectiveness of prevention measures that take account of: (a) population risk factors such as age; gender; cultural and social factors; (b) situational risk factors such as homelessness; drug use in nightlife and recreational settings; the workplace; and driving under the influence of drugs; and (c) individual risk factors such as mental health; problem behaviour and psychosocial development; and other factors known to affect individual vulnerability to drug use such as genetic influences and family circumstances	Ongoing	MS	— Overarching indicators 1, 12 — Level of provision at MS level of evidence-based universal and environmental prevention measures — Level of provision at MS level of targeted prevention measures, including family- and community-based measures — Level of provision at MS level of indicated prevention measures	EMCDDA reporting Reitox national reports MS reporting on results of measures
	2. In addition to the prevention of drug use, strengthen and better target prevention and diversionary measures to delay the age of first use of illicit drugs	Ongoing	MS	— Overarching indicators 1, 5, 12 — Level of provision at MS level of evidence-based prevention and diversionary measures that target young people in family, community, and formal/non-formal education settings	EMCDDA reporting MS reporting on results of measures
	3. Raise awareness of the risks and consequences associated with the use of illicit drugs and other psychoactive substances	Ongoing	MS COM EMCDDA	— Overarching indicators 5, 12 — Level of awareness in general and youth populations of healthy lifestyles and of the risks and consequences of the use of illicit drugs and other psychoactive substances	EMCDDA reporting Eurobarometer surveys ESPAD HBSC

Objective	Action	Timetable	Responsible party	Indicator(s)	Data collection/assessment mechanisms
	4. Enable a more informed response to the challenge of the misuse of prescribed and 'over the counter' opioids and other psychoactive medicines	2014-2016	MS HDG EMA EMCDDA	— Collation of data by MS on levels and patterns of prescribing of psychoactive medicines by end-2014 — Number of initiatives that focus on the promotion of appropriate use of prescribed and 'over the counter' opioids and other psychoactive medicines	MS reporting Report of ALICE RAP project
2. Enhance the effectiveness of drug treatment and rehabilitation, including services for people with co-morbidity, to reduce the use of illicit drugs; problem drug use; the incidence of drug dependency and drug-related health and social risks and harms and to support the recovery and social re/integration of problematic and dependent drug users	5. Develop and expand the diversity, availability, coverage and accessibility of comprehensive and integrated treatment services including those which address polydrug use (combined use of illicit and/or licit substances including alcohol)	Ongoing	MS	— Overarching indicators 1, 6, 11 — Extent of the diversity of comprehensive and integrated treatment services at MS level including those which address polydrug use — MS data on treatment retention and outcomes	EMCDDA reporting Reitox national reports EMCDDA Best practice portal
	6. Expand the provision of rehabilitation/recovery services with an emphasis on services that: (a) focus on providing a continuum of care through case management and interagency collaboration for individuals; (b) focus on supporting the social re/integration (including the employability) of problem and dependent drug users; and (c) strengthen the diagnostic process and the treatment of psychiatric and physical co-morbidity involving drug use	Ongoing	MS	— Overarching indicator 11 MS data on: — Extent of increase in rehabilitation/recovery services adopting case management and inter-agency approaches — Extent of increase in the number of programmes, specifically targeted at drug users with co-morbidity, involving partnerships between both mental health and drug rehabilitation/recovery services — Level and duration of abstentions from consumption of illicit and/or licit drugs by people leaving drug treatment — Availability of treatment options to meet needs of people who experience relapses to drug use	EMCDDA reporting MS reporting on results of services

Objective	Action	Timetable	Responsible party	Indicator(s)	Data collection/assessment mechanisms
	7. Ensure that treatment and outreach services incorporate greater access to risk and harm reduction options to lessen the negative consequences of drug use and to substantially reduce the number of direct and indirect drug-related deaths and infectious blood-borne diseases associated with drug use but not limited to HIV and viral hepatitis, as well as sexually transmittable diseases and tuberculosis	Ongoing	MS	— Overarching indicators 2, 3, 4, 11 — Extent of increased availability of and access to evidence-based risk and harm reduction measures in MS	EMCDDA reporting Reitox national reports MS reporting on services
	8. Scale up the development, availability and coverage of health care measures for drug users in prison and after release with the aim of achieving a quality of care equivalent to that provided in the community	Ongoing	MS	— Overarching indicator 10 — Availability of services for drug users in prisons and the extent to which prison health care policies and practices incorporate care models comprising best practices in needs assessment and continuity of care for prisoners during imprisonment — Extent of decrease in drug-related physical and mental health problems amongst prisoners — Extent to which prison-based services and community-based services provide continuity of care for prisoners upon release with particular emphasis on avoiding drug overdoses	EMCDDA reporting Reitox national reports MS reporting on services
3. Embed coordinated, best practice and quality approaches in drug demand reduction	9. Agree and commence the implementation of EU minimum quality standards, that help bridge the gap between science and practice, for: (a) environmental, universal, selective and indicated prevention measures; (b) early detection and intervention measures;	2014-2016	Council HDG MS COM EMCDDA	— Consensus achieved by MS on minimum quality standards building on previous EU preparatory studies	EMCDDA Best practice portal COM biennial progress report

Objective	Action	Timetable	Responsible party	Indicator(s)	Data collection/assessment mechanisms
	(c) risk and harm reduction measures; and (d) treatment, rehabilitation, social integration and recovery measures				

2. **Drug supply reduction**

Contribute to a measurable reduction of the availability and supply of illicit drugs in the EU

Objective	Action	Timetable	Responsible party	Indicator(s)	Data collection/assessment mechanisms
4. Enhance effective law enforcement coordination and cooperation within the EU to counter illicit drug activity, in coherence, as appropriate, with relevant actions determined through the EU policy cycle	10. Utilise to best effect available intelligence and information-sharing law enforcement instruments, channels and communication tools used to collate and analyse drug-related information	Ongoing	MS Europol Eurojust COSI	— Overarching indicator 7 — Extent of high impact intelligence led and targeted activities, of joint operations, joint investigation teams and cross-border cooperation initiatives focusing on criminal organisations engaged in illicit drug activity — Increased use of Europol's drug-related information sharing, analysis and expert systems — Results achieved from EMPACT projects and bilateral and multilateral initiatives	EMCDDA reporting EU agencies reporting EMPACT driver reports
	11. Identify and prioritise the most pressing threats associated with drug-related organised crime	2014	Council COSI Europol MS COM	— EU policy cycle and crime priorities for 2014-2017 in place	Council conclusions on EU policy cycle EU SOCTA EMPACT evaluation
	12. Strengthen CEPOL's training for law enforcement officers in relation to illicit drug production and trafficking, particularly training methods and techniques:	2014-2016	MS CEPOL Europol COSI COM	— Training needs assessment carried out by end-2014 — Availability and uptake of relevant training courses — Number of law enforcement officers trained and effectively deployed as a result	COM biennial progress report CEPOL annual report CEPOL Curricula EMPACT evaluation

Objective	Action	Timetable	Responsible party	Indicator(s)	Data collection/assessment mechanisms
	(a) to combat the use of new communication technologies in illicit drug production and trafficking; (b) to enhance asset confiscation; (c) to combat money laundering; and (d) to detect and dismantle illicit clandestine laboratories and cannabis cultivation sites				
	13. Improve counter narcotic activities through strengthening and monitoring the effectiveness of regional information-sharing platforms and regional security-sharing platforms with the aim of disrupting and suppressing emerging threats from changing drug trafficking routes	Ongoing	COM MS Europol COSI Regional information-sharing platforms Regional security-sharing platforms	— Overarching indicator 7 — Number of intelligence led activities leading to the disruption and suppression of drug trafficking routes — Level of information sharing through effective activity of the liaison officer network	EMCDDA reporting Security/information-sharing platforms and evaluation reports EU SOCTA EMPACT evaluation
	14. Strengthen actions to prevent the diversion of drug precursors and pre-precursors for use in the illicit manufacture of drugs	Ongoing	MS Europol COM CUG COSI	— Number of cases and quantity of stopped or seized shipments of precursors intended for illicit use — Results achieved from EMPACT projects — Use of Pre-Export Notification (PEN) Online System and increased use of the Precursors Incident Communication System (PICS) — Number of joint follow-up meetings and other activities linked to the prevention of the diversion of precursors and pre-precursors	Reports from EU and MS law enforcement agencies EMPACT evaluation Driver reports

Objective	Action	Timetable	Responsible party	Indicator(s)	Data collection/assessment mechanisms
	15. Counter cross-border drug trafficking and improve border security notably at EU seaports, airports and land border crossing points through intensified efforts, including information and intelligence sharing, by relevant law enforcement agencies	Ongoing	MS Europol CCWP COSI	— Increased number of multi-disciplinary/multi-agency joint operations and cross-border cooperation initiatives — Number of effective memoranda of understanding (MOU) agreed between law enforcement agencies and relevant bodies such as airlines, air express couriers, shipping companies, harbour authorities and chemical companies — Results achieved from EMPACT projects — Improved intelligence and information sharing on cross-border drug trafficking utilising, inter alia, available border surveillance systems	COM biennial progress report EMPACT evaluation and driver reports MS reporting
	16. Develop and progressively implement key indicators on drug supply by standardising, improving and streamlining data collection in this field, building on currently available data	2013-2016	COM MS Council HDG EMCDDA Europol	— Roadmap developed and agreed on the implementation of key drug supply indicators — MS agreement reached on key drug supply indicators	Overview of existing supply data collection in MS EMCDDA reporting COM biennial progress report
5. Enhance effective judicial cooperation and legislation within the EU	17. Strengthen EU judicial cooperation in targeting cross-border drug trafficking, money laundering, and in the confiscation of the proceeds of drug-related organised crime	2013-2016	Council COM MS Eurojust	— Adoption and timely implementation of agreed EU measures and legislation on (a) confiscation and recovery of criminal assets; (b) money laundering; (c) approximation of drug trafficking offences and sanctions across the EU — Increased number of financial investigations and confiscations in relation to the proceeds of drug-related organised crime through EU judicial cooperation — Timely and effective responses to mutual assistance requests and European Arrest Warrants in relation to illicit drug trafficking	Eurojust reporting COM biennial progress report

Objective	Action	Timetable	Responsible party	Indicator(s)	Data collection/assessment mechanisms
	18. Introduce and adopt new EU legislative measures to address the emergence, use and rapid spread of new psychoactive substances	2013-2016	COM Council HDG MS	— EU legislation in place — Implementation of EU legislation in MS	COM biennial progress report
	19. Strengthen EU legislation on drug precursors to prevent their diversion without disrupting lawful trade	Ongoing	Council COM MS	— Adoption and implementation of regulations of the European Parliament and of the Council on drug precursors amending both Council Regulation (EC) No 111/2005 and Regulation (EC) No 273/2004	COM biennial progress report EU annual report on drug precursors
	20. Combat the use of certain pharmacologically active substances (as defined in Directive 2011/62/EU) as cutting agents for illicit drugs	Ongoing	MS COM EMA EMCDDA Europol	— Number of seizures of active substances used as cutting agents for illicit drugs — Timely implementation of new EU legislative requirements aimed at securing the supply chain for active substances under Directive 2011/62/EU, the Falsified Medicines Directive	Reports from the CCWP and CUG MS reporting
	21. Members States to provide, where appropriate and in accordance with their legal frameworks, alternatives to coercive sanctions (such as education, treatment, rehabilitation, aftercare and social integration) for drug-using offenders	2015	MS	— Increased availability and implementation of alternatives to prison for drug-using offenders in the areas of education, treatment, rehabilitation, aftercare and social integration — Increased monitoring, implementation and evaluation of alternatives to coercive sanctions	Reitox national reports
6. Respond effectively to current and emerging trends in illicit drug activity	22. Identify strategic responses to address the role of new communication technologies and the hosting of associated websites, in the production, marketing, purchasing and distribution of illicit drugs, including controlled new psychoactive substances	Ongoing	Council COM HDG MS Europol COSI	— Results achieved from law enforcement actions targeting drug-related crime via the Internet — Increased number of joint operations and cross-border cooperation initiatives	Progress review of EU policy cycle priorities EMPACT evaluation and driver reports MS reporting Reports from EU agencies

3. Coordination

Member States and EU to effectively coordinate drugs policy

Objective	Action	Timetable	Responsible party	Indicator(s)	Data collection/assessment mechanisms
7. Ensure effective EU coordination in the drugs field	23. Enhance information sharing between the HDG and other relevant Council Working Groups	Ongoing	PRES Council EEAS HDG	— Extent to which the EU Drugs Strategy/and Action Plan are taken into account in the programmes of other Council Working Groups including COAFR, COASI, COEST, COLAT and COWEB	Council Working Group reporting
	24. Each presidency may convene meetings of the National Drugs Coordinators, and of other groupings as appropriate, to consider emerging trends, effective interventions and other policy developments of added value to the EU Drugs Strategy and to MS	Biannually	PRES MS	— Extent to which National Drug Coordinators' meeting agenda reflects developments, trends and new insights in policy responses and provides for improved communication and information exchange	Presidency reporting
	25. The HDG will facilitate: (a) monitoring of the implementation of the Action Plan through thematic debates; and (b) an annual dialogue on the state of the drugs phenomenon in Europe	(a) Biannually (b) Annually	PRES HDG MS COM EMCDDA Europol	— Extent of implementation of the Action Plan — Timeliness of dialogue at the HDG on latest drug-related trends and data	Presidency reporting
	26. Ensure consistency and continuity of MS and EU actions across presidencies to strengthen the integrated, balanced and evidence-based approach to drugs in the EU	Biannually	PRES PRES Trio MS COM HDG EMCDDA Europol	— Extent of consistency and continuity of actions across presidencies — Advancement in implementation of EU Drugs Strategy priorities across presidencies	Presidency reporting
	27. Ensure coordination of EU drugs policies and responses, to support international cooperation between the EU, third countries and international organisations	Ongoing	EEAS COM HDG MS	— Level of consistency and coherence in the objectives, expected results and measures foreseen in EU actions on drugs	Annual EEAS report to the HDG COM biennial progress report

Objective	Action	Timetable	Responsible party	Indicator(s)	Data collection/assessment mechanisms
				— Inclusion of drug-related priorities in strategies of relevant EU bodies — Intensified cooperation between the HDG and the geographical/regional working groups, including COAFR, COASI, COEST, COLAT and COWEB	
	28. Achieve a coordinated and appropriate level of resources at EU level and Member State level to fulfil the priorities of the EU Drugs Strategy	Annually	MS COM EEAS Council HDG	— Overarching indicator 14 — Amount of funding at EU level, and where appropriate, MS level — Extent of coordination on drugs-related financial programmes across Council Working Groups	EMCDDA reporting COM biennial progress report
8. Ensure effective coordination of drug-related policy at national level	29. Coordinate actions on drugs policy between government departments/ministries and relevant agencies at MS level and ensure appropriate multi-disciplinary representation on, or input to, HDG delegations	Ongoing	MS	— Overarching indicator 14 — Effectiveness of a horizontal drug policy coordination mechanism at MS level — Number of cross-cutting actions in drug demand and supply reduction at Member State level	EMCDDA reporting Reitox national reporting COM Biennial Progress Report MS reporting
9. Ensure the participation of civil society in drugs policy	30. Promote and support dialogue with, and involvement of, civil society and the scientific community in the development and implementation of drugs policies at MS and EU levels	Ongoing	MS COM HDG PRES	— Timely dialogues between EU Civil Society Forum on Drugs and the HDG during each Presidency period — Engagement of EU Civil Society Forum in reviewing implementation of the EU Drugs Action Plan — Level of involvement of civil society in MS and EU drugs policy development and implementation with particular regard to the involvement of drug users, clients of drug-related services and young people — Timely dialogue between the scientific community (natural and social sciences, including neuroscience and behavioural research) and the HDG	COM biennial progress report Feedback from EU Civil Society Forum on Drugs and from civil society representatives at MS level MS reporting Feedback from scientific community through the EMCDDA Scientific Committee

4. International Cooperation

Strengthen dialogue and cooperation between the EU and third countries and international organisations on drugs issues in a comprehensive and balanced manner

Objective	Action	Timetable	Responsible party	Indicator(s)	Data collection/assessment mechanisms
10. Integrate the EU Drugs Strategy within the EU's overall foreign policy framework as part of a comprehensive approach that makes full use of the variety of policies and diplomatic, political and financial instruments at the EU's disposal in a coherent and coordinated manner	31. Ensure policy coherence between the internal and external aspects of the EU drugs policies and fully integrate drugs issues within the political dialogues and framework agreements between the EU and its partners and in the EU advocacy on global issues or challenges	Ongoing	COM EEAS PRES HDG MS	— Overarching indicator 13 — Drug policy priorities increasingly reflected in EU's external policies and actions — Inclusion of drug-related priorities in EU strategies with third countries and regions — Number of agreements, strategy papers, action plans in place	EEAS reporting Mid-term review of EU Drugs Strategy COM biennial progress report
	32. Ensure that the policy priorities and the balance between demand and supply reduction are well reflected in policy options and in the programming and implementation of external assistance, particularly in source and transit countries, through projects involving: (a) development of integrated, balanced and evidence-based drug policies; (b) supply reduction; (c) the prevention of the diversion of drug precursors and pre-precursors; (d) drug demand reduction; and (e) alternative development measures	Ongoing	COM MS EEAS	— Extent to which EU's drug policy priorities, especially the balance between demand and supply reduction, are reflected in funded priorities and projects — Level of implementation of coordinated actions in action plans between the EU and third countries and regions — Number of third country national strategies and action plans that incorporate integrated drug policies	COM biennial progress report EEAS reporting on programming Monitoring and evaluation by MS
	33. Improve capacity and strengthen the role of EU Delegations to enable them to proactively engage on drugs policy issues	2013-2016	EEAS COM MS	— Relevant expertise, training and policy guidance provided to EU Delegations — Regional networking among EU Delegations on drug issues enhanced	EEAS reporting on EU Delegations

Objective	Action	Timetable	Responsible party	Indicator(s)	Data collection/assessment mechanisms
				— Coordination with MS enhanced	
	34. Ensure an appropriate level of EU and MS funding and expertise to further strengthen and support third countries' efforts in addressing and preventing illicit drug crop cultivation, through rural development measures, in order to deal with the challenges to public health, safety and security	Ongoing	MS EEAS COM	— Number of third country national policies, strategies and action plans that incorporate integrated approaches to the problem of illicit drug crop cultivation — Improvements in human development indicators in drug-cultivating areas — Number of rural development projects and programmes funded by the EU and MS in regions where illicit crop cultivation is taking place, or in regions at risk of illicit crop cultivation — Reported local decrease in illicit drug crop cultivation in the long term	EU and MS project and programme monitoring and evaluation systems and reports UNDP human development reports Third country reports
	35. Promote and implement the EU approach to alternative development (consistent with the EU Drugs Strategy 2013-2020; the EU Approach to Alternative Development and the United Nations Guiding Principles on Alternative Development 2013) in co-operation with third countries, taking into account human rights, human security and specific framework conditions, including: (a) incorporating alternative development into the broader agenda of Member States, encouraging third countries that wish to do so to integrate alternative development into their national strategies; (b) contributing to initiatives that aim to reduce poverty, conflict and vulnerability by supporting sustainable, legal and gender sensitive livelihoods for people	Ongoing	MS COM EEAS	— Number of third country national policies, strategies and action plans that incorporate: — integrated approaches to the problem of illicit drug cultivation, and — effectively organised alternative development initiatives — Number of evaluated projects that demonstrate positive outcomes relating to sustainable, legal and gender sensitive livelihoods — Improvements in human development indicators	Third countries' implementation reports of national drugs strategies EU and MS project and programme monitoring and evaluation system and report UNDP human development reports

Objective	Action	Timetable	Responsible party	Indicator(s)	Data collection/assessment mechanisms
	who were previously, or are currently, involved in illicit drug production				
	36. Support third countries, including civil society in those countries, to develop and implement risk and harm reduction initiatives particularly where there is a growing threat of transmission of drug-related blood-borne viruses associated with drug use including but not limited to HIV and viral hepatitis, as well as sexually transmittable diseases and tuberculosis	Ongoing	MS COM EEAS	— Number and quality of risk and harm reduction initiatives developed — Prevalence of drug-related deaths in third countries and drug-related blood-borne viruses including but not limited to HIV and viral hepatitis, as well as sexually transmittable diseases and tuberculosis	Third country reports COM biennial progress report WHO reports
	37. Support third countries to tackle drug-related organised crime, including drug trafficking, by: (a) intelligence sharing and the exchange of best practices; (b) strengthening counter-narcotics capacity and developing expertise of source and transit countries; (c) working with international partners to tackle the enablers of drug trafficking such as corruption, weak institutions, poor governance and lack of financial regulatory controls; (d) strengthening cooperation in the field of asset identification and recovery, in particular through the creation of dedicated national platforms; and (e) intensifying regional and intra-regional cooperation	Ongoing	MS EEAS COM Europol	— Number and effectiveness of projects and programmes — Sustained reduction in drug trafficking	COM biennial progress report MS reporting Europol reporting EEAS reporting UNODC annual world drug report

Objective	Action	Timetable	Responsible party	Indicator(s)	Data collection/assessment mechanisms
	38. Reinforce cooperation and update and implement dialogues, declarations and EU Drugs Action Plans with partners, including: (a) acceding countries, candidate countries and potential candidates; (b) European Neighbourhood Policy countries; (c) United States of America, the Russian Federation; (d) other countries or regions of priority notably: — Afghanistan and Pakistan, — Central Asian republics, — China, — Latin American and the Caribbean (CELAC), — Africa, in particular West Africa	Ongoing	PRES Trio COM EEAS MS	— Overarching indicator 13 — Strengthened cooperation in the field of drugs with relevant partners — Dialogues organised — Declarations agreed — Programmes and action plans implemented	EEAS reporting Mid-term review of EU Drugs Strategy COM biennial progress report EU reporting matrices Implementation reports of the relevant action plans
	39. Improve the Dublin Group consultative mechanism through intensified EU coordination and participation, better implementation and dissemination of the recommendations of the Mini Dublin Group reports	Ongoing	Dublin Group COM EEAS MS	— Level of activity across Dublin Group structures including number of Dublin Group recommendations effectively implemented	Dublin Group reports
	40. Hold an annual dialogue on EU and MS drugs-related assistance to third countries accompanied by a written update	From 2014	COM EEAS MS	— Annual dialogue on funding held	COM biennial progress report MS reporting EEAS reporting Project and programme monitoring and evaluation system and reports

Objective	Action	Timetable	Responsible party	Indicator(s)	Data collection/assessment mechanisms
	41. Ensure that the promotion and protection of human rights are fully integrated in political dialogues and in the planning and implementation of relevant drugs-related programmes and projects including through the development of a human rights guidance and impact assessment tool	Ongoing	COM EEAS MS	— Human rights effectively mainstreamed into EU external drugs action — Human rights guidance and assessment tool developed and implemented	COM biennial progress report COHOM annual human rights report MS reporting
11. Improve cohesiveness of EU approach and EU visibility in the United Nations (UN) and strengthen EU coordination with international bodies related to the drugs field	42. Contribute to shaping the agenda on international drugs policy, including through: (a) action by EU and MS Delegations at the UN General Assembly and the Commission on Narcotic Drugs (CND); (b) preparation, coordination and adoption of EU common positions and joint resolutions in the UN General Assembly and the CND and ensuring that the EU speaks with one strong voice in these and other international fora; (c) the mid-term review process of the 2009 UN Political Declaration and Action Plan on International Cooperation towards an Integrated and Balanced Strategy to Counter the World Drug Problem; and (d) the 2016 UN General Assembly Special Session on Drugs	Ongoing	EEAS PRES MS COM Council HDG	— Overarching indicator 13 — Effective promotion of EU policies in the UN, including at the CND — Number of EU common positions supported by other regions and international bodies — Frequency with which EU speaks with a single effective voice in international fora and in dialogues with third countries — Level of successful adoption of EU resolutions at UN including at the CND — Outcome of the mid-term review of the 2009 UN Political Declaration and Action Plan on International Cooperation towards an Integrated and Balanced Strategy to Counter the World Drug Problem — Adoption of an EU Joint Position Paper for the 2016 UNGASS and reflection of the EU positions in the UNGASS outcome	EEAS reporting Mid-term review of the EU Drugs Strategy COM biennial progress report Convergence indicator Mid-term review UNGASS outcome
	43. Strengthen partnerships with the UNODC, WHO UNAIDS and other relevant UN agencies, international and regional bodies and organisations and initiatives (such as the Council of Europe and the Paris Pact Initiative)	Ongoing	Council EEAS COM PRES HDG	— Overarching indicator 13 — Number of information exchanges and activities between the EU and relevant international and regional bodies and organisations and initiatives — Effectiveness of partnerships with relevant bodies	EEAS reporting Mid-term review of the EU Drugs Strategy COM biennial progress report

Objective	Action	Timetable	Responsible party	Indicator(s)	Data collection/assessment mechanisms
12. Support the process for acceding countries, candidate countries, and potential candidates to adapt to and align with the EU *acquis* in the drugs field, through targeted assistance and monitoring	44. Provide targeted technical assistance, and other assistance and support as necessary, to acceding countries, candidate countries, and potential candidates to facilitate their adaptation to and alignment with the EU *acquis* in the drugs field	Ongoing	COM MS EMCDDA Europol Eurojust Frontex EEAS	— Increased compliance by countries with EU *acquis* — Number and quality of completed projects — National Drugs Strategies and national drugs coordinating structures established	COM biennial progress report Acceding countries, candidate countries and potential candidates reports

5. Information, research, monitoring and evaluation

Contribute to a better understanding of all aspects of the drugs phenomenon and of the impact of measures in order to provide sound and comprehensive evidence for policies and actions

Objective	Action	Timetable	Responsible party	Indicator(s)	Data collection/assessment mechanisms
13. Ensure adequate investment in research, data collection, monitoring, evaluation and information exchange on all aspects of the drug phenomenon	45. Promote appropriate financing of EU-level drug-related multi-disciplinary research and studies including through EU related financial programmes (2014-2020)	2014-2016	MS COM EMCDDA	— Amount and type of EU funding provided across the different programme and projects	COM biennial progress report
	46. Ensure that EU-supported projects: (a) take account of the priorities of the EU Drugs Strategy and Action Plan on Drugs; (b) take account of gaps in policy formulation; (c) deliver clear added value and ensure coherence and synergy; and (d) avoid duplication with research under other programmes and bodies; (e) take account of the importance of behavioural research and neuroscience	2014-2016	COM EMCDDA	— The inclusion of the priorities of the EU Strategy and Action Plan on Drugs in the funding and assessment criteria of EU-funded drugs-related research — Number, impact, complementarity and value of EU-funded drugs-related research grants and contracts awarded — Number of EU-funded drugs-related articles and research reports published in peer-reviewed journals with high impact factors — Annual debate at the HDG on drug-related research projects funded by the EU	COM biennial progress report Research project reports EMCDDA Scientific Committee recommendations on research priorities Science Citation Index and similar bibliometric tools Strategic research agenda and projects stemming from the ERA-net on drug demand and supply reduction

Objective	Action	Timetable	Responsible party	Indicator(s)	Data collection/assessment mechanisms
	47. Promote scientific evaluations of policies and interventions at national, EU and international level	2013-2016	COM MS EMCDDA	— Overarching indicator 14 — Regular progress review to the Council and European Parliament on Strategy and Action Plan implementation — External mid-term assessment of the Strategy/Action Plan completed — 2016 — European guidelines for the evaluation of national drug strategies and action plans published — Delivery of dedicated studies into the effectiveness and impacts of EU and international drug policies — Completed evaluation of the implementation of the 2003 Council Recommendation on the prevention and reduction of health-related harm associated with drug dependence	EMCDDA reporting COM biennial progress report Mid-term assessment report of EU drugs strategy EMCDDA reporting EMCDDA Scientific Committee reporting Reports of ALICE RAP and LINKSCH and ERA-net Reitox national reports
14. Maintain networking and cooperation and develop capacity within and across the EU's knowledge infrastructure for information, research, monitoring and evaluation of drugs, particularly illicit drugs	48. In collaboration with relevant parties as appropriate, continue to provide comprehensive analyses of: (a) the EU drugs situation; (b) the dynamics of drug use within general populations and target groups; and (c) responses to drug use	Ongoing	EMCDDA Europol MS	— Overarching indicators 1-15 — Current deficits in the knowledge base established and an EU level framework developed to maximise analyses from current data holdings — Number of overviews and topic analyses on the drug situation	EMCDDA reporting MS reporting
	49. Enhance training for those involved in responding to the drugs phenomenon	2014-2016	MS EMCDDA CEPOL	— Number of initiatives at MS and EU level to train professionals in aspects of drug demand reduction and drug supply reduction — Number of initiatives at MS and EU level implemented to train professionals related to data collection and reporting of drug demand reduction and drug supply reduction	MS reporting EMCDDA training report CEPOL annual report Reitox annual reports

Objective	Action	Timetable	Responsible party	Indicator(s)	Data collection/assessment mechanisms
	50. Enhance data collection, research, analysis and reporting on: (a) drug demand reduction; (b) drug supply reduction; (c) emerging trends, such as polydrug use and misuse of prescribed controlled medicines, that pose risks to health and safety; (d) blood-borne viruses associated with drug use including but not limited to HIV and viral hepatitis, as well as sexually transmittable diseases and tuberculosis; (e) psychiatric and physical co-morbidity; (f) drug problems among prisoners and the availability and coverage of drug demand reduction interventions and services in prison settings; and (g) other drug-related consequences	Ongoing	MS COM EMCDDA Europol ECDC EMA	— Increased availability and implementation of evidence-based and scientifically sound indicators on drug supply reduction and drug demand reduction — At MS level, extent of new research initiated on emerging trends such as polydrug use and the misuse of prescribed controlled medicines; blood-borne diseases associated with drug use including but not limited to HIV and viral hepatitis, as well as sexually transmittable diseases and tuberculosis; psychiatric and physical co-morbidity; and other drug-related consequences — EU-wide study carried out on drug-related community intimidation and its impact on individuals, families and communities most affected and effective responses to it — Adoption of evidence-based and scientifically sound indicators on drug problems among prisoners	EMCDDA reporting MS reporting Harmonised data reports from EU bodies including EMCDDA EU SOCTA
	51. Improve the capacity to detect, assess and respond effectively to the emergence and use of new psychoactive substances and monitor the extent to which such new substances impact on the number and profile of users	Ongoing	COM MS EMCDDA Europol	— Overarching indicator 6 — Extent of new epidemiological, pharmacological and toxicological research initiated on new psychoactive substances and supported by MS and EU research programmes — Extent of information, best practice and intelligence exchange — Extent of sharing by toxicology laboratories and by research institutes of toxicological and health data analyses on new psychoactive substances	EMCDDA reporting EMCDDA-Europol implementation report Reports by laboratories and research institutes Reitox national reports

Objective	Action	Timetable	Responsible party	Indicator(s)	Data collection/assessment mechanisms
	52. Strengthen efforts to share forensic science data, including laboratory reference standards, on new psychoactive substances, by enhancing co-operation through existing networks, such as the Drugs Working Group of the European Network of Forensic Science Institutes in the framework of the JHA Council conclusions on the vision for European Forensic Science 2020	2016	COM MS EMCDDA	— Overarching indicator 15 — Extent of sharing of forensic science data on new psychoactive substances — Ease of access to laboratory reference standards by forensic science laboratories and institutes	EMCDDA/Europol reporting COM biennial progress report
	53. Improve the ability to identify, assess and respond at MS and EU levels to (a) behavioural changes in drug consumption and (b) to epidemic outbreaks	Ongoing	MS EMCDDA ECDC EMA	— Number and effectiveness of new drug-related public health initiatives developed and implemented — Number and effectiveness of existing initiatives that are adjusted to take account of drug consumption or epidemic outbreaks — Number and impact of early warning reports, risk assessment and alerts	Reitox national reports Early Warning System reports EMCDDA reporting
15. Enhance dissemination of monitoring, research and evaluation results at EU and national level	54. Member States continue to support EU monitoring and information exchange efforts, including cooperation with, and adequate support for, Reitox national focal points	Ongoing	MS EMCDDA	— Open-access outputs from EU-funded studies disseminated — Extent to which Reitox national focal points funding and other resources match requirements — Number and effectiveness of Reitox national focal points dissemination initiatives	Web dissemination including OpenAire, Cordis EMCDDA website Reitox national reports

ANNEX 1

15 over-arching indicators for the EU Action Plan on Drugs 2013-2016 (existing reporting mechanisms)

1. Percentage of population who use drugs currently (within last month), used drugs recently (within last year), and who have ever used (lifetime use) by drug and age group (EMCDDA General population survey)

2. Estimated trends in the prevalence of problem and injecting drug use (EMCDDA Problem drug use)

3. Trends in drug-induced deaths and mortality amongst drug users (according to national definitions) (EMCDDA Drug-related deaths)

4. Prevalence and incidence, among injecting drug users, of infectious diseases attributable to drug use, including HIV and viral hepatitis, sexually transmittable diseases and tuberculosis (EMCDDA Drug-related infectious diseases)

5. Trends in the age of first use of illicit drugs (European School Survey Project on Alcohol and Other Drugs (ESPAD), Health Behaviour in School-aged Children (HBSC) and General Population Drug Use Survey (EMCDDA Key epidemiological indicator))

6. Trends in numbers of people entering drug treatment (EMCDDA Treatment demand) and the estimated total number of people in drug treatment (EMCDDA Treatment demand and health and social responses)

7. Trends in number of and quantities of seized illicit drugs (EMCDDA Drug seizures: cannabis incl. herbal cannabis, heroin, cocaine, crack cocaine, amphetamine, methamphetamine, ecstasy, LSD and other substances)

8. Trends in retail price and purity of illicit drugs (EMCDDA Price and purity: cannabis incl. herbal cannabis, heroin, cocaine, crack cocaine, amphetamine, methamphetamine, ecstasy, LSD, other substances and composition of drug tablets)

9. Trends in the number of initial reports of drug law offences, by drug and type of offence (supply v use/possession) (EMCDDA Drug offences)

10. Prevalence of drug use amongst prisoners (EMCDDA Drug use in prisons)

11. Assessment of availability, coverage and quality of services and interventions in the areas of prevention, harm reduction, social integration and treatment (EMCDDA Health and social responses)

12. Evidence-based interventions on prevention, treatment, social integration and recovery and their expected impact on drug use prevalence and problem drug use (EMCDDA Best practice portal)

13. Strong dialogue and cooperation, in the drugs-related field, with other regions, third countries, international organisations and other parties (External Mid-Term Evaluation of Strategy/Action Plan; EEAS reporting)

14. Developments in national drug strategies, evaluations, legislation, coordination mechanisms and public expenditure estimates in EU Member States (EMCDDA)

15. Early warning system on new psychoactive substances (EMCDDA/Europol)

ANNEX 2

Glossary of acronyms

ALICE RAP	Addiction and Lifestyles in Contemporary Europe — Reframing Addictions Project
ASEAN	Association of South-East Asian Nations
CCWP	Council of the EU — Customs Cooperation Working Party
CELAC	Comunidad de Estados Latinoamericanos y Caribeños (Community of Latin American and Caribbean States)
CEPOL	European Police College
CICAD	La Comisión Interamericana para el Control del Abuso de Drogas (The Inter-American Drug Abuse Control Commission)
CND	Commission on Narcotic Drugs (UN)
COAFR	Council of the EU — Africa Working Party
COASI	Council of the EU — Asia-Oceania Working Party
COEST	Council of the EU — Working Party on Eastern Europe and Central Asia
COHOM	Council of the EU — Working Party on Human Rights
COLAT	Council of the EU — Working Party on Latin America
COM	European Union Commission
COSI	Council of the EU — Standing Committee on Operational Cooperation on Internal Security
COWEB	Council of the EU — Working Party on the Western Balkans Region
CUG	Council of the EU — Customs Union Group
ECDC	European Centre for Disease Prevention and Control
ECOWAS	Economic Community of West African States
EEAS	European External Action Service
EMA	European Medicines Agency
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction
EMPACT	European Multidisciplinary Platform against Criminal Threats
ENFSI	European Network of Forensic Science Institutes
ERA-net	European Research Area — Network
ESPAD	European School Survey Project on Alcohol and Other Drugs
EU SOCTA	EU Serious and Organised Crime Threat Assessment
Frontex	European Agency for the Management of Operational Cooperation at the External Borders of the Member States of the European Union

HBSC	Health Behaviour in School-aged Children Survey
HDG	Council of the EU — Horizontal Working Group on Drugs
INCB	International Narcotics Control Board (UN)
JHA	Justice and Home Affairs
LINKSCH	The LINKSCH project is a comparative study of two major drug markets, cannabis and heroin, through the prism of the transit chains operating between Central Asia and the EU and those between North Africa and the EU
MS	Member State
PEN	UNODC/INCB developed Pre-Export Notification Online System
PICS	Precursors Incident Communication System
PRES	Rotating presidency of the Council of the European Union
PRES Trio	Grouping of three consecutive rotating presidencies of the Council of the European Union
Reitox	Réseau Européen d'Information sur les Drogues et les Toxicomanies
SOCTA	Serious and Organised Crime Threat Assessment
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNGASS	United Nations General Assembly Special Session
UNODC	United Nations Office on Drugs and Crime
WCO	World Customs Organisation
WHO	World Health Organisation (UN)

(Acts adopted under Title VI of the Treaty on European Union)

COUNCIL DECISION 2005/387/JHA

of 10 May 2005

on the information exchange, risk-assessment and control of new psychoactive substances

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Articles 29, 31(1)(e) and 34 (2)(c) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament [1],

Whereas:

(1) The particular dangers inherent in the development of psychoactive substances require rapid action by the Member States.

(2) When new psychoactive substances are not brought within the scope of criminal law in all Member States, problems may arise in cooperation between the judicial authorities and law enforcement agencies of Member States owing to the fact that the offence or offences in question are not punishable under the laws of both the requesting and the requested State.

(3) The European Union Action Plan on Drugs 2000-2004 provided for the Commission to organise an appropriate assessment of the Joint Action of 16 June 1997 concerning the information exchange, risk assessment and the control of new synthetic drugs [2] (herineafter 'the Joint Action') taking into account the external evaluation commissioned by the European Monitoring Centre on Drugs and Drug Addiction (hereinafter 'the EMCDDA') of the early warning system. The assessment showed that the Joint Action had fulfilled its expectations. Nevertheless, the outcome of the assessment made it clear that the Joint Action was in need of reinforcement and reorientation. In particular, its main objective, the clarity of its procedures and definitions, the transparency of its operation, and the relevance of its scope had to be redefined. The Communication from the Commission to the European Parliament and the Council on the mid-term evaluation of the EU Action Plan on Drugs (2000-2004) indicated that changes to the legislation would be introduced in order to enhance action against synthetic drugs. The mechanism as established by the Joint Action should therefore be adapted.

(4) New psychoactive substances can be harmful to health.

(5) The new psychoactive substances covered by this Decision may include medicinal products as defined in Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to veterinary medicinal products [3] and in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use [4].

(6) The information exchange under the early warning system, established under the Joint Action, has proved to be a valuable asset to the Member States.

(7) Nothing in this Decision should prevent Member States from exchanging information, within the European Information Network on Drugs and Drug Addiction (hereinafter 'the Reitox network'), on emerging trends in new uses of existing psychoactive substances which may pose a potential risk to public health, as well as information on possible public health related measures, in accordance with the mandate and procedures of the EMCDDA.

(8) No deterioration of either human or veterinary health care as a result of this Decision will be permitted. Substances of established and acknowledged medical value are therefore excluded from control measures based on this Decision. Suitable regulatory and public health related measures should be taken for substances of established and acknowledged medical value that are being misused.

[1] Opinion delivered on 13 January 2004 (not yet published in the Official Journal).

[2] OJ L 167, 25.6.1997, p. 1.

[3] OJ L 311, 28.11.2001, p. 1. Directive as last amended by Directive 2004/28/EC (OJ L 136, 30.4.2004, p. 58).

[4] OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).

(9) In addition to what is provided for under the pharmacovigilance systems as defined in Directive 2001/82/EC and in Directive 2001/83/EC, the exchange of information on abused or misused psychoactive substances needs to be reinforced and appropriate cooperation with the European Medicines Agency (hereinafter 'EMEA') ensured. The United Nations Commission on Narcotic Drugs (hereinafter 'CND') Resolution 46/7 'Measures to promote the exchange of information on new patterns of drug use and on psychoactive substances consumed', provides a useful framework for action by the Member States.

(10) The introduction of deadlines into every phase of the procedure established by this Decision should guarantee that the instrument can react swiftly and enhances its ability to provide a quick-response mechanism.

(11) The Scientific Committee of the EMCDDA has a central role in the assessment of the risks associated with a new psychoactive substance, it will for the purpose of this Decision be extended to include experts from the Commission, Europol and the EMEA, and experts from scientific fields not represented, or not sufficiently represented, in the Scientific Committee of the EMCDDA.

(12) The extended Scientific Committee that assesses the risks associated with new psychoactive substances should remain a concise technical body of experts, capable of assessing effectively all risks associated with a new psychoactive substance. Therefore the extended Scientific Committee should be kept to a manageable size.

(13) Since the objectives of the proposed action, namely to bring about an exchange of information, a risk-assessment by a scientific committee and an EU-level procedure for bringing notified substances under control, cannot be sufficiently achieved by the Member States and can therefore, by reason of the effects of the envisaged action, be better achieved at European Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality as set out in that Article, this Decision does not go what is beyond what is necessary in order to achieve those objectives

(14) In conformity with Article 34(2)(c) of the Treaty, measures based upon this Decision can be taken by qualified majority as these measures are necessary to implement this Decision.

(15) This Decision respects fundamental rights and observes the principles recognised by Article 6 of the Treaty and reflected in the Charter of Fundamental Rights of the European Union,

HAS DECIDED AS FOLLOWS:

Article 1

Subject matter

This Decision establishes a mechanism for a rapid exchange of information on new psychoactive substances. It takes note of information on suspected adverse reactions to be reported under the pharmacovigilance system as established by Title IX of Directive 2001/83/EC.

This Decision also provides for an assessment of the risks associated with these new psychoactive substances in order to permit the measures applicable in the Member States for control of narcotic and psychotropic substances to be applied also to new psychoactive substances.

Article 2

Scope

This Decision applies to substances not currently listed in any of the schedules to:

(a) the 1961 United Nations Single Convention on Narcotic Drugs, that may pose a comparable threat to public health as the substances listed in Schedule I or II or IV thereof, and

(b) the 1971 United Nations Convention on Psychotropic Substances, that may pose a comparable threat to public health as the substances listed in Schedule I or II or III or IV thereof.

This Decision relates to end-products, as distinct from precursors in respect of which Council Regulation (EEC) No 3677/90 of 13 December 1990 laying down measures to be taken to discourage the diversion of certain substances to the illicit manufacture of narcotic drugs and psychotropic substances [1], and Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors [2] provide for a Community regime.

Article 3

Definitions

For the purpose of this Decision the following definitions shall apply:

(a) 'new psychoactive substance' means a new narcotic drug or a new psychotropic drug in pure form or in a preparation;

[1] OJ L 357, 20.12.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 1232/2002 (OJ L 180, 10.7.2002, p. 5).
[2] OJ L 47, 18.2.2004, p. 1.

(b) 'new narcotic drug' means a substance in pure form or in a preparation, that has not been scheduled under the 1961 United Nations Single Convention on Narcotic Drugs, and that may pose a threat to public health comparable to the substances listed in Schedule I, II or IV;

(c) 'new psychotropic drug' means a substance in pure form or in a preparation that has not been scheduled under the 1971 United Nations Convention on Psychotropic Substances, and that may pose a threat to public health comparable to the substances listed in Schedule I, II, III or IV;

(d) 'marketing authorisation' means a permission to place a medicinal product on the market, granted by the competent authority of a Member State, as required by Title III of Directive 2001/83/EC (in the case of medicinal products for human use) or Title III of Directive 2001/82/EC (in the case of veterinary medicinal products) or a marketing authorisation granted by the European Commission under Article 3 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency ([1]);

(e) 'United Nations system' means the World Health Organisation (WHO), the Commission on Narcotic Drugs (CND) and/or the Economic and Social Committee acting in accordance with their respective responsibilities as described in Article 3 of the 1961 United Nations Single Convention on Narcotic Drugs or in Article 2 of the 1971 United Nations Convention on Psychotropic Substances;

(f) 'preparation' means a mixture containing a new psychoactive substance;

(g) 'Reporting Form' means a structured form for notification of a new psychoactive substance and/or of a preparation containing a new psychoactive substance agreed between the EMCDDA/Europol and their respective networks in the Member States' Reitox and the Europol National Units.

Article 4

Exchange of information

1. Each Member State shall ensure that its Europol National Unit and its representative in the Reitox network provide information on the manufacture, traffic and use, including supplementary information on possible medical use, of new psychoactive substances and of preparations containing new psychoactive substances, to Europol and the EMCDDA, taking into account the respective mandates of these two bodies.

([1]) OJ L 136, 30.4.2004, p. 1.

Europol and the EMCDDA shall collect the information received from Member States through a Reporting Form and communicate this information immediately to each other and to the Europol National Units and the representatives of the Reitox network of the Member States, the Commission, and to the EMEA.

2. Should Europol and the EMCDDA consider that the information provided by a Member State on a new psychoactive substance does not merit the communication of information as described in paragraph 1, they shall inform the notifying Member State immediately thereof. Europol and the EMCDDA shall justify their decision to the Council within six weeks.

Article 5

Joint Report

1. Where Europol and the EMCDDA, or the Council, acting by a majority of its members, consider that the information provided by the Member State on a new psychoactive substance merits the collection of further information, this information shall be collated and presented by Europol and the EMCDDA in the form of a Joint Report (hereinafter the 'Joint Report'). The Joint Report shall be submitted to the Council, the EMEA and the Commission.

2. The Joint Report shall contain:

(a) a chemical and physical description, including the name under which the new psychoactive substance is known, including, if available, the scientific name (International Non-proprietary Name);

(b) information on the frequency, circumstances and/or quantities in which a new psychoactive substance is encountered, and information on the means and methods of manufacture of the new psychoactive substance;

(c) information on the involvement of organised crime in the manufacture or trafficking of the new psychoactive substance;

(d) a first indication of the risks associated with the new psychoactive substance, including the health and social risks, and the characteristics of users;

(e) information on whether or not the new substance is currently under assessment, or has been under assessment, by the UN system;

(f) the date of notification on the Reporting Form of the new psychoactive substance to the EMCDDA or to Europol;

(g) information on whether or not the new psychoactive substance is already subject to control measures at national level in a Member State;

(h) as far as possible, information will be made available on:

(i) the chemical precursors that are known to have been used for the manufacture of the substance,

(ii) the mode and scope of the established or expected use of the new substance,

(iii) any other use of the new psychoactive substance and the extent of such use, the risks associated with this use of the new psychoactive substance, including the health and social risks.

3. The EMEA shall submit to Europol and the EMCDDA the following information on whether in the European Union or in any Member State:

(a) the new psychoactive substance has obtained a marketing authorisation;

(b) the new psychoactive substance is the subject of an application for a marketing authorisation;

(c) a marketing authorisation that had been granted in respect of the new psychoactive substance has been suspended.

Where this information relates to marketing authorisations granted by Member States, these Member States shall provide the EMEA with this information if so requested by it.

4. Member States shall provide the details referred to under paragraph 2 within six weeks from the date of notification on the Reporting Form as set out in Article 4(1).

5. The Joint Report shall be submitted no more than four weeks after the date of receipt of the information from Member States and the EMEA. The Report shall be submitted by Europol or the EMCDDA, as appropriate, in accordance with Article 5(1) and (2).

Article 6

Risk assessment

1. The Council, taking into account the advice of Europol and the EMCDDA, and acting by a majority of its members, may request that the risks, including the health and social risks, caused by the use of, the manufacture of, and traffic in, a new psychoactive substance, the involvement of organised crime and possible consequences of control measures, be assessed in accordance with the procedure set out in paragraphs 2 to 4, provided that at least a quarter of its members or the Commission have informed the Council in writing that they are in favour of such an assessment. The Member States or the Commission shall inform the Council thereof as soon as possible, but in any case within four weeks of receipt of the Joint Report. The General Secretariat of the Council shall notify this information to the EMCDDA without delay.

2. In order to carry out the assessment, the EMCDDA shall convene a special meeting under the auspices of its Scientific Committee. In addition, for the purpose of this meeting the Scientific Committee may be extended by a further five experts at most, to be designated by the Director of the EMCDDA, acting on the advice of the Chairperson of the Scientific Committee, chosen from a panel of experts proposed by Member States and approved every three years by the Management Board of the EMCDDA. Such experts will be from scientific fields that are not represented, or not sufficiently represented, in the Scientific Committee, but whose contribution is necessary for the balanced and adequate assessment of the possible risks, including health and social risks. Furthermore, the Commission, Europol and the EMEA shall each be invited to send a maximum of two experts.

3. The risk assessment shall be carried out on the basis of information to be provided to the scientific Committee by the Member States, the EMCDDA, Europol, the EMEA, taking into account all factors which, according to the 1961 United Nations Single Convention on Narcotic Drugs or the 1971 United Nations Convention on Psychotropic Substances, would warrant the placing of a substance under international control.

4. On completion of the risk assessment, a report (hereinafter the 'Risk Assessment Report') shall be drawn up by the Scientific Committee. The Risk Assessment Report shall consist of an analysis of the scientific and law enforcement information available, and shall reflect all opinions held by the members of the Committee. The Risk Assessment Report shall be submitted to the Commission and Council by the chairperson of the Committee, on its behalf, within a period of twelve weeks from the date of the notification by the General Secretariat of the Council to the EMCDDA referred to in paragraph 1.

The Risk Assessment Report shall include:

(a) the physical and chemical description of the new psychoactive substance and its mechanisms of action, including its medical value;

(b) the health risks associated with the new psychoactive substance;

(c) the social risks associated with the new psychoactive substance;

(d) information on the level of involvement of organised crime and information on seizures and/or detections by the authorities, and the manufacture of the new psychoactive substance;

(e) information on any assessment of the new psychoactive substance in the United Nations system;

(f) where appropriate, a description of the control measures that are applicable to the new psychoactive substance in the Member States;

(g) options for control and the possible consequences of the control measures, and

(h) the chemical precursors that are used for the manufacture of the substance.

Article 7

Circumstances where no risk assessment is carried out

1. No risk assessment shall be carried out in the absence of a Europol/EMCDDA Joint Report. Nor shall a risk assessment be carried out where the new psychoactive substance concerned is at an advanced stage of assessment within the United Nations system, namely once the WHO expert committee on drug dependence has published its critical review together with a written recommendation, except where there is significant new information that is relevant in the framework of this Decision.

2. Where the new psychoactive substance has been assessed within the United Nations system, but it has been decided not to schedule the new psychoactive substance under the 1961 Single Convention on Narcotic Drugs or the 1971 Convention on Psychotropic Substances, a risk assessment shall be carried out only if there is significant new information that is relevant in the framework of this Decision.

3. No risk assessment shall be carried out on a new psychoactive substance if:

(a) the new psychoactive substance is used to manufacture a medicinal product which has been granted a marketing authorisation; or,

(b) the new psychoactive substance is used to manufacture a medicinal product for which an application has been made for a marketing authorisation or,

(c) the new psychoactive substance is used to manufacture a medicinal product for which a marketing authorisation has been suspended by a competent authority.

Where the new psychoactive substance falls into one of the categories listed under the first subparagraph, the Commission, on the basis of data collected by EMCDDA and Europol, shall assess with the EMEA the need for further action, in close cooperation with the EMCDDA and in accordance with the mandate and procedures of the EMEA.

The Commission shall report to the Council on the outcome.

Article 8

Procedure for bringing specific new psychoactive substances under control

1. Within six weeks from the date on which it received the Risk Assessment Report, the Commission shall present to the Council an initiative to have the new psychoactive substance subjected to control measures. If the Commission deems it is not necessary to present an initiative on submitting the new psychoactive substance to control measures, within six weeks from the date on which it received the Risk Assessment Report, the Commission shall present a report to the Council explaining its views.

2. Should the Commission deem it not necessary to present an initiative on submitting the new psychoactive substance to control measures, such an initiative may be presented to the Council by one or more Member States, preferably not later than six weeks from the date on which the Commission presented its report to the Council.

3. The Council shall decide, by qualified majority and acting on an initiative presented pursuant to paragraph 1 or 2, on the basis of Article 34(2) (c) of the Treaty, whether to submit the new psychoactive substance to control measures.

Article 9

Control measures taken by Member States

1. If the Council decides to submit a new psychoactive substance to control measures, Member States shall endeavour to take, as soon as possible, but no later than one year from the date of that decision, the necessary measures in accordance with their national law to submit:

(a) the new psychotropic drug to control measures and criminal penalties as provided under their legislation by virtue of their obligations under the 1971 United Nations Convention on Psychotropic Substances;

(b) the new narcotic drug to control measures and criminal penalties as provided under their legislation by virtue of their obligations under the 1961 United Nations Single Convention on Narcotic Drugs.

2. Member States shall report the measures taken to both the Council and the Commission as soon as possible after the relevant decision has been taken. Thereafter this information shall be communicated to the EMCDDA, Europol, the EMEA, and the European Parliament.

3. Nothing in this Decision shall prevent a Member State from maintaining or introducing on its territory any national control measure it deems appropriate once a new psychoactive substance has been identified by a Member State.

Article 10

Annual report

The EMCDDA and Europol shall report annually to the European Parliament, the Council and the Commission on the implementation of this Decision. The report will take into account all aspects required for an assessment of the efficacy and achievements of the system created by this Decision. The Report shall, in particular, include experience relating to coordination between the system set out in this Decision and the pharmacovigilance system.

Article 11

Pharmacovigilance system

Member States and the EMEA shall ensure an appropriate exchange of information between the mechanism set up by means of this Decision and the pharmacovigilance systems as defined and established under Title VII of Directive 2001/82/EC and Title IX of Directive 2001/83/EC.

Article 12

Repeal

The Joint Action on New Synthetic Drugs of 16 June 1997 is hereby repealed. Decisions taken by the Council based on Article 5 of that Joint Action shall continue to be legally valid.

Article 13

Publication and taking effect

This Decision shall take effect on the day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 10 May 2005.

For the Council
The President
J. KRECKÉ

(Acts adopted under Title VI of the Treaty on European Union)

COUNCIL FRAMEWORK DECISION 2004/757/JHA

of 25 october 2004

laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 31(e) and Article 34(2)(b) thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the European Parliament [2],

Whereas:

(1) Illicit drug trafficking poses a threat to health, safety and the quality of life of citizens of the European Union, and to the legal economy, stability and security of the Member States.

(2) The need for legislative action to tackle illicit drug trafficking has been recognised in particular in the Action Plan of the Council and the Commission on how best to implement the provisions of the Amsterdam Treaty on an area of freedom, security and justice [3], adopted by the Justice and Home Affairs Council in Vienna on 3 December 1998, the conclusions of the Tampere European Council of 15 and 16 October 1999, in particular point 48 thereof, the European Union's Drugs Strategy (2000-2004) endorsed by the Helsinki European Council from 10 to 12 December 1999 and the European Union's Action Plan on Drugs (2000-2004) endorsed by the European Council in Santa Maria da Feira on 19 and 20 June 2000.

(3) It is necessary to adopt minimum rules relating to the constituent elements of the offences of illicit trafficking in drugs and precursors which will allow a common approach at European Union level to the fight against such trafficking.

(4) By virtue of the principle of subsidiarity, European Union action should focus on the most serious types of drug offence. The exclusion of certain types of behaviour as regards personal consumption from the scope of this Framework Decision does not constitute a Council guideline on how Member States should deal with these other cases in their national legislation.

(5) Penalties provided for by the Member States should be effective, proportionate and dissuasive, and include custodial sentences. To determine the level of penalties, factual elements such as the quantities and the type of drugs trafficked, and whether the offence was committed within the framework of a criminal organisation, should be taken into account.

(6) Member States should be allowed to make provision for reducing the penalties when the offender has supplied the competent authorities with valuable information.

(7) It is necessary to take measures to enable the confiscation of the proceeds of the offences referred to in this Framework Decision.

(8) Measures should be taken to ensure that legal persons can be held liable for the criminal offences referred to by this Framework Decision which are committed for their benefit.

(9) The effectiveness of the efforts made to tackle illicit drug trafficking depends essentially on the harmonisation of the national measures implementing this Framework Decision,

[1] OJ C 304 E, 30.10.2001, p. 172.
[2] Opinion of 9 March 2004 (not yet published in the Official Journal).
[3] OJ C 19, 23.1.1999, p. 1.

HAS DECIDED AS FOLLOWS:

Article 1

Definitions

For the purposes of this Framework Decision:

1. 'drugs': shall mean any of the substances covered by the following United Nations Conventions:

   (a) the 1961 Single Convention on Narcotic Drugs (as amended by the 1972 Protocol);

   (b) the 1971 Vienna Convention on Psychotropic Substances. It shall also include the substances subject to controls under Joint Action 97/396/JHA of 16 June 1997 concerning the information exchange risk assessment and the control of new synthetic drugs [1];

2. 'precursors': shall mean any substance scheduled in the Community legislation giving effect to the obligations deriving from Article 12 of the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 20 December 1988;

3. 'legal person': shall mean any legal entity having such status under the applicable national law, except for States or other public bodies acting in the exercise of their sovereign rights and for public international organisations.

Article 2

Crimes linked to trafficking in drugs and precursors

1. Each Member State shall take the necessary measures to ensure that the following intentional conduct when committed without right is punishable:

(a) the production, manufacture, extraction, preparation, offering, offering for sale, distribution, sale, delivery on any terms whatsoever, brokerage, dispatch, dispatch in transit, transport, importation or exportation of drugs;

(b) the cultivation of opium poppy, coca bush or cannabis plant;

(c) the possession or purchase of drugs with a view to conducting one of the activities listed in (a);

(d) the manufacture, transport or distribution of precursors, knowing that they are to be used in or for the illicit production or manufacture of drugs.

2. The conduct described in paragraph 1 shall not be included in the scope of this Framework Decision when it is committed by its perpetrators exclusively for their own personal consumption as defined by national law.

Article 3

Incitement, aiding and abetting and attempt

1. Each Member State shall take the necessary measures to make incitement to commit, aiding and abetting or attempting one of the offences referred to in Article 2 a criminal offence.

2. A Member State may exempt from criminal liability the attempt to offer or prepare drugs referred to in Article 2(1)(a) and the attempt to possess drugs referred to in Article 2(1)(c).

Article 4

Penalties

1. Each Member State shall take the measures necessary to ensure that the offences defined in Articles 2 and 3 are punishable by effective, proportionate and dissuasive criminal penalties.

Each Member State shall take the necessary measures to ensure that the offences referred to in Article 2 are punishable by criminal penalties of a maximum of at least between one and three years of imprisonment.

2. Each Member State shall take the necessary measures to ensure that the offences referred to in Article 2(1)(a), (b) and (c) are punishable by criminal penalties of a maximum of at least between 5 and 10 years of imprisonment in each of the following circumstances:

(a) the offence involves large quantities of drugs;

(b) the offence either involves those drugs which cause the most harm to health, or has resulted in significant damage to the health of a number of persons.

[1] OJ L 167, 25.6.1997, p. 1.

3. Each Member State shall take the necessary measures to ensure that the offences referred to in paragraph 2 are punishable by criminal penalties of a maximum of at least 10 years of deprivation of liberty, where the offence was committed within the framework of a criminal organisation as defined in Joint Action 98/733/JHA of 21 December 1998 on making it a criminal offence to participate in a criminal organisation in the Member States of the European Union [1].

4. Each Member State shall take the necessary measures to ensure that the offences referred to in Article 2(1)(d) are punishable by criminal penalties of a maximum of at least between 5 and 10 years of deprivation of liberty, where the offence was committed within the framework of a criminal organisation as defined in Joint Action 98/733/JHA and the precursors are intended to be used in or for the production or manufacture of drugs under the circumstances referred to in paragraphs 2(a) or (b).

5. Without prejudice to the rights of victims and of other bona fide third parties, each Member State shall take the necessary measures to enable the confiscation of substances which are the object of offences referred to in Articles 2 and 3, instrumentalities used or intended to be used for these offences and proceeds from these offences or the confiscation of property the value of which corresponds to that of such proceeds, substances or instrumentalities.

The terms 'confiscation', 'instrumentalities', 'proceeds' and 'property' shall have the same meaning as in Article 1 of the 1990 Council of Europe Convention on Laundering, Search, Seizure and Confiscation of the Proceeds from Crime.

Article 5

Particular circumstances

Notwithstanding Article 4, each Member State may take the necessary measures to ensure that the penalties referred to in Article 4 may be reduced if the offender:

(a) renounces criminal activity relating to trafficking in drugs and precursors, and

(b) provides the administrative or judicial authorities with information which they would not otherwise have been able to obtain, helping them to:

(i) prevent or mitigate the effects of the offence,

(ii) identify or bring to justice the other offenders,

(iii) find evidence, or

(iv) prevent further offences referred to in Articles 2 and 3.

Article 6

Liability of legal persons

1. Each Member State shall take the necessary measures to ensure that legal persons can be held liable for any of the criminal offences referred to in Articles 2 and 3 committed for their benefit by any person, acting either individually or as a member of an organ of the legal person in question, who has a leading position within the legal person, based on one of the following:

(a) a power of representation of the legal person;

(b) an authority to take decisions on behalf of the legal person;

(c) an authority to exercise control within the legal person.

2. Apart from the cases provided for in paragraph 1, each Member State shall take the necessary measures to ensure that legal persons can be held liable where the lack of supervision or control by a person referred to in paragraph 1 has made possible the commission of any of the offences referred to in Articles 2 and 3 for the benefit of that legal person by a person under its authority.

3. Liability of legal persons under paragraphs 1 and 2 shall not exclude criminal proceedings against natural persons who are perpetrators, instigators or accessories in any of the offences referred to in Articles 2 and 3.

Article 7

Sanctions for legal persons

1. Member States shall take the necessary measures to ensure that a legal person held liable pursuant to Article 6(1) is punishable by effective, proportionate and dissuasive sanctions, which shall include criminal or non-criminal fines and may include other sanctions, such as:

(a) exclusion from entitlement to tax relief or other benefits or public aid;

(b) temporary or permanent disqualification from the pursuit of commercial activities;

(c) placing under judicial supervision;

[1] OJ L 351, 29.12.1998, p. 1.

(d) a judicial winding-up order;

(e) temporary or permanent closure of establishments used for committing the offence;

(f) in accordance with Article 4(5), the confiscation of substances which are the object of offences referred to in Articles 2 and 3, instrumentalities used or intended to be used for these offences and proceeds from these offences or the confiscation of property the value of which corresponds to that of such proceeds, substances or instrumentalities.

2. Each Member State shall take the necessary measures to ensure that a legal person held liable pursuant to Article 6(2) is punishable by effective, proportionate and dissuasive sanctions or measures.

Article 8

Jurisdiction and prosecution

1. Each Member State shall take the necessary measures to establish its jurisdiction over the offences referred to in Articles 2 and 3 where:

(a) the offence is committed in whole or in part within its territory;

(b) the offender is one of its nationals; or

(c) the offence is committed for the benefit of a legal person established in the territory of that Member State.

2. A Member State may decide that it will not apply, or that it will apply only in specific cases or circumstances, the jurisdiction rules set out in paragraphs 1(b) and 1(c) where the offence is committed outside its territory.

3. A Member State which, under its laws, does not extradite its own nationals shall take the necessary measures to establish its jurisdiction over and to prosecute, where appropriate, an offence referred to in Articles 2 and 3 when it is committed by one of its own nationals outside its territory.

4. Member States shall inform the General Secretariat of the Council and the Commission when they decide to apply paragraph 2, where appropriate with an indication of the specific cases or circumstances in which the decision applies.

Article 9

Implementation and reports

1. Member States shall take the necessary measures to comply with the provisions of this Framework Decision by 12 May 2006.

2. By the deadline referred to in paragraph 1, Member States shall transmit to the General Secretariat of the Council and to the Commission the text of the provisions transposing into their national law the obligations imposed on them under this Framework Decision. The Commission shall, by 12 May 2009, submit a report to the European Parliament and to the Council on the functioning of the implementation of the Framework Decision, including its effects on judicial cooperation in the field of illicit drug trafficking. Following this report, the Council shall assess, at the latest within six months after submission of the report, whether Member States have taken the necessary measures to comply with this Framework Decision.

Article 10

Territorial application

This Framework Decision shall apply to Gibraltar.

Article 11

Entry into force

This Framework Decision shall enter into force on the day following its publication in the *Official Journal of the European Union*.

Done at Luxembourg, 25 October 2004.

For the Council
The President
R. VERDONK

EUROPEAN COMMISSION

Brussels, XXX
COM(2011) 689/2

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

Towards a stronger European response to drugs

1. A STRONGER EUROPEAN RESPONSE TO THE CHALLENGES POSED BY DRUGS

Illicit drugs[1] are a major threat to the health and safety of individuals and societies in the EU. Europe's drugs problem is evolving rapidly. **New and harmful psychoactive substances[2] are emerging at an unprecedented rate**. Drug traffickers change routes and methods for smuggling or for laundering the proceeds of illicit trafficking in drugs.

Drugs particularly affect young people. The use of drugs is one of the major causes of health problems among young people and is one of the most important causes of avoidable death among young Europeans. The 2011 Eurobarometer "Youth attitudes on Drugs"[3] shows that young people can easily obtain even the most harmful drugs within 24 hours. Statistics show that one person dies in Europe every hour because of drug overdose.[4] The use of the internet for selling new drugs and the rapid exchange of information on new drugs through social networks, present new challenges to current drug control policies and to traditional prevention methods.

More needs to be done to address the drug problem. Action should take place where it is more effective, in full respect of subsidiarity. The EU action should be focused where it brings more added value. **Member States are unable to contain the spread of drugs without effective cooperation:** in the internal market goods, but also crime, move freely. If one Member State bans new psychoactive substances, traders open shops in Member States where the law is more permissive. Uncoordinated clamp-downs may force traffickers to move drug production sites to neighbouring countries or to shift trafficking routes, but these measures cannot disrupt trafficking sustainably.

Over the past 15 years, the European Commission has helped develop a comprehensive and balanced EU response to drugs, in the framework of the EU Drugs Strategy (2005-2012)[5]. The two main **EU legal instruments** in anti-drugs policy, one on drug trafficking[6] and the other on the emergence of new drugs (new psychoactive substances)[7], date respectively from 2004 and 2005. However, the past few years have brought fresh challenges: new ways of trafficking drugs and chemicals used for their manufacture ("drug precursors"), the rapid emergence of new drugs and innovative distribution channels for these new substances.

In the 2010-2014 Stockholm Action Plan[8] the European Commission committed itself to measures reinforcing protection against serious and organised crime. With the **Lisbon Treaty**

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1 Illicit drugs are those psychoactive substances for which the unlicensed cultivation, production, trade and possession - other than for medical and scientific purposes - is prohibited.

2 New psychoactive substances are new narcotic or psychotropic drugs which may pose a threat to public health comparable to illicit drugs, and which emerged only recently on the market and are not banned. The large majority of these substances are synthetic.

3 European Commission, Flash Eurobarometer Nr. 330, *Youth attitudes on Drugs*.

4 EMCDDA, *2010 Annual report on the state of the drugs problem in Europe*.

5 The Commission has launched an external evaluation of the EU Drugs Strategy (2005-2012), which will be completed by the end of 2011.

6 Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking, OJ L 335, 11.11.2004, pp 8–11.

7 Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances, OJ L 127, 20.5.2005, pp 32–37.

8 The European Council of 10-11 December 2009 adopted the Stockholm Programme, a comprehensive framework on initiatives in justice and home affairs. To translate these political objectives into concrete

now in place, the European response to drugs needs to be strong and decisive, addressing both drug demand and drug supply. New legislation involving the European Parliament, and implemented by the Member States, will be subject to the scrutiny by the European Commission and ultimately the Court of Justice of the European Union.

The Commission is committed to lend fresh impetus to the EU anti-drugs policy. In its proposed **Budget for Europe 2020**[9] the Commission pledges financial support to meet future challenges posed by drugs. The EU budget should focus on funding those actions that have clear added value, which include: tackling new drugs, developing innovative practices on prevention or treatment and cross-border law enforcement cooperation and training.

2. DRUG TRAFFICKING

The illicit drugs market is constantly evolving to escape controls and seizures[10]. New technologies facilitate the development of **innovative methods for smuggling** into and within the EU. Traffickers use advanced techniques to conceal drugs, for instance, by mixing liquid cocaine into commercial goods (clothes, liquids, plastic), converting it into powder cocaine in laboratories in Europe, or making it odourless. They use remote monitoring of production and storage sites. To increase resilience, traffickers diversify their business, becoming multi-drug (smuggling different drugs or illicit doping substances that have harmful effects on the health of athletes) and poly-criminal (carrying out several illicit activities).

Criminal networks change their **trafficking routes** frequently in order to circumvent controls. The growing importance of the West African route for smuggling cocaine from Latin America into Europe is proof that the networks are able to overcome controls along the Atlantic coast and points to the need for an effective European Border Surveillance System.

The European Pact on international drug trafficking adopted by the Council on 3 June 2010[11], and the forthcoming European Pact against synthetic drugs initiated by the Polish Presidency seek to improve coordination between the various initiatives launched to clamp down on drug trafficking:[12]

Drug trafficking is one of the biggest cross-border law enforcement challenges in the EU. Since 2004, **Eurojust** has dealt with more cases of drug trafficking than any other type of crime. The number of drug trafficking cases referred to Eurojust increased more than threefold over this period, from 77 to 254[13], and this trend is continuing in 2011. In 2010, around a third of operational support provided by **Europol** to national law enforcement agencies was related to illicit drug trafficking[14]. Eurojust and Europol increasingly help coordinate cross border investigations within the EU, and with third countries.

The Lisbon Treaty defines drug trafficking as one of the "***particularly serious crimes with a cross border dimension***", which justify the adoption of directives establishing minimum rules

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proposals, the Commission selected a number of key actions for adoption in 2010-2014. COM(2010) 171 final.

9 COM(2011) 500.

10 Europol, *EU Organised Crime Threat Assessment OCTA 2011*.

11 http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/jha/114889.pdf.

12 On the agenda of the Justice and Home Affairs Council of 27 and 28 October 2011.

13 Eurojust Annual Report 2010.

14 Europol, *General Report on Europol Activities 2010*.

concerning the definition of criminal offences and sanctions[15]. This is a major step forward that will make it possible for the EU to provide a **bolder response**, with stronger involvement of the European Parliament and of national Parliaments.

The existing EU legislation on drug trafficking, namely **Framework Decision 2004/757/JHA**, which provides an EU definition of drug trafficking offences and minimum rules on sanctions, is an important first step towards ensuring a European approach, but it has its **weaknesses.** The Commission's assessment of the implementation of the Framework Decision[16] has shown that this instrument has scarcely led to any alignment of national measures in the fight against drug trafficking. It has not sufficiently contributed to facilitating judicial cooperation in drug trafficking cases.

For instance, in most Member States the trafficking of chemical precursors is directly covered by the criminal law of the respective state. However, in some Member States it only falls under the offence of aiding and abetting drug trafficking. Consequently the judiciary might face obstacles in effectively prosecuting this crime. Similarly, the provisions related to aggravating circumstances (justifying high criminal punishments) set out in the Framework Decision are insufficient: they do not include all aggravating circumstances[17] listed in previous EU or UN instruments.

Common minimum rules are essential in order to establish the level of **trust necessary to enhance cooperation** among Member States' judiciaries. The entry into force of the Lisbon Treaty now enables a legal and political strengthening of this important legal instrument.

The Commission will bring forward new EU legislation, to ensure a more effective approximation of drug trafficking offences and sanctions across the EU. The new proposal would:

(1) **Target major cross-border drug trafficking** and the organised criminal networks, by exploring minimum common aggravating or mitigating circumstances.

(2) **Improve the definition of offences and sanctions**, possibly with a more detailed breakdown of sanctions.

(3) **Introduce stronger reporting obligations** for Member States on the implementation and impacts of legislation.

In addition to strong capabilities in gathering demand side data, the improvement of **data collection in the field of drug supply** is essential for assessing developments in the drugs market. The lack of indicators makes it difficult to evaluate such developments, to estimate the burden of drug-related crime on society and to assess the impact and effectiveness of drug supply reduction.

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15 Article 83(1), Treaty on the Functioning of the European Union.

16 COM(2009) 669 and SEC(2009) 1661.

17 For instance on the victimisation or the use of minors, as foreseen by Art. 3.5.(f) of the 1988 UN Convention against illicit traffic in narcotic drugs and psychotropic substances, and the Council Resolution of 20 December 1996 on sentencing for serious illicit drug-trafficking, OJ C 10, 11.1.1997, p. 3–4.

Building on the technical expertise developed at the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), **the Commission**, with the support of Europol, **will present key indicators** for the monitoring of drug markets, drug-related crime and drug supply reduction. These should help to improve the effectiveness of responses in the area of drug supply.

3. DRUG PRECURSORS

The trafficking of chemicals used for manufacturing drugs is a matter of major concern. Transforming raw opium into heroin, for instance, requires significant quantities of drug precursors. These chemical substances have various legitimate industrial uses, but they may be diverted from legitimate trade into the production of illicit drugs. They are smuggled within the EU and between the EU and different regions of the world. Bilateral agreements between the EU and trading partners on the control of drug precursors provide a strong platform for coordinating policies and exchanging information on the trafficking of drug precursors. The EU has already signed such agreements with Turkey, Mexico, Chile, United States, China and the countries of the Andean region.

To evade control, traffickers change production methods, transform drug precursors into different substances (pre-precursors) from which they are recovered at a later stage, or extract them from pharmaceutical preparations.

Any measures to prevent the diversion of drug precursors must strike a balance between **ensuring an effective control of diversion without disrupting lawful trade** in such substances. Good cooperation between authorities – including the European Medicines Agency, national health/medicines authorities, and economic players – is key in this respect.

The Commission's **assessment[18] of the implementation of EU legislation** on monitoring and control of trade in drug precursors[19] made several recommendations, including: strengthening the implementation of existing rules and possibly introducing a tougher regime for certain chemicals (such as the key precursor for heroin production, acetic anhydride) and ensuring appropriate control of pharmaceutical preparations containing substances used for the production of methamphetamine.

The Commission is examining ways to **strengthen EU rules on the control of production and trade in drug precursors** which comprise different categories of substances and reaction agents frequently used in the manufacture of narcotic drugs or psyochactive substances, and to ensure an effective and uniform implementation of these rules. It is currently assessing the impacts of several policy options, with the aim of presenting legislative proposals to increase the efficiency of rules preventing illicit diversion, while allowing legitimate trade in precursors without excessive administrative burden. Particular attention will be given to the heroin precursor, acetic anhydride, and to pharmaceutical preparations containing ephedrine and pseudoephedrine, used for the production of methamphetamine.

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18 COM(2009) 709.

19 Council Regulation (EC) No 111/2005 of 22 December 2004, OJ L 22, 26.1.2005, p. 1–10; Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004, OJ L 47, 18.2.2004, p. 1–10.

The Commission will take action to enhance international cooperation against the diversion of drug precursors. It is negotiating an agreement with Russia on drug precursors, with the aim of signing it in the coming months as a matter of urgency. Together with the Member States, the Commission will reinforce cooperation with the Latin American countries and will pursue cooperation with China, with which the EU already has such agreements.

4. CONFISCATION AND RECOVERY OF CRIMINAL ASSETS

The main motive for cross-border organised crime is financial gain. In order to be effective, any attempt to prevent and combat organised crime, including drug trafficking, must **focus on tracing, freezing, seizing and confiscating the proceeds from crime.** Organised criminal groups increasingly exploit the advantages of a Europe without internal borders to acquire assets in various EU Member States, and often hide them in third countries. They also change techniques for laundering money.

The tracking, freezing and confiscating the assets of criminal networks is a major challenge. The EU has adopted five legislative instruments (Framework Decisions) designed to deprive traffickers of their gains[20]. These **instruments have not been effective enough**. In particular, they have not enabled public authorities to confiscate large amounts of goods. A functioning network of asset recovery offices in Europe is crucial in order to weaken the financial power of criminal networks and target effectively their illicit proceeds and assets.

The Commission will propose **new, stronger EU legislation on confiscation, recovery of criminal assets and mutual recognition of freezing and confiscation orders.** The aim is to ensure more efficient seizure of the proceeds of crime and to prevent them from being re-invested in the licit economy or used to commit other crimes. The planned legislative package on confiscation and asset recovery will also cover drug trafficking. Its aim is to achieve harmonised minimum rules and to reinforce mutual trust between judicial authorities.

The Commission will review the third **anti-money laundering directive**, in order to further strengthen the EU's defences against the laundering of money generated by organised crime, including drug trafficking.

5. NEW PSYCHOACTIVE SUBSTANCES

During past years new psychoactive substances, which imitate illicit drugs, have frequently emerged in the EU. **Since 2005, Member States have reported 115 new psychoactive substances** through the EU Early Warning System[21]. They are sold in "specialised" shops or over the internet, but some are available from illicit drug sellers. To circumvent national legislation, these drugs are frequently labelled "*not for human consumption*". The speed with which they are launched on the market **challenges the capacity of the authorities to respond**.

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[20] Three Framework Decisions aim at harmonising national measures for freezing and confiscating criminal assets (2001/500, 2005/212, 2007/845) and two relate to mutual recognition of decisions of Member States to freeze and confiscate criminal assets (2003/577, 2006/783).

[21] SEC(2011) 912.

A record number of new substances (41) were reported in 2010, accounting for about one third of all substances since 2005. Two substances, BZP and mephedrone[22], were subjected to **risk assessment at EU level**, following which the Council, based on a proposal from the Commission, subjected them to **control measures and criminal sanctions**. On this basis, Member States must classify these substances as illicit drugs, introducing control measures and criminal sanctions under their legislation in compliance with the UN Conventions.

According to the 2011 Eurobarometer[23] survey, **5% of young people interviewed across the EU have used such substances**. The price of these substances (which is lower than illicit drugs) and the fact that they are "not illegal" – and therefore very easily accessible – could explain their rapid spread in many Member States. However, their toxicity and potential for dependence may pose health threats comparable to illicit drugs.

The Commission continues working closely with EU agencies to improve understanding of this problem and identify more effective answers, including in the field of prevention. The current EU legislation is inadequate for tackling this challenge. The Commission's **assessment of the functioning of Council Decision 2005/387/JHA[24]** on new psychoactive substances concluded that it has three major shortcomings:

- It is unable to tackle the large increase in the number of new psychoactive substances, because it addresses substances one by one, via a lengthy process.
- It is reactive: substances subjected to control measures are quickly replaced with new ones with similar effects.
- It lacks options for regulatory and control measures.

The Commission will propose **stronger EU legislation on new psychoactive substances.** Taking into account the rapid developments in this field and scientific evidence about the risks posed by these substances, the new proposal would:

(1) **Enhance the monitoring and risk assessment of substances**, by extending support for forensic analysis, toxicological, pharmacological and epidemiological studies.

(2) **Provide swifter and more sustainable answers** to the emergence of these substances, possibly by exploring ways to address groups of substances, notwithstanding the need to determine scientifically the harmfulness to health of the individual substance.

(3) **Enable a faster response** to the emergence of substances, including, possibly, through temporary bans on substances that pose immediate risks.

(4) **Better align laws** in the field of drug control, product and food safety, consumer protection and medicines to cover the wide variety of substances that emerge.

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22 BZP in 2008 (OJ L 63, 7.3.2008, p. 45–46) and mephedrone in 2010 (OJ L 322, 8.12.2010, p. 44–45).

23 European Commission, Flash Eurobarometer Nr. 330, *Youth attitudes on Drugs*.

24 COM(2011) 430.

6. REDUCTION OF DEMAND

Various measures are in place across the EU to reduce the demand for drugs. These aim to prevent people from starting to use drugs, to avoid them becoming addicted, to reduce harmful health and social consequences of drug use, and to provide treatment, rehabilitation and social reintegration services. However, the changing patterns of drug use and the increased 'poly-consumption' of substances, such as illicit drugs in combination with alcohol or prescription medicines, is challenging current prevention and treatment methods.

While the provision of treatment has expanded in recent years, **major differences persist in the coverage and quality of drug-related services across the EU**. Around 670 000 Europeans receive substitution treatment for heroin addiction – i.e. only about half of those in need of treatment. The availability of treatment is limited in some EU countries. In certain Member States, the effectiveness of many education, prevention and treatment programmes is still not evaluated.

Measures such as needle and syringe exchange programmes which provide people who inject drugs with access to needles and syringes to prevent them from sharing injecting equipment have helped reduce the spread of HIV and other blood-borne infections among drug users. However, the success of these measures calls for sustainable and integrated strategies across the EU to prevent the spread of drug-related blood-borne infections[25].

There is a clear **need to extend and improve drug-related services**, in order to make sure that prevention works, and that those in treatment recover and reintegrate into society.

The Commission will also promote improved implementation of the key indicators in the field of drug demand reduction, to enable Member States to provide more effective services.

The Commission will help develop **minimum quality standards,** to improve the effectiveness of drug prevention, treatment and harm reduction in the EU. The aim is to set standards for quality in the delivery of drug-related services, for example prescribing a thorough planning of treatment in line with the patient's individual needs or on staff qualification requirements. These standards will be developed together with the EMCDDA, Member States and practitioners involved in drug-related services, and will take into account the different health systems and capacities across the EU.

The Commission will further support and promote **measures to reduce health and social harms associated with drug dependence**, including strengthening educational prevention and early stage support in avoiding addiction, interventions to prevent and control infections among people who inject drugs, and to prevent drug-related deaths[26]. It will continue to support measures to help rehabilitate and reintegrate drug-dependent users in society.[27] It intends to submit a second report on the implementation of the 2003 Recommendation on harm reduction[28], designed to assess the effectiveness of prevention and reduction of health-related harm associated with drug dependence.

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25 EMCDDA, *2010 Annual report on the state of the drugs problem in Europe*.

26 As outlined in the Commission communication on combating HIV/AIDS in the EU and neighbouring countries, COM(2009) 569.

27 Such initiatives will continue to be funded by EU financial programmes, including the Drug Prevention and Information Programme, the Health Programme, as well as the European Social Fund.

28 OJ L165, 03.07.2003, p. 31 – 33.

7. DRUGGED DRIVING

Many road accidents in the EU are caused by **drivers under the influence of psychoactive substances**. Studies show that driving under the influence of illicit drugs increases the risk of causing a fatal road accident. However, because data are not collected systematically at EU level, the adverse effects of drug-driving on road safety needs further study. Developing effective and proportionate responses to tackle drugged driving presents a major challenge as highlighted in the Roadmap to a Single European Transport Area[29].

The Commission is exploring possible actions at EU level to **address drugged driving,** with the aim of increasing road safety. Based on the results of the EU-financed DRUID[30] project, which has assessed the impact of illicit drugs on road safety, the effectiveness of testing devices and possible responses, the Commission will propose measures to help tackle this problem effectively. These responses could include ways of improving the reliability of devices used for road-side testing or providing appropriate training support for traffic officials.

8. INTERNATIONAL COOPERATION

The EU plays a leading role in international cooperation on illicit drugs. It is engaged in an active dialogue with the production and transit countries and provides political, financial and technical support. A stronger response to illicit drugs will require the EU to step up its engagement with neighbouring countries, with strategic partners and along the drugs routes into the EU on the basis of a balanced and comprehensive approach with full respect for human rights.

Apart from illicit drugs originating in the EU, there are two main drug routes through which drugs enter the EU. These are the "cocaine route" (from Latin America via West Africa into the EU) and the "heroin route" (from Afghanistan through either the Western Balkans or Central Asia into the EU). The EU approach to tackling illicit drugs internationally is three-fold:

Comprehensive – the Lisbon Treaty provides an opportunity for the EU to strengthen its law enforcement cooperation with third countries, to help them improve the capacity of judicial systems and to promote the rule of law, in full respect of human rights. The EU focuses on seeking long-term solutions, for example, through promoting alternative livelihoods for drug crop farmers in rural areas, in countries such as Afghanistan, and reducing demand in countries of origin and transit. The EU is committed to work closely both with transit and with producing countries, as both suffer from increasing drug use in their populations, related public health challenges as well as from weak institutional capacity to tackle the problem.

Geographical – the EU will further consolidate its "drug route" approach, which enables it to tackle the problem comprehensively from drug crops cultivation to the entry of drugs onto the EU market. **European Neighbourhood countries** (ENP) will remain a priority. Continued support will be provided to the enlargement countries on capacity-building to enable them to tackle drug trafficking and abuse, notably through the Instrument for Pre-Accession

[29] COM(2011) 144.

[30] Driving under the Influence of Drugs, Alcohol and Medicines. http://www.druid-project.eu.

Assistance (IPA). The EU will reinforce its engagement with **Latin American**[31]**, Caribbean and African** countries, as well as with relevant regional organisations, building on the success of the cooperation platforms of liaison officers in West Africa, to coordinate capacity building.

Cooperation with strategic partners – the EU will build on our engagement with strategic partners with a shared interest in tackling illicit drugs. Cooperation with the United States on Passenger Name Record (PNR) data has been particularly valuable in the fight against drug trafficking. The EU and the United States are exploring ways to establish a joint law enforcement network on drug trafficking and coordinate capacity-building projects in West Africa, Latin America and the Caribbean. The EU is intensifying efforts with the United States and Russia to reduce drug trafficking and prevent drug abuse in **Central Asia**. It is also working with international partners to improve international cooperation to tackle the drugs economy in Afghanistan, which supplies up to 90% of the world's heroin.

Further measures to strengthen international cooperation in the drug field will be considered in the context of the ongoing evaluation of the current EU Drugs Strategy and Action Plans.

9. CONCLUSIONS

The European drugs policy aims to protect and improve the well-being of society and of the individual, to protect public health, to offer a high level of security for the general public and to take a balanced, integrated approach to the drugs problem. The entry into force of the Lisbon Treaty and the dismantling of the pillar structure in EU policy making, provides new opportunities for the integration of all policy areas relevant to the drugs problem. The scale of Europe's drugs problem and its changing nature require **swift, strong and effective EU action**. The Commission is determined to scale up its response to illicit drugs and to new psychoactive substances that imitate their effects (mainly new synthetic drugs)[32], using the new opportunities provided by the Lisbon Treaty.

The Commission will present; as legislative proposals:

(1) A legislative package on drugs, proposing the revision of the Council Framework Decision on drug trafficking and the Council Decision on new psychoactive substances;

(2) Legislative proposals on drug precursors;

(3) Legislative proposals on the confiscation and recovery of criminal assets and on strengthening mutual recognition of freezing and confiscation orders;

(4) New legislative measures to combat money laundering.

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31 The COPOLAD programme provides a solid framework to continue our efforts with the Latin America countries in addressing all aspects of drug policies. Furthermore, in Latin America and the Caribbean, drug-related security issues will be addressed, in light of the growing concern in this area.

32 The first EU initiative on new psychoactive substances was a Joint Action 97/396/JHA of 16 June 1997 on the information exchange, risk assessment and the control of new synthetic drugs. New psychoactive substances are mostly new synthetic drugs but they also include organic substances. The Joint Action has been replaced by Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances.

In addition, the Commission will present:

(5) Indicators to monitor drug supply, drug-related crime and drug-supply reduction to help improve the effectiveness of supply-reduction measures;

(6) Minimum quality standards to improve drug prevention, treatment and harm-reduction services.

The Commission invites the European Parliament and the Council, civil society and other important stakeholders, to take part in a debate on effective responses to illicit drugs and new psychoactive substances. To enable all interested stakeholders to contribute to this debate, the Commission will launch an online public consultation on how best to tackle illicit drugs and the emergence of new substances that imitate them.

EUROPEAN COMMISSION - PRESS RELEASE

European Commission seeks stronger EU response to fight dangerous new synthetic drugs

Strasbourg, 25 October 2011 – The European Commission has today given a fresh impetus to anti-drugs policy by announcing an overhaul of the EU rules to fight illicit drugs, particularly new psychoactive substances, which imitate the effects of dangerous drugs like ecstasy or cocaine and are a growing problem. The EU indentified a record number of 41 such substances in 2010, up from 24 the previous year. These drugs are increasingly available over the internet and have rapidly spread in many Member States, which face difficulties in preventing their sale. More new drugs are entering the market. Over the past two years, one new substance has emerged every week. Member States cannot stop the spread of drugs alone: clampdowns at national level may simply force criminals to move drug production to neighbouring countries or to shift trafficking routes. With the Lisbon Treaty now in place, the EU has new tools to address the drugs scourge. Over the coming months, the Commission will develop clearer and stronger rules on tackling dangerous new drugs and trafficking – both of illicit drugs and chemicals used to make them.

"New synthetic drugs are becoming widely available at an unprecedented pace in Europe. In addition, drug trafficking has become one of the most important crimes committed cross-border in the European Union," said EU Justice Commissioner Viviane Reding. *"Europe's response to drugs needs to be strong and decisive. That's why we need concerted action at the EU level to disrupt the supply of drugs and reduce demand, including by means of deterrent criminal sanctions*. *Effective rules without loopholes are needed so that young people in particular do not fall into the trap of using dangerous drugs, which are a major threat to their health and well-being."*

According to a recent Eurobarometer survey, new synthetic drugs, which can be just as dangerous as banned substances, are increasingly popular with 5% of young Europeans saying they have used them. The figures are the highest in Ireland (16%), followed by Poland (9%), Latvia (9%), the UK (8%) and Luxembourg (7%). The survey reveals that across all 27 EU Member States, a large majority of 15 to 24-year-olds are in favour of banning these substances.

To tackle this increasing threat, the Commission has put forward a new approach for a stronger European response, including:

- Stronger EU legislation on **new psychoactive substances** so that the EU can provide a faster response, including the possibility of temporary bans, as well as tackling their sale over the internet;
- New EU legislation to **target cross-border trafficking in drugs by means of criminal law**: the Commission will improve the definition of offences and sanctions and introduce stronger reporting obligations for Member States;
- New EU laws to strengthen control over chemicals used for drugs production;

IP/11/1236

- More effective rules to **deprive drug traffickers of their financial gains**: in the coming weeks, the Commission will propose rules on the confiscation and recovery of assets involved in serious crime, including drug trafficking;
- More **cooperation at international level**, especially with transit and producing countries outside the EU, as well as with countries considered as major entry points for drugs in Europe.

Background

EU legal instruments in anti-drugs policy, notably on drug trafficking and the control of chemicals used to make drugs, as well as the emergence of new psychoactive substances, date from 2004 and 2005 (Council Decisions 2004/757/JHA and 2005/387/JHA). These rules now need to be updated because of recent changes in how drugs are trafficked and the emergence of new drugs.

With the Lisbon Treaty now in place, the European response to drugs can be stronger and more decisive. The Treaty defines drug trafficking as one of the "particularly serious crimes with a cross-border dimension" allowing the adoption of directives that establish minimum rules on the definition of criminal offences and sanctions (Article 83(1) of the Treaty on the Functioning of the European Union). New legislation involving the European Parliament, and implemented by the Member States, will be subject to the scrutiny by the Commission and ultimately the EU's Court of Justice.

Tackling illicit drugs trafficking and abuse requires an **integrated and coherent approach**, which joins together public health, social and education policies as well as cooperation between law enforcement authorities and international cooperation.

At least 75.5 million Europeans said they have used cannabis at least once in their lifetime, while cocaine and amphetamines have been tried by 14 million and 12 million people respectively. A recent Eurobarometer survey of young people's attitudes to drugs shows confirms that one in three young men (32%) admit having used cannabis at least once in their lifetime compared to one in five young women (20%). 57% of respondents believed they could easily obtain cannabis within 24 hours, while 22% said the same for ecstasy or cocaine.

Various means are in place across Europe to **reduce the demand for drugs** and the consequences of drug abuse. However, major differences still exist among Member States. The Commission will respond to the need to **extend and enhance drug-related services** by developing new tools to improve quality standards of drug prevention, treatment and harm reduction treatments.

Continuous **dialogue with third countries** is key to achieving concrete results in reducing the use of illicit drugs and combating drug trafficking. The EU will consolidate its external assistance and cooperation activities with crucial regions of the world (such as Latin American, Caribbean and African countries, the US, and the Russian Federation).

For more information

European Commission – anti-drugs policy:

http://ec.europa.eu/justice/anti-drugs/index_en.htm

Homepage of Vice-President Viviane Reding, EU Justice Commissioner:

http://ec.europa.eu/reding

ANNEX

Stronger EU action to tackle Europe's drug problem

In the next two years, the Commission will present:

(1) **a drugs legislative package**, proposing the revision of the Framework Decision on drug trafficking and of the Council Decision on new psychoactive substances;

(2) **legislative proposals on drug precursors**;

(3) **legislative proposals on fighting organised crime, including drug trafficking, through confiscation and asset recovery, and new measures against money laundering;**

(4) **indicators to monitor drug supply,** drug-related crime and drug-supply reduction to help improve the effectiveness of supply-reduction interventions;

(5) **minimum quality standards** to improve drug prevention, treatment and harm-reduction services.

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COUNCIL OF
THE EUROPEAN UNION

EN

European pact against synthetic drugs

3121st JUSTICE and HOME AFFAIRS Council meeting
Luxembourg, 27 and 28 October 2011

The Council adopted the following pact:

"1. Synthetic drugs, mainly Amphetamine Type Stimulants (ATS), pose a significant worldwide problem. In the EU, they are the second most popular type of illicit substances in terms of consumption - just after cannabis products (herbal cannabis and cannabis resin). Moreover, based on the findings of the OCTA 2011 report, it is clear that the involvement of organised crime groups in the production and distribution of synthetic drugs makes it a major concern in terms of public order as well.

2. The consumption, illicit production and trafficking in synthetic drugs continue to be a matter of concern and pose a considerably serious problem for the European Union. The EU is not only a region of consumption, as in the case of cocaine and heroin, but also a significant producer of synthetic drugs - especially of amphetamine and MDMA[1]. The EU has, therefore, a major responsibility to address synthetic drugs comprehensively and robustly.

3. The significance of the threat, its cross-border dimension and the strength of criminal groups involved, call for a more centralised, coordinated and effective operational response. This should be fully in line with the EU Policy Cycle and, where relevant, both national and EU law enforcement resources need to be combined and used in a coherent way. Europol should be seen as the designated central responsible body for the coordination of the overall effort against synthetic drugs seeking to use the relevant Analytical Work Files (AWF) to best effect, so that Member States can fully benefit from its unique ability to provide central support to cross-border investigations and to analyse intelligence.

[1] 3,4-Methylenedioxymethamphetamine - the classical active agent in ecstasy tablets

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4. All actions against organised crime groups dealing with synthetic drugs need to be combined with effective tracking, freezing and, ultimately, confiscation of the proceeds of these crimes. There should also be a wider tackling of criminal finances beyond asset recovery; e.g. attacking money laundering, disrupting and denying assets, using financial investigation as a core tool in criminal investigations. Deprivation of illegal gains should become a vital element of the fight against synthetic drugs. Full use of the existing mechanisms, such as Europol and national asset recovery offices - at their respective levels - is essential.

   An effective prevention, detection and disruption policy against the penetration of the licit economy by organised crime requires enhanced expertise from the Member States and EU agencies in the three-dimensional aspects of financial investigations (past, present and future).

   This should help in developing evidence which can be used in criminal proceedings (judicially oriented financial investigation – past), identify the extent of (transnational) criminal networks (dismantling oriented financial investigation – present), assess the nature and evolution of crime and criminal patterns (proactive and strategically oriented financial investigation – future).

5. The use of new psychoactive substances (so called "legal highs", which can pose a serious threat to public health), which are mostly synthetic, is increasing in the EU. New psychoactive substances are often sold in so called “Smart shops” and via internet shops thus becoming accessible to a wide range of potential consumers including children. They are a major challenge for the services responsible for the protection of public health, law enforcement agencies and lawmakers. Little is known about their effects but they can pose major risks to the health and life of people who use them, and more broadly to public health. Their rapid emergence and rising popularity and lack of knowledge of possible health risks before risk assessments are conducted make the growing use of new psychoactive substances a complex issue for national authorities that decide on the regulation or control of such substances. Recent analysis of drug markets in some EU countries seem to suggest that there is a dynamic relationship between the reduction in availability of some traditional illicit compounds for synthetic drugs (MDMA) and the emergence of new psychoactive substances[2].

[2] EU Organized Crime Threat Assessment OCTA 2011

6. Chemical precursors are necessary for the production of synthetic drugs. Key precursors are mainly smuggled into the EU from different regions of the world, but there are also other essential chemicals often diverted inside the EU itself. Drugs produced in the EU are later smuggled to third states. The trafficking of these drugs is in the hands of transnational organised crime groups and can only be effectively disrupted by joint efforts of the European Commission and EU Member States in close cooperation with third states. Active cooperation under the bilateral agreements between the EU and certain third countries on drug precursors is essential in this regard, as is the sharing of this information between EU Member States.

7. A new trend has emerged recently – precursors are masked through transformation into a different substance from which they can be easily recovered at a later stage, or so called pre-precursors are being used. In this respect, specific attention should be given to the risk of organised crime groups evading the relevant EU Regulations by disputing the scope or the judicial interpretation of the legal definitions in these EU Regulations[3].
A review of the legal definitions in these Regulations should be taken into consideration.

8. Although EU Member States are active and efficient in seizing illicit drug precursors, clamping down effectively on the trafficking of chemical precursors and synthetic drugs both to and from the EU requires a better sharing of information and intelligence on precursor false declaration, smuggling concealment methods, as well as stricter controls at external borders and strengthened cooperation among competent authorities of the Member States.

9. Knowledge of methods of production, and the detection and dismantling of illegal laboratories are crucial for effectively combating the illicit production of synthetic drugs. These laboratories pose a serious threat, not only to law enforcement officers but also for the environment, because of the potential risk of accidents and/or illegal disposal of chemicals stored in them. As a consequence, it is necessary to provide law enforcement agencies with specialised training that would allow for a more uniform and safe way of investigating and dismantling illegal laboratories.

10. The patterns and intensity of the production and trafficking in synthetic drugs are likely to differ from one region to another, or even from one Member State to another. In addition, the level of involvement of Member States in countering that type of crime may depend on the extent of the threat posed by synthetic drugs, the levels of perception of the threat and the available resources that may be used for this purpose. There is a need to enhance information gathering and analysis to improve understanding and monitoring of production and trafficking patterns at European level.

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[3] In particular the meaning of "any substance, including mixtures and natural products containing such substances", Regulation (EC) No. 273/2004, Article 2 (a) and Regulation (EC) 111/2005, Article 2 (a).

11. The launching of this initiative results from the European pact on countering international drug trafficking – disrupting cocaine and heroin routes that was adopted by the Council in June 2010. Point 5 of that document invites the Council, European Commission and relevant EU agencies to focus their activities in 2011 on counteracting synthetic drugs, in particular in the field of information sharing, specialised trainings and combating smuggling of precursors in close cooperation with relevant third countries.

12. All these activities to counter production of and trafficking in synthetic drugs and smuggling of precursors call for a coordinated approach by all EU Member States. Drug trafficking is undoubtedly a serious threat that has to be addressed by a joint effort including by coordinating national legislative and control measures to avoid that actions taken by one Member State have a negative impact on other Member States.

13. The pact against synthetic drugs is based on similar principles as the previous one and it is an integral part of the law enforcement aspect of the EU's anti-drug strategy and the EU drugs action plan for 2009-2012 that advocate a global balanced approach based on simultaneous reduction of supply and demand. It is a practical application of the Stockholm Programme and of the EU Internal Security Strategy adopted by the Council in 2010.

The pact against synthetic drugs is a response to the challenges and findings mentioned above. The pact includes four major areas:

i. Countering production of synthetic drugs
ii. Countering trafficking in synthetic drugs and precursors
iii. Tackling new psychoactive substances
iv. Training for law enforcement services in detecting, examining and dismantling clandestine laboratories.

The pact indicates only the main activities which should be undertaken and the objectives to be achieved by Member States, European Commission and relevant EU agencies. The implementation of the pact should be placed under supervision of the Council/COSI, in full cooperation with the European Commission as regards to drug precursors, which is an exclusive competence of the EU. Its implementation should be fully in line with the EU policy cycle for organised and serious international crime, in particular with strategic goals and operational action plans to be developed in the coming months. Other Council working parties, in particular the Horizontal Drugs Group (HDG), should be associated in the implementation of the Pact. The HDG should take the lead on actions to address new psychoactive substances. The pact should serve as an umbrella approach whereas concrete implementing measures both at the strategic and operation level shall be defined and developed within the policy cycle.

I. Countering production of synthetic drugs

I.1 The main objective of the undertaken activities is to reduce the illicit manufacturing of Amphetamine Type Stimulants (ATS) and take measures against new psychoactive substances which are harmful to physical, psychological and public health.

I.2 The European Commission is invited to periodically assess whether new chemicals should be added to the list of "non-scheduled substances" in order to better monitor their circulation and their leaking into the illicit market.

I.3 As Synthetic Drugs, including new psychoactive substances which might be harmful to health, are one of the EU's agreed Crime Priorities, the role of the Europol's Analysis Work File (AWF) Synergy should be provided with an appropriate level of support. Member States shall commit to improving information exchange relating to the illicit production of synthetic drugs and by fully using relevant Comprehensive, Operational, Strategic Planning for the Police (COSPOL) projects and through other existing instruments, including those managed by Europol.

I.4 Europol and Eurojust shall assist in the coordination of investigations/operational activities carried out by Member States related to the illicit production of synthetic drugs across the European Union involving the same precursor sources or cross-border criminal groups.

I.5 The existing system for information exchange among Member States regarding new methods of illicit production of synthetic drugs and diversion of precursors and the modus operandi of both producers and traffickers shall be improved and intensified. In case of precursors, close cooperation is needed between the competent national authorities and private operators in order to promote information exchange with the producers and the agents who sell those products.

I.6 Sound information and analysis is the key to assessing progress in the fight against synthetic drugs. There is a need to monitor efforts implemented under the pact and the effects of the activities of Member States on the synthetic drugs market. Member States should assess their national efforts against a wider European background with the assistance of the information and analysis provided by the EMCDDA in cooperation with Europol.

I.7 The European Drugs Profiling System (EDPS) and its database should be fully used to help reduce organised crime involved in the production and trafficking of illicit synthetic drugs by integrating forensic profiling in intelligence and law enforcement operations. To this end, close cooperation with Europol, as the EU agency that will host the database as of 2012, should be ensured.

II. Countering trafficking in synthetic drugs and precursors

II.1 Measures aiming to combat trafficking in synthetic drugs are based on the same principles as depicted in the European pact on disrupting cocaine and heroine routes, and comprise similar activities in particular with regard to the need for reinforced coordination, sharing of tasks and enhanced regional cooperation.

II.2 Actions in the field of drug precursors control should be seen in the context of the Council conclusions on the functioning and implementation of EU drug precursors legislation of 25 May 2010 and of the further work to review the legislation carried out by the European Commission, in order to prevent the diversion of pharmaceutical preparations containing ephedrine and pseudo-ephedrine[4] towards the production of synthetic drugs.

II.3 In cooperation with the European Commission, OLAF and the Member States' law enforcement authorities, Europol – in accordance with its mandate - is invited to intensify its cooperation with Eastern European and Asian countries in preventing the diversion of drug precursors and pre–precursors from licit trade.

II.4 The role of Liaison Officers accredited in Eastern European and Asian countries in the monitoring of the market for the illicit production and trade in synthetic drugs and the diversion of drug precursors shall be increased. For this kind of exchange of information proper communication channels, national rules and regulations as well as EU-laws are to be observed. Structural exchange of operational information or information about capacity building projects among EU Liaison Officers posted to relevant Eastern European or Asian countries with the European Commission and OLAF should be encouraged, in order to maximize synergies and avoid duplications.

II.5 Coordination of the activities of Member States, EU institutions (including OLAF) and agencies (in particular EMCDDA, Europol and Eurojust) shall be further improved. The objective is to guarantee coherence – both inside and outside of the EU – of the activities aimed at regulating or combating illicit trafficking in synthetic drugs and drug precursors.

II.6 Cooperation between competent authorities (e.g. police, customs - if allowed under national legislation) shall be strengthened, in accordance with the Council Conclusions on the contribution of the customs authorities to the implementation of the Stockholm Programme in the fight against serious and organised cross-border crime, adopted on 11 April 2011. The possibility for law enforcement agencies of setting-up of joint investigation teams[5] in order to foster cooperation in combating precursors and synthetic drugs smuggling shall be encouraged and the barriers and obstacles encountered regarding this instrument in the past decade shall be examined by COSI in cooperation with other relevant bodies. The JIT Secretariat hosted at Eurojust and its experience in the field of JITs should be further used in the JIT setting up and coordination.

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4 The issue of red phosphorus will be addressed when elaborating the Operational Action Plan on synthetic drugs in the framework of the EU policy cycle.

5 2002/465/JHA, OJ L 162, 20.6.2002, p. 1.

II.7 The situation and the needs of transit countries and countries of origin of precursors, in terms of training or capacity building, for instance, shall be taken into consideration while establishing or enhancing close cooperation with them. These elements shall be also considered in the process of drawing up EU overall policy towards third countries. This cooperation needs to be coherent and consistent with the EU external and enlargement policies and structures, as well as the EU policy on drug precursors.

III. Tackling new psychoactive substances

III.1 In recent years new psychoactive substances, mainly synthetic, have increasingly emerged on the EU market. Member States, the Commission and relevant agencies (EMCDDA, Europol, Eurojust and the European Medicines Agencies) shall intensify their efforts to rapidly and proactively monitor and assess the diffusion, composition and related health risks of these substances. Information on these new substances should rapidly circulate among national authorities, European Commission and EU agencies. Accordingly, substances that pose a threat to health should be swiftly eliminated from legal circulation, for instance as a temporary measure during the period of assessment.

III.2 Further investment should be made in identifying and developing legally sustainable approaches that effectively regulate the market for new psychoactive substances and prevent substances that pose a threat to health from entering the market.

III.3 Information exchange between Member States regarding new psychoactive substances and new distribution patterns shall be improved, by making full use and if needed reinforcing the Early Warning System.

III.4 A joint EU approach to effectively addressing the rapid spread of new psychoactive substances shall be considered, including through legislative measures.

III.5 Joint efforts should be considered to address sales and distribution of new psychoactive substances over the internet or in specialised shops.

III.6 The Council invites the European Commission to consider the revision of the existing legislative framework on the information exchange, risk assessment and control of new psychoactive substances. The revised instrument should aim to balance effectiveness of measures with a scientifically robust and rapid response.
The Commission may analyse how the relevant regulations are applied across the EU and, if necessary, take the necessary measures to ensure their coordinated application.

IV. Training for law enforcement services in detecting, examining and dismantling clandestine laboratories

IV.1 Enhancing accurate and up-to-date knowledge about the methods and approaches used by criminal organisations for the illicit production of synthetic drugs and diversion of precursors as well as information on effective methods and best practices in the detection and dismantling of illicit production facilities is key in ensuring the efficiency of activities undertaken by law enforcement agencies. It is crucial to harmonise training provided in this field so that safe and effective methods of dismantling illicit production facilities can be attained.

IV.2 Training in methods and techniques for the detection and dismantling of illicit clandestine laboratories should be provided from an international perspective and become a structural element in the training programmes of the European Police College (CEPOL) in coherence with the EU police training strategy and the future European Training Scheme policy. Experts from Member States and Europol should be involved in this process.

IV.3 A dedicated training infrastructure should be used to provide professional training for law enforcement officers. Such an infrastructure was created as part of the International Training Center for Combating Clandestine Laboratories project (co–financed by the ISEC programme)[6]."

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[6] The project comprises, among other things, reconstructed illegal drug laboratories that had been shut down in Poland and the Netherlands.

COUNCIL OF
THE EUROPEAN UNION

EN

European pact to combat international drug trafficking – disrupting cocaine and heroin routes

3018th JUSTICE and HOME AFFAIRS Council meeting
Luxembourg, 3 June 2010

"The consumption of and increased trafficking in drugs continue to be a matter of concern for all Member States of the European Union and its Institutions. It is a major concern in terms of public order and public health.

The international drug trafficking situation prompts two observations:

– Organised crime networks involved in drug trafficking are transnational. They can adapt to the counter measures taken by individual States. The most effective response is to be found at the European level.

– EU Member States are affected by drug trafficking in different ways; they can all agree to join in countering these traffickings by taking specific measures, according to their geographical location, the extent of their resources and the intensity of the threats that in particular affect them.

These observations are the grounds for the Council's decision to conclude a European pact against international drug trafficking focused at this stage on cocaine and heroin. This project is a first step which should serve in the future as a model for the fight against other categories of drugs, primarily cannabis and synthetics. It is an integral part of the law enforcement aspect of the EU's anti-drug strategy (established in 2005) and the EU action plan for 2009-2012 that advocate a global balanced approach based on simultaneous reduction of supply and demand. It is a practical application of the Stockholm programme and of the European internal security strategy adopted by the Council.
Its implementation must take place in accordance with relevant EU and national law, especially that on data protection.

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P R E S S

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The European pact to combat international drug trafficking shall be based on the following principles:

1. We shall be committed to reinforce political coordination between Member States, the Institutions of the European Union and the relevant European agencies, in particular with Europol and Eurojust. Our aim is to ensure coherence of action both inside and outside the European Union against drug trafficking.

2. We shall make the best possible use of our resources. We shall bring together more specialised services of Member States in operational networks, which shall be based on the existing multilateral structures for information exchange including Europol and Eurojust**,** according to their respective competences. We shall make use of existing groups of high-level experts whenever necessary.

3. We shall « share our tasks » within the European Union. In this way, groups of Member States and the Commission can unite their efforts and give priority use of their resources to the kind of combat they are best equipped for, while benefiting from the actions carried out by their partners against other forms of trafficking. For example, the experience of Member States in tackling the trafficking in cocaine in the Western route and the equivalent for those Member States in tackling the trafficking in heroin on the Eastern route should be capitalised upon.

4. We shall take into account the situation and needs of the source and transit countries and shall work in partnership with them. We shall involve the EU's major partner countries outside the EU as well as UNODC and Interpol. Accordingly, we shall take these elements into consideration when defining the European policies towards these various third countries. This cooperation should be consistent and in synergy with the EU external and enlargement policies and structures.

5. In the first instance we shall choose to focus our action against cocaine and heroin. with an increased use in some Member States Other types of drugs (synthetic drugs, cannabis) will be the object of forthcoming initiatives. A comparable initiative concerning synthetic drugs, will be launched in 2011, together with the Commission, in order to establish a common approach among the States most affected in particular in terms of information sharing and specialised training, to combat the diversion of chemical precursors and to intensify regional cooperation between Member States as well as partnership with relevant third countries. Furthermore there is a high expectation on a similar initiative on tackling cannabis will be envisaged.

6. We shall decide to combine this targeted action with a two-fold common undertaking. Within the Union we shall examine and improve where appropriate the instruments indispensable to strike at traffickers by means of their criminal earnings. We shall also support the development of comparable instruments in third countries.

7. shall be resolved to fight against drug trafficking in order to deal a severe blow against the criminal organisations that are major threats to our civil societies as well as societies of origin and transit countries, by reason of their versatility, their disposition to violence, their available resources and their trans-national nature.

8. We shall encourage Member States to closely cooperate in order to enhance external border control with a view to prevent illicit drug trafficking into the EU.

* * *

Accordingly, this European Pact shall be hinged on three main commitments:

I – Disrupting cocaine routes

- The regional information exchange centres set up in West Africa at Accra (Ghana) and Dakar (Senegal) shall become a special instrument in the combat against cocaine trafficking, as part of a common action by the European States and the EU Institutions on the Atlantic coast and the Mediterranean. In this regard:

  – their resources and their capacity to work together shall be reinforced (target: September 2010);

  – their functions shall include exchanging intelligence between partners, providing expert advice to improve the effectiveness of local investigations and supporting the assistance and cooperation policies with the transit countries in West Africa (target: as from September 2010);

  – the information exchange centres shall be linked to each other, to MAOC-N and CECLAD-M by means of a secure ICT network put into place by Europol under the authority of the Member States (target: January 2011);

  – Europol's Secure Information Exchange Network Application (SIENA) shall be used by Member States in the regional centres in the form of a SIENA terminal (target: as from January 2011);

  – in order to improve the flow of information, Europol shall liaise with the regional centres within the applicable legal framework (target: 2010-2011).

  These initiatives will be implemented keeping in mind upcoming evaluations of regional information exchange centres**.**

- Europol shall provide analytical support to the participating Member States in the regional centres under different forms:

  – On the basis of the first Organised Crime Threat Assessment – West Africa (OCTA-WA) that will be updated, if needed, strategic analysis included in the OCTA shall be made available and complemented by customised "threat notices" (OC-SCAN) (target: September 2010);

  – in parallel operational analysis shall be provided by using specific "target groups" within the existing analysis files such as AWF COLA (target: January 2011).

- Information exchange between Europol and CSDP missions in West Africa (notably EUSSR Guinea Bissau) shall be explored carefully as a way forward to support capacity building of the local authorities.

- The combat against drugs shall remain an important element of the external relations between the European Union and key countries:

  – In full coherence and synergy with EU other external policies partnerships with source countries (South and Central America) and transit countries (West Africa) and the main partners of the EU (notably the United States) shall be reinforced and their operational aspect developed (target: 2010-2012);

  – regular contacts with the relevant international information exchange structures, such as the JIATF in Key West, shall be established within the applicable legal frameworks (target: as from September 2010).

- Following the philosophy of regional partnerships and shared efforts, technical assistance to source countries (Latin America and Caribbean) and to transit countries (West Africa) shall be intensified and streamlined.
  In this regard, the strategic and concerted action to improve cooperation in combating organised crime originating in West Africa included in the action oriented paper adopted by the Council on [22-23 April 2010], as well as the EU-LAC coordination and cooperation mechanism on drugs shall be the reference framework:

  – cooperation activities led by EU States and the Commission in training to the fight against illegal drug trafficking shall be made coherent in order to avoid duplications and to cover possible gaps (target: to be effective as from 2011);

  – to this end, an ad hoc flexible and consultative mechanism shall be set up to coordinate the technical assistance activities destined to West Africa, in association with the Commission and in accordance with the conclusions adopted by the Council on 30 November 2009 (target: 2011). This should be done in full respect of the EU financial instrument's rules and procedures;

  – technical assistance activities shall meet the needs and priorities expressed by the countries of the region in the framework of the Regional action plan adopted by ECOWAS and supported by the Commission and implemented also by UNODC (target: as from September 2010).

- Improve the efforts to prevent the diversion of precursors for illicit drug production in cooperation with the Commission.

- Skills and capacity of resources in terms of information and conducting sea interception and air intervention operations shall be improved:

  – a list of the resources and funding implemented by the Member States and the EU shall be drawn up and updated on a regular basis (target: 2nd semester 2010);
  – agreements shall be sought with the relevant third countries in the region and some "flag States" to facilitate boarding procedures as provided by the United Nations Convention against illicit traffic in narcotic drugs and psychotropic substances 1988 (target: 2011-2012);
  – joint land, sea, river and air operations shall be developed (target: as from September 2010, as many operations as needed).

II - Disrupting heroin routes

- The Member States concerned by heroin trafficking shall adopt a common approach that takes into account the large variety of routes and partners involved. This common approach shall be built mainly on the Member States' liaison officers network and the EU delegations in the Balkans and other transit regions, building upon Member States and EU existing efforts:

  – the capacity and the relevance of the existing network shall be assessed according to operational needs (target: 2011);

  – the network shall be consolidated, as necessary, by the posting of additional Member States' liaison officers in the relevant third countries (target: 1st semester 2012);

  – information exchanges by liaison officers of EU Member States shall be strongly encouraged and the results, where appropriate, shared on the level of the responsible law enforcement agencies (target: as from September 2010, to be fully effective in January 2011);

  – this approach shall involve, as necessary, the existing regional law enforcement cooperation agencies, such as SECI /SELEC in Bucharest and CARICC in Almaty (Kazakhstan) (target start from September 2010).

- Operational cooperation with the third countries concerned by heroin trafficking on the Balkans and Black Sea routes as well as cooperation with Eastern European neighbouring Countries shall be intensified as much as possible:

  – the States on the Balkan route shall take part, as necessary, in the projects led by Europol and in the feeding of its Analysis Work Files (AWFs) within the applicable legal framework (target: start from September 2010);

  – controlled deliveries and the use of undercover agents shall be carried out in suitable cases and in cooperation with the relevant third countries (target: to start 2011);

  – special techniques shall be used when appropriate for the surveillance of the heroin routes in cooperation with the relevant third countries (target: 2011-2012);

- where possible and necessary joint investigations shall be conducted with the third countries concerned, if necessary within the framework of bilateral cooperation with these countries (target: 2011-2012);

- initiatives shall be carried out by the European Union to increase information and know-how exchanges between Member States and the Balkan States concerned (target: as from the 2nd semester 2010).

- In full coherence and synergy with external and enlargement policies, partnerships shall be developed with some third countries whose cooperation is deemed essential, in particular those countries with a role to play in impacting on the drugs trade at source (target: 2011-2012).

- The technical cooperation activities led by Member States and the Commission with third countries concerned by heroin trafficking in the Balkans shall be better coordinated in order to avoid duplications and to share certain investments agreed by Member States; this should be done in full respect of the EU financial instruments, rules and procedures.

  - an ad hoc flexible and consultative mechanism shall be set up to coordinate the technical assistance to the relevant third countries, in association with the Commission (target: September 2010); This should be done in full respect of the EU financial instrument's rules and procedures;

  - with this prospect in mind, a schedule of cooperation activities led by the Commission and Member States shall be set up, distributed to the Member States concerned and analysed in order to improve the European Union's overall offer of cooperation (target: 2011, regularly updated);

  - The results of ongoing European projects shall be assessed and European Projects should be supported and continued as necessary (target: 1st semester 2011, updated regularly).

- The role of Europol in the region shall be reinforced within the applicable legal framework as necessary:

  - the cooperation between Europol and the SELEC / SECI in Bucharest shall may be enhanced by Europol's making available analysis capacities and by the posting of Europol representatives at the headquarters of SECI /SELEC (target September 2010);

  - Europol shall provide analytical support to the Member States concerned, including the liaison officers network, SECI /SELEC and CARICC, on the basis of the OCTA and in the form of customized "threat notices" (OC-SCAN) (target: September 2010);

  - Europol shall supply operational analyses to the Member States concerned, including the liaison officers network, SECI /SELEC and CARICC using the specific "target groups" in the existing Analysis Work Files like the HEROIN AWF (target: start from January 2011);

- Information exchanges between Europol and the Common Security and Defense Policy missions (EUPM and EULEX Kosovo) shall be improved (target: start from 2011);

- Europol's Secure Information Exchange Network Application (SIENA) shall be used by Member States in the regional centres in the form of a SIENA terminal (target: January 2011).

- Countering the diversion of chemical precursors shall become a common priority of the Member States that are particularly involved in countering heroin:

  - Invite the Member States to support the Commission in its efforts to reinforce control and to address weaknesses identified in the European law on precursors by the evaluation report on the respective EC precursor legislation (target: end of 2011);

  - Improve the efforts to prevent the diversion of precursors for illicit drug production in cooperation with the Commission;

  - the special monitoring measures shall be continued, within the framework of the COHESION and PRISM projects (target : 2010-2011);

  - ongoing European projects, such as the EU's ISEC programme, shall be supported and continued (target : 2012).

- We reiterate the importance of an effective fight against drug trafficking, in cooperation with the EU Member States and also within the framework of the EU enlargement policy.

III – Countering the proceeds of crime

- Instruments allowing the identification of the proceeds of crime shall be reinforced within the European Union keeping in mind the ongoing evaluations:

  - Member States shall continue to take steps towards making their criminal asset recovery agencies rapidly operational, pursuant to Decision 2007/845/JAI of 6 December 2007, bearing in mind the recent financial Action Task Force best practice guidance in asset recovery and provide them with substantial means (target: end of 2010 at the latest);

  - Member States shall undertake necessary steps with a view to identifying effective means of identification of crime proceeds, (target: as from September 2010);

  - within the framework of Europol, cooperation of money laundering investigation units and other police services of the Member States dealing with money laundering should be strengthened and the added value of an informal specific network shall be examined (target: end of 2010);

– Europol Information System (IS) and Analysis Work Files (e.g. SUSTRANS) should be used to process data and intelligence pertaining in particular to money laundering clandestine financial circuits linked to drug trafficking and identification of criminal assets. (target: 1st semester 2011).

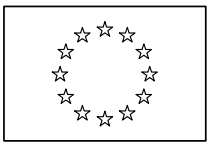
- Eurojust shall, when requested by Member States, help facilitating execution of decisions pertaining to seizure or confiscation of proceeds of crime within the EU, whenever such facilitation is useful.

- The EU should consider providing technical assistance to third countries willing to develop instruments for identification and seizure / confiscation and to adopt the necessary legislation to make them effective. This will take into account existing international initiatives (eg the UNODC/World Bank STAR initiative).

- The Member States are encouraged whenever applicable to use the proceeds of seizure/confiscation and other similar measures, in accordance with national legislation, of criminal assets generated by drug trafficking to improve the fight against drugs, as much as possible and with full respect of the budgetary competences of the Member States:

  – Common goals shall be identified for Member States to attain within the EU (target: 2011).

Following the recommendations of the COSI, the JHA Council will periodically review the state of the implementation of this pact. The said pact will also be supplemented during future presidencies by complementary actions with regard to other drugs.".



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 10.12.2009
COM(2009)669 final

REPORT FROM THE COMMISSION

on the implementation of Framework Decision 2004/757/JHA laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking

[SEC(2009)1661]

1. METHODOLOGY

Framework Decision 2004/757/JHA[1] sets out to establish minimum rules relating to the constituent elements of the offences of illicit trafficking in drugs and precursors, so as to allow a common approach at European Union level to the fight against such trafficking [2].

The effectiveness of the efforts made depends essentially on the harmonisation of the national measures implementing the Framework Decision[3], and the Commission is required to assess this and to submit the present report[4]. To this end, the Commission has used the evaluation criteria usually employed to analyse implementation of Framework Decisions (practical effectiveness, clarity and legal certainty, full application and compliance with the implementation deadline)[5], as well as specific criteria such as the efficiency (practical implementation) and effectiveness (with respect to international judicial cooperation) of the Framework Decision.

By 1 June 2009, the Commission had received replies from 21 Member States[6]. This means that six Member States did not comply with the obligation in Article 9(2) of the Framework Decision to transmit information, and will not be covered in the report. These are Cyprus, Spain[7], Greece[8], Italy, Malta and the United Kingdom.

2. ANALYSIS OF NATIONAL IMPLEMENTING MEASURES

2.1. Definitions (Article 1)

In its definition of drugs and precursors, Article 1 refers to the United Nations Conventions of 1961, 1971 and 1988[9], ratified by all Member States, and to directly applicable Community legislation[10] regarding precursors.

In spite of the fact that certain Member States have not submitted their definitions (CZ, DE, HU, SI, BG), the Commission is able to conclude on the basis of the information received

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1 OJ L 335, 11.11.2004, p. 8.
2 Third recital.
3 Ninth recital.
4 Article 9.
5 See COM(2001) 771, 13.12.2001, section 1.2.2.
6 Bulgaria sent only a few extracts from the legal texts to which it refers in its reply, so its account may be regarded only as an indication.
7 Spain informed the Commission in 2006 and 2008 that the transposition measures were included in the ongoing reform of the country's Penal Code.
8 Greece informed the Commission in 2008 that a law implementing the Framework Decision would be debated in Parliament shortly.
9 The Single Convention on Narcotic Drugs of 1961 (as amended by the 1972 Protocol); the 1971 Vienna Convention on Psychotropic Substances; and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 20 December 1988.
10 Regulations (EC) No 111/2005 and No 273/2004, see p. 7 of the working paper.

from other Member States that Article 1 does not raise any implementation problems, since appropriate national measures were already in force.

In Article 1(3), the term "legal person" uses the standard definition employed in various Framework Decisions. Seven Member States did not send any information regarding this point (CZ, DE, LU, PT, SE, SI, SK)[11].

2.2. Crimes linked to trafficking in drugs and precursors (Article 2)

The activities described under Article 2 are the same as those listed in Article 3 of the 1988 Convention. There is a difference in scope, however, in that the Framework Decision does not apply to activities relating to personal consumption (Article 2(2)).

With respect to drug precursors, this report limits itself to trafficking-related crimes: it does not analyse penalties for violations of the provisions of Community Regulations in this area.

2.2.1. Crimes linked to trafficking in drugs (Article 2(1) (a), (b) and c))

As a general point, the wordings of Article 2 are never incorporated into the national legislation of the Member States in their entirety. It would appear that these formal shortcomings are overcome by using generic legal wordings or broad interpretations where necessary. For example, it seems that the terms "production" and "manufacture" are in practice often interchangeable, and that acts not expressly referred to in the law are punished using provisions banning possession, which is obviously a prerequisite to all types of trafficking.

Ten Member States (AT, BE, FI, HU, IE, LV, LU, NL, PT, RO) have listed all, or most, of the activities concerned in their national legislation. Four Member States (DE, EE, FR, SE) have listed only parts, but comply with the Framework Decision through the use of generic terms. Seven Member States (BG, CZ, DK, LT, PL, SI, SK) have more ambiguous legislation[12] which does not guarantee full application of the Framework Decision in a sufficiently clear and precise manner.

2.2.2. Crimes linked to trafficking in precursors (Article 2.1(d))

Pre-existing legislation in most Member States complies with Article 2(1)(d), either in that it treats precursor trafficking and drug trafficking in the same way by penalising the same activities (BE, BG, CZ, DE, SI, SK), or in that it recognises certain offences specifically involving trafficking in precursors, which is broader in scope without being directly comparable to drug trafficking (AT, EE, FI, HU, IE, LT, LU, LV, NL, PL, PT). Import, export and possession are often included under this heading (HU, IE, LU, LV, PT).

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11 BG explained that its legislation did not include a definition of a legal person.

12 See working paper, p. 9.

Since the adoption of the Framework Decision, only two Member States (RO, SE) have actually amended their legislation to comply with Article 2(1)(d).

Two Member States (DK, FR) stated that trafficking in precursors is not covered *per se* in their criminal law, but can fall within the offences of drug trafficking or aiding and abetting drug trafficking. The Commission has serious doubts about the compliance of these systems, particularly with respect to Article 3[13]; the Commission's fear is that the absence of a separate offence of precursor trafficking will prevent this trafficking from being properly recorded, particularly with respect to attempt, incitement and aiding and abetting.

While the precursor-related activities prohibited by the Framework Decision are also prohibited in national law, therefore, it has to be acknowledged that the Framework Decision has had only marginal impact.

2.3. Incitement, aiding and abetting and attempt (Article 3)

Article 3 has not caused any major implementation problems. The Commission estimates that of the 21 Member States which sent the requested information, 18 have legislation that complies with the Framework Directive[14]. Of these 18 Member States, two (FI, SE) have amended their legislation to ensure compliance and two (DE, SE) have also made use of Article 3(2).

2.4. Penalties (Article 4)

2.4.1. Standard offences (Article 4(1))

The legislation of five Member States (BG, LT, LV, NL, SE) raises problems of interpretation, owing largely to a lack of information. While the one-year minimum is always respected, maximum penalties are actually much higher in most Member States. In twelve Member States (BG, FR, HU, IE, LT, LV, NL, PL, PT, RO, SI, SK), penalties are more than twice the range proposed by the Framework Decision, meaning that there are maximum penalties of six years or more – sometimes as much as twenty years – or even life imprisonment. On the whole, legislative disparities between the Member States seem to remain unchanged.

At the same time, maximum sentences are meaningful only in the context of proceedings actually initiated and penalties actually imposed by the courts. A comparison of judicial practice in each Member State would enable an assessment of the extent to which the objective of aligning national systems has been achieved in practice.

In this context, the complexity of the Dutch system and the controversies relating to coffee shops merit particular attention. The sale of soft drugs in coffee shops is the result of a policy

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[13] DK specified that attempted attempt (sic) or aiding and abetting was punishable. FR did not make any comment.

[14] Three Member States (BG, HU, RO) did not provide sufficient information.

of highly regulated tolerance of a practice which remains a criminal offence. According to the public prosecution services' guidelines, coffee-shop transactions involving 5 grammes of cannabis per person will not be prosecuted. Dutch legislation is in compliance with Article 4(1): the tolerance policy towards coffee shops rests primarily on the principle of discretionary prosecution, an area outside the Commission's remit. However, the Framework Decision is concerned with the most serious crimes, and the Commission has particular concerns regarding the wider problem of the supply of such coffee shops by criminal networks.

The Commission thus concludes that all the national legislation of which it has been informed is formally compliant[15], but expresses regret at the heterogeneous nature of this legislation and has concerns regarding its practical application.

2.4.2. Aggravated drug trafficking offences (Article 4(2))

Of the 21 Member States which replied, 20 comply with the level of penalties required by Article 4(2)[16] . However, the range of penalties runs from 10 to 15 years. Ten Member States have established maximum sentences of ten years (AT, BE, CZ, DK, EE, FI, HU, LT, LU, SE), while eight have established maximum sentences of fifteen years (BE, CZ, DK[17], DE, HU, LT, LV, SK). Six Member States have even higher sentences (FR, HU, IE, LU, RO, SE), while four have maximum sentences ranging from five to eight years (AT, LT, NL, PL).

Eight Member States take the aspects of quantity and harm to health into account (AT, CZ, DK, DE, FI, NL SK), while eight others take only one of these aspects into account (BE, EE, HU, LT, LU, LV, PL, RO). The legislation of five Member States makes no reference to this (BG, FR, IE, PT, SI), But since in these Member States the maximum penalty applying to the basic offence is already equivalent to, or exceeds, the level required by Article 4(2), this failure to make a distinction is unimportant.

The Commission considers that Article 4(2) has been satisfactorily implemented in terms of the scale of penalties. It should be noted that penalties are often higher than those set out in Article 4(2) and that thirteen Member States have not incorporated the aspects of quantity and/or harm to health into their legislation.

2.4.3. Aggravated offences committed within the framework of a criminal organisation (Article 4(3) and 4(4))

(1) Aggravated offences involving drugs committed within the framework of a criminal organisation (Article 4(3))

Criminal law in the EU regarding drug trafficking generally takes the role of organised crime into account. Seventeen Member States (AT, BE, CZ, DE, EE, FI, FR, HU, LT, LU, LV, NL, PL, PT, RO, SI, SK) apply maximum sentences of at least 10 years for offences committed within the framework of a criminal organisation. The Netherlands has amended its narcotics

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15 For marginal reservations with respect to BG, LT, LV and SE, please see the working paper.

16 In the absence of specific information, the situation in BG is not included.

17 16 years.

legislation to expressly include offences relating to participation in a criminal organisation, in addition to the general provisions in the penal code. DK, IE and SE do not have specific provisions covering organised crime, but comply with the prescribed level of penalties. The Commission did not have enough information for three Member States (BE, LU, SI) to be able to analyse the issue of organised crime.

Unlike the Framework Decision, the Member States do not require the offence to involve large quantities of drugs, or drugs that cause the most harm to health[18].

In addition, a number of Member States have a range of different penalties that vary with the offender's role in the criminal organisation (such as member, leader or provider of finance). For the standard offence of membership, maximum sentences are generally more than 10 years. In eight Member States (BE, CZ, DE, LT, LV, NL, PT, SI) the maximum sentence is in fact 15 years or more, while in six (EE, FR, LU, PT, RO, SK) it is 20 years or more. Thus offences relating to drug trafficking within the framework of a criminal organisation are subject to much higher sentences than those established in the Framework Decision, and we can conclude that the penalty scales are respected.

(2) Aggravated offences involving precursors committed within the framework of a criminal organisation (Article 4(4))

The role of organised crime is also generally taken into account in criminal law covering precursor trafficking throughout the EU, but there are wider variations than in the case of drug trafficking.

Thirteen Member States (CZ, DE, FI, HU, LT, LU, LV, NL, PL, PT, RO, SI, SK) have legislation against precursor trafficking that takes organised crime into account. The penalties are also more severe. Five Member States (CZ, FI, HU, LV, PL) have maximum penalties of between six and ten years, while eight (DE, LT, LU, NL, PT[19], RO, SI, SK) have maximum penalties of 15 years or more[20].

It should be noted that seven Member States (AT, BE, DK, EE, FR, IE, SE) have no legislation regarding criminal organisations and precursors (or have failed to inform the Commission of such legislation)[21]. However, the maximum sentences applying to basic offences involving trafficking in precursors in the above-mentioned Member States are already at five years or more, so Article 4(4) has been satisfactorily implemented.

2.5. Confiscation (Article 4(5))

Thirteen of the 21 Member States which replied (AT, DE, DK, EE, FI, FR, LU, LV, PL, PT, RO, SK) informed the Commission of express provisions in their narcotics law regarding confiscation, while six (CZ, HU, IE, LT, NL, SI) informed the Commission of provisions in their penal codes. BE and BG have not furnished any information on such provisions. Substances which are the objects of offences are generally confiscated. For the confiscation of instrumentalities, proceeds and property of corresponding value, the Commission refers to its

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18 Only Estonia mentions the trafficking of large quantities of drugs.

19 Portugal increases the maximum 10-year sentence by a third, which makes it just under 15 years.

20 LT, LU, NL, RO and SK provide for maximum 20-year prison sentences.

21 For Denmark and France, see comments on Article 2(1)(d).

report[22] on the implementation of Framework Decision No 2005/212/JHA[23] of the Council of 24 February 2005 on Confiscation of Crime-Related Proceeds, Instrumentalities and Property.

2.6. Particular circumstances (Article 5)

Under Article 5, Member States may have a system of reducing penalties in cases in which the offender assists the authorities. All Member States provided information on their national penalty reduction system, except BG, FI, NL and SI. In six Member States (AT, HU, LU, LV, PT, RO) a penalty reduction system for offenders cooperating with the authorities is expressly established in narcotics legislation. Several Member States make a distinction according to whether charges have already been brought, and some also provide for penalty waivers in addition to reductions. None, however, have amended their legislation as a result of the Framework Decision.

2.7. Liability of legal persons and sanctions for legal persons (Articles 6 and 7)

With respect to Article 6, the principal stumbling block is the recognition of passive liability on the part of a legal person (Article 6(2)). The legislation of ten Member States (AT, DE, DK, FI, HU, IE, LT, NL, PL, RO) complies with Article 6, but eight (BE, BG, EE, FR, LU, LV, PT, SI) did not provide enough information, particularly concerning Article 6(2). Additionally, two Member States have no legal framework establishing the liability of legal persons (CZ, SK), while Sweden's narrow interpretation of the concept of passive liability means that it does not fully comply with Article 6(2). Article 6(3) does not pose any major problems for the Member States.

As for Article 7, two Member States (CZ, SK) have stated that they do not yet have a relevant legal framework, while Luxembourg has a form of liability for legal persons which does not result in financial penalties, which is contrary to Article 7(1). Ten Member States (AT, BE, DE, FI, FR, LT, LV, PL, RO, SE) informed the Commission of legislation that formally complies with Article 7, unlike eight other Member States (BG, DK, EE, HU, IE, NL, PT, SI) which furnished no information, or insufficient information that mainly concerned the size of fines.

Only three Member States (FI, RO and SE) have amended their legislation to comply with Articles 6 and 7. The Commission draws the attention of the Member States to the lack of information received concerning implementation of the Framework Decision in respect of the liability of legal persons.

2.8. Jurisdiction and prosecution (Article 8)

All Member States accept the principle of territorial jurisdiction (Article 8(1)(a)), so the analysis will concentrate on points (b) and (c) and offences committed outside national

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22 COM(2007) 805 final, adopted on 17 December 2007.

23 OJ L, 15.3.2005.

territory. Article 8(3) no longer serves any purpose since the introduction of the European arrest warrant.

No information has been provided concerning offences committed in part on national territory, but the Commission considers, despite this, that eleven Member States (AT, CZ, DE, DK, EE, FI, FR, LT, NL, PL, SE) have legislation that is in overall compliance with Article 8. Ten Member States (BE, BG, HU, IE, LU, LV, PT, RO, SI, SK), however, did not supply the necessary information.

Six Member States (AT, DE, DK, EE, FR, SE) have informed the Commission, pursuant to Article 8(4), of their decision to apply paragraph 2, in particular stating their intention to waive or limit their jurisdiction in cases where the offence committed outside their territory was committed for the benefit of a legal person established in their territory (8(1)(c)).

Despite this, the degree of implementation remains unclear, because eight Member States (BE, BG, HU, IE, PT, RO, SI, SK) have not provided enough information concerning the implementation of paragraph 1(c), and only five (CZ, FI, LT, NL, PL) are in conformity with this paragraph.

3. OPERATION AND EFFECTS ON JUDICIAL COOPERATION

The difficulty of studying the operation of the Framework Decision and its effects on judicial cooperation lies primarily in the collection of data on judicial practice in the Member States. The Commission has relied in this respect on information from Eurojust and the European Judicial Network (EJN). On 14 November 2008, Eurojust supplied a summary of statistics on drug trafficking cases recorded by Eurojust between 1 January 2004 and 12 November 2008. The Commission also requested information from the EJN by means of a questionnaire which was sent to all its contact points[24].

3.1. Eurojust's input

During the above-mentioned period, the College of Eurojust recorded 771 drug trafficking cases, which showed a significant increase from 77 cases in 2004 to 207 in 2007. Drug cases account for 20% of the cases handled by Eurojust between 2004 and 2008.

The Member States that have reported the largest number of drug trafficking cases to Eurojust are Italy (81 cases), France (72) and the Netherlands (71), while the Member States with the smallest numbers are Malta (1 case), Cyprus (1), Ireland (2) and Slovakia (2).

The Member States in receipt of most applications to take action are the Netherlands (264 applications), Spain (243) and Italy (171), while the Member States in receipt of the fewest applications are Malta (3 applications), Cyprus (8), Slovakia (9), and Latvia (9).

Overall, the statistics point to the prominent role of the Netherlands, Italy, France and Germany, either as applicant countries or countries of enforcement. Sweden and Portugal notified a relatively large number of drug trafficking cases (64 and 57, respectively), while

[24] These documents are included in the working paper.

Spain and the United Kingdom received many applications from other countries (243 and 102 times, respectively). The Member States least involved, whether as applicant countries or countries of enforcement, are Malta, Cyprus, Latvia and Slovakia.

Finally, it is interesting to note that of 151 drug trafficking cases associated with one or more other crimes, 65 involved participation in a criminal organisation.

This information shows that there has been a clear increase in judicial cooperation on drug trafficking between Member States through Eurojust since 2004. However, it is at this stage impossible to distinguish how the Framework Decision has affected such cooperation, or to measure its impact. This question was the focus of the questionnaire to the EJN.

3.2. Input of the European Judicial Network

The contact points of the EJN in ten Member States (CZ, DE, FI, FR, HU, IE, LV, LU, PL, PT) replied to the Commission's questionnaire.

The general impression given by their data is that although specialists are familiar with the Framework Decision, they regard its importance as minor, because it has not resulted in many changes to national legislation. The question of the Framework Decision's effect on cooperation remains open, because the Framework Decision does not concern judicial cooperation directly, and because no Member State seems to have a centralised system enabling it to measure trends in judicial cooperation in drug trafficking cases. The replies often point to a degree of uncertainty amongst specialists, for example in Finland, France and Portugal.

In Finland, for example, the contact point considers that the changes that have taken place since the adoption of the Framework Decision are only minor and that they have had no impact on judicial cooperation, but also says that it is impossible to draw any objective conclusions, given the short perspective and the lack of a monitoring system that would allow any such impact to be measured.

In France, the contact point also mentions the absence of a system providing the central administration with an accurate overview of all requests for assistance concerning narcotics. The French courts are finding an overall improvement in the quality of implementation of their requests for assistance in narcotics trafficking cases, but the quality remains very variable depending on the country involved. The intervention of liaison magistrates or Eurojust representatives often permits complex coordinated action to be taken. The contact point concludes, however, that it is difficult to determine whether these improvements are the result of Member States' transposition of the Framework Decision, and that general improvements in cooperation over the past five years seem to be a result of the emergence of a "European judicial culture" amongst magistrates rather than of the transposition of the Decision.

In Portugal, according to the contact point, the Framework Decision is known but little used, since national legislation was already along the same lines. No particular changes have been noted with respect to judicial cooperation, and greater use of already existing rules in the new cooperation instruments is recommended.

4. CONCLUSION

Implementation of the Framework Decision has not been completely satisfactory. While the majority of Member States already had a number of the provisions in place, a number have also demonstrated – often in sketchy answers – that they have not always amended their existing legislation where the Framework Decision required it. Six Member States provided no information whatsoever. There has thus been little progress in the alignment of national measures in the fight against drug trafficking. The weak impact of the Framework Decision is confirmed by the EJN's input. It is difficult to establish a link between the Framework Decision and the progress in judicial cooperation described by Eurojust. The Commission consequently invites those Member States which have submitted no information, or incomplete information, to comply with their obligations under Article 9 of the Framework Decision and furnish the Commission and the General Secretariat of the Council with all their implementing provisions very rapidly.

REGULATION (EU) No 1258/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 20 November 2013

amending Regulation (EC) No 273/2004 on drug precursors

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee [1],

Acting in accordance with the ordinary legislative procedure [2],

Whereas:

(1) On 7 January 2010, the Commission adopted a report pursuant to Article 16 of Regulation (EC) No 273/2004 of the European Parliament and of the Council [3] on the implementation and functioning of the Community legislation on monitoring and control of trade in drug precursors.

(2) In that report, the Commission recommended further analysing ways to strengthen the control of the trade of acetic anhydride, a scheduled substance in category 2 of Annex I to Regulation (EC) No 273/2004, pursuant to Article 2(a) of that Regulation, in order to better prevent the diversion of acetic anhydride for the illicit production of heroin.

(3) In its Conclusions of 25 May 2010 on the functioning and implementation of the EU drug precursors legislation, the Council invited the Commission to propose legislative amendments after carefully assessing their potential impact on Member States' authorities and economic operators.

(4) This Regulation clarifies the definition of a scheduled substance: in this regard, the term 'pharmaceutical preparation', which stems from the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances adopted in Vienna on 19 December 1988, is deleted as it is already covered by the relevant terminology of Union legal acts, namely 'medicinal products'. Moreover, the term 'other preparations' is deleted as it duplicates the term 'mixtures' already used in that definition.

(5) A definition of the term 'user' should be introduced for persons possessing substances for purposes other than placing them on the market and it should be clarified that persons using scheduled substances in category 1 of Annex I to Regulation (EC) No 273/2004 for other purposes than placing them on the market are obliged to obtain a licence.

(6) More detailed rules on registration should be introduced to ensure uniform conditions of registration in all Member States for scheduled substances in category 2 of Annex I to Regulation (EC) No 273/2004. For substances scheduled in a new subcategory 2A of Annex I to that Regulation, in addition to operators users should also be subject to a registration requirement.

(7) Where fees are levied for obtaining a licence or registration, Member States should consider adjusting such fees in order to safeguard the competitiveness of microenterprises.

(8) It should be made clear that Member States have the possibility to act with regard to suspicious transactions involving non-scheduled substances in order to enable them to react more quickly with regard to new trends in the illicit production of drugs.

(9) A European database on drug precursors ('the European database') should be created to simplify the reporting by Member States with regard to seizures and stopped shipments, where possible in an aggregated and anonymised manner and in the least intrusive manner as regards the processing of personal data, taking into account the state of the art of privacy-enhancing technologies and the principle of data limitation. The European database should also serve as a European register of operators and users holding a licence or registration which will facilitate verification of the legitimacy of commercial transactions involving scheduled substances, and should enable operators to provide the competent authorities with information about their transactions involving scheduled substances.

(10) Regulation (EC) No 273/2004, as amended by this Regulation, envisages the processing of information, including the processing of personal data, for the purposes of enabling the competent authorities to monitor the placing on the market of drug precursors and to

[1] OJ C 76, 14.3.2013, p. 54.

[2] Position of the European Parliament of 23 October 2013 (not yet published in the Official Journal) and decision of the Council of 15 November 2013.

[3] Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors (OJ L 47, 18.2.2004, p. 1).

prevent the diversion of scheduled substances. The processing of personal data should be carried out in a manner compatible with the purpose of that Regulation and in accordance with Directive 95/46/EC of the European Parliament and of the Council [1] and Regulation (EC) No 45/2001 of the European Parliament and of the Council [2] and, in particular, with Union requirements relating to data quality, proportionality, purpose limitation, and rights to information, access, rectification of data, erasure and blocking, organisational and technical measures and international transfers of personal data.

(11) The processing of personal data for the purposes of Regulation (EC) No 273/2004, as amended by this Regulation, and any delegated and implementing acts adopted pursuant thereto should respect the fundamental right to respect for private and family life recognised by Article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms as well as the rights to respect for private and family life, and the right to the protection of personal data recognised, respectively, by Articles 7 and 8 of the Charter of Fundamental Rights of the European Union. The delegated and implementing acts should also ensure that any processing of personal data takes place in accordance with Directive 95/46/EC and Regulation (EC) No 45/2001.

(12) Acetic anhydride, currently scheduled in category 2 of Annex I to Regulation (EC) No 273/2004, should be included in a new subcategory 2A of Annex I thereto to allow increased control of its trade. The remaining substances of category 2 of Annex I to Regulation (EC) No 273/2004 should be listed as subcategory 2B of Annex I thereto.

(13) Regulation (EC) No 273/2004 confers powers on the Commission in order to implement some of its provisions, to be exercised in accordance with the procedures laid down in Council Decision 1999/468/EC [3].

(14) As a consequence of the entry into force of the Treaty of Lisbon, those powers should be aligned to Articles 290 and 291 of the Treaty on the Functioning of the European Union (TFEU).

(15) In order to achieve the objectives of Regulation (EC) No 273/2004, as amended by this Regulation, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to specify the requirements and conditions for the granting of the licence and registration, for listing operators and users having obtained a licence or registration in the European database, for obtaining and using customer declarations, for the documentation and labelling of mixtures containing scheduled substances, for the provision of information by the operators on transactions involving scheduled substances, and for information to be provided by Member States on the implementation of the monitoring measures laid down in Regulation (EC) No 273/2004, and in order to amend the Annexes thereto. Such delegated acts should also determine the categories of personal data which can be processed by Member States and operators pursuant to Regulation (EC) No 273/2004, the categories of personal data which can be stored in the European database and the safeguards for the processing of personal data. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure the simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(16) It is also important that the Commission seek the opinion of the European Data Protection Supervisor when preparing delegated acts relating to the processing of personal data.

(17) In order to ensure uniform conditions for the implementation of Regulation (EC) No 273/2004, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council [4]. The examination procedure should be used for the adoption of the implementing acts in order to set up details on how customer declarations should be provided in electronic form and on how to provide the information about transactions of operators with scheduled substances to a European database.

(18) Since the objective of this Regulation, namely to strengthen the rules for registration of operators placing on the market or possessing scheduled substances of category 2 of Annex I to Regulation (EC) No 273/2004, in particular acetic anhydride, in order to prevent its diversion towards the illicit production of drugs, cannot be sufficiently achieved by the Member States because traffickers gain from national differences in registration and move their illicit business where drug precursors are easiest to divert, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In

[1] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

[2] Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

[3] Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).

[4] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

(19) The European Data Protection Supervisor was consulted in accordance with Article 28(2) of Regulation (EC) No 45/2001 and delivered an opinion on 18 January 2013 ([1]).

(20) Regulation (EC) No 273/2004 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 273/2004 is amended as follows:

(1) Article 1 is replaced by the following:

'*Article 1*

Scope and objectives

This Regulation establishes harmonised measures for the intra-Union control and monitoring of certain substances frequently used for the illicit manufacture of narcotic drugs or psychotropic substances with a view to preventing the diversion of such substances.';

(2) in Article 2:

(a) point (a) is replaced by the following:

'(a) "scheduled substance" means any substance listed in Annex I that can be used for the illicit manufacture of narcotic drugs or psychotropic substances, including mixtures and natural products containing such substances but excluding mixtures and natural products which contain scheduled substances and which are compounded in such a way that the scheduled substances cannot be easily used or extracted by readily applicable or economically viable means, medicinal products as defined in point 2 of Article 1 of Directive 2001/83/EC of the European Parliament and of the Council (*) and veterinary medicinal products as defined in point 2 of Article 1 of Directive 2001/82/EC of the European Parliament and of the Council (**);

(*) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

(**) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).';

(b) point (c) is replaced by the following:

'(c) "placing on the market" means any supply, whether in return for payment or free of charge, of scheduled substances in the Union; or the storage, manufacture, production, processing, trade, distribution or brokering of these substances for the purpose of supply in the Union;';

(c) the following points are added:

'(h) "user" means a natural or legal person other than an operator who possesses a scheduled substance and is engaged in the processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, transformation or any other utilisation of scheduled substances;

(i) "natural product" means an organism or a part thereof, in any form, or any substances which occur in nature as defined in point 39 of Article 3 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (*).

(*) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).';

(3) in Article 3:

(a) paragraphs 2 and 3 are replaced by the following:

'2. Operators and users shall obtain a licence from the competent authorities of the Member State in which they are established before they may possess or place on the market scheduled substances of category 1 of Annex I. The competent authorities may grant special licences to pharmacies, dispensaries of veterinary medicine, certain types of public authorities or armed forces. Such special licences shall be valid only for the use of scheduled substances of category 1 of Annex I within the scope of the official duties of the operators concerned.

3. Any operator holding a licence shall supply scheduled substances of category 1 of Annex I only to operators or users who also hold a licence and have signed a customer declaration as provided for in Article 4(1).';

(b) paragraphs 5, 6 and 7 are replaced by the following:

'5. Without prejudice to paragraph 8, the competent authorities may either limit the validity of the licence to a period not exceeding three years or

([1]) Not yet published in the Official Journal.

may oblige the operators and users to demonstrate at intervals not exceeding three years that the conditions under which the licence was granted are still fulfilled. The licence shall mention the operation or operations for which it is valid, as well as the scheduled substances concerned. The competent authorities shall, in principle, grant special licences for an unlimited duration but may suspend or revoke them where there are reasonable grounds for believing that the holder is no longer a fit and proper person to hold a licence, or that the conditions under which the licence was granted are no longer fulfilled.

6. Operators shall obtain registration from the competent authorities of the Member State in which they are established before placing on the market scheduled substances of category 2 of Annex I. From 1 July 2015 users shall obtain a registration from the competent authorities of the Member State in which they are established before possessing scheduled substances of subcategory 2A of Annex I. The competent authorities may grant special registrations to pharmacies, dispensaries of veterinary medicine, certain types of public authorities or the armed forces. Such special registrations shall be considered valid only for the use of scheduled substances of category 2 of Annex I within the scope of the official duties of the operators or users concerned.

6a. Any operator holding a registration shall supply scheduled substances of subcategory 2A of Annex I only to other operators or users who also hold a registration and have signed a customer declaration as provided for in Article 4(1).

6b. When considering whether to grant registration, the competent authorities shall take into account, in particular, the competence and integrity of the applicant. They shall refuse registration if there are reasonable grounds for doubting the suitability and reliability of the applicant or of the officer responsible for the trade in scheduled substances. They may suspend or revoke registration where there are reasonable grounds for believing that the holder is no longer a fit and proper person to hold a registration, or that the conditions under which registration was granted are no longer fulfilled.

6c. The competent authorities may require operators and users to pay a fee for the application for a licence or for registration.

Where a fee is levied, competent authorities shall consider adjusting the level of the fee depending on the size of the enterprise. Such a fee shall be levied in a non-discriminatory manner and shall not exceed the cost of processing the application.

7. The competent authorities shall list the operators and users that have obtained a licence or a registration in the European database referred to in Article 13a.

8. The Commission shall be empowered to adopt delegated acts in accordance with Article 15a concerning the requirements and conditions for:

(a) granting the licence, including, where relevant, the categories of personal data to be provided;

(b) granting registration, including where relevant the categories of personal data to be provided;

(c) listing operators and users in the European database referred to in Article 13a, in accordance with paragraph 7 of this Article.

The categories of personal data referred to in points (a) and (b) of the first subparagraph of this paragraph shall not include special categories of data as referred to in Article 8(1) of Directive 95/46/EC of the European Parliament and of the Council (*).

(*) Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).';

(4) in Article 4:

(a) paragraph 1 is replaced by the following:

'1. Without prejudice to paragraph 4 of this Article, and to Articles 6 and 14, any operator established within the Union who supplies a customer with a scheduled substance of category 1 or 2 of Annex I shall obtain a declaration from the customer which shows the specific use or uses of the scheduled substances. The operator shall obtain a separate declaration for each scheduled substance. That declaration shall conform to the model set out in point 1 of Annex III. In the case of legal persons, the declaration shall be made on headed notepaper.';

(b) paragraph 3 is replaced by the following:

'3. An operator supplying scheduled substances of category 1 of Annex I shall stamp and date a copy of the declaration, certifying it to be a true copy of the original. Such copy shall always accompany those substances being moved within the Union and shall be presented on request to the authorities responsible for checking vehicle contents during transport operations.

4. The Commission shall be empowered to adopt delegated acts in accordance with Article 15a concerning the requirements and conditions for obtaining and using customer declarations.';

(5) in Article 5, the following paragraph is added:

'7. The Commission shall be empowered to adopt delegated acts in accordance with Article 15a concerning the requirements and conditions for the documentation of mixtures containing scheduled substances.';

(6) in Article 7, the following paragraph is added:

'The Commission shall be empowered to adopt delegated acts in accordance with Article 15a concerning the requirements and conditions for the labelling of mixtures containing scheduled substances.';

(7) Article 8 is replaced by the following:

'Article 8

Notification of the competent authorities

1. Operators shall notify the competent authorities immediately of any circumstances, such as unusual orders or transactions involving scheduled substances to be placed on the market, which suggest that such substances might be diverted for the illicit manufacture of narcotic drugs or psychotropic substances. To that end, operators shall provide any available information allowing the competent authorities to verify the legitimacy of the relevant order or transaction.

2. Operators shall provide the competent authorities with relevant information in summary form about their transactions involving scheduled substances.

3. The Commission shall be empowered to adopt delegated acts in accordance with Article 15a concerning the requirements and conditions for operators to provide information as referred to in paragraph 2 of this Article including, where relevant, the categories of personal data to be processed for that purpose and the safeguards for processing such personal data.

4. Operators shall not disclose any personal data collected pursuant to this Regulation other than to the competent authorities.';

(8) in Article 9, paragraph 1 is replaced by the following:

'1. The Commission shall draw up, and keep up to date, guidelines to facilitate cooperation between the competent authorities, the operators, and the chemical industry, in particular as regards non-scheduled substances.';

(9) in Article 10:

(a) points (b) and (c) of paragraph 1 are replaced by the following:

'(b) to enter operators' and users' business premises in order to obtain evidence of irregularities;

(c) where necessary, to detain and seize consignments that fail to comply with this Regulation.';

(b) paragraph 2 is replaced by the following:

'2. Each Member State may adopt the measures necessary to enable its competent authorities to control and monitor suspicious transactions involving non-scheduled substances, and in particular:

(a) to obtain information on any orders for non-scheduled substances or operations involving non-scheduled substances;

(b) to enter business premises in order to obtain evidence of suspicious transactions involving non-scheduled substances;

(c) where necessary, to detain and seize consignments to prevent the use of specific non-scheduled substances for the illicit manufacture of narcotic drugs or psychotropic substances.

3. The competent authorities shall respect confidential business information.';

(10) Articles 13 to 16 are replaced by the following:

'Article 13

Communications from Member States

1. To permit any necessary adjustments to the arrangements for monitoring trade in scheduled substances and non-scheduled substances, the competent authorities in each Member State shall communicate to the Commission in electronic form via the European database referred to in Article 13a in a timely manner all relevant information on the implementation of the monitoring measures laid down in this Regulation, in particular as regards substances used for the illicit manufacture of narcotic drugs or psychotropic substances and methods of diversion and illicit manufacture, and their licit trade.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 15a specifying the conditions and requirements concerning the information to be provided under paragraph 1 of this Article.

3. A summary of the communications made pursuant to paragraph 1 of this Article shall be submitted by the Commission to the International Narcotics Control Board in accordance with Article 12(12) of the United Nations Convention and in consultation with the Member States.

Article 13a

European database on drug precursors

1. The Commission shall establish a European database on drug precursors with the following functions:

(a) to facilitate the communication of information, where possible in an aggregated and anonymised manner, pursuant to Article 13(1), the synthesis and analysis of that information at the Union level, and the reporting to the International Narcotics Control Board pursuant to Article 13(3);

(b) to create a European register of operators and users, which have been granted a licence or registration;

(c) to enable operators to provide the competent authorities with information about their transactions in accordance with Article 8(2) in electronic form, as specified in implementing measures adopted pursuant to Article 14.

Personal data shall be included in the European database only after the adoption of the delegated acts referred to in Articles 3(8) and 8(3).

2. The Commission and the competent authorities shall take all necessary measures to ensure the security, confidentiality and accuracy of personal data contained in the European database and to ensure that the rights of data subjects are protected in accordance with Directive 95/46/EC and Regulation (EC) No 45/2001 of the European Parliament and of the Council (*).

3. Information obtained pursuant to this Regulation, including personal data, shall be used in accordance with the applicable law on personal data protection and shall not be retained for longer than necessary for the purposes of this Regulation. The processing of special categories of data as referred to in Article 8(1) of Directive 95/46/EC and in Article 10(1) of Regulation (EC) No 45/2001 shall be prohibited.

4. The Commission shall make publicly available, in a clear, comprehensive and understandable manner, information concerning the European database in accordance with Articles 10 and 11 of Regulation (EC) No 45/2001.

Article 13b

Data protection

1. The processing of personal data by the competent authorities in the Member States shall be carried out in accordance with national laws, regulations and administrative provisions transposing Directive 95/46/EC and under the supervision of the supervisory authority of the Member State referred to in Article 28 of that Directive.

2. Without prejudice to Article 13 of Directive 95/46/EC, personal data obtained or processed pursuant to this Regulation shall be used solely for the purpose of preventing the diversion of scheduled substances.

3. The processing of personal data by the Commission, including for the purpose of the European database, shall be carried out in accordance with Regulation (EC) No 45/2001 and under the supervision of the European Data Protection Supervisor.

4. Member States and the Commission shall not process personal data in a manner incompatible with the purposes set out in Article 13a.

Article 14

Implementing acts

1. The Commission may adopt the following implementing acts:

(a) rules on how to provide customer declarations referred to in Article 4 in electronic form, where appropriate;

(b) rules on how to provide the information referred to in Article 8(2), including, where appropriate, in electronic form to a European database;

(c) procedural rules for granting licences and registrations and for listing operators and users in the European database, as referred to in Article 3(2), (6) and (7).

2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 14a(2).

Article 14a

Committee procedure

1. The Commission shall be assisted by the Drug Precursors Committee established by Article 30 of Council Regulation (EC) No 111/2005 (**). That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council (***).

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Article 15

Adaptation of Annexes

The Commission shall be empowered to adopt delegated acts in accordance with Article 15a in order to adapt Annexes I, II and III to new trends in diversion of drug precursors and to follow any amendment to the tables in the Annex to the United Nations Convention.

Article 15a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Articles 3(8), 4(4) and 5(7), the second paragraph of Article 7, Articles 8(3) and 13(2) and Article 15 shall be conferred on the Commission for a period of five years from 30 December 2013. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Articles 3(8), 4(4) and 5(7), the second paragraph of Article 7, Articles 8(3) and 13(2) and Article 15 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Articles 3(8), 4(4) and 5(7), the second paragraph of Article 7, Articles 8(3) and 13(2) and Article 15 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 16

Information about measures adopted by Member States

1. Member States shall inform the Commission of the measures they adopt pursuant to this Regulation, and in particular of the measures adopted pursuant to Articles 10 and 12. They shall also notify any subsequent amendments thereof.

2. The Commission shall communicate that information to the other Member States.

3. The Commission shall, by 31 December 2019, submit a report to the European Parliament and to the Council on the implementation and functioning of this Regulation, and in particular on the possible need for additional action to monitor and control suspicious transactions with non-scheduled substances.

(*) Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

(**) Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors (OJ L 22, 26.1.2005, p. 1).

(***) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).';

(11) in Annex I:

(a) the title is replaced by the following:

'List of scheduled substances';

(b) in category 1, the CN code for Norephedrine is replaced by the following:

'2939 44 00';

(c) in category 1, the following substance is added to the list of substances:

'Alpha-phenylacetoacetonitrile, CN code 2926 90 95, CAS No 4468-48-8';

(d) the text of category 2 is replaced by the text of the Annex to this Regulation;

(12) in Annex III, the text 'authorisation/' is deleted.

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 20 November 2013.

For the European Parliament	*For the Council*
The President	*The President*
M. SCHULZ	V. LEŠKEVIČIUS

ANNEX

CATEGORY 2

SUBCATEGORY 2A

Substance	CN designation (if different)	CN code [1]	CAS No [2]
Acetic anhydride		2915 24 00	108-24-7
The salts of the substances listed in this category, whenever the existence of such salts is possible.			

SUBCATEGORY 2B

Substance	CN designation (if different)	CN code [1]	CAS No [2]
Phenylacetic acid		2916 34 00	103-82-2
Anthranilic acid		2922 43 00	118-92-3
Piperidine		2933 32 00	110-89-4
Potassium permanganate		2841 61 00	7722-64-7
The salts of the substances listed in this category, whenever the existence of such salts is possible.			

[1] OJ L 290, 28.10.2002, p. 1.

[2] The CAS No is the 'chemical abstracts service registry number', which is a unique numeric identifier specific to each substance and its structure. The CAS No is specific to each isomer and to each salt of each isomer. It must be understood that the CAS Nos for the salts of the substances listed above will be different to those given.

REGULATION (EU) No 1259/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 20 November 2013

amending Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 207(2) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Acting in accordance with the ordinary legislative procedure ([1]),

Whereas:

(1) On 7 January 2010, the Commission adopted a report, pursuant to Article 32 of Council Regulation (EC) No 111/2005 ([2]), on the implementation and functioning of the Community legislation on monitoring and control of trade in drug precursors.

(2) Trade in medicinal products is not controlled in the existing Union control system for drug precursors, since they are currently excluded from the definition of scheduled substances.

(3) The Commission report pointed out that medicinal products containing ephedrine and pseudoephedrine were diverted into the illicit drug manufacture outside the Union, as a substitute for internationally controlled ephedrine and pseudoephedrine. The Commission therefore recommended strengthening the control of international trade in medicinal products containing ephedrine or pseudoephedrine exported from or transiting through the customs territory of the Union in order to prevent their diversion for the illicit manufacture of narcotic drugs or psychotropic substances.

(4) In its Conclusions of 25 May 2010 on the functioning and implementation of EU drug precursors legislation, the Council invited the Commission to propose legislative amendments after carefully assessing their potential impact on Member States' authorities and economic operators.

(5) This Regulation clarifies the definition of a scheduled substance: in this regard, the term 'pharmaceutical preparation', which stems from the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances adopted in Vienna on 19 December 1988 ('the United Nations Convention'), is deleted as it is already covered by the relevant terminology of Union legal acts, namely 'medicinal products'. Moreover, the term 'other preparations' is deleted as it duplicates the term 'mixtures' already used in that definition.

(6) Rules on suspending or revoking the registration of an operator should be introduced in order to match the existing rules for suspending or revoking a licence.

(7) Medicinal products and veterinary medicinal products ('medicinal products') containing ephedrine or pseudoephedrine should be controlled without impeding their legitimate trade. To that end, a new category (Category 4) should be added to the Annex to Regulation (EC) No 111/2005 listing medicinal products containing certain scheduled substances.

(8) The export of medicinal products listed in Category 4 of the Annex to Regulation (EC) No 111/2005, as amended by this Regulation, should be preceded by an export authorisation, and a pre-export notification sent by the competent authorities in the Union to the competent authorities of the country of destination.

(9) Member States' competent authorities should be given the powers to stop or seize those medicinal products where there are reasonable grounds for suspecting that they are intended for the illicit manufacture of narcotic drugs or psychotropic substances, when they are exported, imported or in transit.

(10) With a view to enabling Member States to react more quickly with regard to new trends in drug precursors' diversion, their possibilities to act in cases of suspicious transactions involving non-scheduled substances should be clarified. To that end, Member States should be able to empower their competent authorities to obtain information on any orders for or operations involving non-scheduled substances, or to enter business premises to obtain evidence of suspicious transactions involving such substances. In addition, competent authorities should prevent the introduction into, or the departure from, the customs territory of the Union of non-scheduled substances, where it can be demonstrated

([1]) Position of the European Parliament of 23 October 2013 (not yet published in the Official Journal) and decision of the Council of 15 November 2013.

([2]) Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors (OJ L 22, 26.1.2005, p. 1).

that such substances will be used in the illicit manufacture of narcotic drugs or psychotropic substances. Such non-scheduled substances should be considered as proposed for inclusion in the voluntary monitoring list of non-scheduled substances.

(11) Member States' competent authorities should share between themselves and with the Commission, through the European database on drug precursors ('the European database'), established under Regulation (EC) No 273/2004 of the European Parliament and of the Council ([1]), information on seizures and stopped shipments in order to improve the overall level of information on trade in drug precursors, including medicinal products. The European database should be used to simplify the reporting by Member States with regard to seizures and stopped shipments. It should also serve as a European register of operators holding a licence or registration which will facilitate verification of the legitimacy of their transactions involving scheduled substances, and should enable operators to provide the competent authorities with information about their export, import or intermediary activities involving scheduled substances. That European register should be regularly updated and the information it contains should be used by the Commission and Member States' competent authorities only for the purpose of preventing the diversion of drug precursors onto the illegal market.

(12) Regulation (EC) No 111/2005 provides for the processing of data. Such processing may also cover personal data and should be carried out in accordance with Union law.

(13) The processing of personal data for the purposes of Regulation (EC) No 111/2005, as amended by this Regulation, and any delegated and implementing acts adopted pursuant thereto should respect the fundamental right to respect for private and family life recognised by Article 8 of the Convention for the Protection of Human Rights and Fundamental Freedoms as well as the right to respect for private and family life, and the right to the protection of personal data recognised, respectively, by Articles 7 and 8 of the Charter of Fundamental Rights of the European Union.

(14) Member States and the Commission should process personal data only in a manner compatible with the purposes of Regulation (EC) No 111/2005, as amended by this Regulation, and the delegated and implementing acts adopted pursuant thereto. Those data should be processed in accordance with Union legislation concerning the protection of individuals with regard to the processing of personal data, in particular Directive 95/46/EC of the European Parliament and of the Council ([2]) and Regulation (EC) No 45/2001 of the European Parliament and of the Council ([3]).

(15) Regulation (EC) No 111/2005 confers powers on the Commission in order to implement some of its provisions, to be exercised in accordance with the procedures laid down in Council Decision 1999/468/EC ([4]).

(16) As a consequence of the entry into force of the Treaty of Lisbon, those powers should be aligned to Articles 290 and 291 of the Treaty on the Functioning of the European Union (TFEU).

(17) In order to achieve the objectives of Regulation (EC) No 111/2005, as amended by this Regulation, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission to set out the conditions for granting licences and registration and for determining cases where a licence or a registration is not required, to establish the criteria to determine how the licit purposes of the transaction may be demonstrated, to determine the information that is required by the competent authorities and by the Commission to allow them to monitor export, import or intermediary activities of operators, to determine the lists of the countries of destination to which exports of scheduled substances of Categories 2 and 3 of the Annex to Regulation (EC) No 111/2005 are to be preceded by a pre-export notification, to determine simplified pre-export notification procedures and to establish the common criteria to be applied by the competent authorities, to determine simplified export authorisation procedures and to establish the common criteria to be applied by the competent authorities, and to adapt the Annex to Regulation (EC) No 111/2005 in order to respond to new trends in diversion of drug precursors and to follow any amendment to the tables

([1]) Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors (OJ L 47, 18.2.2004, p. 1).

([2]) Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

([3]) Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).

([4]) Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission (OJ L 184, 17.7.1999, p. 23).

in the Annex to the United Nations Convention. It is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including at expert level. The Commission, when preparing and drawing up delegated acts, should ensure a simultaneous, timely and appropriate transmission of relevant documents to the European Parliament and to the Council.

(18) In order to ensure uniform conditions for the implementation of Regulation (EC) No 111/2005, as amended by this Regulation, implementing powers should be conferred on the Commission, namely to establish a model for licences, the procedural rules on the provision of information that is required by the competent authorities to monitor export, import or intermediary activities of operators, and the measures to ensure the effective monitoring of trade between the Union and third countries in drug precursors, in particular with regard to the design and use of export and import authorisation forms, for the purpose of preventing the diversion of drug precursors. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council ([1]).

(19) The delegated and implementing acts adopted pursuant to Regulation (EC) No 111/2005, as amended by this Regulation, should guarantee a systematic and consistent control and monitoring of operators.

(20) The European Data Protection Supervisor was consulted in accordance with Article 28(2) of Regulation (EC) No 45/2001 and delivered an opinion on 18 January 2013 ([2]).

(21) Regulation (EC) No 111/2005 should therefore be amended accordingly,

HAVE ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 111/2005 is amended as follows:

(1) in the title of the Regulation and in Article 1, in points (d) and (e) of Article 2, in Article 10(1), in the first paragraph of Article 17, in the first paragraph of Article 20 and in Article 25, the noun 'Community' is replaced by the noun 'Union'. In point (e) of Article 2, in point (d) of Article 13(1), in the first subparagraph of Article 14(1), in Article 14(2), in Article 18 and in the first paragraph of Article 22, the term 'Community customs territory' is replaced by the term 'customs territory of the Union'. In the first subparagraph of Article 12(1), the term 'Customs territory from the Community' is replaced by the term 'customs territory of the Union';

(2) in Article 2:

(a) point (a) is replaced by the following:

'(a) "scheduled substance" means any substance listed in the Annex that can be used for the illicit manufacture of narcotic drugs or psychotropic substances, including mixtures and natural products containing such substances, but excluding mixtures and natural products which contain scheduled substances and which are compounded in such a way that the scheduled substances cannot be easily used or extracted by readily applicable or economically viable means, medicinal products as defined in point 2 of Article 1 of Directive 2001/83/EC of the European Parliament and of the Council (*) and veterinary medicinal products as defined in point 2 of Article 1 of Directive 2001/82/EC of the European Parliament and of the Council (**), except medicinal products and veterinary medicinal products listed in the Annex;

(b) point (c) is replaced by the following:

'(c) "import" means any entry of scheduled substances having the status of non-Union goods into the customs territory of the Union, including temporary storage, the placing in a free zone or free warehouse, the placing under a suspensive procedure and the release for free circulation within the meaning of Council Regulation (EEC) No 2913/92 (*);

([1]) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

([2]) Not yet published in the Official Journal.

(*) Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

(**) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).';

(*) Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code (OJ L 302, 19.10.1992, p. 1).';

(c) point (j) is replaced by the following:

'(j) "natural product" means an organism or a part thereof, in any form, or any substances which occur in nature as defined in point 39 of Article 3 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council (*);

(*) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, p. 1).';

(3) the first paragraph of Article 3 is replaced by the following:

'All imports, exports or intermediary activities involving scheduled substances, with the exception of substances listed in Category 4 of the Annex, shall be documented by the operator by way of customs and commercial documents, such as summary declarations, customs declarations, invoices, cargo manifests, transport and other shipping documents.';

(4) Article 5 is replaced by the following:

'Article 5

Operators shall ensure that labels are affixed on any packaging containing scheduled substances, except substances listed in Category 4 of the Annex, indicating their name as stated in the Annex, or, in the case of a mixture or a natural product, its name and the name of any scheduled substance, except substances listed in Category 4 of the Annex, as stated in the Annex, contained in the mixture or in the natural product. Operators may, in addition, affix their customary labels.';

(5) in Article 6:

(a) paragraph 1 is replaced by the following:

'1. Unless otherwise provided, operators established in the Union, other than customs agents and transporters when acting solely in that capacity, engaged in import, export or intermediary activities involving scheduled substances listed in Category 1 of the Annex, shall hold a licence. The competent authority of the Member State in which the operator is established shall issue the licence.

In considering whether to grant a licence, the competent authority shall take into account the competence and integrity of the applicant, in particular the absence of any serious infringement or repeated infringements of legislation in the field of drug precursors and the absence of a record of any serious criminal offence.

The Commission shall be empowered to adopt delegated acts in accordance with Article 30b to set out the conditions for granting licences and for determining cases where a licence is not required.';

(b) the following paragraph is added:

'3. The Commission shall establish a model for licences by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(2).';

(6) Article 7 is replaced by the following:

'Article 7

1. Unless otherwise provided, operators established in the Union, other than customs agents and transporters when acting solely in that capacity, engaged in import, export or intermediary activities involving scheduled substances listed in Category 2 of the Annex, or in the export of scheduled substances listed in Category 3 of the Annex, shall hold a registration. The competent authority in the Member State in which the operator is established shall issue the registration.

In considering whether to grant a registration, the competent authority shall take into account the competence and integrity of the applicant, in particular the absence of any serious infringement or repeated infringements of legislation in the field of drug precursors and the absence of a record of any serious criminal offence.

The Commission shall be empowered to adopt delegated acts in accordance with Article 30b to set out the conditions for granting registrations and for determining cases where a registration is not required.

2. The competent authority may suspend or revoke the registration where the conditions under which the registration was issued are no longer fulfilled or where there are reasonable grounds for suspecting that there is a risk of diversion of scheduled substances.';

(7) Article 8 is replaced by the following:

'*Article 8*

1. When the scheduled substances are entered into the customs territory of the Union for unloading or transhipment, for temporary storage, for their storage in a free zone of control type I or a free warehouse, or for their placing under the external Union transit procedure, the licit purposes must be demonstrated by the operator, upon request by the competent authorities.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 30b to establish the criteria to determine how the licit purposes of the transaction may be demonstrated, in order to ensure that all movements of scheduled substances within the customs territory of the Union can be monitored by the competent authorities and the risk of diversion be minimised.';

(8) Article 9 is replaced by the following:

'*Article 9*

1. Operators established in the Union shall notify the competent authorities immediately of any circumstances, such as unusual orders and transactions involving scheduled substances, which suggest that such substances intended for import, export or intermediary activities might be diverted for the illicit manufacture of narcotic drugs or psychotropic substances.

To that end, operators shall provide any available information, such as:

(a) the name of the scheduled substance;

(b) the quantity and weight of the scheduled substance;

(c) the names and addresses of the exporter, the importer, the ultimate consignee and, where applicable, the person involved in the intermediary activities.

That information shall only be collected for the purposes of preventing the diversion of scheduled substances.

2. Operators shall provide the competent authorities with information in summary form about their export, import or intermediary activities.

The Commission shall be empowered to adopt delegated acts in accordance with Article 30b to determine the information that is required by the competent authorities in order to allow them to monitor those activities.

The Commission shall specify by means of implementing acts the procedural rules on the provision of such information, including, where appropriate, in electronic form to the European database on drug precursors established under Regulation (EC) No 273/2004 of the European Parliament and of the Council (*) ("the European database"). Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(2).

(*) Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors (OJ L 47, 18.2.2004, p. 1).';

(9) in Article 10, the following paragraphs are added:

'4. In order to respond rapidly to new diversion trends, the competent authorities of the Member States and the Commission may propose to add a non-scheduled substance to the list referred to in paragraph 2(b) in order to temporarily monitor its trade. Detailed arrangements and criteria for the inclusion or deletion from that list shall be specified in the guidelines referred to in paragraph 1.

5. If voluntary monitoring by the industry is considered insufficient to prevent the use of a non-scheduled substance for the illicit manufacture of narcotic drugs or psychotropic substances, the Commission may add the non-scheduled substance to the Annex by means of delegated acts in accordance with Article 30b.';

(10) in Article 11:

(a) in paragraph 1, the first subparagraph is replaced by the following:

'1. All exports of scheduled substances listed in Categories 1 and 4 of the Annex and exports of scheduled substances listed in Categories 2 and 3 of the Annex to certain countries of destination shall be preceded by a pre-export notification sent from the competent authorities in the Union to the competent authorities of the country of destination, in accordance with Article 12(10) of the United Nations Convention. The Commission shall be empowered to adopt delegated acts in accordance with Article 30b of this Regulation to determine the lists of the countries of destination for export of scheduled substances listed in Categories 2 and 3 of the Annex in order to minimise the risk of diversion of scheduled substances.';

(b) paragraph 3 is replaced by the following:

'3. Simplified pre-export notification procedures may be applied by the competent authorities where they are satisfied that this will not result in any risk of diversion of scheduled substances. The Commission shall be empowered to adopt delegated acts in accordance with Article 30b to determine such procedures and to establish the common criteria to be applied by the competent authorities.';

(11) in Article 12(1), the third subparagraph is replaced by the following:

'However, exports of scheduled substances listed in Category 3 of the Annex shall only be subject to an export authorisation where pre-export notifications are required.';

(12) in Article 13(1), the following subparagraph is added:

'An application for an export authorisation for exports of scheduled substances listed in Category 4 of the Annex shall contain the information set out in points (a) to (e) of the first subparagraph.';

(13) Article 19 is replaced by the following:

'*Article 19*

Simplified procedures to grant an export authorisation may be applied by the competent authorities where they are satisfied that this will not result in any risk of diversion of scheduled substances. The Commission shall be empowered to adopt delegated acts in accordance with Article 30b to determine such procedures and to establish the common criteria to be applied by the competent authorities.';

(14) in Article 20, the second paragraph is replaced by the following:

'However, where the substances referred to in the first paragraph are unloaded or transhipped, under temporary storage, stored in a free zone of control type I or a free warehouse, or placed under the external Union transit procedure, such import authorisation shall not be required.';

(15) in Article 26:

(a) paragraph 1 is replaced by the following:

'1. Without prejudice to Articles 11 to 25 and to paragraphs 2 and 3 of this Article, the competent authorities of each Member State shall prohibit the introduction of scheduled substances into the customs territory of the Union or their departure from it, where there are reasonable grounds for suspecting that such substances are intended for the illicit manufacture of narcotic drugs or psychotropic substances.';

(b) the following paragraphs are inserted:

'3a. The competent authorities of each Member State shall prohibit the introduction of consignments of non-scheduled substances into the customs territory of the Union or their departure from it where there is sufficient evidence that those substances are intended for the illicit manufacture of narcotic drugs or psychotropic substances.

The competent authority shall immediately inform the competent authorities of the other Member States and the Commission thereof, using the procedure referred to in Article 27.

Those substances shall be considered as proposed for inclusion in the list of non-scheduled substances referred to in point (b) of Article 10(2).

3b. Each Member State may adopt the measures necessary to enable its competent authorities to control and monitor suspicious transactions involving non-scheduled substances, in particular:

(a) to obtain information on any orders for or operations involving non-scheduled substances;

(b) to enter business premises in order to obtain evidence of suspicious transactions involving non-scheduled substances.';

(16) the title of Chapter V is replaced by the following:

'DELEGATED AND IMPLEMENTING ACTS';

(17) Article 28 is replaced by the following:

'*Article 28*

In addition to the measures referred to in Article 26, the Commission shall be empowered to lay down, where necessary, by means of implementing acts, measures to ensure the effective monitoring of trade between the Union and third countries in drug precursors, in particular with regard to the design and use of export and import authorisation forms, for the purpose of preventing the diversion of drug precursors. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(2).';

(18) Article 29 is deleted;

(19) Article 30 is replaced by the following:

'*Article 30*

1. The Commission shall be assisted by the Drug Precursors Committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council (*).

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

(*) Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).';

(20) the following Articles are inserted:

'*Article 30a*

The Commission shall be empowered to adopt delegated acts in accordance with Article 30b of this Regulation in order to adapt the Annex hereto to new trends in diversion of drug precursors, in particular substances which can be easily transformed into scheduled substances, and to follow any amendment to the tables in the Annex to the United Nations Convention.

Article 30b

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in the third subparagraph of Article 6(1), the third subparagraph of Article 7(1), Article 8(2), the second subparagraph of Article 9(2), Article 10(5), Article 11(1) and (3), Articles 19 and 30a and Article 32(2) shall be conferred on the Commission for a period of five years from 30 December 2013. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in the third subparagraph of Article 6(1), the third subparagraph of Article 7(1), Article 8(2), the second subparagraph of Article 9(2), Article 10(5), Article 11(1) and (3), Articles 19 and 30a and Article 32(2) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to the third subparagraph of Article 6(1), the third subparagraph of Article 7(1), Article 8(2), the second subparagraph of Article 9(2), Article 10(5), Article 11(1) and (3), Articles 19 and 30a and Article 32(2) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.';

(21) Article 32 is replaced by the following:

'*Article 32*

1. The competent authorities in each Member State shall communicate to the Commission in electronic form via the European database in a timely manner all relevant information on the implementation of the monitoring measures laid down in this Regulation, in particular as regards substances used for the illicit manufacture of narcotic drugs or psychotropic substances and methods of diversion and illicit manufacture, and their licit trade.

2. The Commission shall be empowered to adopt delegated acts in accordance with Article 30b in order to specify the conditions and requirements concerning the information to be provided under paragraph 1 of this Article.

3. On the basis of the information referred to in paragraph 1 of this Article, the Commission shall, in consultation with the Member States, evaluate the effectiveness of this Regulation and, in accordance with Article 12(12) of the United Nations Convention, draw up an annual report to be submitted to the International Narcotics Control Board.

4. The Commission shall submit by 31 December 2019 a report to the European Parliament and to the Council on the implementation and functioning of this Regulation, and in particular on the possible need for additional action to monitor and control suspicious transactions with non-scheduled substances';

(22) the following Article is inserted:

'*Article 32a*

The competent authorities of the Member States and the Commission shall use the European database under the conditions for its use for the following functions:

(a) to facilitate the communication of information pursuant to Article 32(1) as well as the reporting to the International Narcotics Control Board pursuant to Article 32(3);

(b) to manage a European register of operators, which have been granted a licence or registration;

(c) to enable operators to provide the competent authorities with information about their export, import or intermediary activities according to Article 9(2), in electronic form.';

(23) Article 33 is replaced by the following:

'*Article 33*

1. The processing of personal data by the competent authorities in the Member States shall be carried out in accordance with national laws, regulations and administrative provisions transposing Directive 95/46/EC of the European Parliament and of the Council (*) and under the supervision of the supervisory authority of the Member State referred to in Article 28 of that Directive.

2. The processing of personal data by the Commission, including for the purpose of the European database, shall be carried out in accordance with Regulation (EC) No 45/2001 of the European Parliament and of the Council (**) and under the supervision of the European Data Protection Supervisor.

3. No special categories of data within the meaning of Article 8(1) of Directive 95/46/EC shall be processed for the purposes of this Regulation.

4. The personal data collected for the purposes of this Regulation shall not be further processed in a way inconsistent with Directive 95/46/EC or Regulation (EC) No 45/2001 and shall not be retained longer than necessary for the purposes for which it was collected.

5. Member States and the Commission shall not process personal data in a manner incompatible with the purposes set out in Article 32a.

Without prejudice to Article 13 of Directive 95/46/EC, personal data obtained or processed pursuant to this Regulation shall be used for the purpose of preventing the diversion of scheduled substances.

(*) Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p. 31).

(**) Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p. 1).';

(24) in the Annex:

(a) the title is replaced by the following:

'List of scheduled substances';

(b) before the first table, the following subtitle is inserted:

'Category 1';

(c) in Category 1, the CN Code for Norephedrine is replaced by the following:

'2939 44 00';

(d) in Category 1, the following substance is added to the list of substances:

'Alpha-phenylacetoacetonitrile, CN Code 2926 90 95, CAS No 4468-48-8';

(e) the following category is added:

'Category 4

Substance	CN designation (if different)	CN Code
Medicinal products and veterinary medicinal products containing ephedrine or its salts	Containing ephedrine or its salts	3003 40 20 3004 40 20
Medicinal products and veterinary medicinal products containing pseudo-ephedrine or its salts	Containing pseudoep-hedrine (INN) or its salts	3003 40 30 3004 40 30'

Article 2

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 20 November 2013.

For the European Parliament
The President
M. SCHULZ

For the Council
The President
V. LEŠKEVIČIUS

COMMISSION REGULATION (EU) No 225/2011

of 7 March 2011

amending Commission Regulation (EC) No 1277/2005 laying down implementing rules for Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors and for Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors [1], and in particular Article 11(1) and the third subparagraph of Article 12(1) thereof,

Whereas:

(1) Commission Regulation (EC) No 1277/2005 [2] determines whether specific monitoring measures upon export of drug precursors from the European Union are required. Annex IV to that Regulation lists for each of the scheduled substances of categories 2 and 3 of the Annex to Regulation (EC) No 111/2005, the countries for which a pre-export notification is required. The lists involve third countries which have requested to receive pre-export notifications in accordance with Article 12(10) of the United Nations Convention against illicit traffic in narcotic drugs and psychotropic substances of 1988.

(2) The United Nations Commission on Narcotic Drugs has, at its second meeting, on 8 March 2010, decided to include phenylacetic acid in Table I of the United Nations Convention against illicit traffic in narcotic drugs and psychotropic substances of 1988. Article 12(10) of that Convention sets out that each Party from whose territory a substance in Table I is to be exported shall ensure that, prior to such export, information on the export consignment is supplied by its competent authorities to the competent authorities of the importing country.

(3) Following the decision to include phenylacetic acid in Table I of the United Nations Convention, it is necessary to amend Annex IV to Regulation (EC) No 1277/2005 to ensure that pre-export notifications are sent for all exports of phenylacetic acid from the European Union.

(4) Annex IV to Regulation (EC) No 1277/2005 does not list all third countries which have requested to receive pre-export notifications for certain scheduled substances of categories 2 and 3 since the entry into force of Commission Regulation (EC) No 297/2009 [3]. Afghanistan, Australia and Ghana have made such requests and should therefore be added.

(5) Regulation (EC) No 1277/2005 should be amended accordingly.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 30(1) of Regulation (EC) No 111/2005,

HAS ADOPTED THIS REGULATION:

Article 1

Annex IV to Regulation (EC) No 1277/2005 is replaced by the text set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 7 March 2011.

For the Commission
The President
José Manuel BARROSO

[1] OJ L 22, 26.1.2005, p. 1.
[2] OJ L 202, 3.8.2005, p. 7.
[3] OJ L 95, 9.4.2009, p. 13.

ANNEX

'ANNEX IV

1. List of countries referred to in Article 20 for which a pre-export notification is required for exports of scheduled substances of category 2 of the Annex to Regulation (EC) No 111/2005

Substance	Destination	
Acetic anhydride **Potassium permanganate** **Phenylacetic acid**	Any third country	
Anthranilic acid	Afghanistan Australia Antigua and Barbuda Benin Bolivia Brazil Canada Cayman Islands Chile Colombia Costa Rica Dominican Republic Ecuador Ethiopia Ghana Haiti India Indonesia Jordan Kazakhstan Lebanon Madagascar	Malaysia Maldives Mexico Nigeria Oman Paraguay Peru Philippines Republic of Moldova Russian Federation Saudi Arabia South Africa Tajikistan Turkey United Arab Emirates United Republic of Tanzania Venezuela
Piperidine	Afghanistan Australia Antigua and Barbuda Benin Bolivia Brazil Canada Cayman Islands Chile Colombia Costa Rica Dominican Republic Ecuador Ethiopia Ghana Haiti India Indonesia Jordan Kazakhstan Lebanon Madagascar	Malaysia Maldives Mexico Nigeria Oman Paraguay Peru Philippines Republic of Moldova Russian Federation Saudi Arabia Tajikistan Turkey United Arab Emirates United Republic of Tanzania United States of America Venezuela

2. List of countries referred to in Articles 20 and 22 for which a pre-export notification and an export authorisation is required for exports of scheduled substances of category 3 of the Annex to Regulation (EC) No 111/2005

Substance	Destination	
Methylethyl ketone (MEK) (1) **Toluene** (1) **Acetone** (1) **Ethyl ether** (1)	Afghanistan Australia Antigua and Barbuda Argentina Benin Bolivia Brazil Canada Cayman Islands Chile Colombia Costa Rica Dominican Republic Ecuador Egypt El Salvador Ethiopia Ghana Guatemala Haiti Honduras India Jordan Kazakhstan	Lebanon Madagascar Malaysia Maldives Mexico Nigeria Oman Pakistan Paraguay Peru Philippines Republic of Moldova Republic of Korea Russian Federation Saudia Arabia Tajikistan Turkey United Arab Emirates United Republic of Tanzania Uruguay Venezuela
Hydrochloric acid **Sulphuric acid**	Bolivia Chile Colombia Ecuador	Peru Turkey Venezuela

(1) This includes the salts of these substances whenever the existence of such salts is possible.'

COMMISSION REGULATION (EC) No 297/2009

of 8 April 2009

amending Regulation (EC) No 1277/2005 laying down implementing rules for Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors and for Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors [1], and in particular Article 11(1) and the third subparagraph of Article 12(1) thereof,

Whereas:

(1) Commission Regulation (EC) No 1277/2005 [2] determines third countries of destination requiring specific monitoring measures upon export of drug precursors from the Community. Annex IV to that Regulation lists for each of the scheduled substances of categories 2 and 3 of the Annex to Regulation (EC) No 111/2005, the countries for which a pre-export notification is required. The lists involve third countries which have requested to receive pre-export notifications in accordance with Article 12(10) of the United Nations Convention against illicit traffic in narcotic drugs and psychotropic substances of 1988.

(2) Romania is listed in Annex IV to Regulation (EC) No 1277/2005. Since Romania has become a Member State, it is necessary to remove it from the lists.

(3) Annex IV to Regulation (EC) No 1277/2005 does not list all third countries which have requested to receive pre-export notifications since the entry into force of Regulation (EC) No 1277/2005. Since 2005, Canada, Maldives, Oman and the Republic of Korea have made such requests and should therefore be added.

(4) Regulation (EC) No 1277/2005 should therefore be amended accordingly.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Committee established by Article 30(1) of Regulation (EC) No 111/2005,

HAS ADOPTED THIS REGULATION:

Article 1

Annex IV to Regulation (EC) No 1277/2005 is replaced by the text set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 8 April 2009.

For the Commission
László KOVÁCS
Member of the Commission

[1] OJ L 22, 26.1.2005, p. 1.
[2] OJ L 202, 3.8.2005, p. 7.

ANNEX

'ANNEX IV

1. List of countries referred to in Article 20 for which a pre-export notification is required for exports of scheduled substances of category 2 of the Annex to Regulation (EC) No 111/2005

Substance	Destination	
Acetic anhydride **Potassium permanganate**	Any third country	
Anthranilic acid	Antigua and Barbuda Benin Bolivia Brazil Canada Cayman Islands Chile Colombia Costa Rica Dominican Republic Ecuador Ethiopia Haiti India Indonesia Jordan Kazakhstan Lebanon Madagascar	Malaysia Maldives Mexico Nigeria Oman Paraguay Peru Philippines Republic of Moldova Russian Federation Saudi Arabia South Africa Tajikistan Turkey United Arab Emirates United Republic of Tanzania Venezuela
Phenylacetic acid **Piperidine**	Antigua and Barbuda Benin Bolivia Brazil Canada Cayman Islands Chile Colombia Costa Rica Dominican Republic Ecuador Ethiopia Haiti India Indonesia Jordan Kazakhstan Lebanon Madagascar	Malaysia Maldives Mexico Nigeria Oman Paraguay Peru Philippines Republic of Moldova Russian Federation Saudi Arabia Tajikistan Turkey United Arab Emirates United Republic of Tanzania United States of America Venezuela

2. List of countries referred to in Articles 20 and 22 for which a pre-export notification and an export authorisation is required for exports of scheduled substances of category 3 of the Annex to Regulation (EC) No 111/2005

Substance	Destination	
Methylethyl ketone (MEK) (1)	Antigua and Barbuda	Lebanon
Toluene (1)	Argentina	Madagascar
Acetone (1)	Benin	Malaysia
Ethyl ether (1)	Bolivia	Maldives
	Brazil	Mexico
	Canada	Nigeria
	Cayman Islands	Oman
	Chile	Pakistan
	Colombia	Paraguay
	Costa Rica	Peru
	Dominican Republic	Philippines
	Ecuador	Republic of Moldova
	Egypt	Republic of Korea
	El Salvador	Russian Federation
	Ethiopia	Saudi Arabia
	Guatemala	Tajikistan
	Haiti	Turkey
	Honduras	United Arab Emirates
	India	United Republic of Tanzania
	Jordan	Uruguay
	Kazakhstan	Venezuela
Hydrochloric acid	Bolivia	Peru
Sulphuric acid	Chile	Turkey
	Colombia	Venezuela
	Ecuador	

(1) This includes the salts of these substances whenever the existence of such salts is possible.'

COMMISSION REGULATION (EC) No 1277/2005

of 27 July 2005

laying down implementing rules for Regulation (EC) No 273/2004 of the European Parliament and of the Council on drug precursors and for Council Regulation (EC) No 111/2005 laying down rules for the monitoring of trade between the Community and third countries in drug precursors

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors [1], and in particular Article 14(a) and (f) thereof,

Having regard to Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors [2], and in particular the third subparagraph of Article 6(1), Articles 7(2), 8(2) and 9(2), Article 11(1) and (3), the third subparagraph of Article 12(1) and Articles 19 and 28 thereof,

Whereas:

(1) Council Regulation (EEC) No 3677/90 of 13 December 1990 laying down measures to be taken to discourage the diversion of certain substances to the illicit manufacture of narcotic drugs and psychotropic substances [3] which was implemented by Commission Regulation (EEC) No 3769/92 of 21 December 1992 implementing and amending Council Regulation (EEC) No 3677/90 laying down measures to be taken to discourage the diversion of certain substances to the illicit manufacture of narcotic drugs and psychotropic substances [4] has been replaced by Regulation (EC) No 111/2005. It is necessary to bring the implementing measures contained in Regulation (EEC) No 3769/92 in line with the new set of rules provided for in Regulation (EC) No 111/2005. Regulation (EEC) No 3769/92 should therefore be repealed.

(2) Regulation (EC) No 273/2004 on drug precursors, which replaces Council Directive 92/109/EEC [5], harmonises the provisions concerning the placing on the market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances within the Community. In order to enhance the smooth operation of the internal market, for the trade in drug precursors, the provisions for the application for a licence, the granting or refusal of the granting of a licence, its suspension or revocation, should be harmonised at Community level.

(3) It is important to avoid the unauthorised removal of Category 1 substances, and therefore the business premises where these substances are stored or used should be secured against the unauthorised removal.

(4) The types of operators engaged in intra-Community trade who may benefit from special licences and special registrations should be further determined. The cases where operators engaged in trade between the Community and third countries may be exempted from the licensing and registration requirement should be determined.

(5) The provisions governing the licence conditions and the notification obligations of operators engaged in intra-Community trade and trade between the Community and third countries should to the extent possible be identical.

(6) Provisions should be set up allowing to verify the licit purposes of all drug precursor consignments entering the Community customs territory, including, in particular, transit and transhipment consignments and sensitive areas such as Community free zones.

(7) Specific import authorisation procedures are necessary to monitor individual import consignments of Category 1 substances in order to prevent diversion at an early stage and in particular to address the growing problem of amphetamine-type stimulants.

(8) Detailed rules concerning pre-export notification should allow it to adapt the information transfer and the necessary type of response to the sensitivity of the export consignment. In order to fully exploit the pre-export notification and export authorisation system, efforts should in principle target high risk consignments. Detailed rules on the simplified use of pre-export notifications and the granting of export authorisations by simplified procedure should allow the easening of the administrative burden for mass chemicals with common licit uses.

(9) In view of an efficient monitoring of trade Member States should enable the competent authorities to perform their tasks efficiently and to exchange information between themselves.

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[1] OJ L 47, 18.2.2004, p. 1.
[2] OJ L 22, 26.1.2005, p. 1.
[3] OJ L 357, 20.12.1990, p. 1.
[4] OJ L 383, 29.12.1992, p. 17. Regulation as last amended by Regulation (EC) No 1232/2002 (OJ L 180, 10.7.2002, p. 5).
[5] OJ L 370, 19.12.1992, p. 76. Directive as last amended by Commission Directive 2003/101/EC (OJ L 286, 4.11.2003, p. 14).

(10) To improve the coordination of the monitoring of drug precursors it is appropriate that the Member States provide the Commission regularly with information on the prevention of the diversion of drug precursors.

(11) This Regulation should apply from the same date as Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005.

(12) The measures provided for in this Regulation are in accordance with the opinion of the drug precursors committee,

HAS ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

This Regulation lays down rules for the implementation of Regulations (EC) No 273/2004 and (EC) No 111/2005 as regards the responsible officer, the licensing and registration of operators, the provision of information, pre-export notifications and authorisation of exports and imports in the field of drug precursors.

Article 2

For the purposes of this Regulation, in addition to the definitions contained in regulations (EC) No 273/2004 and (EC) No 111/2005 'business premises' shall mean building(s) together with the land occupied by an operator at a single location.

CHAPTER II

RESPONSIBLE OFFICER

Article 3

Operators engaged in import, export or intermediary activities referred to in Article 2 of Regulation (EC) No 111/2005 involving scheduled substances of Category 1 or 2, shall appoint an officer responsible for the trade in scheduled substances, notify the competent authorities of the name and contact details of that officer and notify them immediately of any subsequent modification of this information.

Article 4

The responsible officer referred to in Article 3 shall ensure that import, export or intermediary activities take place in compliance with the pertinent legal provisions and shall be empowered to represent the operator and to take the decisions necessary for performing that task.

CHAPTER III

LICENSING AND REGISTRATION OF OPERATORS

Article 5

1. In order to obtain a licence pursuant to Article 3(2) of Regulation (EC) No 273/2004 the operator concerned shall make an application in writing.

That application shall contain the following:

(a) the full name and address of the applicant;

(b) the full name of the responsible officer;

(c) a description of the position and tasks of the responsible officer;

(d) the full addresses of the business premises;

(e) the description of all the places of storage, production, manufacture and processing of scheduled substances;

(f) information showing that adequate measures have been taken against the unauthorised removal of scheduled substances from the places listed in point (e);

(g) the name and the CN code of the scheduled substances as stated in Annex I to Regulation (EC) No 273/2004;

(h) in the case of a mixture or natural product an indication of the following:

(i) the name of the mixture or natural product;

(ii) the name and CN code of the scheduled substances as stated in Annex I to Regulation (EC) No 273/2004 in the mixture or natural product;

(iii) the maximum percentage of such scheduled substances in the mixture or natural product;

(i) a description of the envisaged type of operations referred to in Article 3 of Regulation (EC) No 273/2004;

(j) an authenticated copy of the Register of companies or activities, where appropriate;

(k) a certificate of good conduct of the applicant and the responsible officer or a document showing that they offer the necessary guarantee for the proper conduct of the operations, as appropriate.

The applicant shall provide the competent authorities, upon their request, with access to relevant additional information and documents.

2. Paragraph 1 shall apply as regards licences referred to in Article 6(1) of Regulation (EC) No 111/2005.

For the purposes of point (e) of paragraph 1, the application shall contain a description of all places of storage, working, processing, usual forms of handling and use of scheduled substances.

For the purposes of point (g) and point (h)(ii) of paragraph 1 the name and CN code of the scheduled substances as stated in the Annex to Regulation (EC) No 111/2005 shall be given.

For the purposes of point (i) of paragraph 1, a description of the envisaged type of operations referred to in Article 6(1) of Regulation (EC) No 111/2005 shall be given.

Article 6

Operators shall take adequate measures to secure the business premises against the unauthorised removal of scheduled substances listed in Category 1.

Article 7

1. The competent authority shall take a decision on the application for the licences referred to in Article 5 within 60 working days from the date of receipt of that application.

In the case of a renewal of a licence, the decision shall be taken within 30 working days.

2. The competent authority may suspend the periods referred to in paragraph 1 to allow the applicant to provide any missing information. In that case the suspension shall begin on the day when the competent authority informs the applicant about the missing information.

3. The licence may cover the operations referred to in Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005.

4. When granting the licence, the competent authorities shall use the model set out in Annex I.

5. The competent authorities may grant a licence in either of the following forms:

(a) a licence which covers all scheduled substances and all operations per business premises;

(b) a licence which covers all scheduled substances and all operations per Member State.

Article 8

1. Provided that measures adopted in accordance with Article 10 of Regulation (EC) No 273/2004 are not prejudiced, the competent authorities shall refuse the granting of the licence if the conditions set out in Article 5(1) of this Regulation are not fulfilled or if there are reasonable grounds for suspecting that the scheduled substances are intended for the illicit manufacture of narcotic drugs or psychotropic substances.

2. Subject to Article 5(2), paragraph 1 of this Article shall apply in respect of applications under Regulation (EC) No 111/2005 and provided that measures adopted in accordance with Article 26(3) of that Regulation are not prejudiced.

Article 9

In the case of trade between the Community and third countries referred to in Regulation (EC) No 111/2005, the competent authorities may either limit the validity of the licence to a period not exceeding three years or may require operators to demonstrate at intervals not exceeding three years that the conditions under which the licence was granted are still fulfilled.

The validity of licences issued before the entry into force of Regulation (EC) No 111/2005 shall not be affected.

Article 10

1. A licence shall not be transferable.

2. The licence holder shall, in accordance with Article 5, apply for a new licence where any of the following are envisaged:

(a) the addition of a scheduled substance;

(b) the start of a new operation;

(c) the change of the location of the business premises where the operations take place.

In such cases, the existing licence shall cease to be valid on the earlier of the following dates:

(i) the date of expiry of validity where a term of validity has been fixed in accordance with Article 9 of this Regulation or in accordance with Article 3(5) of Regulation (EC) No 273/2004;

(ii) the date of commencement of validity of the new licence.

3. In cases of changes of the information provided in accordance with Article 5 other than those referred to in paragraph 2 of this Article, in particular the name of the responsible officer, the licence holder shall inform the competent authorities within 10 working days following such change.

Where, after the change, the conditions referred to in Article 5 continue to be fulfilled, the competent authorities shall amend the licence accordingly.

4. Licence holders shall return licences which are no longer valid to the competent authorities.

5. Paragraph 2 shall apply to licences issued before the date of application of Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005.

Article 11

1. Provided that measures adopted in accordance with Article 10 of Regulation (EC) No 273/2004 are not prejudiced, the competent authorities may suspend or revoke a licence in the following cases:

(a) the conditions set out in Article 5(1) of this Regulation are no longer fulfilled;

(b) there are reasonable grounds for suspecting that the scheduled substances are intended for the illicit manufacture of narcotic drugs or psychotropic substances;

(c) the licence holder has not used the licence for a period of three years.

2. Subject to Article 5(2), paragraph 1 of this Article shall apply in respect of licences under Regulation (EC) No 111/2005 and provided that measures adopted in accordance with Article 26(3) of that Regulation are not prejudiced.

Article 12

1. Articles 5 to 11 shall not apply to special licences referred to in Article 3(2) of Regulation (EC) No 273/2004.

2. The public authorities referred to in Article 3(2) and (6) of Regulation (EC) No 273/2004 shall comprise customs, police and official laboratories of competent authorities.

Article 13

Pharmacies, dispensaries of veterinary medicine, customs, police, official laboratories of competent authorities and armed forces shall be exempted from the requirement of licensing and registration under Regulation (EC) No 111/2005 where these operators use drug precursors within the scope of their official duties, only.

The operators set out in the first paragraph are also exempted from the following:

(a) the provision of documentation referred to in Article 3 of Regulation (EC) No 111/2005;

(b) the obligation to appoint a responsible officer set out in Article 3 of this Regulation.

Article 14

1. Operators engaged in the export of scheduled substances listed in Category 3 of the Annex to Regulation (EC) No 111/2005 shall be exempt from the registration requirement referred to in Article 7(1) of that Regulation if the sum of quantities concerned by their exports during the course of the preceding calendar year (1 January-31 December) does not exceed the amounts specified in Annex II to this Regulation.

When those amounts are exceeded within the current calendar year, the operator shall comply with the registration requirement immediately.

2. Operators engaged in export of mixtures containing scheduled substances listed in Category 3 of the Annex to Regulation (EC) No 111/2005, shall be exempt from the registration requirement referred to in Article 7(1) of that Regulation if the amount of the scheduled substance contained in the mixtures does not exceed, during the course of the preceding calendar year, the amounts specified in Annex II to this Regulation.

When those amounts are exceeded within the current calendar year, the operator shall comply with the registration requirement immediately.

Article 15

For the purposes of Article 6 of Regulation (EC) No 273/2004, customers shall inform their suppliers whether that Article is applicable to them.

Article 16

Where, pursuant to Article 8(1) of Regulation (EC) No 111/2005, the competent authorities request the licit purposes of the transaction to be demonstrated, the operator shall, using the model set out in Annex III to this Regulation, provide a written declaration allowing the competent authorities to satisfy themselves that the consignment has left the country of export in accordance with the national provisions in force adopted pursuant to Article 12 of the Convention of the United Nations against illicit traffic in Narcotic Drugs and Psychotropic substances (hereinafter the United Nations Convention).

However, the operator may also present the import authorisation referred to in Article 20 of Regulation (EC) No 111/2005 or the customer declaration referred to in Article 4 of Regulation (EC) No 273/2004.

CHAPTER IV

PROVISION OF INFORMATION

Article 17

For the purposes of Article 8(2) of Regulation (EC) No 273/2004 operators shall inform the competent authorities in a summary form of the quantities of scheduled substances used or supplied and, in the case of supply, of the quantity supplied to each third party.

The first paragraph shall apply to scheduled substances of Category 3, only upon request by the competent authorities.

Article 18

1. For the purposes of Article 9(2) of Regulation (EC) No 111/2005 operators holding a licence or registration shall inform the competent authorities about the following:

(a) exports of scheduled substances subject to an export authorisation;

(b) all imports of scheduled substances of Category 1 requiring an import authorisation or all cases where scheduled substances of Category 2 are entered into a free zone of control type II, placed into a suspensive procedure other than transit, or released for free circulation;

(c) all intermediary activities involving scheduled substances of Categories 1 and 2.

2. The information referred to in point (a) of paragraph 1 shall be organised by making reference to the countries of destination, quantities exported and the reference numbers of the export authorisations as the case may be.

3. The information referred to in point (b) of paragraph 1 shall be organised by making reference to the third country of export and the reference number of the import authorisations as the case may be.

4. The information referred to in point (c) of paragraph 1 shall be organised by making reference to the third countries involved by these intermediary activities and the export or import authorisation as the case may be. Operators shall provide further information, upon request of the competent authorities.

Article 19

The information referred to in Articles 17 and 18 shall be provided once a year before 15 February.

The operator shall also inform the competent authorities, where no operations have taken place.

The information shall be treated as confidential business information.

CHAPTER V

PRE-EXPORT NOTIFICATION

Article 20

Lists as referred to in Article 11(1) of Regulation (EC) No 111/2005 shall at least involve the following:

(a) countries with whom the Community has concluded a specific agreement on drug precursors;

(b) third countries which have requested to receive pre-export notifications in accordance with Article 12(10) of the United Nations Convention.

Such lists are set out in Annex IV.

Article 21

1. In the case of exports intended for the simplified export authorisation procedure referred to in Article 19 of Regulation (EC) No 111/2005 and Articles 25, 26 and 27 of this Regulation, the competent authorities may send a simplified pre-export notification covering several export operations carried out within a specific time period of either 6 or 12 months.

2. The competent authorities shall supply the information specified in Article 13(1) of Regulation (EC) No 111/2005 and indicate to the competent authorities of the third country of destination that the pre-export notification covers several export operations carried out within a specific time period of either 6 or 12 months.

3. The competent authorities shall send a pre-export notification to the country of destination using the 'multilateral chemical reporting notification' form set out in Annex V.

CHAPTER VI

EXPORT/IMPORT AUTHORISATION

Article 22

The countries of destination of exports of scheduled substances listed in Category 3 requiring an export authorisation are set out in Annex IV.

Article 23

1. Export and import authorisations shall be made out on the forms given in Annex VI and Annex VII respectively. The layout of the forms shall be binding.

An export or import authorisation may also be granted by electronic means. In that case Member States may adapt the box relating to the authorisation number.

2. An export authorisation shall be established in four copies numbered 1 to 4.

Copy No 1 shall be kept by the authority issuing the authorisation.

Copies No 2 and No 3 shall accompany the scheduled substances and be presented to the customs office where the customs export declaration is made and subsequently to the competent authorities at the point of exit from the customs territory of the Community. The competent authorities at the point of exit shall return Copy No 2 to the issuing authority. Copy No 3 shall accompany the scheduled substances to the competent authority of the importing country.

Copy No 4 shall be kept by the exporter.

3. The import authorisation shall be established in four copies numbered 1 to 4.

Copy No 1 shall be kept by the authority issuing the authorisation.

Copy No 2 shall be sent to the competent authority of the exporting country by the issuing authority.

Copy No 3 shall accompany the scheduled substances from the point of entry into the Community customs territory to the business premises of the importer, who sends this copy to the issuing authority.

Copy No 4 shall be kept by the importer.

4. An export or import authorisation shall not be granted for more than two scheduled substances.

Article 24

1. The authorisation forms shall be printed in one or more of the official languages of the Community.

2. The forms shall be A4 format. It shall have a printed guilloche pattern background making any falsification by mechanical or chemical means apparent to the eye.

3. Member States may reserve the right to print the authorisation forms themselves or may have them printed by printers approved by them. In the latter case, each authorisation form must include a reference of such approval. In addition, the authorisation form must bear the name and address of the printer or a mark by which the printer can be identified.

Article 25

On an application by the operator concerned the competent authority may grant an export authorisation by simplified procedure, as referred to in Article 19 of Regulation (EC) No 111/2005, in cases of frequent exports of one specific scheduled substance listed in Category 3 involving the same exporter established in the Community and the same importer in the same third country of destination covering a specific time period of either 6 or 12 months.

Such simplified export authorisation may only be granted in the following cases:

(a) where during previous exports the operator has shown the capacity to fulfil all obligations in relation to those exports, and has not committed any offences against relevant legislation;

(b) where the competent authority can satisfy itself as to the licit purposes of those export operations.

Article 26

1. The application for a simplified export authorisation referred to in Article 25 shall contain at least the following:

(a) the names and addresses of the exporter, importer in the third country, and the ultimate consignee;

(b) the name of the scheduled substance, as stated in the Annex to Regulation (EC) No 111/2005, or, in the case of a mixture or natural product, its name and CN code and the name of any scheduled substance, as stated in the Annex to Regulation (EC) No 111/2005, contained in the mixture or natural product;

(c) the maximum quantity of the scheduled substance intended for export;

(d) the intended specific time period for the export operations.

2. The competent authority shall take the decision on the application for simplified export authorisation within a period of 15 working days from the date on which it received the required information.

Article 27

1. An export authorisation granted by simplified procedure shall be established using copies No 1, 2 and 4 of the form set out in Annex VI.

Copy No 1 shall be kept by the authority issuing the authorisation.

Copy No 2 and Copy No 4 shall remain with the exporter.

The exporter shall indicate details of each export operation on the back side of Copy No 2, in particular the quantity of the scheduled substance of each export operation and the remaining quantity. Copy No 2 shall be presented to the customs office when the customs declaration is made. That customs office shall confirm the details and return the copy to the exporter.

2. The operator shall enter the authorisation number and the words 'simplified export authorisation procedure' on the customs declaration for each export operation.

Where the customs office of exit is not at the point of exit from the customs territory of the Community, the information referred to in the first subparagraph shall be provided on the documents accompanying the export consignment.

3. The exporter shall return Copy No 2 to the issuing authority at the latest 10 working days following the expiry of the period of validity of the export authorisation granted by simplified procedure.

CHAPTER VII

FINAL PROVISIONS

Article 28

1. Each Member State shall adopt the measures necessary to enable the competent authorities to perform their control and monitoring duties, including inspections to examine the suitability of the business premises.

2. The Member States shall ensure the exchange of information between all authorities involved.

Article 29

1. In the month following each calendar quarter, each Member State shall send the Commission a list providing information on the cases where the release of scheduled substances was suspended or the scheduled substances were detained.

That information shall include the following:

(a) the of name of the scheduled substances; if known their origin, provenance and destination;

(b) the quantity of the scheduled substances, their customs status and the means of transport used.

2. At the end of every calendar year, the Commission shall communicate to all Member States the information received pursuant to paragraph 1.

Article 30

Regulation (EEC) No 3769/92 is repealed with effect from 18 August 2005.

References to the repealed Regulation shall be construed as references to this Regulation.

Article 31

By 31 December 2005 at the latest, the competent authorities shall revoke open individual export authorisations granted pursuant to Articles 5(3) and 5a(3) of Regulation (EEC) No 3677/90. Such revocation shall not, however, affect scheduled substances which have been declared for export before 1 January 2006.

Article 32

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

It shall apply from the 18 August 2005.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 27 July 2005.

For the Commission
Günter VERHEUGEN
Vice-President

ANNEX I

European Community

Licence
(Article 3(2) of Regulation (EC) No 273/2004)
(Article 6(1) of Regulation (EC) No 111/2005)

MS: .....
(Licence Number)

ORIGINAL

1. Licence holder (name, address, phone, fax, e-mail)	**2. Issuing authority**
1a. Additional information	1b. Additional information

3. Validity

Beginning:	**End:**

4. The licence covers the following:

Scheduled substance(s)	CN Code	Operation	Business premises

5. Additional information/conditions

6. Date	**Signature**	**Stamp**
	Name	

Notes

1. The layout of the model is not binding.

2. The order numbers and the text of the model are binding. The completion of the boxes marked in bold is mandatory.

3. Details of the boxes:

   Box 1 (Licence holder): The name of the responsible officer may be added.

   Box 3 (validity/end): Specify the term of validity or whether operators are obliged to demonstrate at intervals not exceeding three years that the conditions under which the licence was granted are still fulfilled.

   Box 4 (scheduled substances): Name of the scheduled substance as stated in the Annex, or, in the case of a mixture or a natural product, its name and the name of any scheduled substance, as stated in the Annex, contained in the mixture or in the natural product. Indicate salts, where appropriate.

   Box 4 (CN code): In addition to the CN code, the CAS number may be added.

   Box 4 (operation): Specify export, import and/or intermediary activities. In the case of import, specify whether storage, working, processing, use, usual forms of handling and/or release for free circulation, where appropriate. For operations covered by Regulation (EC) No 273/2004, specify: storage, production, manufacture, processing, trade, distribution and/or brokering.

   Box 4 (business premises): In the case of intermediary activities referred to in Article 2 of Regulation (EC) No 111/2005, the business premises need not be specified.

4. The Member States may provide for boxes for national purposes. These boxes shall be indicated by an order number followed by a capital letter (e.g. 4A).

ANNEX II

Substance	Quantity
Acetone (1)	50 kg
Ethyl ether (1)	20 kg
Methylethylketone (1)	50 kg
Toluene (1)	50 kg
Sulphuric acid	100 kg
Hydrochloric acid	100 kg

(1) The salts of these substances whenever the existence of such salts is possible.

ANNEX III

European Community

Declaration of the operator
on the entry of the scheduled substances into the Community customs territory
(Article 8 of Regulation (EC) No 111/2005)

Article 12 of the United Nations' Convention against illicit traffic in narcotic drugs and psychotropic substances

ORIGINAL

1. Operator (name, address, phone, fax, e-mail)	2a. Country of export 2b. Transit country/countries 2c. Country of final destination
3a. Exporter in the country of export (name, address, phone, fax, e-mail)	3b. Competent authority in country of export (name, address, phone, fax, e-mail)
4a. Importer in the country of destination (name, address, phone, fax, e-mail)	4b. Competent authority in the country import (name, address, phone, fax, e-mail)
5a. Scheduled Substance	5a. CN Code 5a. Net weight 5a. % of mixture
5b. Scheduled Substance	5b. CN Code 5b. Net weight 5b. % of mixture
6a. Bill of lading/Airway bill/or other transport document number of country of export	6b. Reference number of the export authorisation of the exporter in the third country of export *(optional)*

7. Declaration by the Operator:

Name: _____ Representing: _____ (Operator)

I hereby declare that — to my knowledge — the scheduled substances have left the country of export in accordance with the provisions in force adopted pursuant to Article 12 of the United Nations' Convention against illicit traffic in narcotic drugs and psychotropic substances. The following supporting evidence is attached *(optional)*:

☐ copy of export authorisation ☐ copy of licence/registration

Signature: _____ Place: _____ Date: _____

Notes

1. The layout of the model is not binding.
2. The order numbers and the text of the model are binding.

ANNEX IV

I. List of countries referred to in Article 20:

Substance	Destination	
Acetic anhydride **Potassium permanganate**	Any third country	
Anthranilic acid	Antigua and Barbuda	Madagascar
	Benin	Malaysia
	Bolivia	Mexico
	Brazil	Nigeria
	Cayman Islands	Paraguay
	Chile	Peru
	Colombia	Philippines
	Costa Rica	Republic of Moldova
	Dominican Republic	Romania
	Ecuador	Russia
	Ethiopia	Saudi Arabia
	Haiti	South Africa
	India	Tajikistan
	Indonesia	Turkey
	Jordan	United Arab Emirates
	Kazakhstan	United Republic of Tanzania
	Lebanon	Venezuela
Phenylacetic Acid **Piperidine**	Antigua and Barbuda	Madagascar
	Benin	Malaysia
	Bolivia	Mexico
	Brazil	Nigeria
	Cayman Islands	Paraguay
	Chile	Peru
	Colombia	Philippines
	Costa Rica	Republic of Moldova
	Dominican Republic	Romania
	Ecuador	Russia
	Ethiopia	Saudi Arabia
	Haiti	Tajikistan
	India	Turkey
	Indonesia	United Arab Emirates
	Jordan	United Republic of Tanzania
	Kazakhstan	United States of America
	Lebanon	Venezuela

II. List of countries referred to in Articles 20 and 22:

Substance	Destination	
Methylethyl ketone (MEK) (1)	Antigua and Barbuda	Lebanon
Toluene (1)	Argentina	Madagascar
Acetone (1)	Benin	Malaysia
Ethyl ether (1)	Bolivia	Mexico
	Brazil	Nigeria
	Cayman Islands	Pakistan
	Chile	Panama
	Colombia	Paraguay
	Costa Rica	Peru
	Dominican Republic	Philippines
	Ecuador	Republic of Moldova
	Egypt	Romania
	El Salvador	Russia
	Ethiopia	Saudia Arabia
	Guatemala	Tajikistan
	Haiti	Turkey
	Honduras	United Arab Emirates
	India	United Republic of Tanzania
	Jordan	Uruguay
	Kazakhastan	Venezuela
Hydrochloric acid	Bolivia	Peru
Sulphuric acid	Chile	Turkey
	Colombia	Venezuela
	Ecuador	

(1) The salts of these substances whenever the existence of such salts is possible.

ANNEX V

MULTILATERAL CHEMICAL REPORTING NOTIFICATION

1. ACTION ADDRESSEE		
2. Additional addressee		
3. Additional addressee		
4. Name	**5. Agency (name and address)**	**6. Country**
7. Telephone	**8. Fax**	**9. E-mail**
10. Signature and date		

11. This shipment ☐ **WILL** ☐ **WILL NOT proceed if a reply is not received within … days.**

12. Does your office have any objection to this shipment? ☐ **Yes** ☐ **No** ☐ **Further inquiries required**
If YES, please provide details and reasons.

PART A

This multilateral chemical reporting notification covers: ☐ **one export operation, or** ☐ **several export operations to be carried out within a specific time frame (Beginning: ..... End: .....).**		
13. Name of scheduled substance	**14. Quantity and weight**	**15. CN code**
16. Exporting country	17. Point of exit	18. Departure date
19. Importing country	20. Point of entry	21. Estimated arrival date
22. Transhipment route (including Free Zones, and Final Destination)		23. Means of transport:
24. Importer (name, address, telephone and fax)		
25. Import/export authorisation number		
26. Ultimate consignee (name, address, telephone and fax)		
27. Other remarks		

PART B

32. Exporter, manufacturer or supplier (name, address, telephone and fax)
33. Intermediaries (name, address, telephone and fax)
34. Transit companies (name, address, telephone and fax)
35. Transportation details (Flight No/vessel, etc.)

Notes

1. The layout of the model is not binding.

2. The order numbers and the text of the model are binding. The completion of the boxes marked in bold is mandatory.

3. Further details of the boxes:

   Box 'Part A': Indicate whether the MCRN covers one or several export operations. Where it covers several operations, indicate the intended time frame.

   Box 14 (quantity and weight): In the case of a MCRN to cover several export operations, indicate the maximum quantity and weight.

   Item 18 (Departure date): In the case of a MCRN to cover several export operations, this box must be filled out indicating the final estimated departure date.

ANNEX VI

EUROPEAN COMMUNITY
GOODS SUBJECT TO EXPORT CONTROL

DRUG PRECURSORS — REGULATION (EC) No 111/2005 **EXPORT AUTHORISATION**

COPY FOR THE ISSUING AUTHORITY

1

1. Exporter (name and address)

2. AUTHORISATION number:

Issued (date): _____ at: _____

3. Simplified export authorisation procedure YES ...../NO .....

4. Period of validity:

Beginning: End:

5. Importer in the country of destination (name and address)

Import authorisation No

6. (For completion by the issuing authority) Issuing Authority (name, address, phone, fax, e-mail)

7. Other Operator(s) (name and address)

8. Customs office where the customs declaration will be made (name and address)

9. Ultimate consignee (name and address)

10. Point of exit

11. Point of entry into the importing country

12. Means of transport

13. Itinerary

1

14a. Scheduled substance

15a. CN code

16a. Net weight

17a. % of mixture

18a. Invoice number

14b. Scheduled substance

15b. CN code

16b. Net weight

17b. % of mixture

18b. Invoice number

19. Declaration by the applicant

Name: _____

Representing: _____ (Applicant)

Signature: _____ Date: _____

20. (For completion by the customs office where the export declaration is made unless the simplified export authorisation procedure is applied)

Reference number of customs declaration: _____

Stamp:

21. (For completion by issuing authority unless the simplified export authorisation procedure is applied)

Box 18 information still required: YES ...../NO .....

Boxes 7, 8, 10-13 information still required YES ...../NO .....

Signature: _____

Function: _____

Date: _____ Stamp:

22. CONFIRMATION OF EXIT FROM THE EC
(For completion by the competent authorities at the point of exit from the Community customs territory unless the simplified export authorisation procedure is applied)

Date of exit: _____

Signature of officer: _____

Function: _____ Place: _____

Date: _____ Stamp:

EUROPEAN COMMUNITY
GOODS SUBJECT TO EXPORT CONTROL

DRUG PRECURSORS — REGULATION (EC) No 111/2005 **EXPORT AUTHORISATION**

COPY TO ACCOMPANY THE GOODS TO POINT OF EXIT (*)

2

1. Exporter (name and address)

2. AUTHORISATION number:

Issued (date): _____ at: _____

3. Simplified export authorisation procedure YES ...../NO .....

4. Period of validity:

Beginning: End:

5. Importer in the country of destination (name and address)

Import authorisation No

6. (For completion by the issuing authority) Issuing Authority (name, address, phone, fax, e-mail)

7. Other Operator(s) (name and address)

8. Customs office where the customs declaration will be made (name and address)

9. Ultimate consignee (name and address)

10. Point of exit

11. Point of entry into the importing country

12. Means of transport

13. Itinerary

2

14a. Scheduled substance

15a. CN code

16a. Net weight

17a. % of mixture

18a. Invoice number

14b. Scheduled substance

15b. CN code

16b. Net weight

17b. % of mixture

18b. Invoice number

19. Declaration by the applicant

Name: _____

Representing: _____ (Applicant)

Signature: _____ Date: _____

20. (For completion by the customs office where the export declaration is made unless the simplified export authorisation procedure is applied)

Reference number of customs declaration: _____

Stamp:

21. (For completion by issuing authority unless the simplified export authorisation procedure is applied)

Box 18 information still required: YES ...../NO .....

Boxes 7, 8, 10-13 information still required YES ..../NO .....

Signature: _____

Function: _____

Date: _____ Stamp:

22. CONFIRMATION OF EXIT FROM THE EC
(For completion by the competent authorities at the point of exit from the Community customs territory unless the simplified export authorisation procedure is applied)

Date of exit: _____

Signature of officer: _____

Function: _____ Place: _____

Date: _____ Stamp:

(*) Unless the simplified export authorisation procedure is used.

Simplified export authorisation procedure			
23. Net weight		26. Customs declarations (reference number and date)	27. (For completion by the customs office where the customs declaration is made) Member State, name and address of the customs office, date, stamp and signature of the officer.
24. Available quantity (1) and partial export quantity (2)	25. Partial export quantity in words		
1			
2			
1			
2			
1			
2			
1			
2			
1			
2			
1			
2			
1			
2			
1			
2			
1			
2			
1			
2			
1			
2			

EUROPEAN COMMUNITY
GOODS SUBJECT TO EXPORT CONTROL

DRUG PRECURSORS — REGULATION (EC) No 111/2005 **EXPORT AUTHORISATION**

COPY TO ACCOMPANY THE GOODS TO IMPORTING COUNTRY

3	1. Exporter (name and address)	2. Authorisation number: Issued (date): _____ at: _____
		3. Simplified export authorisation procedure YES ...../NO .....
		4. Period of validity: Beginning: End:
	5. Importer in the country of destination (name and address) Import authorisation No	6. (For completion by the issuing authority) Issuing Authority (name, address, phone, fax, e-mail)
	7. Other Operator(s) (name and address)	8. Customs office where the customs declaration will be made (name and address)
	9. Ultimate consignee (name and address)	10. Point of exit / 11. Point of entry into the importing country
		12. Means of transport / 13. Itinerary
3	14a. Scheduled substance	15a. CN code 16a. Net weight 17a. % of mixture 18a. Invoice number
	14b. Scheduled substance	15b. CN code 16b. Net weight 17b. % of mixture 18b. Invoice number
	19. Declaration by the applicant Name: _____ Representing: _____ (Applicant) Signature: _____ Date: _____	20. (For completion by the customs office where the export declaration is made unless the simplified export authorisation procedure is applied) Reference number of customs declaration: _____ Stamp:
	21. (For completion by issuing authority unless the simplified export authorisation procedure is applied) Box 18 information still required: YES ...../NO ..... Boxes 7, 8, 10-13 information still required YES ..../NO ..... Signature: _____ Function: _____ Date: _____ Stamp:	22. CONFIRMATION OF EXIT FROM THE EC (For completion by the competent authorities at the point of exit from the Community customs territory unless the simplified export authorisation procedure is applied) Date of exit: _____ Signature of officer: _____ Function: _____ Place: _____ Date: _____ Stamp:

EUROPEAN COMMUNITY
GOODS SUBJECT TO EXPORT CONTROL

DRUG PRECURSORS — REGULATION (EC) No 111/2005 **EXPORT AUTHORISATION**

COPY FOR THE EXPORTER

4

1. Exporter (name and address)

2. AUTHORISATION number:

Issued (date): _____ at: _____

3. Simplified export authorisation procedure YES ...../NO .....

4. Period of validity:

Beginning: End:

5. Importer in the country of destination (name and address)

Import authorisation No

6. (For completion by the issuing authority) Issuing Authority (name, address, phone, fax, e-mail)

7. Other Operator(s) (name and address)

8. Customs office where the customs declaration will be made (name and address)

9. Ultimate consignee (name and address)

10. Point of exit

11. Point of entry into the importing country

12. Means of transport

13. Itinerary

4

14a. Scheduled substance

15a. CN code

16a. Net weight

17a. % of mixture

18a. Invoice number

14b. Scheduled substance

15b. CN code

16b. Net weight

17b. % of mixture

18b. Invoice number

19. Declaration by the applicant

Name: _____

Representing: _____ (Applicant)

Signature: _____ Date: _____

20. (For completion by the customs office where the export declaration is made unless the simplified export authorisation procedure is applied)

Reference number of customs declaration: _____

Stamp:

21. (For completion by issuing authority unless the simplified export authorisation procedure is applied)

Box 18 information still required: YES ...../NO .....

Boxes 7, 8, 10-13 information still required YES ...../NO .....

Signature: _____

Function: _____

Date: _____ Stamp:

22. CONFIRMATION OF EXIT FROM THE EC
(For completion by the competent authorities at the point of exit from the Community customs territory unless the simplified export authorisation procedure is applied)

Date of exit: _____

Signature of officer: _____

Function: _____ Place: _____

Date: _____ Stamp:

Notes

I.

1. The authorisation shall be completed in one of the official languages of the Community; if it is handwritten, it shall be completed in ink in capital letters.

2. Boxes 1, 3, 5, 7, 9 to 19 are to be provided by the applicant at the time of the request; however, the information required in boxes 7, 8 and 10 to 13 and 18 may be supplied at a later stage, if the information is not known at the time of the request. In this case, the information for box 18 is to be supplemented at the latest when the export declaration is made and the supplementary information for boxes 7, 8, 10 to 13 is to be given to the customs or other authority at the point of exit from the Community territory at the latest before the physical departure of the goods.

3. Boxes 1, 5, 7 and 9: Enter full names and addresses (phone, fax, e-mail where available).

4. Box 5: Enter reference number to the import authorisation document of the third country importer, (for example a 'letter of no-objection', import permit, other statement of the third country of destination), where appropriate.

5. Box 7: Enter full name and address (phone, fax, e-mail where available) of any other operator involved in the export operation such as transporters, intermediaries, customs agents.

6. Box 9: Enter full name and address (phone, fax, e-mail where available) of the person or company to which the goods are delivered in the country of destination (not necessarily the end-user).

7. Boxe 10: Give the name of the Member State, port, airport or border point, where appropriate.

8. Box 11: Give the name of the country, port, airport or border point, where appropriate.

9. Box 12: Specify all means of transport to be used (e.g. lorry, ship, plane, train, etc.). In the case of an export authorisation covering several export operations, this box need not be filled in.

10. Box 13: Give as full details as possible of the route to be taken.

11. Boxes 14a, b: Enter name of the scheduled substance as stated in the Annex to Regulation (EC) No 111/2005 or in the case of a mixture or natural product, the name and 8 digit CN code of the mixture or natural product.

12. Boxes 14a, b: Identify packages and substances with precision (e.g. 2 cans of 5 litres each). In the case of a mixture, natural product or preparation, indicate commercial name concerned.

13. Boxes 15a, b: Enter the 8 digit CN code of the scheduled substance as stated in the Annex to Regulation (EC) No 111/2005.

14. Box 19:

    — Indicate in block letters the name of the applicant or, where appropriate, of the authorised representative who signs this application.

    — The signature by the applicant or authorised representative, according to the modalities provided for by the Member State concerned, indicates that the person concerned is declaring that all the particulars provided on the application are correctly and fully stated. Without prejudice to the possible application of penal provisions, this declaration is equivalent to the engagement of responsibility, under the provisions in force in the Member States, in respect of the following:

        — the accuracy of the information given in the declaration;

        — the authenticity of any documents attached;

        — the observance of all the obligations inherent in the export of scheduled substances listed in the Annex to Regulation (EC) No 111/2005.

    — Whenever the authorisation is issued by means of a computerised procedure, that authorisation may not contain the signature of the applicant in this box, if the application as such contains such signature.

II. **(Simplified export authorisation procedure)**

1. In the case of a simplified export authorisation procedure, boxes 7 to 13 and 18 need not be completed.
2. On the backside of Copy No 2, boxes 24 to 27 must be completed for each export operation.
3. Box 23: Indicate the authorised maximum quantity and net weight.

   Column 24: Indicate the quantity available in part 1 and the quantity of the partial export quantity in part 2.

   Column 25: Indicate the partial export quantity in words.

   Box 26: Reference number and the date of the customs declaration.

ANNEX VII

EUROPEAN COMMUNITY
GOODS SUBJECT TO IMPORT CONTROL

DRUG PRECURSORS — REGULATION (EC) No 111/2005 **IMPORT AUTHORISATION**

COPY FOR THE ISSUING AUTHORITY

1

1. Importer (name and address)	2. AUTHORISATION number: _____ Issued (date): _____ at: _____
	3. Period of validity: Beginning: End:
4. Exporter (name and address)	5. (For completion by the issuing authority) Issuing Authority (name, address, telephone, fax, e-mail of responsible officer)
6. Other Operator(s) (name and address)	7. Competent authority of the exporting country
8. Ultimate consignee (name and address)	9. Point of entry into the Community Customs territory
	10. Methods/Means of transport

11a. Scheduled substance	12a. CN code
	13a. Net weight
	14a. % of mixture
	15a. Invoice number

1

11b. Scheduled substance	12b. CN code
	13b. Net weight
	14b. % of mixture
	15b. Invoice number

16. Declaration by the applicant

Name: _____ Representing: _____ (Applicant)

Signature: _____ Date: _____

17. (For completion by issuing authority) Boxes 7, 9, 10 still required YES ...../NO ..... Signature: _____ Function: _____ Date: _____ Stamp:	18. (For completion by the customs office in the Community) Customs reference _____ (declaration of entry into the procedure or reference number to the customs approved treatment or use) Signature of officer: _____ Function: _____ Place: _____ Date: _____ Stamp:

EUROPEAN COMMUNITY
GOODS SUBJECT TO IMPORT CONTROL

DRUG PRECURSORS — REGULATION (EC) No 111/2005 **IMPORT AUTHORISATION**

COPY FOR THE AUTHORITY IN THE COUNTRY OF EXPORT

2

1. Importer (name and address)

2. AUTHORISATION number: _____

Issued (date): _____ at: _____

3. Period of validity:

Beginning: End:

4. Exporter (name and address)

5. (For completion by the issuing authority) Issuing Authority (name, address, telephone, fax, e-mail of responsible officer)

6. Other Operator(s) (name and address)

7. Competent authority of the exporting country

8. Ultimate consignee (name and address)

9. Point of entry into the Community Customs territory

10. Methods/Means of transport

2

11a. Scheduled substance

12a. CN code

13a. Net weight

14a. % of mixture

15a. Invoice number

11b. Scheduled substance

12b. CN code

13b. Net weight

14b. % of mixture

15b. Invoice number

16. Declaration by the applicant

Name: _____ Representing: _____ (Applicant)

Signature: _____ Date: _____

17. (For completion by issuing authority)

Boxes 7, 9, 10 still required YES ...../NO .....

Signature: _____

Function: _____

Date: _____ Stamp:

18. (For completion by the customs office in the Community)

Customs reference _____
(declaration of entry into the procedure or reference number to the customs approved treatment or use)

Signature of officer: _____

Function: _____

Place: _____ Date: _____ Stamp:

EUROPEAN COMMUNITY
GOODS SUBJECT TO IMPORT CONTROL

DRUG PRECURSORS — REGULATION (EC) No 111/2005 **IMPORT AUTHORISATION**

COPY TO ACCOMPAGNY THE GOODS

3	1. Importer (name and address)
	2. AUTHORISATION number: _____ Issued (date): _____ at: _____
	3. Period of validity: Beginning: End:
	4. Exporter (name and address)
	5. (For completion by the issuing authority) Issuing Authority (name, address, telephone, fax, e-mail of responsible officer)
	6. Other Operator(s) (name and address)
	7. Competent authority of the exporting country
	8. Ultimate consignee
	9. Point of entry into the Community Customs territory
	10. Methods/Means of transport

11a. Scheduled substance	12a. CN code
	13a. Net weight
	14a. % of mixture
3	15a. Invoice number
11b. Scheduled substance	12b. CN code
	13b. Net weight
	14b. % of mixture
	15b. Invoice number

16. Declaration by the applicant

Name: _____ Representing: _____ (Applicant)

Signature: _____ Date: _____

17. (For completion by issuing authority) Boxes 7, 9, 10 still required YES ...../NO ..... Signature: _____ Function: _____ Date: _____ Stamp:	18. (For completion by the customs office in the Community) Customs reference _____ (declaration of entry into the procedure or reference number to the customs approved treatment or use) Signature of officer: _____ Function: _____ Place: _____ Date: _____ Stamp:

EUROPEAN COMMUNITY
GOODS SUBJECT TO IMPORT CONTROL

DRUG PRECURSORS — REGULATION (EC) No 111/2005 **IMPORT AUTHORISATION**

COPY FOR THE IMPORTER

4

1. Importer (name and address)

2. AUTHORISATION number: _____

Issued (date): _____ at: _____

3. Period of validity:

Beginning: End:

4. Exporter (name and address)

5. (For completion by the issuing authority) Issuing Authority (name, address, telephone, fax, e-mail of responsible officer)

6. Other Operator(s) (name and address)

7. Competent authority of the exporting country

8. Ultimate consignee (name and address)

9. Point of entry into the Community Customs territory

10. Methods/Means of transport

4

11a. Scheduled substance

12a. CN code

13a. Net weight

14a. % of mixture

15a. Invoice number

11b. Scheduled substance

12b. CN code

13b. Net weight

14b. % of mixture

15b. Invoice number

16. Declaration by the applicant

Name: _____ Representing: _____ (Applicant)

Signature: _____ Date: _____

17. (For completion by issuing authority)

Boxes 7, 9, 10 still required YES ...../NO .....

Signature: _____

Function: _____

Date: _____ Stamp:

18. (For completion by the customs office in the Community)

Customs reference _____
(declaration of entry into the procedure or reference number to the customs approved treatment or use)

Signature of officer: _____

Function: _____

Place: _____ Date: _____ Stamp:

Notes

1. The authorisation shall be completed in one of the official languages of the Community. If it is handwritten, it shall be completed in ink in capital letters.

2. Boxes 1, 4, 6, 8 and 11 to 16 are to be provided by the applicant at the time of the request; however, information as required in boxes 7, 9, 10 and 15 may be supplied at a later stage. In this case, this information is to be supplemented at the latest when the goods are entered into the Community customs territory.

3. Boxes 1, 4: Enter full names and addresses (phone, fax, e-mail where available).

4. Box 6: Enter full name and address (phone, fax, e-mail where available) of any other operator involved in the import operation such as transporter, intermediaries, customs agent.

5. Box 8: Enter full name and address of the ultimate consignee. The ultimate consignee may be identical with the importer.

6. Box 7: Enter name and address (phone, fax, e-mail where available) of the third country authority.

7. Box 9: Give the name of the Member State and the port, airport or border point.

8. Box 10: Specify all means of transport to be used (e.g. lorry, ship, plane, train, etc.).

9. Boxes 11a, 11b: Enter name of the scheduled substance as stated in the Annex to Regulation (EC) No 111/2005 or in the case of a mixture or natural product the name and 8 digit CN code of the mixture or natural product.

10. Boxes 11a, 11b: Identify packages and substances with precision (e.g. 2 cans of 5 litres each). In the case of a mixture, a natural product or preparations, indicate the commercial name concerned.

11. Boxes 12a, 12b: Enter the 8 digit CN code of the scheduled substance as stated in the Annex to Regulation (EC) No 111/2005.

12. Box 16:

    — Indicate in block letters the name of the applicant or, where appropriate, of his authorised representative who signs this application.

    — The signature by the applicant or his authorised representative, according to the modalities provided for by the Member State concerned, indicates that the person concerned is declaring that all the particulars provided on the application are correctly and fully stated. Without prejudice to the possible application of penal provisions, this declaration is equivalent to the engagement of responsibility, under the provisions in force in the Member States, in respect of the following:

        — the accuracy of the information;

        — the authenticity of any documents attached;

        — the observance of all other obligations.

    — Whenever the authorisation is issued by means of a computerised procedure, that authorisation may not contain the signature of the applicant in this box, if the application as such contains such signature.

I

(Acts whose publication is obligatory)

COUNCIL REGULATION (EC) No 111/2005

of 22 December 2004

laying down rules for the monitoring of trade between the Community and third countries in drug precursors

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 133 thereof,

Having regard to the proposal from the Commission,

Whereas:

(1) The United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances adopted in Vienna on 19 December 1988, hereinafter referred to as the 'United Nations Convention', is part of the worldwide effort to combat illegal drugs. Within its sphere of competence, the Community participated in the negotiation and concluded the Convention on behalf of the Community by means of Council Decision 90/611/EEC [1].

(2) Article 12 of the United Nations Convention concerns trade in substances frequently used in the illicit manufacture of narcotic drugs and psychotropic substances. As provisions on trade in drug precursors affect Community rules in customs matters, it is appropriate to lay down Community rules on trade between the Community and third countries.

(3) Article 12 of the United Nations Convention requires a system to monitor international trade in drug precursors, taking account of the fact that, in principle, trade in these substances is lawful. Consequently, measures have been taken to strike an appropriate balance between the desire to exploit all possible means to prevent drug precursors reaching illicit drug manufacturers and the commercial needs of the chemical industry and other operators.

(4) To implement the requirements of Article 12 of the United Nations Convention and, taking account of the report of the Chemical Action Task Force created by the Houston Economic Summit (G-7) on 10 July 1990, Council Regulation (EEC) No 3677/90 of 13 December 1990 laying down measures to be taken to discourage the diversion of certain substances to the illicit manufacture of narcotic drugs and psychotropic substances [2], established a system for reporting suspicious transactions. This system, which is based on close cooperation with operators, is reinforced through measures such as documentation and labelling, licensing and registration of operators as well as procedures and requirements governing exports.

(5) Following the European Union Action Plan on Drugs 2000 to 2004, endorsed by the European Council at Feira in June 2000, the Commission organised an assessment of the Community control system of trade in drug precursors to draw conclusions from the implementation of Community legislation in this field.

(6) According to that assessment and in order to improve the control mechanisms aiming at preventing diversion of drug precursors, it is necessary to extend monitoring requirements with regard to operators based within the Community facilitating trade between third countries, to introduce a Community approach with regard to procedures for granting licences and to strengthen monitoring requirements governing suspensive customs procedures.

(7) Procedures and requirements for exports should be further intensified to target and concentrate controls on the most sensitive drug precursors, whilst reducing excessive administrative burden through simplified procedures for exports of high volume substances. While the effectiveness and practicability of pre-export notifications is fully recognised, a strategy should be developed striving to exploit the system to the fullest extent possible.

(8) In order to address the heightened concern about the production of amphetamine-type stimulants, import control mechanisms for the main synthetic drug precursors should be further strengthened through common procedures and requirements allowing individual consignment-based controls to be carried out.

[1] OJ L 326, 24.11.1990, p. 56.

[2] OJ L 357, 20.12.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 1232/2002 (OJ L 180, 10.7.2002, p. 5).

(9) So as to allow operators to fulfil these requirements, provisions governing external trade in drug precursors should, to the extent possible, be aligned with the provisions governing intra-Community trade in drug precursors wholly obtained or produced, or released for free circulation, in the Community.

(10) Taking account of the requirements of the internal market, and in the interests of this Regulation's effectiveness, uniform application of the provisions should be ensured through adoption of comparable and converging means of action by Member States.

(11) Mutual assistance between the Member States and between the Member States and the Commission should be reinforced, in particular by recourse to Council Regulation (EC) No 515/97 of 13 March 1997 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of the law on customs and agricultural matters [1].

(12) In accordance with the principle of proportionality, it is necessary and appropriate for the achievement of the basic objective of preventing the diversion of drug precursors for the illicit manufacture of narcotic drugs or psychotropic substances to lay down rules for the thorough monitoring of trade between the Community and third countries of these substances. This Regulation does not go beyond what is necessary in order to achieve the objectives pursued, in accordance with the third paragraph of Article 5 of the Treaty.

(13) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [2].

(14) Regulation (EEC) No 3677/90 should therefore be repealed.

(15) This Regulation respects the fundamental rights and observes the principles recognised, in particular, by the Charter of Fundamental Rights of the European Union,

HAS ADOPTED THIS REGULATION:

[1] OJ L 82, 22.3.1997, p. 1. Regulation as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).
[2] OJ L 184, 17.7.1999, p. 23.

CHAPTER I

SUBJECT MATTER AND DEFINITIONS

Article 1

This Regulation lays down rules for the monitoring of trade between the Community and third countries in certain substances frequently used for the illicit manufacture of narcotic drugs and psychotropic substances (hereinafter referred to as drug precursors) for the purpose of preventing the diversion of such substances. It applies to imports, exports and intermediary activities.

This Regulation shall be without prejudice to special rules in other fields pertaining to trade in goods between the Community and third countries.

Article 2

For the purposes of this Regulation the following definitions shall apply:

(a) 'scheduled substance' means any substance listed in the Annex, including mixtures and natural products containing such substances, but excluding medicinal products as defined by Directive 2001/83/EC of the European Parliament and of the Council [3], pharmaceutical preparations, mixtures, natural products and other preparations containing scheduled substances that are compounded in such a way that such substances cannot be easily used or extracted by readily applicable or economically viable means;

(b) 'non-scheduled substance' means any substance which, although not listed in the Annex, is identified as having been used for the illicit manufacture of narcotic drugs or psychotropic substances;

(c) 'import' means any entry of scheduled substances having the status as non-Community goods into the customs territory of the Community, including temporary storage, the placing in a free zone or free warehouse, the placing under a suspensive procedure and the release for free circulation within the meaning of Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code [4];

(d) 'export' means any departure of scheduled substances from the customs territory of the Community, including the departure of scheduled substances that requires a customs declaration and the departure of scheduled substances after their storage in a free zone of control type I or free warehouse within the meaning of Regulation (EEC) No 2913/92;

[3] OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC of the European Parliament and of the Council (OJ L 136, 30.4.2004, p. 34).
[4] OJ L 302, 19.10.1992, p. 1. Regulation as last amended by the 2003 Act of Accession.

(e) 'intermediary activities' means any activity to arrange purchase and sale or supply of scheduled substances carried out by any natural or legal person who aims to obtain agreement between two parties or to do so through acting on behalf of at least one of these parties without taking these substances into its possession or taking control of the carrying out of such transaction; this definition shall also include any activity carried out by any natural or legal person established in the Community involving purchase and sale or supply of scheduled substances without these substances being introduced into the Community customs territory;

(f) 'operator' means any natural or legal person engaged in import, export of scheduled substances or intermediary activities relating thereto, including persons pursuing the activity of making customs declarations for clients on a self-employed basis, either as their principal occupation or as a secondary activity related to another occupation;

(g) 'exporter' means the natural or legal person chiefly responsible for export activities by virtue of the economic and legal relationship to the scheduled substances and to the consignee and, where appropriate, who lodges the customs declaration or on whose behalf the customs declaration is lodged;

(h) 'importer' means the natural or legal person chiefly responsible for the import activities by virtue of the economic and legal relationship to the scheduled substances and to the consignor and who lodges the customs declaration or on whose behalf the customs declaration is lodged;

(i) 'ultimate consignee' means any natural or legal person to which the scheduled substances are delivered; this person may be different from the end-user;

(j) 'committee procedure' means the procedure provided for in Article 30(2);

(k) 'International Narcotics Control Board' means the Board established by the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol.

CHAPTER II

MONITORING OF TRADE

SECTION 1

Documentation and labelling

Article 3

All imports, exports or intermediary activities involving scheduled substances shall be documented by the operators by way of customs and commercial documents, such as summary declarations, customs declarations, invoices, cargo manifests, transport and other shipping documents.

Those documents shall contain the following information:

(a) the name of the scheduled substance as stated in the Annex, or, in the case of a mixture or a natural product, its name and the name of any scheduled substance, as stated in the Annex, contained in the mixture or in the natural product, followed by the term 'DRUG PRECURSORS';

(b) the quantity and weight of the scheduled substance and, in the case of a mixture or a natural product, the quantity, weight, and, if available, the percentage of any scheduled substance contained therein; and

(c) the names and addresses of the exporter, the importer, the ultimate consignee and, where applicable, the person involved in the intermediary activities.

Article 4

The documentation referred to in Article 3 shall be kept by the operators for a period of three years from the end of the calendar year in which the operation took place. The documentation shall be organised in such a way, electronically or in paper form, that it is readily available for inspection by the competent authorities upon request. The documentation may be provided via image medium or other data medium, provided that the data, when made readable, match the documentation in appearance and content, are available at all times, can be made readable without delay and can be analysed by automated means.

Article 5

Operators shall ensure that labels are affixed on any packaging containing scheduled substances indicating their name as stated in the Annex, or, in the case of a mixture or a natural product, its name and the name of any scheduled substance, as stated in the Annex, contained in the mixture or in the natural product. Operators may, in addition, affix their customary labels.

SECTION 2

Licensing and registration of operators

Article 6

1. Operators established in the Community, other than customs agents and transporters when acting solely in that capacity, engaged in import, export or intermediary activities involving scheduled substances listed in Category 1 of the Annex, shall hold a licence. The licence shall be issued by the competent authority of the Member State in which the operator is established.

In considering whether to grant a licence, the competent authority shall take into account the competence and integrity of the applicant.

The committee procedure shall be used to lay down provisions determining cases where a licence is not required, setting out further conditions for the granting of licences and establishing a model for licences. These provisions shall guarantee a systematic and consistent control and monitoring of operators.

2. The licence may be suspended or revoked by the competent authorities whenever the conditions under which the licence was issued are no longer fulfilled or where there are reasonable grounds for suspecting that there is a risk of diversion of scheduled substances.

Article 7

1. Operators established in the Community, other than customs agents and transporters when acting solely in that capacity, engaged in import, export or intermediary activities involving scheduled substances listed in Category 2 of the Annex, or in the export of scheduled substances listed in Category 3 of the Annex, shall register immediately and update as necessary the addresses of the premises at which they conduct those activities. This obligation shall be carried out with the competent authority in the Member State in which the operator is established.

2. The committee procedure shall be used to establish the conditions for exemption from the controls of certain categories of operators and of operators engaged in the export of small quantities of scheduled substances listed in Category 3. These conditions shall ensure that the risk of diversion of scheduled substances is minimised.

Article 8

1. When the scheduled substances are entered into the customs territory of the Community for unloading or transhipment, for temporary storage, for their storage in a free zone of control type I or a free warehouse, or for their placing under the Community external transit procedure, the licit purposes must be demonstrated by the operator, upon request by the competent authorities.

2. The committee procedure shall be used to establish the criteria to determine how the licit purposes of the transaction may be demonstrated, in order to ensure that all movements of scheduled substances within the Community customs territory can be monitored by the competent authorities and the risk of diversion be minimised.

SECTION 3

Provision of information

Article 9

1. Operators established in the Community shall notify the competent authorities immediately of any circumstances, such as unusual orders and transactions involving scheduled substances, which suggest that such substances intended for import, export or intermediary activities might be diverted for the illicit manufacture of narcotic drugs or psychotropic substances.

2. Operators shall provide the competent authorities with information in summary form about their export, import or intermediary activities. The committee procedure shall be used to determine the information that is required by the competent authorities in order to allow them to monitor these activities.

Article 10

1. In order to facilitate cooperation between the competent authorities of the Member States, operators established in the Community and the chemical industry, in particular as regards non-scheduled substances, the Commission shall, in consultation with the Member States, draw up and update guidelines.

2. These guidelines shall provide, in particular:

(a) information on how to identify and notify suspect transactions;

(b) a regularly updated list of non-scheduled substances to enable the industry to monitor on a voluntary basis the trade in such substances.

3. The competent authorities shall ensure that the guidelines are regularly disseminated in accordance with the objectives of these guidelines.

SECTION 4

Pre-export notification

Article 11

1. All exports of scheduled substances listed in Category 1 of the Annex and exports of scheduled substances listed in Categories 2 and 3 of the Annex to certain countries of destination, shall be preceded by a pre-export notification sent from the competent authorities in the Community to the competent authorities of the country of destination, in accordance with Article 12(10) of the United Nations Convention. The committee procedure shall be used to determine the list of the countries of destination in order to minimise the risk of diversion by ensuring systematic and consistent monitoring of exports of scheduled substances to these countries.

The country of destination shall be allowed a period of 15 working days to reply, at the end of which the export operation may be authorised by the competent authorities of the Member State of export, if no advice from the competent authorities of the country of destination is received indicating that this export operation might be intended for the illicit manufacture of narcotic drugs or psychotropic substances.

2. In the case of the scheduled substances to be notified in accordance with paragraph 1, the competent authorities of the Member State concerned shall, prior to the export of such substances, supply the information specified in Article 13(1) to the competent authorities of the country of destination.

The authority supplying such information shall require the authority in the third country receiving the information to keep confidential any trade, business, commercial or professional secret or any trade process referred to therein.

3. Simplified pre-export notification procedures may be applied by the competent authorities where they are satisfied that this will not result in any risk of diversion of scheduled substances. The committee procedure shall be used to determine such procedures and to establish the common criteria to be applied by the competent authorities.

SECTION 5

Export authorisation

Article 12

1. Exports of scheduled substances that require a customs declaration, including exports of scheduled substances leaving the customs territory from the Community following their storage in a free zone of control type I or free warehouse for a period of at least 10 days, shall be subject to an export authorisation.

Where scheduled substances are re-exported within 10 days from the date of their placing into a suspensive procedure or under a free zone of control type II, an export authorisation shall not be required.

However, exports of scheduled substances listed in Category 3 of the Annex shall only be subject to an export authorisation where pre-export notifications are required, or where these substances are exported to certain countries of destination to be determined in accordance with the committee procedure in order to ensure an appropriate level of control.

2. Export authorisations shall be issued by the competent authorities of the Member State where the exporter is established.

Article 13

1. The application for export authorisations referred to in Article 12 shall contain at least the following:

(a) the names and addresses of the exporter, the importer in the third country, any other operator involved in the export operation or shipment, and the ultimate consignee;

(b) the name of the scheduled substance as stated in the Annex or, in the case of a mixture or a natural product, its name and eight-digit CN code and the name of any scheduled substance, as stated in the Annex, contained in the mixture or in the natural product;

(c) the quantity and weight of the scheduled substance and, in the case of a mixture or a natural product, the quantity, weight, and, if available, the percentage of any scheduled substance contained therein;

(d) details of the transport arrangements, such as the expected date of dispatch, method of transport, name of the customs office where the customs declaration is to be made and, where available at this stage, identification of the means of transport, itinerary, expected point of exit from Community customs territory and the point of entry into the importing country;

(e) in the cases referred to in Article 17, a copy of the import authorisation issued by the country of destination; and

(f) the number of the licence or registration referred to in Articles 6 and 7.

2. A decision on the application for an export authorisation shall be taken within a period of 15 working days from the date on which the competent authority considers the file to be complete.

That period shall be extended if, in the cases referred to in Article 17, the competent authorities are obliged to make further enquiries under the second subparagraph of that Article.

Article 14

1. If the details of the itinerary and means of transport are not provided in the application, the export authorisation shall state that the operator must supply those details to the customs office of exit or other competent authorities at the point of exit from the Community customs territory before the physical departure of the consignment. In such cases the export authorisation shall be annotated accordingly at the time of issue.

Where the export authorisation is presented to a customs office in a Member State other than that of the issuing authority, the exporter shall make available any certified translation of parts or all of the information contained on the authorisation, upon request.

2. The export authorisation shall be presented to the customs office when the customs declaration is made, or in the absence of a customs declaration, at the customs office of exit or other competent authorities at the point of exit from the Community customs territory. The authorisation shall accompany the consignment to the third country of destination.

The customs office of exit or other competent authorities at the point of exit from the Community customs territory shall insert the necessary details referred to in Article 13(1)(d) in the authorisation and affix its stamp thereon.

Article 15

Without prejudice to measures adopted in accordance with Article 26(3), the granting of the export authorisation shall be refused if:

(a) details supplied in accordance with Article 13(1) are incomplete;

(b) there are reasonable grounds for suspecting that the details supplied in accordance with Article 13(1) are false or incorrect;

(c) in the cases referred to in Article 17, it is established that the import of the scheduled substances has not been authorised by the competent authorities of the country of destination, or

(d) there are reasonable grounds for suspecting that the substances in question are intended for the illicit manufacture of narcotic drugs or psychotropic substances.

Article 16

The competent authorities may suspend or revoke an export authorisation whenever there are reasonable grounds for suspecting that the substances are intended for the illicit manufacture of narcotic drugs or psychotropic substances.

Article 17

Whenever, under an agreement between the Community and a third country, exports are not to be authorised unless an import authorisation has been issued by the competent authorities of that third country for the substances in question, the Commission shall communicate to the competent authorities of the Member States the name and address of the competent authority of the third country, together with any operational information obtained from it.

The competent authorities in the Member States shall satisfy themselves as to the authenticity of such import authorisation, if necessary by requesting confirmation from the competent authority of the third country.

Article 18

The period of validity of the export authorisation within which the goods must have left the Community Customs territory shall not exceed six months from the date of issue of the export authorisation. Under exceptional circumstances, the period of validity may be extended, upon request.

Article 19

Simplified procedures to grant an export authorisation may be applied by the competent authorities where they are satisfied that this will not result in any risk of diversion of scheduled substances. The committee procedure shall be used to determine such procedures and to establish the common criteria to be applied by the competent authorities.

SECTION 6

Import authorisation

Article 20

Imports of scheduled substances listed in Category 1 of the Annex shall be subject to an import authorisation. An import authorisation may only be granted to an operator established in the Community. The import authorisation shall be issued by the competent authorities of the Member State where the importer is established.

However, where the substances referred to in subparagraph 1 are unloaded or transhipped, under temporary storage, stored in a free zone of control type I or free warehouse, or placed into the Community transit procedure, such import authorisation shall not be required.

Article 21

1. The application for the import authorisations referred to in Article 20 shall contain at least the following:

(a) the names and addresses of the importer, the exporter of the third country, any other operator involved and the ultimate consignee;

(b) the name of the scheduled substance as stated in the Annex or, in the case of a mixture or a natural product, its name and the eight-digit CN code and the name of any scheduled substance, as stated in the Annex, contained in the mixture or in the natural product;

(c) the quantity and weight of the scheduled substance and, in the case of a mixture or a natural product, the quantity, weight, and, if available, the percentage of any scheduled substance contained therein;

(d) if available, details of the transport arrangements, such as methods and means of transport, and date and place of envisaged import activities, and

(e) the number of the licence or registration referred to in Articles 6 and 7.

2. A decision on the application for an import authorisation shall be taken within a period of 15 working days from the date on which the competent authority considers the file to be complete.

Article 22

The import authorisation shall accompany the consignment from the point of entry into the Community customs territory to the premises of the importer or ultimate consignee.

The import authorisation shall be presented to the customs office when the scheduled substances are declared for a customs procedure.

Where the import authorisation is presented to a customs office in a Member State other than that of the issuing authority, the importer shall make available any certified translation of parts or all information contained on the authorisation, upon request.

Article 23

Without prejudice to measures adopted in accordance with Article 26(3), the granting of the import authorisation shall be refused if:

(a) details supplied in accordance with Article 21(1) are incomplete;

(b) there are reasonable grounds for suspecting that the details supplied in accordance with Article 21(1) in the application are false or incorrect, or

(c) there are reasonable grounds for suspecting that the scheduled substances are intended for the illicit manufacture of narcotic drugs or psychotropic substances.

Article 24

The competent authorities may suspend or revoke the import authorisation whenever there are reasonable grounds for suspecting that the substances are intended for the illicit manufacture of narcotic drugs or psychotropic substances.

Article 25

The period of validity of the import authorisation within which the scheduled substances must have been entered into the customs territory of the Community shall not exceed six months from the date of issue of the import authorisation. Under exceptional circumstances, the period of validity may be extended, upon request.

CHAPTER III

POWERS OF COMPETENT AUTHORITIES

Article 26

1. Without prejudice to the provisions of Articles 11 to 25 and of paragraphs 2 and 3 of this Article, the competent authorities of each Member State shall prohibit the introduction of scheduled substances into the Community customs territory or their departure from it, if there are reasonable grounds for suspecting that the substances are intended for the illicit manufacture of narcotic drugs or psychotropic substances.

2. The competent authorities shall detain or suspend release of the scheduled substances for the time necessary to verify the identification of the scheduled substances or compliance with the rules of this Regulation.

3. Each Member State shall adopt the measures necessary to enable the competent authorities, in particular:

(a) to obtain information on any orders for or operations involving scheduled substances;

(b) to enter operators' business premises in order to obtain evidence of irregularities;

(c) to establish that a diversion or attempted diversion of scheduled substances has taken place.

4. For the purpose of preventing specific risks of diversion in free zones as well as in other sensitive areas such as customs warehouses, Member States shall ensure that effective controls are applied to operations carried out in these areas at every stage of these operations, and that the controls are no less stringent than those applied in the other parts of the customs territory.

5. The competent authorities may require the operators to pay a fee for the issuing of licences, registrations and authorisations. Such fees shall be levied in a non-discriminatory way and shall not exceed the approximate cost of processing the application.

CHAPTER IV

ADMINISTRATIVE COOPERATION

Article 27

For the purposes of applying this Regulation and without prejudice to Article 30, the provisions of Regulation (EC) No 515/97 shall apply *mutatis mutandis*. Each Member State shall communicate to the other Member States and to the Commission the name of the competent authorities appointed to act as correspondents in accordance with Article 2(2) of that Regulation.

CHAPTER V

IMPLEMENTING MEASURES AND AMENDMENTS

Article 28

In addition to the implementing measures referred to in this Regulation, the Committee shall lay down, where necessary, detailed rules to ensure the effective monitoring of trade between the Community and third countries in drug precursors for the purpose of preventing the diversion of such substances, in particular with regard to the design and use of export and import authorisation forms.

Article 29

The committee procedure shall be used to adapt the Annex to this Regulation, to take account of any amendments to the Annex to the United Nations Convention.

Article 30

1. The Commission shall be assisted by the Drug Precursors Committee (hereinafter referred to as the Committee).

2. Where reference is made to this paragraph, Articles 4 and 7 of Decision 1999/468/EC shall apply.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its rules of procedure.

CHAPTER VI

FINAL PROVISIONS

Article 31

Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive.

Article 32

The competent authorities in each Member State shall, at least once each year, communicate to the Commission all relevant information on the implementation of the monitoring measures laid down in this Regulation, and on scheduled substances used for the illicit manufacture of narcotic drugs or psychotropic substances and methods of diversion and illicit manufacture, and their licit trade, uses and needs.

On the basis of that information, the Commission shall, in consultation with the Member States, evaluate the effectiveness of this Regulation and, in accordance with Article 12 (12) of the United Nations Convention, draw up an annual report to be submitted to the International Narcotics Control Board.

The Commission shall report to the Council on the functioning of this Regulation by the end of August 2008.

Article 33

The Commission is hereby authorised to adopt a position, on behalf of the Community, in favour of amendments to tables I and II of the Annex to the United Nations Convention which conform to the Annex to this Regulation.

Article 34

Regulation (EEC) No 3677/90 is repealed with effect from 18 August 2005.

References to the repealed Regulation shall be construed as references to this Regulation.

Article 35

This Regulation shall enter into force on the 20th day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 18 August 2005. However, Articles 6(1), 7(2), 8(2), 9(2), 11(1) and (3), 12(1), 19, 28 and 30 shall apply as from the day of entry into force of this Regulation in order to permit the adoption of the measures provided for in those Articles. Such measures shall enter into force at the earliest on 18 August 2005.

This Regulation shall be binding in its entirety and directly applicable in all Member States

Done at Brussels, 22 December 2004.

For the Council
The President
C. VEERMAN

ANNEX

Scheduled substances Category 1

Substance	CN designation (if different)	CN Code [1]	CAS No [2]
1-Phenyl-2-propanone	Phenylacetone	2914 31 00	103-79-7
N-acetylanthranilic acid	2-Acetamidobenzoic acid	2924 23 00	89-52-1
Isosafrol (cis + trans)		2932 91 00	120-58-1
3,4-Methylenedioxyphenylpropan-2-one	1-(1,3-Benzodioxol-5-yl)propan-2-one	2932 92 00	4676-39-5
Piperonal		2932 93 00	120-57-0
Safrole		2932 94 00	94-59-7
Ephedrine		2939 41 00	299-42-3
Pseudoephedrine		2939 42 00	90-82-4
Norephedrine		ex 2939 49 00	14838-15-4
Ergometrine		2939 61 00	60-79-7
Ergotamine		2939 62 00	113-15-5
Lysergic acid		2939 63 00	82-58-6
The stereoisomeric forms of the substances listed in this Category not being cathine [3], whenever the existence of such forms is possible.			
The salts of the substances listed in this Category whenever the existence of such salts is possible and not being the salts of cathine.			

[1] OJ L 290, 28.10.2002, p. 1.
[2] The CAS No is the 'Chemical abstracts service registry number', which is a unique numeric identifier specific to each substance and its structure. The CAS No is specific to each isomer and to each salt of each isomer. It must be understood that the CAS Nos for the salts of the substances listed above will be different from those given.
[3] Also named (+)-norpseudoephedrine, CN code 2939 43 00, CAS No 492-39-7.

Category 2

Substance	CN designation (if different)	CN Code [1]	CAS No [2]
Acetic anhydride		2915 24 00	108-24-7
Phenylacetic acid		2916 34 00	103-82-2
Anthranilic acid		2922 43 00	118-92-3
Piperidine		2933 32 00	110-89-4
Potassium permanganate		2841 61 00	7722-64-7
The salts of the substances listed in this Category whenever the existence of such salts is possible.			

[1] OJ L 290, 28.10.2002, p. 1.
[2] The CAS No is the 'Chemical abstracts service registry number', which is a unique numeric identifier specific to each substance and its structure. The CAS No is specific to each isomer and to each salt of each isomer. It must be understood that the CAS Nos for the salts of the substances listed above will be different from those given.

Category 3

Substance	CN designation (if different)	CN Code [1]	CAS No [2]
Hydrochloric acid	Hydrogen chloride	2806 10 00	7647-01-0
Sulphuric acid		2807 00 10	7664-93-9
Toluene		2902 30 00	108-88-3
Ethyl ether	Diethyl ether	2909 11 00	60-29-7
Acetone		2914 11 00	67-64-1
Methylethylketone	Butanone	2914 12 00	78-93-3

The salts of the substances listed in this Category whenever the existence of such salts is possible and not being the salts of hydrochloric acid and sulphuric acid.

[1] OJ L 290, 28.10.2002, p. 1.
[2] The CAS No is the 'Chemical abstracts service registry number', which is a unique numeric identifier specific to each substance and its structure. The CAS No is specific to each isomer and to each salt of each isomer. It must be understood that the CAS Nos for the salts of the substances listed above will be different from those given.

I

(Acts whose publication is obligatory)

REGULATION (EC) No 273/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 February 2004 on drug precursors

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 95 thereof,

Having regard to the proposal from the Commission [1],

Having regard to the opinion of the European Economic and Social Committee [2],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [3],

Whereas:

(1) The United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, adopted in Vienna on 19 December 1988, hereinafter referred to as the 'United Nations Convention', was concluded by the Community by Council Decision 90/611/EEC [4].

(2) The requirements of Article 12 of the United Nations Convention in respect of trade in drug precursors (i.e. substances frequently used in the illicit manufacture of narcotic drugs and psychotropic substances) have been implemented, as far as trade between the Community and third countries is concerned, by Council Regulation (EEC) No 3677/90 of 13 December 1990 laying down measures to be taken to discourage the diversion of certain substances to the illicit manufacture of narcotic drugs and psychotropic substances [5].

(3) Article 12 of the United Nations Convention envisages adoption of appropriate measures to monitor the manufacture and distribution of precursors. This requires the adoption of measures relating to the trade in precursors among Member States. Such measures were introduced by Council Directive 92/109/EEC of 14 December 1992 on the manufacture and the placing on the market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances [6]. To better ensure that harmonised rules are applied at the same time in all Member States, a regulation is considered to be more adequate than the current Directive.

(4) In the context of the enlargement of the European Union, it is important to replace Directive 92/109/EEC by a regulation, as each modification of that Directive and its Annexes would trigger national implementation measures in 25 Member States.

(5) By decisions taken at its 35th session in 1992, the United Nations Commission on Narcotic Drugs included additional substances in the tables of the Annex to the United Nations Convention. Corresponding provisions should be laid down in this Regulation in order to detect possible cases of illicit diversion of drug precursors in the Community and to ensure that common monitoring rules are applied in the Community market.

(6) The provisions of Article 12 of the United Nations Convention are based on a system of monitoring trade in the substances in question. Most trade in these substances is entirely lawful. The documentation of consignments and labelling of these substances should be sufficiently explicit. It is furthermore important, whilst providing competent authorities with the necessary means of action, to develop, within the spirit of the United Nations Convention, mechanisms based on close cooperation with the operators concerned and on the development of intelligence gathering.

(7) The measures applicable to sassafras oil are currently interpreted in different ways in the Community, since in some Member States it is regarded as a mixture containing Safrole and is therefore controlled, while other Member States regard it as a natural product not subject to controls. Inserting a reference to natural products in the definition of 'scheduled substances' will resolve this discrepancy and therefore allow controls to be applied to sassafras oil; only natural products from which scheduled substances can be extracted easily should be covered by the definition.

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[1] OJ C 20 E, 28.1.2003, p. 160.
[2] OJ C 95, 23.4.2003, p. 6.
[3] Opinion of the European Parliament of 11 March 2003 (not yet published in the Official Journal), Council common position of 29 September 2003 (OJ C 277 E, 18.11.2003, p. 31) and position of the European Parliament of 16 December 2003 (not yet published in the Official Journal).
[4] OJ L 326, 24.11.1990, p. 56.
[5] OJ L 357, 20.12.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 1232/2002 (OJ L 180, 10.7.2002, p. 5).
[6] OJ L 370 19.12.1992, p. 76. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

(8) Substances commonly used in the illicit manufacture of narcotic drugs or psychotropic substances should be listed in an Annex.

(9) It should be ensured that the manufacture or use of certain scheduled substances listed in Annex I is subject to possession of a licence. In addition, the supply of such substances should be permitted only where the persons to whom they are to be supplied are holders of a licence and have signed a customer declaration. The detailed rules concerning the customer declaration should be laid down in Annex III.

(10) Measures should be adopted to encourage operators to notify the competent authorities of suspect transactions involving scheduled substances listed in Annex I.

(11) Measures should be adopted in order to guarantee better control of intra-Community trade in scheduled substances listed in Annex I.

(12) All transactions leading to the placing on the market of scheduled substances of categories 1 and 2 of Annex I should be properly documented. Operators should notify the competent authorities of any suspect transactions involving the substances listed in Annex I. However, exemptions should apply to transactions involving substances of category 2 of Annex I where the quantities involved do not exceed those indicated in Annex II.

(13) A significant number of other substances, many of them traded legally in large quantities, have been identified as precursors to the illicit manufacture of synthetic drugs and psychotropic substances. To subject these substances to the same strict controls as those listed in Annex I would present an unnecessary obstacle to trade involving licences to operate and documentation of transactions. Therefore, a more flexible mechanism at Community level should be established whereby the competent authorities in the Member States are notified of such transactions.

(14) The introduction of a cooperation procedure is provided for in the European Union action plan against drugs approved by the European Council of Santa Maria da Feira on 19 and 20 June 2000. In order to support cooperation between the competent authorities of the Member States and the chemicals industry, in particular with regard to substances which, although not referred to in this Regulation, might be used in the illicit manufacture of synthetic drugs and psychotropic substances, guidelines should be drawn up aimed at helping the chemical industry.

(15) It is appropriate to make provision for the Member States to lay down rules on penalties applicable for infringement of the provisions of this Regulation. Given that the trade in drug precursors may lead to the illicit manufacture of synthetic drugs and psychotropic substances, Member States should be free to choose the most dissuasive penalties available under their national legislation.

(16) The measures necessary for the implementation of this Regulation should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission [1].

(17) Since the objectives of this Regulation, namely the harmonised monitoring of the trade in drug precursors and the avoidance of its diversion to the illicit manufacture of synthetic drugs and psychotropic substances, cannot be sufficiently achieved by the Member States and can therefore, by reason of the international and changeable nature of such trade, be better achieved at Community level, the Community may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

(18) Council Directive 92/109/EEC, Commission Directives 93/46/EEC [2], 2001/8/EC [3] and 2003/101/EC [4] and Commission Regulations (EC) No 1485/96 [5] and (EC) No 1533/2000 [6] should be repealed,

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[1] OJ L 184, 17.7.1999, p. 23.

[2] Commission Directive 93/46/EEC of 22 June 1993 replacing and modifying the Annexes to Council Directive 92/109/EEC on the manufacture and placing on the market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances (OJ L 159, 1.7.1993, p. 134).

[3] Commission Directive 2001/8/EC of 8 February 2001 replacing Annex I to Council Directive 92/109/EEC on the manufacture and placing on the market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances (OJ L 39, 9.2.2001, p. 31).

[4] Commission Directive 2003/101/EC of 3 November 2003 amending Council Directive 92/109/EEC on the manufacture and placing on the market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances (OJ L 286, 4.11.2003, p. 14).

[5] Commission Regulation (EC) No 1485/96 of 26 July 1996 laying down detailed rules for the application of Council Directive 92/109/EEC, as regards customer declarations of specific use relating to certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances (OJ L 188, 27.7.1996, p. 28). Regulation as amended by Regulation (EC) No 1533/2000 (OJ L 175, 14.7.2000, p. 75).

[6] Commission Regulation (EC) No 1533/2000 of 13 July 2000 amending Regulation (EC) No 1485/96 laying down detailed rules for the application of Council Directive 92/109/EEC, as regards customer declarations of specific use relating to certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances.

HAVE ADOPTED THIS REGULATION:

Article 1

Scope and objectives

This Regulation establishes harmonised measures for the intra-Community control and monitoring of certain substances frequently used for the illicit manufacture of narcotic drugs or psychotropic substances with a view to preventing the diversion of such substances.

Article 2

Definitions

For the purposes of this Regulation the following definitions shall apply:

(a) 'scheduled substance' means any substance listed in Annex I, including mixtures and natural products containing such substances. This excludes medicinal products as defined by Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [1], pharmaceutical preparations, mixtures, natural products and other preparations containing scheduled substances that are compounded in such a way that they cannot be easily used or extracted by readily applicable or economically viable means;

(b) 'non-scheduled substance' means any substance which, although not listed in Annex I, is identified as having been used for the illicit manufacture of narcotic drugs or psychotropic substances;

(c) 'placing on the market' means any supply, whether in return for payment or free of charge, of scheduled substances in the Community; or the storage, manufacture, production, processing, trade, distribution or brokering of these substances for the purpose of supply in the Community;

(d) 'operator' means any natural or legal person engaged in the placing on the market of scheduled substances;

(e) 'International Narcotics Control Board' means the Board established by the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol;

(f) 'special licence' means a licence that is granted to a particular type of operator;

(g) 'special registration' means a registration that is made for a particular type of operator.

Article 3

Requirements for the placing on the market of scheduled substances

1. Operators wishing to place on the market scheduled substances of categories 1 and 2 of Annex I shall be required to appoint an officer responsible for the trade in scheduled substances, to notify the competent authorities of the name and contact details of that officer and to notify them immediately of any subsequent modification of this information. The officer shall ensure that the trade in scheduled substances conducted by the operator takes place in compliance with this Regulation. The officer shall be empowered to represent the operator and to take the decisions necessary for performing the tasks specified above.

2. Operators shall be required to obtain a licence from the competent authorities before they may possess or place on the market scheduled substances of category 1 of Annex I. Special licences may be granted by the competent authorities to pharmacies, dispensaries of veterinary medicine, certain types of public authorities or armed forces. Such special licences shall only be valid for the use of precursors within the scope of the official duties of the operators concerned.

3. Any operator holding a licence referred to in paragraph 2 shall supply scheduled substances of category 1 of Annex I only to natural or legal persons who hold such a licence and have signed a customer declaration as provided for in Article 4(1).

4. When considering whether to grant a licence, the competent authorities shall take into account in particular the competence and integrity of the applicant. The licence is to be refused if there are reasonable grounds for doubting the suitability and reliability of the applicant or of the officer responsible for the trade in scheduled substances. The licence may be suspended or revoked by the competent authorities whenever there are reasonable grounds for believing that the holder is no longer a fit and proper person to hold a licence, or that the conditions under which the licence was granted are no longer fulfilled.

5. Without prejudice to Article 14, the competent authorities may either limit the validity of the licence to a period not exceeding three years or may oblige the operators to demonstrate at intervals not exceeding three years that the conditions under which the licence was granted are still fulfilled. The licence shall mention the operation or operations for which it is valid, as well as the substances concerned. Special licences within the meaning of paragraph 2 shall be granted in principle for an unlimited duration but may be suspended or revoked by the competent authorities under the conditions of paragraph 4, third sentence.

6. Without prejudice to Article 6, operators engaged in the placing on the market of scheduled substances of category 2 of Annex I shall be required to register and update with the competent authorities without delay the addresses of the premises at which they manufacture or from which they trade in these substances, before placing them on the market. Pharmacies, dispensaries of veterinary medicine, certain types of public authorities or the armed forces may be made subject to a special registration. Such registrations shall be considered valid only for the use of precursors within the scope of the official duties of the operators concerned.

[1] OJ L 311, 28.11.2001, p. 67. Directive as last amended by Commission Directive 2003/63/EC (OJ L 159, 27.6.2003, p. 46).

7. The competent authorities may require operators to pay a fee for the application for a licence or a registration. Such fees shall be levied in a non-discriminatory way and shall not exceed the cost of processing the application.

Article 4

Customer declaration

1. Without prejudice to Articles 6 and 14, any operator established within the Community who supplies a customer with a scheduled substance of categories 1 or 2 of Annex I shall obtain a declaration from the customer which shows the specific use or uses of the scheduled substances. A separate declaration shall be required for each scheduled substance. This declaration shall conform to the model set out in point 1 of Annex III. In the case of legal persons, the declaration shall be made on headed notepaper.

2. As an alternative to the above declaration for an individual transaction, an operator who regularly supplies a customer with a scheduled substance of category 2 of Annex I may accept a single declaration in respect of a number of transactions involving this scheduled substance over a period not exceeding one year, provided that the operator is satisfied that the following criteria have been met:

(a) the customer has been supplied by the operator with the substance on at least three occasions in the preceding 12 months;

(b) the operator has no reason to suppose that the substance will be used for illicit purposes;

(c) the quantities ordered are consistent with the usual consumption for that customer.

This declaration shall conform to the model set out in point 2 of Annex III. In the case of legal persons, the declaration shall be made on headed notepaper.

3. An operator supplying scheduled substances of category 1 of Annex I shall stamp and date a copy of the declaration, certifying it to be a true copy of the original. Such copy must always accompany category 1 substances being moved within the Community and must be presented on request to the authorities responsible for checking vehicle contents during transport operations.

Article 5

Documentation

1. Without prejudice to Article 6, operators shall ensure that all transactions leading to the placing on the market of scheduled substances of categories 1 and 2 of Annex I are properly documented in accordance with paragraphs 2 to 5 below. This obligation shall not apply to those operators who hold special licences or are subject to special registration pursuant to Article 3(2) and (6) respectively.

2. Commercial documents such as invoices, cargo manifests, administrative documents, transport and other shipping documents shall contain sufficient information to identify positively:

(a) the name of the scheduled substance as given in categories 1 and 2 of Annex I;

(b) the quantity and weight of the scheduled substance and, where a mixture or natural product is concerned, the quantity and weight, if available, of the mixture or natural product as well as the quantity and weight, or the percentage by weight, of any substance or substances of categories 1 and 2 of Annex I which are contained in the mixture;

(c) the name and address of the supplier, distributor, consignee, and, if possible, of other operators directly involved in the transaction, as referred to in Article 2(c) and (d).

3. The documentation must also contain a customer declaration as referred to in Article 4.

4. Operators shall keep such detailed records of their activities as are required to comply with their obligations under paragraph 1.

5. The documentation and records referred to in paragraphs 1 to 4 shall be kept for at least three years from the end of the calendar year in which the transaction referred to in paragraph 1 took place, and must be readily available for inspection by the competent authorities upon request.

6. The documentation may also be kept in the form of reproductions on an image medium or other data media. It must be ensured that the data stored:

(a) match the documentation in appearance and content when made readable, and

(b) are readily available at all times, can be made readable without delay and can be analysed by automated means for the duration of the period specified in paragraph 5.

Article 6

Exemptions

The obligations according to Articles 3, 4 and 5 shall not apply to transactions involving scheduled substances of category 2 of Annex I where the quantities involved do not exceed those indicated in Annex II over a period of one year.

Article 7

Labelling

Operators shall ensure that labels are affixed to scheduled substances of categories 1 and 2 of Annex I before they are supplied. The labels must show the names of the substances as given in Annex I. Operators may in addition affix their customary labels.

Article 8

Notification of the competent authorities

1. Operators shall notify the competent authorities immediately of any circumstances, such as unusual orders or transactions involving scheduled substances to be placed on the market, which suggest that such substances might be diverted for the illicit manufacture of narcotic drugs or psychotropic substances.

2. Operators shall provide the competent authorities in summary form with such information about their transactions involving scheduled substances as is specified in implementing measures adopted pursuant to Article 14.

Article 9

Guidelines

1. In order to facilitate cooperation between the competent authorities, the operators, and the chemical industry, in particular as regards non-scheduled substances, the Commission shall, in accordance with the procedure referred to in Article 15(2), draw up and update guidelines to assist the chemical industry.

2. The guidelines shall provide in particular:

(a) information on how to recognise and notify suspect transactions;

(b) a regularly updated list of non-scheduled substances to enable the industry to monitor on a voluntary basis the trade in such substances;

(c) other information which may be deemed useful.

3. The competent authorities shall ensure that the guidelines and the list of non-scheduled substances are regularly disseminated in a manner deemed appropriate by the competent authorities in accordance with the objectives of the guidelines.

Article 10

Powers and obligations of competent authorities

1. In order to ensure the correct application of Articles 3 to 8, each Member State shall adopt the measures necessary to enable its competent authorities to perform their control and monitoring duties, and in particular:

(a) to obtain information on any orders for scheduled substances or operations involving scheduled substances;

(b) to enter operators' business premises in order to obtain evidence of irregularities;

(c) where necessary, to detain consignments that fail to comply with this Regulation.

2. The competent authorities shall respect confidential business information.

Article 11

Cooperation between the Member States and the Commission

1. Each Member State shall designate the competent authority or authorities responsible for ensuring the application of this Regulation and shall inform the Commission thereof.

2. For the purposes of applying this Regulation and without prejudice to Article 15, the provisions of Council Regulation (EC) No 515/97 of 13 March 1997 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of the law on customs and agricultural matters ([1]), and in particular those on confidentiality, shall apply *mutatis mutandis*. The competent authority or authorities designated under paragraph 1 of this Article shall act as competent authorities within the meaning of Article 2(2) of Regulation (EC) No 515/97.

Article 12

Penalties

The Member State shall lay down the rules on penalties applicable for infringement of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive.

Article 13

Communications from Member States

1. To permit any necessary adjustments to the arrangements for monitoring trade in scheduled substances and non-scheduled substances, the competent authorities in each Member State shall each year communicate to the Commission all information on the implementation of the monitoring measures laid down in this Regulation, in particular as regards substances frequently used for the illicit manufacture of narcotic drugs or psychotropic substances and methods of diversion and illicit manufacture.

2. A summary of the communications made pursuant to paragraph 1 shall be submitted by the Commission to the International Narcotics Control Board in accordance with Article 12(12) of the United Nations Convention and in consultation with the Member States.

Article 14

Implementation

Where necessary, the following measures for the implementation of this Regulation shall be adopted in accordance with the procedure referred to in Article 15(2):

(a) determination of the requirements and conditions for the granting of the licence as provided for in Article 3 and the details pertaining to the licence;

(b) determination, whenever necessary, of the conditions which shall apply to the documentation and labelling of mixtures and preparations containing substances listed in Annex I, as provided for in Articles 5 to 7;

([1]) OJ L 82, 22.3.1997, p. 1. Regulation as amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).

(c) any amendments to Annex I made necessary by amendments to the tables in the Annex to the United Nations Convention;

(d) amendments to the thresholds set in Annex II;

(e) determination of the requirements and conditions for customer declarations referred to in Article 4, as well as the detailed rules concerning their use. This shall include rules on how to provide customer declarations in electronic form, where appropriate;

(f) other measures needed for the efficient implementation of this Regulation.

Article 15

Committee

1. The Commission shall be assisted by the committee set up by Article 10 of Regulation (EEC) No 3677/90.

2. Where reference is made to this paragraph, Articles 4 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 4(3) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its Rules of Procedure.

Article 16

Information about measures adopted by Member States

Each Member State shall inform the Commission of the measures it adopts pursuant to this Regulation, and in particular of the measures adopted pursuant to Articles 10 and 12. They shall also notify any subsequent amendments thereof.

The Commission shall communicate this information to the other Member States. It shall evaluate the implementation of the Regulation three years after its entry into force.

Article 17

Repeals

1. Council Directive 92/109/EEC, Commission Directives 93/46/EEC, 2001/8/EC and 2003/101/EC and Commission Regulations (EC) No 1485/96 and (EC) No 1533/2000 are hereby repealed.

2. References to the repealed directives or regulations shall be construed as being made to this Regulation.

3. The validity of any register established, any licences granted and any customer declarations issued under the repealed directives or regulations shall not be affected.

Article 18

Entry into force

This Regulation shall enter into force on 18 August 2005, except for Articles 9, 14 and 15, which shall enter into force on the day of publication of this Regulation in the *Official Journal of the European Union*, in order to permit the adoption of the measures provided for in those Articles. Such measures shall enter into force at the earliest on 18 August 2005.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Strasbourg, 11 February 2004.

For the European Parliament
The President
P. COX

For the Council
The President
M. McDOWELL

ANNEX I

Scheduled substances within the meaning of Article 2(a)

CATEGORY 1

Substance	CN designation (if different)	CN code (1)	CAS No (2)
1-phenyl-2-propanone	Phenylacetone	2914 31 00	103-79-7
N-acetylanthranilic acid	2-acetamidobenzoic acid	2924 23 00	89-52-1
Isosafrol (cis + trans)		2932 91 00	120-58-1
3,4-methylenedioxyphenyl-propan-2-one	1-(1,3-Benzodioxol-5-yl)propan-2-one	2932 92 00	4676-39-5
Piperonal		2932 93 00	120-57-0
Safrole		2932 94 00	94-59-7
Ephedrine		2939 41 00	299-42-3
Pseudoephedrine		2939 42 00	90-82-4
Norephedrine		ex 2939 49 00	14838-15-4
Ergometrine		2939 61 00	60-79-7
Ergotamine		2939 62 00	113-15-5
Lysergic acid		2939 63 00	82-58-6

The stereoisomeric forms of the substances listed in this category not being cathine (3), whenever the existence of such forms is possible.

The salts of the substances listed in this category, whenever the existence of such salts is possible and not being the salts of cathine.

(1) OJ L 290, 28.10.2002, p. 1.
(2) The CAS No is the 'chemical abstracts service registry number', which is a unique numeric identifier specific to each substance and its structure. The CAS No is specific to each isomer and to each salt of each isomer. It must be understood that the CAS Nos for the salts of the substances listed above will be different to those given.
(3) Also named (+)-norpseudoephedrine, CN code 2939 43 00, CAS No 492-39-7.

CATEGORY 2

Substance	CN designation (if different)	CN code (1)	CAS No (2)
Acetic anhydride		2915 24 00	108-24-7
Phenylacetic acid		2916 34 00	103-82-2
Anthranilic acid		2922 43 00	118-92-3
Piperidine		2933 32 00	110-89-4
Potassium permanganate		2841 61 00	7722-64-7

The salts of the substances listed in this category, whenever the existence of such salts is possible.

(1) OJ L 290, 28.10.2002, p. 1.
(2) The CAS No is the 'chemical abstracts service registry number', which is a unique numeric identifier specific to each substance and its structure. The CAS No is specific to each isomer and to each salt of each isomer. It must be understood that the CAS Nos for the salts of the substances listed above will be different to those given.

CATEGORY 3

Substance	CN designation (if different)	CN code (1)	CAS No (2)
Hydrochloric acid	Hydrogen chloride	2806 10 00	7647-01-0
Sulphuric acid		2807 00 10	7664-93-9
Toluene		2902 30 00	108-88-3
Ethyl ether	Diethyl ether	2909 11 00	60-29-7
Acetone		2914 11 00	67-64-1
Methylethylketone	Butanone	2914 12 00	78-93-3

The salts of the substances listed in this category, whenever the existence of such salts is possible and not being the salts of hydrochloric acid and sulphuric acid.

(1) OJ L 290, 28.10.2002, p. 1.
(2) The CAS No is the 'chemical abstracts service registry number', which is a unique numeric identifier specific to each substance and its structure. The CAS No is specific to each isomer and to each salt of each isomer. It must be understood that the CAS Nos for the salts of the substances listed above will be different to those given.

ANNEX II

Substance	Threshold
Acetic anhydride	100 l
Potassium permanganate	100 kg
Anthranilic acid and its salts	1 kg
Phenylacetic acid and its salts	1 kg
Piperidine and its salts	0,5 kg

ANNEX III

1. **Model declaration relating to individual transactions (category 1 or 2)**

CUSTOMER DECLARATION OF SPECIFIC USE(S) OF THE SCHEDULED CATEGORY 1 OR 2 SUBSTANCE
(individual transactions)

I/We,

Name: .....

Address: .....

.....

Reference number of authorisation/licence/registration: .....
(delete as appropriate)

issued on..... by .....
(name and address of the authority)

.....

and without time limit/valid until .....
(delete as appropriate)

have ordered from

Name: .....

Address: .....

.....

the following substance

Description: .....

.....

Combined nomenclature (CN) code: ..... Quantity: .....

The substance will be used solely for .....

.....

I/We hereby certify that the substance referred to above will not be re-sold or otherwise supplied to any other customer unless the latter furnishes a declaration of use in accordance with this model or, for category 2 substances, a declaration relating to multiple transactions.

Signature . ..... Name: .....
(in block capitals)

Position: ..... Date: .....

2. **Model declaration relating to multiple transactions (category 2)**

CUSTOMER DECLARATION OF SPECIFIC USE(S) OF THE SCHEDULED CATEGORY 2 SUBSTANCE
(multiple transactions)

I/We,

Name: .....

Address: .....

.....

Registration reference number: .....

issued on..... by .....
(name and address of the authority)

.....

and without time limit/valid until .....
(delete as appropriate)

intend to order from

Name: .....

Address: .....

.....

the following substance

Description: .....

.....

Combined nomenclature (CN) code: ..... Quantity: .....

The substance will be used solely for.....

.....

and represents a quantity that is normally considered sufficient for ..... months
(up to a maximum of 12 months)

I/We hereby certify that the substance referred to above will not be re-sold or supplied to any other customer unless the latter submits a similar declaration of use or a declaration relating to individual transactions.

Signature: ..... Name: .....
(in block capitals)

Position: ..... Date: .....

EUROPEAN
COMMISSION

Brussels, 17.9.2013
COM(2013) 619 final

2013/0305 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on new psychoactive substances

(Text with EEA relevance)

{SWD(2013) 319 final}
{SWD(2013) 320 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

1.1. General context

A growing number of new psychoactive substances, which imitate the effects of substances controlled under the UN Conventions on Drugs and are marketed as legal alternatives to them ('legal highs'), are emerging and spreading fast in the internal market. These substances, which act on the central nervous system, modifying mental functions, also have uses in industry or research - as active substances for medicines, for instance. A rising number of individuals, in particular young people, consume new psychoactive substances, despite the risks that they may pose, which may be comparable to those posed by UN-controlled drugs.

During the past years, one new psychoactive substance was reported every week in the EU, and the rapid pace of notification is expected to continue in the coming years. These substances are sold freely, unless public authorities subject them to various restriction measures, underpinned by administrative or criminal sanctions, because of the risks that they pose when consumed by humans. Such national restriction measures, which may differ depending on the Member State and on the substance, can hamper trade in the internal market and hinder the development of future industrial or commercial uses.

New psychoactive substances are not subjected to control measures under the UN Conventions on Drugs, unlike psychoactive substances such as cocaine or amphetamines, although they could be considered for UN-level control on the basis of a risk assessment conducted by the World Health Organisation at the request of at least one UN Member State.

The Commission Communication "Towards a stronger European response to drugs"[1], adopted in October 2011, identified the spread of new psychoactive substances as one of the most challenging developments in drugs policy requiring a firmer EU response. The Communication set the ground for new EU legislative proposals on new psychoactive substances, building on the Council Decision 2005/387/JHA on the information exchange, risk assessment and control of new psychoactive substances[2]. In December 2011[3], the Council requested the Commission to table a legislative proposal revising Council Decision 2005/387/JHA. A legislative proposal on new psychoactive substances is foreseen in the Commission's 2013 Work Programme[4].

This proposal for a Regulation aims at improving the functioning of the internal market regarding licit uses of new psychoactive substances, by reducing obstacles to trade, preventing the emergence of such obstacles and increasing legal certainty for economic operators, while reducing the availability of substances that pose risks through swifter, more effective and more proportionate EU action. It is accompanied by a proposal for a Directive amending Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of

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1 COM(2011) 689 final.
2 OJ L 127, 10.5.2005, p.32.
3 http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/jha/126879.pdf
4 COM(2012) 629 final.

illicit drug trafficking[5]. This aims at expanding the scope of application of the Framework Decision to cover the most harmful new psychoactive substances, which pose severe risks. This means that substances that pose severe health, social and safety risks and are, therefore, submitted to permanent market restriction under this proposed Regulation, are also covered, through the proposed amended Framework Decision, by the criminal law provisions applying to controlled drugs.

The case for swifter, more effective and more proportionate action on new psychoactive substances at EU level is compelling, considering the rapid changes in this market, which put national authorities under pressure to act. During the past years, Member States have notified an increasing number of new psychoactive substances to the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA). Between 1997 and 2012 they reported around 290 substances. The number of notified substances tripled between 2009 and 2012 (from 24 to 73). Around 80% of these substances were reported by more than one Member State. The number of substances that can emerge may run into the thousands because many variations of existing or new, still unexploited substances, can be manufactured at relatively low cost. The issue has been further highlighted in the 2012[6] and 2013[7] EMCDDA annual reports, as well as in the EMCCDA-Europol "EU drug markets report: a strategic analysis"[8], published in January 2013.

Consumption of new psychoactive substances appears to be increasing in Europe and use is predominant among young people. According to the 2011 Eurobarometer "Youth attitudes on drugs", 5% of young people in the EU have used such substances at least once in their life, with a peak of 16% in Ireland, and close to 10% in Poland, Latvia and the UK. According to the results of snapshot surveys conducted by the EMCDDA, the number of online shops selling new psychoactive substances increased four-fold between 2010 and 2012, to 690.

The consumption of new psychoactive substances can cause harms to individuals' health and safety, resulting in deaths, injury or disease, and can pose risks to and burdens on society, as it may lead to violent behaviour and crime. These risks are amplified by the fact that many such substances are sold to consumers without appropriate labelling and instructions of use. In some cases they are sold on the black market alongside, or instead of, controlled drugs.

The rapid emergence and spread of these substances, and the potential risks that they pose, have led national authorities to subject them to various restriction measures. Hundreds such substances or mixtures of substances have been subjected to different restriction measures in the Member States in the past years. Such national measures disrupt trade in licit uses of these substances. Around a fifth of the substances notified by the Member States have other uses (but information on such uses is not collected systematically across the EU).

National restriction measures, which can vary depending on the Member State and on the substance, lead to obstacles to trade in licit uses, fragmentation, an uneven level playing field and legal uncertainties for economic operators, and make it difficult for companies to operate across the internal market. They make research more cumbersome, hampering the

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5 OJ L 335, 11.11.2004, p. 8.

6 EMCDDA, *2012 Annual report on the state of the drugs problem in Europe*; available at: http://www.emcdda.europa.eu/publications/annual-report/2012

7 EMCDDA, *European Drug Report 2013*; available at: http://www.emcdda.europa.eu/edr2013.

8 Available at: http://www.emcdda.europa.eu/publications/joint-publications/drug-markets

development of new uses for these substances. They have a chain-reaction impact on operators in different markets, because such substances are used in the production of other substances or mixtures, which in turn are used for manufacturing various goods. As the market for new psychoactive substances is likely to grow, so will these obstacles to licit trade.

In order to facilitate the functioning of the internal market while protecting consumers from harmful new psychoactive substances, EU-level action shall ensure the free movement of new psychoactive substances for commercial and industrial use, and for scientific research and development, and provide for a graduated set of restriction measures for substances posing risks, proportionate to their level of risk.

This proposal, therefore, sets up a robust system for exchanging rapidly information on new psychoactive substances emerging on the market, including on their commercial and industrial uses, for assessing the risks of substances that cause EU-wide concern and for withdrawing from the market those substances that pose risks.

The substances suspected to pose immediate public health risk will be withdrawn from the consumer market temporarily, pending their risk assessment. Once the risk assessment is completed, measures will be taken proportionate to the risks of substances. While no restrictions will be introduced at the EU level on substances posing low health, social and safety risks, substances posing moderate risks will be subjected to consumer market restriction, which means that they cannot be sold to consumers (except for uses specifically authorised, for instance by medicines legislation) but their trade is allowed for commercial and industrial purposes as well as for scientific research and development.

New psychoactive substances posing severe risks will be subjected to permanent market restriction, covering both the consumer and commercial markets, and their use will only be possible for specifically authorised industrial and commercial purposes, as well as for scientific research and development. In addition, as explained above, these substances will be subjected to EU criminal law provisions under the accompanying proposal for a Directive amending the Framework Decision on illicit drug trafficking.

In relation to new psychoactive substances on which the EU has not acted, Member States may introduce national technical regulations, in full compliance with the EU provisions preventing the emergence of unjustified barriers to trade[9].

1.2. Legal context

Soon after a borderless internal market was created, and following the emergence and rapid spread of synthetic drugs, such as amphetamines and ecstasy, it became clear that the effectiveness of national actions is limited and that EU action was necessary to contain the spread of harmful substances. The EU Joint Action 97/396/JHA concerning the information exchange, risk assessment and the control of new synthetic drugs[10] was adopted in 1997 to address this problem.

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[9] Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations and of rules on Information Society Services, OJ L 204, 21.7.1998, p. 37.

[10] OJ L 167, 25.6.1997, p.1.

Council Decision 2005/387/JHA, which repealed Joint Action 97/396/JHA, established an EU-wide system for tackling new psychoactive substances (synthetic and natural) that raise concern at EU level. It lays down rules on the exchange of information on these substances between Member States, coordinated by the EMCDDA and Europol, on the assessment of their risks and the submission to control and criminal penalties across the EU of those substances that pose risks.

The Commission's assessment report[11] of July 2011, concluded that, while Council Decision 2005/387/JHA is a useful instrument, it is inadequate, considering the scale and complexity of the problem, and it, therefore, requires revision. This is because it involves a lengthy process, it is reactive and it lacks options to the submission to control and criminal penalties.

This Regulation replaces Council Decision 2005/387/JHA.

2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENT

2.1. Consultations with interested parties

Broad stakeholder and expert consultations together with a web-based public consultation and an external study have informed the preparatory work for this proposal. The Commission involved all Member States in the assessment of the functioning of Council Decision 2005/387/JHA, through written consultation. In the context of the external study, the Commission collected and examined the views of a host of national authorities (responsible for drug legislation, justice and health ministries, health institutes and law enforcement agencies) and of EU agencies involved in the implementation of Council Decision 2005/387/JHA. It also collected and examined the views of international organisations (including the World Health Organisation), civil society organisations, economic operators in various markets, research institutes and academic experts.

The survey conducted among Member States in the context of the assessment report showed that a large number of Member States view the lack of alternatives to control and criminal penalties in the current instrument as inadequate and suggest that a wider range of options should be considered, backed by administrative law. Moreover, all Member States agreed that swifter action is necessary to address new psychoactive substances (including temporary measures) and that the current decision-making process is too slow.

During the two experts' meetings organised by the Commission on 15 December 2011 and 1 March 2012, academic experts and practitioners stressed that the Council Decision and product safety legislation are inadequate to tackle the large number of new psychoactive substances emerging on the market, whose effects and risks are mostly unknown. They pointed out that new legislation on new psychoactive substances should be calibrated to the different levels of risks posed by these substances. Certain participants expressed concern that too rigorous policy responses (such as blanket restrictions on entire groups of substances or a wide recourse to criminal penalties) could have adverse effects. Such adverse effects include a displacement of substances from the licit to the illicit market, a replacement of the substances

[11] COM(2011) 430 final and SEC(2011) 912 final.

withdrawn from the market with other substances, possibly even more harmful, and rendering such substances inaccessible for research.

Surveys and interviews were conducted with economic operators which manufacture such substances for various industrial uses, and with their trade associations, as well as with those who produce or distribute new psychoactive substances for recreational use. Recreational users of new psychoactive substances were also interviewed.

The views of young people (15-24 years' old) were collected through the 2011 Eurobarometer "Youth attitudes on drugs". Almost half of respondents (47%) thought that only those substances which are proved to pose risks to health should be restricted, while 34% held that all substances which imitate the effects of controlled drugs should be restricted.

The Commission run a public consultation on drugs policy from 28 October 2011 to 3 February 2012. It included a question on regulatory measures that the EU should develop to contain the spread of new psychoactive substances. Among the 134 replies, most stressed the need for more rapid action on new psychoactive substances and warned against imposing criminal sanctions indiscriminately. The European Economic and Social Committee has urged[12] the Commission to explore options that avoid making the personal use of such substances a criminal offence.

2.2. Impact Assessment

The Commission conducted an impact assessment of policy alternatives, taking into account the consultation of interested parties and the results of external studies. The impact assessment concluded that the following solution would be preferred:

– a more graduated and better targeted set of restriction measures on new psychoactive substances, which should not hinder the industrial use of substances.

– restriction measures should be introduced earlier and substances suspected to pose immediate public health risks should be subjected to temporary restrictions.

– restriction measures should be proportionate to a better determined level of risk of substances, with substances posing moderate risks subjected to restrictions on the consumer market (covered by administrative law), while substances posing severe risks should be subjected to a wider market restriction, as well as being covered by criminal law.

– restriction measures should be introduced through a quicker procedure.

The impact assessment concluded that the most effective way to keep harmful new psychoactive substances out of the market is to apply the EU provisions on illicit drug trafficking to new psychoactive substances that pose severe risks. Applying the same criminal law provisions to controlled drugs and to equally harmful new psychoactive substances, posing severe risks, will help deter trafficking in such substances and the involvement of criminal groups, while streamlining and clarifying the EU legal framework on drugs.

[12] OJ C 229, 31.7.2012, p. 85.

3. LEGAL ELEMENTS OF THE PROPOSAL

3.1. The legal base

The proposal aims at ensuring that trade in new psychoactive substances having industrial and commercial uses is not hindered and that the functioning of this market is improved, while the health and safety of individuals are protected from harmful substances, which cause concern at the EU level.

The proposal is based on Article 114 of the Treaty on the Functioning of the European Union (TFEU), which empowers the European Parliament and the Council to adopt measures for the approximation of the provisions laid down by law, regulation or administrative action in the Member States which have as their object the establishment and functioning of the internal market. Article 114(3) TFEU requires the Commission to ensure a high level of health, safety and consumer protection in its proposals envisaged in paragraph 1 of Article 114 TFEU. This proposal falls within the scope of action to improve the functioning of the internal market for the following reasons:

– it addresses obstacles to trade in new psychoactive substances having dual uses, while enabling the adoption of measures to restrict the availability to consumers of substances posing risks.

– it addresses the lack of legal certainty for economic operators by harmonising the response given to substances causing concern across the EU.

– it connects the market for industrial uses of new psychoactive substances to the wider internal market.

3.2. Subsidiarity, proportionality and the respect for fundamental rights

There is a clear need for EU action on new psychoactive substances. This is because Member States alone cannot reduce the problems caused by the spread in the internal market of harmful new psychoactive substances and by the proliferation of divergent national responses. Uncoordinated national action in this area can produce adverse knock-on effects, for instance hindrance to the operation of the internal market as far as licit trade in these substances is concerned or displacement of harmful substances from one Member State to another.

Consequently, EU-level action is necessary to ensure that potentially harmful new psychoactive substances, which cause EU-wide concern, can be identified, assessed and, if they pose risks, withdrawn from the market rapidly in all Member States.

The proposal is relevant for the following rights and principles enshrined in the EU Charter of Fundamental Rights: the right to health care (notably to a high level of human health protection, Article 35) and to consumer protection (Article 38), the respect of the freedom to conduct a business (Article 16), the right to property (Article 17), the right to an effective remedy and to a fair trial (Article 47), the presumption of innocence and right to defence (Article 48). These rights and freedoms can be subject to limitations, but only under the limits and requirements set by Article 52(1) of the EU Charter.

The proposal is proportionate and does not go beyond what is necessary to achieve the objectives because it only addresses new psychoactive substances that are a concern at the EU

level and because it sets out a calibrated, graduated approach, under which measures are proportionate to the actual risks of substances.

Explicit safeguards laid down in the instrument itself guarantee that any person whose rights are affected by the implementation of any administrative measures or sanctions pursuant to the Regulation shall have the right to an effective remedy before a tribunal.

3.3. Choice of instrument

In order to establish uniform rules, ensure clarity of concepts and procedures, and provide legal certainty for market operators, while ensuring that restriction measures are directly applicable in all Member States, a Regulation is the appropriate instrument.

3.4 Specific provisions

Article 1: Subject matter and scope – this provision sets out the purpose and scope of the proposal, and in particular that it establishes rules for restrictions to the free movement of new psychoactive substances in the internal market.

Article 2: Definitions – this provision sets out definitions which apply throughout the instrument.

Article 3: Free movement – this provision lays down the principle of free movement of new psychoactive substances for industrial and commercial uses, and for research and development.

Article 4: Prevention of barriers to free movement – this provision clarifies under what conditions Member States may introduce restrictions on new psychoactive substances.

Article 5: Information exchange – this provision establishes the respective roles of Member States, the EMCDDA and Europol in the process of exchange of information on new psychoactive substances.

Article 6: Joint report – this provision lays down the contents and the procedures for the drawing up and the transmission by the EMCDDA and Europol of a joint report on a new psychoactive substance. The Commission, the European Medicines Agency, the European Chemicals Agency and the European Food Safety Authority are associated to the collection of information for a joint report.

Article 7: Risk assessment procedure and report – this provision empowers the Commission to request the EMCDDA to assess the risks of a new psychoactive substance on which a joint report was drawn up. It lays down the procedures for the risk assessment, which is to be conducted by the Scientific Committee of the EMCDDA, and for the drawing up and the transmission of a risk assessment report.

Article 8: Exclusion from risk assessment – this provision details such circumstances in which no risk assessment is to be conducted on a new psychoactive substance.

Article 9: Immediate risks to public health and temporary consumer market restriction – this provision lays down the criteria on the basis of which the Commission determines whether a new psychoactive substance poses immediate risks to public health, and empowers the

Commission to prohibit, temporarily, the making available of this substance on the consumer market, if it poses such immediate risks to public health.

Article 10: Determination of the level of health, social and safety risks following the risk assessment – this provision lays down the criteria on the basis of which the Commission determines the level of health, social and safety risks posed by a new psychoactive substance.

Article 11: Low risks – this provision sets out that the Commission shall introduce no restriction measures on new psychoactive substances posing low health, social and safety risks and provides a definition of low risks.

Article 12: Moderate risks and permanent consumer market restriction – this provision empowers the Commission to prohibit the making available on the consumer market of new psychoactive substances which pose moderate health, social and safety risks, and provides a definition of moderate risks.

Article 13: Severe risks and permanent market restriction – this provision empowers the Commission to prohibit the production, manufacture, making available on the market, transport, importation or exportation of new psychoactive substances which pose severe health, social and safety risks, and provides a definition of severe risks.

Article 14: Authorised uses – this provision sets out the exceptions to the market restrictions introduced under the Regulation.

Article 15: Monitoring – this provision lays down monitoring obligations with regard to substances on which a joint report has been drawn up.

Article 16: Re-examination of the level of risks – this provision sets out the procedure for re-examining the level of risks posed by a new psychoactive substance in the light of new information and evidence on the substance.

Article 17: Sanctions – this provision establishes the obligation for the Member States to lay down the rules on administrative sanctions applicable to infringements to market restriction, and to ensure that they are effective, proportionate and dissuasive.

Article 18: Remedy – this provision sets out the right to an effective judicial remedy enshrined in Article 47 of the Charter of Fundamental Rights.

Articles 19: Committee – this provision lays down the standard rules for the exercise of implementing powers in line with Article 291 TFEU.

Article 20: Research and analysis – this provision describes the ways in which the EU shall support the development, sharing and dissemination of information and knowledge on new psychoactive substances, to support the rapid exchange of information on and risk assessment of new psychoactive substances.

Article 21: Reporting – this provision requests the EMCDDA and Europol to report annually on the implementation of certain aspects of the Regulation.

Article 22: Evaluation – this provision sets out an obligation for the Commission to regularly assess the implementation, application and effectiveness of this Regulation and to report to the European Parliament and Council.

Article 23: Replacement of Decision 2005/387/JHA – this provision sets out that this Regulation replaces Council Decision 2005/387/JHA.

Article 24: Entry into force – this establishes when the Regulation shall enter into force.

4. BUDGETARY IMPLICATION

The proposal has no direct impact on the EU budget and does not create new tasks for the EMCDDA, Europol, the European Medicines Agencies, the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA). For the purpose of this Regulation, the ECHA and the EFSA are only required to share the information at their disposal, on a limited number of substances, and are not requested to produce new information.

2013/0305 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on new psychoactive substances

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee[13],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) New psychoactive substances, which may have numerous commercial and industrial uses, as well as scientific uses, can pose health, social and safety risks when consumed by humans.

(2) During the past years, Member States have notified an increasing number of new psychoactive substances via the mechanism for rapid exchange of information which was established by Joint Action 97/396/JHA of 16 June 1997 adopted by the Council on the basis of Article K.3 of the Treaty on European Union, concerning the information exchange, risk assessment and the control of new synthetic drugs[14] and was further strengthened by the Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances[15]. A large majority of these new psychoactive substances were reported by more than one Member State. Many such new psychoactive substances were sold to consumers without appropriate labelling and instructions of use.

(3) Member States' competent public authorities introduce various restriction measures on these new psychoactive substances to address the risks that they pose or may pose

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13 OJ C […], […], p. […].
14 OJ L 167, 25.6.1997, p. 1.
15 OJ L 127, 20.5.2005, p. 32.

when consumed. As new psychoactive substances are often used in the production of various goods or of other substances which are used for manufacturing goods, such as medicines, industrial solvents, cleaning agents, goods in the hi-tech industry, restricting their access for this use can have an important impact on economic operators, potentially disrupting their business activities in the internal market.

(4) The increasing number of new psychoactive substances available in the internal market, their growing diversity, the speed with which they emerge on the market, the different risks that they may pose when consumed by humans and the growing number of individuals who consume them, challenge the capacity of public authorities to provide effective responses to protect public health and safety without hampering the functioning of the internal market.

(5) Restriction measures vary significantly in different Member States, meaning that economic operators that use them in the production of various goods must comply, in the case of the same new psychoactive substance, with different requirements, such as pre-export notification, export authorisation, or import and export licences. Consequently, the differences between the Member States' laws, regulations and administrative provisions on new psychoactive substances hinder the functioning of the internal market, by causing obstacles to trade, market fragmentation, lack of legal clarity and of an even level playing field for economic operators, making it difficult for companies to operate across the internal market.

(6) Restriction measures not only cause barriers to trade in the case of new psychoactive substances that already have commercial, industrial or scientific uses, but can also impede the development of such uses, and are likely to cause obstacles to trade for economic operators that seek to develop such uses, by making access to those new psychoactive substances more difficult.

(7) The disparities between the various restriction measures applied to new psychoactive substances can also lead to displacement of harmful new psychoactive substances between the Member States, hampering efforts to restrict their availability to consumers and undermining consumer protection across the Union.

(8) Such disparities are expected to increase as Member States continue to pursue divergent approaches to addressing new psychoactive substances. Therefore, the obstacles to trade and market fragmentation, and the lack of legal clarity and of a level playing field are expected to increase, further hindering the functioning of the internal market.

(9) Those distortions to the functioning of the internal market should be eliminated and, to that end, the rules relating to new psychoactive substances that are of concern at Union level should be approximated, while, at the same time, ensuring a high level of health, safety and consumer protection.

(10) New psychoactive substances and mixtures should be able to move freely in the Union when intended for commercial and industrial use, as well as for scientific research and development. This Regulation should establish rules for introducing restrictions to this free movement.

(11) New psychoactive substances that pose health, social and safety risks across the Union should be addressed at the Union level. Action on new psychoactive substances under

this Regulation should contribute to a high level of protection of human health and safety, as enshrined in the Charter of Fundamental Rights of the European Union.

(12) This Regulation should not apply to drug precursors because the diversion of those chemical substances for the purpose of manufacturing narcotic drugs or psychotropic substances is addressed under Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors[16] and Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors[17].

(13) Any Union action on new psychoactive substances should be based on scientific evidence and subject to a specific procedure. Based on the information notified by Member States, a report should be drawn up on new psychoactive substances that give rise to concerns across the Union. The report should indicate whether it is necessary to carry out a risk assessment. Following the risk assessment, the Commission should determine whether the new psychoactive substances should be subjected to any restriction measures. In case of immediate public health concerns, the Commission should subject them to temporary consumer market restriction before the conclusion of the risk assessment. In case new information emerges on a new psychoactive substance, the Commission should re-assess the level of risks that it poses. Reports on new psychoactive substances should be made publicly available.

(14) No risk assessment should be conducted under this Regulation on a new psychoactive substance if it is subject to an assessment under international law, or if it is an active substance in a medicinal product or in a veterinary medicinal product.

(15) Where the new psychoactive substance on which a report is drawn up is an active substance in a medicinal product or in a veterinary medicinal product, the Commission should assess with the European Medicines Agency the need for further action.

(16) The measures taken on new psychoactive substances at Union level should be proportionate to the health, social and safety risks that they pose.

(17) Certain new psychoactive substances pose immediate public health risks, requiring urgent action. Therefore, their availability to consumers should be restricted for a limited time, pending their risk assessment.

(18) No restriction measures should be introduced at Union level on new psychoactive substances which pose low health, social and safety risks.

(19) Those new psychoactive substances which pose moderate health, social and safety risks should not be made available to consumers.

(20) Those new psychoactive substances which pose severe health, social and safety risks should not be made available on the market.

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16 OJ L 47, 18.2.2004, p. 1.
17 OJ L 22, 26.1.2005, p. 1.

(21) This Regulation should provide for exceptions in order to ensure the protection of human and animal health, to facilitate scientific research and development, and to allow the use of new psychoactive substances in industry, provided that they cannot be abused or recovered.

(22) In order to ensure the efficient implementation of this Regulation, the Member States should lay down rules on the sanctions applicable to infringements of restriction measures. Those sanctions should be effective, proportionate and dissuasive.

(23) The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) established by Regulation 1920/2006/EC of the European Parliament and of the Council of 12 December 2006[18] should have a central role in the exchange of information on new psychoactive substances and in the assessment of the health, social and safety risks that they pose.

(24) The mechanism for rapid exchange of information on new psychoactive substances has proved to be a useful channel for sharing information on new psychoactive substances, on new trends in the use of controlled psychoactive substances and on related public health warnings. That mechanism should be further strengthened to enable a more effective response to the rapid emergence and spread of new psychoactive substances across the Union.

(25) Information from Member States is crucial for the effective functioning of the procedures leading to decision on market restriction of new psychoactive substances. Therefore, Member States should collect, on a regular basis, data on the use of new psychoactive substances, related health, safety and social problems and policy responses, in accordance with the EMCDDA framework for data collection for the key epidemiological indicators and other relevant data. They should share this data.

(26) A lack of capacity to identify and anticipate the emergence and spread of new psychoactive substances and a lack of evidence about their health, social and safety risks hamper the provision of an effective response. Therefore, support should be provided, including at Union level, to facilitate cooperation between the EMCDDA, research institutes and forensic laboratories with relevant expertise, in order to increase the capacity to assess and address effectively new psychoactive substances.

(27) The procedures for information exchange, risk assessment and adoption of temporary and permanent restriction measures on new psychoactive substances established by this Regulation should enable swift action. Market restriction measures should be adopted without undue delay, not later than eight weeks from receipt of the joint report or risk assessment report.

(28) As long as the Union has not adopted measures to subject a new psychoactive substance to market restriction under this Regulation, Member States may adopt technical regulations on that new psychoactive substance in compliance with the provisions of Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of

[18] OJ L 376, 27.12.2006, p. 1.

technical standards and regulations and of rules on Information Society Services[19]. In order to preserve the unity of the Union's internal market and to prevent the emergence of unjustified barriers to trade, Member States should immediately communicate to the Commission any draft technical regulation on new psychoactive substances, in accordance with the procedure established by Directive 98/34/EC.

(29) Prevention, treatment and harm reduction measures are important for addressing the growing use of new psychoactive substances and their potential risks. The internet, which is one of the important distribution channels through which new psychoactive substances are sold, should be used for disseminating information on the health, social and safety risks that they pose.

(30) Medicinal products and veterinary medicinal products are addressed under Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products[20], Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[21] and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[22]. Their abuse or misuse should, therefore, not be covered by this Regulation.

(31) In order to ensure uniform conditions for the implementation of temporary and permanent market restrictions, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers[23].

(32) The Commission should adopt immediately applicable implementing acts where, in duly justified cases relating to a rapid increase in the number of reported fatalities in several Member States associated with the consumption of the new psychoactive substance concerned, imperative grounds of urgency so require.

(33) In the application of this Regulation, the Commission should consult Member States' experts, relevant Union agencies, civil society and economic operators.

(34) Since the objectives of the proposed action cannot be sufficiently achieved by the Member States, and can therefore, by reason of the effects of the envisaged action, be better achieved at the Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.

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19 OJ L 204, 21.7.1998. p. 37.
20 OJ L 311, 28.11.2001, p. 67.
21 OJ L 311, 28.11.2001, p. 1.
22 OJ L 136, 30.4.2004, p. 1.
23 OJ L 55, 28.02.2011, p.13.

(35) In order to establish uniform rules and ensure clarity of concepts and procedures, as well as to provide legal certainty for economic operators, it is appropriate to adopt this act in the form of a Regulation.

(36) This Regulation respects fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union, including the freedom to conduct a business, the right to property and the right to an effective remedy,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

SUBJECT MATTER - SCOPE - DEFINITIONS

Article 1

Subject matter and scope

1. This Regulation establishes rules for restrictions to the free movement of new psychoactive substances in the internal market. For that purpose it sets up a mechanism for information exchange on, risk assessment and submission to market restriction measures of new psychoactive substances at Union level.

2. This Regulation shall not apply to scheduled substances as defined in Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005.

Article 2

Definitions

For the purpose of this Regulation, the following definitions apply:

(a) 'new psychoactive substance' means a natural or synthetic substance that, when consumed by a human, has the capacity to produce central nervous system stimulation or depression, resulting in hallucinations, alterations in motor function, thinking, behaviour, perception, awareness or mood, which is intended for human consumption or is likely to be consumed by humans even if not intended for them with the purpose of inducing one or more of the effects mentioned above, which is neither controlled under the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, nor the 1971 United Nations Convention on Psychotropic Substances; it excludes alcohol, caffeine and tobacco, as well as tobacco products within the meaning of Council Directive 2001/37/EC of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products [24];

[24] OJ L 194, 18.7.2001, p. 26.

(b) ‘mixture’ means a mixture or solution containing one or more new psychoactive substances;

(c) ‘medicinal product’ means a product as defined in point 2 of Article 1 of Directive 2001/83/EC;

(d) ‘veterinary medicinal product’ means a product as defined in point 2 of Article 1 of Directive 2001/82/EC;

(e) ‘marketing authorisation’ means an authorisation to place a medicinal product or a veterinary medicinal product on the market, in accordance with Directive 2001/83/EC, Directive 2001/82/EC or Regulation (EC) No 726/2004;

(f) ‘making available on the market’ means any supply of a new psychoactive substance for distribution, consumption or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(g) ‘consumer’ means any natural person who is acting for purposes which are outside his/her trade, business or profession;

(h) ‘commercial and industrial use’ means any manufacture, processing, formulation, storage, mixing, production and sale to natural and legal persons other than consumers;

(i) ‘scientific research and development’ means any scientific experimentation, analysis or research carried out under strictly controlled conditions, in accordance with Regulation (EC) No 1907/2006;

(j) ‘United Nations system’ means the World Health Organisation, the Commission on Narcotic Drugs and the Economic and Social Committee acting in accordance with their respective responsibilities as described in Article 3 of the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, or in Article 2 of the 1971 United Nations Convention on Psychotropic Substances.

CHAPTER II

FREE MOVEMENT

Article 3

Free movement

New psychoactive substances and mixtures shall move freely in the Union for commercial and industrial use, as well as for scientific research and development purposes.

Article 4

Prevention of barriers to free movement

Insofar as the Union has not adopted measures to subject a new psychoactive substance to market restriction under this Regulation, Member States may adopt technical regulations on such new psychoactive substance in accordance with Directive 98/34/EC.

Member States shall immediately communicate to the Commission any such draft technical regulation on new psychoactive substances, in accordance with Directive 98/34/EC.

CHAPTER III

EXCHANGE AND COLLECTION OF INFORMATION

Article 5

Information exchange

National Focal Points within the European Information Network on Drugs and Drug Addiction ("Reitox") and Europol National Units shall provide to the EMCDDA and Europol the available information on the consumption, possible risks, manufacture, extraction, importation, trade, distribution, trafficking, commercial and scientific use of substances that appear to be new psychoactive substances or mixtures.

The EMCDDA and Europol shall communicate that information immediately to Reitox and the Europol National Units.

Article 6

Joint report

1. Where the EMCDDA and Europol, or the Commission, consider that the information shared on a new psychoactive substance notified by several Member States gives rise to concerns across the Union because of the health, social and safety risks that the new psychoactive substance may pose, the EMCDDA and Europol shall draw up a joint report on the new psychoactive substance.

2. The joint report shall contain the following information:

   (a) the nature of the risks that the new psychoactive substance poses when consumed by humans and the scale of the risk to public health, as referred to in Article 9(1);

   (b) the chemical and physical identity of the new psychoactive substance, the methods and, if known, the chemical precursors used for its manufacture or extraction, and other new psychoactive substances with a similar chemical structure that have emerged;

(c) the commercial and industrial use of the new psychoactive substance, as well as its use for scientific research and development purposes;

(d) the human and veterinary medical use of the new psychoactive substance, including as an active substance in a medicinal product or veterinary medicinal product;

(e) the involvement of criminal groups in the manufacture, distribution or trade in the new psychoactive substance, and any use of the new psychoactive substance in the manufacture of narcotic drugs or psychotropic substances;

(f) whether the new psychoactive substance is currently under assessment, or has been under assessment, by the United Nations system;

(g) whether the new psychoactive substance is subject to any restriction measures in the Member States;

(h) any existing prevention and treatment measure in place to address the consequences of the use of the new psychoactive substance.

3. The EMCDDA and Europol shall request the National Focal Points and the Europol National Units to provide additional information on the new psychoactive substance. They shall provide that information within four weeks from receipt of the request.

4. The EMCDDA and Europol shall request the European Medicines Agency to provide information on whether, in the Union or in any Member State, the new psychoactive substance is:

(a) an active substance in a medicinal product or a veterinary medicinal product that has obtained a marketing authorisation;

(b) an active substance in a medicinal product or a veterinary medicinal product that is the subject of an application for a marketing authorisation;

(c) an active substance in a medicinal product or a veterinary medicinal product that has obtained a marketing authorisation, but the marketing authorisation has been suspended by the competent authority;

(d) an active substance in an unauthorised medicinal product in accordance with Article 5 of Directive 2001/83/EC or in a veterinary medicinal product prepared extemporaneously by a person authorised to do so under national legislation in accordance with Article 10(c) of Directive 2001/82/EC.

Member States shall provide the European Medicines Agency with the above information, if so requested by it.

The European Medicines Agency shall provide the information at its disposal within four weeks from receipt of the request from the EMCDDA.

5. The EMCDDA shall request the European Chemicals Agency and the European Food Safety Authority to provide the information and data at their disposal on the new psychoactive substance. The EMCDDA shall respect the conditions on use of

the information, which are communicated to the EMCDDA by the European Chemicals Agency and the European Food Safety Authority, including conditions on information and data security and protection of confidential business information.

The European Chemicals Agency and the European Food Safety Authority shall provide the information and data at their disposal within four weeks from receipt of the request.

6. The EMCDDA and Europol shall submit the joint report to the Commission within eight weeks from the request for additional information referred to in paragraph 3.

When the EMCDDA and Europol collect information on mixtures or on several new psychoactive substances with similar chemical structure, they shall submit individual joint reports to the Commission within ten weeks from the request for additional information referred to in paragraph 3.

CHAPTER IV

RISK ASSESSMENT

Article 7

Risk assessment procedure and report

1. Within four weeks from the receipt of the joint report referred to in Article 6, the Commission may request the EMCDDA to assess the potential risks posed by the new psychoactive substance and to draw up a risk assessment report. The risk assessment shall be conducted by the Scientific Committee of the EMCDDA.

2. The risk assessment report shall include an analysis of the criteria and of the information referred to in Article 10(2) to enable the Commission to determine the level of health, social and safety risks that the new psychoactive substance poses.

3. The Scientific Committee of the EMCDDA shall assess the risks during a special meeting. The Committee may be extended by not more than five experts, representing the scientific fields relevant for ensuring a balanced assessment of the risks of the new psychoactive substance. The Director of the EMCDDA shall designate them from a list of experts. The Management Board of the EMCDDA shall approve the list of experts every three years. The Commission, the EMCDDA, Europol and the European Medicines Agency shall each have the right to nominate two observers.

4. The Scientific Committee of the EMCDDA shall carry out the risk assessment on the basis of information on the risks of the substance and on its uses, including commercial and industrial uses, provided by the Member States, the Commission, the EMCDDA, Europol, the European Medicines Agency, the European Chemicals Agency, the European Food Safety Authority and on the basis of any other relevant scientific evidence. It shall take into consideration all opinions held by its members.

The EMCDDA shall support the risk assessment and shall identify information needs, including targeted studies or tests.

5. The EMCDDA shall submit the risk assessment report to the Commission within twelve weeks from the date when it received the request from the Commission.

6. Upon request of the EMCDDA, the Commission may extend the period to complete the risk assessment by no more than twelve weeks to allow for additional research and data collection to take place. The EMCDDA shall submit such a request to the Commission within six weeks from the launch of the risk assessment. If within two weeks of such request being made the Commission has not objected to such request, the risk assessment shall be so extended.

Article 8

Exclusion from risk assessment

1. No risk assessment shall be carried out where the new psychoactive substance is at an advanced stage of assessment within the United Nations system, namely once the World Health Organisation expert committee on drug dependence has published its critical review together with a written recommendation, except where there is significant information that is new or of particular relevance for the Union and that has not been taken into account by the United Nations system.

2. No risk assessment shall be carried out where the new psychoactive substance has been assessed within the United Nations system, but it has been decided not to schedule it under the 1961 Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, or the 1971 Convention on Psychotropic Substances, except where there is significant information that is new or of particular relevance for the Union.

3. No risk assessment shall be carried out where the new psychoactive substance is:

   (a) an active substance in a medicinal product or a veterinary medicinal product that has obtained a marketing authorisation;

   (b) an active substance in a medicinal product or a veterinary medicinal product that is the subject of an application for a marketing authorisation;

   (c) an active substance in a medicinal product or a veterinary medicinal product that has obtained a marketing authorisation, but the marketing authorisation has been suspended by the competent authority.

CHAPTER V

MARKET RESTRICTIONS

Article 9

Immediate risks to public health and temporary consumer market restriction

1. Where it requests a risk assessment of a new psychoactive substance pursuant to Article 7(1), the Commission shall, by means of a Decision, prohibit the making available on the market to consumers of the new psychoactive substance if, based on existing information, it poses immediate risks to public health, evidenced by:

   (a) reported fatalities and severe health consequences associated with the consumption of the new psychoactive substance in several Member States, related to the serious acute toxicity of the new psychoactive substance;

   (b) the prevalence and patterns of use of the new psychoactive substance in the general population and in specific groups, in particular frequency, quantities and modality of use, its availability to consumers and the potential for diffusion, which indicate that the scale of the risk is considerable.

2. The Commission shall adopt the Decision referred to in paragraph 1 by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 19(2).

   On duly justified imperative grounds of urgency relating to a rapid increase in the number of reported fatalities in several Member States associated with the consumption of the new psychoactive substance concerned, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure laid down in Article 19(3).

3. The market restriction contained in the Decision referred to in paragraph 1 shall not exceed a period of twelve months.

Article 10

Determination of the level of health, social and safety risks following the risk assessment

1. The Commission shall determine the level of the health, social and safety risks posed by the new psychoactive substance on which a risk assessment report was drafted. It shall do so on the basis of all available evidence, in particular the risk assessment report.

2. The Commission shall take the following criteria into account when determining the level of risk of a new psychoactive substance:

   (a) the harm to health caused by the consumption of the new psychoactive substance associated with its acute and chronic toxicity, abuse liability and

dependence-producing potential, in particular injury, disease, and physical and mental impairment;

(b) the social harm caused to individuals and to society, in particular its impact on social functioning, public order and criminal activities, organised crime activity associated with the new psychoactive substance, illicit profits generated by the production, trade and distribution of the new psychoactive substance, and associated economic costs of the social harm;

(c) the risks to safety, in particular the spread of diseases, including transmission of blood borne viruses, the consequences of physical and mental impairment on the ability to drive, the impact of the manufacture, transport and disposal of the new psychoactive substance and associated waste materials on the environment.

The Commission shall also take into account the prevalence and patterns of use of the new psychoactive substance in the general population and in specific groups, its availability to consumers, its potential for diffusion, the number of Member States where it poses health, social and safety risks, the extent of its commercial and industrial use, and its use for scientific research and development purposes.

Article 11

Low risks

The Commission shall not adopt restriction measures on a new psychoactive substance if, based on existing evidence, it poses, overall, low health, social and safety risks, in particular:

(a) the harm to health caused by the consumption of the new psychoactive substance associated with its acute and chronic toxicity, abuse liability and dependence-producing potential, is limited, as it provokes minor injury and disease, and minor physical or mental impairment;

(b) the social harm caused to individuals and to society is limited, in particular regarding its impact on social functioning and public order, criminal activities associated with the new psychoactive substance is low, illicit profits generated by the production, trade and distribution of the new psychoactive substance and associated economic costs are non-existent or negligible;

(c) the risks to safety are limited, in particular low risk of spread of diseases, including transmission of blood borne viruses, non-existent or low consequences of physical and mental impairment on the ability to drive, and the impact of the manufacture, transport and disposal of the new psychoactive substance and associated waste materials on the environment is low.

Article 12

Moderate risks and permanent consumer market restriction

1. The Commission shall, by means of a Decision, without undue delay, prohibit the making available on the market to consumers of the new psychoactive substance if,

based on existing evidence, it poses, overall, moderate health, social and safety risks, in particular:

(a) the harm to health caused by the consumption of the new psychoactive substance associated with its acute and chronic toxicity, abuse liability and dependence-producing potential, is moderate, as it generally provokes non-lethal injury and disease, and moderate physical or mental impairment;

(b) the social harm caused to individuals and to society is moderate, in particular regarding its impact on social functioning and public order, producing public nuisance; criminal activities and organised crime activity associated with the substance are sporadic, illicit profits and economic costs are moderate;

(c) the risks to safety are moderate, in particular sporadic spread of diseases, including transmission of blood borne viruses, moderate consequences of physical and mental impairment on the ability to drive, and the manufacture, transport and disposal of the new psychoactive substance and associated waste materials results in environmental nuisance.

2. The Commission shall adopt the Decision referred to in paragraph 1 by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 19(2).

Article 13

Severe risks and permanent market restriction

1. The Commission shall, by means of a Decision, without undue delay, prohibit the production, manufacture, making available on the market including importation to the Union, transport, and exportation from the Union of the new psychoactive substance if, based on existing evidence, it poses, overall, severe health, social and safety risks, in particular:

(a) the harm to health caused by the consumption of the new psychoactive substance associated with its acute and chronic toxicity, abuse liability and dependence-producing potential, is life threatening, as it generally provokes death or lethal injury, severe disease, and severe physical or mental impairment;

(b) the social harm caused to individuals and to society is severe, in particular regarding its impact on social functioning and public order, resulting in public order disruption, violent and anti-social behaviour causing damage to the user, to others and to property; criminal activities and organised crime activity associated with the new psychoactive substance are systematic, illicit profits, and economic costs are high;

(c) the risks to safety are severe, in particular significant spread of diseases, including transmission of blood borne viruses, severe consequences of physical and mental impairment on the ability to drive, and the manufacture, transport and disposal of the new psychoactive substance and associated waste materials result in environmental harm.

2. The Commission shall adopt the Decision referred to in paragraph 1 by means of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 19(2).

Article 14

Authorised uses

1. The Decisions referred to in Article 9(1) and Article 12(1) shall not impede the free movement in the Union and the making available on the market to consumers of new psychoactive substances that are active substances in medicinal products or veterinary medicinal products that have obtained a marketing authorisation.

2. The Decisions referred to in Article 13(1) shall not impede the free movement in the Union and the production, manufacture, making available on the market including importation to the Union, transport, and exportation from the Union of new psychoactive substances:

   (a) for scientific research and development purposes;

   (b) for uses authorised under Union legislation;

   (c) that are active substances in medicinal products or veterinary medicinal products that have obtained a marketing authorisation;

   (d) for use in the manufacture of substances and products provided that the new psychoactive substances are transformed in such a condition that they cannot be abused or recovered.

3. The Decisions referred to in Article 13(1) may set requirements and conditions for the production, manufacture, making available on the market including importation to the Union, transport, and exportation from the Union of new psychoactive substances posing severe health, social and safety risks for the uses listed in paragraph 2.

CHAPTER VI

MONITORING AND RE-EXAMINATION

Article 15

Monitoring

The EMCDDA and Europol, with the support of Reitox, shall monitor all new psychoactive substances on which a joint report has been drawn up.

Article 16

Re-examination of level of risks

Where new information and evidence is available on the risks posed by a new psychoactive substance the health, social and safety risks of which have already been determined in accordance with Article 10, the Commission shall request the EMCDDA to update the risk assessment report drafted on the new psychoactive substance and shall re-examine the level of risks that the new psychoactive substance poses.

CHAPTER VII

SANCTIONS AND REMEDY

Article 17

Sanctions

Member States shall lay down the rules on sanctions applicable to infringements of the Decisions referred to in Article 9(1), Article 12(1) and Article 13(1) and shall take all necessary measures to ensure that they are implemented. The sanctions provided for shall be effective, proportionate and dissuasive. Member States shall notify those rules on sanctions and any subsequent amendment affecting those provisions to the Commission without delay.

Article 18

Remedy

Any person whose rights are affected by the implementation of a sanction taken by a Member State in accordance with Article 17 shall have the right to an effective remedy before a tribunal in that Member State.

CHAPTER VIII

PROCEDURES

Article 19

Committee

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

CHAPTER IX

FINAL PROVISIONS

Article 20

Research and analysis

The Commission and the Member States shall support the development, sharing and dissemination of information and knowledge on new psychoactive substances. They shall do so by facilitating cooperation between the EMCDDA, other Union agencies, and scientific and research centres.

Article 21

Reporting

The EMCDDA and Europol shall report annually on the implementation of this Regulation.

Article 22

Evaluation

By [*five years after the entry into force of this Regulation*] at the latest and every five years thereafter, the Commission shall assess the implementation, application and effectiveness of this Regulation and publish a report.

Article 23

Replacement of Decision 2005/387/JHA

Decision 2005/387/JHA is hereby repealed and replaced, without prejudice to the obligations of the Member States relating to the time limit for transposition of that Decision into national law. References to Decision 2005/387/JHA shall be construed as reference to this Regulation.

Article 24

Entry into force

This Regulation shall enter into force on the [*twentieth*] day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Regulation of the European Parliament and of the Council on new psychoactive substances

1.2. Policy area(s) concerned in the ABM/ABB structure[25]

Title 33: Justice

1.3. Nature of the proposal/initiative

☒ The proposal/initiative relates to **a new action**

☐ The proposal/initiative relates to **a new action following a pilot project/preparatory action**[26]

☐ The proposal/initiative relates to **the extension of an existing action**

☐ The proposal/initiative relates to **an action redirected towards a new action**

1.4. Objective(s)

1.4.1. The Commission's multiannual strategic objective(s) targeted by the proposal/initiative

Building a safe and secure Europe: to improve the capacity to detect, assess and respond rapidly and effectively to the emergence of new psychoactive substances

1.4.2. Specific objective(s) and ABM/ABB activity(ies) concerned

Specific objective No:
Prevent and reduce drug use, drug dependence and drug-related harm
ABM/ABB activity(ies) concerned

[25] ABM: activity-based management – ABB: activity-based budgeting.

[26] As referred to in Article 54(2)(a) or (b) of the Financial Regulation.

1.4.3. Expected result(s) and impact

To reduce the availability in the EU internal market of new psychoactive substances that pose health, social and safety risks, and to prevent the emergence of obstacles to legitimate trade and increase legal certainty for economic operators.

1.4.4. Indicators of results and impact

- Number of new psychoactive substances notified, of Member States that notified it.
- Known commercial and industrial uses of new psychoactive substances.
- Characteristics and availability (including on the internet) of the substances.
- Number of joint reports and risk assessments conducted.
- Number and type of restriction measures on new psychoactive substances at the EU and national level.
- Number of health alerts issued on new psychoactive substances and follow-up given by responsible authorities.

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term

- To reduce obstacles to legitimate trade in new psychoactive substances and prevent the emergence of such obstacles.
- To protect the health and safety of consumers from the risks posed by harmful new psychoactive substances.
- To address substances that pose health, social and safety risks, and that raise immediate public health concerns.
- To improve the capacity to rapidly identify and assess new psychoactive substances, and to address them depending on their risks.
- To facilitate legitimate trade in such substances within the internal market.
- To improve consistency between national responses to harmful new psychoactive substances which raise cross-border concerns and to reduce the risk of their displacement between the Member States.

1.5.2. Added value of EU involvement

EU action on new psychoactive substances would boost the exchange of information among the Member States, with the clear added value of alerting Member States to potentially harmful substances that have emerged in other Member States, to help them anticipate a potential public health threat. The assessment of risks of substances at the EU level has the added value of pooling scientific resources and analytical

capacities from across the EU, to provide the best evidence available on a substance and help develop effective responses to it. EU-level decisions on restricting the availability of harmful substances would increase legal certainty and reduce obstacles for economic operators in the market for legitimate uses, while improving consumer protection across the EU.

1.5.3. Lessons learned from similar experiences in the past

The 2011 Commission's assessment report[27] on the implementing of the current Council Decision 2005/387/JHA on the information exchange, risk-assessment and control of new psychoactive substances, based on an extensive consultation of Member State stakeholders, concluded that the Council Decision is a useful instrument for tackling new substances at the EU level, but that it has several major shortcomings, including:

(1) It is slow and reactive, and it is therefore not able to address effectively the increase in the number of new psychoactive substances.

(2) Insufficient evidence is available to take appropriate and sustainable decisions under this instrument.

(3) It lacks options for restriction measures.

1.5.4. Compatibility and possible synergy with other appropriate instruments

Action in the field of new psychoactive substances is in compliance with the existing rules on the functioning of the internal market, as well as with EU strategic policy documents, including the EU Drugs Strategy 2013-2020, the Stockholm Programme and the Commission Communication "Towards a stronger European response to drugs". EU action in the field of new psychoactive substances is also fully consistent with action at the United Nations' level.

1.6. Duration and financial impact

☐ Proposal/initiative of **limited duration**

– ☐ Proposal/initiative in effect from [DD/MM]YYYY to [DD/MM]YYYY

– ☐ Financial impact from YYYY to YYYY

☒ Proposal/initiative of **unlimited duration**

– Implementation with a start-up period from YYYY to YYYY,

– followed by full-scale operation.

[27] COM(2011) 430 final and SEC(2011) 912.

1.7. Management mode(s) planned[28]

From the 2014 budget

☒ **Direct management** by the Commission

– ☒ by its departments, including by its staff in the Union delegations;

– ☐ by the executive agencies;

☐ **Shared management** with the Member States

☐ **Indirect management** by delegating implementation tasks to:

– ☐ third countries or the bodies they have designated;

– ☐ international organisations and their agencies (to be specified);

– ☐the EIB and the European Investment Fund;

– ☐ bodies referred to in Articles 208 and 209 of the Financial Regulation;

– ☐ public law bodies;

– ☐ bodies governed by private law with a public service mission to the extent that they provide adequate financial guarantees;

– ☐ bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that provide adequate financial guarantees;

– ☐ persons entrusted with the implementation of specific actions in the CFSP pursuant to Title V of the TEU, and identified in the relevant basic act.

– *If more than one management mode is indicated, please provide details in the "Comments" section.*

Comments:

The only minor costs expected for the EU budget relate to the evaluation of the legislative instrument and meetings of the committee of Member States.

[28] Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: http://www.cc.cec/budg/man/budgmanag/budgmanag_en.html

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

The Commission will evaluate the implementation, functioning, effectiveness, efficiency, utility and added value of the future mechanism on new psychoactive substances every five years, publish the results and propose amendments, if necessary.

2.2. Management and control system

2.2.1. Risk(s) identified

None identified.

2.2.2. Information concerning the internal control system set up

Standard Commission control/infringement procedures concerning the application of the future Regulation and Directive.

2.2.3. Estimate of the costs and benefits of the controls and assessment of the expected level of risk of error

Not relevant as no specific risk identified.

2.3. Measures to prevent fraud and irregularities

In order to combat fraud, corruption and other unlawful activities, the provisions of Regulation (EC) No 1073/1999 apply.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing expenditure budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number […]Heading……..……]	Diff./non-diff. (29)	from EFTA countries[30]	from candidate countries[31]	from third countries	within the meaning of Article 21(2)(b) of the Financial Regulation
3	[33 03 03]	Diff.	NO	NO	NO	NO

- New budget lines requested

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number […]Heading……..……]	Diff./non-diff.	from EFTA countries	from candidate countries	from third countries	within the meaning of Article 21(2)(b) of the Financial Regulation
	[…][XX.YY.YY.YY]		YES/NO	YES/NO	YES/NO	YES/NO

29 Diff. = Differentiated appropriations / Non-Diff. = Non-differentiated appropriations.
30 EFTA: European Free Trade Association.
31 Candidate countries and, where applicable, potential candidate countries from the Western Balkans.

3.2. Estimated impact on expenditure

3.2.1. Summary of estimated impact on expenditure

EUR million (to three decimal places)

Heading of multiannual financial framework	Number	[Heading 3: Security and Citizenship]

DG JUST			Year **2014**	Year **2015**	Year **2016**	Year **2017**	Year **2018**	Year **2019**	Yean **2020**	Enter as many years as necessary to show the duration of the impact (see point 1.6)			**TOTAL**
• Operational appropriations													
33 03 03	Commitments	(1)						0,150					**0,150**
	Payments	(2)						0,150					**0,150**
Number of budget line	Commitments	(1a)											
	Payments	(2a)											
Appropriations of an administrative nature financed from the envelope of specific programmes[32]													
Number of budget line		(3)											
TOTAL appropriations for DG JUST	Commitments	=1+1a +3						0,150					**0,150**
	Payments	=2+2a +3						0,150					**0,150**

[32] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, direct research.

• TOTAL operational appropriations	Commitments	(4)						0,150					**0,150**
	Payments	(5)						0,150					**0,150**
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)											
TOTAL appropriations for HEADING 3 of the multiannual financial framework	Commitments	=4+ 6						0,150					**0,150**
	Payments	=5+ 6						0,150					**0,150**

If more than one heading is affected by the proposal / initiative: N/A

• TOTAL operational appropriations	Commitments	(4)									
	Payments	(5)									
• TOTAL appropriations of an administrative nature financed from the envelope for specific programmes		(6)									
TOTAL appropriations under HEADINGS 1 to 4 of the multiannual financial framework (Reference amount)	Commitments	=4+ 6									
	Payments	=5+ 6									

Heading of multiannual financial framework	**5**	"Administrative expenditure"

EUR million (to three decimal places)

		Year **2014**	Year **2015**	Year **2016**	Year **2017**	Year **2018**	Year **2019**	Year **2020**	**TOTAL**
DG JUST									
• Human resources		0,013	0,013	0,013	0,013	0,013	0,065	0,013	**0,143**
• Other administrative expenditure		0,025	0,025	0,025	0,025	0,025	0,025	0,025	**0,175**
TOTAL DG JUST	Appropriations								
TOTAL appropriations for HEADING 5 of the multiannual financial framework	Total commitments = Total payments	0,038	0,038	0,038	0,038	0,038	0,09	0,038	**0,318**

EUR million (to three decimal places)

		Year **2014**	Year **2015**	Year **2016**	Year **2017**	Year **2018**	Year **2019**	Year **2020**	**TOTAL**
TOTAL appropriations under HEADINGS 1 to 5 of the multiannual financial framework	Commitments	0,038	0,038	0,038	0,038	0,038	0,240	0,038	**0,468**
	Payments	0,038	0,038	0,038	0,038	0,038	0,240	0,038	**0,468**

3.2.2. Estimated impact on operational appropriations

– ☐ The proposal/initiative does not require the use of operational appropriations

– ☒ The proposal/initiative requires the use of operational appropriations, as explained below:

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs			Year **2014**		Year **2015**		Year **2016**		Year **2017**		Year **2018**		Year **2019**		Year **2020**		**TOTAL**	
	OUTPUTS																	
⇩	Type[33]	Average cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No	Cost	No total	Total cost
SPECIFIC OBJECTIVE No 1 Prevent and reduce drug use, drug dependence and drug-related harm																		
- Output	Evaluation	0,158											1	0,150			1	0,150
- Output																		
- Output																		
Subtotal for specific objective No 1													1	0,150			1	0,150
SPECIFIC OBJECTIVE NO 2 ...																		
- Output																		
Subtotal for specific objective No 2																		

[33] Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

TOTAL COST											1	0,150			1	0,150

3.2.3. Estimated impact on appropriations of an administrative nature

3.2.3.1. Summary

– ☐ The proposal/initiative does not require the use of appropriations of an administrative nature

– ☒ The proposal/initiative requires the use of appropriations of an administrative nature, as explained below:

EUR million (to three decimal places)

	Year **2014**	Year **2015**	Year **2016**	Year **2017**	Year **2018**	Year **2019**	Year **2020**	**TOTAL**
HEADING 5 of the multiannual financial framework								
Human resources	0,013	0,013	0,013	0,013	0,013	0,065	0,013	**0,143**
Other administrative expenditure	0,025	0,025	0,025	0,025	0,025	0,025	0,025	**0,175**
Subtotal HEADING 5 of the multiannual financial framework	0,038	0,038	0,038	0,038	0,038	0,090	0,038	**0,318**

Outside HEADING 5[34] of the multiannual financial framework								
Human resources								
Other expenditure of an administrative nature								
Subtotal outside HEADING 5 of the multiannual financial framework								

TOTAL	0,038	0,038	0,038	0,038	0,038	0,090	0,038	**0,318**

The human resources appropriations required will be met by appropriations from the DG that are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

[34] Technical and/or administrative assistance and expenditure in support of the implementation of EU programmes and/or actions (former "BA" lines), indirect research, direct research.

3.2.3.2. Estimated requirements of human resources

– ☐ The proposal/initiative does not require the use of human resources.

– ☒ The proposal/initiative requires the use of human resources, as explained below:

Estimate to be expressed in full time equivalent units

	Year **2014**	Year **2015**	Year **2016**	Year **2017**	Year **2018**	Year **2019**	Year **2020**	**TOTAL**
• Establishment plan posts (officials and temporary staff)								
33 01 01 01 (Headquarters and Commission's Representation Offices)	0,1	0,1	0,1	0,1	0,1	0,5	0,1	1,1
XX 01 01 02 (Delegations)								
XX 01 05 01 (Indirect research)								
10 01 05 01 (Direct research)								
• External staff (in Full Time Equivalent unit: FTE)[35]								
XX 01 02 01 (CA, SNE, INT from the "global envelope")								
XX 01 02 02 (CA, LA, SNE, INT and JED in the delegations)								
XX 01 04 yy[36] - at Headquarters								
XX 01 04 yy[36] - Delegations								
XX 01 05 02 (CA, SNE, INT - Indirect research)								
10 01 05 02 (CA, INT, SNE - Direct research)								
Other budget lines (specify)								
TOTAL	**0,1**	**0,1**	**0,1**	**0,1**	**0,1**	**0,5**	**0,1**	**1,1**

33 is the policy area or budget title concerned.

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

Description of tasks to be carried out:

Officials and temporary staff	Preparation of one committee meeting of Member States per year. Coordination of an external study for the evaluation of the instrument every five years.
External staff	

35 CA= Contract Staff; LA = Local Staff; SNE= Seconded National Expert; INT = agency staff; JED= Junior Experts in Delegations).

36 Sub-ceiling for external staff covered by operational appropriations (former "BA" lines).

3.2.4. Compatibility with the current multiannual financial framework

– ☒ Proposal/initiative is compatible with the current multiannual financial framework.

– ☐ Proposal/initiative will entail reprogramming of the relevant heading in the multiannual financial framework.

Explain what reprogramming is required, specifying the budget lines concerned and the corresponding amounts.

– ☐ Proposal/initiative requires application of the flexibility instrument or revision of the multiannual financial framework[37].

Explain what is required, specifying the headings and budget lines concerned and the corresponding amounts.

3.2.5. Third-party contributions

– The proposal/initiative does not provide for co-financing by third parties.

– The proposal/initiative provides for the co-financing estimated below:

Appropriations in EUR million (to 3 decimal places)

	Year **N**	Year **N+1**	Year **N+2**	Year **N+3**	Enter as many years as necessary to show the duration of the impact (see point 1.6)			Total
Specify the co-financing body								
TOTAL appropriations cofinanced								

[37] See points 19 and 24 of the Interinstitutional Agreement (for the period 2007-2013).

3.3. Estimated impact on revenue

– ☒ Proposal/initiative has no financial impact on revenue.

– ☐ Proposal/initiative has the following financial impact:

- ☐ on own resources

- ☐ on miscellaneous revenue

EUR million (to three decimal places)

Budget revenue line:	Appropriations available for the current financial year	Impact of the proposal/initiative[38]						
		Year **N**	Year **N+1**	Year **N+2**	Year **N+3**	Enter as many years as necessary to show the duration of the impact (see point 1.6)		
Article …….								

For miscellaneous 'assigned' revenue, specify the budget expenditure line(s) affected.

Specify the method for calculating the impact on revenue.

[38] As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 25% for collection costs.

EUROPEAN
COMMISSION

Brussels, 17.9.2013
COM(2013) 618 final

2013/0304 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking, as regards the definition of drug

{SWD(2013) 319 final}
{SWD(2013) 320 final}

EN

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

1.1. General context

Illicit drug trafficking and drug abuse are major threats to the health and safety of individuals and to societies in the EU. They affect the social and economic fabric and undermine the quality of life of individuals, as well as the security of the Member States. Although consumption of substances controlled under the UN Conventions on drugs[1], such as cocaine, ecstasy or cannabis ('controlled drugs'), seems to have stabilised in recent years[2], albeit at high levels, a major challenge is to address new substances that emerge on the market at a rapid speed.

New psychoactive substances, which imitate the effects of controlled drugs and are often marketed as legal alternatives to them because they are not subjected to similar control measures, and which have numerous uses in the industry, are increasingly available in the Union. Between 1997 and 2012, Member States reported around 290 substances, with more than one new substance notified every week in 2012. The number of reported substances tripled between 2009 and 2012 (from 24 to 73).

A growing number of individuals, in particular young people, consume new psychoactive substances. However, these substances can cause harms to individuals' health and safety, and can put burdens on society, just like controlled drugs do. The risks that new psychoactive substances can pose have prompted national authorities to submit them to various restriction measures. However, such national restriction measures have limited effectiveness, since these substances can be moved freely in the internal market - around 80% of the substances notified were detected in more than one Member State.

The Commission Communication "Towards a stronger European response to drugs"[3], adopted in October 2011, identified new psychoactive substances as one of the problems requiring a firm response at the EU level.

Council Decision 2005/387/JHA of 10 May 2005[4] provides a mechanism for addressing the risks posed by new psychoactive substances, which can lead to the submission of substances to control measures and criminal penalties across the Union. To address more sustainably the frequent emergence of new psychoactive substances and their rapid spread across the Union, the Commission proposed stronger rules, under [*Regulation (EU) No …/… on new psychoactive substances]*.

To effectively reduce the availability of harmful new psychoactive substances, which pose severe health, social and safety risks to individuals and society, and to deter trafficking in these substances as well as the involvement of criminal organisations in their production or distribution, along with controlled drugs, it is necessary to cover new psychoactive substances by criminal law provisions.

Council Framework Decision 2004/757/JHA of 25 October 2004[5] provides a common approach to the fight against illicit drug trafficking. It sets out minimum common rules on the

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1 The 1961 United Nations Single Convention on Narcotic Drugs (as amended by the 1972 Protocol) and the 1971 United Nations Convention on Psychotropic Substances.

2 European Monitoring Centre for Drugs and Drug Addiction, The state of the drugs problem in Europe, Annual Report 2012. http://www.emcdda.europa.eu/publications/annual-report/2012

3 COM(2011) 689 final.

4 OJ L 127, 20.5.2005, p. 32.

5 OJ L 335, 11.11.2004, p. 8.

definition of drug trafficking offences and sanctions to avoid that problems arise in cooperation between the judicial authorities and law enforcement agencies of Member States, owing to the fact that the offence or offences in question are not punishable under the laws of both the requesting and the requested State. However, while these provisions apply to substances covered by the UN Conventions and to synthetic drugs submitted to control under Joint Action 97/396/JHA of 16 June 1997[6], they do not apply to new psychoactive substances.

In order to streamline and clarify the legal framework applicable to drugs, the most harmful new psychoactive substances should be covered by the same criminal law provisions as substances controlled under the UN Conventions.

It is, therefore, necessary to extend the scope of application of Framework Decision 2004/757/JHA to new psychoactive substances subjected to control measures under Council Decision 2005/387/JHA as well as to those substances subjected to permanent market restriction measures under *[Regulation (EU) No …/… on new psychoactive substances]*.

A legislative proposal on illicit drug trafficking was foreseen in the Commission's 2012 Work Programme.

1.2. Grounds for and objectives of the proposal

This proposal amends Framework Decision 2004/757/JHA to include new psychoactive substances posing severe risks within its scope of application.

This proposal accompanies the proposal for a *[Regulation (EU) No …/… on new psychoactive substances]*. The two proposals are linked, so that new psychoactive substances that pose severe health, social and safety risks and are therefore submitted to permanent market restriction under that Regulation are also subjected to the criminal law provisions on illicit drug trafficking set by the Framework Decision 2004/757/JHA.

2. RESULTS OF CONSULTATIONS WITH THE INTERESTED PARTIES AND IMPACT ASSESSMENT

2.1. Stakeholders' consultation

Broad stakeholder and expert consultations and a web-based public consultation have informed the preparatory work for this proposal.

The Commission consulted all Member States in the assessment of the functioning of Framework Decision 2004/757/JHA and Council Decision 2005/387/JHA. Moreover, in the context of external studies on illicit drug trafficking and new psychoactive substances, the Commission collected and examined the views of a broad range of stakeholders, practitioners and experts, including EU agencies involved in the implementation of these instruments.

The Commission also organised two experts' meeting on illicit drug trafficking, on 10 November 2011 and 29 February 2012, and two experts' meetings on new psychoactive substances, on 15 December 2011 and 1 March 2012. During these meetings, academic experts and practitioners stressed the importance of criminal law provisions in helping clamp down and deter illicit drug trafficking, and tackling the spread of harmful new psychoactive substances. At the same time, they pointed out that legislation on new psychoactive substances should be proportionate and calibrated to the different levels of risks that they pose.

A survey was conducted among young people (15-24 years' old) in 2011, through the Eurobarometer "Youth attitudes on drugs". Almost half of respondents (47%) thought that

[6] OJ L 167, 25.6.1997, p. 1.

only those substances which are proved to pose risks to health should be restricted, while 34% held that all substances which imitate the effects of controlled drugs should be restricted.

2.2. Impact assessment

The Commission assessed the impacts of this proposal for an amendment to Framework Decision 2004/757/JHA in an impact assessment on new psychoactive substances. The analysis concluded that, as under the Council Decision 2005/387/JHA, harmful new psychoactive substances (those posing severe health, social and safety risks) should be subjected to criminal law provisions. It further concluded that they should, therefore, be subjected to the criminal law provisions on illicit drug trafficking. This represented part of the preferred policy option, which foresees a graduated set of restriction measures that are proportionate to the level of risks posed by new psychoactive substances, and which do not cause obstacles to legitimate trade in the internal market.

3. LEGAL ELEMENTS OF THE PROPOSAL

3.1. The legal base

This proposal is based on Article 83(1) TFEU, which empowers the European Parliament and the Council to establish minimum rules concerning the definition of offences and sanctions in the area of illicit drug trafficking, by means of a Directive adopted in accordance with the ordinary legislative procedure.

3.2. Subsidiarity, proportionality and respect of fundamental rights

The EU is better placed than the Member States to take action to restrict the availability in the internal market of harmful new psychoactive substances for consumers, while simultaneously ensuring that legitimate trade is not impeded.

This is because individually Member States cannot address effectively and sustainably the rapid emergence and spread of these substances. Uncoordinated national action and the proliferation of diverse national regimes on new psychoactive substances can produce knock-on effects on other Member States (displacement of harmful substances) and can pose problems in cooperation between national judicial authorities and law enforcement agencies.

The proposal is proportionate and does not go beyond what is necessary to achieve the objectives because it only addresses through criminal law those new psychoactive substances that are a serious concern at the EU level.

This proposal indirectly impacts on certain fundamental rights and principles enshrined in the EU Charter of Fundamental Rights, because it expands the scope of application of the Framework Decision 2004/757/JHA, whose provisions impact on the following fundamental rights and principles: the right to liberty and security (Article 6), the right to property (Article 17), the right to an effective remedy and to a fair trial (Article 47), the presumption of innocence and right to defence (Article 48), and the principle of legality and proportionality of criminal offences and penalties (Article 49). These rights and freedoms can be subject to limitations, but only under the limits and requirements set by Article 52(1) of the EU Charter.

3.3. Choice of instrument

In accordance with Article 83(1) TFEU, a Directive is the appropriate instrument to ensure minimum harmonisation at the EU level in the area of illicit drug trafficking, while leaving flexibility to Member States when implementing the principles, rules and their exemptions at national level.

3.4. Explanatory documents accompanying notification of transposition measures

Member States are requested to communicate to the Commission the national measures adopted to comply with this Directive.

Member States are not requested to submit to the Commission explanatory documents (including correlation tables) accompanying the notification of national measures adopted for transposing the provisions of this Directive. This is not necessary because of the reduced scope of the proposed amendment. The submission of additional explanatory documents would add an unjustified administrative burden on Member States' competent authorities.

3.5. Main provisions

Article 1 – this provision lays down the amendments to the Framework Decision 2004/757/JHA, in relation to the definition of the term "drug", to the provision for covering by criminal law new psychoactive substances posing severe health, social and safety risks, and to the assessment of the implementation and impacts of the Framework Decision by the Commission.

Article 2 – this provision lays down the deadline for the transposition of the provisions of the Directive in national legislation.

Articles 3 and 4 – these provisions relate to the entry into force and addressees of the Directive.

4. BUDGETARY IMPLICATION

The proposal has no implications for the Union budget.

2013/0304 (COD)

Proposal for a

DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

amending Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking, as regards the definition of drug

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 83(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking[7] provides a common approach to the fight against illicit drug trafficking, which poses a threat to the health, safety and quality of life of citizens of the Union, and to the legal economy, stability and security of the Member States. It sets out minimum common rules on the definition of drug trafficking offences and sanctions, to avoid that problems may arise in cooperation between the judicial authorities and law enforcement agencies of Member States, owing to the fact that the offence or offences in question are not punishable under the laws of both the requesting and the requested State.

(2) Framework Decision 2004/757/JHA applies to the substances covered by the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, and the 1971 United Nations Convention on Psychotropic Substances ('UN Conventions'), as well as to the synthetic drugs subjected to control across the Union pursuant to Joint Action 97/396/JHA of 16 June 1997 concerning the information exchange, risk assessment and the control of new synthetic drugs[8], which pose public health risks comparable to those posed by the substances scheduled under the UN Conventions.

(3) Framework Decision 2004/757/JHA should also apply to the substances subjected to control measures and criminal penalties pursuant to Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk assessment and control of new psychoactive substances[9], which pose public health risks comparable to those posed by the substances scheduled under the UN Conventions.

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7 OJ L 335, 11.11.2004, p. 8.
8 OJ L 167, 25.06.1997, p. 1.
9 OJ L 127, 10.05.2005, p. 32.

(4) New psychoactive substances, which imitate the effects of substances scheduled under the UN Conventions, are emerging frequently and are spreading fast in the Union. Certain new psychoactive substances pose severe health, social and safety risks, as ascertained by *[Regulation (EU) No …/… on new psychoactive substances]*. Under that Regulation, measures may be taken to prohibit the production, manufacture, making available on the market including importation to the Union, transport, and exportation from the Union of new psychoactive substances posing severe health, social and safety risks. To effectively reduce the availability of new psychoactive substances that pose severe risks to individuals and society, and to deter trafficking in those substances across the Union, as well as the involvement of criminal organisations, permanent market restriction measures adopted under that Regulation should be underpinned by criminal law provisions.

(5) The new psychoactive substances subjected to permanent market restriction pursuant to *[Regulation (EU) No …/… on new psychoactive substances]* should, therefore, be covered by the Union criminal law provisions on illicit drug trafficking. This would also help streamline and clarify the Union legal framework, as the same criminal law provisions would apply to substances covered by the UN Conventions and to the most harmful new psychoactive substances. The definition of 'drug' in the Framework Decision 2004/757/JHA should, therefore, be amended.

(6) In order to swiftly address the emergence and spread of harmful new psychoactive substances in the Union, Member States should apply the provisions of the Framework Decision 2004/757/JHA to new psychoactive substances posing severe health, social and safety risks within twelve months from their submission to permanent market restriction under *[Regulation (EU) No …/… on new psychoactive substances]*.

(7) Since the objective of this Directive, namely to extend the application of the Union criminal law provisions that apply to illicit drug trafficking to new psychoactive substances posing severe health, social and safety risks, cannot be sufficiently achieved by the Member States acting alone, and can therefore be better achieved at the Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on the European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve its objective.

(8) This Directive respects the fundamental rights and observes the principles recognised by the Charter of Fundamental Rights of the European Union, and notably the right to an effective remedy and to a fair trial, the presumption of innocence and the right of defence, the right not to be tried or punished twice in criminal proceedings for the same criminal offence and the principles of legality and proportionality of criminal offences.

(9) [In accordance with Article 3 of the Protocol (No 21) on the position of the United Kingdom and Ireland in respect of the area of freedom, security and justice, annexed to the Treaty on the European Union and to the Treaty on the Functioning of the European Union, the United Kingdom and Ireland have notified their wish to take part in the adoption and application of this Directive.]

AND/OR

(10) [In accordance with Articles 1 and 2 of the Protocol (No 21) on the position of the United Kingdom and Ireland in respect of the area of freedom, security and justice, annexed to the Treaty on the European Union and to the Treaty on the Functioning of

the European Union, and without prejudice to Article 4 of that Protocol, the United Kingdom and Ireland are not taking part in the adoption of this Directive and are not bound by or subject to its application.]

(11) In accordance with Articles 1 and 2 of the Protocol (No 22) on the position of Denmark annexed to the Treaty on the European Union and to the Treaty on the Functioning of the European Union, Denmark is not taking part in the adoption of this Directive and is therefore not bound by or subject to its application.

(12) Framework Decision 2004/757/JHA should therefore be amended accordingly,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Framework Decision 2004/757/JHA is amended as follows:

(1) In Article 1, point 1 is replaced by the following:

"'drug' means:

(a) any of the substances covered by the 1961 United Nations Single Convention on Narcotic Drugs (as amended by the 1972 Protocol) and the 1971 United Nations Convention on Psychotropic Substances;

(b) any of the substances listed in the Annex;

(c) any new psychoactive substance posing severe health, social and safety risks, subjected to permanent market restriction on the basis of *[Article 13(1) of Regulation (EU) No …/… on new psychoactive substances]*;"

(2) In Article 9, the following paragraphs 3 and 4 are added:

"3. In respect of new psychoactive substances subjected to permanent market restriction on the basis of [*Article 13(1) of Regulation (EU) No …/… on new psychoactive substances*], Member States shall bring into force the laws, regulations and administrative provisions necessary to apply the provisions of this Framework Decision to these new psychoactive substances within twelve months after entry into force of the permanent market restriction. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Framework Decision or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

4. By [*5 years after entry into force of this Directive and every 5 years thereafter*], the Commission shall assess the extent to which the Member States have taken the necessary measures to comply with this Framework Decision and publish a report."

(3) An Annex, as set out in the Annex to this Directive, is added.

Article 2

Transposition

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by [*twelve months after entry into force*] at the latest. They shall forthwith communicate to the Commission the text of those provisions.

When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made.

Article 3

Entry into force

This Directive shall enter into force on [*the same day as entry into force of Regulation (EU) No …/… on new psychoactive substances*].

Article 4

Addressees

This Directive is addressed to the Member States in accordance with the Treaties.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

ANNEX

List of substances referred to in point (1)(b) of Article 1

(a) P-Methylthioamphetamine or 4-Methylthioamphetamine, as referred to in Council Decision 1999/615/JHA of 13 September 1999 defining 4-MTA as a new synthetic drug which is to be made subject to control measures and criminal penalties[10].

(b) Paramethoxymethylamphetamine or N-methyl-1-(4-methoxyphenyl)-2-aminopropane, as referred to in Council Decision 2002/188/JHA of 28 February 2002 concerning control measures and criminal sanctions in respect of the new synthetic drug PMMA[11].

(c) 2,5-dimethoxy-4-iodophenethylamine, 2,5-dimethoxy-4-ethylthiophenethylamine, 2,5-dimethoxy-4-(n)-propylthiophenethylamine and 2,4,5-trimethoxyamphetamine, as referred to in Council Decision 2003/847/JHA of 27 November 2003 concerning control measures and criminal sanctions in respect of the new synthetic drugs 2C-I, 2C-T-2, 2C-T-7 and TMA-2[12].

(d) 1-benzylpiperazine or 1-benzyl-1,4-diazacyclohexane or N-benzylpiperazine or benzylpiperazine as referred to in Council Decision 2008/206/JHA of 3 March 2008 on defining 1-benzylpiperazine (BZP) as a new psychoactive substance which is to be made subject to control measures and criminal provisions[13].

(e) 4-methylmethcathinone, as referred to in Council Decision 2010/759/EU of 2 December 2010 on submitting 4-methylmethcathinone (mephedrone) to control measures[14].

(f) 4-methylamphetamine, as referred to in Council Decision 2013/129/EU of 7 March 2013 on subjecting 4-methylamphetamine to control measures[15].

(g) 5-(2-aminopropyl)indole, as referred to in [*Council Decision 2013/…/JHA of … on subjecting 5-(2-aminopropyl) indole to control measures*[16]].

10 OJ L 244, 16.09.1999, p.1.
11 OJ L 063, 06.03.2002, p. 14.
12 OJ L 321, 6.12.2003, p. 64.
13 OJ L 63, 7.03.2008, p. 45.
14 OJ L 322, 8.12.2010, p. 44.
15 OJ L 72, 15.03.2013, p. 11.
16 OJ L […], […], p. […].

(Acts adopted under Title VI of the Treaty on European Union)

COUNCIL DECISION 2005/387/JHA

of 10 May 2005

on the information exchange, risk-assessment and control of new psychoactive substances

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Articles 29, 31(1)(e) and 34 (2)(c) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament [1],

Whereas:

(1) The particular dangers inherent in the development of psychoactive substances require rapid action by the Member States.

(2) When new psychoactive substances are not brought within the scope of criminal law in all Member States, problems may arise in cooperation between the judicial authorities and law enforcement agencies of Member States owing to the fact that the offence or offences in question are not punishable under the laws of both the requesting and the requested State.

(3) The European Union Action Plan on Drugs 2000-2004 provided for the Commission to organise an appropriate assessment of the Joint Action of 16 June 1997 concerning the information exchange, risk assessment and the control of new synthetic drugs [2] (herineafter 'the Joint Action') taking into account the external evaluation commissioned by the European Monitoring Centre on Drugs and Drug Addiction (hereinafter 'the EMCDDA') of the early warning system. The assessment showed that the Joint Action had fulfilled its expectations. Nevertheless, the outcome of the assessment made it clear that the Joint Action was in need of reinforcement and reorientation. In particular, its main objective, the clarity of its procedures and definitions, the transparency of its operation, and the relevance of its scope had to be redefined. The Communication from the Commission to the European Parliament and the Council on the mid-term evaluation of the EU Action Plan on Drugs (2000-2004) indicated that changes to the legislation would be introduced in order to enhance action against synthetic drugs. The mechanism as established by the Joint Action should therefore be adapted.

(4) New psychoactive substances can be harmful to health.

(5) The new psychoactive substances covered by this Decision may include medicinal products as defined in Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to veterinary medicinal products [3] and in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use [4].

(6) The information exchange under the early warning system, established under the Joint Action, has proved to be a valuable asset to the Member States.

(7) Nothing in this Decision should prevent Member States from exchanging information, within the European Information Network on Drugs and Drug Addiction (hereinafter 'the Reitox network'), on emerging trends in new uses of existing psychoactive substances which may pose a potential risk to public health, as well as information on possible public health related measures, in accordance with the mandate and procedures of the EMCDDA.

(8) No deterioration of either human or veterinary health care as a result of this Decision will be permitted. Substances of established and acknowledged medical value are therefore excluded from control measures based on this Decision. Suitable regulatory and public health related measures should be taken for substances of established and acknowledged medical value that are being misused.

[1] Opinion delivered on 13 January 2004 (not yet published in the Official Journal).

[2] OJ L 167, 25.6.1997, p. 1.

[3] OJ L 311, 28.11.2001, p. 1. Directive as last amended by Directive 2004/28/EC (OJ L 136, 30.4.2004, p. 58).

[4] OJ L 311, 28.11.2001, p. 67. Directive as last amended by Directive 2004/27/EC (OJ L 136, 30.4.2004, p. 34).

(9) In addition to what is provided for under the pharmacovigilance systems as defined in Directive 2001/82/EC and in Directive 2001/83/EC, the exchange of information on abused or misused psychoactive substances needs to be reinforced and appropriate cooperation with the European Medicines Agency (hereinafter 'EMEA') ensured. The United Nations Commission on Narcotic Drugs (hereinafter 'CND') Resolution 46/7 'Measures to promote the exchange of information on new patterns of drug use and on psychoactive substances consumed', provides a useful framework for action by the Member States.

(10) The introduction of deadlines into every phase of the procedure established by this Decision should guarantee that the instrument can react swiftly and enhances its ability to provide a quick-response mechanism.

(11) The Scientific Committee of the EMCDDA has a central role in the assessment of the risks associated with a new psychoactive substance, it will for the purpose of this Decision be extended to include experts from the Commission, Europol and the EMEA, and experts from scientific fields not represented, or not sufficiently represented, in the Scientific Committee of the EMCDDA.

(12) The extended Scientific Committee that assesses the risks associated with new psychoactive substances should remain a concise technical body of experts, capable of assessing effectively all risks associated with a new psychoactive substance. Therefore the extended Scientific Committee should be kept to a manageable size.

(13) Since the objectives of the proposed action, namely to bring about an exchange of information, a risk-assessment by a scientific committee and an EU-level procedure for bringing notified substances under control, cannot be sufficiently achieved by the Member States and can therefore, by reason of the effects of the envisaged action, be better achieved at European Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty. In accordance with the principle of proportionality as set out in that Article, this Decision does not go what is beyond what is necessary in order to achieve those objectives

(14) In conformity with Article 34(2)(c) of the Treaty, measures based upon this Decision can be taken by qualified majority as these measures are necessary to implement this Decision.

(15) This Decision respects fundamental rights and observes the principles recognised by Article 6 of the Treaty and reflected in the Charter of Fundamental Rights of the European Union,

HAS DECIDED AS FOLLOWS:

Article 1

Subject matter

This Decision establishes a mechanism for a rapid exchange of information on new psychoactive substances. It takes note of information on suspected adverse reactions to be reported under the pharmacovigilance system as established by Title IX of Directive 2001/83/EC.

This Decision also provides for an assessment of the risks associated with these new psychoactive substances in order to permit the measures applicable in the Member States for control of narcotic and psychotropic substances to be applied also to new psychoactive substances.

Article 2

Scope

This Decision applies to substances not currently listed in any of the schedules to:

(a) the 1961 United Nations Single Convention on Narcotic Drugs, that may pose a comparable threat to public health as the substances listed in Schedule I or II or IV thereof, and

(b) the 1971 United Nations Convention on Psychotropic Substances, that may pose a comparable threat to public health as the substances listed in Schedule I or II or III or IV thereof.

This Decision relates to end-products, as distinct from precursors in respect of which Council Regulation (EEC) No 3677/90 of 13 December 1990 laying down measures to be taken to discourage the diversion of certain substances to the illicit manufacture of narcotic drugs and psychotropic substances [1], and Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors [2] provide for a Community regime.

Article 3

Definitions

For the purpose of this Decision the following definitions shall apply:

(a) 'new psychoactive substance' means a new narcotic drug or a new psychotropic drug in pure form or in a preparation;

[1] OJ L 357, 20.12.1990, p. 1. Regulation as last amended by Commission Regulation (EC) No 1232/2002 (OJ L 180, 10.7.2002, p. 5).
[2] OJ L 47, 18.2.2004, p. 1.

(b) 'new narcotic drug' means a substance in pure form or in a preparation, that has not been scheduled under the 1961 United Nations Single Convention on Narcotic Drugs, and that may pose a threat to public health comparable to the substances listed in Schedule I, II or IV;

(c) 'new psychotropic drug' means a substance in pure form or in a preparation that has not been scheduled under the 1971 United Nations Convention on Psychotropic Substances, and that may pose a threat to public health comparable to the substances listed in Schedule I, II, III or IV;

(d) 'marketing authorisation' means a permission to place a medicinal product on the market, granted by the competent authority of a Member State, as required by Title III of Directive 2001/83/EC (in the case of medicinal products for human use) or Title III of Directive 2001/82/EC (in the case of veterinary medicinal products) or a marketing authorisation granted by the European Commission under Article 3 of Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency ([1]);

(e) 'United Nations system' means the World Health Organisation (WHO), the Commission on Narcotic Drugs (CND) and/or the Economic and Social Committee acting in accordance with their respective responsibilities as described in Article 3 of the 1961 United Nations Single Convention on Narcotic Drugs or in Article 2 of the 1971 United Nations Convention on Psychotropic Substances;

(f) 'preparation' means a mixture containing a new psychoactive substance;

(g) 'Reporting Form' means a structured form for notification of a new psychoactive substance and/or of a preparation containing a new psychoactive substance agreed between the EMCDDA/Europol and their respective networks in the Member States' Reitox and the Europol National Units.

Article 4

Exchange of information

1. Each Member State shall ensure that its Europol National Unit and its representative in the Reitox network provide information on the manufacture, traffic and use, including supplementary information on possible medical use, of new psychoactive substances and of preparations containing new psychoactive substances, to Europol and the EMCDDA, taking into account the respective mandates of these two bodies.

([1]) OJ L 136, 30.4.2004, p. 1.

Europol and the EMCDDA shall collect the information received from Member States through a Reporting Form and communicate this information immediately to each other and to the Europol National Units and the representatives of the Reitox network of the Member States, the Commission, and to the EMEA.

2. Should Europol and the EMCDDA consider that the information provided by a Member State on a new psychoactive substance does not merit the communication of information as described in paragraph 1, they shall inform the notifying Member State immediately thereof. Europol and the EMCDDA shall justify their decision to the Council within six weeks.

Article 5

Joint Report

1. Where Europol and the EMCDDA, or the Council, acting by a majority of its members, consider that the information provided by the Member State on a new psychoactive substance merits the collection of further information, this information shall be collated and presented by Europol and the EMCDDA in the form of a Joint Report (hereinafter the 'Joint Report'). The Joint Report shall be submitted to the Council, the EMEA and the Commission.

2. The Joint Report shall contain:

(a) a chemical and physical description, including the name under which the new psychoactive substance is known, including, if available, the scientific name (International Non-proprietary Name);

(b) information on the frequency, circumstances and/or quantities in which a new psychoactive substance is encountered, and information on the means and methods of manufacture of the new psychoactive substance;

(c) information on the involvement of organised crime in the manufacture or trafficking of the new psychoactive substance;

(d) a first indication of the risks associated with the new psychoactive substance, including the health and social risks, and the characteristics of users;

(e) information on whether or not the new substance is currently under assessment, or has been under assessment, by the UN system;

(f) the date of notification on the Reporting Form of the new psychoactive substance to the EMCDDA or to Europol;

(g) information on whether or not the new psychoactive substance is already subject to control measures at national level in a Member State;

(h) as far as possible, information will be made available on:

(i) the chemical precursors that are known to have been used for the manufacture of the substance,

(ii) the mode and scope of the established or expected use of the new substance,

(iii) any other use of the new psychoactive substance and the extent of such use, the risks associated with this use of the new psychoactive substance, including the health and social risks.

3. The EMEA shall submit to Europol and the EMCDDA the following information on whether in the European Union or in any Member State:

(a) the new psychoactive substance has obtained a marketing authorisation;

(b) the new psychoactive substance is the subject of an application for a marketing authorisation;

(c) a marketing authorisation that had been granted in respect of the new psychoactive substance has been suspended.

Where this information relates to marketing authorisations granted by Member States, these Member States shall provide the EMEA with this information if so requested by it.

4. Member States shall provide the details referred to under paragraph 2 within six weeks from the date of notification on the Reporting Form as set out in Article 4(1).

5. The Joint Report shall be submitted no more than four weeks after the date of receipt of the information from Member States and the EMEA. The Report shall be submitted by Europol or the EMCDDA, as appropriate, in accordance with Article 5(1) and (2).

Article 6

Risk assessment

1. The Council, taking into account the advice of Europol and the EMCDDA, and acting by a majority of its members, may request that the risks, including the health and social risks, caused by the use of, the manufacture of, and traffic in, a new psychoactive substance, the involvement of organised crime and possible consequences of control measures, be assessed in accordance with the procedure set out in paragraphs 2 to 4, provided that at least a quarter of its members or the Commission have informed the Council in writing that they are in favour of such an assessment. The Member States or the Commission shall inform the Council thereof as soon as possible, but in any case within four weeks of receipt of the Joint Report. The General Secretariat of the Council shall notify this information to the EMCDDA without delay.

2. In order to carry out the assessment, the EMCDDA shall convene a special meeting under the auspices of its Scientific Committee. In addition, for the purpose of this meeting the Scientific Committee may be extended by a further five experts at most, to be designated by the Director of the EMCDDA, acting on the advice of the Chairperson of the Scientific Committee, chosen from a panel of experts proposed by Member States and approved every three years by the Management Board of the EMCDDA. Such experts will be from scientific fields that are not represented, or not sufficiently represented, in the Scientific Committee, but whose contribution is necessary for the balanced and adequate assessment of the possible risks, including health and social risks. Furthermore, the Commission, Europol and the EMEA shall each be invited to send a maximum of two experts.

3. The risk assessment shall be carried out on the basis of information to be provided to the scientific Committee by the Member States, the EMCDDA, Europol, the EMEA, taking into account all factors which, according to the 1961 United Nations Single Convention on Narcotic Drugs or the 1971 United Nations Convention on Psychotropic Substances, would warrant the placing of a substance under international control.

4. On completion of the risk assessment, a report (hereinafter the 'Risk Assessment Report') shall be drawn up by the Scientific Committee. The Risk Assessment Report shall consist of an analysis of the scientific and law enforcement information available, and shall reflect all opinions held by the members of the Committee. The Risk Assessment Report shall be submitted to the Commission and Council by the chairperson of the Committee, on its behalf, within a period of twelve weeks from the date of the notification by the General Secretariat of the Council to the EMCDDA referred to in paragraph 1.

The Risk Assessment Report shall include:

(a) the physical and chemical description of the new psychoactive substance and its mechanisms of action, including its medical value;

(b) the health risks associated with the new psychoactive substance;

(c) the social risks associated with the new psychoactive substance;

(d) information on the level of involvement of organised crime and information on seizures and/or detections by the authorities, and the manufacture of the new psychoactive substance;

(e) information on any assessment of the new psychoactive substance in the United Nations system;

(f) where appropriate, a description of the control measures that are applicable to the new psychoactive substance in the Member States;

(g) options for control and the possible consequences of the control measures, and

(h) the chemical precursors that are used for the manufacture of the substance.

Article 7

Circumstances where no risk assessment is carried out

1. No risk assessment shall be carried out in the absence of a Europol/EMCDDA Joint Report. Nor shall a risk assessment be carried out where the new psychoactive substance concerned is at an advanced stage of assessment within the United Nations system, namely once the WHO expert committee on drug dependence has published its critical review together with a written recommendation, except where there is significant new information that is relevant in the framework of this Decision.

2. Where the new psychoactive substance has been assessed within the United Nations system, but it has been decided not to schedule the new psychoactive substance under the 1961 Single Convention on Narcotic Drugs or the 1971 Convention on Psychotropic Substances, a risk assessment shall be carried out only if there is significant new information that is relevant in the framework of this Decision.

3. No risk assessment shall be carried out on a new psychoactive substance if:

(a) the new psychoactive substance is used to manufacture a medicinal product which has been granted a marketing authorisation; or,

(b) the new psychoactive substance is used to manufacture a medicinal product for which an application has been made for a marketing authorisation or,

(c) the new psychoactive substance is used to manufacture a medicinal product for which a marketing authorisation has been suspended by a competent authority.

Where the new psychoactive substance falls into one of the categories listed under the first subparagraph, the Commission, on the basis of data collected by EMCDDA and Europol, shall assess with the EMEA the need for further action, in close cooperation with the EMCDDA and in accordance with the mandate and procedures of the EMEA.

The Commission shall report to the Council on the outcome.

Article 8

Procedure for bringing specific new psychoactive substances under control

1. Within six weeks from the date on which it received the Risk Assessment Report, the Commission shall present to the Council an initiative to have the new psychoactive substance subjected to control measures. If the Commission deems it is not necessary to present an initiative on submitting the new psychoactive substance to control measures, within six weeks from the date on which it received the Risk Assessment Report, the Commission shall present a report to the Council explaining its views.

2. Should the Commission deem it not necessary to present an initiative on submitting the new psychoactive substance to control measures, such an initiative may be presented to the Council by one or more Member States, preferably not later than six weeks from the date on which the Commission presented its report to the Council.

3. The Council shall decide, by qualified majority and acting on an initiative presented pursuant to paragraph 1 or 2, on the basis of Article 34(2) (c) of the Treaty, whether to submit the new psychoactive substance to control measures.

Article 9

Control measures taken by Member States

1. If the Council decides to submit a new psychoactive substance to control measures, Member States shall endeavour to take, as soon as possible, but no later than one year from the date of that decision, the necessary measures in accordance with their national law to submit:

(a) the new psychotropic drug to control measures and criminal penalties as provided under their legislation by virtue of their obligations under the 1971 United Nations Convention on Psychotropic Substances;

(b) the new narcotic drug to control measures and criminal penalties as provided under their legislation by virtue of their obligations under the 1961 United Nations Single Convention on Narcotic Drugs.

2. Member States shall report the measures taken to both the Council and the Commission as soon as possible after the relevant decision has been taken. Thereafter this information shall be communicated to the EMCDDA, Europol, the EMEA, and the European Parliament.

3. Nothing in this Decision shall prevent a Member State from maintaining or introducing on its territory any national control measure it deems appropriate once a new psychoactive substance has been identified by a Member State.

Article 10

Annual report

The EMCDDA and Europol shall report annually to the European Parliament, the Council and the Commission on the implementation of this Decision. The report will take into account all aspects required for an assessment of the efficacy and achievements of the system created by this Decision. The Report shall, in particular, include experience relating to coordination between the system set out in this Decision and the pharmacovigilance system.

Article 11

Pharmacovigilance system

Member States and the EMEA shall ensure an appropriate exchange of information between the mechanism set up by means of this Decision and the pharmacovigilance systems as defined and established under Title VII of Directive 2001/82/EC and Title IX of Directive 2001/83/EC.

Article 12

Repeal

The Joint Action on New Synthetic Drugs of 16 June 1997 is hereby repealed. Decisions taken by the Council based on Article 5 of that Joint Action shall continue to be legally valid.

Article 13

Publication and taking effect

This Decision shall take effect on the day following that of its publication in the *Official Journal of the European Union*.

Done at Brussels, 10 May 2005.

For the Council
The President
J. KRECKÉ

EUROPEAN COMMISSION

Brussels, 24.1.2013
C(2013) 98 final

Lord Boswell
Chairman of the European Union
Select Committee
House of Lords
Palace of Westminster
UK-LONDON SW1A 0PW

Dear Lord Boswell,

The European Commission would like to thank the House of Lords for its Opinion on the evaluation of the EU Drugs Strategy 2005-2012, and apologizes for the delay in replying. Your Opinion includes an extensive assessment of the implementation of the Drugs Strategy over the past eight years, and provides food for thought for the development of the next EU Drugs Strategy, post 2013.

The Commission would like to make the following observations regarding the House of Lords' Opinion:

The EU Drugs Strategy 2005-2012

The Commission shares the view of the House of Lords concerning the value of the EU Drugs Strategy 2005-2012. The final report of the evaluation of the EU Drugs Strategy, financed by the European Commission and carried out by an external contractor (RAND Europe), which has recently been published[1], shows that the Strategy has clear added value for cooperation in the drugs policy field at EU level. The evaluation report shows that the strategy provides political guidance for Member States' drugs policies and has helped achieve convergence between national policies. Although direct impacts of the Strategy are difficult to identify due to the complexity of the implementation mechanisms and the necessity to translate its objectives into national responses, the available evidence suggests that the Strategy has had some success in aligning policies in the field of drug demand reduction, notably on harm reduction, that it is perceived by third countries and by international organizations as a 'model of good practice' and that it has helped achieve important gains in the field of information, research and evaluation of drugs policies.

New psychoactive substances

The Commission is planning to present new legislation on new psychoactive substances in 2013. As indicated in the Commission Communication 'Towards a stronger EU response to drugs'[2], the new legislation would seek to enhance the monitoring and risk assessment of

[1] The final evaluation report is added in the annex to this response

[2] COM(2011) 689/2

substances, to provide more sustainable responses to the emergence of these substances, including through alternative control options, and to enable a swifter response to the spread of substances, including, possibly, through temporary bans on substances that pose immediate risks. The Commission will explore, inter alia, ways to address groups of substances, notwithstanding the need to determine scientifically the harmfulness to health of each individual substance, through an evidence-based approach. The analogue approach to new psychoactive substances, as proposed by the House of Lords, poses legal issues in certain EU Member States and may have undesirable effects, among others regarding legal certainty for EU citizens and legitimate economic activities involving these substances.

Harm reduction

Over the past 15 years, the Commission has promoted and supported a wide range of initiatives, projects and proposals in the field of drug-demand reduction. The evaluation of the EU Drugs Strategy shows that some progress has been made, but that drug demand reduction measures based on the best available evidence do not seem to be applied commonly across the board in all Member States and by all services within Member States. As indicated in its Communication, the Commission intends to present a proposal on EU minimum quality standards in the field of drug demand reduction, to promote evidence-based prevention, treatment and harm reduction services in the Member States.

Drug trafficking

The effect of displacement of drug trafficking, referred to in your Opinion, can, in the Commission's view, only be effectively tackled by improving cooperation and coordination at EU level, as envisaged by the EU Drug Strategy and its implementing Action Plans, and by making full use of all other EU instruments in the field of drug demand and drug supply reduction.

Countering drug trafficking is an important element of a number of the Commission's initiatives aiming at combatting organised crime, including the new Europol legal basis, the Communication on the Exchange of Information Model and actions on border control through the implementation of the Internal Security Strategy. The involvement of transnational networks and the existence of transnational routes in drug-trafficking require a coordinated approach. The Commission promotes this under the aegis of COSI, where 4 of the 8 priorities retained for the policy cycle 2011-2013 concern drugs trafficking.

Under the future Multiannual Financial Framework 2014-2020, the Commission has proposed funding programmes, presently under negotiation by the co-legislators, which aim to provide comprehensive funding for all aspects of drug policies, including drug trafficking. The Justice Programme and the Internal Security Fund would ensure that funding is available for projects related to drug-trafficking, while the Justice programme would also fund all horizontal drug policies issues. In particular it should be noted that the Internal Security Fund, would, for the first time, allow the financing of activities against drug trafficking in third countries key to the internal security of EU Member States.

The European Monitoring Centre for Drugs and Drugs Addition (EMCDDA)

Both the Opinion of the House of Lords and the external evaluation of the EU Drugs Strategy 2005-2012 have found that the investments made in data collection, monitoring, information

and evaluation in the field of drugs have paid off. The work of the EMCDDA and that of the network of Reitox National Focal Points on drugs has provided the EU with high quality data on the drugs situation. A report on the external evaluation of the EMCDDA, covering the period 2006-2012, will be published soon.

The Commission takes note of the request of the EU Committee to maintain the budget of the EMCDDA in the next few years at adequate levels. The Commission has concerns about the impact of the various budget cuts in the Member States on the funding of the Reitox National Focal Points on drugs. It is essential that Member States continue to fund the provision of timely, adequate and reliable data from national authorities to the EMCDDA.

Statistics and threat assessment

Regarding data in the field of drug supply, the Commission has been the driving force behind the development and improvement of supply side data in the field of drugs, which is necessary for a better understanding of the drugs problem and of the drugs markets. Building on the technical expertise developed at the EMCDDA, the Commission, with the support of EMCDDA and Europol, will present key indicators for the monitoring of drugs markets, drug-related crime and drug supply reduction. These should help improve the effectiveness of responses in the area of drug supply, by enhancing analysis of the different trends and interactions between markets, crimes and the effectiveness of law enforcement responses. The Commission set out its strategy for the development of key indicators on drug markets, drug-related crime and drug supply reduction in a Commission Staff Working Document[3] from October 2010. Furthermore, at the beginning of 2013, a targeted drug report encompassing available information on all illicit drug markets, including a comprehensive overview of the criminal chain, including market analysis and future trends, will be published. It will also contribute to the EU policy cycle for organised and serious international crime.

Research

Under the current EU Drug Action Plan, the Commission has developed various activities to support research in the field of drugs. At the Commission's suggestion, the Horizontal Drugs Group organises an annual debate on priorities for drug-related research. In 2011, funding has been made available for a five-year, 10 million Euro research project on addiction, which covers all aspects of drug addiction. Cooperation on drugs research between Member States will receive a boost with the setting up of a European Research Area Network on illicit drugs (ERA NET), which is expected to start its activities in 2013. On the basis of an EU-financed 23 million Euro research project on driving under influence of drugs, alcohol and medicines, which has been finalised in September 2011, the Commission is exploring possible actions at EU level to address drugged driving, with the aim of increasing road safety. Finally, the Commission has financed and continues to fund various research projects that further examine the functioning of the EU drugs market, the (un)intended impact of drug policies on safety and security as well as projects in the field of drug-demand reduction.

Institutional questions

As in Member States, drugs policy coordination can be organised in different ways. While in certain Member States (for instance in the UK), it is placed within the Interior Ministry, in

[3] Commission Staff Working Document on improving the collection of data on drug markets, drug-related crime and drug supply reduction measures in the European Union, SEC(2010) 1216 final, , 8.10.2010

others (including Germany, the Netherlands and Denmark), it is situated in the Health Ministry. On the other hand, in Spain, France and the Czech Republic, among others, drugs policy coordination is situated within an inter-ministerial coordination body where the various disciplines come together.

Several Commission Directorates General are involved in the elaboration and implementation of the Commission's drugs policy, in order to cover all its aspects. As the Commission is a collegial body, they work closely together, each within their relevant mandate and field of expertise. The Directorate General for Justice is responsible for the overall coordination of drugs policy within the Commission and for ensuring, by working closely with other Directorates General, an integrated and balanced approach to drugs policy, addressing both drug demand and drug supply.

The Commission hopes that these clarifications address the issues raised in the Opinion of the House of Lords and looks forward to continuing our dialogue in the future.

Yours faithfully,

Maroš Šefčovič
Vice-President

European Monitoring Centre
for Drugs and Drug Addiction

New psychoactive substances in Europe

The market

Legal highs

Marketed in bright and attractive packaging. Sold openly in head/smart shops and online. Aimed at recreational users.

Research chemicals

Sold under the guise of being used for scientific research. Aimed at 'psychonauts' who explore the effects of psychoactive substances. Sold openly online.

Food supplements

Sold under the guise of being food or dietary supplements. Aimed at people wanting to enhance their body and mind. Sold openly in fitness shops and online.

Designer drugs

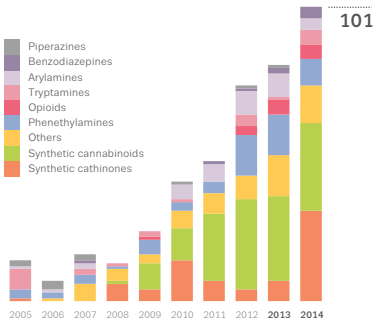
Passed off as drugs such as MDMA and heroin. Produced in clandestine labs by organised crime. Sold on illicit drug market by drug dealers.

Medicines

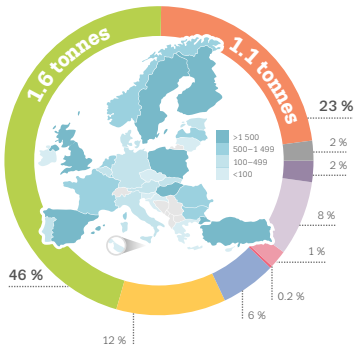
Medicines that are diverted from patients or illegally imported into Europe. Sold on illicit drug market by drug dealers.

New psychoactive substances (NPS) — at a glance

Number of NPS reported to the EU Early Warning System, 2005–14



Number of NPS seizures and proportion of seizures by category of substance, 2013

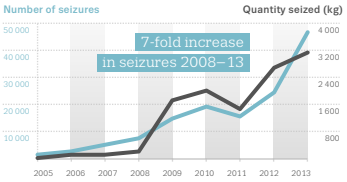


101 NPS reported for the first time in 2014

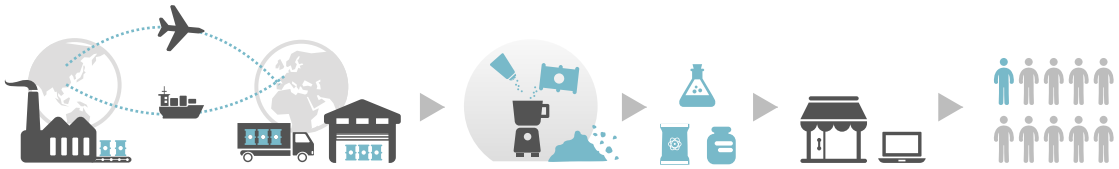
>450 NPS currently monitored

46 730 seizures amounting to more than 3.1 tonnes in Europe

Number of NPS seizures and quantity seized, 2005–13



From synthesis to consumer



Chemical companies based in China and India synthesise NPS in bulk quantity

Shipped by air or sea to Europe

Processed and packaged into legal highs, research chemicals and food supplements

Sold openly in head/smart shops and online

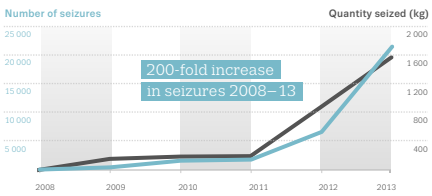
8 % of young adults have used NPS in their life (Eurobarometer)

Synthetic cannabinoids

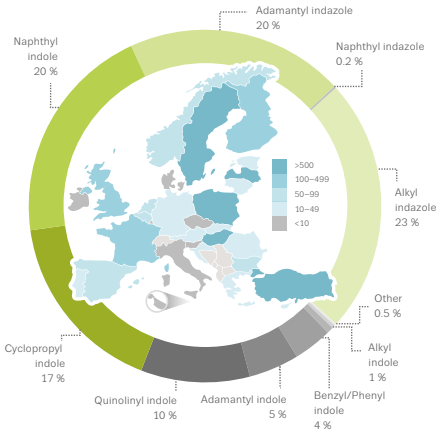
Sold as 'legal' replacements for cannabis

21 495 seizures amounting to almost 1.6 tonnes in 2013

Number of synthetic cannabinoid seizures and quantity seized, 2008–13



Number of synthetic cannabinoid seizures and proportion of seizures by sub-category, 2013



EU Early Warning System

Since 1997, the EMCDDA has played a central role in Europe's **response to new psychoactive substances**. Its main responsibilities in this field are to operate the EU Early Warning System, with its partner Europol, and to undertake risk assessments of new substances when necessary. The EU Early Warning System works by collecting information on the appearance of new substances from the **28 EU Member States**, **Turkey** and **Norway**, and then monitoring them for signals of harm, allowing the EU to respond rapidly to emerging threats.

Synthetic cannabinoids (left panel) and **synthetic cathinones** (right) make up the largest groups of new psychoactive substances monitored by the EMCDDA and, respectively, reflect the demand for cannabis and stimulants in Europe. However, the EMCDDA also monitors many new substances that come from a range of other groups, including **phenethylamines**, **opioids**, **tryptamines**, **benzodiazepines**, **arylalkylamines** and **piperazines**. All these substances require monitoring in order to identify signals of serious harms as early as possible. Opioids, for example, are of special concern for public health because they pose a very high risk of overdose and death. During 2014, serious harms that required urgent attention led to **16 public health alerts** being issued by the EMCDDA, while **6 new substances** — 25I-NBOMe, AH-7921, methoxetamine, MDPV, 4,4'-DMAR and MT-45 — **required risk assessment** by the EMCDDA's Scientific Committee.

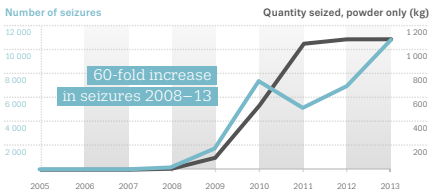
Read the full report at
emcdda.europa.eu/publications/2015/new-psychoactive-substances

Synthetic cathinones

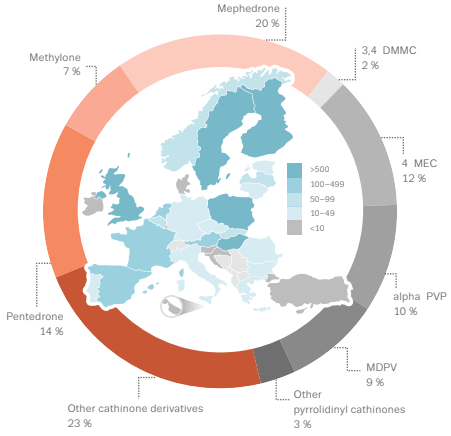
Sold as 'legal' replacements for stimulants

10 657 seizures amounting to more than 1.1 tonnes in 2013

Number of synthetic cathinone seizures and quantity seized, 2005–13



Number of synthetic cathinone seizures and proportion of seizures by substance, 2013



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European Monitoring Centre
for Drugs and Drug Addiction

New psychoactive substances in Europe

An update from the EU Early Warning System

March 2015




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Introduction

This short report provides an update on new psychoactive substances (NPS) in Europe for 2014. It is based on an analysis of information collected by the EU Early Warning System, which includes the 28 Member States of the European Union, Turkey and Norway (see opposite). The report highlights recent developments, including the growth of the market over the past few years, as illustrated by seizures by law enforcement and other indicators, as well as the growing number of serious harms that are being reported as a result. The seizure data collected on NPS presented in this report should be regarded as minimum estimates due to the lack of standardised reporting in this area. It should be noted that these data are not directly comparable with the data on established illicit drugs.

At a glance

Over the past five years or so there has been an unprecedented increase in the number, type and availability of new psychoactive substances in Europe. Continuing this trend, during 2014 a total of 101 new substances were reported for the first time to the EU Early Warning System: 31 cathinones, 30 cannabinoids, 9 phenethylamines, 5 opioids, 5 tryptamines, 4 benzodiazepines, 4 arylalkylamines and 13 substances that do not conform to the aforementioned groups (Figure 1). This brings the total number of substances being monitored by the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) to more than 450 — close to double the number of substances controlled under the United Nations international drug control conventions — with more than half of these being reported in the last three years alone.

Seizure data from law enforcement also confirm the growth and importance of this drug market. Between 2008 and 2013 there was a seven-fold increase in the number of seizures reported across Europe. In 2013 almost 47 000 seizures weighing more than 3.1 tonnes (Figures 2 and 3) were reported to the EU Early Warning System. Synthetic cannabinoids, which are sold as legal replacements for cannabis, accounted for the majority of these figures, with over 21 000 seizures weighing almost 1.6 tonnes. Synthetic cathinones, which are sold as legal replacements for stimulants such as amphetamine and MDMA, were the second largest group, with almost 11 000 seizures weighing more than 1.1 tonnes. Together, synthetic cannabinoids and cathinones accounted for almost 70 % of the total number of seizures and over 85 % of the weight seized during 2013 (Figure 3).

Key figures

101 new psychoactive substances reported for the first time in 2014

More than 450 new psychoactive substances currently being monitored by the EMCDDA

46 730 seizures of new psychoactive substances amounting to **more than 3.1 tonnes** in 2013

21 495 seizures of synthetic cannabinoids amounting to **almost 1.6 tonnes** in 2013

10 657 seizures of synthetic cathinones amounting to **more than 1.1 tonnes** in 2013

Seven-fold increase in reported seizures of new psychoactive substances between 2008 and 2013

299 different new psychoactive substances detected across Europe in 2013, including many of those seen in previous years

16 public health alerts issued in 2014

6 risk assessments in 2014

EU Early Warning System

Since 1997, the EMCDDA has played a central role in Europe's response to new psychoactive substances. Its main responsibilities in this field are to operate the EU Early Warning System, with its partner Europol, and to undertake risk assessments of new substances when necessary. The EU Early Warning System works by collecting information on the appearance of new substances from the 28 Member States, Turkey and Norway, and then monitoring them for signals of harm, allowing the EU to respond rapidly to emerging threats.

More information can be found on the EMCDDA website under Action on new drugs (emcdda.europa.eu/activities/action-on-new-drugs).

FIGURE 1

Number of new psychoactive substances reported to the EU Early Warning System, 2005–14

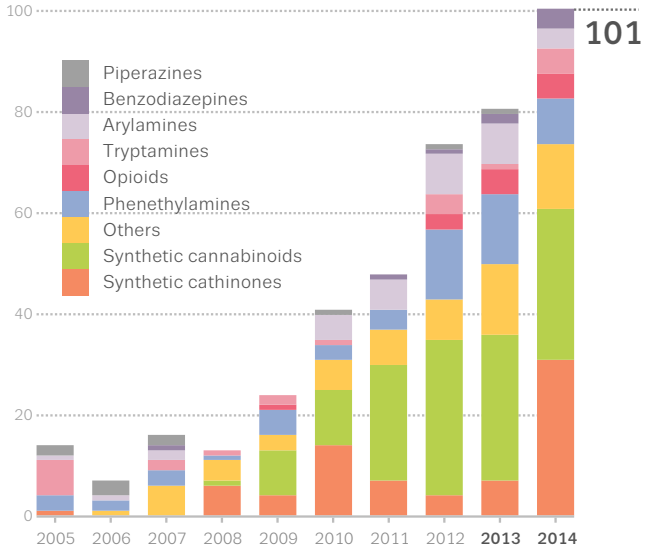
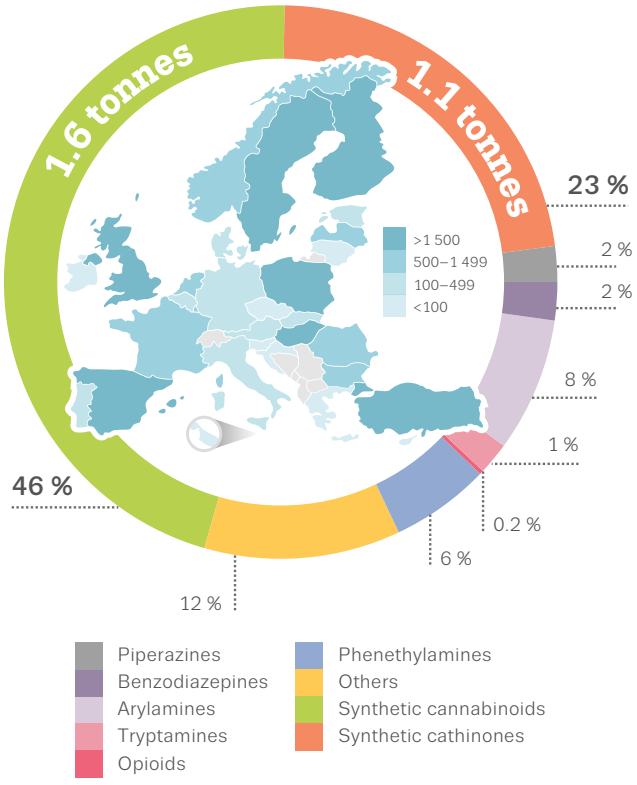


FIGURE 2

Number of seizures of new psychoactive substances per country (map) and proportion of seizures by category of substance (pie chart), 2013

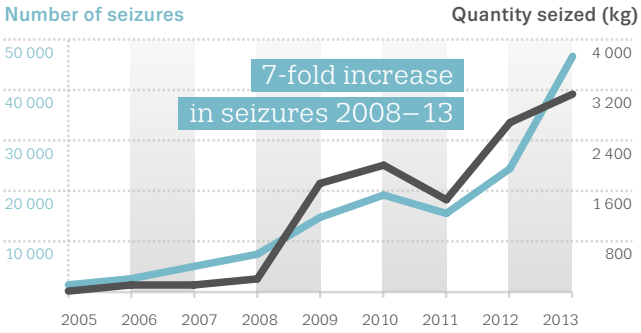


The growth in the market is also responsible for the increase in serious harms reported to the EMCDDA in recent years. Most of these concern non-fatal intoxications and deaths, but they also include broader social harms, such as those caused by high-risk drug users switching from injecting heroin to synthetic cathinones. During 2014 serious harms that required urgent attention led to 16 public health alerts being issued by the EMCDDA, while 6 new substances — 25I-NBOMe, AH-7921, methoxetamine, MDPV, 4,4'-DMAR and MT-45 — required risk assessment by the EMCDDA's Scientific Committee.

It is likely that the growth of the market in new psychoactive substances will continue to pose a range of challenges for public health and drug policy over the next few years. The major drivers of many of these are the speed at which they appear, their open sale, and that there is little or no information on their effects and harms. The stimulant 4,4'-DMAR and the opioid MT-45 are prime examples of the challenges faced, and demonstrate just how rapidly new psychoactive substances can move from obscurity to infamy by causing serious harm, with 59 deaths from these two substances reported in just one year. It is here that strong early warning systems can play a critical role in ensuring a timely response in order to protect public health.

FIGURE 3

Number of seizures of new psychoactive substances and quantity seized, 2005–13



Note: 2009 data exclude six tonnes of ketamine seized by one country, due to a lack of contextual information.

The market in new psychoactive substances

Until about a decade ago, only a handful of new psychoactive substances were reported each year in Europe. Most were sold on the illicit drug market, where they would usually be passed off as amphetamine or ecstasy. Some were specifically sold and sought after by name; others were sold as a new type of 'ecstasy'. They were produced in small amounts in amateur laboratories or on a commercial scale in clandestine laboratories by organised crime groups. These new psychoactive substances were called 'designer drugs'. Today, such drugs are still a part of Europe's drug market. Usually they appear as a result of the activities of organised crime. Sometimes this is because these criminal groups use an uncontrolled precursor chemical and end up making a new substance either accidentally or deliberately; this has been the case with MDMA manufacturers making PMMA, and, more recently, amphetamine manufacturers making 4-methylamphetamine (see 'Organised crime and the new psychoactive substances market'). At other times, new psychoactive substances can emerge from this route because established illicit drugs are in short supply.

The emergence of the 'legal highs' and 'research chemicals' markets, which took off in the mid-2000s with the stimulants BZP and methylone (soon followed by mephedrone), was largely responsible for the dramatic growth in the market in recent years, and for catapulting new psychoactive substances onto the global policy agenda. Key to the success of both these markets was the fact that they were sold openly in specialised 'head shops' in towns and cities as well as via the Internet.

One of the largest groups of 'legal high' products is smoking mixtures that contain synthetic cannabinoids, which are intended as legal replacements to cannabis. These products were first popularised in Europe by the 'Spice' brand in the mid-2000s which were sold as herbal smoking mixtures under the guise of incense or room odorisers, but since then hundreds of different products have been advertised and sold. These products have also been responsible for a large number of serious harms in recent years, exemplified by outbreaks of intoxications requiring emergency treatment in hospital in the United States and Russia.

Organised crime and the new psychoactive substances market

Although there is limited evidence of the involvement of organised crime groups in the market, it appears that this is an emerging threat. Perhaps in an effort to increase profits, clandestine synthetic production within the EU — normally associated with synthetic drugs such as amphetamine and MDMA — has been reported for new psychoactive substances in the past few years; while chemical precursors for producing these substances have also been seized by law enforcement agencies at clandestine synthetic drug production facilities.

Alongside the 'legal highs' and 'research chemicals' markets is a range of products containing new psychoactive substances that are sold under the guise of being 'food supplements' (Figure 4). These products are aimed not at recreational drug users but at the growing number of people looking to enhance their body and mind, allowing new psychoactive substances to reach new groups of consumers. One such substance that was detected for the first time in Europe in 2014 is adrafinil, which is a derivative of the medicine modafinil. This substance is sold as a 'nootropic' supplement with claims that it will increase energy, focus and memory.

New psychoactive substances can also emerge on the drug market from the diversion of medicines. In recent years this group has become more important as a result of the misuse of prescribed medicines within the EU and the growing illegal importation of medicines from outside the EU.

FIGURE 4

The new psychoactive substances market

Overall, the growth in the market of new psychoactive substances has only been possible because of the growing interconnectedness of the world, driven by globalisation and the Internet. Many of the new psychoactive substances that are destined for these markets are produced in bulk by chemical companies based in China and India, and shipped to Europe by air freight, where they are processed, packaged and then sold to consumers (see 'Processing and packaging "legal highs" in Europe'). In 2013 the EMCDDA's monitoring of Internet shops identified 651 selling 'legal highs' or 'research chemicals' to EU consumers. There are many more shops that sell food supplements that contain new psychoactive substances, but these are not routinely monitored by drug monitoring systems.

Processing and packaging 'legal highs' in Europe

In 2014, in one EU country police dismantled a processing and packaging facility that was producing a range of 'legal high' products, including smoking mixtures, which were intended as legal replacements for cannabis. The seizure included large quantities of the synthetic cannabinoid cumyl-5F-PINACA in liquid form; 1 tonne of non-processed herbal material sent from two other EU countries and Australia; acetone, propylene glycol, vegetable glycerine, various aromas and food colourants. At this facility the synthetic cannabinoid was mixed with acetone, sprayed onto plant material and then packaged as smoking mixtures using the 150 kg of empty printed foil bags sent from China.

Estimating the prevalence of use of new psychoactive substances is often a challenge, especially through general population surveys. One insight is provided by the 2014 Flash Eurobarometer, a survey of just over 13 000 young adults aged 15–24 in the EU Member States, which asked about the use of new psychoactive substances. It found that 8 % of respondents had used a new psychoactive substance at least once, with 3 % using them in the last year. The highest levels of use in the last year were in Ireland (9 %), Spain, France (both 8 %), and Slovenia (7 %), with the lowest reported by Malta and Cyprus (0 %). Most respondents who had used new substances in the last year either bought them from, or were given them by, a friend (68 %). Just over a quarter (27 %) bought them from a drug dealer, while 10 % purchased them from a specialised shop and 3 % bought them on the Internet (multiple answers were possible).

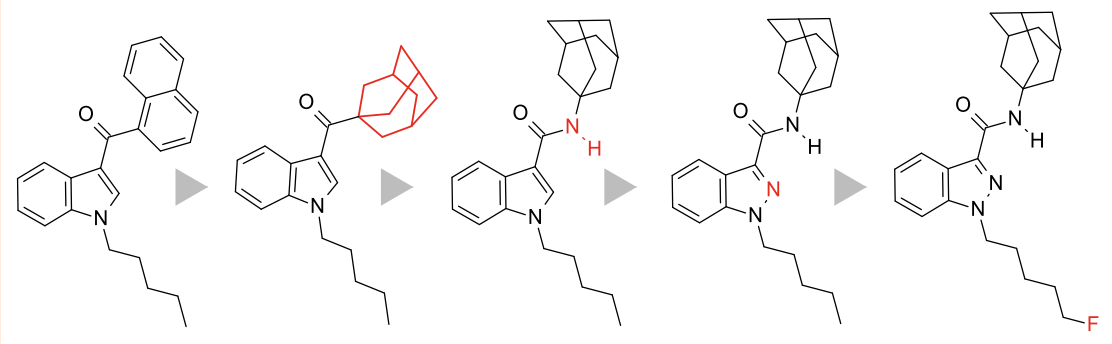
While the 101 new substances reported for the first time in 2014 to the EU Early Warning System are from a diverse number of chemical families with various pharmacological effects that span the range of drugs controlled under the UN International Drug Control Treaties, this report focuses on three groups: the synthetic cannabinoids and synthetic cathinones, which together are the largest group of new psychoactive substances that are monitored; and the opioids, many of which pose an especially serious risk to public health.

Synthetic cannabinoids

Synthetic cannabinoids were first detected in Europe towards the end of 2008. In 2014 a further 30 new synthetic cannabinoids were reported for the first time, bringing the total number reported to the EU Early Warning System to 134. This makes the synthetic cannabinoids the largest group of substances monitored by the EMCDDA, and reflects the overall demand for cannabis within Europe and the rapid pace by which manufacturers can produce and supply new cannabinoids in order to circumvent drug laws (Figure 5). The overall importance of these substances is also reflected in seizure data. In 2013 over 21 000 seizures were reported, comprising more than 40 % of the total number of seizures for new psychoactive substances (Figure 3). The total weight of the seizures in 2013 came to just under 1.6 tonnes (Figures 6 and 7); about 0.6 tonnes was seized as powder, often in bulk amounts; the remaining amount was often seized as plant material. These powders are used to manufacture 'legal high' products, and represent millions of doses; 10 cannabinoids accounted for approximately 90 % of the total weight of powders seized in 2013, with 39 other cannabinoids making up the remainder. Notable seizures of powders in 2013 include 182 kg of AM-2201, 115 kg of 5F-UR-144, and 114 kg of 5F-AKB48. Between 2008 and 2013 there has been a 200-fold increase in the number of seizures of synthetic cannabinoids.

FIGURE 5

Rapid replacement of synthetic cannabinoids on the European market



Substance	JWH-018	JWH-018 adamantyl derivative	JWH-018 adamantyl carboxamide (Apica)	AKB48 (Apinaca)	5F-AKB48
Year of first detection	2008	2011	2012	2012	2012
Number of seizures in 2013	162	8	98	404	3 362

FIGURE 6

Number of seizures of synthetic cannabinoids per country (map) and proportion of seizures by sub-category (pie chart), 2013

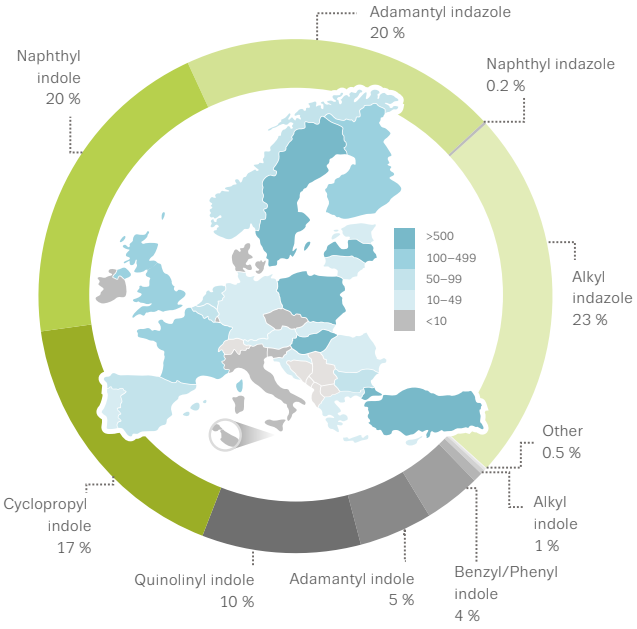


FIGURE 7

Number of synthetic cannabinoid seizures and quantity seized, 2008–13

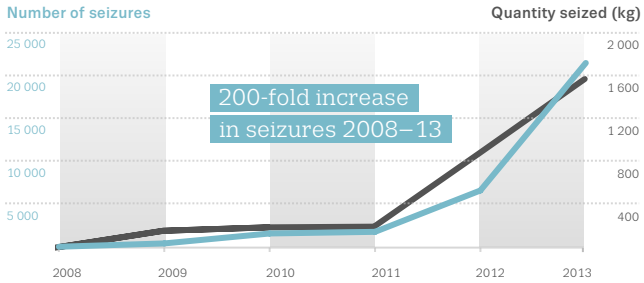


FIGURE 8

Number of seizures of synthetic cathinones per country (map) and proportion of seizures by substance (pie chart), 2013

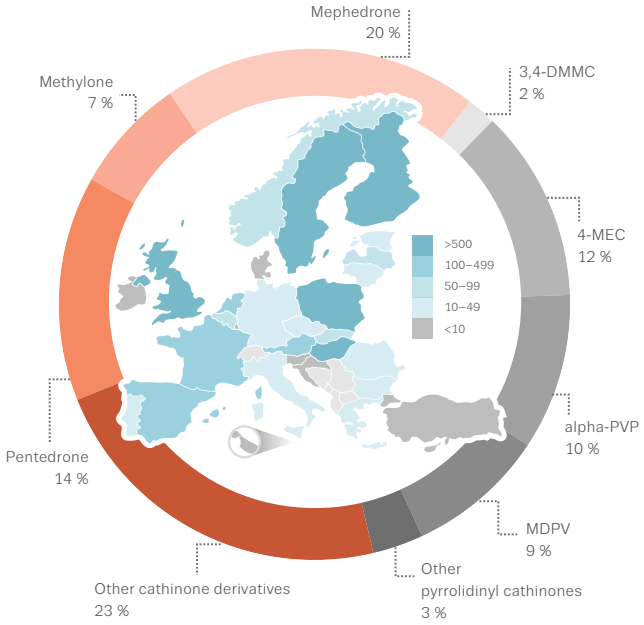
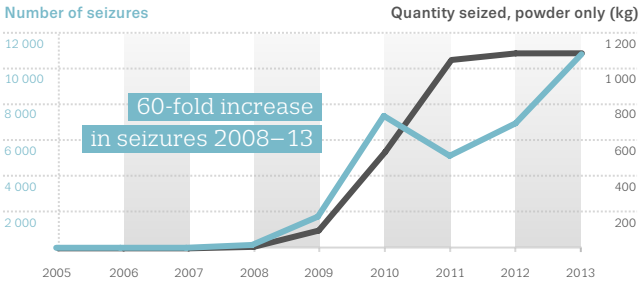


FIGURE 9

Number of synthetic cathinone seizures and quantity seized (powders), 2005–13



Synthetic cathinones

The large number of seizures of synthetic cathinones reflects the demand for stimulants in Europe, with many of them used as replacements for MDMA, amphetamine and cocaine. During 2014 some 31 synthetic cathinones were reported for the first time. This brings the total number of cathinones to 77, making them the second largest group of substances monitored by the EMCDDA. Almost 11 000 seizures of synthetic cathinones weighing more than 1.1 tonnes were made in Europe during 2013 (Figure 8). In terms of the main cathinones seized, 3-MMC (an isomer of the popular drug mephedrone) (341 kg), 4-MEC (201 kg), pentedrone (197 kg) and alpha-PVP (115 kg) accounted for almost 80 % of the total amount seized. Between 2008 and 2013 there has been a 60-fold increase in the number of seizures of synthetic cathinones (Figure 9).

Opioids

New opioids are of special concern for public health. This is because they are often highly potent and are sold as heroin to unsuspecting users, and thus pose a high risk of overdose and death. The fentanyls, for example, are a family of drugs that have caused hundreds of deaths in Europe and the United States since they first appeared as 'designer drugs' sold as 'synthetic heroin' in California in the late 1970s. During 2014 three of the five opioids reported to the EU Early Warning System were fentanyls. This includes two fentanyls that were seized at a clandestine laboratory in Europe and acetylfentanyl which has been linked to more than 14 deaths in the United States after it was sold as heroin.

But it is not just the fentanyls that pose risks to users. More than 40 deaths were reported to the EMCDDA within months of the detection of the opioids AH-7921 and MT-45 on the European drug market. These substances were both sold as 'research chemicals', with Internet shops based in Europe and China selling kilogram quantities of the drugs.

Monitoring and responding to serious harms

Alongside information on the appearance of new psychoactive substances on the market, a key function of the EU Early Warning System is to identify signals of serious harms and respond as necessary. This requires monitoring each of the more than 450 substances that have been reported so far. As the market has grown in recent years, the EMCDDA has also had to deal with a growing number of reports of serious harms, often related to acute toxicity leading to hospitalisation and deaths. The EMCDDA has responded to this challenge by working to strengthen the ability of the EU Early Warning System and its network to identify, report, understand and respond to such harms. One of the core activities in this respect is issuing public health alerts, which serve to alert the network on serious and urgent issues. Since 2005 the EMCDDA has issued 117 public health alerts, with more than 70 % of these issued in the last five years. During 2014 some 16 alerts were issued. These included alerts on 4,4'-DMAR and MT-45 after deaths within Europe were reported (both of these substances were risk assessed during 2014), and on synthetic cannabinoids such as 5F-PB-22, ADB-PINACA and MDMB-FUBINACA after media monitoring by the EMCDDA identified serious harms in countries outside Europe.

The risk assessments conducted by the EMCDDA's Scientific Committee are another core activity in responding to serious harms. Six risk assessments were conducted in 2014. These were: 25I-NBOMe, a substance with hallucinogenic properties that was being sold as LSD; AH-7921, an opioid with similar properties to morphine that was linked to 15 deaths over a short period of time; MDPV, a stimulant sold as a 'legal high' that was being sold as cocaine on the illicit market and injected by high-risk drug users; methoxetamine, which was sold as a legal replacement for the dissociative anaesthetic ketamine; 4,4'-DMAR, a stimulant initially sold as a 'research chemical' that rapidly found its way into ecstasy tablets and has been linked to 31 deaths; and MT-45, an opioid that was sold as a 'research chemical' and was linked to 28 deaths over a nine-month period.

Summary

The data presented in this report suggest that the growth of the market in new psychoactive substances will continue to pose a range of challenges for public health and drug policy over the next few years. Particular challenges relate to the speed at which new psychoactive substances appear, their open sale and the lack of information on their effects and harms. Critically, strong national and regional early warning systems will continue to play a central role in the early detection of harms and help to ensure timely public health responses.

Resources

- Learn more about the EU Early Warning System: emcdda.europa.eu/ews
- Learn more about the EMCDDA risk assessments: emcdda.europa.eu/publications/risk-assessments
- Follow the EU Early Warning System on Twitter: @toxicovigilance

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The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) is the central source and confirmed authority on drug-related issues in Europe. For over 20 years, it has been collecting, analysing and disseminating scientifically sound information on drugs and drug addiction and their consequences, providing its audiences with an evidence-based picture of the drug phenomenon at European level.

The EMCDDA's publications are a prime source of information for a wide range of audiences including: policymakers and their advisors; professionals and researchers working in the drugs field; and, more broadly, the media and general public. Based in Lisbon, the EMCDDA is one of the decentralised agencies of the European Union.

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European Monitoring Centre
for Drugs and Drug Addiction

The Internet and drug markets

Summary of results from an EMCDDA Trendspotter study

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Rationale and methods

This EMCDDA Trendspotter study on Internet drug markets in Europe was undertaken during September and October 2014. It commenced with a phase of data collection and literature review, culminating in an expert meeting in Lisbon on 30–31 October 2014. The aim of the study was to increase understanding of the online supply of drugs and undertake a mapping of the range of Internet drug markets in existence. Specific focuses were on the role of social media and apps; online sale of new psychoactive substances (NPS); online sales of medicinal products for illicit use; and the sale of drugs on the deep web.

Fourteen international experts attended the meeting, sharing their experiences and contributing to an analysis of the topic, providing insights from IT, research and monitoring, law enforcement, and Internet and drug user perspectives. The Trendspotter study methodology incorporates a number of different investigative approaches and data collection from multiple sources. This study included a review of the international literature; 15 expert presentations (one by video); and three facilitated working groups. Analysis was based on triangulation of the available data, with a view to providing as complete and verified a picture as possible.

Social media and drug markets

Social media are 'Web 2.0 technologies', characterised by increased participation and multidirectional lines of communication. The world of social media is developing rapidly: Facebook has more than 1.6 billion registered users, YouTube has more than 1 billion active users and Twitter has more than 500 million registered users. They operate largely on the surface web, although Facebook, for example, has recently established its services through Tor as well. Social media may have an active role in drug markets, with sites and apps being used for buying and selling drugs, or they may have a more indirect role — utilising various forms of 'marketing': experience sharing, photo and video sharing, opinion forming, etc.

It is perhaps more accurate to talk about virtual social networks (VSN) than online social networks, as much communication takes place using smart phones and tablets. VSN can be classified as either static networks, which are more permanent and may include user profiles and terms of use (e.g. Facebook), or dynamic networks (e.g. Skype or ooVoo video chat), which are temporary and often by invitation only. VSN can also be categorised in relation to their approaches to drug use, ranging from prohibitive to tolerant to promoting. A feature of VSN is the creative use of slang and argot to get around moderation. Static (and especially) dynamic VSN that utilise webcams have recently been associated with 'chem sex' parties and/or 'slamming' among gay men and men-who-have-sex-with-men (MSM). 'Chem sex' refers to sex while on various drugs, including mephedrone, methamphetamine, cocaine, etc.; 'slamming' is often used by gay men and MSM to refer to the injection of these and other drugs.

Another new development relates to drug supply and the sharing of drugs or drug experiences using smartphone apps. Examples include Grindr and Scruff, GPS location-based dating services used mainly by gay men and MSM. Bindhim et al. (2014) monitored Google Play and App Store over a three-month period and recorded growth in 'apps that promote illicit drug use'. The majority of these apps were about cannabis (98 %). For example, an app entitled 'How to sell weed' provided instructions for production and selling. 'Leafy App' offers an interactive catalogue of different varieties of cannabis, their characteristics and availability (including a search for the nearest source based on GPS location). Cavazos-Rehg et al. (2014) looked at 'Characterizing the Followers and Tweets of a Marijuana-Focused Twitter Handle.' They analysed a pro-cannabis Twitter handle with around 1 million followers, most of them young males.

A number of sources confirm that law enforcement monitoring of social media in relation to drugs does occur, but the volume of the content is to a large extent prohibitive. Media reports of arrests resulting from such monitoring usually refer to the cases of young people found with small amounts of an illicit drug and having little other criminal involvement. Most media reports of such police activity relate to the sale of prescription drugs rather than illicit drugs.

Legal highs, research chemicals, trade sites

The use of the surface web for the sale of NPS is a topic that has received increasing attention over the last decade. In 2013, EMCDDA online monitoring identified 651 websites selling 'legal highs' to Europeans. During 2014, the EMCDDA undertook a number of targeted Internet snapshots to gain an understanding of the supply of NPS and inform the risk assessment of, for example, 4,4′-DMAR and MT-45. New methods for automated monitoring of this arena are being developed by the I-TREND project led by the French Monitoring Centre for Drugs and Drug Addiction (OFDT), with partners in the Czech Republic, the United Kingdom, Poland and the Netherlands. I-TREND built on a 2011 study which categorised the online NPS market into four primary segments: shops selling NPS as research chemicals, mostly under their chemical names; a commercial segment, with products sold under brand names; classified ads, often located within public websites; and a deep web segment (Lahaie et al., 2013) . A breakdown of more than 1 000 active sites identified as selling to the five I-TREND countries included unique shops with unique design and IP addresses, as well as domain redirects to shops, and parallel web pages with the same design and/or IP address. At least 18 % of the online shops were somehow connected with another one (or duplicated). Recent developments identified in the online NPS market included both an increased hybridisation between commercial and research chemical segments, and rapid growth of NPS sales on the deep web. This hybridisation is resulting in a 'grey market' where, for example, some websites have simultaneously a surface web presence and a hidden element on the deep web. For example, an online shop might be referenced by search engines as selling NPS, but its catalogue will be accessible only if the client is co-opted by a previous customer.

Online sales of medicines and illicit supply

The online sale of medicines, which took off in the early 2000s, initially focused on lifestyle products (e.g. erectile dysfunction medicines such as Viagra®, slimming tablets, hair-restorers and smoking cessation products). More recently, the market has shifted towards performance enhancement products; controlled prescription drugs, including opioid painkillers, benzodiazepines, antidepressants and antibiotics (Orizio et al., 2011); and 'life-saving' medicines. A US study classified online pharmacies as either legitimate or illegitimate. Legitimate websites comply with national and international regulations and standards, thus guaranteeing the quality of the product, selling controlled medicines only with a valid medical prescription and ultimately assuring consumer safety. Reports suggest that the vast majority of online pharmacies fall into the illegitimate category. These are not registered with any recognised accreditation system and do not abide by regulations and professional standards. A growing concern related to illegitimate online pharmacies is their potential role as a source of drugs of misuse. However, the limited studies in this area indicate that online pharmacies are unlikely to be a reliable source of supply for the illicit drug market. In addition, there are suggestions that the growing expansion of cryptomarkets on the deep web may prove a more reliable and less expensive alternative.

A related issue is increasing online sales of food and dietary supplements such as Phenibut (β-phenyl-γ-aminobutyric acid), which is an authorised medicine in Russia, used since the 1960s for treating anxiety, alcohol withdrawal, OCD, stammering and insomnia. Phenibut is not licensed as a medicine in Europe or approved as a pharmaceutical in the US, but is sold as a dietary supplement

online (eBay, Amazon), aimed at the general population and marketed as a natural product: ‘an amino acid related to GABA’, which ‘improves mood, induces relaxation, enhances sexual desire’. Side effects include dependence and withdrawal symptoms.

Within the EU, five Member States allow online sales of prescription drugs, and the focus is on regulating the supply not regulating pharmacies. In the UK, there is currently a voluntary logo scheme for registered pharmacies that trade online, but from July 2015 a mandatory logo scheme for the legal supply of medicines ‘at a distance’ will be introduced across the EU.

The global law enforcement operation Pangea has been active in making seizures of illegally traded medicines. The results of Pangea VII included seizures: 1 855 884 doses were seized at all mail hubs, including 30 498 doses of suspected counterfeit/falsified medicines. A wide range of medicines were seized, including painkillers, antibiotics, anti-depressants, anti-anxiety medication, weight loss products and medicines to treat acne, narcolepsy, erectile dysfunction, asthma, diabetes and epilepsy.

Anonymous online drug marketplaces

The *deep web* is defined as a part of the Internet not accessible to traditional search engines such as Google, and the *dark web* may be defined as a small portion of the deep web that has been intentionally hidden and is inaccessible through standard web browsers. In recent years, the development of tools such as Tor has made it possible for anybody to browse the Internet anonymously, and several anonymous online markets, specialised in areas such as pornography, weapons or narcotics, have emerged. On the deep web, drug sales can take place in a marketplace (such as Silk Road), within a decentralised network or between individuals. However, it is drug cryptomarkets that have received the most attention.

The anonymous online drug marketplace Silk Road began operating in February 2011. Silk Road was not the only drug cryptomarket. Martin found more than 20 different cryptomarkets offering a range of illicit goods and services (Martin, 2014). Although Silk Road had at one stage been the largest, it was surpassed by both Agora and Evolution in early 2014. While offering anonymity, Silk Road provided the infrastructure for sellers and buyers to conduct transactions in an online environment, similarly to other online marketplaces such as eBay, with professional dispute resolution mechanisms, use of vendor and buyer ratings, hosting of member discussion forums, etc. While a wide variety of products were advertised on Silk Road, traditional street drugs and some prescription medicines were reported to be most popular. In the US, the UK and Australia, MDMA was the most commonly purchased drug on Silk Road (Barratt et al., 2014), followed by cannabis and LSD. Sale of NPS on the dark web seems to be limited. Looking at the revenue generated by large versus small quantity listings, bulk discounts and terminologies used, Aldridge and Decary-Hetu (2014) argued that a substantial proportion of transactions on Silk Road were best characterised as ‘business to business’, with many users making purchases for resale.

Silk Road kept its operators anonymous and its location secret by combining two technologies: Tor and bitcoin. While use of Tor meant that the Silk Road website did not know where the buyer or vendor was located (because IP addresses were clouded), bitcoin was used to facilitate anonymous transactions. Silk Road supported bitcoin as a trading currency. Instead of paying the seller directly, buyers placed the corresponding amount in escrow with Silk Road and payments were released to vendors only when the item reached its destination and the delivery was confirmed. In reality, cryptocurrencies such as bitcoin are not anonymous (as there is a central ledger) and they need to be laundered, for example using a service such as Bitcoin Fog. Anonymising bitcoin is a new trend. An important feature of Silk Road was that both sellers and buyers received ratings, with trust built on reputation. This system was weakened by various scams.

User perspective

The main reasons given by users for buying drugs on Silk Road were ‘a wider range of drugs’, ‘better quality’, ‘more convenient to order online’ and ‘more comfortable buying from sellers with high ratings’ (Barratt et al. 2014). In addition, the site’s anonymity, its member forums and its transaction system with speedy delivery were cited as benefits. Silk Road buyers also referred to poor drug quality in their locality and fear for personal safety when buying drugs on the streets (Van Hout and Bingham, 2013). Common reasons for not purchasing drugs on Silk Road included ‘having adequate access to drugs through own networks’ and ‘fear of being caught by police/customs if drugs are sent’; furthermore, the process of accessing the site using the Tor browser, arranging credit and purchasing products was time consuming and relatively difficult.

Competition with street markets

There seems to be a consensus that while the overall proportion of illicit drugs currently channelled through cryptomarkets is comparatively small, this will not necessarily remain the case for long. Silk Road has been described as a paradigm-shifting, transformative criminal innovation, as it provides drug dealers with (1) a worldwide market for their products; (2) the capacity to sell to customers not already known to them; (3) the ability to trade anonymously; and (4) the opportunity to trade in a relatively low-risk environment (Aldridge and Decary-Hetu, 2014).

Online marketplaces may also offer the benefit of increased personal safety (for buyer and seller) and reduce the possibility of violence, as buyers and sellers never reveal their identities and never meet face to face. Improved product quality (purity, price, type of product) and reduced risk of detection have been cited as perceived advantages in studies. Some challenging questions were posed; for example, are online drug markets better for public health and safety than street markets, with reduced levels of violent crime? Are they better for individual health, with higher quality drugs?

Recent developments

On 3 October 2013, the FBI shut down the original Silk Road and arrested its alleged founder, known as ‘Dread Pirate Roberts’. A new version of the Silk Road (Silk Road 2.0) was launched on 6 November and, while no scientific studies have been published yet on the functioning of Silk Road 2.0, blogs and online articles seem to indicate that, despite problems with stolen bitcoins early in 2014, Silk Road 2.0 flourished. On 6 November 2014 Interpol announced the closing down of 400 deep websites, including Silk Road 2.0. Other websites have been closing down since, supposedly trying to evade arrest and taking the bitcoin money stored in their accounts (www.deepdotweb.com/2013/10/28/updated-llist-of-hidden-marketplaces-tor-i2p/).

Harm reduction interventions

A number of studies suggest that Silk Road provided users with ways to reduce the harm caused by illicit drug use, particularly compared with street-based drug marketplaces. Examples included the sale of high-quality products with low risk for contamination, vendor-tested products, trip reporting and online discussion on harm reduction, with resources for people who wished to reduce their consumption (Barratt et al., 2014; Van Hout and Bingham, 2013). There is growing interest in the potential for offering harm reduction interventions directly to users of the deep web, and Doctor X (www.elsubmarinodeldoctorx.com) has been providing services to Silk Road users, including information, advice and drug-testing services.

Trafficking and supply reduction challenges

An important question is whether or not the Internet provides new criminal opportunities for drug trafficking. A recent analysis indicates that drug trafficking over the Internet can be categorised into two distinct flows, one for synthetic drugs and NPS, another for traditional illicit drugs. It is recognised that there remains a physical component to Internet trafficking activities, primarily at the cultivation/production stage and at the distribution stage (e.g. postal systems are involved). Compared with non-Internet trafficking, there seem to be reduced activities or layers in the chain for production aspects and increased stages for distribution. There has been more online activity in the area of trafficking NPS and synthetics, taking advantage of the possibility of managing the process from the destination country. Criminals are exploiting legal loopholes, for example taking advantage of differences in national regulation. Postal systems are seen as the major bottleneck in the system, as the goods still need to be delivered through the (inter)national mail system.

For law enforcement agencies, online monitoring is a new approach and they are building experience. Law enforcement strategies are focused on market disruption; this includes reducing the trust around anonymity, as well as the identification, arrest and prosecution of sellers in cryptomarkets. Practically, law enforcement agencies may engage in covert operations, infiltrating online markets, establishing an agent as a trustworthy buyer and perhaps arranging a face-to-face meeting. More overt tactics involve making other users of online marketplaces aware of police presence and ensuring that the takedown of markets receives media attention. At the EU level, strategy includes the Illegal Trade on Online Marketplaces (ITOM) project, which set up an EU cybercrime network to establish effective ways of combating illegal trading on online marketplaces.

Discussion and analysis

Rapid changes in technology such as development of easy online payment systems are transforming how we interact both commercially and socially across the board. Web 2.0 technologies are expanding their reach, and while they currently and appear to primarily involve small-scale sellers/buyers/sharers of drugs, occurrences of offers to buy and discussion of buying and using drugs are numerous.

The online sale of counterfeit medicines is clearly a major global enterprise; however, at present, evidence of sourcing for the illicit drug market from online sources is slim. Nevertheless, it is an area likely to require further monitoring. Information on online sales of NPS and research chemicals is steadily emerging, with some evidence of overlap with illicit markets, through so-called grey marketplaces. Much of the evidence identified in this study has focused on the functioning of drug marketplaces on the deep web and, with reports of exponential growth in both markets and sales, these have been identified as an important area for future monitoring.

It is interesting to note that, while Internet markets have global reach, national characteristics still have a significant impact. Many buyers prefer sellers from their home country, perceiving less risk with fewer borders to cross. A new Finnish marketplace was established on the deep web after Silk Road closed, specifically to cater to Finnish users who might not want to buy from abroad. Similarly, it appeared that most US and Australian vendors were not willing to ship drugs across international borders, and Australian buyers prefer local sellers. Furthermore, there appears to be interaction with existing domestic drug markets and consumer preferences; for example, I-TREND noticed product choices that were linked with country and cultural preferences. In addition, there are some global trends expressed within local subcultures that have both commonalities and differences (e.g. slamming, psychonauts).

Drivers of change

A wide range of factors were identified as drivers of change in terms of the Internet and drug markets:

- technology, globalisation and market innovation;
- secure encryption and web hosting (Tor, PGP, etc.);
- new marketplaces, both hidden and public;
- innovation, including decentralised sites, argot, apps, exploiting the learning from conventional Internet sites;
- online communities of likeminded people, online activism;
- market economics — competitive advantages and disadvantages;
- law enforcement and regulation, e.g. closing of bricks-and-mortar legal high shops may have led to increased Internet sales.

Threats, opportunities, challenges

A range of potential threats and opportunities were identified, both for market players themselves and for those trying to restrict their development.

- Global demographics are changing rapidly, and increasing market opportunities are likely to exist in developing countries with weak jurisdiction and growing computer literacy.
- The involvement of organised crime in online drug markets is unclear at present; however, if online drug trading offers significant threats or opportunities, organised criminals will undoubtedly become a presence.
- In addition to supporting markets, both the surface web and the deep web offer new ways to access help, and potentially to reduce barriers to help seeking. This could build on the strong online tradition for community involvement.
- A range of new methodological issues arise with regard to researching the web. In some respects, this opens up a golden age for ethnographic research, accompanied by innovative developments in online research methodologies (e.g. netnography, infodemiology, etc.). It also requires new ethical considerations.

New trends

A number of significant new trends were identified in the fast-changing Internet drug markets. These include:

- criminal innovation with a new breed of entrepreneurial drug dealer (‘disorganised’ crime);
- a tendency towards decentralisation of market structures and activities;
- a move downwards, from developments in surface (via grey?) to deep websites;
- a move to more covert communication and sophisticated encryption;
- growth in multi-key escrow and rating systems;
- increasing availability of high-potency products in online markets;
- growth in sex drugs apps, especially in the MSM dating scene;
- growth in drug advertising and exchange on social media;
- Increased uncertainty in the deep web community as a result of the latest police interventions and of scams.

Conclusion

The Internet facilitates movement of products, money and information across global borders. It also allows the movement of drugs, medicines, NPS, precursors and information on production techniques. Social media play a role in facilitating interaction, advertising and marketing drugs, in addition to providing sales forums, shop access via apps and classified ads. The dividing line between surface websites, for example selling so-called legal highs, and cryptomarkets operating on the deep web seems to be increasingly blurred, as one level can increasingly provide access to another. At present, the extent of Internet-enabled drug transactions taking place on the deep web is very limited; however, growth has been exponential and there is no evidence to suggest these markets will remain restricted for long. The ongoing cat-and-mouse game between law enforcement and Internet vendors is noted. It appears that buyers and sellers adapt rather easily to cryptomarket takedowns, in a similar way to buyers and sellers using surface web stores: when one shop closes, others quickly appear to replace them. Undoubtedly, the speed with which the Internet allows transformation to occur in drug markets poses a major challenge across the board, to law enforcement and public health, as well as to research and monitoring agencies.

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Glossary

The **surface web** or **clear web** is the Internet that can be found by link-crawling techniques used by a typical search engine such as Google, Bing or Yahoo.

The **deep web** is a part of the Internet not accessible to these search engines; the only way to access the deep web is by conducting a search within a particular website (for example, government databases and libraries contain huge amounts of deep web data).

The **dark web** may be defined as a small portion of the deep web that has been intentionally hidden and is inaccessible through standard web browsers. This is the portion of the Internet most widely known for illicit activities, because of the anonymity associated with this network.

Cryptomarkets are located in the dark web and accessed using Tor. A cryptomarket can be defined as an online forum where goods and services are exchanged between parties who use digital encryption to conceal their identities. It is not necessarily a site for the commission of cybercrime, as legal exchanges may also be conducted in such a forum (Martin, 2014: 356).

Tor is an acronym for The Onion Router. Anonymisation services such as Tor hide a computer's IP address when accessing the site. Tor is a 'circuit-based low-latency anonymous communication service' developed in collaboration with US military intelligence and launched in 2004. Tor is a free encrypting software for enabling online anonymity, protecting the personal privacy of the Internet user and resisting censorship, and it has many societal benefits. However, as it makes it more difficult for Internet activity to be traced back to the user, Tor is also used for illegal matters.

Silk Road was a cryptomarket that operated as a Tor-hidden service and used bitcoin as its currency. Silk Road was an archetypical cryptomarket, being the most well known and remaining the largest for a long period.

Pretty Good Privacy (PGP) is a data encryption and decryption computer program that provides cryptographic privacy and authentication for data communication. PGP is often used for signing, encrypting and decrypting texts, emails, files, directories and whole disk partitions, and to increase the security of email communications.

A **Twitter handle** is a username selected by anyone using Twitter; it must contain fewer than 15 characters. Each Twitter handle has a unique URL, with the handle added after twitter.com (e.g. http://twitter.com/username).

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EMCDDA–Europol 2013 Annual Report on the implementation of Council Decision 2005/387/JHA

In accordance with Article 10 of Council Decision 2005/387/JHA on the information exchange, risk assessment and control of new psychoactive substances

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Contents

About this report

This report presents the key activities performed by the EMCDDA and Europol in 2013, with details on all the relevant activities in support of the implementation of Council Decision 2005/387/JHA on the information exchange, risk assessment and control of new psychoactive substances, including new psychoactive substances notified in 2013, Joint Reports produced, risk assessments conducted and public health alerts and advisories issued.

Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances, OJ L 127, 20.5.2005, p. 32.

Available at:

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32005D0387:EN:HTML

1. Background to this report

As part of the response to new psychoactive substances within the European Union (EU), the *Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances* (hereafter 'the Council Decision') established a mechanism for the rapid exchange of information on substances that may pose public health and social threats, including the involvement of organised crime. This provides a legal basis for the institutions of the EU and the Member States to monitor all new narcotic and psychotropic substances that appear on the European drug scene. Where necessary, the Council Decision also provides for an assessment of the risks associated with these new substances, so that control measures deriving from Member States' obligations to the United Nations drug control conventions ([1]) can also be applied to new psychoactive substances.

Under Article 4 of the Council Decision, the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and Europol, in close collaboration with their respective expert networks, the Reitox National Focal Points and Europol National Units, are assigned a central role in detecting, notifying and monitoring new psychoactive substances. The information exchange element of the Council Decision has been implemented by the EMCDDA and Europol as the *European Union Early Warning System on New Psychoactive Substances* (hereafter 'Early Warning System'). In addition, where necessary, and in cooperation with the European Medicines Agency (EMA), the EMCDDA and Europol may collect, analyse and present information on a new psychoactive substance in the form of a *Joint Report* (Article 5). This report provides evidence to the Council of the European Union and the European Commission on the need to request a *risk assessment* on a new psychoactive substance. Such a risk assessment examines the health and social risks posed by a new substance, including: the use of, manufacture of and traffic in a new psychoactive substance; the involvement of organised crime; and the possible consequences of control measures. In order to conduct the risk assessment, the EMCDDA convenes a special meeting under the auspices of its Scientific Committee, extended with additional experts as necessary (Article 6).

To ensure transparency in the implementation of the Council Decision, Article 10 stipulates that:

'*The EMCDDA and Europol shall report annually to the European Parliament, the Council and the Commission on the implementation of this Decision. The report will take into account all aspects required for an assessment of the efficacy and achievements of the system created by this Decision. The report shall, in particular, include experience relating to coordination between the system set out in this Decision and the Pharmacovigilance system.*'

In compliance with Article 10, the EMCDDA and Europol herewith present the eighth such annual report, which covers the period 1 January to 31 December 2013. The report outlines the results of the implementation, describes key issues arising from accumulated experiences and serves as a monitoring tool. The reader is referred to the full text of the Council Decision, to facilitate the reading of this report ([2]).

([1]) The 1961 United Nations Single Convention on Narcotic Drugs and the 1971 United Nations Convention on Psychotropic Substances.

([2]) Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances, OJ L 127, 20.5.2005, p. 32.

This report is written as a standalone document in which annexes have been kept to a minimum. The annex provides a list of new psychoactive substances that were first notified in 2013. It includes the systematic chemical name, the reporting country and the date of notification for each substance. Further information on these substances is available from the EMCDDA and Europol.

2. New psychoactive substances in 2013

Since 1997 the EMCDDA and Europol have played central roles in the response to new psychoactive substances. Together, the two agencies, supported by their networks and other partners, have operated the world's only regional early warning system on new psychoactive substances, a system that has underpinned the ability to identify and respond to new psychoactive substances that pose social and public health harms within the EU.

During 2013 a total of 81 new psychoactive substances were reported for the first time within the EU (section 4.1). This compares to 74 in 2012 ([3]), 49 in 2011 and 41 in 2010.

It should come as little surprise to most people that the majority of new psychoactive substances are intended as 'legal' replacements of controlled drugs. The year 2013 provided further evidence that entrepreneurs and, increasingly, organised crime groups are expanding on the types of substances they plan to offer as 'legal' alternatives. Of particular concern to the EMCDDA and Europol in this respect are the new synthetic opioids — such as AH-7921, MT-45, carfentanil and ocfentanil — reported in the past two years.

Until about a decade ago, most new psychoactive substances that emerged were typically sold on the illicit drug market. They were sometimes sold as drugs in their own right or as a new type of 'ecstasy', but often they were sold surreptitiously as amphetamine and MDMA. Only a few were reported each year. Usually these were stimulant-type or hallucinogenic drugs produced in Europe or the United States either in small amounts in amateur laboratories or on a commercial scale in clandestine laboratories by organised crime groups. New substances also occasionally emerged from the diversion of medicines. Importantly, this continues to be the case, with some of these substances simply acting as temporary substitutes for established controlled drugs that are in short supply, such as MDMA; while others, such as 4-methylamphetamine, appear to be produced accidentally as a result of the use of uncontrolled precursors in the production of amphetamine.

Only a few years ago the issue of new psychoactive substances was regarded as having limited significance to drug policy. In the past few years, however, there have been phenomenal changes in this market. Today the question of how to respond to the challenges posed by the emergence of new drugs has become a major concern within the EU and at the international level.

The sale of new psychoactive substances through an open market took off in mid-2000s with the stimulants 1-benzylpiperazine (BZP, a piperazine derivative) and methylone, followed by mephedrone (cathinone derivatives). This marked the start of the modern 'legal highs' and the 'research chemicals' market. Many of the new substances that are destined for these markets are produced in bulk outside the EU (e.g. China and India) and imported into Member States, where they are processed, packaged and sold. Europol has received reports that such operations occur in a number of Member States. The marketing and distribution of these drugs has reached a new level of sophistication. This includes through the Internet (with next day delivery to consumers), bricks and mortar 'head shops' in towns and cities, and via street-level drug dealers.

([3]) The 2012 Annual Report listed 73 substances as notified through the Early Warning System in 2012; this figure should have been 74. The synthetic cannabinoid JWH-302 (1-pentyl-3-(3-methoxyphenylacetyl)indole) was identified by Germany in August 2012 but was not included in the 2012 Annual Report.

Globalisation and the new opportunities provided by developments in information technology have transformed many aspects of the new psychoactive substance market. A key player here is the Internet. Commerce and communication are no longer constrained by physical or geographical boundaries. This has also meant that the back catalogue of chemical substances developed by the pharmaceutical and medical research industries, whose psychoactive properties may make them attractive to consumers, is easily accessible to those wishing to identify such substances. Manufacturers in the chemical industries in China and India are able to synthesise the substances in bulk amounts. New trends also diffuse more rapidly, and a market for psychoactive substances has been created that exists, to a large extent, outside the established regulatory frameworks.

As noted, 81 new psychoactive substances were reported for the first time within the EU during 2013. Twenty-nine of these substances were synthetic cannabinoids ([4]). This brings the total number of synthetic cannabinoids reported since December 2008 to 104, making them the largest group of substances monitored by the Early Warning System; the large number clearly illustrating the continuing attempts by manufacturers to produce new substances in order to circumvent drug control measures. Also reported in 2013 were: 14 phenethylamines, 7 synthetic cathinones, 7 arylalkylamines, 5 opioids, 2 benzodiazepines, 1 tryptamine, 1 aminoindane, 1 arylcyclohexylamine, 1 piperidines/pyrrolinde, 1 piperazine, and 12 substances that do not conform to any of these groups.

Nine of the new substances reported in 2013 are used as active pharmaceutical ingredients in medicines. The monitoring of such substances under the Council Decision can provide essential early warning on the emerging misuse and abuse of medicines authorised within the EU and also in third countries ([5]). An example of this in 2013 was the report from Italy that tropicamide, which is used in medicine to dilate the pupils, was being injected by opioid users. A review of the available information suggests that the injection of tropicamide has been reported in some eastern European countries. It appears to be used to self-treat opioid withdrawal symptoms and for its euphorigenic and hallucinogenic effects.

A substantial part of the market in new psychoactive substances is those that are sold on the open market in head shops and online shops as 'legal highs' and 'research chemicals'. In 2013 the EMCDDA's monitoring of the Internet ([6]) identified 651 online shops selling these types of products to consumers in the EU (section 3.1.3). Europol has also gathered information from Member States on investigations regarding the online distribution of new substances in order to better understand how this market operates and the threats it poses.

Adding to the complexity of this online market is the sale of new substances as 'food supplements'. This includes the plant *kava kava* and the medicine *phenibut*. These 'supplements' are of particular concern because the retailers and products are typically not covered by existing drug monitoring systems, effectively creating a blind spot in our understanding of the market. Some of these products are widely available on popular e-commerce sites and online health-food shops, and in fitness equipment shops. In some cases these 'supplements' are marketed as 'natural', exploiting the general belief that they

([4]) The term 'synthetic cannabinoids' is used here to include: synthetic cannabinoid receptor agonists (such as JWH-018 which is a CB_1 and CB_2 receptor agonist); allosteric modulators (such as Org 27569) that change the structure of the cannabinoid receptors leading to altered activity when a ligand binds to the receptors; and substances that act as inhibitors of the fatty acid amide hydrolase (FAAH), which catalyses the intracellular hydrolysis of the endocannabinoid anandamide (such as URB597).

([5]) The terms 'misuse' and 'abuse' are used in their regulatory sense within the medicine regulatory system. See: www.ema.europa.eu/docs/en_GB/document_library/Other/2013/05/WC500143294.pdf

([6]) Monitoring was limited to retailers on the Surface Web selling direct to consumers.

are safe and healthy options for consumers. One product that that was sold as a sport supplement and analysed in 2013 was found to contain a derivative of methamphetamine (substance 17, Annex). This product has been sold in a number of countries including Sweden, the United Kingdom and the United States.

In 2013 the sale of controlled drugs on the 'hidden' Deep Web, such as the now-defunct Silk Road, really came to the public's attention. Less well known is that new psychoactive substances are also sold on the Deep Web, and work is required to better understand the importance to the EU drug market of such distribution networks, including sales to consumers.

It is of serious concern that illicit production within the EU was reported to Europol in 2013. Hungary, Poland and Slovakia have all reported the dismantling of illicit facilities where synthesis, processing and/or tableting of new psychoactive substances was taking place. These reports demonstrate that the processing of new substances within the EU is no longer limited to mixing and packaging, as organised crime groups have begun to invest resources in illicit production facilities.

The number and type of new psychoactive substances reported each year is critical to understanding the development and growth of the market. These numbers, however, fail to convey the enormous amount of work undertaken by the Early Warning System Network at the national and the EU level. For the EMCDDA and Europol, each report of a new substance requires that the information and analytical data is checked and assessed, that literature searches are run to find out what is known about the substance, and that a technical profile is created on the European Database on New Drugs (EDND) at the EMCDDA. Simultaneously, the information is recorded and analysed by the Focal Point Synergy at Europol, which is the hub for law enforcement data on synthetic drug crime, including new psychoactive substances. From there, the Early Warning System Network is formally notified about the substance, allowing laboratories, law enforcement, healthcare agencies, researchers, practitioners and policymakers to receive this critical data. This stage also marks the point at which the EMCDDA and Europol begin to monitor the new substance. Currently, more than 380 new substances are monitored. The EDND, which is updated on a daily basis, plays a critical role in this monitoring by providing round-the-clock access for the Early Warning System Network to the latest information on new substances, including, chemistry, pharmacology, toxicity, law enforcement seizures and epidemiology.

In 2013 the EMCDDA and Europol also produced four Joint Reports on very different substances, in terms of their chemistry, pharmacology and the individuals who use them: AH-7921, an opioid with similar effects to morphine; 25I-NBOMe, a potent hallucinogen; MDPV, a stimulant that in animal studies appears to be more potent and longer lasting than cocaine; and methoxetamine, a dissociative sold as a 'legal' and 'safer' alternative to ketamine (section 4.2). Reflecting the growing diversity of the market, 2013 marked the first time that formal action on an opioid (AH-7921) has been required at the EU level. Also in 2013 the EMCDDA's Scientific Committee conducted a risk assessment on the stimulant 5-IT after 24 deaths associated with its use were reported over a short time period (section 4.3).

While it is clear that many new substances will not gain a foothold as drugs in their own right and spread to broader groups of users, they are still capable of causing serious harm. The largely unknown pharmacology can pose serious risks to users. This is compounded by both the growing range of substances and the generally high availability. These problems are especially apparent when they are sold as 'legal highs' with no information provided to

the user of the actual substance(s) present, and as a result of an increasing number finding their way to the black market where they are sold as ecstasy, cocaine, ketamine, heroin or LSD to unsuspecting users. In addition, while much attention has been paid to the use of new substances by recreational users, these substances are also being used by problem drug users, including those who inject. This situation is presenting challenges for service providers, including low-threshold services such as needle and syringe programmes that often have limited experience of these drugs and their effects. Little is also known about the treatment requirements of users of new psychoactive substances, which in part may reflect the fact that many have emerged only recently.

Estimating the prevalence of use of new psychoactive substances continues to present challenges, especially through general population surveys. In some cases, such as with the synthetic cannabinoids, there is a clear discordance between the large number of multi-kilogram seizures reported to the Early Warning System and the levels of use reported in surveys. During 2013 the EMCDDA continued to work with its partners on ways to strengthen epidemiological methods and indicators related to the use of new substances. This includes exploring the development of indicators based on waste water analysis.

Reports of serious adverse events from the Early Warning System Network — such as non-fatal intoxications that require hospital treatment, and deaths — provide signals of emerging harms. Reflecting the growing number of such reports, in 2013 the EMCDDA began to develop a framework to strengthen the toxicovigilance component of the Early Warning System. This system will facilitate the identification and reporting of serious events and will optimise the reported data in order to best analyse these signals. Ultimately this should allow the Member States and the EU to respond earlier to emerging harms. While there is still a long way to go to reach its full development, the EMCDDA has already begun to improve the quality of data that is reported by the Early Warning System Network related to serious adverse events. In addition, as a component of this system, the EMCDDA is developing a framework that allows it to more systematically monitor the media to pick up on these signals as early as possible and from a broader number of sources, including from countries outside Europe. In fact, the EMCDDA monitors the scientific and medical literature on a daily basis for reports of serious adverse events and data from nonclinical studies that help explain the cause of these events. These data are analysed and prioritised and are then fed into the broader monitoring process.

In 2013 the EMCDDA issued 16 public health alerts and advisories to the Early Warning System Network (section 4.4). Many of these concerned serious adverse events, particularly deaths, and/or hazards that had the potential to cause serious harm. Notably, alerts were issued on three potent new opioids — AH-7921, carfentanil, ocfentanil — that appear to have only been sold on the drug market for the past two years or so. The EMCDDA and Europol are highly concerned about the number and type of new synthetic opioids reported to the Early Warning System in the past two years. Five of these opioids are fentanyls, a family of drugs that have already caused hundreds of deaths in Europe and the United States since they first appeared as ‘designer drugs’ sold as ‘synthetic heroin’ or ‘China white’ in California in the late 1970s. Adding to this concern is that some of the new opioids have already been sold as replacements for heroin. This includes a seizure made in Lithuania containing carfentanil (substance 6, Annex), which is usually used to tranquillise large animals such as elephants, and a seizure of ocfentanil in the Netherlands (substance 62, Annex).

In September 2013 Europol initiated the collection of available information on the new substance 4,4'-DMAR, after eight deaths associated with the substance were reported by Hungarian police. 4,4'-DMAR is a derivative of the designer drug ‘U4Euh’

(4-methylaminorex) and the weight-loss medicine aminorex, which was withdrawn after it caused an epidemic of pulmonary hypertension. As a result of the information provided by Hungary, Europol and the EMCDDA issued alerts to their respective partners within the Early Warning System Network (see 'Update from 2014', below).

The effective exchange of information on new psychoactive substances underpins an effective response. During 2013 the EMCDDA and Europol provided formal training in order to strengthen early warning at both the national and the EU level. Reflecting the globalised nature of this phenomenon, international cooperation with third countries was strengthened further. This included the bilateral exchange of technical information with law enforcement and healthcare agencies from the United States, Japan and Australia, among others. The importance of these global partnerships continues to be highlighted by the exchange of information on serious adverse events. In 2013 alerts were issued related to outbreaks of serious adverse events associated with synthetic cannabinoids that were reported to the EMCDDA by law enforcement agencies in the United States. In addition, during the Third International Forum on New Drugs experts from around the world came together to exchange experiences, identify information gaps and research needs and anticipate future developments and challenges.

Update from 2014

There appears to have been no slowdown in the growth of the phenomenon in 2014. As of May, 37 new psychoactive substances had been reported to the Early Warning System.

The eight deaths associated with 4,4'-DMAR that were reported by Hungary in 2013 were joined by a further 18 deaths reported by the United Kingdom in February 2014, leading the EMCDDA and Europol to launch a Joint Report on 4,4'-DMAR in the same month. The substance continues to be intensively monitored by the Early Warning System. Twenty-seven deaths associated with the substance have now been reported; a particular concern in this respect is that more than 260 kg of 4,4'-DMAR has been seized in the Netherlands, and in some countries it has been sold as ecstasy on the illicit drug market. The availability of 4,4'-DMAR may also mark an astonishing development in the 'research chemical' market after the suggestion that the distributors have conducted tests of the substance on animals, with the data from these tests being used as part of the marketing. If this is correct then distributors may be attempting to consolidate a 'legal' market in new substances.

Also in 2014 some 21 deaths and 13 non-fatal intoxications associated with the new opioid MT-45 have so far been reported. Of particular concern in this respect is that this substance appears to have only been sold on the drug market for the past six months or so. On the basis of these reports, a Joint Report on MT-45 was launched in April by the EMCDDA and Europol (substance 73, Annex). The substance continues to be intensively monitored by the Early Warning System.

The growing involvement of organised crime groups, apparently attracted by the large profits available in this market, is of serious concern to Europol. Analysis of intelligence reports provided by the Member States indicates that in the near future criminal groups based within the EU will expand their involvement in the trade, manufacture, trafficking and distribution of new psychoactive substances.

There is little doubt that enhanced monitoring systems within some national early warning systems are playing a key role in the early identification of serious adverse events and

other harms by the Early Warning System. Such systems will require adequate resources if they are to continue to supply this essential data and scale-up to provide enhanced coverage. Resources will also be required in order to replicate these enhancements in other settings and regions.

For the past few years the EDND has begun to feel the strain as a result of the huge increase in both the amount and the types of data now being reported. Resources are urgently required to ensure it can meet the needs of the EU both in the near future and in the longer term.

3. Implementation arrangements and cooperation with the European Union Pharmacovigilance system

3.1. Specific implementation arrangements

3.1.1. Assistance to national early warning systems

In 2013 the EMCDDA and Europol continued to provide support to the national early warning systems within the Reitox National Focal Points and Europol National Units in order to assist them in the identification of new substances. Assistance related to new psychoactive substances was also provided to Member States, institutions and agencies of the EU.

The analytical data available to the Early Warning System Network continued to be expanded during 2013. In addition, data and information is now routinely provided on an informal basis by international partners, including Australia, the United States and Japan. This is an important aspect of the exchange of information and emphasises the global nature of the phenomenon.

The EMCDDA also collects national risk assessments on new psychoactive substances, which are made available on the EDND in order to help identify emerging harms and to inform policy responses in the Member States. Similarly, legislative developments related to new substances reported by the Member States are also recorded and tracked.

Training was also provided to some of the Member States (section 3.1.4).

3.1.2. Annual meeting of the Early Warning System Network

The 13th annual meeting of the Reitox Early Warning System Network took place on 27 June 2013. The meeting was organised in conjunction with the second Europol law enforcement meeting on new psychoactive substances and the Third International Multidisciplinary Forum on New Drugs.

Over 70 representatives from the Early Warning System Network and Europol networks in the 28 Member States, Turkey and Norway attended the forum together with delegates from 10 third countries. Experts also attended from a wide range of disciplines. This included individuals from academic and operational backgrounds, such as epidemiology, forensic science, healthcare, law enforcement, criminology and policy. The forum aimed to identify information gaps and research needs, anticipate future developments and challenges and explore the role that can be played by law enforcement. The topics discussed included:

- historical context, public health perspective, the motivations of users, the role of law enforcement, challenges for drug policy;
- national, regional and global perspectives on new drugs, including presentations on significant developments and initiatives taking place around the globe;
- how emerging harms can be detected, monitored and understood by the work of forensic science, toxicology and healthcare disciplines;

- the role of law enforcement in the response to new drugs, including the difficulties faced by the growing interplay between new drugs and illicit drug markets;
- good practice and novel approaches, including what can be learned from the users of new drugs; and,
- the response to new drugs, which included a discussion of the recent policy developments in New Zealand.

3.1.3. Monitoring the online availability of new psychoactive substances

In 2013 the EMCDDA, in partnership with some of the national focal points, undertook an Internet monitoring exercise in 18 languages of the EU, Norwegian and Russian. The aim of the exercise was to provide a snapshot of the online sale of new psychoactive substances to consumers within the EU. The snapshot identified 651 shops that typically sold new substances as 'legal high' products or 'research chemicals'; in some cases products were also identified that were sold as 'food supplements'. In comparison, the previous snapshot exercise in January 2012 identified 693 shops, while the snapshots conducted in January 2011 and 2010 identified 314 and 170 shops, respectively ([7],[8]).

A targeted Internet snapshot in English was also conducted in 2013 to provide data to support the risk assessment of 5-IT (section 4.3.1).

3.1.4. Supporting activities

During 2013 the EMCDDA and Europol continued to be prominently involved in organising events and participating in activities that are designed to develop the Early Warning System Network and provide support to others working in the field of new psychoactive substances. These events and activities provide a platform to improve collaboration among partners and promote best practice in order to strengthen early warning activities. Significant activities carried out in 2013 are reported below.

In April a Reitox Academy training event examining contemporary approaches to drug monitoring was organised in Prague, the Czech Republic for Western Balkan countries and Turkey. The EMCDDA provided a keynote lecture on new psychoactive substances, including the critical role that the Internet plays in this phenomenon. The event also incorporated a training session on monitoring the supply of new psychoactive substances on the Internet. A pilot Internet snapshot in Balkan languages (Montenegrin, Macedonian, Bosnian, Serbian, Albanian, Croatian and Turkish) was implemented during the training session.

In May training was provided at the Workshop on New Psychoactive Substances, the Health Dimension in Zagreb, Croatia, funded under the European Commission's TAIEX instrument and organised by the Croatian Office for Combatting Drug Abuse. Also in May the annual meeting of the Drugs Working Group of the European Network of Forensic Science Institutes (ENFSI) was held in Dubrovnik, Croatia, in which the EMCDDA actively participated as an associate member of the network.

([7]) EMCDDA (2011), *Online sales of new psychoactive substances/'legal highs': summary of results from the 2011 multilingual snapshots*, EMCDDA, Lisbon (www.emcdda.europa.eu/publications/scientific-studies/2011/snapshot).

([8]) It is important to note that the data included in different snapshots may not be directly comparable, due to changes in the methodology that have increased the quality and coverage of these surveys over time; in addition, changes in technology, such as the algorithms used by search engine, can also affect the comparability between different snapshots.

In June the EMCDDA assisted Europol by providing training input at the Cepol–Europol International Illicit Synthetic Drug Laboratory Dismantling Course, held at the national police-training centre in Legionowo, Poland.

In September the Second International Conference on Novel Psychoactive Substances took place in Swansea, the United Kingdom. As well as co-organising the event, the EMCDDA participated with two keynote speeches and chaired or co-chaired the plenary and parallel sessions of the conference.

In October a meeting of forensic drug experts representing different institutions took place at the EMCDDA in Lisbon, Portugal. During this meeting the participants explored the possibilities for improving processes, particularly in relation to the interaction of the forensic community with the Early Warning System.

In November the EMCDDA attended the Spanish National Early Warning System meeting in Madrid to provide a European overview and best practice example to strengthen the national network.

The EMCDDA also organised or participated in a number of meetings with dedicated sessions on new psychoactive substances, reflecting the relevance of this area for traditional illicit drug areas, and established key epidemiological indicators. This included meetings covering general population surveys, drug-related deaths and problem drug use. In May the EMCDDA organised the first international multidisciplinary conference on detecting illicit drugs in wastewater, Testing the Waters, with a dedicated session on the potential of sewage analysis for identifying and monitoring population-level trends of new drugs in wastewater. In October the EMCDDA co-organised with COPOLAD ([9]) a thematic twinning training on analysis, interpretation and dissemination of drug-related data to facilitate decision-making.

3.2. Cooperation with the EMA and the Pharmacovigilance system

During 2013 the EMA and EMCDDA continued to regularly exchange information on new psychoactive substances according to their respective obligations under the Council Decision and EU pharmacovigilance legislation and the working arrangement between the two agencies ([10]). This included ad hoc reports relating to the misuse and abuse of medicinal products, or the active pharmaceutical ingredients used therein, that had been notified as new psychoactive substances, in order to support the Pharmacovigilance system. At the request of the EMCDDA, the EMA provided pharmacovigilance data on phenibut (notified in 2010) and information on authorised medicinal products containing tropicamide (substance 25, Annex), and pharmacovigilance data on these products related to their misuse, including by injection. Formal consultations and exchange of information took place in order to prepare the Joint Reports on 25I-NBOMe, AH-7921, MDPV and methoxetamine (section 4.2). In addition, at the request of the EMA, the EMCDDA undertook a data collection exercise with the Early Warning System Network to provide information on the misuse and abuse of pregabalin (notified in 2009).

([9]) Cooperation programme between the European Union and Latin America, aiming to improving the coherence, balance and impact of drugs policies, trough the exchange of mutual experiences, bi-regional coordination and the promotion multisectoral, comprehensive and coordinated responses.

([10]) www.emcdda.europa.eu/attachements.cfm/att_185319_EN_EMA-EMCDDA-2012workingarrangement.pdf

4. Activities

4.1. New psychoactive substances notified in 2013

Eighty-one new psychoactive substances were notified for the first time in 2013 (Table 1 and Annex). This continues the year on year increase in the number of new substances that have been notified since 2008 (Figure 1).

Technical profiles were created on the EDND for each of the notified substances and five substances of interest. During the course of 2013 a total of 444 reporting forms were submitted by the Early Warning System Network, which were processed, analysed and added to the EDND; while 300 technical profiles on the EDND were updated with the information from these forms and from other sources, including regular searches of the scientific and medical literature that are conducted by the EMCDDA and additional law enforcement information provided by Europol.

Technical assistance, advice and feedback were provided to the Member States on a daily basis. Sixteen public health alerts or advisories were issued to the Early Warning System Network (section 4.4). Additional data collection and analysis took place on an ad hoc basis, including for the Joint Reports on 25I-NBOMe, AH-7921, MDPV and methoxetamine (section 4.2).

As part of a process that began in 2012, the EMCDDA has been reviewing its classification system for new psychoactive substances. In the main it is possible to group some substances by their chemical family, or in the case of the synthetic cannabinoids by their mode of action. The former has long been the case with the phenethylamines, tryptamines, piperazines and cathinones. To take account of the increasing diversity of substances that have been notified in recent years, six new categories have been introduced during 2013: arylcyclohexylamines, aminoindanes, arylalkylamines, benzodiazepines, piperidines and pyrrolidines. The category of 'opioids' has also been introduced based on mode of action; this group contains eleven substances, ten of which have been notified since 2012. A category has also been created for plants and extracts of plants; no substances were reported in this group in 2013. Substances that do not conform to the groups described above were grouped separately, in an 'others' category.

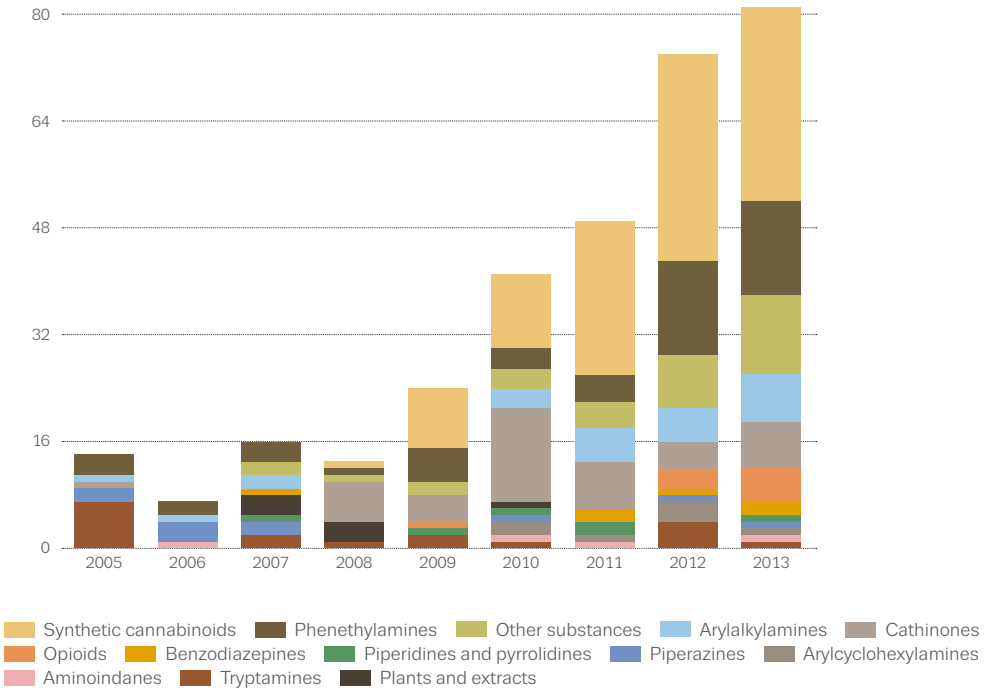
TABLE 1

The number of new psychoactive substances first notified in 2013, by category

Substance category	2013
Synthetic cannabinoids	29
Phenethylamines	14
Other substances	12
Arylalkylamines	7
Cathinones	7
Opioids	5
Benzodiazepines	2
Tryptamines	1
Aminoindanes	1
Arylcyclohexylamines	1
Piperazines	1
Piperidines and pyrrolidines	1
Plants and extracts	0

FIGURE 1

The number of new psychoactive substances notified for the first time to the Early Warning System since May 2005, by year ([11])



([11]) As noted, the 2012 Annual Report listed 73 substances as notified through the Early Warning System in 2012; this figure should have been 74. The synthetic cannabinoid JWH-302 (1-pentyl-3-(3-methoxyphenylacetyl)indole) was identified by Germany in August 2012 but was not included in the 2012 Annual Report.

4.2. EMCDDA–Europol Joint Reports

In accordance with Article 5 of the Council Decision, after a review of the available information on the new psychoactive substances 25I-NBOMe, AH-7921, MDPV and methoxetamine, a formal procedure for the collection of information on these four new substances was launched by the EMCDDA and Europol on 7 October 2013. The Joint Reports were submitted to the Council, the Commission and the EMA on 16 December 2013. A summary of the key findings for each of the four Joint Reports is provided below.

On the basis of the information provided therein, on 29 January 2014 the Council requested that formal risk assessments be conducted on the substances. In accordance with Article 6 of the Council Decision, the risk assessments were conducted by the extended Scientific Committee of the EMCDDA on 1 and 2 April 2014. A Risk Assessment Report for each substance was submitted to the Council and the Commission on the 22 April 2014 ([12]).

4.2.1. Joint Report on 25I-NBOMe

25I-NBOMe is a substituted phenethylamine. It is a potent full agonist of the serotonin 5-HT_{2A} receptor and appears to have hallucinogenic effects. It has been available on the EU drug market since at least May 2012 and has been detected in 23 Member States and Norway. Severe toxicity associated with its use has been reported in four Member States and one death associated with 25I-NBOMe has been analytically confirmed. Seven countries have reported that it has been sold as LSD or as a 'legal' alternative to LSD. On this basis the potential impact from the further spread of 25I-NBOMe (and related 'NBOMe' compounds) on public health is a key concern ([13]).

4.2.2. Joint Report on AH-7921

AH-7921 is a synthetic opioid. It has been available in the EU since at least July 2012 and has been detected in seven Member States and Norway. In most cases it has been seized in small quantities as a powder. Over a short period of time it has been associated with 15 deaths and six non-fatal intoxications in three countries. The similarity of AH-7921 to morphine in terms of pharmacology is a key concern. This may play an important role in the further spread of AH-7921 by opioid users, including the injecting population ([14]).

4.2.3. Joint Report on MDPV

MDPV is a synthetic cathinone derivative, which is closely related to pyrovalerone. MDPV has been present in the EU drug market since at least November 2008 and has been detected in 99 deaths and up to 107 non-fatal intoxications, particularly in Finland and the United Kingdom. There are some indications that it has been sold as a 'legal' or synthetic version of cocaine and it has also been found in tablets resembling 'ecstasy'. Large seizures have been made at borders and police operations have targeted its supply.

([12]) The Risk Assessment Reports are available at www.emcdda.europa.eu/publications/risk-assessments.
([13]) EMCDDA and Europol (2014), *EMCDDA–Europol Joint Report on a new psychoactive substance: 25I-NBOMe (4-iodo-2,5-dimethoxy-N-(2-methoxybenzyl)phenethylamine)*, EMCDDA, Lisbon, January 2014 (www.emcdda.europa.eu/publications/joint-report/25I-NBOMe).
([14]) EMCDDA and Europol (2014), *EMCDDA–Europol Joint Report on a new psychoactive substance: AH-7921 (3,4-dichloro-N-[[1-(dimethylamino)cyclohexyl]methyl]benzamide)*, EMCDDA, Lisbon, January 2014 (www.emcdda.europa.eu/publications/joint-report/AH-7921).

Powder seizures have been reported, including multi-kilogram quantities. Most Member States have control measures at the national level that cover MDPV; however, it continues to be available and this is concerning ([15]).

4.2.4. Joint Report on methoxetamine

Methoxetamine is an arylcyclohexylamine, closely related in many respects to ketamine. It has been available on the EU drug market since at least September 2010 and has been detected in 22 Member States, Turkey and Norway. Multi-kilogram quantities of the substance in powder form have been seized. Twenty deaths and 110 non-fatal intoxications associated with the substance have been reported. As methoxetamine is marketed as a legal and 'bladder-friendly' alternative to ketamine and is being sold directly on the illicit drug market at the same time as ketamine, a key concern is that these factors may play a role in the further spread of the substance ([16]).

4.3. Risk assessments

4.3.1. Risk assessment of 5-IT

During 2012 a Joint Report on 5-IT (5-(2-aminopropyl)indole) was prepared by the EMCDDA and Europol. It was submitted to the Council, Commission and EMA on 12 December 2012 ([17]). This led to a request from the Council for a formal risk assessment in January 2013. The risk assessment was conducted, in accordance with Article 6 of the Council Decision, by the extended Scientific Committee of the EMCDDA on 16 April 2013, which included a representative from Europol, the EMA and the Commission. Discussions during the risk assessment focused on the 24 deaths and 20 non-fatal intoxications associated with 5-IT that had been reported. The deaths occurred in four Member States over a period of five months in 2012, raising concern that if 5-IT were to become more widely available and used, the implications for public health could be significant. Full details are provided in the EMCDDA report on the risk assessment ([18]).

On 7 October 2013 the Council adopted a decision to subject 5-IT to control measures across the EU ([19]).

4.4. Public health alerts and advisories

One of the activities of the Early Warning System that provides added value to the Member States is public health alerts and advisories. Usually these concern deaths or other serious adverse events associated with new psychoactive substances; they can also include

([15]) EMCDDA and Europol (2014), *EMCDDA–Europol Joint Report on a new psychoactive substance: MDPV (3,4-methylenedioxypyrovalerone)*, EMCDDA, Lisbon, January 2014 (www.emcdda.europa.eu/publications/joint-report/MDPV).
([16]) EMCDDA and Europol (2014), *EMCDDA–Europol Joint Report on a new psychoactive substance: methoxetamine (2-(3-methoxyphenyl)-2-(ethylamino)cyclohexanone)*, EMCDDA, Lisbon, January 2014 (www.emcdda.europa.eu/publications/joint-report/methoxetamine).
([17]) EMCDDA and Europol (2012), *EMCDDA–Europol Joint Report on a new psychoactive substance, 5-(2-aminopropyl)indole*, EMCDDA, Lisbon (www.emcdda.europa.eu/publications/joint-reports/5-IT).
([18]) EMCDDA (2014), *Report on the risk assessment of 5-(2-aminopropyl)indole in the framework of the Council Decision on new psychoactive substances*, Publications Office of the European Union, Luxembourg (www.emcdda.europa.eu/publications/risk-assessment/5-IT).
([19]) Council Decision of 7 October 2013 on subjecting 5-(2-aminopropyl)indole to control measures (2013/496/EU), OJ L 272, 12.10.2013, pp. 44–45.

hazards that have the potential to cause serious harm ([20]). In addition, information is exchanged on emerging trends in new uses of psychoactive substances that are controlled under the United Nations drug conventions and that may pose a potential risk to public health. Alerts and advisories may also provide information on possible public health related measures in accordance with the mandate and procedures of the EMCDDA.

Sixteen public health alerts and advisories were issued to the Early Warning System Network during 2013. A selection is provided below ([21]).

Carfentanil

An alert was issued in February 2013 after the Latvian National Focal Point reported that the highly potent opioid and fentanyl derivative had been identified in a seizure of powder by Latvian Police. The information also noted that this substance had been associated with a number of unconfirmed deaths in the country.

AH-7921

An alert was issued in February 2013 after the Norwegian National Focal Point reported that the opioid AH-7921 had been identified in a seizure of powder and in the contents of a used syringe that was seized in connection with a death that was believed to be linked to the substance. Other alerts were issued during 2013 related to AH-7921 after reports of deaths associated with the substance were received from Sweden and Norway.

25I-NBOMe

An alert was issued in February 2013 after the United Kingdom National Focal Point reported seven serious non-fatal intoxications associated with the use of the potent hallucinogen 25I-NBOMe that occurred in January 2013.

4,4'-Dimethylaminorex (4,4'-DMAR)

An alert was issued in October 2013 after the Hungarian National Focal Point reported eight deaths associated with 4,4'-DMAR, which is believed to be a stimulant-type substance. This alert facilitated work by the United Kingdom National Early Warning System in identifying 18 deaths associated with 4,4'-DMAR, which were subsequently reported to the Early Warning System in February 2014.

Ocfentanil

An alert was issued in September 2013 after the Netherlands National Focal Point reported the identification of the opioid and fentanyl derivative ocfentanil in a seizure by Dutch police, which may have been intended for sale on the drug market as 'synthetic heroin'.

ADB-PINACA and 5F-ADBICA

An advisory was issued in September 2013 after information provided by law enforcement agencies in the United States, supplemented by information from the EMCDDA's

([20]) Alerts and advisories issued by the Early Warning System are not legally binding and Member States are not obliged to act upon them.

([21]) Note that the detection of new psychoactive substances in post-mortem biological samples does not necessarily imply a causal role in the death.

monitoring of open source information, identified a series of non-fatal intoxications in the United States associated with ADB-PINACA and 5F-ADBICA. These substances are known to be present on the EU drug market and have been reported by several Member States.

5-EAPB

An alert was issued in December 2013 after the Swedish National Focal Point reported a death associated with 5-EAPB, a substance that has a chemical structure very similar to the well-known ecstasy drug MDMA.

5. Conclusions

The year 2013 saw the sustained growth of the market in new psychoactive substances within the EU. The new psychoactive substances reported in that year unequivocally demonstrate a growing diversity in the types of substances being sold as 'legal' alternatives to controlled drugs. Of particular concern from a public health perspective are the new synthetic opioids that have been identified on the drug market in the past two years, such as AH-7921, MT-45, carfentanil and ocfentanil. These developments are compounded by the increasing involvement of organised crime groups, which appear to be drawn to the market by the potentially large profits. Europol's analysis of intelligence reports indicates that in the near future criminal groups based within the EU may expand their involvement in the trade, manufacture, trafficking and distribution of new psychoactive substances.

Despite these challenges, the Early Warning System and the EMCDDA–Europol Joint Reports and the risk assessment conducted by the EMCDDA extended Scientific Committee continue to demonstrate the added value and strength of the EU system by ensuring robust data-driven analysis, assessment and response to the harms posed by new psychoactive substances.

The EMCDDA and Europol have devoted substantial internal resources to ensure that the current information exchange system set up under Council Decision 2005/387/JHA, and operationalised as the Early Warning System, has been successfully implemented on a continuous basis. Through the support of its partners, including the EMA, the Early Warning System provides added value to the Member States by playing an essential role as a sentinel network that ensures that they have access to the most up-to-date information on new psychoactive substances both from across Europe and beyond. The Early Warning System Network continues to grow, as does the amount and quality of the information that it collects. This continued development is underpinned by the Reitox National Focal Points and the Europol National Units, which need to be adequately supported. There is little doubt that enhanced national monitoring systems are playing a key role in the early identification of harms by the Early Warning System. Such systems will require adequate resources if they are to continue to supply this essential data and scale-up to provide enhanced coverage. Resources will also be required in order to replicate these enhancements in other settings and regions. In addition, there is a critical need for a strengthened data collection mechanism so that the Early Warning System can both effectively cope with the recent significant growth in the data and ensure that it can be monitored.

Monitoring new psychoactive substances is event-based. It is driven by the identification of new psychoactive substances in laboratory settings that are predominantly not research focused. These analytical and toxicological laboratories are the cornerstones of the Early Warning System. They are located at law enforcement, private sector, (public) health, academic establishments, etc. This is routine work for these laboratories and they urgently require both the enhanced provision of analytical data through a strengthened European Database on New Drugs (EDND) (see below) and a cost-effective mechanism to share reference standards easily and rapidly within the EU.

Given the growing role that organised crime groups are likely to play in the manufacture and supply of new psychoactive substances in the future, it is essential that adequate resources and expertise are available to law enforcement agencies at both the national and the EU level.

The toxicovigilance component of the Early Warning System is the mechanism that allows the early detection of an emerging toxicological problem — and an initial assessment of the potential scale of the problem — related to a new substance at both the national and the EU level. This allows public health warnings to be issued to the Early Warning System Network, and the substance to be placed under intensive monitoring. In some cases this may also lead to formal action through a Joint Report, and, where necessary a risk assessment. In order for the EMCDDA to meet the increased needs and demands arising from the phenomenon, at both the national and the EU level, the identification, reporting and monitoring of serious adverse events requires strengthening.

For many years the European Database on New Drugs (EDND) has served the EU well by acting as a reference point for the available information on new psychoactive substances. However, adequate resources are not available to enable its development to keep pace with the amount and type of data arising from the increasing number of substances that are being identified and to ensure effective monitoring. The EDND should be strengthened. A core part of this work will require the development of a new infrastructure that will allow the secure electronic submission of data through standard web-based structured forms and facilitate the central analysis of data and production of reports. In addition to being able to provide real time information on a new drug (or a particular aspect of a new drug such as its detection in a particular 'legal high' product or reports of serious adverse events), the system should be able to provide an overview of the phenomenon as a whole to stakeholders. Resources are urgently required in order to ensure it can meet the needs of the EU both in the near future and in the longer term.

By its very nature, the risk assessment process is completed in a short time frame. As a result, limited data is available, and the process is principally focused on the data related to acute harm. It is important to recognise here that the data provided and collected through the Early Warning System will be essential to this process, particularly in relation to serious adverse events. In addition, targeted non-clinical studies that characterise the pharmacological and toxicological properties of the new psychoactive substances will be required for the risk assessment process in order to understand the data reported through the Early Warning System. Sufficient resources must be made available so that these data can be provided.

It is hoped that the information and analysis provided by the EMCDDA and Europol in this report will provide a greater insight into the growing complexity of the market in new psychoactive substances and the subsequent challenges that the Member States and the EU are likely to face in the near future. It is also hoped that the report will inform the policy responses currently being discussed at the EU level.

Annex

New psychoactive substances first notified to the Early Warning System in 2013 under the terms of Council Decision 2005/387/JHA

1. **5-MAPB** (1-(benzofuran-5-yl)-*N*-methylpropan-2-amine) — 3 January 2013, United Kingdom.

2. **4-Fluorocathinone** (2-amino-1-(4-fluorophenyl)propan-1-one) — 10 January 2013, Finland.

3. **JWH-methylcyclohexane-8quinolinol** (Quinolin-8-yl 1-(cyclohexylmethyl)-1*H*-indole-3-carboxylate) — 29 January 2013, Spain.

4. **A-834,735** ([1-(tetrahydropyran-4-ylmethyl)indol-3-yl]-(2,2,3,3-tetramethylcyclopropyl) methanone) — 29 January 2013, Poland.

5. **JWH-368** ([5-(3-fluorophenyl)-1-pentyl-pyrrol-3-yl]-(1-naphthyl)methanone) — 7 February 2013, Latvia.

6. **Carfentanil** (methyl 1-(2-phenylethyl)-4-[phenyl(propionyl)amino]-4-piperidinecarboxylate) — 12 February 2013, Latvia.

7. **EAM-2201** ((4-ethyl-1-naphthyl)-[1-(5-fluoropentyl)indol-3-yl]methanone) — 15 February 2013, Sweden.

8. **Flubromazepam** (7-bromo-5-(2-fluorophenyl)-1,3-dihydro-2*H*-1,4-benzodiazepin-2-one) — 7 March 2013, Germany.

9. **5F-PB22** (8-quinolyl 1-(5-fluoropentyl)indole-3-carboxylate) — 15 March 2013, Belgium.

10. **JWH-307 brominated derivative** ((5-(2-bromophenyl)-1-pentyl-1*H*-pyrrol-3-yl) (naphthalen-1-yl)methanone) — 4 April 2013, Germany.

11. **JWH-030** (naphthalen-1-yl(1-pentyl-1*H*-pyrrol-3-yl)methanone) — 4 April 2013, Germany.

12. **JWH-145** (naphthalen-1-yl(1-pentyl-5-phenyl-1*H*-pyrrol-3-yl)methanone) — 4 April 2013, Germany.

13. **UR-144 heptyl derivative** ((1-heptyl-1*H*-indol-3-yl)(2,2,3,3-tetramethylcyclopropyl)-methanone) — 17 April 2013, Sweden.

14. **3,4-dichloromethylphenidate** (methyl (2*R*)-2-(3,4-dichlorophenyl)-2-[(2*R*)-piperidin-2-yl]acetate) — 17 April 2013, Sweden.

15. **25H-NBOMe** (2-(2,5-dimethoxyphenyl)-*N*-(2-methoxybenzyl)ethanamine) — 24 April 2013, Sweden.

16. **URB-597** ([3-(3-carbamoylphenyl)phenyl] *N*-cyclohexylcarbamate) — 24 April 2013, Poland.

17. ***N*-ethyl-1-phenylbutan-2-amine** — 2 May 2013, Sweden.

18. **AB-PINACA** (*N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-pentyl-1*H*-indazole-3-carboxamide) — 21 May 2013, Sweden.

19. **α-PVT** (2-(pyrrolidin-1-yl)-1-(thiophen-2-yl)pentan-1-one) — 21 May 2013, Hungary.

20. **A-836,339** (*N*-[3-(2-methoxyethyl)-4,5-dimethyl-1,3-thiazol-2-ylidene]-2,2,3,3-tetramethylcyclopropane-carboxamide) — 3 June 2013, Hungary.

21. **4-methylbuphedrone**, *N*-benzyl derivative (2-(benzylamino)-1-(4-methylphenyl) butan-1-one) — 5 June 2013, Finland.

22. **2-Me-DMT** (*N*,*N*-dimethyl-2-(2-methyl-1*H*-indol-3-yl)ethanamine) — 5 June 2013, Finland.

23. **4-MeO-α-PVP** (1-(4-methoxyphenyl)-2-(pyrrolidin-1-yl)pentan-1-one) — 12 June 2013, Finland.

24. **NMP** (1-methylpyrrolidin-2-one) — 13 June 2013, Italy.

25. **Tropicamide** (*N*-ethyl-3-hydroxy-2-phenyl-*N*-(pyridin-4-ylmethyl)propanamide) — 2 July 2013, Italy.

26. **RH-34** (3-[2-(2-methoxybenzylamino)ethyl]-1*H*-quinazoline-2,4-dione) — 4 July 2013, France.

27. **2-(2,3-dimethoxyphenyl)-*N*-(3,4,5-trimethoxybenzyl)ethanamine** — 4 July 2013, France.

28. **JTE-907** (*N*-(benzo[1,3]dioxol-5-ylmethyl)-7-methoxy-2-oxo-8-pentyloxy-1,2-dihydroquinolin-3-carboxamide) — 4 July 2013, Germany.

29. **AB-FUBINACA** *(N*-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide) — 4 July 2013, Belgium.

30. **5F-AB-PINACA** (*N*-(1-carbamoyl-2-methyl-propyl)-1-(5-fluoropentyl)indazole-3-carboxamide) — 5 July 2013, Belgium.

31. **Mebroqualone** (3-(2-bromophenyl)-2-methylquinazolin-4(3*H*)-one) — 5 July 2013, United Kingdom.

32. **Allylescaline** (4-allyloxy-3,5-dimethoxy-phenethylamine) — 8 July 2013, Denmark.

33. **α-PEP** (1-phenyl-2-(1-pyrrolidinyl)heptan-1-one) — 8 July 2013, Sweden.

34. **5-EAPB** (1-(1-benzofuran-5-yl)-*N*-ethylpropan-2-amine) — 11 July 2013, United Kingdom.

35. **Mephtetramine** (2-((methylamino)methyl)-3,4-dihydronaphthalen-1(2*H*)-one) — 11 July 2013, United Kingdom.

36. **Escaline** (3,5-dimethoxy-4-ethoxyphenethylamine) — 15 July 2013, Germany.

37. **βk-PBDB** (1-(1,3-benzodioxol-5-yl)-2-(propylamino)butan-1-one) — 17 July 2013, Czech Republic.

38. **Proscaline** (2-(3,5-dimethoxy-4-propoxyphenyl)ethanamine) — 7 August 2013, Netherlands.

39. **W-15** ((*E*)-4-chloro-N-(1-phenethylpiperidin-2-ylidene)benzenesulfonamide) — 12 August 2013, Spain.

40. **Nitracaine** (3-(*N*,*N*-diethylamino)-2,2-dimethylpropyl-4-nitrobenzoate) — 13 August 2013, Sweden.

41. **Diclazepam** (7-chloro-5-(2-chlorophenyl)-1-methyl-1,3-dihydro-2*H*-1,4-benzodiazepin-2-one) — 26 August 2013, Germany.

42. **Methoxetamine brominated derivative** (2-(2-bromo-5-methoxy-phenyl)-2-(ethylamino) cyclohexanone) — 28 August 2013, Poland.

43. **25iP-NBOMe** (2-[2,5-dimethoxy-4-(propan-2-yl)phenyl]-*N*-(2-methoxybenzyl) ethanamine) — 6 September 2013, Finland.

44. **3C-P** (1-(3,5-dimethoxy-4-propoxyphenyl)propan-2-amine) — 6 September 2013, Finland.

45. **3C-E** (1-(4-ethoxy-3,5-dimethoxyphenyl)propan-2-amine) — 6 September 2013, Finland.

46. **25I-NBMD** (N-(1,3-benzodioxol-4-ylmethyl)-2-(4-iodo-2,5-dimethoxy-phenyl) ethanamine) — 6 September 2013, Poland.

47. **6-MAPB** (1-(benzofuran-6-yl)-*N*-methylpropan-2-amine) — 10 September 2013, United Kingdom.

48. **LY2183240** (*N*,*N*-dimethyl-5-[(4-biphenyl)methyl]tetrazole-1-carboxamide) — 10 September 2013, United Kingdom.

49. **Methoxypiperamide** ((4-methoxyphenyl)(4-methylpiperazine-1-yl)methanone) — 11 September 2013, United Kingdom.

50. **bk-MPA** (2-(methylamino)-1-(thiophenyl-2-yl)propan-1-one) — 12 September 2013, Hungary.

51. **AM-1248 azepane isomer** ((adamant-1-yl)[1-(1-methylazepan-3-yl)-1*H*-indol-3-yl] methanone) — 26 September 2013, Hungary.

52. **Methallylescaline** (2-[3,5-dimethoxy-4-[(2-methyl-prop-2-en-1-yl)oxy]phenyl] ethanamine) — 11 October 2013, Sweden.

53. **C30-NBOMe** (2-(4-chloro-2,5-dimethoxy-phenyl)-N-[(3,4,5-trimethoxyphenyl)methyl] ethanamine) — 11 October 2013, Sweden.

54. **ADBICA** (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indole-3-carboxamide), 11 October 2013, Sweden.

55. **Gabapentin** (2-[1-(aminomethyl)cyclohexyl]acetic acid) — 15 October 2013, Belgium.

56. **Sibutramine** (1-[1-(4-chlorophenyl)cyclobutyl]-*N*,*N*,3-trimethyl-1-butanamine) — 15 October 2013, United Kingdom.

57. **Venlafaxine** (1-[(2-dimethylamino)-1-(4-methoxyphenyl)ethyl]cyclohexanol) — 15 October 2013, Austria.

58. **2-FMC** (1-(2-fluorophenyl)-2-(methylamino)propan-1-one) — 23 October 2013, Hungary.

59. **25B-N(BOMe)$_2$** (2-(4-bromo-2,5-dimethoxyphenyl)-*N*,*N*-bis(2-methoxybenzyl) ethanamine) — 23 October 2013, Hungary.

60. **Diphenhydramine** (2-(diphenylmethoxy)-*N*,*N*-dimethylethanamine) — 23 October 2013, United Kingdom.

61. **Atomoxetine** ((3*R*)-*N*-methyl-3-(2-methylphenoxy)-3-phenylpropan-1-amine) — 24 October 2013, Denmark.

62. **Ocfentanil** (*N*-(2-fluorophenyl)-2-methoxy-*N*-[1-(2-phenylethyl)-4-piperidinyl] acetamide) — 24 October 2013, Netherlands.

63. **6-EAPB** (1-(benzofuran-6-yl)-*N*-ethylpropan-2-amine) — 28 October 2013, Netherlands.

64. **AM-6527 5-fluoropentyl derivative** (1-(5-fluoropentyl)-*N*-(napthalen-2-yl)-1*H*-indole-3-carboxamide) — 7 November 2013, Germany.

65. **4-MMA** (*N*-methyl-1-(4-methylphenyl)propan-2-amine) — 13 November 2013, Poland.

66. **AM-2201 indazole analogue** ([1-(5-fluoropentyl)-1*H*-indazol-3-yl](naphthalen-1-yl) methanone) — 15 November 2013, Sweden.

67. ***N*-methyl-2-aminoindane** (*N*-methylindan-2-amine) — 20 November 2013, Denmark.

68. **Embutramide** (*N*-[2-ethyl-2-(3-methoxyphenyl)butyl]-4-hydroxy-butanamide) — 26 November 2013, Bulgaria.

69. **ADB-FUBINACA** (*N*-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(4-fluorobenzyl)-1*H*-indazole-3-carboxamide) — 28 November 2013, Turkey and Germany.

70. **ADB-PINACA** (N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-pentyl-1H-indazole-3-carboxamide) — 3 December 2013, United Kingdom.

71. **βk-2C-B** (2-amino-1-(4-bromo-2,5-dimethoxyphenyl)ethan-1-one) — 3 December 2013, United Kingdom.

72. **Butorphanol** (17-cyclobutylmethyl-morphinan-3,14-diol) — 3 December 2013, Denmark.

73. **MT-45** (1-cyclohexyl-4-(1,2-diphenylethyl)-piperazine) — 5 December 2013, Sweden.

74. **Lysergic acid 2,4-dimethylazetidide** ('LSZ') ([(2S,4S)-2,4-dimethylazetidin-1-yl]-[(9*R*)-7-methyl-6,6*a*,8,9-tetrahydro-4*H*-indolo[4,3-*fg*]quinoline-9-yl]methanone) — 10 December 2013, Slovenia.

75. ***N,N*-diethyl-2-(1-pentyl-1*H*-indol-3-yl)-4-thiazole-methanamine** — 18 December 2013, Germany.

76. ***N*-(2-methoxyethyl)-*N*-(1-methylethyl)-2-(1-pentyl-1*H*-indol-3-yl)-4-thiazole-methanamine** — 18 December 2013, Germany.

77. **1-(Cyclohexylmethyl)-2-[(4-ethoxyphenyl)methyl]-*N,N*-diethyl-1H-benzimidazole-5-carboxamide** — 18 December 2013, Germany.

78. **A-796,260 isomer**, ((E)-3,4,4-trimethyl-1-[1-(2-morpholinoethyl)indol-3-yl]pent-2-en-1-one) — 18 December 2013, Germany.

79. **SDB-006** (*N*-benzyl-1-pentyl-1*H*-indole-3-carboxamide) — 19 December 2013, Finland.

80. **5F-SDB-006** (*N*-benzyl-1-(5-fluoropentyl)-1*H*-indole-3-carboxamide) — 19 December 2013, Finland.

81. **FUB-PB-22** (8-quinolyl 1-[(4-fluorophenyl)methyl]-3*H*-indole-3-carboxylate) — 19 December 2013, Sweden.

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About the EMCDDA

The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) is the central source and confirmed authority on drug-related issues in Europe. For over 20 years, it has been collecting, analysing and disseminating scientifically sound information on drugs and drug addiction and their consequences, providing its audiences with an evidence-based picture of the drug phenomenon at European level.

The EMCDDA's publications are a prime source of information for a wide range of audiences including: policymakers and their advisors; professionals and researchers working in the drugs field; and, more broadly, the media and general public. Based in Lisbon, the EMCDDA is one of the decentralised agencies of the European Union.

Related publications and websites

EMCDDA

- *Risk assessment of 5-IT,* Risk assessments, 2014
- *Risk assessment of new psychoactive substances — operating guidelines, 2010*

EMCDDA and Europol

- *Joint Report on 25I-NBOMe,* EMCDDA–Europol Joint Reports, 2014
- *Joint Report on AH-7921,* EMCDDA–Europol Joint Reports, 2014
- *Joint Report on MDPV,* EMCDDA–Europol Joint Reports, 2014
- *Joint Report on methoxetamine,* EMCDDA–Europol Joint Reports, 2014
- *Early-warning system on new psychoactive substances — operating guidelines,* 2007

These and all other EMCDDA publications are available from www.emcdda.europa.eu/publications

- EMCDDA Action on new drugs: www.emcdda.europa.eu/drug-situation/new-drugs

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A year in review

Highlights from the EMCDDA's General Report of Activities 2013

As I reflect on the overall mood at the EMCDDA in 2013, I would say it was one of resilience. Faced with a constantly changing European drug situation, the Centre's staff had to perform more tasks with fewer resources, continually improving systems and finding ways of working more efficiently. New psychoactive substances appeared at a prolific rate and more established drugs still represented a heavy social burden. Several thousand young Europeans died following drug use in 2013, and many more died from the indirect consequences of taking drugs; but they are just the tip of the iceberg. The information provided by the EMCDDA, along with its monitoring and alert functions, feeds into actions to prevent this from happening.

Wolfgang Götz, Director

Introduction

This leaflet provides insight into the work of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), drawing content from its *General Report of Activities* for 2013 ([1]). A decentralised European agency based in Lisbon, the EMCDDA is the hub of credible, robust data on the European drug situation and responses to it. Our annual progress report provides an overview of the Centre's achievements for the period concerned, for those interested in what we do, and how we do it. For further information on the agency, please visit our website or follow us on Twitter and Facebook.

([1]) emcdda.europa.eu/publications/gra/2013

The EMCDDA: 2013 figures

41 key outputs (online and printed), in a range of EU and non-EU languages
34 articles authored or co-authored by EMCDDA staff published in scientific journals
Active involvement in 277 external events, conferences and technical meetings
13 videos with around 12 000 views, 270 tweets and retweets, 1 871 'likes' on Facebook
Budget: EUR 16.3 million. By 31 December, 99.74 % of this budget had been committed

Monitoring the drug situation

The work of the EMCDDA is built on the core tasks of collecting, managing and analysing the data provided by the Reitox national focal points (NFPs) in 30 countries — the 28 European Union (EU) Member States, Turkey and Norway. The findings gathered through this collective effort form the basis for our outputs during the year.

The first *EU drug markets report: a strategic analysis*, produced jointly by the EMCDDA and Europol, was launched in Brussels by Commissioner Cecilia Malmström and the directors of the two agencies ([2]). An essential reference tool for law enforcement professionals, policymakers, the academic community and the general public, the report combines the EMCDDA's ongoing monitoring and analysis of the drug phenomenon with Europol's strategic and operational understanding of trends and developments in organised crime.

([2]) emcdda.europa.eu/publications/joint-publications/drug-markets

Continued on page 2

Continued from page 1

Another innovation in 2013 was the press launch on 28 May of a reshaped version of our annual overview of the European drug situation, now called the *European Drug Report* (EDR). This fresh information package was more timely, interactive and interlinked than its predecessor. The launch event opened with a video message from Commissioner Malmström. In her video, the Commissioner expressed concern at the increasingly complex stimulant market.

'…we need reliable data to define robust and updated policies: the European Drug Report and its valuable information will serve as a reference for policymakers, specialists and practitioners working with drug-related issues.'

The EDR package, made up of complementary elements in an easy-to-use format, makes full use of the data and analyses prepared by the EMCDDA.
It includes the *Trends and developments report* — a top-level overview of the drug phenomenon in Europe ([3]); a new series of online analyses on specific topics called Perspectives on drugs; national data in Country overviews; the Statistical bulletin; and Health and social responses profiles.

Established expert networks were further consolidated in 2013, in a range of areas including epidemiological key indicators, prevention, treatment and best practice, laws, and new drugs and trends. New networks, such as the EMCDDA Reference Group on drug supply and the expert network of forensic scientists, were created. The drug supply group met for the first time to set the practical framework for its operations and to discuss the main challenges it faces.

In the area of demand reduction responses, 2013 was productive and we released seven new outputs, including an Insights report providing a critical review of existing addiction theories, called *Models of addiction* ([4]). Significant advances were made in the area of best practice, including the drafting of several scientific articles and online analyses, along with the development of the agency's Best practice portal ([5]).

In 2013, the agency also made progress in developing key indicators in the areas of drug markets, drug-related crime and drug supply reduction. Priority was given to developing sub-indicators on drug seizures and on drug production facilities. A paper was released on Europe's specialised drug police units ('drug squads') ([6]). ■

Elements from the EDR package

Working in partnership

Pursuing successful partnerships and seeking synergies help promote efficiency. In 2013, we continued to develop our activities with a range of partners, including EU institutions and agencies, international organisations, Member States and third countries, and renowned academic institutions.

Collaboration with EU agencies was strengthened, in particular with Europol, the European Police College (CEPOL), Eurojust, the Fundamental Rights Agency, the European Medicines Agency (EMA), the European Centre for Disease Prevention and Control (ECDC) and the Consumers, Health and Food Executive Agency, while operational synergies were sought with the European Maritime Safety Agency.

Cooperation with candidate and potential candidate countries continued within the framework of the Instrument for Pre-accession Assistance (IPA) technical assistance project started in 2012 concerning Albania, Bosnia and Herzegovina, Croatia, the former Yugoslav Republic of Macedonia, Iceland, Kosovo ([7]), Montenegro and Serbia. Project work to date received excellent results in an external evaluation carried out in 2013, with top marks ('very good') for four out of the six criteria monitored (relevance, quality of design, efficiency and impact).

In 2013, the EMCDDA was awarded funding of EUR 450 000 for a new, two-year technical assistance project in European Neighbourhood Policy (ENP) countries. The project, called 'Towards a gradual improvement of ENP partner countries capacity to monitor and to meet drug-related challenges', aims to strengthen the capacity of selected ENP partner countries (Armenia, Azerbaijan, Georgia, Israel, Moldova, Morocco and Ukraine) to react to new challenges and developments in the drug situation in their respective countries. Implementation will start in 2014.

Disseminating scientific knowledge is vital for the EMCDDA. This can be achieved through collaboration with academic

([3]) emcdda.europa.eu/publications/edr/trends-developments/2013

([4]) emcdda.europa.eu/publications/insights/models-addiction

([5]) emcdda.europa.eu/best-practice

([6]) emcdda.europa.eu/publications/emcdda-papers/drug-squads

([7]) This designation is without prejudice to positions on status, and is in line with United Nations Security Council Resolution 1244/99 and the International Court of Justice Opinion on the Kosovo declaration of independence.

Group photo from the Reitox Academy held in Bruges in February

initiatives, as illustrated by our training projects. Following the partnership launched in 2012 between the Instituto Superior das Ciências do Trabalho e da Empresa — Instituto Universitário de Lisboa (ISCTE–IUL) and the EMCDDA, the second edition of the summer school called 'Drugs in Europe: supply, demand and public policies' took place in July 2013, with 28 students attending.

Two other training initiatives were developed as part of the Reitox Academies programme in our IPA project: the Academy on 'The European Union, the EU drugs policy and the enlargement process under the Lisbon Treaty', implemented jointly with the College of Europe in Bruges, and the training course on 'Contemporary approaches in drug monitoring', organised with the First Faculty of Medicine of Charles University in Prague. The latter was adapted and repeated in Lisbon, bringing together experts and heads of national drug observatories from Latin American and Caribbean countries.

We should add here that our achievements in 2013 hinged on the close partnership the agency maintains with experts working across Europe, and in particular the Reitox NFPs. An important priority during the year was the review of the system for reporting national data on the drug situation. In the future, this revised system will allow both the EMCDDA and the NFPs to better address the information needs of European and national stakeholders while rationalising resources. In addition, the second Reitox week for network member countries and third countries took place in May. ■

About Reitox…

Reitox is the European information network on drugs and drug addiction. It started working in 1995 and is now made up of 30 partners, including the EU Member States plus Turkey and Norway, along with the European Commission. The abbreviation 'Reitox' comes from the French *Réseau Européen d'Information sur les Drogues et les Toxicomanies*. Members of the Reitox network are designated national institutions or agencies responsible for data collection and reporting on drugs and drug addiction and help promote the work of the EMCDDA at country level. These institutions are called 'national focal points' or 'national drug observatories'.

Alerting and anticipating

The EU Early Warning System on new drugs (EWS), implemented by the EMCDDA together with Europol and partners in the Member States, met serious demands in 2013 as the number of new psychoactive substances (NPS) arriving on the market continued the upward trend started in previous years (81 NPS formally notified, representing an increase of nearly 300 % from figures reported in 2009). Sixteen public-health-related alerts were also issued.

The annual meeting of the Reitox EWS network was organised in conjunction with the Europol second law enforcement meeting on NPS, and followed by the Third international multidisciplinary forum on new drugs, which attracted 130 participants from around the world. The EMCDDA was also co-organiser of the Second international conference on novel psychoactive substances. This brought together 250 researchers and practitioners in the NPS field.

Monitoring new developments was a focus of our work in 2013. The EMCDDA launched a trendspotter study on methamphetamine in Europe and a related expert meeting. The conference 'Testing the waters: first international multidisciplinary conference on detecting illicit drugs in wastewater' was a high point. This was organised with the SEWPROF project ([8]) and brought together 90 experts from 20 countries on a topic that is receiving increasing attention in the EU.

Both the ECDC and the EMCDDA continued to collaborate closely on how to detect and respond to outbreaks of HIV among people who inject drugs, to help strengthen Member State capacity to monitor and prevent further HIV infections in this population group. The two agencies took part in a regional HIV risk assessment exercise, followed by the publication of a joint risk assessment report. ■

([8]) Sewage profiling at the community level (SEWPROF) is a research project funded by the European Commission, Marie Curie Actions, Seventh Framework Programme, Initial Training Network.

Informing policy

In 2013, the EMCDDA continued to support drug policy dialogue at EU level by providing expertise and technical information to the European Parliament, the Council of the EU and the European Commission.

Mr Götz presented the *EU drug markets report* and the EDR to the Committee on Civil Liberties, Justice and Home Affairs (LIBE) of the European Parliament. He also presented the EDR to the European Ministers for Justice and Home Affairs.

The agency provided input to the preparation of the EU drugs action plan 2013–16, adopted in June, and the EU policy cycle for organised and serious international crime 2013–17 within the Council's Standing Committee on Operational Cooperation on Internal Security (COSI). In 2013, we fulfilled tasks under the operational action plan for 2012–13, namely in the field of synthetic drugs, and helped define the priorities for the next policy cycle. Furthermore, the EMCDDA contributed to the Council Conclusions on improving the monitoring of drug supply in the EU, adopted at the Economic and Financial Affairs Council meeting of 15 November in Brussels.

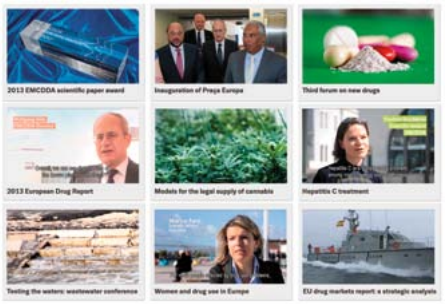
In terms of policy issues linked to NPS, at the Council's request the EMCDDA's Scientific Committee carried out a risk assessment of 5-(2-aminopropyl)indole (5-IT). Data collection exercises were launched with the EWS network on four new substances and EMCDDA–Europol Joint Reports were prepared and submitted to the European Commission, the Council of the EU and the EMA.

The EMCDDA launched several short reports during the year, including papers on drug supply reduction and internal security policies in the EU, drug policy advocacy organisations in Europe, and a drug policy profile on Ireland ([9]). ■

Dynamic and diverse communication

October 2013 marked two decades since the EMCDDA's founding Regulation (Council Regulation (EEC) No 302/93) came into effect. Over the years, the agency has established strong and credible mechanisms for the regular, sustained monitoring of developments in the European drugs field, along with rapid responses to new trends and substances. A central challenge we face today as we look to the future is to continue to deliver high-quality analyses on established topics while developing our work in other strategically important areas, with diminished resources.

The EMCDDA continues to improve and extend its communication outputs. Activities in 2013 were guided by the integrated communication strategy adopted in 2012, where communication activities are inextricably linked to the agency's scientific and technical work.



Some of the videos released in 2013

([9]) All available at emcdda.europa.eu/publications

The agency's main outputs to its audiences over the period included a complementary set of online tools and web-based resources, along with 41 products. The website is increasingly the preferred channel for disseminating all of our outputs. The EMCDDA has also invested more time in social media communications and has produced several videos to promote its results, whilst maintaining news releases to mark the launch of key products. In addition, 34 scientific articles were published over the same period in well-established journals.

Furthermore, in 2013 EMCDDA staff participated in 277 international conferences, technical and scientific meetings. The agency also disseminated findings from its work to over 260 visitors to our offices, including policymakers, scientists and researchers, practitioners and European citizens. ■

Scientific distinction

Three publications produced by the EMCDDA were nominated among the 'Notable Government Documents of 2012' by the American Library Association. These were the *EU drug markets report: a strategic analysis* and two Insights reports on *Cannabis production and markets in Europe* and *New heroin-assisted treatment: recent evidence and current practices of supervised injectable heroin treatment in Europe and beyond*. This accolade brought further recognition for the scientific excellence of the agency's work.

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PERSPECTIVES ON DRUGS

The EU drugs strategy (2013–20)

EU drugs strategies and action plans direct collective action in the field of drugs both within the European Union and at international level. They do not impose legal obligations on EU Member States but promote a shared model with defined priorities, objectives, actions and metrics for measuring performance. Member States, and also some candidate and pre-accession countries, use this framework to develop their own national policy documents, which are increasingly synchronised with the EU strategy. They remain free to emphasise different national priorities within the overall framework of an integrated, balanced and evidence-based approach to the drugs problem.

Full edition of this article with interactive features available online at

emcdda.europa.eu/topics/pods/eu-drugs-strategy-2013-20

Internationally, the EU drug strategies aim to add value to Member States' policies by offering a platform for coordination in relation to international issues and promoting the EU approach to tackling the drugs problem. The strategies also play an important role in the definition of tasks for EU institutions, bodies and agencies, and are taken into consideration by the European Commission when setting funding priorities in the drugs field.

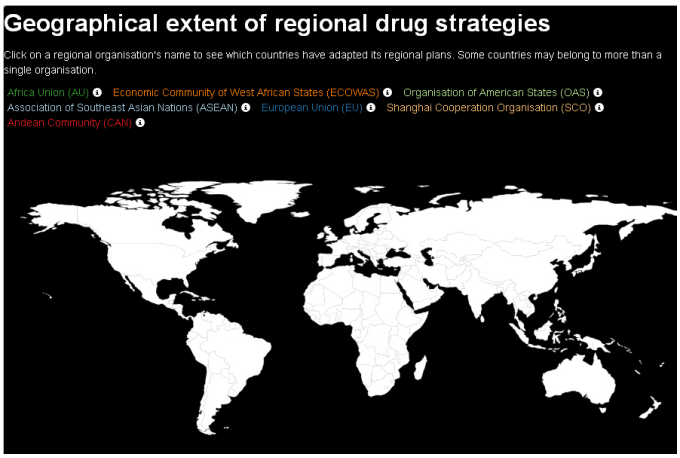
A final external evaluation of the EU drug strategy (2005–12) found that it provided a forum for consensus building and decision-making and a platform for information sharing and mutual learning. It also enhanced the 'voice' of the EU in international fora and promoted a culture of harmonised data collection and best practices identification. The review recommended, among others, to further promote the development and use of evidence for drug policy, as there remain instances of insufficient evidence about the effectiveness of specific measures.

A new strategy...

A new EU drugs strategy (2013–20) ([1]) was endorsed by the Justice and Home Affairs Council of the European Union on 7th December 2012. It constitutes the ninth strategic document on illicit drugs endorsed by EU Member States since 1990 and presents their current drug policy position and aspirations, identifying common objectives to reduce drug demand, dependence and supply. Two consecutive four-year action plans will translate the strategic priorities into specific actions with a timetable, responsible parties, indicators and

([1]) http://register.consilium.europa.eu/pdf/en/12/st17/st17547.en12.pdf .

Interactive element: map



Interactive: world regional strategies available on the EMCDDA website: emcdda.europa.eu/topics/pods/eu-drugs-strategy-2013-20

Facts and figures

European Union:

Member States: 27

Population: 503.6 million

Surface: 4 million km^2

EU drugs strategies:

First European plan to combat drugs: 1990

Horizontal working party on drugs: 1997

First EU drugs strategy: 2000

First evaluation of a EU drugs strategy: 2004

First external evaluation of a EU drugs strategy: 2012

assessment tools. These are drafted by corresponding EU Presidencies in 2013 and 2017. The first of these action plans for 2013–16 was adopted under the Irish Presidency of the EU in July 2013. It is structured around two policy areas: drug demand reduction and drug supply reduction; and three cross-cutting themes: coordination; international cooperation; and information, research, monitoring and evaluation. A second action plan for the period 2017–20 will be prepared following an external mid-term assessment of the EU drugs strategy by 2016.

...responding to new challenges in the drugs market

There are a number of significant changes in the EU drugs market which the 2013–20 strategy aims to address. In particular the rapid increase in number of new psychoactive substances becoming available on the drug market as well as diversification in drug trafficking routes and methods of transport are among the challenges that Member States now face. In response, the new strategy sets objectives geared towards the disruption of illicit drug trafficking through intelligence-led law enforcement and a more effective use of the criminal justice system. It also proposes that special attention be paid to communication technologies, which play a significant role in the spread of drugs, particularly new psychoactive substances. It calls for the development of alternatives to traditional law enforcement approaches, which it recognises are increasingly challenged by issues such as the combined use of illicit drugs and alcohol, the misuse of prescription medicines, as well as the so-called 'legal highs' phenomenon.

...addressing health and social issues

For the first time, the 2013–20 strategy incorporates the 'reduction of the health and social risks and harms caused by drugs' as a policy objective, alongside the two traditional drug policy aims of reducing supply and demand. The role of civil society in the drug policy-making process is also enhanced, with explicit support given to the involvement of young people, drug users and clients of drug-related services in policy development. The social reintegration and recovery of all drug users is expected to receive increased attention over the eight-year period as the ultimate goal of drug treatment services. Drug use in prison has also been given increased emphasis, to ensure that the care received by drug users in penal institutions is equivalent to that provided by health services in the community.

... and supporting evidence-based decision making

The new strategy stresses the need for an empirical and evidence-based approach to drugs policy. It expands the main principles on which international drugs policies are based by adding the principle of evidence-based decision-making to the integrated and balanced approach enshrined in the 2009 UN political declaration on drugs ([2]). The strategy outlines a model for EU drugs policy that is: integrated, combining all aspects of drugs activities; balanced, concentrating equally on demand and supply reduction measures; and evidence based, drawing on scientific findings. It aims for an improved understanding of the impact of drug policy measures, the adoption of quality standards and best practice in drug demand reduction alongside the implementation of key

([2]) http://www.unodc.org/unodc/en/frontpage/2009/June/political-declaration_--states-renew-commitment-to-eliminate-drug-abuse.html .

indicators to measure success in the area of drug supply reduction. The strategy provides Member States with a forum for open debate about the effectiveness of demand reduction measures and, increasingly, supply reduction measures, and explicitly supports drug monitoring and collection of data on best practices.

Timeline: other regional drugs strategies

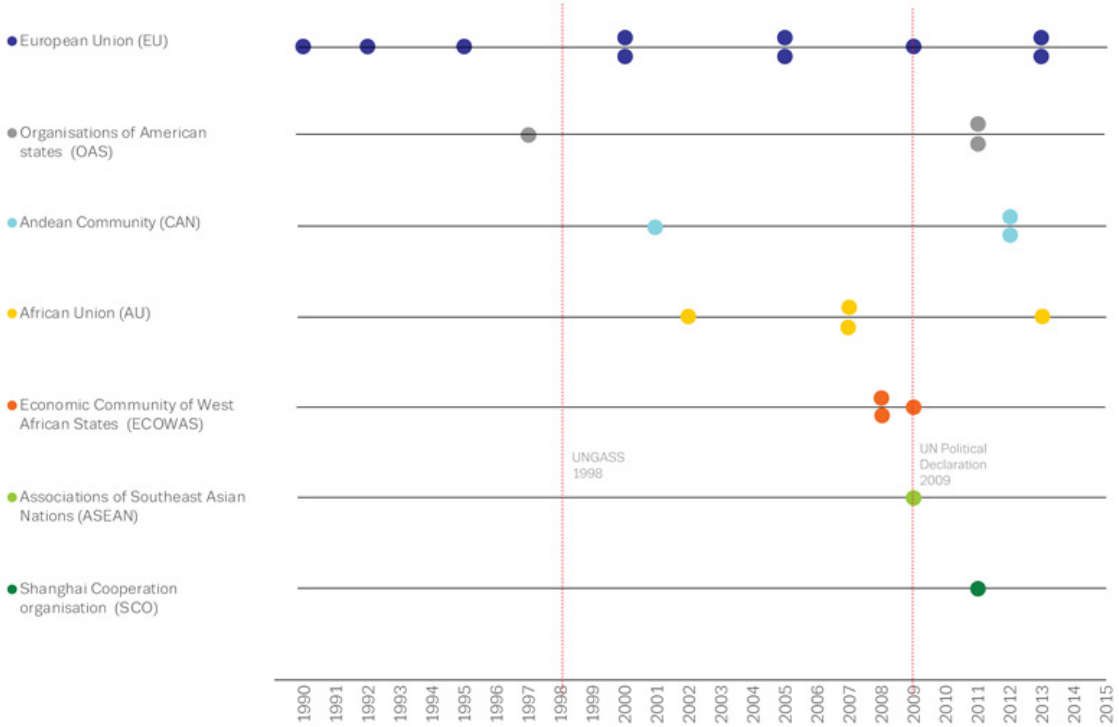
Alongside the European Union, other international organisations have developed regional drug strategies and action plans in recent years. These now cover 147 countries in four continents (see online interactive map).

In the Americas, the Organization of American States (OAS) adopted the Hemispheric Drug Strategy in 2010 and, a year later, a Plan of Action (2011–15) to implement the strategy's objectives. In parallel, the Andean Community adopted its own drug strategy 2012–19 and action plan 2012–16.

In Africa, the African Union (AU) adopted the Plan of Action on drug control (2013–17), while the Economic Community of West African States (ECOWAS) adopted the Regional Action Plan to Address the Growing Problem of Illicit Drug Trafficking, Organised Crime and Drug Abuse 2008–11.

In Asia, the Association of Southeast Asian Nations (ASEAN) adopted the Work Plan on Combating Illicit Drug Production, Trafficking, and Use 2009–15, with the aim of achieving a drug-free region. In addition, the Shanghai Cooperation Organisation (SCO) aims to drastically reduce the scale of trafficking in and consumption of drugs and precursors through the Counternarcotic Strategy of the SCO Member States 2011–16.

The objectives and content of these strategies reflect differences in drug situations and available resources between the regions where they are to be implemented. There is however also a certain degree of similarity in key policy areas and a common use of a comprehensive approach to reduce both drugs supply and demand. The increasing number of regional strategies also reflects a growing understanding that drugs are an issue that cannot be tackled only at the national level and that coordinated regional approaches to common problems can be developed.



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EU DRUG MARKETS REPORT
A STRATEGIC ANALYSIS

Case study 1
Cannabis: changing demand and an increase in domestic production

Europe remains one of the world's largest consumer markets for cannabis resin, the majority of which continues to be sourced from Morocco. Traditionally associated with resin consumption, the western part of the region is now increasingly dominated by herbal cannabis.

An estimated 2 500 tonnes of cannabis are consumed every year in the EU and Norway, corresponding to a retail value of between 18 and 30 billion euros. The largest markets for cannabis resin are Italy, Spain and France, and for cannabis herb, the United Kingdom and Germany.

Indoor cannabis cultivation site.
Photo: Spanish Guardia Civil via Europol.

Cannabis cultivation techniques have advanced and indoor cultivation has spread, reducing the demand for imported products ('import substitution'). Domestic cannabis production is widespread throughout Europe, taking place both indoors and outdoors, and is increasing.

Although there are a number of growers catering for their own needs, the use of large-scale production facilities run by criminal groups is increasing in some countries, while some of them now tend to run multiple small-scale plantations to mitigate risks.

Domestic production of herbal cannabis in Europe is a major challenge for law enforcement. Production is difficult to detect, especially when occurring indoors, and trafficking of the drug, now often intra-regional, is more difficult to interdict than that of imported resin. This is reflected in the estimated interdiction rates at around 30 % for resin and below 10 % for herb in the EU.

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A STRATEGIC ANALYSIS

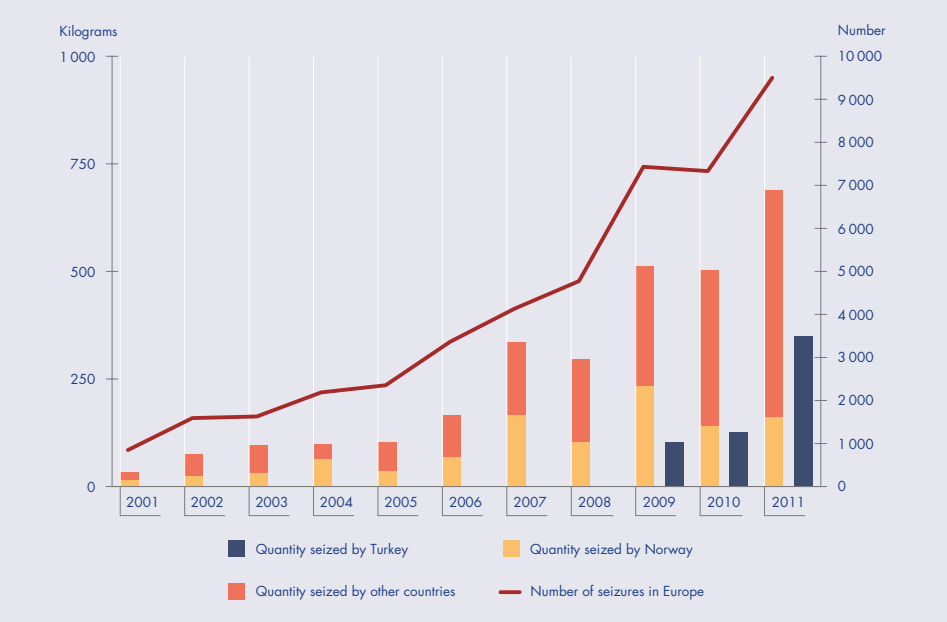
Case study 2
Methamphetamine production and trafficking increasing in Europe

Production and trafficking of methamphetamine is increasing in Europe, and it is spreading outside its traditional consumer markets of the Czech Republic and Slovakia.

Manufacturing of methamphetamine is now occurring or increasing in countries where it was previously absent or low-level, including Austria, Bulgaria, Germany, Hungary, Lithuania, the Netherlands, Poland and the United Kingdom.

Europe is also now used as a transit territory for methamphetamine made in Africa and the Middle East and trafficked by air to East Asia. For instance, Turkey, a country traditionally associated with the heroin trade, is now a significant transit area for methamphetamine exports to Asia.

Seizures of methamphetamine in Europe, 2001–2011



Note: All 26 European countries reporting methamphetamine seizures are included, except the Netherlands and Poland where *Number of seizures* data are not available. The total amounts represent the sum of the quantities of methamphetamine seized under different forms; for calculation purposes, tablets were assumed to weigh 250 mg.
Four countries—Spain, Malta, the United Kingdom and Croatia—do not report methamphetamine seizure data.

Source: EMCDDA/Reitox national focal points, EMCDDA (2012a).

As a result, the quantities of methamphetamine seized in Europe, including Turkey, have increased six-fold since 2006, while the number of seizures was multiplied by three during that period (see graph).

The main new consumer markets for the drug are in Central Europe and Scandinavia. They include Germany, Norway and Sweden, three countries traditionally associated with the use of amphetamine.

Although compared to other world regions, such as Asia and North America, production and use of methamphetamine is limited in Europe, the spread of this drug is worrying and warrants careful monitoring.

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Case study 3
New psychoactive substances: 73 detected in 2012

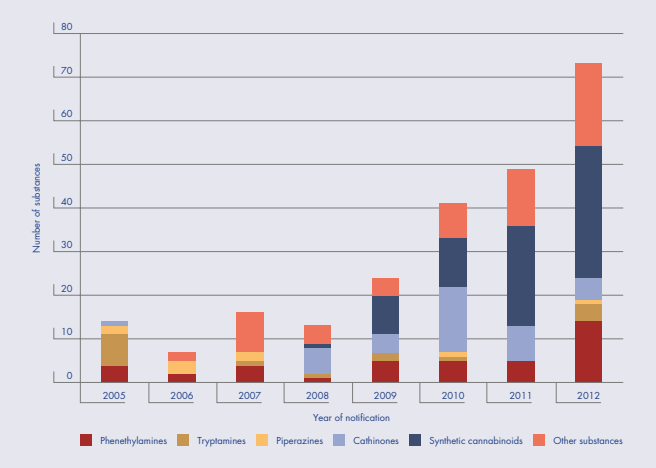
New psychoactive substances are a diverse group of drugs that are not controlled under international law.

They are emerging at an unprecedented rate: 73 substances were notified in 2012, up from 49 in 2011 and 41 in 2010. More than 200 new substances have been notified across the EU since 2005.

Often marketed as 'legal highs', the substances are sourced legally as powders from China and India in bulk quantities. They are then imported into Europe and turned into final products. These in turn are sold on the open market as replacements for controlled drugs using aggressive and sophisticated marketing strategies.

Some new psychoactive substances are sold directly on the illicit market as drugs in their own right or deceptively as MDMA (ecstasy), amphetamine or cocaine.

Number of new psychoactive substances notified to the European Early warning system, 2005–2012



Source: EMCDDA/EWS.

The Internet plays a key role in reshaping the 'new drugs' market: a growing number of Internet shops have been identified by EMCDDA monitoring with almost 700 identified in 2012.

A recent EU survey in young people aged 15–24 found that lifetime use of 'legal highs' in most Member States was 5 % or less, with use in the United Kingdom, Latvia, Poland and Ireland being 8 %, 9 %, 9 % and 16 % respectively.

Tablets resembling 'ecstasy' found to contain 5-(2-aminopropyl) indole (5-IT).
Photo: Hungarian national focal point.

'Annihilation': a so-called 'legal high' that led to hospitalisations in Europe. Analysis of samples found different combinations of synthetic cannabinoids, some of which are controlled drugs in some countries.
Photo: Simon D. Brandt, Liverpool John Moores University.

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A STRATEGIC ANALYSIS

Case study 4
Twenty-seven arrested as European police dismantle drug smuggling network

An international drug smuggling network responsible for trafficking large quantities of illegal drugs into and out of Spain has been dismantled. Operation Capea, led by Spain's Guardia Civil in Navarra, was coordinated by Europol and Eurojust, working in cooperation with French and Dutch law-enforcement authorities.

Over a period of years, this organised criminal group from Navarra was the main importer of amphetamine sulphate into Spain. Together with another criminal group based in Valencia, which supplied consignments of cannabis resin shipped in horse transporters, the drugs were concealed in cans and then transported by lorry to The Netherlands. On 30 November 2011, French police intercepted a lorry bound for The Netherlands which contained over half a tonne of cannabis resin. This was to be exchanged for 200 kg of amphetamine and sent back to the criminals in Spain for onward distribution.

Photo: Europol.

The effective law enforcement cooperation demonstrated by this operation resulted in:

- a seizure of 675 kg of cannabis resin by French police.
- Spain's Guardia Civil carrying out 25 house searches and seizing:
    - 4.3 kg of amphetamine plus ketamine, cocaine and other illegal substances
    - an indoor cannabis plantation and more than 100 cannabis plants
    - four firearms
- 27 arrests in Spain in Valencia, Madrid, La Rioja, Zaragoza and Navarra. Those arrested were linked to three international drug trafficking organisations.
- Spanish customs (AEAT) blocking 97 bank accounts and seizing 19 apartments, six companies and eight vehicles as part of a parallel money-laundering investigation.

Supporting the investigation were two Europol specialists who were present in Spain for the action day, deploying the Europol mobile office, as well as assisting with the secure dismantling of outdoor and indoor cannabis plantations. In the initial stages of the investigation, Europol hosted an operational coordination meeting in The Hague, and Europol drugs experts facilitated the exchange and analysis of key criminal intelligence.

EU DRUG MARKETS REPORT
A STRATEGIC ANALYSIS

Case study 5
Synthetic drugs network broken up

Photo: Europol.

In early 2012, an international organised crime network, responsible for the large-scale production and trafficking of synthetic drugs, was broken up following an extensive investigation by European law-enforcement authorities. The operation resulted in the arrest of the key members of the criminal network, the discovery of three illegal drug production facilities and the seizure of over 100 kg of amphetamine, significant quantities of drug precursors, ammunition, firearms and explosives.

The investigation began when Swedish authorities identified large quantities of amphetamine being trafficked into Sweden. Cooperation was then launched with Europol and other EU Member States when enquiries confirmed that an international criminal network was involved. Based on intelligence and links identified between different countries, Europol initiated 'Operation Fire', working together with several European law-enforcement agencies. The aim of the operation was to dismantle the organised crime network and stop the large-scale production and trafficking of synthetic drugs within the European Union.

Parallel investigations started in Sweden and Germany, while other countries involved supported the operation and conducted their own enquiries. Europol helped coordinate 'Operation Fire' and foster the exchange of criminal intelligence.

During the operational phase of the investigation, 30 kg of amphetamine were seized in Sweden and three suspects arrested as well as two in Germany and one in the Netherlands. In addition, cooperation with Bulgarian authorities led to the arrest of three members of the organised crime network and the dismantling of three illegal synthetic drug production facilities. The Bulgarian authorities seized approximately 75 litres of amphetamine base (enough to produce around 120 kg of pure amphetamine), 15 kg of amphetamine substance and over 1 400 litres of various chemicals used to produce synthetic drugs. Equipment, including two tableting machines, together with five firearms, 150 rounds of ammunition and 6.4 kg of trinitrotoluene (TNT) was also seized.

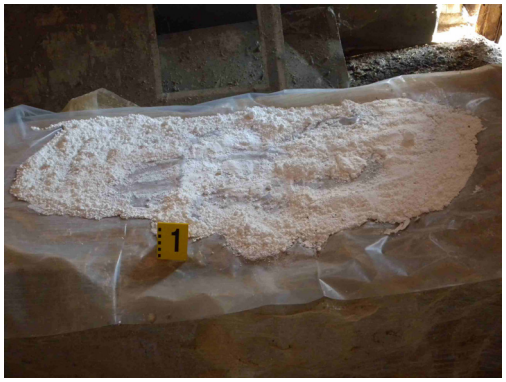

Photo: Europol.

Following the results of this operation, Europol's Director, Rob Wainwright, commented: 'The successful cooperation between Europol and our European law-enforcement partners has delivered a major blow to this dangerous criminal network of drug producers and traffickers, and will bring justice to those concerned. Europol will continue to proactively support such investigations with our intelligence and technical capabilities and we anticipate further results in this area of serious organised crime.'

'Crime knows no borders, and neither should we. This joint operation goes to show just how immensely important it is for national law enforcement and Europol to effectively exchange information about dangerous criminal activities,' said Cecilia Malmström, European Commissioner for Home Affairs.

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Case study 6
6.5 tonnes of heroin precursor seized

As a result of an intensive cooperation between Slovakia, Hungary and several other EU Member States, supported by Europol and Eurojust, 6.5 tonnes of acetic anhydride, a critical heroin precursor, were seized in Hungary on 5 April 2011 by Hungarian Police services.

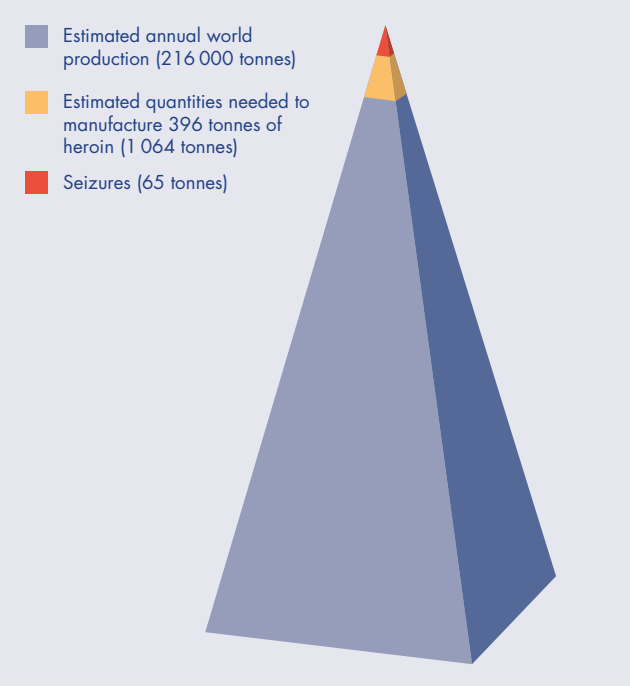
These efforts led to the dismantling of a major organised criminal group network heavily involved in acetic anhydride trafficking. Several house searches were successfully executed in the Czech Republic, Slovakia, Hungary, Slovenia and the main suspects were arrested. The organised crime group concerned was involved in the trafficking of at least of 30 tonnes of the precursor.

The significance of the seizure was recognised in terms of the quantity involved and the amount of heroin that could have been manufactured had the consignment reached the heroin laboratories in Afghanistan, for which it was destined.

Europol supports several such multi-lateral operations and continues to target wider organised crime groups involved in this activity. Through analysis of case data a number of operational links were found and operational meetings were convened by Europol to exchange information in support of investigative teams in the field.

On an international level, the case was regarded as significant, and it was a follow-up from a recent 10-tonne seizure of acetic anhydride in Turkey that originated in the EU. In total, more then 30 tonnes of the precursor were seized by European law-enforcement authorities, supported by a Europol sub-project on heroin precursors.

Acetic anhydride: estimated annual world production, estimated requirements for heroin manufacture and seizures in 2010



Note: Between 1.08 and 4.32 kg of acetic anhydride is required to manufacture 1 kg of heroin (INCB, 2012a). Therefore, in 2010, between 417 and 1 711 tonnes (a mid-range point of 1 064 tonnes) of diverted acetic anhydride would have been needed to manufacture the 396 tonnes of heroin estimated to have been produced worldwide (UNODC, 2011a).

Sources: UNODC (2011a), INCB (2012a).

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A STRATEGIC ANALYSIS

Case study 7
International judicial and law-enforcement cooperation leads to trial against major Swedish cocaine smugglers

On 26 March 2012, a highly organised drug trafficking network was brought to trial in Sweden. Eight members of the group faced criminal charges for trafficking multi-tonne shipments of high-quality cocaine from South America to Europe. Another trial on the money laundering activities related to drug trafficking was also held in Spain.

The indictments came as a result of more than three years of joint international effort at both law-enforcement and judicial level in Sweden, Spain and France, with continuous support from Eurojust and Europol. Several other Member States (the Netherlands, Malta, the United Kingdom, Estonia, Cyprus and Germany), as well as several third States (Colombia, USA, Switzerland, Venezuela, Israel and Andorra), also provided valuable assistance.

Photo: Europol.

The investigation started in Sweden in December 2008. The international dimensions of the case soon became clear, and consequently, a Joint Investigation Team (JIT) was established for the purpose of coordinating operational and judicial activity. The JIT legal framework enabled a prompt exchange of information to take place without the need for lengthy rogatory procedures.

A first success for the JIT came with the seizure of 1.4 tonnes of cocaine found on board a 15-metre sailboat bound for Europe. The boat was boarded by French authorities in the Caribbean and was brought to Martinique in June 2010. The only person on board, a 56-year-old Swede, was arrested. The investigations continued, focusing on the main criminal figure and his accomplices, who were still at large. The investigators linked the suspected criminals to a sophisticated network of companies created to facilitate money laundering, money transfers and property acquisitions.

More than 30 people were subsequently arrested throughout the world. Spanish authorities froze several bank accounts as part of the investigations into money laundering and approximately 6 million euros were seized in five different countries, linked to reinvestments in real estate, a discotheque and other legal businesses, luxury vehicles and ships. The network appears to have invested and spent at least 12 million euros between 2007 and 2010.

Europol provided operational analysis and facilitated the identification of key players in the organised crime group in Colombia, USA, France, French West Indies, Spain and Sweden. Additionally, they provided expertise and investigative support to the financial part of the case by facilitating the recovery of the assets obtained by the illicit activities of the organised crime group.

Eurojust facilitated the exchange of information and coordination of investigations. It hosted 13 coordination/JIT meetings to decide where the prosecutions should take place and to solve possible conflicts of jurisdiction and to coordinate the division of tasks among the various jurisdictions involved. Eurojust provided expertise in relation to the maritime interception.

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EU DRUG MARKETS REPORT
A STRATEGIC ANALYSIS

Case study 8
Mobile production units

The manufacture of synthetic drugs mainly takes place in stationary production units, such as farm houses, factories, apartments or sheds. However, a new trend of using mobile production units has been identified during several recent investigations, with the units being subsequently seized. Latest developments to the trend favour using mobile production units which are transported to a site where manufacture can start almost immediately. This saves considerable time as, in the past, stationary units needed to be built, installed and then rendered operational. Such instances are becoming more common.

Sound insulation, air ventilation and a purification system are present inside this mobile tableting unit.
Photo: Europol.

Seized mobile production units are designed, constructed and used for the:

- manufacture of amphetamine via reductive amination including distillation
- manufacture of MDMA via reductive amination with the use of hydrogen gas and platinum oxide and distillation
- manufacture of (MDMA) tablets with the use of a tableting machine, including mixing, packing and sealing
- manufacture of cannabis in a mobile cannabis nursery.

Mobile MDMA production unit with pressure reaction vessel and distillation (front, left); a mobile tableting unit (back, right).
Photo: Europol.

Trailers and trucks are often used for the construction of mobile production units. In most cases, the units are designed, built and installed in a professional manner with the production equipment, including cables and piping, being fitted to the floor, roof or side walls of the trailer or truck. In some mobile tableting units, sound insulation and air purification with both a ventilation system and absorption system (active carbon filter) are installed.

The introduction of mobile units has led to production at various locations for limited periods of time. The low cost and short time needed to set up a professional production unit are attractive and the use of timing devices means that the producer only needs to be physically present during a limited part of the production process.

In all cases, mobile production units can be up and running in a few hours. Often, all they need in order to function is an electricity and water supply. The use of the aforementioned timing devices in some units means that after starting the process (amphetamine or MDMA production), the producers can leave the unit unattended. The equipment shuts down automatically after a set period of time, which is the time needed to achieve synthesis.

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Strategic meeting on drug trafficking

The Hague, 29-30 September 2014

OUTCOME REPORT

Eurojust

01 December 2014

1. Introduction

The strategic meeting on drug trafficking, organised by Eurojust, was held in The Hague on 29 and 30 September 2014. In total, 80 prosecutors, law enforcement authorities and experts in the drug trafficking field from across the Member States of the European Union met at Eurojust's premises for two days of intensive workshops and discussions. Contributions were also received from representatives of Brazil, the USA and Norway, as well as EU bodies and international organisations, including Europol, the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), the Council of Europe (Pompidou Group) and the United Nations Office on Drugs and Crime (UNODC).

With a focus on increasing the effectiveness of international judicial cooperation in drug trafficking cases, this strategic meeting followed Eurojust's strategic seminar on drug trafficking held in Krakow in October 2011, together with the Polish Presidency of the EU. The Krakow seminar called for a multi-disciplinary and coordinated response at international level against organised criminal groups (OCGs) involved in the trafficking of drugs.

Progress with respect to the drug trafficking action plan for Eurojust was presented, together with areas in which further work is required: **controlled deliveries, (pre)precursors and new psychoactive substances (NPS), and cooperation with third States**. The three workshops addressed these areas and gave participants the opportunity to discuss, with reference to case scenarios, pressing issues face-to-face and in-depth.

Prior to the strategic meeting, Eurojust circulated two questionnaires to the Member States: one on controlled deliveries and one on judicial perspectives on NPS and pre-precursors. Based on the replies to the questionnaires, in-depth analysis was carried out. The results of the analysis served as a starting point for discussions.

2. Opening session

Klaus Rackwitz, Administrative Director of Eurojust, welcomed the participants and briefly presented the efforts of Eurojust in enacting its Action Plan against drug trafficking, in which almost all objectives were achieved. Drug trafficking remains one of the EU crime priorities, as demonstrated by the large number of drug trafficking cases referred to Eurojust and the large number of coordination meetings organised by Eurojust to solve judicial cooperation and coordination issues in drug trafficking cases. In 2013 alone, 239 cases were opened, 56 coordination meetings held and 26 joint investigation teams (JITs) formed.

Francisco Jiménez-Villarejo, Vice-President of Eurojust and National Member for Spain, highlighted that drug trafficking is a serious crime that continues to be a major concern and a threat to the safety and well-being of EU citizens, and therefore is an EU and Eurojust priority. He indicated that the focus of the strategic meeting was to identify ways to increase the effectiveness of international judicial cooperation in drug trafficking cases with support from Eurojust and other EU agencies. Eurojust has been actively involved in identifying practical and legal obstacles in judicial cooperation in drug trafficking cases, and has provided possible solutions to address them within the framework of the Eurojust 2012 strategic project, *Enhancing the work of Eurojust in Drug Trafficking Cases (*the 'strategic project'*)*. Mr Jiménez-Villarejo introduced the agenda of the strategic meeting, highlighting the three areas of judicial cooperation identified by the strategic project as presenting challenges and requiring further insight.

Axel Voss, Member of the European Parliament and Rapporteur for the Eurojust Regulation, expressed strong concern about the increased threat posed by serious crime, including drug trafficking, trafficking in human beings and illicit trafficking of firearms. These crime types are highly profitable activities that present many challenges in investigation and prosecution. In the area of drug trafficking in particular, significant challenges are encountered due to the cross-border aspect of the crimes and the rate at which the synthetic drugs market, and especially the new psychoactive substances market, evolves. Mr Voss stressed that drugs are dangerous and their consumption poses public health challenges. Therefore, the fight against drug trafficking should be high on the EU agenda. OCGs have increased their activities. Drug trafficking crimes are committed by mobile OCGs that are active in more than one country. One Member State acting alone cannot easily detect and combat drug trafficking. Mr Voss called for a coordinated response and highlighted the essential role played by Eurojust in improving coordination of investigations and prosecutions and in assisting judicial authorities in dealing with cases involving third States. As Rapporteur for the Eurojust Regulation, Mr Voss concluded his presentation by stressing the importance of reforming Eurojust in light of the provisions of Articles 85 and 86 of the Lisbon Treaty.

Paola Tardioli-Schiavo, Deputy Head of the Anti-Drugs Policy Unit in the European Commission, DG Justice, agreed that Member States, EU and international organisations need to stay firmly committed and strengthen action against the main challenges brought about by drug trafficking. She highlighted that the level of use of traditional drugs in most countries is stable or declining, but the emergence of NPS puts increasing pressure on Europe's drug control models. Ms Tardioli-Schiavo explained how the European Commission has taken firm action to protect young people from the dangers of 'legal highs' through an innovative legislative proposal. She also mentioned other challenges (e.g. more sophisticated concealement methods, drug traffickers adapting quickly to changes in demand or supply, the need to use alternative trafficking routes, trafficking groups diversifying their business and criminal groups become increasingly interconnected) and how the Commission has responded to these challenges. The Commission has two main objectives when responding to the challenges: to disrupt trafficking flows and prevent drugs from reaching the European Union, and to address the harmful consequences of trafficking. The Commission presented two legislative proposals in September 2013 to strengthen the EU's ability to respond to the challenges posed by the NPS: a proposal for a Regulation to replace Council Decision 2005/387/JHA and a proposal for a Directive that amends the 2004 Framework Decision on drug trafficking. The Commission has also developed new legislation to clamp down on the trafficking in drug precursors. In September 2013, new legislation was adopted to strengthen EU rules on the control of production and trade in drug precursors. Ms Tardioli-Schiavo reminded the participants that the Commission also enhances international cooperation via bilateral agreements against the diversion of drug precursors. An agreement with Russia on precursors was ratified in 2013, although its implementation is now delayed due to the present political situation. Similar agreements with Turkey, Mexico, Chile, the USA, China and the countries of the Andean region are proceeding. Ms Tardioli-Schiavo also mentioned that the European Union has adopted five legislative instruments to deprive traffickers of their gains. The newest instrument is a directive on confiscation and asset recovery, adopted by the European Union in April 2014. Ms Tardioli-Schiavo encouraged the enhancement of operational and international cooperation and the development of supply reduction indicators. Uncoordinated national action may force traffickers to move drug production sites to neighbouring countries or to shift trafficking routes, but will not ultimately disrupt trafficking.

Benedikt Welfens, Chair of the Trafficking and Related Crimes Team at Eurojust, presented Eurojust's *action plan on drug trafficking* and the results of implementation of the action plan. As background, he explained that the action plan was agreed in 2012 as a result of the strategic project. The action plan highlights eight areas for improving cooperation: coordination meetings, secure channels, Europol and third States, JITs and other coordination tools, conflicts of jurisdiction, cross-border asset recovery, controlled deliveries and number of coordination cases. Thirteen Key Performance Indicators (KPI) measure enhanced cooperation in these areas. Mr Welfens introduced the draft implementation report, which shows that 11 of the 13 objectives have been fully achieved or are in progress. Confidentiality and disclosure guidelines were approved in 2014, together with other guidance on coordination meetings, to be included in the Eurojust Operational Manual. Ten secure connections were established with Member States. Eurojust was also linked to the Europol Secure Information Exchange Network Application (SIENA), which fostered increased exchange of information between the two organisations and increased the level of Europol's attendance at coordination meetings. JITs were used in 30 per cent of cases (compared to 4 per cent during the previous analysis period), showing a greater awareness of the potential usefulness of this tool in drug trafficking cases. Guidelines on Article 7.2 of the Eurojust Decision were adopted in July 2012. These guidelines establish an internal procedure for the opinion of Eurojust regarding conflicts of jurisdiction and recurring refusals or difficulties concerning the execution of requests for judicial cooperation. Preliminary analysis was provided by Eurojust's Case Analysis Unit in 27 per cent of cases to prepare and facilitate discussions during coordination meetings. In conclusion, Mr Welfens mentioned three areas that required further work by Eurojust in 2014: cross-border controlled deliveries from a judicial perspective, judicial cooperation with third States and judicial cooperation in cases involving NPS, which had emerged from recent casework analysis. The in-depth analysis of the three areas have been added to the implementation report as *Issues in focus*.

3. Plenary session

3.1. Results of the Eurojust questionnaire on controlled deliveries

Ioana van Nieuwkerk, Legal Officer at Eurojust, presented the analysis of Member States' responses (26 in total) to a Eurojust questionnaire on judicial aspects of controlled deliveries. The analysis revealed a large number of obstacles encountered in judicial cooperation in this area, mainly due to persistent and significant differences between the legal systems of the Member States as regards the authorisation and execution of these special investigative techniques. The main reported obstacles were encountered due to uncertainties in the route/timing of the drug consignment (reported by 11 Member States) and due to difficulties in obtaining permission for placing GPS devices in vehicles suspected of transporting drugs (reported by 10 Member States). Moreover, the analysis showed that in a large number of Member States, a judicial authorisation based on an MLA request is needed for executing controlled deliveries, while in a few others, the police are responsible for granting such authorisation. The analysis also showed that 13 Member States have a central contact point for authorisation of controlled deliveries, while 13 Member States have not established one. These differences have created difficulties (in nine Member States) in the identification of competent authorities in other Member States or in obtaining their authorisation. Other major obstacles reported by the national authorities were related to insufficient resources or to differences between the legal requirements of the Member States with regard to: (i) substitution of unlawful drugs; (ii)

postponement of drug seizures; (iii) cross-border deployment of undercover officers; (iv) admissibility of evidence gathered in the context of controlled deliveries; (v) involvement of participating informants; (vi) deployment of armed police officers in other Member States; (vii) sharing of declassified information gathered in the context of controlled deliveries; etc. Problems in cooperation with third States in controlled deliveries have also been reported, as well as their limited experience in the use of controlled deliveries within JITs. Solutions were proposed by a number of Member States, including the harmonisation of legislation, the availability of updated information on the competent authorities and legal requirements of controlled deliveries in all Member States, as well as the involvement of Eurojust and Europol in such cross-border operations. The detailed findings of the questionnaire on controlled deliveries are reported in *Issue in Focus Number 1*, attached to the draft implementation report distributed to the participants.

3.2. Case study on cooperation with third States

Ingrid Maschl-Clausen, National Member for Austria, explained the background and challenges posed by the so-called 'JIT Vineyard', involving the investigating and prosecuting authorities from Austria, Germany, the Netherlands and the former Yugoslav Republic of Macedonia. The case focused on heroin trafficking rings. The drug was stored in the Netherlands, transported in small quantities to Austria and Germany, and sold there by an OCG whose heads were nationals of the former Yugoslav Republic of Macedonia. The arrest of low-level members of this OCG in Austria and Germany did not seem to have an adverse effect on their activities. The OCG leaders could not be extradited from their country. Eurojust's coordination meetings facilitated the opening of a parallel investigation in the former Yugoslav Republic of Macedonia and cooperation among all countries involved, which led to the execution of simultaneous actions and arrests. In view of the quantity of information to be exchanged among these countries as well as activities of restructured groups, a JIT was formed, allowing for measures, particularly telephone interceptions, to be carried out without the need for an MLA request for each action. Eurojust assisted in finding the legal basis for the JIT agreement (more than one legal arrangement applicable among the members) and with drafting and translating the JIT agreement into Macedonian. The JIT was active for one year with the involvement of four countries plus Eurojust and Europol. Prolongation for an additional year (until September 2014) took place between only two of the involved countries. In total, Eurojust held eight coordination meetings to facilitate the work of the JIT. The operation resulted in 360 convictions and the confiscation of approximately 91 kg of heroin.

3.3. Judicial perspectives on NPS and (pre)precursors

Federica Curtol, Senior Analyst at Eurojust, presented the methodology and main results of a survey among prosecutors in the matter of (pre)precursors and NPS. The relevance of the topic emerged from Eurojust's casework itself. An increasing number of cases were referred to Eurojust due to the difficulties posed by different legal frameworks operating in the Member States. Member States follow different approaches to the prosecution of non-regulated (pre)precursors (e.g. APAAN). Prosecution is not possible in almost half of the countries considered. In some Member States, the production of these substances is considered as a 'preparatory act' to the commission of drug production offences. In other Member States, an 'analogy or generic approach' is enforced to equate non-regulated (pre)precursors to chemically or functionally equivalent substances. An analogy approach is also in

place in some Member States to target NPS belonging to families of substances with similar chemical composition (i.e. synthetic cannabinoids or synthetic cathinones, such as mephedrone). Several Member States reported using legislation on or administrative regulation of medical products to address the problem of NPS and expressed some concerns about a possible legal gap caused by the European Court of Justice decision of 10 July 2014, in which the term 'medical product' is not considered to cover substances such as synthetic cannabinoids, which 'are consumed solely to induce a state of intoxication and are, as such, harmful to human health'[1]. Other judicial cooperation challenges were mentioned, including the length of procedures required to regulate this innovative drug market and the difficulties in identifying new substances due to the lack of capacity and technical methods. The detailed findings of the survey conducted by Eurojust are reported in *Issue in Focus Number 2*, attached to the draft implementation report distributed to the participants.

3.4. Global trends in drug trafficking routes and NPS

Karen Kramer, Senior Expert, Organized Crime Branch UNODC, presented global trends in drug trafficking. She outlined that in her presentation, as sources of information, she had used an annual report questionnaire (ARQ), crop surveys, country reports on regional Heads of National Drug Law Enforcement Agencies (HONLEA) meetings and the World Drug Report. She highlighted recent trends in the production and trafficking of the principal illicit drugs, specifically opiates, cocaine, amphetamine-type stimulants and cannabis and provided information on NPS and NPS trafficking. Afghanistan and Myanmar continue to account for the majority of illicit opium poppy cultivation worldwide. The majority of global opium seizures continues to be made by the Islamic Republic of Iran. Compared to opium and illicit morphine, heroin seizures cover a wider range of countries. Global seizures of heroin increased gradually over the period 2006-2011, peaking at 81 tons. Since 2010, heroin seizures in Africa, particularly East Africa, have increased. This shift in seizure trends potentially indicates that traffickers are increasing using the so called 'southern route' to traffic heroin from Afghanistan to consumer markets. Coca bush cultivation remains concentrated in Colombia, Peru and Bolivia. Ms Kramer explained the declines and increases in cocaine seizures per continent. Cocaine seizures in Europe remained stable. A secondary route for cocaine involves the use of countries in Africa, notably West Africa, as transit countries. Limited data from African countries means that establishing trends is difficult. However, significant seizures also continue to be made in West Africa. Cocaine seizures have increased in both Asia and Oceania in recent years. This change indicates that traffickers are using new routes and looking to establish new markets. Cannabis continues to be the most widely cultivated, produced, trafficked and consumed illicit drug worldwide. The most prominent countries in the production of cannabis resin are Afghanistan and Morocco. The global supply of amphetamine-type stimulants continued to evolve in terms of the extent of manufacture, patterns in trafficking routes and nature of substances involved. In general, NPS is an umbrella term for unregulated (new) psychoactive substances or products intended to mimic the effects of controlled drugs. Of 103 countries for which information on NPS was available as of December 2013, 94 countries reported the emergence of such substances on their markets. The number of NPS on the global market more than doubled over the period 2009-2013. By December 2013, the number of such substances reported to UNODC reached 348, up from 251 such substances

[1] European Court of Justice (Fourth Chamber), 10 July 2014, preliminary ruling under Article 267 TFEU in joined Cases C 358/13 and C 181/14. Available at: http://curia.europa.eu/juris/celex.jsf?celex=62013CJ0358&lang1=en&type=TXT&ancre.

as of July 2012, and 166 substances in 2009. UNODC recently launched an early warning advisory on NPS, which will serve as a global monitoring system for NPS.

3.5. EMPACT - A multi-disciplinary fight against drug trafficking (focus on priority synthetic drugs)

Laimonas Vasilauskas, Drugs Coordinator at Operations Department of Europol, presented the EU priorities in the fight against organised crime and the European Multidisciplinary Platform Against Criminal Threats (EMPACT). He emphasized that an integrated approach via the EU policy cycle and EMPACT is a business model to tackle the threat of organised crime at EU level. The model is needed for several reasons: organised crime networks operate in multiple crime areas, diversifying their routes and *modus operandi*; the market for illicit drugs remains the most dynamic of all criminal markets; horizontal cooperation needs further development and alignment; and law enforcement needs support and engagement at political level. Mr Vasilauskas explained that the EU policy cycle starts with the EU Serious Organised Crime Threat Assessment (SOCTA), highlighting current and new threats. The SOCTA is used for defining the EU crime priorities. The EU policy cycle continues with Multi-Annual Strategic Planning, which leads to EMPACT Operational Action Plans for each crime priority. In the end, the activities and situation are reviewed and assessed. EMPACT has two crime priorities focused directly on drugs: 1) synthetic drugs and 2) cocaine and heroin. Mr Vasilauskas introduced the strategic goals and actions for both priorities, showing that the goals of EMPACT regarding synthetic drugs are to reduce the trafficking of pre-precursors and other chemicals and to improve knowledge about NPS. Other goals of EMPACT regarding synthetic drugs are improving judicial cooperation among the Member States, third States and the private sector by conducting joint and parallel investigations and prosecutions; focusing on asset recovery and money laundering activities; improving the strategic and operational picture of synthetic drugs; developing intelligence and gathering information; and developing multi-disciplinary training and awareness. Mr Vasilauskas concluded by explaining the operational and strategic support Europol provides in the fight against drug trafficking.

3.6. The EU drug situation: drug penalties and indicators

Brendan Hughes, Senior Scientific Analyst, European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), gave an overview of the EU drug situation, drug penalties and indicators. He explained the Drugs Action Plan 2009-2012, which provided the framework to develop key indicators for the collection of policy-relevant data on drug-related crime, illegal cultivation, drug markets and supply reduction interventions, and to develop a strategy to collect these indicators. EMCDDA has collected data on drug law offences, seizures, prices, composition of tablets, potency, purity, plantations, trafficking routes, *modus operandi* and production facilities. The first European conference on drug supply indicators was held in 2010 and brought together forensic scientists, law enforcement authorities, criminologists, data analysts, monitoring professionals and other professionals dealing with the subject. Three main areas emerged: drug markets, drug-related crime and drug supply reduction. In 2013, Council Conclusions on improving the monitoring of the drug supply in the European Union were given. A strategic analysis was conducted jointly by EMCDDA and Europol, resulting in an evidence-based, coherent overview of the dynamic drug markets in Europe and contributing factors. In the EU drug markets report, synergies between EMCDDA's scientific approach

and structured data sets and Europol's operational information on latest trends and intelligence on organised crime were combined. Mr Hughes illustrated findings of the EU Drug Markets Report 2013 by explaining the prescribed penalty ranges for supplying heroin in some Member States, types of sentences for supply offences and estimated trafficking penalties expected by practitioners in 2014. For 1 kg of heroin, 1 kg of cannabis and 10 kg of cannabis, the estimated penalties vary considerably depending on the Member State and the person replying.

3.7. Website/online course for magistrates on precursors

Tony Verachtert, Chief Commissioner, Belgian Federal Judicial Police, Representative of the POMPIDOU Group, presented the state of play of a project to develop a website and a long-distance training course for prosecutors in the field of chemical precursors for the production of drugs/NPS. This project , carried out by the Council of Europe's Human Rights Education for Legal Professionals (HELP) Programme, together with the Pompidou Group, capitalises on the initiative and benefits from cooperation between the European Network of Prosecutors in Synthetic Drugs and Precursors (ENPSDP) and Eurojust. Mr Verachtert explained that, at the moment, access to the website is restricted to the pilot group members, but the promoters of this project intend to extend access to other prosecutors and experts from police, customs and tax authorities. The website currently includes legal materials (legislation and case law) and chat facilities to allow the exchange of relevant information among specialised prosecutors in the field of precursors. The development of the website and the distance learning course are related. All relevant information available on the website might be used as background and training materials for the course. Some experts are currently developing a full-fledged curriculum for the course. When all the background materials are uploaded and the content is drafted, an interactive product will be built by the HELP Secretariat and the course will be launched in some pilot countries for a selected group of prosecutors.

3.8. Study on judicial cooperation, mutual legal assistance and extradition of drug traffickers and other drug-related crime offenders

Mr Javier L. Parra Garcia, Government Secretary & EJN Contact Point, Tribunal Superior de Justicia Región de Murcia (Spain), presented the study on judicial cooperation, mutual legal assistance and extradition of drug traffickers and other drug-related crime offenders between the European Union and its Member States and Latin American and Caribbean (LAC) countries. The objectives of the study are to provide facts and figures as well as detailed analysis on the functioning, utilisation and obstacles to the implementation of and potential gaps in existing mutual legal assistance (MLA) and extradition agreements. The study also seeks to provide the Commission with the relevant elements to enable an in-depth evaluation of the need and potential added value of entering into EU-level MLA and extradition agreements, notably with those LAC countries recognised as leading suppliers of cocaine and those that serve as a gateway for smuggling cocaine into Europe. Mr Parra Garcia introduced the principal findings of the study, and also relevant problems and other considerations that have arisen from the research. In particular, he highlighted the role to be played by Eurojust in the following areas: speeding up MLA assistance; use of legal contact point networks active across the continents; confiscation and asset recovery in drug trafficking cases; and solutions to problems in multi-jurisdictional cases. Mr Parra Garcia concluded by presenting 13 key conclusions of the study. One is the creation of the 'EU Liaison Magistrate' to be posted in competent authorities in selected LAC

countries located along significant drug trafficking routes. Some other key conclusions particularly relevant for Eurojust are to strengthen and extend existing Memoranda of Understanding (MoUs) (IberRed-Eurojust and Iber-Red – EJN) and to study the possibilities of contact with REMJA (Meetings of Ministers of Justice or Other Ministers or Attorneys General of the Americas).

4. Outcome of workshops

All workshops were based on a common methodology, which consisted of a drug trafficking case to be discussed among prosecutors and experts on the basis of their own legal systems and prosecution practices. The conclusions of the three workshops, addressing the case scenario from three different perspectives, were reported to the Plenary by the Chairs and Co-Chairs. During the final session, the participants were given the possibility to comment and provide feedback.

4.1. Workshop 1: Judicial aspects of controlled deliveries and the role of Eurojust and Europol

Chair: Mr Ladislav Hamran, National Member for Slovakia at Eurojust and Vice-President
Co-Chair: Mr Laimonas Vasiliauskas, Drugs Coordinator at Operations Department of Europol

The goal of the workshop was to address challenges encountered by national authorities in the authorisation and execution of controlled deliveries of drugs, particularly (pre)precursors and NPS. The participants were invited to discuss whether a cross-border controlled delivery can be organised in the context of the given case scenario and the pre-conditions for executing this special investigative technique. Furthermore, participants were invited to explore whether obstacles in judicial cooperation and solutions thereto could be foreseen in the controlled delivery in the given case.

The discussions revealed that the organisation of a controlled delivery is practically impossible in a number of Member States that do not include the specific (pre)precursors and NPS in the lists of controlled substances and therefore cannot criminalise their trafficking. Other Member States would be able to organise the controlled delivery, even if the (pre)precursors and NPS are not regulated, by relying on other offences, such as customs fraud, participation in a criminal organisation or preparatory acts to commit a drug offence.

Regarding the preconditions for a controlled delivery, the discussions showed that most of the Member States would require an MLA request (which could, in some Member States, in urgent situations, be submitted even after the operation takes place), while others would be content with a request on a police-to-police basis. If an MLA request is required, the request should be addressed in most Member States to the local prosecution office in which the drug consignment crosses the border. However, if the route of the consignment is unknown, problems may arise in identifying the competent authorities. Some Member States have overcome this problem by providing a subsidiary competence of the central prosecution office if the route is unknown or changes unexpectedly. Other preconditions for the execution of the controlled delivery include the constant monitoring of the drug consignment and the seizure of drugs if a potential risk arises that they may disappear and subsequently enter the market.

Among the obstacles foreseen in the execution of the cross-border operation, the participants also mentioned: (i) the complexity of the case, involving many jurisdictions; (ii) reluctance to execute requests for placing a vehicle tracking device and, in some Member States, even the absence of

legislation for using such devices in controlled deliveries; (iii) difficulties related to the deployment of undercover officers, including the need, in some Member States, for their testimony in court and the differences among the Member States with regard to their status; and (iv) cooperation with third States could be problematic.

Several solutions to address practical and legal obstacles in controlled deliveries were proposed, including:

- Proper communication between the competent authorities in the Member States
- For long-term investigations, the use of JITs to facilitate faster exchange of information and more effective communication
- Harmonisation of legislation on controlled deliveries
- Some Member States proposed the consideration of a unified set of requirements for controlled deliveries and, in this respect, the adoption of a form similar to the EAW form, to minimise the risk of receiving requests for additional information
- Assistance from Eurojust and Europol in organising operational meetings and coordination meetings, clarification of legal requirements in the Member States, identification of contact points for controlled deliveries in the Member States, analysis of information, tactical and technical support, etc.

4.2. Workshop 2: Judicial cooperation in cases involving (pre)precursors and NPS

Chair: *Mr Lambert Schmidt, Principal Administrator, Anti-Drugs Policy Unit – DG JUSTICE, European Commission*

Co-Chair: *Ms Cornelia Geldermans, National Public Prosecutor Synthetic Drugs and Precursors and Teammanager, National Public Prosecutor's Office, Netherlands*

The goal of the workshop was to discuss how prosecutors would address a cross-border case involving (pre)precursors and NPS. Several participants underlined that the possibility to open an investigation of trafficking in (pre)precursors is linked to the presence of these substances in European regulation or national lists of proscribed drugs. Failing this requisite, prosecution is still possible in some countries if the production of these substances can be considered as a 'preparatory act' to the commission of drug offences.

As to NPS, in some Member States, prosecution is based on medical laws. A legal gap may exist as a consequence of the European Court of Justice decision of 10 July 2014. Further possibilities for prosecution were explored, including participation in an OCG (possible only if other offences are committed), consumer legislation (for products) and some best practice, such as including NPS in a temporary list for a month and then, after this test period, officially listing it.

The role of Eurojust was mentioned, particularly with regard to advice in the setting up of JITs or parallel investigations, organising coordination meetings and helping with the difficulties posed by differences in legislation. Coordination meetings at Eurojust were deemed a good platform to discuss issues related to the leadership in a cross-border case involving (pre)precursors and NPS in which several possible factors apply (e.g. criminal offences, severity of sanctions, interest of the country, advancement of the investigation, capacity and expertise).

Even in the absence of a JIT (due to the fact that not all countries might be able to open an investigation on NPS), several cooperation possibilities were still open, including spontaneous

exchange of information, execution of MLA requests (though particular attention should be paid to the issue of double criminality in the event of requests dealing with intrusive actions).

Finally, some recommendations were formulated:

- To explore 'creative' solutions to address the problems related to the prosecution of 'legal' NPS/pre-precursors. For example, consider the use of administrative laws (e.g. withdrawing permits for shops), consumer legislation, and food safety legislation.
- To consider using special investigative techniques adopted for OCGs to investigate and prosecute NPS cases.
- To exchange expertise across countries (e.g. forensic reports, judgements, etc). See, e.g., the website launched by a joint initiative among ENPSDP/Pompidou Group/Eurojust.
- To provide an overview of the legal situation/innovative approaches to combating NPS/pre-precursors. For instance, both EMCCDA and Eurojust have collected relevant materials that could be further developed.

4.3. Workshop 3: Judicial cooperation with third States

Chair: Ms Malči Gabrijelčič, National Member for Slovenia at Eurojust and Chair of the External Relations Team
Co-Chair: Ms Lidia Paloma-Montaño, Magistrate, Consejo General del Poder Judicial

The goal of the workshop was to discuss how prosecutors, given a case scenario presenting some legal challenges, could cooperate with third States in the best possible way. Reference to Brasil, Norway and the USA was often made, due to the fact that representatives from those third States participated in this workshop. The participants strove to find best practice and define the legal basis for information exchange with the three third States. They also strove to find best practice in coooperation with and without a JIT agreement and expressed their expectations regarding how Eurojust could best support them.

Exchange of information with third States could become an obstacle to judicial cooperation, especially when exchanging personal data. The participants could solve the potential obstacle by using Eurojust's coordination meetings as a tool for the safe exchange of information and by reaching a common agreement on disclosure matters at the beginning of the coordination meeting. The culture of establishing direct contacts with judicial authorities in Europe has not yet fully developed in some countries, e.g. in Brazil. Participants suggested that promoting spontaneous exchange of information would contribute positively. The participants listed several legal instruments for exchanging information with third States, e.g. Memorandum of Understanding with Iber-Red, Palermo Convention Art. 18, EU-US MLA Agreement, Member States – US agreements and EU 2000 Convention.

A JIT agreement with a third State would be possible under the Palermo Convention, EU 2000 Convention, the EU-US MLA Agreement, and 26 MS - US agreements, bilateral agreements, the 2nd Additional Protocol to the CoE convention on criminal matters, the UN Convention against illicit trafficking in narcotic drugs and psychotropic substances and national legislation in third States. Participants concluded that a JIT may be a useful tool, but neither always necessary nor the best tool for cooperation in a complex case. In practice, reflecting the facts given in the fictional case scenario: (1) the USA would be reluctant to join a JIT because of a disclosure issue; (2) Italy, as a leader of the investigation, could not participate in a JIT because it has not ratified the EU 2000 Convention ; and

(3), in the end, the JIT might not be efficient, since more than 10 Member States would be involved. In such cases, the participants would prefer cooperation without a JIT agreement, using MLA requests for investigative measures. Eurojust's judicial assistance via coordination meetings and Europol's analytical support were mentioned as essential tools for cooperation. Other useful avenues of cooperation were via Iber-Red, Ameripol and other networks.

The participants listed the following expectations from Eurojust in relation to third States:

- To identify the competent authorities, names and contact details for police and prosecutors;
- To facilitate information exchange on judicial level;
- To involve Europol for cross-checking data;
- To provide advice to build a common legal framework for cooperation;
- To organise coordination meetings timely and proactively;
- To use contact points in the third States;
- To support the spontaneous and open exchange of information;
- To facilitate MLA requests; and
- To provide feedback and updates on the state of play of parallel investigations and proceedings (information in accordance to Article 13).

Finally, the participants supported the idea of establishing 'Eurojust liaison magistrates' who would be located in third States. From the participants' point of view, such postings would improve cooperation, and their role could be vital for three reasons: (1) Eurojust liaison magistrates would serve all Member States; (2) they would provide in-house expertise by virtue of their familiarity with the laws and practice of the host countries; and (3) they would give visibility to Eurojust and enhance cooperation.

5. Closing remarks

Ladislav Hamran, Vice-President of Eurojust and National Member for the Slovak Republic, thanked the participants for sharing their experience in fighting drug trafficking and their feedback on Eurojust's support in this area. He summarised the main ideas that arose as a result of the strategic meeting and ensured participants that Eurojust is committed to following up on the conclusions of the workshops. In addition to distributing the outcome report of this strategic meeting by the end of 2014, Eurojust is committed to finalise the three *Issues in Focus*, based on the results of the discussions and further feedback from the participants to be received by mid-November. Once finalised, these documents will be distributed to the participants and to other practitioners in the Member States to assist, for example, in locating the authorities competent to authorisea controlled delivery in another Member State, or identifying the legal provisions of a Member State on drug precursors and (pre)precursors. Eurojust will regularly update this information. Another step that Eurojust is planning in the near future is a joint Eurojust-EMCDDA publication in the area of drug trafficking. An MoU on cooperation with EMCDDA was recently concluded and the organisations will soon initiate discussions on the subject of this publication.

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EUROJUST News
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Dear reader,

I am pleased to present the third issue of Eurojust News. Following priorities set by the European Union, Eurojust's work focuses on the fight against terrorism, drug trafficking, trafficking in human beings, fraud, corruption, cybercrime, money laundering, and other activities related to the presence of organised crime groups in the economy.

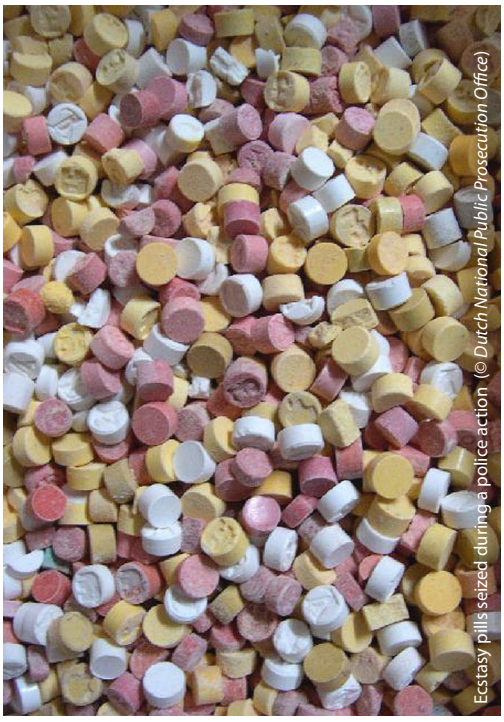
This issue of the Eurojust News is concerned with the fight against drug trafficking. It illustrates some aspects of Eurojust's contribution to the struggle against a criminal activity that generates human suffering on a global scale. If you have any comments regarding this newsletter, please contact our Press & PR Service at info@eurojust.europa.eu.

Aled Williams, President of Eurojust

IN THIS ISSUE

Drug trafficking

The movement of illegal drugs worldwide has increased in recent years, with the freedom of movement principle of the EU creating more opportunities for cross-border organised crime.



Ecstasy pills seized during a police action (© Dutch National Public Prosecution Office)

Worldwide, the UN Office for Drugs and Crime (UNODC) estimates that in 2009 between 172 million and 250 million people used illicit drugs. Of these it is estimated that between 18 million and 38 million people were dependent on drugs. For organised crime, the whole world is a single marketplace. As borders disappear or become unimportant, criminals are taking advantage of globalisation. The four freedoms, which form part of the substantive law of the European Union, allow goods, capital, services and people to move freely. This freedom of movement has many positive elements, but criminal networks exploit that freedom to distribute their "merchandise" and to link up with other criminal organisations.

Drug trafficking is a common and unifying theme of much transnational organised crime. Both the smuggling of drugs into Europe and their production within the European Union continue to pose significant threats to its citizens.

To disrupt these criminal networks, a coordinated, integrated and transnational response is required. Eurojust is the forum where decisions to resolve possible conflicts of jurisdiction and to prosecute efficiently can be most effectively made.

Since 2003, in terms of number of cases, Eurojust has dealt with more drug trafficking than any other type of crime. The number of drug trafficking cases referred to Eurojust increased from, from 77 in 2004 to 230 in 2009, representing a three-fold increase.

In 2009, of the 230 cases registered at Eurojust concerning drug trafficking, Italy requested Eurojust's assistance most

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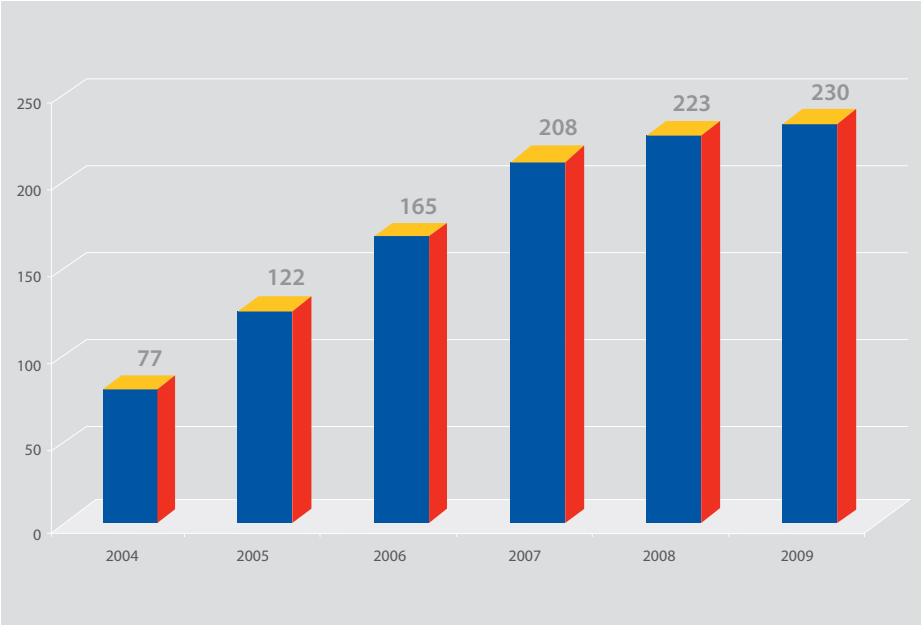
frequently, with 30 cases; Spain was the country most frequently requested by other Member States, followed by the Netherlands and again Italy. Eurojust held 40 co-ordination meetings on drug trafficking cases in 2009, where decisions on cross-border investigations and prosecutions were made. Europol was invited to 6 of these meetings; and 13 meetings involved participants from third States (Colombia, Iceland, Norway, Switzerland, Turkey, the USA, Ukraine and Serbia).

Final figures for 2010 are not yet available, but preliminary figures show that drug trafficking remains the most frequent crime type at Eurojust (116 out of 681 cases registered in the first six months of 2010). In this same period, 15 of the 70 co-ordination meetings held were concerned with drug trafficking.



Number of drug trafficking cases addressed by Eurojust in the period 2004-2009 (*source: Eurojust*)

Legal obstacles

A purely national approach to combating organised crime is no longer sufficient; today we need to understand justice and the rule of law in ways that transcend borders. As with all crimes committed by criminal networks operating across borders, prosecution of drug trafficking cases frequently gives rise to jurisdictional problems (with producers and distributors usually located in different countries and many significant seizures and arrests being made in the transit countries).

Controlled deliveries, joint investigation teams (JITs), and interceptions of communications are co-operation tools frequently used to fight drug-trafficking. Problems can arise in using these tools because of differences in national law and practice. For example, controlled deliveries are subject in some Member States to judicial co-operation, in others to police co-operation, and yet in others to the co-operation of customs authorities.

> Drug trafficking is a common and unifying theme of much transnational organised crime.

Illegal drug lab: manufacturing of precursor chemicals (© *Dutch National Public Prosecution Office*)

In such cases, a requested Member State, whose system for controlled deliveries implies judicial co-operation, may not be able to comply with a police request. Eurojust provides solutions to difficulties of this type. It also draws on its daily casework experience to resolve difficulties caused by delay in implementing the 2000 EU Convention on Mutual Assistance in Criminal Matters.

Because drug cartels control such immense amounts of money, they have the power to influence politics and business at the highest levels, gaining control of entire regions. One of the most effective ways to weaken these criminal syndicates is to attack their finances. Eurojust works closely with its partners to strengthen existing crime control agreements and to promote stronger measures against money laundering.

Co-operation at European level

Eurojust works with the analyses provided by its law enforcement partner Europol to fight drug trafficking. Europol is empowered under Article 14 of its Decision to open

analysis work files (AWFs). AWFs are repositories of data used for detailed analysis of specific crime areas, accessed under strict data protection guidelines. Europol has invited Eurojust to participate in three of its AWFs dealing with specific drug trafficking networks, as well as an AWF dealing with organised crime networks in relation to drug trafficking. Co-ordination between Eurojust and Europol has led to excellent strategic and operational successes in 2010: one operation concluded with the arrest and trial of more than 50 people; a second operation dismantled a criminal organisation of 100 people involved in cocaine trafficking. At a more strategic level, Eurojust is involved in the AWF which deals with the phenomenon of West African drug trafficking networks.

Joint Investigation Teams

Eurojust plays an important role in supporting Joint Investigation Teams (JITs), providing legal advice and administering funding from the European Commission. Eurojust has run a pilot JIT Funding Project on "financial, logistical and administrative support to JITs with the establishment of a centre of expertise with a central contact point", which ends in 2010.

This support consists of two common types of expenses incurred in fighting cross-border crime: travel and accommodation costs for the JIT members, and translation and interpretation costs. Eurojust has also loaned equipment (laptops and BlackBerrys) to ensure communication and information exchange.

Eurojust considered 34 applications for financial and logistical support during the first JIT Funding Project. Applications included a request for support for a JIT to investigate drug trafficking from South America to Europe and laundering the proceeds by a criminal organisation. Eurojust approved the application and funding was made available. Another successful application related to a JIT investigating a drug-related killing.

Because of the success of the first JIT Funding Project, the European Commission has granted Eurojust further funds to support JITs. This second grant of over 2 million euros from the European Commission runs from October 2010 until September 2013.

Eurojust is the forum where decisions to resolve possible conflicts of jurisdiction and to prosecute efficiently can be most effectively made.

Police and experts investigating a drug lab (© *Dutch National Public Prosecution Office*)

Case example 1: Trafficking cocaine

When investigation showed a Colombian criminal organisation was trafficking cocaine, via Spain and France, to Italy, the *Direzione Antimafia* in Rome asked Eurojust to assist in the co-ordination of investigations in the three Member States, and two co-ordination meetings were held. One issue resolved was a potential conflict of jurisdiction.

After consideration of relevant factors, the participants agreed to transfer the case to the Italian authorities. The Italian investigations discovered that all persons arrested were linked to the same criminal organisation. It was discovered that the same route through France was used several times.

The case resulted in the arrest of 32 suspects and the seizure of 100 kg of cocaine, and was a successful example of co-operation between the Italian, Spanish and French National Members at Eurojust, the Spanish *Guardia Civil* and French Customs agents, police, investigative judges and prosecutors.

This case confirmed the existence of one of the main drug trafficking routes, from Colombia as the source country, with Spain, Belgium, France and the Netherlands acting as very important gateways into the EU. The drugs were then sold in other EU countries, such as Italy. The international dimension of illicit drug trafficking, with the differing legal and procedural requirements of the involved countries, required a co-ordinated approach. Eurojust played a crucial role.

Eurojust Trafficking and Related Crimes Team (© *Eurojust*)

Trafficking and Related Crimes Team at Eurojust

The mission of the Trafficking and Related Crimes Team is to provide expertise, ideas, best practice, etc, especially in the fight against Trafficking in Human Beings and Drug Trafficking linked to organised crime and to support the Contact Point for Child Protection.

The team has set objectives for 2010 and 2011 based on the priorities of Eurojust, the Council Conclusions on the eighth Eurojust Annual Report 2009, the Stockholm Programme, the Organised Crime Threat Assessment (OCTA) and the experiences of its members.

The first objective of the team is to improve the regular reporting tools on Eurojust cases related to Trafficking in Human Beings (THB), sexual exploitation of children and child pornography, drug trafficking and trafficking in firearms and other related crimes as foreseen in the new Council Decision on Eurojust. This objective will be achieved by implementing the strategic project "Eurojust's Contribution to the European Drug Policy Action Plan 2009-2012"; by developing a similar project in the field of THB; and by monitoring the number of trafficking and related crimes cases registered, the number of relevant co-ordination and other operational meetings held at Eurojust, and identifying underlying problems encountered in trafficking and related crimes cases.

The second objective is to support and monitor the EU legislative and policy process in the relevant fields of interest to the team. In particular, the team analyses the obstacles to judicial co-operation in the areas of drug trafficking and THB and contributes to the identification of criminal trends and priorities needed to shape an effective policy to fight trafficking.

Following the adoption by the Council on 03 June 2010 of the *European pact to combat international drug trafficking-disrupting cocaine and heroin routes*, the Trafficking and Related Crimes Team will also participate at expert meetings convened by the EU institutions, in particular the European Commission, and contribute to the Eurojust report to the Presidency of the Council on the implementation of the EU priorities in the fight against organised crime in the areas of drug trafficking and THB, and to the OCTA 2010 and 2011.

The team's third objective is to develop a closer relationship with relevant EU institutions and international organisations, by organising at least one tactical and/or strategic meeting in 2011; by ensuring regular updates of existing legal information on national, European and international legal instruments related to trafficking and related crimes; by enhancing co-operation with the European Commission, the Council and the European Parliament; by strengthening co-operation with Europol in light of the European pact to combat international drug trafficking-disrupting cocaine and heroin routes to support the reinforcement of political co-ordination between Member States, European Union institutions and relevant European agencies in the area of drug trafficking; and by enhancing co-operation with the European Fundamental Rights Agency, Frontex, EMCDDA, UNODC and Interpol.

The Contact Point for Child Protection, whose creation was suggested at the informal Justice and Home Affairs meeting in Lisbon in October 2007, is part of the team; therefore, the fourth objective is to enhance the role as much as possible. Eurojust has undertaken important co-ordination work in this area in 2010. The "Lost Boy" case at Eurojust resulted in the dismantling of a global criminal network using the internet to disseminate child pornography and promote child abuse.

Interview with Mr Cees van Spierenburg, National Prosecutor, Dutch National Public Prosecution Office

Mr Cees van Spierenburg is a National Prosecutor in the Dutch National Public Prosecution Office, which is responsible for the fight against international organised crime. He holds a unique position as the National Public Prosecutor for Synthetic Drugs & Precursors.

Can you tell us something about the work of the National Public Prosecutor's Office?

Cees van Spierenburg: The Dutch Public Prosecution Office's policy towards international drug crime focuses on the fight against production and trade in heroin, cocaine, synthetic drugs (e.g. ecstasy and amphetamine) and their precursors (basic substances), as well as the growth of cannabis. We also deal with the fight against smuggling and trafficking of human beings, terrorism, war crimes - including piracy at sea - cybercrime and money laundering.

Why is the fight against drugs so important?

CvS: First of all, there is the health risk caused by the use of drugs. Secondly, we see that international organised crime has taken over this trade and is making a great deal of money out of it. This money, when poured into 'regular' activities, affects the economy in an unfavourable way. For example, the illegal growth of cannabis and hemp in the Netherlands amounts to €2 – 5 billion. And this is only a small part of the huge economic power behind this trade.
Moreover, this phenomenon also has other criminal sides to it. It is all about money, and money is power: there are real drug wars taking place on a global scale. At least 20 murder cases in the Netherlands have been linked to the growth of and trade in cannabis in just the last few years.

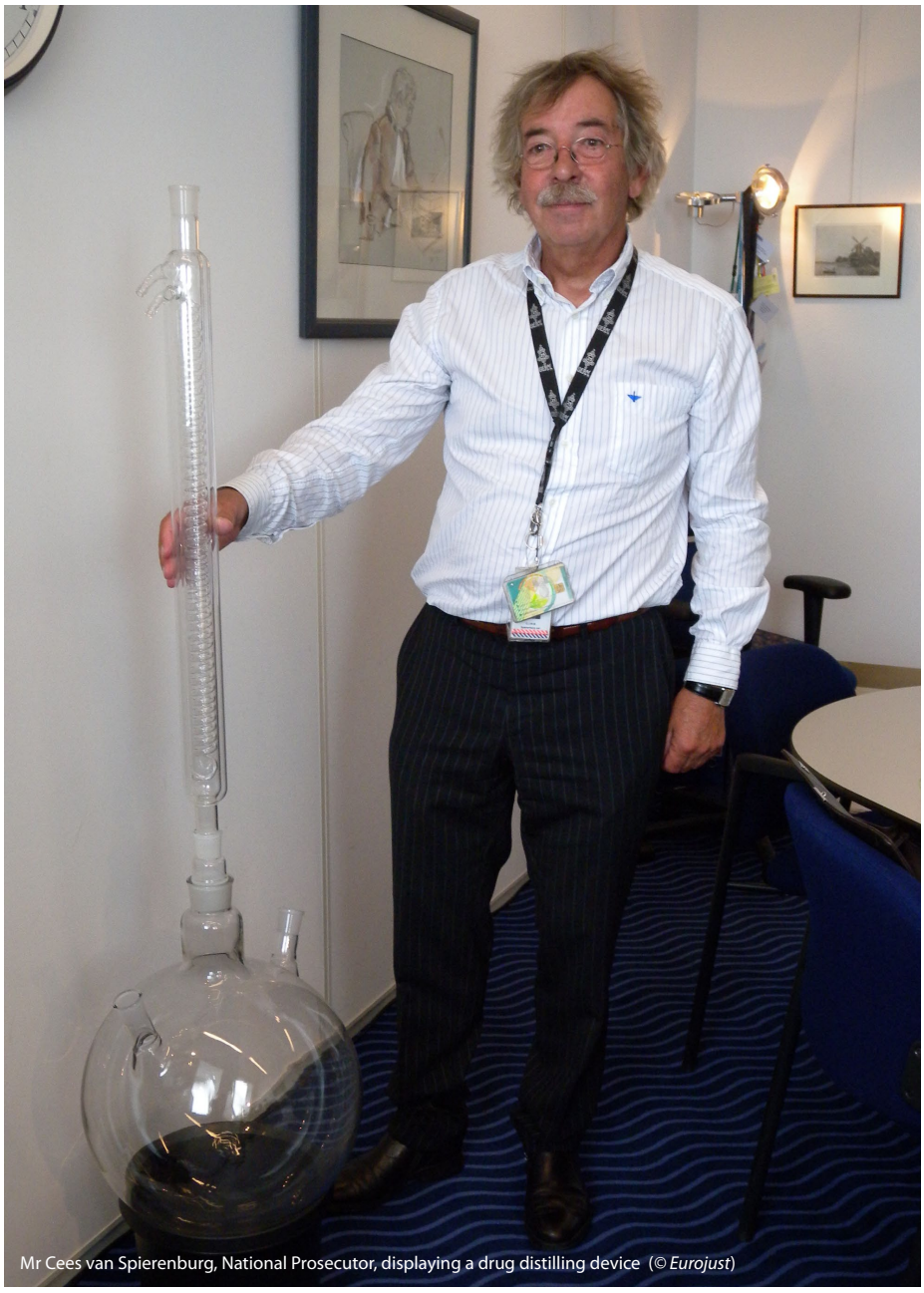
When I attended the International Drug Enforcement Conference hosted by the US Drug Enforcement Agency in Rio de Janeiro this year, I was not happy to see and hear about the limited progress we are making in fighting drugs on a global level. We have achieved partial results, but at an international level we are still running behind the criminals.

In what way do criminals have an advantage?

CvS: Drug crimes generate an enormous amount of money. For example, if a criminal invests €10 million in 1000 kilos of cocaine, at every new step in the trading process, the price of the goods increases by 100 per cent. The same happens with any drug, whether it is heroin, cannabis, ATS (amphetamine-type stimulants) or even their precursor chemicals; every person involved makes a 100 per cent profit, from those who harvest coca leaves to the last dealer at the end of the chain.

What can you really do?

CvS: Drug trafficking is all about logistics. Coca leaves, for instance, are grown somewhere in Colombia, and



Mr Cees van Spierenburg, National Prosecutor, displaying a drug distilling device (© *Eurojust*)

these become cocaine for individual users in Europe. To achieve that end result, many processes are needed: criminals need equipment, laboratories, and transport. We must monitor this transport activity. If we look, for example, at Rotterdam Harbour, and other large harbours in the world, every year approximately 11 million containers are handled. We know that only a small part of these containers are linked to drug trafficking. You understand that we cannot stop normal economic activity to check every container for drugs. The same situation occurs in the harbours in countries known to be the origins of precursors: China, Colombia and India. Criminals also rely on other means of transportation, such as trains and trucks. Due to the threat of terrorism, freight is thoroughly checked at airports.

This is one of the negative aspects of the 'freedom of movement' in Europe. Our outside borders are now the borders of the EU Member States. My backyard is in Romania, or in Lithuania or Italy, so to speak. It makes no sense to have strict checks in Rotterdam, as we have no idea how checks are made on the outside borders of Europe. I do not intend to blame others, but this freedom of movement makes the issue very difficult to deal with.

Taking all this into account, how do you start an investigation?

CvS: The approach should always be multi-disciplinary. In the synthetic drugs approach in the Netherlands, we co-ordinate and co-operate among customs, national police, and the financial investigation service. We know that the criminal and judicial systems of the various European countries are very different. In every country, responsibilities are allocated differently and even national power is organised differently. If I just look at our neighbours, Belgium and Germany, there are already significant differences between them and the Dutch system.

I am in contact with my counterparts in China, Russia, the USA, Austral-

Case example 2: Trafficking cannabis

Eurojust acted to help overcome a conflict of jurisdiction in a case concerning trafficking of cannabis from Spain through France into the UK. An initial decision had been taken to conduct simultaneous investigations in France and the UK on different aspects of the case. In 2009 a co-ordination meeting was held at Eurojust to decide which judicial authority would be in a better position to undertake investigations against the entire network to avoid overlapping investigations and a resulting conflict of jurisdiction. The French judicial authority agreed during the meeting to transfer the case to the UK. The French investigating magistrate was invited to present the French investigation results in the UK court. Five individuals were convicted in the UK and sentenced to a total of 37 years.

We have achieved partial results, but at an international level we are still running behind the criminals.

Illegal drug distilling lab (© *Dutch National Public Prosecution Office*)

ia, and many EU Member States. In addition, with a grant from the European Commission, we have been able to assemble a network for prosecutors dealing with ATS and precursors: the European Network for Prosecutors in Synthetic Drugs & Precursors (ENPSDP). This network, started in September 2009, will continue this year and we are currently preparing for the 2011 conference. In 2009, prosecutors from 19 different countries attended the meeting, including non-EU countries such as Switzerland, Norway and the Russian Federation.

There are no clearly identifiable victims in this kind of organised crime, and therefore no official complaints are introduced against it. Of course, we are aware of the crimes, but there is no information from the victims or witnesses. So, we have to look for information ourselves – this is of paramount importance. We need informants, criminals who talk about criminals, intercepts, observations, etc. Investigating is gathering information. In most countries, this information-based type of investigation is still at beginners' level.

Sometimes, in our country, we even know too much. For example, we have information on five criminal organisations, but we cannot attack them all at the same time because we do not have the capacity to do so. This is the dark side of information-led investigating. We need to make a choice, set priorities. In the Netherlands, we have much information on organised crime, but our resources allow us to handle only 20 per cent of it effectively. In other countries, the situation may be completely different. A while ago, we participated in a JIT with Belgium and noticed that our Belgian colleagues worked three years to infiltrate a criminal organisation. I can only dream of having that much time to devote to a single case.

How is the transportation of drugs organised?

CvS: As we are more and more following in the tracks of the criminal activities, criminals are always on the lookout for other paths. At the moment, the majority of amphetamine trafficking is directed to the UK and Scandinavia. Spain, Portugal and the Netherlands are nowadays the main transit countries for cocaine. Heroin comes via Eastern European countries, such as Turkey. Criminals are looking for other pathways; West Africa is now becoming an important stop for cocaine, which is then shipped via the Mediterranean and Black Sea to Romania.

Another example: precursors, coming from India and transported to Mexico, the main producer of methamphetamine for the USA, are transported via DR Congo and other West African countries. Ecstasy produced in the Netherlands is transported to Australia through Italy. On one occasion, 15 million tablets were seized, giving the Netherlands the dubious honour of being placed on the list of major drug-producing countries. All this has led to a political decision on judicial priorities for the Dutch Public Prosecution Service.

From a transportation point of view, all countries in the world are involved in the world drug problem.

What is the most effective approach?

CvS: We must attack the production and export of precursors. China was the main producer of PMK and BMK, the major chemical substances needed to produce ecstasy and amphetamine. Bowing to international pressure, China changed its laws, making production illegal. The main component of PMK is safrol, a natural product extracted from trees. Criminals are quick to adapt to changes in market demand and are now looking for ways to transport safrol from other Southeast Asian countries to the producing countries. On a global level, the fight against precursors is important, as chemicals are necessary to produce all sorts of drugs, including heroin and cocaine. The relevant legal basis is the UN Treaty of Vienna of 1988 (Final Act of the United Nations conference for the adoption of a convention against illicit traffic in narcotic drugs and psychotropic substances), which is the most global tool in the fight against chemical drugs, with an important role for the UNODC.

As to the European Union system, European Union legislation on classification is limited to precursors, via Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors, which regulates intra-Community trade, and by the Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors. These rulings oblige nations to implement laws against the misuse of chemicals.

Most of the chemicals used to produce illicit drugs are legal and easily available. They are in fact normal chemical substances used to produce medicines, perfumes, plastics or other legal products. The chemical industry plays a huge role in the world economy. And there is the economic aspect again: the production, export and transportation of substances must be regulated and controlled, entrepreneurs must be warned against the misuse of chemicals and suppliers must be warned against individual orders placed over the telephone, and by anonymous cash transactions.

The International Narcotics Control Board of the United Nations provides instructions in its 'Guidelines for Governments on Preventing the Ille-

Case example 3: THB and drug trafficking

Following co-ordination meetings at Eurojust, the Italian, Dutch and Colombian authorities, led by the Antimafia Public Prosecutor in Naples, made simultaneous arrests in a case of THB to finance drug trafficking. The criminals trafficked human beings from Nigeria to the Netherlands, to finance their drug operations. With the money earned from prostitution, the criminals were able to buy large amounts of cocaine in Colombia, to be shipped to Europe. The co-ordination meetings at Eurojust identified all the legal and factual difficulties for extradition and surrender of the suspects after arrest, and uncovered the links between the THB, the exploitation of women and the financing of drug activities by criminals.

gal Sale of Internationally Controlled Substances through the Internet'.

From a precursor point of view, all countries that trade in chemicals are co-responsible for the drug problem in the world.

How do you see the future?

CvS: Our strategy is the following: without precursors, the basic substances, there can be no drugs. But we cannot make precursor chemicals illegal if there are legal uses for them. When the Chinese government took measures against the production of PMK, there was a 'dip' in drug production and trade. Unfortunately, criminals started to look for other substances to produce drugs, and turned to dangerous products like mephedron.

There is a "need for speed". Our reaction time on new drug substances should be much shorter. At the EU level, we now have the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), located in Portugal, but, in my view, this organisation represents just another bureaucratic approach.

We can get results through close co-operation between the police and judiciary on a European and global scale. Every country should have a prosecutor, like me, specialised in drugs and precursors. Also, the role of Europol is quite crucial; there is an Analysis Work File (AWF) called 'Synergy', a huge database of information about all synthetic drug investigations in Europe. For other drugs, there are other databases like this, but national investigators must provide the information; this does not always happen. There are international conferences and global networks of drug fighters, but I know that this fight is bound to continue forever.

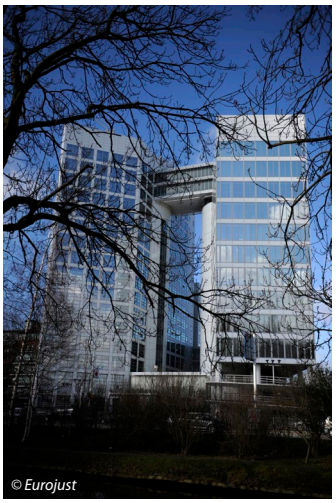
In your opinion, what can be the role of Eurojust?

CvS: Eurojust can play a vital role in building bridges between the different legal systems in the EU, the investigations and the prosecutions, the responsibilities and the power. My team has already co-operated with Eurojust in drug-related cases with Spain, Lithuania and Poland.

For example, in Belgium I sometimes need to deal with a local prosecutor, in another case with the national prosecutor, in another case with an investigative judge. This process works because Belgium is our close neighbour, they (mainly) speak the same language and we made a co-operation agreement between our office and the Federal Prosecution Office (Fedland). The same could happen when I would need to work with French colleagues, but would be far more difficult. In Spain, prosecutors have completely different responsibilities and powers compared to mine. Between the three Baltic States, we see a great difference in the way they fight organised crime. There I see an important task for Eurojust, i.e. to create links between the Member States to solve these system problems. We also need names and contact details, or we end up lost in bureaucracy.

Case example 4: Europe-wide cocaine trafficking

After more than a year of investigations in Belgium, France, Germany, Italy and the Netherlands, a cocaine-trafficking network of nearly 100 people was dismantled in five operations involving extensive co-operation between international judicial and police authorities. Eurojust served as the platform for judicial co-operation, facilitating the activities of the prosecuting authorities, including the execution of the European Arrest Warrants. Heroin, cannabis, cutting substances, firearms and cash were seized in addition to significant quantities of cocaine.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Eurojust is a European Union body established in 2002 to stimulate and improve the co-ordination of investigations and prosecutions among the competent judicial authorities of EU Member States when they deal with serious cross-border crime. Each Member State seconds a judge, prosecutor or police officer to Eurojust, which is supported by its administration. In certain circumstances, Eurojust can also assist investigations and prosecutions involving an EU Member State and a State outside the European Union, or involving a Member State and the Community.

Eurojust supports Member States by:

- *co-ordinating cross-border investigations and prosecutions in partnership with judges, prosecutors and investigators from Member States, and helping resolve conflicts of jurisdiction;*
- *facilitating the execution of EU legal instruments designed to improve cross-border criminal justice, such as the European Arrest Warrant;*
- *requesting Member States to take certain actions, such as setting up joint investigation teams, or accepting that one is better placed than another to investigate or prosecute; and*
- *exercising certain powers through the national representatives at Eurojust, such as the authorisation of controlled deliveries.*

Colophon

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INTERPOL

FACT SHEET

Drug trafficking

Large-scale drug abuse and the problems associated with it affect much of the world and continue to grow in certain regions.

The drug trade affects almost all INTERPOL's member countries, be it in a capacity as producer transit or destination country.

Drug trafficking has provided criminal organizations with unprecedented opportunities to generate enormous profits which are at times used to finance other criminal or even political activities.

▶ ENHANCING INTERNATIONAL COOPERATION

INTERPOL's primary drug intelligence role has been and continues to be the identification of new drug trafficking trends and criminal organizations operating at the international level and to alert INTERPOL National Central Bureaus (NCBs) to their criminal activities. Investigations into the production of illicit drugs and the street-level sale of drugs are handled by the relevant local and national authorities.

INTERPOL provides several types of support to national and international police bodies concerned with countering the illicit production and trafficking of controlled substances and precursor chemicals. For example:

- Collecting and analysing post-seizure data provided by member countries and national drug law enforcement agencies;
- Issuing drug alerts via I-24/7, INTERPOL's secure global police communications system, to warn the law enforcement community of unique cases, new trafficking techniques or emerging trends — within minutes, information and images can be distributed to NCBs all over the world and then shared with national drug law enforcement agencies;
- Producing analytical studies to highlight criminal links between reported cases;
- Running regional or global conferences on specific drug topics, to assess the extent of a particular drug problem, share the latest investigative techniques and strengthen cooperation within law enforcement communities;
- Organizing investigative training courses for national drug law enforcement agents.

INTERPOL also maintains close working relationships with the United Nations, its specialized agencies and other international and regional organizations, such as the World Customs Organization, involved in drug-control activities.

Drug trafficking

▶ PROJECTS AND OPERATIONAL SUPPORT

INTERPOL's criminal intelligence officers focus on the most commonly used and trafficked narcotic drugs – cannabis, cocaine, heroin and synthetic drugs – as well as precursor chemicals and doping substances. Examples of ongoing initiatives are:

- **Project Drug.net** - to tackle the growing area of drug trafficking via the Internet. Having achieved its initial aim of creating a global network of specialists, this Project now concentrates on supporting ongoing operations in the field.
- **Project White Flow** - to boost intelligence exchange on South American-produced cocaine smuggled into Europe via West Africa. Project White flow aims to gather identification material on mid- to upper-level cocaine traffickers linked to Africa and to better disseminate this data among INTERPOL's member countries.
- **Operation Ice Trail** - to target organized crime groups trafficking huge quantities of methamphetamine by courier and/or cargo shipment from Iran via Turkey to destination countries in Southeast Asia and the Pacific.
- **Anti-doping initiatives** - INTERPOL works in partnership with the World Anti-Doping Agency to fight the use of performance-enhancing drugs in sport. A Memorandum of Understanding signed in 2009 formalizes the sharing of information and expertise with a view to dismantling the organized networks behind trafficking in doping substances.

In an operational case from 2010, known as Siska, INTERPOL helped coordinate the investigative activities and flow of information between Belgium, Germany, Sierra Leone, Switzerland and the USA to successfully dismantle an organized crime group trafficking cocaine from South America to Europe via Sierra Leone. In July, a number of involved member countries began coordinated, targeted operational activity against several members of this syndicate, resulting in several arrests, house searches and seizure of numerous exhibits.

INTERPOL also responds to and helps coordinate international drug investigations by organizing operational working meetings and dispatching Incident Response Teams to assist national investigators subsequent to a significant drug seizure.

INTERPOL

▶ **CONTACT INFORMATION:**
Contact us via our web site. For matters relating to specific crime cases, please contact your local police or the INTERPOL National Central Bureau in your country.

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UNODC

United Nations Office on Drugs and Crime

EXECUTIVE SUMMARY

WORLD DRUG REPORT 2014

EXECUTIVE SUMMARY

The World Drug Report provides an annual overview of the major developments in drug markets for the various drug categories, ranging from production to trafficking, including development of new routes and modalities, as well as consumption. Chapter 1 of the *World Drug Report 2014* provides a global overview of the latest developments with respect to opiates, cocaine, cannabis and amphetamines (including "ecstasy") and the health impact of drug use. Chapter 2 zeroes in on the control of precursor chemicals used in the manufacture of illicit drugs.

On the basis of comprehensive information on supply, as well as the relatively limited new information on demand, it can be concluded that overall the global situation with regard to the prevalence of illicit drug use and problem drug use[1] is generally stable, with the total global number of drug users increasingly commensurate with the growth of the world population.

That said, each region exhibits its own peculiarities with respect to specific drugs. Polydrug use, which is generally understood as the use of two or more substances at the same time or sequentially, remains a major concern, both from a public health and a drug control perspective.

Drug use and its health and social consequences

Drug use continues to exact a significant toll, with valuable human lives and productive years of many persons being lost. An estimated 183,000 (range: 95,000-226,000) drug-related deaths were reported in 2012. That figure corresponds to a mortality rate of 40.0 (range: 20.8-49.3) deaths per million among the population aged 15-64. While that estimate is lower than for 2011, the reduction can be ascribed to the lower number of deaths reported in a few countries in Asia.

Globally, it is estimated that in 2012, between 162 million and 324 million people, corresponding to between 3.5 per cent and 7.0 per cent of the world population aged 15-64, had used an illicit drug — mainly a substance belonging to the cannabis, opioid, cocaine or amphetamine-type stimulants group — at least once in the previous year.

The extent of problem drug use — by regular drug users and those with drug use disorders or dependence — remains stable at between 16 million and 39 million people. However, there continues to be a gap in service provision, as in recent years, only one in six problem drug users globally have had access to or received drug dependence treatment services each year.

Although the general public may perceive cannabis to be the least harmful illicit drug, there has been a noticeable increase in the number of persons seeking treatment for cannabis use disorders over the past decade, particularly in the Americas, Oceania and Europe. Nonetheless, opiates remained the most prevalent primary drug of abuse among those seeking treatment in Asia and in Europe, as did cocaine in the Americas.

With regard to injecting drug use, the United Nations Office on Drugs and Crime (UNODC), the Joint United Nations Programme on HIV/AIDS (UNAIDS), the World Bank and the World Health Organization (WHO), drawing on the most recent data available, jointly estimate that the number of people who inject drugs is 12.7 million (range: 8.9 million-22.4 million). That corresponds to a prevalence of 0.27 per cent (range: 0.19-0.48 per cent) of the population aged 15-64.[2] The problem is particularly stark in Eastern and South-Eastern Europe, where the rate of injecting drug use is 4.6 times higher than the global average.

The sharing of used injecting equipment makes people who inject drugs particularly vulnerable to HIV and hepatitis C. It is estimated that an average of 13.1 per cent of the total number of people who inject drugs are living with HIV. UNODC, the World Bank, WHO and UNAIDS jointly arrived at a global estimate of the number of people who inject drugs living with HIV of 1.7 million persons (range: 0.9-4.8 million). That situation is particularly pronounced in two regions of the world: South-West Asia and Eastern/South-Eastern Europe, where it is estimated that the prevalence of HIV among people who inject drugs is 28.8 and 23.0 per cent, respectively. More than half of the people who inject drugs are estimated to be living with hepatitis C.

Addressing HIV among people who inject drugs, through the implementation of an evidence-based comprehensive package of nine interventions,[3] as a component of what is

1 There is no standard definition of problem drug use. The definition may differ from country to countryand may include people who engage in the high-risk consumption of drugs, for example people who inject drugs, people who use drugs on a daily basis and/or people diagnosed with drug use disorders or as drug-dependent based on clinical criteria contained in the International Classification of Diseases (tenth revision) of the World Health Organization and the Diagnostic and Statistical Manual of Mental Disorders (fourth edition) of the American Psychiatric Association, or any similar criteria or definition that may be used.

2 These estimates reflect the most recent data available from different sources, including integrated biological and behavioural surveillance surveys, the improved coverage and quality of surveillance within countries and the increase in the number of countries reporting. Therefore, these estimates should be understood as an update of previous global estimates and not be used as a comparison for the purposes of trend analysis.

3 *WHO, UNODC, UNAIDS Technical Guide for Countries to Set Targets for Universal Access to HIV Prevention, Treatment and Care for Injecting Drug Users: 2012 Revision* (Geneva, World Health Organization, 2012).

also known as "harm reduction services", is a major component of the global response to stop the spread of HIV. Of them, the four most effective interventions for HIV prevention, treatment and care are needle and syringe programmes, opioid substitution therapy (or other evidence-based drug dependence treatment in the case of people who inject non-opioid drugs), HIV testing and counselling, and antiretroviral therapy.

The coverage of the four most effective interventions is greatest in Western and Central Europe, where harm reduction interventions have been scaled up for more than a decade, leading to a decline in the number of newly diagnosed cases of HIV among people who inject drugs and of AIDS-related deaths attributed to unsafe injecting drug use. However, recent outbreaks of HIV among people who inject drugs in parts of Europe demonstrate how the HIV epidemic situation can change very rapidly in areas where services and interventions are scaled down.

It is well documented that a very high percentage of people who inject drugs have a history of imprisonment. Also, both drug use and injecting drug use are highly prevalent among prison populations. The lack of access to and availability of health care, especially drug dependence treatment and HIV prevention, treatment and care services in prisons, is of major concern, since the prison population, at a minimum, should have access to services equivalent to those available to the general public. For instance, in Europe, the proportion of prisoners who had used an illicit substance during incarceration ranged from 4-56 per cent.

In Europe, the financial crisis seems to have had an impact on drug use modalities, with related health and social consequences. While there are no comprehensive data available yet, two phenomena seem to have emerged in parts of Europe that have appeared in parallel to the financial crisis. First, there appears to be a shift in the pattern of drug use which sometimes results in a higher risk of harm; and secondly, there has been a reduction in coverage of harm reduction services, which, according to recently published research, has increased the likelihood of unsafe injecting behaviour, thus influencing the spread of infections such as HIV and hepatitis C.

Drug profiles by category

Opiates

Opiates and opioids top the list of problem drugs that cause the most burden of disease and drug-related deaths worldwide. For the third consecutive year, Afghanistan, which has the world's largest opium poppy cultivation, saw an increase in the area under cultivation (from 154,000 hectares in 2012 to 209,000 hectares in 2013). In addition, Myanmar witnessed expansion in the area of opium poppy cultivation, although less pronounced. In 2013, the estimated global production of heroin rebounded to the levels seen in 2008 and 2011.

The global area of illicit opium cultivation in 2013 stood at 296,720 hectares — the largest area since 1998, when estimates became available.

There is evidence that Afghan heroin is increasingly reaching new markets, such as Oceania and South-East Asia, that had been traditionally supplied from South-East Asia. The long-established Balkan route seems to remain a corridor for the transit of Afghan heroin to the lucrative markets in Western and Central Europe, but its importance has declined due to various factors such as more effective law enforcement and a shrinking market in Western and Central Europe, as seen by the decline in opiate use and seizures in the subregion and the reduced level of supply compared with the peak levels of 2007.

The so-called "southern route" is expanding, with heroin being smuggled through the area south of Afghanistan reaching Europe, via the Near and Middle East and Africa, as well as directly from Pakistan.

An emerging phenomenon among opioid-dependent drug users in the United States of America is that synthetic opioids are being replaced with heroin, driven by the increased availability of heroin in parts of the United States, and lesser costs to regular users to maintain their dependency. Further, the reformulation of one of the main prescription pharmaceuticals abused, OxyContin, now makes it more difficult to snort or inject it.

Following a sharp increase in 2011, global seizures of heroin and illicit morphine declined in 2012, while remaining higher than the levels of 2010 and prior years. The fluctuations were mainly driven by seizures in South-West Asia and Western and Central Europe. However, in 2012, there was an increase in heroin seizures in many other regions, mainly Eastern and South-Eastern Europe, South Asia and Oceania. Significantly, heroin seizures, and therefore presumably the flow of heroin, in key countries located along the "northern route" from Afghanistan to the Russian Federation, have gone down. At the same time, there is evidence of a significant number of small seizures of home made desomorphine, which is likely serving as a substitute for heroin.

The emergence of potentially more harmful behaviour, including the abuse of opioids such as fentanyl, has been noted among opioid-dependent persons in Estonia, Finland and the United States. It has been observed that opioid users may alternate between pharmaceutical and/or prescription opioids and heroin, depending on which substance is more available, accessible and cheaper in the market.

Cocaine

While cocaine manufacture and trafficking have had a serious impact in the Western hemisphere, there are indications that overall global availability of cocaine has fallen. The estimated net area under coca bush cultivation as of 31 December 2012 was the lowest since the beginning of

available estimates in 1990: 133,700 hectares, a decline of 14 per cent from the estimate for 2011.

Global cocaine seizures increased to 671 tons in 2012, compared with the 634 tons seized in 2011. The main increase in the quantities of cocaine seized were in South America and Western and Central Europe.

Cocaine use is still relatively concentrated in the Americas, Europe and Oceania, and practically all of the world's cocaine is produced in three countries in South America. While there is no conclusive evidence with respect to the extent of cocaine use in Africa and Asia, expert opinion indicates that there may be pockets of emerging cocaine use in those two regions, related to the rise in trafficking through Africa and increased affluence in both continents.

The most problematic use of cocaine is in the Americas. In North America, cocaine use has been declining since 2006, partly due to a sustained shortage. However, more recently, a slight increase in prevalence has been observed in the United States, as has an increase in maritime seizures.

In South America, cocaine consumption and trafficking have become more prominent, particularly in Brazil due to factors including its geographical location and a large urban population.

In Western and Central Europe, the second largest market after the Americas, indicators of overall supply suggest a possible rebound in the availability of cocaine; retail purity has increased in some countries with sizable consumer markets. On the other hand, they do not show an increase in demand. There has even been a decline in cocaine use in some of the countries that have had higher levels of use.

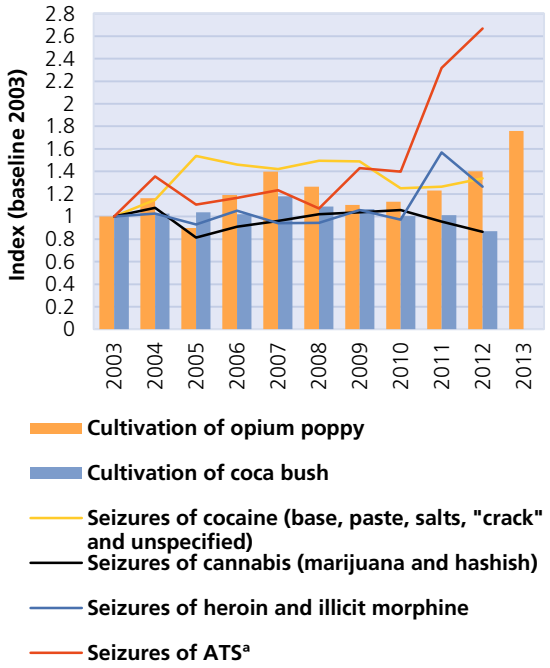
The market has expanded in Oceania in recent years, but the region has a different pattern of use compared with other consumer markets because it has a large body of users (a high prevalence) who use the substance with low frequency, perhaps due to the high price of cocaine.

Cannabis

Cultivation and production of cannabis herb ("marijuana") remains widespread, while production of cannabis resin ("hashish") remains confined to a few countries in North Africa, the Middle East and South-West Asia. In Afghanistan, despite the fact that the area under cannabis cultivation has been decreasing, the potential cannabis resin production in 2012 was higher than in 2011 due to the greater yield per hectare.

Global cannabis use seems to have decreased, essentially reflecting a decrease in cannabis use estimates reported by a number of countries in Western and Central Europe. However, in the United States, the lower perceived risk of cannabis use has led to an increase in its use. At the same time, more people using cannabis are seeking treatment each year.

Trend in main indicators of drug supply and drug supply reduction, 2003-2013



Source: Seizure data: annual report questionnaire supplemented by other official sources.
Cultivation data: UNODC estimates based on national illicit crop monitoring systems supported by UNODC supplemented by other official data.

[a] *Including amphetamine, "ecstasy"-type substances, methamphetamine, non-specified ATS, other stimulants and prescription stimulants. For the categories of other stimulants and prescription stimulants, seizures reported by weight or volume only are included.*

In Europe, the market has changed over the past decade, with cannabis herb produced locally or regionally now gaining ground over cannabis resin, largely sourced from Morocco, which previously was the dominant cannabis substance in Europe, as evidenced by seizure data.

New regulatory frameworks in the States of Colorado and Washington in the United States and in Uruguay now make the recreational use of cannabis legal under some restrictions. The new laws also include provisions for the supply chain, including both licensed and personal cultivation. It is too early to understand the impact of these changes on recreational and problematic use of cannabis and in the broad range of areas that they may affect, including health, criminal justice, and public revenues and expenditures. It will take years of careful monitoring to understand the broader effects of those novel regulatory frameworks in order to inform future policy decisions.

Based on existing research, it can be argued that with declining risk perception and increased availability, use and youth initiation may increase. Tax revenues from retail cannabis sales are expected to provide public revenue. However, expected revenue will need to be cautiously weighed against the costs of prevention and health care.

Amphetamine-type stimulants

While it is difficult to quantify the global manufacture of amphetamine-type stimulants, the number of dismantled laboratories manufacturing amphetamine-type stimulants, which were mostly manufacturing methamphetamine, continued to rise. Manufacture of methamphetamine in North America expanded once again, with a large increase in the number of methamphetamine laboratories reported dismantled in the United States and Mexico.

Of the total of 144 tons of amphetamine-type stimulants seized globally, half were seized in North America and a quarter in East and South-East Asia. Large quantities of amphetamine seizures continue to be reported in the Middle East, in particular in Jordan, Saudi Arabia and the Syrian Arab Republic.

Central and South-West Asia are emerging as new markets, with low levels of methamphetamine seizures and use being reported by two countries in those subregions. South-West Asia has also emerged as a significant production area for methamphetamine destined for East and South-East Asia. Production in West and Central Africa is also emerging.

Seizures of "ecstasy" increased in 2012, with major quantities of "ecstasy" being seized in East and South-East Asia, followed by Europe (South-Eastern and Western and Central Europe), which together accounted for over 80 per cent of global seizures of "ecstasy".

The misuse of prescription stimulants or medications for attention-deficit hyperactivity disorder (ADHD) is not uncommon, although only a few countries report any prevalence of misuse among the general and youth population. Although misuse of prescription stimulants in other regions is not negligible, such abuse is reported mainly by countries in North and South America.

New psychoactive substances and web-based marketplaces

While the Internet continues to be used as a means of drug trafficking and illicit trade in precursor chemicals, use of the so-called "dark net" has been growing. The "dark net" constitutes a virtual marketplace, which is inaccessible by web search, and where it is difficult for law enforcement authorities to identify website owners and users, as their identities remain hidden by means of sophisticated concealment methods. That makes the "dark net" a safe haven for buyers and sellers of illicit drugs, who trade principally in a digital currency (Bitcoin).

While the overall proportion of drug transactions that take place in the "dark net" is unclear, the value of transactions, as well as the range of drugs available, appears to be growing. The dismantling of one prominent "dark net" site, the "Silk Road", uncovered that the site had approximately $1.2 billion worth of total revenue from two to five years of operations. There is evidence of a niche market on the "dark net" for new psychoactive substancesas well as for high-quality cannabis, heroin, methylenedioxymethamphetamine (MDMA) and cocaine.

Finally, the proliferation of new psychoactive substances continues to pose a challenge, with the number of new psychoactive substances (348 such substances in December 2013, up from 251 in July 2012) clearly exceeding the number of psychoactive substances controlled at the international level (234 substances).

Drug-related crime

Crime recorded by the authorities in relation to personal use and trafficking of drugs assessed separately has shown an increase over the period 2003-2012, in contrast to the general declining trend in property-related and violent crime. However, the proportion of drug offenders who were drug users with recorded offences for personal use has remained stable, given the increased number of users during that period. Worldwide, the large majority of drug use offences are associated with cannabis.

Crime related to drug trafficking varies depending on the type of drug and the supply patterns involved in different regions.

The majority of persons arrested for or suspected of drug offences are men; the involvement of women in drug offences varies according to drug type, reflecting the drugs of preference among women. The highest percentage of women arrestees or suspects can be observed in relations to crimes involving sedatives and tranquillizers (25 per cent).

Precursor control

Most drugs, whether plant-based or synthetic, require chemicals to transform them into the final product. While chemicals are only one of the components required for the clandestine manufacture of plant-based drugs (heroin and cocaine), they constitute the essential components of illicitly manufactured synthetic drugs.

Given the growing manufacture of synthetic drugs, the control of such chemicals, known as precursors, has emerged as a key supply control strategy because the traditional approaches, such as eradication of illicit crops and alternative development, cannot be applied to synthetic drugs.

There are potential vulnerabilities in the structure of and trends in the production of and trade in chemicals that are used in the illicit manufacture of drugs. The international community has, over the years, strenghtened a control system aimed at enabling the legal trade of such chemicals while preventing their diversion into illicit manufacture.

Some successes have been achieved in precursor control, but they have prompted a range of reactions from the traffickers and manufacturers of illicit drugs, which create new challenges for the international drug control system.

Vulnerabilities of the chemical industry to diversion of precursors

The chemical industry has seen strong growth rates and geographical shifts over the past few decades, notably the past two decades, when global production doubled and trade more than tripled. Also during that period, the bulk of production shifted to Asia, where the emerging chemical industry is now characterized by a sizeable cluster of small competing enterprises. In contrast to the past situation, when the chemical industry was dominated by large, vertically integrated conglomerates, these new developments have made the chemical industry potentially more vulnerable to the diversion of precursors.

Moreover, with more and more chemicals being traded across borders, a greater number of transit countries and the emergence of a number of chemical brokers and other intermediaries, the potential avenues for diversion of precursors to the clandestine manufacture of drugs have been increasing.

Response by the international community

Precursor control emerged as one of the key pillars of international drug control in the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988. The Convention sets out specific measures for the manufacture and distribution of and international trade in a number of chemicals frequently used in the manufacture of drugs. These are listed under two categories: the more strictly controlled substances in Table I and the relatively less controlled substances in Table II. The 1988 Convention entrusts the International Narcotics Control Board with the implementation of precursor control at the international level.

The system has been further enhanced by means of a number of resolutions adopted by the United Nations Commission on Narcotic Drugs, the Economic and Social Council and the General Assembly, as well as the Political Declaration adopted by the General Assembly at its twentieth special session, in 1998, and the Political Declaration and Plan of Action on International Cooperation towards an Integrated and Balanced Strategy to Counter the World Drug Problem, adopted by the General Assembly in 2009, including their related action plans. As of December 2013, 23 substances were under international control: 15 substances in Table I and 8 substances in Table II of the 1988 Convention. In March 2014, the Commission on Narcotic Drugs decided to schedule *alpha*-phenylacetoacetonitrile (APAAN) in Table I of the Convention.

Production and trade of precursor chemicals

There is licit use and licit trade of precursors, and control includes the monitoring of the licit trade while preventing diversion. Through the analysis of information provided by countries to UNODC and international trade statistics, it can be concluded that over the period 2010-2012, some 77 countries were engaged in the manufacture of precursor chemicals.

A much larger number of countries were involved in trade in precursors. 122 countries reported exports of precursor chemicals over the period 2010-2012, while 150 countries reported imports. The largest exports of precursors were reported by countries in Asia, followed by Europe and the Americas. If only net exporting countries of precursor chemicals are considered, Asian countries account for 59 per cent of total net exports over the 2010-2012 period. Global exports in precursor chemicals rose at a rate similar to that of chemicals in general.

The licit requirements for and applications of various precursors differ from country to country. The bulk (93 per cent) of the international trade in precursor chemicals, in terms of economic value, is of substances listed in Table II of the 1988 Convention. In 2012, the more strictly controlled substances in Table I accounted for only 7 per cent of international trade in precursor chemicals, or 0.04 per cent of overall international trade in chemicals, and their export growth has been far lower than for Table II substances. The most important Table I substances, in economic terms, are acetic anhydride, used in the manufacture of heroin, followed by potassium permanganate, used in the manufacture of cocaine, and pseudoephedrine, used in the manufacture of methamphetamine.

The illicit trade in precursor chemicals cannot be quantified as easily as can the licit market, but information on seizures can provide some partial information on trends.

Although annual seizures of precursor chemicals fluctuate greatly, the overall trend for Table I precursors seems to show an increase over the last two decades. By contrast, seizures of Table II substances, although fluctuating, have been following a stable trend overall. The regional distribution of seizures of precursors in Table I and Table II shows a concentration in the Americas, followed, depending on the time frame examined, by Europe or, in more recent years, Asia.

Impact of precursor control on drug supply

Measures employed to control precursor chemicals have had a tangible impact on reducing the diversion of chemicals to the illicit manufacture of drugs, as could be observed through various methods of analysis:

a) *Increased volume of chemicals saved from diversion*. The number of shipments stopped before being diverted increased sharply, and seizures of Table I precursors rose 12-fold from the period 1990-1992 to the period 2010-2012, the former period being the initial years of international precursor control. This may point to the effectiveness of precursor control, although it is not conclusive proof;

b) *High interception rates*. Measuring seizures compared with the overall amount estimated to have been di-

verted into illicit manufacture, show that about 15 per cent of diverted potassium permanganate (in the range of 10-28 per cent) and 15 per cent of diverted acetic anhydride (in the range of 7-22 per cent) have been intercepted over the period 2007-2012. Estimated diversions are equivalent to just 2 per cent of international trade in potassium permanganate and 0.2 per cent of international trade in acetic anhydride;

c) *Higher volumes of precursor seizures compared with the volume of seizures of the substances those precursors are used to manufacture*. Seizures of precursors of "ecstasy", expressed in terms of the amount of "ecstasy" they could be used to manufacture (end-product equivalent), were almost a fifth larger than "ecstasy" seizures over the period 2007-2012. Seizures of amphetamine and methamphetamine precursors calculated in terms of their end-product equivalents were more than twice as high as amphetamine and methamphetamine seizures over the same period;

d) *Reduced availability of drugs due to precursor control*. Three examples can be cited in which precursor control appears to have reduced the supply of precursors and led to a consequent reduction in the availability of the drug. The first is the shrinking of the market for lysergic acid diethylamide (LSD), which could be at least partly attributed to improved control of LSD precursors. The shrinking of that market is reflected in the 75 per cent decline in use of LSD among high school students in the United States over the period 1996-2013, which is highly correlated to the decreased availability of the substance. The second example is the decline in "ecstasy" use in many countries, associated with a lower purity of the substance, connected with the limited availability of that drug's main precursor in the period 2007-2010. Thirdly, the improved control of precursors of methaqualone seems to have led to a decline in its availability and thus also its use over the past two decades;

e) *Prices in the illicit market*. While the price of acetic anhydride in the licit market fluctuated between $1 and $1.50 per litre in recent years, the price of illicit acetic anhydride in Afghanistan rose over the years, at times reaching peaks of some $430 per litre (2011), up from $8 in 2002. The price rises can be linked to improvements in precursor control. They also had an impact on the cost of heroin production. The proportion of acetic anhydride in total production costs of heroin in Afghanistan rose from 2 per cent in 2002 to 26 per cent in 2010 before falling to some 20 per cent in 2013.

New strategies by operators of drug laboratories

Improved precursor controls at the global level have prompted clandestine operators of illegal laboratories to develop a number of counter-strategies. Those strategies include:

- the use of more sophisticated ways to obtain precursor chemicals
- the use of transit countries with weak control systems
- the emergence of organized criminal groups specialized in the supply of precursor chemicals
- the creation of front companies to conceal illegal imports
- the domestic diversion and subsequent smuggling of precursor chemicals to final destinations in order to bypass the international control system
- the use of the Internet
- the misuse of pharmaceutical preparations (notably preparations containing ephedrine or pseudoephedrine) and,
- the emergence of non-scheduled precursor chemicals, including various pre-precursors that can be easily converted into the required precursors.

Thus, new pre-precursors for the manufacture of amphetamine-type stimulants have emerged in recent years, including APAAN, various esters of phenylacetic acid, 3,4-methylenedioxyphenyl-2-propanone, methyl glycidate and methylamine. Some of those substances, which are controlled only in a limited number of countries, have become major substitutes for the precursor chemicals used in the past and are now seized in greater quantities than are the internationally controlled precursors of amphetamine-type stimulants.

Another counter-strategy is the manufacture of new psychoactive substances that can be manufactured with chemicals not under international control.

All of these strategies used by clandestine manufacturers create a new set of challenges for the international precursor control system. At the same time, they reflect the fact that precursor control does have an impact. There are already some instruments available at the international level to deal with the emerging problems — use of the "know-your customer" principle, the limited international special surveillance list, the Pre-Export Notifications (PEN) Online and the Precursors Incident Communication System (PICS) — but they are yet to be implemented in a number of countries. Their universal and effective implementation would be a step forward in meeting these challenges.