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COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Accompanying the document

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REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on new psychoactive substances

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{COM(2013) 619 final}
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{SWD(2013) 320 final}

EN

TABLE OF CONTENTS

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Accompanying the document

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on new psychoactive substances

and proposal for a

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This report commits only the Commission's services involved in its preparation and does not prejudge the final form of any decision to be taken by the Commission.

Executive Summary Sheet

Impact assessment on a proposal for a Regulation on new psychoactive substances

A. Need for action

Why? What is the problem being addressed?

New psychoactive substances are increasingly available in the EU internal market and a growing number of individuals, in particular young people, consume such substances, which are also used for various other, legitimate purposes.

The potential risks that certain new psychoactive substances pose when consumed by people (for instance they can cause disease, injury, death) have prompted national authorities to submit them to various restriction measures (e.g. market bans, underpinned by either administrative or criminal law). These uncoordinated measures have negative effects on the internal market because they can hamper the legitimate trade and hinder the development of existing and new industrial, commercial and research uses of these substances.

The main causes are the divergent national approaches to new psychoactive substances, which can result in displacement of harmful substances between Member States and disruption of legitimate trade, and the ineffectiveness of the current EU instrument on new psychoactive substances.

What is this initiative expected to achieve?

The main objectives of the proposal are: to protect the health and safety of consumers from the risks posed by harmful new psychoactive substances; to reduce obstacles to legitimate trade in new psychoactive substances and prevent the emergence of such obstacles.

These general objectives will be achieved by improving the EU's capacity to rapidly identify and assess the risks posed by new psychoactive substances, by reducing the availability on the market of substances that raise immediate concerns to public health and that are proven to pose considerable health, social and safety risks. By harmonising the approach towards substances posing EU-wide risks, it will provide legal clarity to economic operators in the legitimate trade for these substances, facilitating the functioning of the internal market.

What is the value added of action at the EU level?

EU-level action would increase legal certainty and reduce obstacles for economic operators in the market for legitimate uses of new psychoactive substances, helping avoid the loss of business and facilitating the operation of companies across the internal market. It would also improve consumer protection, as harmful substances would be withdrawn from the market rapidly across the EU, thus avoiding their displacement. Member States individually cannot solve the problem, since substances withdrawn from the market in one country can still be sold in neighbouring countries or over the internet, which renders national action ineffective. EU-level action would also have the benefit of alerting Member States to harmful substances that have emerged in other countries, helping them anticipate and address potential health threats.

B. Solutions

What legislative and non-legislative policy options have been considered? Is there a preferred choice or not? Why?

The policy options assessed have been grouped in four thematic clusters to address the main problems identified (the preferred option for each cluster is in bold):

(a) Improving knowledge of new psychoactive substances: status quo; **facilitating structural cooperation between the EMCDDA, research institutes and forensic laboratories**; establishment of an EU-level research infrastructure on new psychoactive substances.

(b) Approach to address new psychoactive substances (individually or in groups): individual approach (status quo); approach by group of substances; **individual approach supported by information on an 'intelligently clustered' group of substances**.

(c) Temporary emergency measures: no temporary emergency measures (status quo); EU recommendation to introduce temporary emergency measures; **EU decision to introduce temporary emergency measures**.

(d) Decision on a new psychoactive substance: EU decision to submit substances to restriction measures backed by criminal sanctions or no action (status quo); status quo plus EU recommendation to submit substances to market restriction measures backed by administrative sanctions; **status quo plus EU decision to submit substances to market restriction measures backed by administrative sanctions**.

Who supports which option?

Each preferred option enjoys the support of a broad majority of stakeholders. Consultation of Member States showed the need for improving the knowledge-base on new psychoactive substances, as well as the speed of reaction and range of options available to act on substances posing risks, including through administrative measures. The proposed measures address these requests.

Economic operators in the market for legitimate uses of new psychoactive substances have stressed the need for an approach proportionate to the risks posed by substances, to avoid unjustified restrictions of economic activities. In general, stakeholders' opinions do not indicate different combinations of options. Practitioners and academic experts have also expressed wide support for the preferred options.

1. INTRODUCTION

This Impact Assessment covers measures aimed at reducing the availability in the EU internal market of new psychoactive substances that pose health, social and safety risks, while preventing the emergence of obstacles to legitimate trade and increasing legal certainty for economic operators.

What are new psychoactive substances?

New psychoactive substances (also known as "legal highs") are natural or synthetic substances that act on the central nervous system and modify mental functions by inducing a stimulating or depressant effect, causing hallucinations, alterations in motor function, thinking, behaviour, perception, awareness or mood (psychoactive effects). Individuals use them to experience such psychoactive effects. They are sold freely, unless evidence about the risks that they pose when consumed prompts authorities to submit them to restriction measures[1].

Many new psychoactive substances have or could have different other uses ('**legitimate uses**'), including in the industry, in research, as active substances for medicines. Around **a fifth of the substances** notified through the EU-level mechanism of exchange of information have some other, legitimate, uses.

New psychoactive substances are **not subjected to control measures under the UN Conventions on Drugs**[2], unlike other psychoactive substances such as cocaine, cannabis or amphetamines ('illicit drugs'), which were submitted to such measures because of their risks and potential for abuse. They could be considered for restriction measures under the UN Conventions on Drugs, if deemed necessary on the basis of a risk assessment conducted by the World Health Organisation (WHO) at the request of one or more UN Member States.

The current EU instrument tackling new psychoactive substances, the **Council Decision 2005/387/JHA** on the information exchange, risk assessment and control of new psychoactive substances[3] ("the Council Decision"), does not enable an effective response to the rapid emergence and spread in the internal market of a growing number of such substances.

On the other hand, **Member States cannot reduce the problem alone**. In addition, divergent national approaches implemented by the Member States can have adverse effects on other Member States, as they can lead to displacement of harmful substances and disruption of trade in legitimate uses of these substances ('**legitimate trade**').

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1 Restriction measures include limiting the availability of the substance to legitimate uses only (e.g. production of medicines) and various regulatory requirements (for instance concerning applications for marketing authorisation for such substances).

2 UN Single Convention on Narcotic Drugs of 1961 (amended in 1972) and UN Convention on Psychotropic Substances of 1971.

3 OJ L 127, 20.5.2005, p. 32-37.

2. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

2.1. Policy context

The rapid emergence and spread of new psychoactive substances in the internal market is one of the most **challenging developments** in EU drugs policy in recent years. Soon after a borderless internal market was created, and following the emergence and rapid spread of synthetic drugs such as ecstasy and amphetamines, it became clear that the effectiveness of national action on new psychoactive substances was limited and that EU-level action was necessary. Consequently, in 1997 the Council adopted the EU Joint Action on new synthetic drugs[4], which was subsequently replaced with the Council Decision.

The Council Decision established an **EU-wide system for tackling new psychoactive substances**, which follows six stages (see Annex 1 for details):

(1) A Member State notifies detection by its authorities of a new psychoactive substance and provides **information** on its manufacture, traffic and use to the Early Warning System (EWS) managed by the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA); this information is shared with the other Member States and Europol.

(2) If the EMCDDA and Europol consider it necessary, they request the Member States and the European Medicines Agency (EMA) to provide additional information on a substance; they prepare a **joint report** on the substance and submit it to the Council and the Commission.

(3) The Council can **request the EMCDDA to conduct a risk assessment** on the substance, which is drafted by the EMCDDA's Scientific Committee.

(4) The Scientific Committee conducts the risk assessment, the EMCDDA **submits the risk assessment report** to the Council and the Commission.

(5) The **Commission presents to the Council a proposal** to subject the substance to control (restriction) measures and criminal sanctions or a report explaining why it is not necessary to do so.

(6) The **Council decides on the submission of the substance to restriction measures** and on the obligation for the Member States to subject it to criminal law measures in accordance with their obligations under the UN Conventions on Drugs (which effectively means that the substance becomes an illicit drug).

[4] 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, OJ L 167, 25.6.1997, p. 1-3.

The Council Decision enables the EU to **address new psychoactive substances that raise concern at EU level**, without preventing Member States from introducing national measures on substances if they deem it necessary to do so.

When does a new psychoactive substance raise concerns at the EU level?

The EMCDDA and Europol apply six criteria for determining if a substance raises EU-level concerns and is to be made subject of a joint report, for which they will request the Member States and the EMA to provide more detailed information: (1) amount of material seized; (2) evidence of international trafficking; (3) evidence of organised crime involvement; (4) toxico-pharmacological properties or analogy with similar, better researched, substances; (5) evidence of the potential for further (rapid) spread; (6) evidence of intoxication or fatalities.

The Commission's assessment report[5] on the functioning of the Council Decision concluded that, while it is a useful instrument for addressing new psychoactive substances at the EU level, it is inadequate, considering the scale and complexity of the problem, and it is therefore necessary to revise it.

The Commission Communication "Towards a stronger European response to drugs"[6] identified the spread of new psychoactive substances as one of the problems requiring a firm response at the EU level and set the ground for revising the Council Decision; it also identified the evolving nature of illicit trafficking in drugs and the interactions between the market for new psychoactive substances and the one for illicit drugs as a challenge that needs to be addressed. It therefore called for the revision of the EU legislative framework on new psychoactive substances and on illicit drug trafficking, to enhance the effectiveness of EU action on drugs. The revision of the Council Decision and that of the Framework Decision are included in the Commission's 2013 Work Programme[7].

In its Conclusions of December 2011[8], the Council requested the Commission to take further action to address new psychoactive substances and invited it to **revise the Council Decision**. A large number of written questions from the European Parliament to the Commission enquire about new initiatives to address new psychoactive substances.

5 COM(2011) 430 final and SEC(2011) 912.
6 COM(2011) 689 final.
7 COM(2012) 629 final, see; http://ec.europa.eu/atwork/key-documents/index_en.htm.
8 http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/jha/126879.pdf.

2.2. Gathering information and consultation

The identification and analysis of the problems, objectives, policy options and assessment of impacts were informed by **broad stakeholders' and experts' consultations,** as well as a web-based public consultation**,** which met the Commission's general principles and minimum standards. An external study[9] was commissioned to support the preparation of this Impact Assessment report. This study ran between September 2011 and June 2012.

2.2.1. Consultation of stakeholders

The Commission involved all Member States in the assessment of the functioning of the Council Decision, through written consultation. In the context of the external study, the Commission collected and examined the views of national authorities (responsible for drugs legislation, from ministries of health and justice, health institutes, law enforcement authorities) and EU agencies involved in the implementation of the Council Decision - the EMCDDA, Europol and the EMA. It also gathered and analysed the views of concerned international organisations (e.g. the WHO), civil society organisations, research institutes and academic experts (see Annex 2).

The Commission organised two **meetings with experts** in the field of new psychoactive substances (on 15 December 2011 and 1 March 2012). Experts stressed that the Council Decision and existing legislation on product safety, consumer protection and drug control are not adequate to deal with the large number of substances whose effects are often unknown and which need to be assessed, and that therefore specific and more adequate legislation on new psychoactive substances is necessary. They pointed out that new legislation should be proportionate to the different levels of risk posed by various new psychoactive substances.

Certain experts expressed concern that too rigorous policy responses (for instance restriction measures on groups of substances or a wide use of restrictions backed by criminal sanctions) could have **adverse effects**, notably resulting in some substances moving to the illicit drug market, being replaced by more harmful ones or being inaccessible for research.

Economic operators producing or distributing new psychoactive substances for use aimed at inducing a psychoactive response in humans ('**recreational use**'), as well as those manufacturing such substances for various industrial uses and their trade associations, were consulted as part of the preparatory study. Consultation was conducted through surveys (users, distributors and sellers), as well as through face-to-face and phone interviews (economic operators, distributors and sellers, trade associations). Users of new psychoactive substances were also consulted. However, the rate of response does not allow for the generalisation of the results, which must be triangulated with other sources (see Annex 2).

[9] Specific contract N° JUST/2011/EVAL-DPIP/FW/0014/A4-ABAC 30-CE-0441776/00-61.

A survey was conducted among young people (15-24 years' old) in 2011, through the **Eurobarometer "Youth attitudes on drugs"**[10]. Results show that 34% of respondents were in favour of restricting the availability of all substances that imitate the effects of illicit drugs, 47% were in favour of only restricting the availability of those substances which posed risks to health, 15% believed that sale and consumption should be regulated in a way similar to licit substances like alcohol or tobacco, while 2% thought that nothing needed to be done.

The **public consultation** on drugs policy that the Commission ran from 28 October 2011 to 3 February 2012 included the question: "What regulatory measures should the EU develop to contain the spread of new psychoactive substances?". The Commission received 205 replies in total and 134 respondents specifically addressed this question. In general, replies stressed the need for quicker action on new psychoactive substances and warned against using criminal sanctions indistinctly, because of their adverse consequences (see Annex 3). Certain stakeholders (NGOs and individuals, in particular) suggested that the market for new psychoactive substances should be regulated in a similar fashion to that of alcohol or tobacco.

The **European Economic and Social Committee** has urged the Commission, in an opinion[11], to explore options that avoid making the use of such substances a criminal offence.

These contributions have informed the problem definition and form the basis for the formulation of policy options and for their assessment.

2.2.2. Internal consultation

DG JUSTICE, which is responsible for the initiative presented in this report, set up an **Inter-Service Steering Group** (ISSG) to which the following services were invited: the Secretariat-General, the Legal Service, DGs ENTR, MOVE, RTD, INFSO, MARKT, TAXUD, EAC, SANCO and HOME. The EMCDDA, Europol and the EMA participated as observers. ISSG meetings were held on 8 November 2011, 31 January and 23 March 2012. Services were supportive of the initiative and provided useful feedback during the ISSG meetings and in subsequent communications, which has been taken into account in the drafting of this report.

2.3. Scrutiny of the Impact Assessment Board

2.3.1. First opinion of the Board

The European Commission's Impact Assessment Board (IAB) examined a first version of this report and issued an opinion on 4 May 2012. The revised report took on board the recommendations of the IAB and introduces the following **main modifications and clarifications**:

[10] European Commission, Flash Eurobarometer 330, *Youth attitudes on drugs*, 2011.
[11] OJ C 229, 31.7.2012, p. 85.

(1) **Improved problem definition,** which better explains why differences in national approaches impede legitimate trade, provides a clearer description of the nature and the scale of the problem with regard to substances that raise cross-border concerns, provides additional information on the functioning and characteristics of the market, differentiating between the market for substances used for recreational purposes and that for legitimate uses, and clarifies the scope and limitations of existing EU and Member States actions. The **intervention logic** has been clarified, also by adding a graph. The revised problem definition better explains the reliance on internal market competences for action on new psychoactive substances.

(2) **The design of the policy options has been strengthened** by providing additional details on their content and by adding a new option in cluster 2. Further explanations have been provided to justify why other options have been discarded. A timeline comparing the preferred policy option and the existing Council Decision has been added to clarify how the new instrument will increase speed of reaction.

(3) **The assessment of costs and benefits** of the policy options, including administrative and compliance costs for the Member States and for economic operators in the market for legitimate uses, has been improved. **Proportionality** has been assessed in relation to all relevant options, in particular with respect to temporary restriction measures. Stakeholders' opinions have been more extensively referred to throughout the report. The positive and negative impacts of restriction measures have been better highlighted and trade-offs acknowledged.

2.3.2. Second opinion of the Board

The IAB examined this report and issued an opinion on 30 October 2012. The revised report takes on board the recommendations of the IAB and introduces the following **main modifications and clarifications**:

(1) **Improved presentation of the problem**, further strengthening the argumentation that divergent national approaches to new psychoactive substances affect legitimate uses of such substances, by making reference to case studies, information and views of industry representatives, and to some research on the matter. The revised report also better explains that **data on legitimate uses** of new psychoactive substances is not systematically collected or available, and therefore it is not possible to provide additional evidence in this respect. The report also explains more clearly that the proportion of substances notified through the EWS that have known legitimate uses (one fifth) is significant, considering that data on such uses is not systematically collected, and that these are often substances newly synthetized and still not well known or researched.

(2) **More detailed explanation of the content of policy options**, to clarify the meaning and consequences of **administrative and criminal sanctions** for the infringement to the restriction measures introduced on a new psychoactive substance that poses health, social and safety risks, and to clarify how temporary (and permanent) restriction measures would work.

(3) **Extended assessment of the preferred option**, better explaining what would be Member States' possibilities to apply national measures and what consequences would be on the effectiveness of the option in meeting the policy objectives.

3. PROBLEM DEFINITION

New psychoactive substances are increasingly available in the EU internal market and a growing number of individuals, in particular young people, consume such substances, which are also increasingly used for various other, legitimate purposes.

The potential risks that new psychoactive substances pose when they are consumed have prompted authorities to submit them to various restriction measures. These measures can hamper the **legitimate trade** and hinder the development of existing and new legitimate uses.

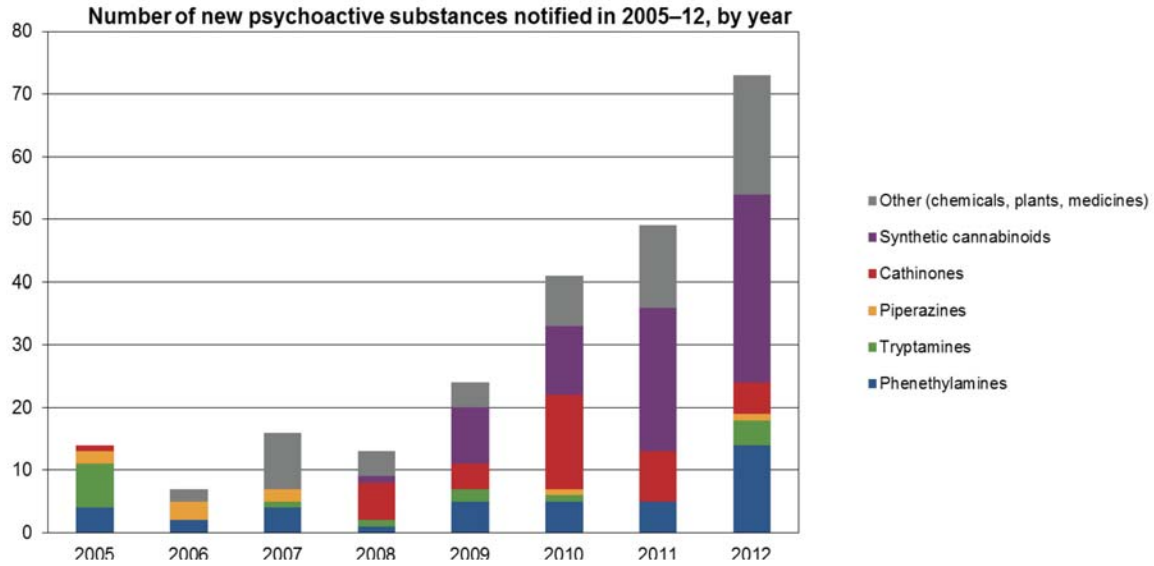
The main causes of these problems are: **divergent national approaches** to new psychoactive substances (which can result in **displacement** of harmful substances between Member States and **disruption** of legitimate trade) and the **ineffectiveness of the current EU instrument** on new psychoactive substances.

3.1. The market for new psychoactive substances

3.1.1. Rising number and diversity of substances across the EU

During the past years, Member States have notified **an increasing number** of new psychoactive substances to the EMCDDA through the EWS. Between 1997 and 2012, they reported around 290 substances - and the pace of notification intensified recently, with more than one new substance notified every week in 2012. The number of notified substances **tripled** between 2009 and 2012 (from 24 to 73, see figure 1).

Figure 1: Number of notifications and groups of substances notified via the EWS (as of 31 December 2012)



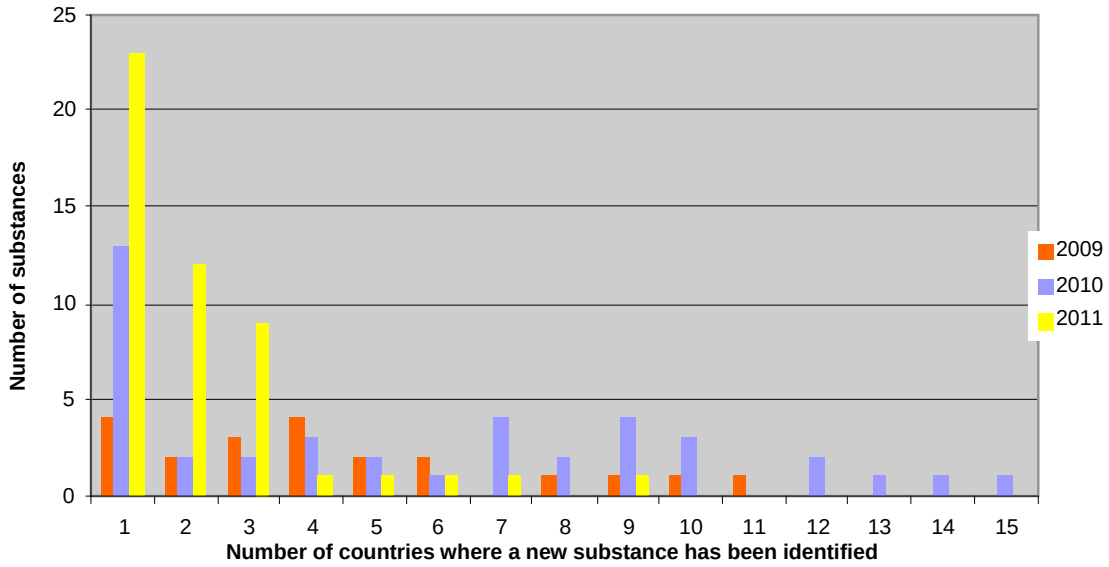
Source: EMCDDA

The number of new psychoactive substances that can emerge on the market may run into the **thousands** because many variations of existing substances or new, still unexploited, substances can be extracted, manufactured or synthesised at relatively low cost.

New psychoactive substances that emerge in one Member State can spread quickly in the internal market. According to the information gathered through the EWS, a **considerable number** of the new psychoactive substances reported in 2009-2011 - 81% (71 out of 114) - were notified by more than one EU country, and more substances were present in more than one country in 2011 compared to 2009 (see figure 2).

This percentage is likely to be higher in reality because **not all Member States report** to the EWS information on all substances that they detected. This is because they are not obliged to do so and may refrain from reporting on a substance detected in very small quantities or that another Member State has already notified.

Figure 2: Geographical diffusion of new psychoactive substances notified in 2009-2011



Source: EMCDDA, European Database on New Drugs

3.1.2. The market for recreational use of new psychoactive substances

Evidence suggests that **the levels of use of new psychoactive substances for recreational purposes have increased** and that use is predominant among young people. For instance, results of research in Poland show an increase in the use of new psychoactive substances at least once in a lifetime by students aged 18 from 3.5% in 2008 to 11.4% in 2010. Use during the last 12 months was reported by 2.6% of students in 2008 and increased to 7.2% in 2010[12].

Surveys in other Member States show that the **level of use of new psychoactive substances is considerable**, although no trend surveys are available yet. In the Czech Republic, a survey of internet users in 2011 found that 4.5% of respondents aged 15-34 had tried new psychoactive substances before. In Ireland, a survey conducted in 2010-2011 among 15-64 year olds found that 3.5% had taken new psychoactive substances in the last year – the percentage for 15-34 year olds was 6.7%. In Slovakia a survey carried out in 2011 found that 5% of students from primary and secondary schools used "legal highs". The UK Advisory Council on the Misuse of Drugs has acknowledged that "new psychoactive substances' use appears firmly embedded in the UK drug scene"[13].

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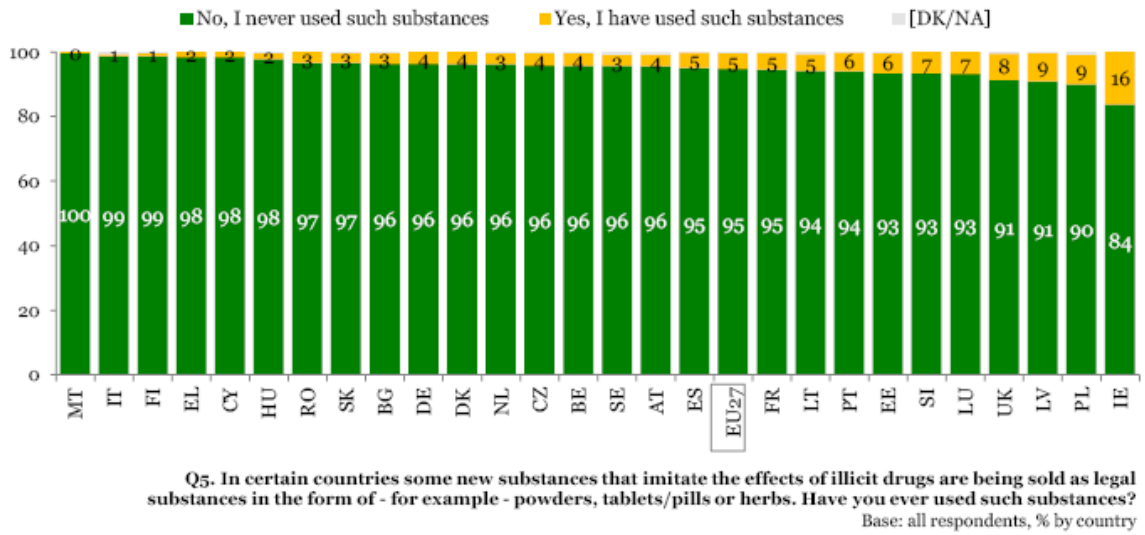
12 EMCDDA, *2011 Annual Report on the state of the drug problem in Europe*, 2011.

13 Advisory Council on the Misuse of Drugs (ACMD), *Consideration of the Novel Psychoactive Substances ('Legal Highs')*, 2011.

According to the EMCDDA[14], the studies available (see Annex 4) indicate that there is a potential for a further rapid rise of use among certain categories, particularly young people. The 2011 Eurobarometer survey "Youth attitudes on drugs" found that 5% of young people (15-24 years' old) in the EU reported having 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.

Figure 1: Experience with legal substances which imitate the effects of illicit drugs



Q5. In certain countries some new substances that imitate the effects of illicit drugs are being sold as legal substances in the form of - for example - powders, tablets/pills or herbs. Have you ever used such substances?
Base: all respondents, % by country

Source: European Commission, Flash Eurobarometer 330, Youth attitudes on drugs, 2011

The number of last-year users can be estimated to be around **2.2 million** in the EU (see Annex 5 for details).

Individuals use new psychoactive substances to **obtain various effects** - pleasure, performance enhancement or relaxation - which are also produced by certain illicit drugs. The use of new psychoactive substances **differs strongly from one country to another** and may be influenced by the strictness of national illicit drug policies or the availability of certain illicit drugs. Availability, legality and price seem to be the main **drivers for the demand** of new psychoactive substances for recreational use by individuals.

[14] EMCDDA-Europol, *2011 Annual report on the implementation of Council Decision 2005/387/JHA*, 2012.

Availability appeared to be the main factor for the use of mephedrone before it was submitted to restriction measures, while legality seems to be the main reason for the use of synthetic cannabinoids[15]. After they were subjected to restriction measures in certain Member States, between 2008 and 2010, the use of synthetic cannabinoids dropped considerably and some users reverted to using natural cannabis instead. **Their price** - new psychoactive substances are relatively cheap, particularly when compared to illicit drugs[16] (see Annex 6) - may have contributed to their rapid dissemination.

New psychoactive substances are sometimes launched to attract the users of illicit drugs[17] or to replace substances submitted to restriction measures, to take over their market. Several classes of new psychoactive substances have been modelled on existing illicit drugs[18]. This is principally driven by the fact that there is demand for substances which **produce psychoactive effects while remaining legal**.

Certain people who would not use illicit drugs, because they do not want to break the law or because they think that illicit drugs are dangerous, could be tempted to use new psychoactive substances, because they are **sold freely and are therefore deemed safe**, although most of them have never been tested in humans[19]. Chemists can readily identify the substances that are similar to those covered by restriction measures but which are legal, and the production methods are easily accessible from the relevant literature[20].

The main channels through which new psychoactive substances are distributed for recreational use in the EU are the internet and specialised shops selling psychoactive substances ('**head shops**').

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15 ACMD, *Consideration of the Novel Psychoactive Substances ('Legal Highs')*, 2011.

16 http://www.emcdda.europa.eu/publications/drug-profiles/synthetic-cathinones.

17 For example, mephedrone has similar effects to ecstasy and seeks to appeal to users of stimulant substances, including cocaine; subsequently, the cathinone methylone was launched to replace mephedrone after it was submitted to restriction measures in several Member States.

18 Particularly those from the phenylethylamine, phencyclidine and tryptamine classes. For example 3,4-Dimethoxy-N-methylamphetamine (DMMA) is a phenethylamine, structurally related to methamphetamine.

19 ACMD, *Consideration of the Novel Psychoactive Substances ('Legal Highs')*, 2011.

20 S. Gibbons, "'Legal Highs' – novel and emerging psychoactive drugs: a chemical overview for the toxicologist", in: Clinical Toxicology, Vol. 50, p. 15-24.

The **internet and social networks**, which offer new opportunities for businesses and individuals alike, have facilitated the spread of new psychoactive substances across the EU. The role of the internet in selling such substances for recreational use has sharply increased over the past years, illustrating their growing availability and demand for them. However, it is unclear what share of the total distribution and sales takes place over the internet.

The EMCDDA's internet snapshot survey of January 2012 identified 690 **online shops** selling new psychoactive substances[21]. This was more than twice the number of shops identified in January 2011 (314) and a four-fold increase since January 2010 (170).

In the past three years, **head shops**, which had traditionally only existed in a few Member States[22], have opened up in several Member States at a rapid pace. New psychoactive substances are now reported to be sold via head shops in at least 13 Member States[23]. Certain Member States have taken action to close down such shops. As a result, the number of operating shops fell across the EU, although comprehensive data is not available, and a parallel increase in the activity of online shops selling new psychoactive substances was reported. In certain Member States new psychoactive substances are also sometimes sold in petrol stations, kiosks, video rental stores (Germany), sex shops (France, Luxembourg) and tobacconists (Greece).

According to the available information[24], companies that produce new psychoactive substances, mostly as a secondary chemical product, are based **outside the EU** (China and India mostly). They are responsive to changes in national and EU legislation on new psychoactive substances and are able to rapidly adapt their offer and produce alternative substances to those subjected to restriction. EU companies usually import, re-package and distribute on to private vendors in different Member States. Although complete information is not available, there are indications that EU companies operating in the market for recreational uses of new psychoactive substances (in particular retailers) are mostly small or micro enterprises. The EU can address the production of new psychoactive substances outside the EU through political dialogue with these countries and with other countries concerned by the spread of new psychoactive substances, through cooperation programmes and projects implemented with third countries.

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21 EMCDDA-Europol, *2011 Annual report on the implementation of Council Decision 2005/387/JHA*, 2012.

22 In the Netherlands, where up to 90 head shops exist today, such shops were already reported at the end of the 1990s. The head shops in the Netherlands are mostly regulated through Municipal Ordinances.

23 AT, BG, CZ, DE, HU, IE, IT, LU, LV, NL, PT, SI, UK.

24 Information confirmed by an industry representative, who asked to remain anonymous.

Annual turnover and profit in this market can be significant: for example, one company responding to the survey has an annual turnover of €1 million with a profit margin of 50%. But other companies involved in this trade are likely to have a much smaller turnover. This differs widely depending on the country and on the head shop, as some shops may also sell other, non-psychoactive products (smoking equipment, herbal products, vitamins).

Information from a **head shop owners' association in Ireland** indicates that annual turnover in the approximately 100 head shops that existed in the country prior to government intervention[25] in 2010 has amounted to between €200.000 and €400.000 per shop on annual basis, resulting in a total, for Ireland, of between €20 and €40 million. These shops, which paid VAT and income tax, employed approximately 500 staff between them. Following drastic measures taken by the government to restrict the availability of new psychoactive substances, only ten head shops operate in Ireland today[26], with an estimated turnover of 5-10% of the original.

It is difficult to provide an estimate of the overall **size of the market for recreational use** of new psychoactive substances because little information is collected, across the EU, on market operators, sales, products and use of such substances. In addition, the market is volatile, because many substances disappear from the market quickly, either because users do not like them (if they produce unpleasant side-effects) or because they are subjected to restriction measures.

For this Impact Assessment report, estimations of the EU market for recreational use of new psychoactive substances have been made through an analogy with the ecstasy[27] market. Based on those calculations, the turnover in this market is estimated to be approximately **€0.5 billion** per year[28] (see Annex 5).

3.1.3. The market for legitimate uses of new psychoactive substances

Many new psychoactive substances have or could have **various other uses**, in addition to being used for recreational purposes. Despite the fact that collection of information on the legitimate uses of new psychoactive substances is sporadic, also because this is not foreseen under the current EU legislative framework, numerous legitimate uses of these substances have been documented so far, mainly in the industry, in research, as active substances in medicines (including in medically assisted drug treatment, to treat drug addiction, as substitutes for illicit drugs), but also for traditional, cultural or religious purposes.

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25 The Misuse of Drugs Act 1977 Order 2010 put approximately 200 new psychoactive substances under criminal control. The Psychoactive Substances Act 2010 introduced a general control for all psychoactive substances that do not have an authorized use.

26 National Advisory Committee on Drugs (NACD), *An Overview of New Psychoactive Substances and the Outlets Supplying Them*, 2011.

27 Ecstasy emerged in the 1990s and was subsequently banned, at the UN level.

28 This concerns a rough estimate and needs to be interpreted and quoted with caution.

For instance, the substance 4-methylamphetamine, which was subjected to restriction measures in March 2013, was studied in the 1950s as an anorectic medicine by Smith, Kline & French laboratories, under the trade name Aptrol, but its development and marketing was abandoned[29]. Some of the substances notified under the EWS have also been notified or registered in the REACH database in line with the provisions of Regulation 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals.

However, **comprehensive information about legitimate uses of new psychoactive substances is not available** across the EU. This is because Member States' authorities are often not aware of these legitimate uses and do not report them to the EWS systematically. The EMCDDA collects data on certain legitimate uses, mostly on human and veterinary medicinal use, only when it produces a joint report on a substance, under the Council Decision. For such a joint report, Member States and the EMA are asked to provide information about legitimate uses. Joint reports have been drawn on only 11 substances since 1997 but the Member States have shared some additional information on legitimate uses through the EWS.

Among the new psychoactive substances notified through the EWS since 1997, the EMCDDA has received information[30] on other uses, often primary uses, for over **45 substances** (see Annex 8), or almost a fifth of the substances notified. This is a significant proportion and it may be underestimated, considering that data on legitimate uses is not systematically collected, and that these are often substances newly synthetized that are still not well known or researched. The following types of legitimate uses of new psychoactive substances have been documented:

Substances used as active substances in human or veterinary medicinal products

This group includes human or veterinary medicinal products that have marketing authorisation in the EU, in certain Member States or in EU neighbouring countries, but that are diverted or misused for recreational purposes. At least 12 substances notified since 1997 are part of a range of registered medicines[31] (for instance *m*CPP, which is an API).

This group also includes medicinal products that have received marketing authorisation in certain countries outside the EU, but which have no marketing authorisation at EU level or in the Member States[32], and which are advertised as 'legal highs'.

It also includes new psychoactive substances that are used recreationally in certain Member States, and are therefore submitted to restriction measures in these Member States, but that are used as medicines in other Member States. This is the case for certain synthetic cannabinoids, for instance, which have emerged on the market in recent years. For example nabilone, which has been subjected to restriction measures in several Member States, is used in the UK in the treatment of nausea and vomiting caused by chemotherapeutical agents used to treat cancer.

29 EMCDDA-Europol Joint Report on a new psychoactive substance: 4-methylamphetamine.

30 Information based on the data shared through the EWS until June 2012.

31 Under the Council Decision, substances having human or veterinary medical uses are excluded from action at the EU level, they are supposed to be followed up under the pharmacovigilance system.

32 For example phenazepam, which is a member of the benzodiazepine family and is sold on the internet as a 'legal high', and is also sold as counterfeit valium. It is used as a medicine in Russia and other Commonwealth of Independent State countries.

Substances with potential legitimate uses, some of which are modifications of known medicinal or veterinary medicinal products

This group includes substances that are still subject to research and clinical trials by the pharmaceutical industry, and substances that are used, for instance, as food dietary supplements. Data on such research is often not available as it may involve confidential business information. Some substances may even be patented[33].

Plants and herbs

This group covers plants and herbs that grow free in nature, and whose flower core, leaves or roots have psychoactive potential (sometimes when extracted). They have been and may still be traditionally used in Africa, Asia or the Americas. Examples include Kratom ("traditional medicinal" leaf used in Southeast Asia), Salvia Divinorum ("healing medicine" traditionally used in Mexico), kava (common herbal product used in the South Pacific Islands, where the roots of the plant are brewed into a tea and taken by the indigenous population for relaxation), Ibogaine (hallucinogenic substance extracted from plants and used for traditional and ritual purposes in Africa, and which is marketed in France as a medical drug for dieting).

Substances that have been researched for medicinal purposes but not marketed

This group includes substances that have been subject to pharmaceutical research, but that were finally not approved or marketed as medicinal products, possibly because of adverse side-effects or toxicity (for example 4-MTA and 4-methylamphetamine).

Substances with other (potential) chemical and industrial uses

This involves substances that have various uses in the industry, for instance as radioisotopes for medical examinations. It also includes precursors for the manufacture of industrial products (e.g. glue, reagents), such as gamma-butyrolactone (GBL), or precursors for a medicinal product like CPCPP[34], which also have psychoactive effect when consumed for recreational purposes.

It is not possible to provide an overall estimate of the **size of the market for legitimate uses** of new psychoactive substances, because this depends on each specific substance and because information is not collected systematically on such uses, on market operators, distribution, sales and products. But it is reasonable to assume that the size of this market is considerable.

[33] For example, one of the substances notified in 2011 (Ethylphenidate) is a metabolite of methylphenidate, which is commercialised as the medicine Ritalin for the treatment of attention deficit hyperactivity (ADHD). Another substance in this group is an extract of the geranium plant (1,3-dimethylamylamine), an ingredient in dietary supplement, often described as a 'natural' stimulant.

[34] CPCPP (1-(3-chloropropyl)piperazine), a substance from the piperazine family that is used in the manufacture of the antidepressant medicine Nefazodone. CPCPP was placed under drug control legislation in the UK in 2009. As it was not used in the UK pharmaceutical industry, domestic controls were applied. However, TEVA, an Israeli pharmaceutical company producing the medicine has branches all over the EU (Source: UK Home Office).

This assumption is based on the following elements: the number of new psychoactive substances present on the market; the potential number of substances with psychoactive effects that may yet be launched, which runs into the thousands; the likelihood that they will be launched, considering the demand for them; the potential for **'dual use' -** substances consumed for recreational purposes and also used in the industry, for instance as active substances in medicine (as shown before, a considerable number of substances notified to the EWS have been researched for medicinal or other commercial purposes before being launched on the market for recreational use – see Annex 5 for more details).

It is expected that **a large number of new psychoactive substances could have uses in the industry**, in particular as active ingredients for human or veterinary medicinal products. This is because their psychoactive properties can be valuable for medical treatment. But the appropriate conditions need to be provided for companies to conduct research in order to develop such uses, without disproportionate administrative burden and red tape - and certain restriction measures, aimed at limiting the availability of substances for recreational use, can create such burden.

The box below presents three **case-studies** of dual-use substances, which are used recreationally while having wide uses in the industry:

GBL is an industrial chemical that, according to the industry, offers excellent solvent qualities with low toxicity and diminished environmental concerns and is used in a wide range of legitimate end uses, for example as an aroma compound, stain remover, superglue remover, paint stripper. It is used in the manufacture of products including hospital supplies, beverage filtration and purification aids. It is also used for various applications, including circuit board cleaning in the electronics and high-tech industries, the production of herbicides and as a processing aid in the production of vitamins and pharmaceuticals. It is also one of the precursors for the manufacture of the illicit psychoactive substance GHB. When consumed by humans it is converted into GHB inside the body and it is therefore used for inducing psychoactive effects for recreational purposes with effects similar to those of alcohol.

The industrial use of GBL is considerable. According to data provided by the industry[35] there is one producer of GBL in the EU, with a production capacity of 30.000t (±25% of world production capacity).

1,4-BDO (1,4-butanediol) is an industrial chemical that serves predominantly as an intermediate ingredient in common industrial and commercial products. 1,4-BDO is reacted to make items such as engineering plastics, polyurethane systems (e.g. golf balls, skateboard wheels, car bumpers) and as a carrier solvent in printing inks and cleaning agents. Like GBL, it is also one of the precursors for the manufacture of the illicit psychoactive substance GHB. And as with GBL, when consumed by humans 1,4-BDO is converted inside the body into GHB and it is therefore used for inducing psychoactive effects for recreational purposes with effects similar to those of alcohol.

[35] European Chemical Industry Council – Cefic Aisbl, background paper on gamma-butyrolactone (GBL) and 1,4-butanediol (1,4-BDO), 14 October 2005, update provided in July 2012 following consultations with the spokesperson of CEFIC's Drug Precursors Working Group.

According to data provided by the industry[36] there are three producers of 1,4-BDO in the EU, with a combined production of app. 500.000t (±36% of world capacity).

Both GBL and 1,4-BDO are voluntarily monitored by economic operators under the EU's drug precursor control system[37].

***m*CPP** - a mild stimulant - was subject of a joint report under the Council Decision in 2006. Because it was a metabolite of the psychoactive compound Trazodone, which was used as an active ingredient in medicinal products in Belgium and France, it was not submitted to risk assessment and no action was undertaken on it at the EU level.

Several Member States have subjected these three substances to various restriction measures under different types of legislation, with different constraints on economic operators in the market for legitimate uses (see section 3.3.).

3.2. Problem 1: Risks posed by the recreational use of new psychoactive substances to individuals and society

The rising number of new psychoactive substances available in the EU internal market, their growing diversity, both in type and risk level, the speed with which they emerge 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 legitimate trade.

The recreational use of certain new psychoactive substance can cause **harms[38] to individuals' health and safety**, and can pose **risks to and burdens on society**. These risks are amplified by the fact that many such substances are sold to consumers without appropriate labelling and instructions of use and are sometimes mislabelled to evade rules on consumer products.

36 Ibidem.

37 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 (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.

38 The harms described in this section relate to a limited number of substances, whose risks were assessed at the EU level. However, since the majority of substances reported through the EWS were not submitted to risk assessment, the effects presented may over-estimate the actual risks of new psychoactive substances.

There is a wide variety of new psychoactive substances on the market, which pose **different levels of health, social and safety risks**. For instance, the level of risk posed by mephedrone is higher than that of certain "magic mushrooms", in particular those containing the hallucinogen active components psilocine and psilocybine[39]; at the same time, the risk-level of mephedrone is lower than that of an illicit drug such as crack cocaine (see figure 9 in Annex 5). The restrictions applied to new psychoactive substances, at national and at the EU level, often do not take into account the different risk-levels of these substances and fail, therefore, to provide proportionate responses. Disproportionate responses can undermine the effectiveness of restriction measures and can have severe adverse effects (see section 3.4.2.).

It is difficult to provide a complete picture of the risks associated with the use of new psychoactive substances soon after they appear on the market, because of scarce research on and information about their toxicity, long-term effects, historic trends and future projections of use[40]. There are two broad categories of harms that new psychoactive substances may cause to individuals and to society:

(a) Health harms

The consumption of new psychoactive substances may cause physical or psychological harms, including (see Annex 7 for details):

- **Acute harm and toxicity** (significant agitation, psychosis, delirium, tachycardia, hypertension, chest pain and seizures, including potential risk of overdose[41]).

- **Spread of blood borne infections,** such as HIV or hepatitis C, among users that inject new psychoactive substances[42].

39 Amsterdam, Jan v., Antoon Opperhuizen & Wim van den Brink, *Harm Potential of magic mushrooms: A review*, in: Regulatory Toxicology and Pharmacology, Vol. 59 (2011), p. 423-429.

40 J. Birdwell, J. Chapman and N. Singleton, *Taking drug seriously – A Demos and UK Drug Policy Commission report on legal highs*.

41 ACMD, *Consideration of the Novel Psychoactive Substances ('Legal Highs')*, 2011.

42 A. Botescu, *Evaluating new synthetic drugs' use risks concerning children and youth in Romania*, 2011 showed that among users participating in the survey, 1 in 6 was injecting new psychoactive substances.

- **Severe psychiatric problems**, in particular in the case of synthetic cannabinoids, which may have a greater potential to cause harm than natural cannabis[43].

- **Fatalities** were reported in relation to several new psychoactive substances recently[44].

- **Dependence**: some evidence[45] suggests that amphetamine type psycho-stimulants have an increased risk of dependence[46].

The risk of physical and psychological harm is higher when several new psychoactive substances are consumed together or with alcohol[47]. The use of such substances may, in fact, lead to higher consumption of alcohol or of illicit drugs[48], which increases the risk of harm[49].

Lack of information about the correct administration of these substances and misleading labelling can further increase the risks to health and safety. This is because even substances that would cause limited harm under certain conditions of use can be risky if used in combination with other substances, illicit drugs, certain medicines or alcohol.

Research in several Member States has shown that new psychoactive substances are **often sold without information** regarding their chemical composition, pharmacology or toxicology, without safety assessments (side-effects, contra-indications, interaction with other substances) and without instructions as to how they should be administered[50]. Certain Irish[51] and UK[52] studies have revealed that information that is crucial for consumers is often not presented on labels and that most packages containing these substances either do not list ingredients or incorrectly claim to contain various natural extracts.

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43 EMCDDA, *Understanding the Spice phenomenon*, 2009.

44 For instance, BE, UK, FI, HU, SE, NL, NO reported fatalities in relation to pregabalin, MDPV, para-methoxyamphetamine, para-methoxymethylamphetamine, desoxypipradrol, 4-methylamphetamine, 5-(2-aminopropyl) indole.

45 ACMD, *Consideration of the Novel Psychoactive Substances ('Legal Highs')*, 2011.

46 According to a UK-based online survey, among 1,506 respondents who declared that they had taken mephedrone, 14% felt unable to stop taking it until they had used all supplies; 11% reported very strong need for it after having run out of supply; 14% described it as very addictive. R.L. Carhart-Harris, L.A. King, D.J. Nutt, "A Web-based Survey on Mephedrone", in *Drug and Alcohol Dependence*, 2011.

47 D.M. Wood, M. Nicolauo, P.I. Dargan, "Epidemiology of recreational drug toxicity in a nightclub environment", in: *Substance Use and Misuse*, vol. 44, n. 11, p. 1495–1502.

48 EMCDDA–Europol, *Joint Report on a new psychoactive substance: 4-methylmethcathinone (mephedrone)*, 2010.

49 On the other hand, some new psychoactive substances may reduce the use of more harmful substances (some illicit drugs). Experts suggest that the peak in the use of mephedrone in the UK coincided with a drop in cocaine overdose deaths.

50 Advisory Council on the Misuse of Drugs (ACMD), *Consideration of the Novel Psychoactive Substances ('Legal Highs')*, 2011.

51 NACD, *An Overview of New Psychoactive Substances and the Outlets Supplying Them*.

52 M. Schmidt, A. Sharma, F. Schifano, C. Feinmann, ""Legal highs" on the net-Evaluation of UK-based Websites, products and product information".

Studies have also shown that certain new psychoactive substances that were sold as alternatives to substances subjected to restriction measures (e.g. to mephedrone) actually contained the substances that they claimed they replaced[53], posing serious risks to users' health. In other cases, new psychoactive substances were sold by dealers as illicit drugs (for instance, 4-methylamphetamine was sold as amphetamine). On the other hand, certain products marketed as new psychoactive substances only contained caffeine[54], but sometimes in toxic doses.

Substances are sometimes **intentionally mislabelled** in order to circumvent rules on the marketing of specific products. For example, mephedrone was variously advertised and labelled as "research chemical", "bath salts" or "plant food" often with a note saying "not for human consumption" to evade product safety and food safety legislation. However, the intended use was clearly human consumption.

(b) Social harms

The recreational use of new psychoactive substances can pose **risks to society.** Because they may affect mental health and social functioning, the frequent use of such substances, like that of any psychoactive substance, can have a negative impact on society, adversely affecting personal development, family life, communities and the social fabric in general.

The use of new psychoactive substances can impair the ability to drive a car, with serious **consequences for road safety**. The degree of impairment depends on the type of substance, on its effects and on whether it is used together with alcohol or other psychoactive substances. Current road safety testing equipment still lacks accuracy and reliability for the most prevalent illicit drugs, and may not even detect these new psychoactive substances. And testing equipment cannot keep pace with the increase in the number and variety of such substances on the market.

The use of new psychoactive substances can place a significant burden on public authorities, especially in the health policy and law enforcement areas. **Emergency services** must cope with an increasing number of cases of people intoxicated following their use. For instance, a new Club Drug Clinic has been set up at the Chelsea and Westminster Hospital in London to deal with special cases related to the misuse of recreational drugs[55]. In its first year, the clinic reported that most patients use new psychoactive substances alongside illicit drugs.

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53 S.D. Brandt, H.R. Sumnall, F. Measham, J. Cole, "Analyses of second-generation 'legal highs' in the UK: initial findings", in: *Drug testing and analysis*, Vol. 2(8), p. 377-382.

54 ACMD, *Consideration of the Novel Psychoactive Substances ('Legal Highs')*, 2011, p.14.

55 http://www.euronews.com/2012/07/09/club-drug-clinic-a-first-in-london.

Media reports suggest that use of some new psychoactive substances may lead to **violent behaviour and crime**. The risk assessment of mephedrone[56] reported geographically restricted (Guernsey) episodes of crime among users who injected the drug, including burglary and theft. In addition, since certain products marketed and sold as new psychoactive substances actually contain illicit drugs, consumers commit an offence when they possess and use them, without necessarily being aware of it (the use or possession for personal use of illicit drugs is a criminal offence in several Member States[57]). Therefore, new psychoactive substances also put a **burden on the criminal justice system**.

Violence may increase proportionally to the **involvement of organised crime** in the market for recreational use of new psychoactive substances. Available information shows that there is a limited involvement of organised crime, which is sometimes active in the distribution and sale of new psychoactive substances on the black market, in combination with illicit drugs[58].

Stakeholders from ten Member States[59] reported that criminal groups are involved in the market to some extent, e.g. in repackaging or tableting, while five Member States consider the involvement of organised crime to be minimal or non-existent[60]. This information is confirmed by the joint report[61] and the risk assessment report on mephedrone, which pointed to a limited involvement of organised crime groups, mostly in tableting. The risk assessment on BZP[62] provided no clear indication of the involvement of organised crime.

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56 EMCDDA, *Report on the risk assessment of mephedrone in the framework of the Council Decision on new psychoactive substances*, 2011.

57 *Simplified overview:* It is up to each Member State to decide whether the possession and use of illicit drugs amounts to a criminal or an administrative offence. Important variations apply across Member States. Drug use is not an offence in: BE, CZ, DK, DE, IT, HU, NL, SI, SK; drug use is an administrative offence in: BG, EE (misdemeanour), LT, LV, LU (cannabis), PT, RO (referral); drug use is a criminal offence in: IE (heroin), EL, FR (possession), CY, MT (heroin), FI, SE, UK (smoking of opium only).

58 ACMD, *Consideration of the Novel Psychoactive Substances ('Legal Highs')*: forensic analysis of seized samples of new psychoactive substances in the UK indicated that 19% contained a controlled substance such as mephedrone and piperazines.

59 AT, BE, CZ, EE, HU, LV, RO, SK, SI, UK.

60 EE and SI reported very small organised crime involvement, CY, FI and LU reported no involvement.

61 EMCDDA–Europol, *Joint Report on a new psychoactive substance: 4-methylmethcathinone (mephedrone)*, 2010.

62 EMCDDA, *Report on the risk assessment of BZP in the framework of the Council Decision on new psychoactive substances*, 2009.

The cultivation, manufacture or extraction of new psychoactive substances can cause **environmental harms**. For instance, the manufacture of synthetic substances in residential areas, where potentially hazardous substances are combined in chemical processes in clandestine laboratories, without proper safeguards, may result in explosions, fire or the release of toxic substances[63]. The dumping of chemical residues and packaging after the manufacture has been completed can cause further harms to the environment.

(c) Costs

The harms caused by the recreational use of new psychoactive substances to individuals and to society can have considerable costs. These include **tangible costs**, mainly in the public health and law enforcement area, and in the economic sector, and **intangible costs**, such as pain, suffering, reduction of quality of life and death.

The tangible economic costs are **borne by the economy** as a whole but also by consumers. They revolve around loss of productivity for paid workdays and incapacity benefits for individuals who are affected in the long-term, including expenses to cover medical care, and lost wages and productivity. Long periods of sickness absences may cause loss of earnings. The harms caused to individuals' health can have negative consequences on their ability to work, resulting in lower incomes.

The **health-related harms** of new psychoactive substances are estimated to cost around €211 million per year and the cost of **criminal law enforcement** is estimated at between €117 million and €144 million per year (for an estimation of other costs, for instance, cost of sanitary inspections, loss of tax revenues, see Annex 5).

3.3. Problem 2: Obstacles to legitimate trade in the EU internal market

The risks posed by the recreational use of new psychoactive substances have led public authorities to introduce various restriction measures on these substances, which **impede legitimate trade.** Such restriction measures make it more difficult for economic operators in the market for legitimate uses to get access to the restricted substances and can, therefore, cause the loss of business. They can make research more cumbersome, since various authorisations may be required before substances can be obtained, and can, therefore, hinder the development of new uses for these substances.

[63] For example, the manufacture of mephedrone involves toxic bromides.

Restriction measures vary depending on the Member State and on the specific substance, leading to **obstacles to trade, fragmentation and an uneven level playing field** for economic operators, and making it difficult for companies to operate across the EU internal market. As the market for new psychoactive substances is likely to grow, so will the obstacles to future legitimate trade in the internal market.

Certain Member States have introduced wide-ranging restriction measures, covering entire chemical groups of new psychoactive substances ('blanket bans'), sometimes without assessing the risks posed by the consumption of these substances or the benefits of their uses for other purposes. Such approaches can severely **impede the development of legitimate uses** of these substances, for instance uses that companies registered through the REACH mechanism, especially since substances subjected to restrictions are unlikely to be 'rescheduled' (restriction measures are not lifted), even if more information becomes available on their risks and benefits.

The potential benefits and risks of new psychoactive substances, for instance as active substances for human or veterinary medicinal products, can only be determined through research. Restriction measures can make it **more difficult for companies to conduct research** on new psychoactive substances, in particular when the measures are backed by criminal law. This is because companies need to prove that the intended use of the substance is legitimate, sometimes following cumbersome authorisation procedures.

The advocacy group "Youth Rise for Reform", has warned that an overall ban on certain categories of new psychoactive substances may **seriously affect research** and availability of such substances for therapeutic purposes. In particular, such bans could hamper the research and use of new psychoactive substances in substitution treatment for illicit drugs, to treat drug addiction[64]. For instance, one substance that has been notified to the EWS is vanorexine, which is being researched by pharmaceutical companies for use in the treatment of cocaine dependence. The advocacy group argues that other substances could be used for drug substitution treatment, but that restriction measures make research difficult.

Table 1.4 provides an overview of the restriction measures applied across the EU on the three substances presented before as case studies - GBL, 1,4 BDO and *m*CPP:

[64] Youth Rise for Reform *New Psychoactive Substances: Need for Policy Reform*, available at: https://dl.dropbox.com/u/16336789/Drug%20policy%20series/new%20psychoactive%20substances%20report.pdf.

Table 2: Restriction regimes in Member States

Substance type	Not-restricted/ controlled	Drug control legislation[65] or drug precursor legislation[66]	Other
GBL	BE, CY, DK, EL, ES, LV, LT, LU, MT, NL, PL, PT, SI	AT, BG, CZ, EE, HU[67], IE, IT, RO, SK, UK[68]	Medicines: DE, FI Restricted sale: FR[69], SE[70]
1,4-BDO	BE, CY, DK, EL, LV, LT, LU, MT, PL, PT, SI	CZ, EE, IE[71],UK[72]	FR[73], SE
*m*CPP	FR, IE, IT, LU, PL, PT, SI, SE, UK	BE, BG, CY, CZ, DK, EE, FI, DE, EL, HU, LV, LT, MT, RO, SK	NL, ES (Medicines Act)

Depending on the type of legislation under which a substance is subjected to restriction measures, only **certain uses** are allowed at national level, and lack of compliance is sanctioned by either administrative or criminal law (see section 3.4.1. for an overview of national legislation applied to new psychoactive substances). Within a specific restriction regime there may be exceptions and differences between countries.

To be able to research, develop and commercialise a substance after the introduction of restrictions, economic operators must undergo through various procedures, which can be very cumbersome. They entail, in certain cases, a system of **licensing** and registration as applied to UN-controlled substances, to avoid that they are diverted for illicit uses (for instance, under the UN Conventions, morphine can be traded only under very strict controls, because it is derived from opium and the illicit drug heroin can be manufactured from it). These procedures are different from a Member State to another and the types of uses of substances that are allowed at national level also differ according to the type of legislation applied.

65 Source: information available to the EMCDDA and European Commission.
66 GBL only.
67 New list added for new psychoactive substances, not prohibiting possession for personal use.
68 MODA 2001 Regulation 4B: it is lawful to import, export, produce, supply, possess (without licence), except in cases where use for human ingestion is apparent or suspected.
69 Restrictions on making GBL available to the public and/ or limiting its concentration and quantities sold to consumers in preparations/ mixtures.
70 Act Prohibiting Certain Commodities which are Dangerous to Health.
71 Lawful to import, export, produce, supply or possess GBL or 1,4 BDO, except for the purpose of human ingestion other than as flavoring in food. MODA (Amendment), Regulations 2010.
72 See footnote 68.
73 See footnote 69.

Except for certain uses, for example the use of a veterinary medicinal product for which EU-wide marketing authorisations are available, **no mutual recognition of licenses** or of nationally authorised uses exists. The result is that operators trading across the borders need to obtain different types of authorisations in different Member States, which creates obstacles to trade in the internal market. This causes **additional costs to economic operators** that can negatively affect the production, distribution and trade in these substances for legitimate uses.

For instance, certain Member States' regulations require industry and trade operators to register and to apply for individual licences for regular trade in new psychoactive substances. According to a representative of the European Chemical Industry Council (CEFIC), such requirements are a **concern for the industry**. This is because they hamper legal trade and the free movement of goods within the EU, effectively weakening the functioning of the internal market, by introducing trade restrictions at Member State level.

In relation to GBL and 1,4-BDO, which are chemicals used for legitimate purposes while also being consumed as new psychoactive substances for recreational purposes, as well as to certain pre-precursors[74], CEFIC points out that these are **widely used industrial chemicals**, serving as critical ingredients in many different products and applications. These substances have an important role in the business activities of certain companies and it would be difficult to find equivalent substances presenting as favourable characteristics in terms of environmental impact and occupational health[75].

Moreover, restriction measures have a **chain-reaction impact** on economic operators, because these substances are often used in the production of other substances which are used for manufacturing various goods. For instance, the majority of the GBL produced in the EU is used by industrial companies as an intermediate in the manufacturing of other chemicals[76].

According to CEFIC, control measures on these substances, including requirements for a pre-export notification and an export authorization, have serious implications for the industrial use of these chemicals and affect the **competitiveness of the EU industry**. Depending on the Member State, it may take up to four weeks for a company to obtain an export authorization. Thus, just-in-time deliveries to third country customers would be impossible, according to the industry. As a consequence, third country customers will either have to increase their stocks in these substances (which may increase the risk of diversion of the substance in those countries, facilitating trafficking and abuse of the substance for recreational purposes) or alternatively will have to turn to a supplier outside the EU, which is able to supply the required quantity immediately.

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74 Substances that are used to manufacture drug precursors.

75 See footnote 35.

76 Ibidem.

The industry therefore points out that such requirements put EU suppliers at a competitive disadvantage and warns about the **risk of loss of export business**[77]. Intra-company shipments in a globally active company are equally affected by such requirements and control measures, the industry adds.

In addition, the current **lack of clarity** about how drug control legislation, at national level, and the Council Decision, at the EU level, connect to the internal market and relate to specific internal market legislation, in so far as dual-use substances are concerned, further impedes legitimate trade and affects the functioning of the internal market.

This is because **gaps** exist between drug legislation, on one hand, and medicines legislation and other relevant legislation (for instance the EU chemicals legislation REACH). The result of such gaps is twofold: the recreational use of certain new psychoactive substances cannot be addressed, because they fall between two regulatory regimes (for instance *m*CPP, which was neither tackled under the Council Decision, because it is an active substance for a medicine, nor under the EU's pharmacovigilance system, which primarily targets the misuse of authorised medicinal products); and, the legitimate use of certain other substances is impeded by restriction measures introduced to address their recreational use (for instance the use of GBL in industry in the Member States that have subjected it to drug control legislation).

In conclusion, the consequences of the various restrictions applied across the EU are obstacles to trade, legal uncertainty, market fragmentation, uneven level playing field for economic operators and, more broadly, **difficulties for companies** operating across the internal market or globally. Finally, the **lack of predictability** of the type of legislation likely to be applied, which can vary depending on the substance and the Member State, and of restrictions that this entails, further increases legal uncertainty for economic operators, which may struggle to adapt their businesses to new requirements or to find alternatives to restricted substances.

Since the number of new psychoactive substances on the market is expected to grow and the variety of restrictions aimed at reducing their availability for recreational use is likely to increase (see section 3.4.1.) the obstacles to legitimate trade that have been identified in this section are expected to be amplified. This is likely to **seriously affect the functioning of the internal market**.

3.4. Main causes of the problems

The **two main causes** of the problems identified are:

(1) Divergent national approaches to new psychoactive substances.

(2) Ineffectiveness of the EU instrument on new psychoactive substances.

[77] Ibidem.

3.4.1. Cause 1: Divergent national approaches

The Member States have **wide discretion** in addressing new psychoactive substances and they use different types of legislation to tackle them. Most Member States have their own identification, risk assessment and restriction measures in place, which vary in terms of the level of scrutiny, duration, the stakeholders involved and outcomes.

Overview of legislation used to address new psychoactive substances at national level

Drug control legislation (criminal law-based) is the most common type of regulation applied in all Member States to address new psychoactive substances. Based on the UN Conventions on Drugs (see Annex 9), this provides the legal framework under which the use of psychoactive substances that have been scheduled under the UN Conventions is allowed for specifically authorised purposes, and defines the offences and level of sanctions for illicit trafficking in the scheduled substances. In certain Member States, the use or possession for personal use of scheduled substances is also criminalised.

The UN Conventions provide a control regime and specific schedules for psychoactive substances that have been analysed on the basis of their risk potential and liability for abuse, likelihood to cause harm to health and society, set off against their therapeutic usefulness. Some other uses are allowed, e.g. for traditional (coca leaf chewing) or industrial (hemp) purpose, but under strict conditions and requirements, backed by criminal law.

The second most commonly used instrument to restrict the availability of new psychoactive substances at national level is **medicines legislation**[78]. The use of medicines law does not imply that the new psychoactive substance is considered a medicinal product.

This legislation enables measures on new psychoactive substances to be adopted quicker than under drug control legislation, which, because it involves criminal law, has longer procedures. Medicines legislation does not criminalise the use or possession for personal use of new psychoactive substances subjected to restrictions. In certain Member States only new psychoactive substances presented in the form of a capsule can be addressed under medicines legislation, but not those marketed and sold as a white powder without packaging. At least **11 Member States** have used medicines legislation to restrict new psychoactive substances[79].

Certain Member States also use **general consumer protection legislation**[80] - product safety[81] or food safety legislation[82] - and legislation relating to dangerous chemicals[83] to address new psychoactive substances. For instance the Netherlands, the UK and Italy have applied food and product safety legislation to regulate the market for certain, mostly natural, new psychoactive substances.

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78 Directive 2001/83/EC (6.11.2001) Article 1(2): Medicinal product: Any substance or combination of substances presented for treating or preventing disease in human beings. Any substance or combination of substances which may be administered to human beings with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in human beings is likewise considered a medicinal product.

79 BE, BG, CZ, FI, FR, LU, NL, SE, SI, SK, UK.

80 BE, FR, IT, LU, SI, SK, RO, UK.

81 BE, LU, RO, SK, UK.

82 BE, NL, PL, UK.

83 LT, RO, SE, UK.

In the **UK**, since mephedrone was labelled as "plant food" or "bath salts" but the authorities confirmed that it had no such uses, in 2010 the Home Secretary asked local authorities to seize mephedrone under the 2008 Consumer Protection from Unfair Trading Regulations. In addition, the UK has imposed **importation bans** on certain substances.

In **Italy**, in 2010 the Executive Board for Prevention and Health Promotion forbade the sale of the product referred to as "n-Joy" and its analogous product "Spice", for violation of the Consumer Code, because it was sold without Italian-language indications. In Poland and Romania economic operators are required to obtain a market authorisation before commercialising products containing new psychoactive substances, but in practice substances that have psychoactive effects are unlikely to obtain such authorisation.

Twelve EU Member States[84] have modified their legislation or have adopted specific legislation in the past years to respond to the increasing availability of new psychoactive substances. The **new laws follow different approaches** on certain issues such as risk assessment of substances[85], fast-track or temporary emergency procedures (see Annexes 10, 11 and 12), increasing the risk that the responses given to new psychoactive substances will further diverge.

In the majority of Member States the risks posed by the recreational use of each substance are **assessed individually**. Five Member States implement the "generic risk assessment" approach (assessment of a group of chemically related substances), three use the "analogue" approach (assessing the similarity between the effects of a new psychoactive substance and those of an illicit psychoactive substance), while five Member States do not perform any risk assessment at national level and rely on the system set up by the Council Decision.

These different approaches to risk assessment can lead the Member States to take **different decisions** on the same substance or to introduce restriction measures on different substances. For instance, certain Member States have recently introduced restriction measures on a host of new psychoactive substances[86] (Bulgaria has adopted restriction measures on 45 substances, the Czech Republic on 33, Latvia on 27, Romania on 44[87]). These measures are backed by either criminal sanctions (particularly if drug control legislation is applied) or by administrative sanctions (if consumer protection, medicine or food legislation is applied), depending on the substance and on the country.

Member States can introduce national restriction measures on new psychoactive substances even before the risk assessment of substances has been completed at the EU level (for example 16 Member States adopted restriction measures on mephedrone before it was submitted to such measures at the EU level).

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84 AT, BG, CY, FI, IE, LT, LU, PL, RO, SE, UK, DK.

85 EMCDDA, *Early Warning System: National Profiles*, 2012.

86 Such measures are sometimes notified to the Commission under Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations. OJ L 204, 21.7.1998, p. 37-48.

87 Results of the survey of Member States' authorities.

The **substantial differences** between the Member States' laws and administrative provisions on new psychoactive substances have **adverse effects on consumers** using such substances recreationally. This is because uncoordinated decisions by the Member States can lead economic operators in the market for recreational use to relocate from Member States that introduced restriction measures to those with less strict legislation on new psychoactive substances, or with weaker capacities to detect, seize or identify such substances. Consumers in countries with weaker capacities to act on new psychoactive substances are, therefore, exposed to the risks of these substances.

The distributors and retailers of new psychoactive substances for recreational use interviewed in preparation of this impact assessment indicated that they do not intend to break any laws by importing (or exporting) a substance to a Member State where it has been restricted. At the same time, they make use of the opportunity to divert trade to other Member States where there may be demand for the substance and where it has not been restricted. Such **displacement of potentially harmful substances** between countries can diminish the level of consumer protection across the EU and can lead to ambiguity about the risks of substances.

Geographical displacement

Following the Polish authorities' decision to close around 1,300 shops selling new psychoactive substances in Poland in December 2010[88], Polish companies opened more than 30 shops in bordering countries, including in the Czech Republic, which had not witnessed such shops before. A similar dynamic has been observed between Sweden and Norway, with substances submitted to restrictions in Sweden moving to the market in Norway.

The **substantial differences** between the Member States' laws and administrative provisions on new psychoactive substances also have significant **adverse effects on economic operators in the market for legitimate uses**, as section 3.3 has shown. As the case studies on GBL, 1,4-BDO and *m*CPP have shown, and as the information from the chemical industry representatives and some research have demonstrated, different national approaches make it more difficult for companies to operate across the internal market because they cause obstacles to trade, market fragmentation, and an uneven level playing field for economic operators. They also create legal uncertainty, due to the lack of predictability of the type of legislation that may apply in each Member State.

88 Polish National Medicines Institute, *The approach adopted by Poland for detection and evaluation of new psychoactive substances*, presentation at the Horizontal Drugs Group, 4 October 2011. Almost 12,000 samples were confiscated, 8,000 were analysed, some 55 psychoactive compounds were found.

The industry representatives consulted during the preparation of this impact assessment indicated that the national measures on substances that are used for legitimate purposes while also being consumed recreationally can hamper the free circulation of the good for legitimate uses, create administrative burden - because of the necessity to comply with different national procedures - and ultimately affect the competitiveness of the EU industry.

3.4.2. Cause 2: Ineffectiveness of the EU instrument

The Council Decision, which is a former third pillar instrument**,** enables the EU to **address new psychoactive substances that raise concern at EU level** (see page 5 for criteria for substances causing concern at the EU level), without preventing Member States from introducing national measures on substances.

Since 1997, the risks of 13 substances were assessed under the Council Decision and its predecessor, the Joint Action 97/396/JHA. Nine of these substances[89] were submitted to **restriction measures** and criminal sanctions across the EU. The latest substances submitted to such measures at the EU level were BZP in 2008, mephedrone in 2010 and 4-methylamphetamine in 2013[90]; to implement these measures, Member States usually include the substance within the scope of the national legislation on drugs, which have to comply with the provisions of the Framework Decision 2004/757/2004 on drug trafficking[91].

Many of the almost 280 substances that were not addressed at the EU level, because they did not meet the criteria described above, were tackled by the Member States, individually, and were subjected to **various restriction measures**, which may differ according to the substance and to the Member State (see section 3.4.1. for an overview of types of national legislation applied to new psychoactive substances). But certain substances were not addressed at national level either, or only in a few Member States, either because public authorities did not have sufficient information about these substances to adopt measures or because the substances disappeared from the market quickly.

89 4-MTA (1999), PMMA (2002), 2C-I, 2C-T-2, 2C-T-7, TMA-2 (2003), BZP (2008), mephedrone (2010), 4-methylamphetamine (2013); MBDB (1998), GHB and ketamine (2000) were assessed but no measures were introduced; the risk assessment of 5-(2-aminopropyl)indole was finalised in April 2013 and the Commission has proposed to subject this substance to control measures [COM(2013) XXX final].

90 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, OJ L 63, 7.3.2008, p. 45; Council Decision of 2 December 2010 on submitting 4-methylmethcathinone (mephedrone) to control measures, OJ L 322, 8.12.2010, p. 44; Council Decision 2013/129/EU of 7 March 2013 on subjecting 4- methylamphetamine to control measures, OJ L 72, 15.3.2013, p. 11.

91 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, p 8.

The Commission's assessment report[92], which was 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) Slow and reactive instrument

The speed at which new substances emerge on the market and spread across the EU challenges the capacity of the instrument to respond: 17 Member States believe that the **decision-making procedure under the Council Decision is too slow**[93]. The Council took the decisions on BZP and on mephedrone 15 months and 12 months respectively after the launch of the procedure, with a joint report, and during this time these substances caused serious concern across the EU. In addition, from the moment when the Council decides to submit a substance to control and criminal sanctions, Member States have a year to adopt national legislation to that effect.

There are two reasons why the decision-making process under the Council Decision is slow:

(a) The decision whether to introduce restriction measures on a substance can be taken only after the completion of a risk assessment. Risk assessments are essential for making the appropriate decision on a substance. But a risk assessment needs time to be completed because limited information is readily available to the EMCDDA Scientific Committee (see point (2) in this section), and because a thorough review of this evidence is needed to identify the risks that a substance poses. However, public authorities are sometimes under pressure to act quickly, in particular when a substance causes immediate concern, for instance because fatalities were reported in connection to the substance.

To address this, more than half of the Member States use various **fast procedures, urgency procedures or temporary emergency measures**. Nine Member States have fast-track procedures for adopting restriction measures on new psychoactive substances. Some also have the possibility to introduce temporary measures – for example, in Germany a substance can be taken off the market for a period of at most one year.

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92 See footnote 5.

93 Results of the survey of national authorities conducted for the assessment of the Council Decision.

The Council Decision does not provide for this possibility at the EU level. The Commission's assessment report showed that 18 Member States would favour **temporary emergency market restrictions** at the EU level for substances causing concern of an immediate nature, pending their risk assessment. One Member State suggested that substances submitted to risk assessment at the EU level should always be subjected to temporary restrictions across the EU, until the risk assessment is completed.

(b) The decision-making procedure to introduce restriction measures is lengthy. The Council Decision foresees that, after completion of a risk assessment, the Commission can table a legislative proposal for restriction measures backed by criminal sanctions, which the Council shall adopt by qualified majority, following which Member States need to adopt national legislation to submit the substance to such restriction measures.

Because of the length of this process, many Member States, which were under **pressure to act quicker** because of public concerns relating to possible risks of substances, have pre-empted EU-level decisions (see section 3.4.1.).

In addition, certain Member States consider that the Council Decision is **reactive** and unable to anticipate or to slow down developments in the market for new psychoactive substances, because as soon as a substance is submitted to control measures, new ones are often developed to replace it, possibly because the Council Decision does not foresee the possibility to address groups of substances. The consequence of this is that public authorities lag behind market developments.

(2) Insufficient evidence to take decisions

The **lack of knowledge** about the emergence of new psychoactive substances, their effects, risks, modalities and prevalence of use undermines the effectiveness of the Council Decision and the capacity of decision-makers to provide swift and proportionate responses. Unless a substance has been used or studied for various purposes, for instance as a potential active substance for a medicinal product, there is scarce information on its properties, toxicology, pharmacology and long-term effects.

Member States' authorities point out that **major gaps exist in the evidence** base underpinning decisions taken on new psychoactive substances at EU level, ranked as follows[94]:

- Lack of evidence on the effects of these substances on human health (59%).

- Lack of capacity to monitor the emergence of new psychoactive substances (36%).

- Lack of evidence on the involvement of criminal groups (36%).

[94] Results of the survey of national stakeholders.

First, the EU decisions on restriction measures on substances are often taken on the basis of **limited and sometimes insufficient evidence**. The risk assessment reports on BZP and on mephedrone acknowledged that insufficient evidence was available on the harms caused by the substances. The main reasons for this are that Member States do not have sufficient information and that limited research is conducted on new psychoactive substances. At the same time, the Council Decision does not envisage support for research, analysis and testing of new psychoactive substances causing concern at the EU level, which are essential in order to determine the risks of a substance. Furthermore, there is very limited information available on the prevalence of use of a substance, and on the type and frequency of use, which would help ascertain the potential risks to public health and to society.

Restriction measures underpinned by criminal sanctions that are not based on substantial and reliable evidence about the risks of the substance in question can **unduly hurt economic operators.** They can also undermine the credibility of the mechanism and the effectiveness of the measure: if consumers have the impression that the decision to restrict the availability of a substance was not backed by convincing evidence about its harms, they are more likely to continue using it, potentially also buying it from the black market.

Secondly, limited information is available about the overwhelming majority of substances, those which have not been submitted to risk assessment at EU or national level. Since 2005, around 2% of the substances notified by the Member States through the EWS have been assessed by the Scientific Committee of the EMCDDA (five out of around 230[95]). Information is collected on the other notified substances when available, but there is **no possibility to conduct analysis and research** on the chemical properties, risks and prevalence of the different groups of substances or on their interaction following – for example – combined use.

The Council Decision does not require Member States[96] to monitor substances which they notify through the EWS or those that were subjected to a joint report, risk assessment or to restriction measures at the EU level. Furthermore, existing drug surveys do not cover new psychoactive substances that have been recently submitted to restriction measures. On the other hand, the EMCDDA does not currently have the mandate or the capacity to monitor all substances notified by the Member States.

In addition, very few Member States (the UK, Ireland, Luxembourg) **proactively monitor** the market for new psychoactive substances, for instance via controlled test purchases, in order to spot emerging trends early, before harmful substances are disseminated across borders.

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95 A joint report was drafted on *m*CPP, but the EMCDDA and Europol concluded that because the substance was used in the manufacture of medicinal products, no risk assessment should be carried out.

96 The Member States are responsible for the collection of data, which is then provided to the EMCDDA for collation and analysis through the REITOX National Focal Points.

The fact that there is **no systematic monitoring of substances** with a heightened risk profile notified through the EWS (e.g. to obtain information about their availability, use and effects), weakens the capacity to analyse, at EU or national level, this rapidly evolving market, to anticipate developments, the emergence of new substances, to react quickly and provide the appropriate response. Basing decisions to restrict or not substances on weak evidence about their risks is a major shortcoming, in particular since the Council Decision does not foresee the possibility to review the status of a substance submitted to restriction measures, when more information becomes available.

Member States consulted by the Commission for the preparation of the assessment report[97] pointed out that **additional resources** should be made available in order to produce information at EU level on new psychoactive substances, notably toxicology, forensic and pharmacological information. Most Member States indicate that substances that are not submitted to risk assessment following a joint report should be actively monitored.

(3) Lack of options for restriction measures

Under the Council Decision, once the risk assessment of a substance is completed, **only two options are available for decision-makers**: the Commission either presents a proposal to have the substance subjected to restriction measures backed by criminal sanctions across the EU[98], or it presents a report to the Council justifying why it deems it not necessary to do so[99]. If the Council adopts the Commission's proposal to subject the substance to control, Member States will have to include it under the scope of application of their national legislation on illicit drugs, implementing the UN Conventions, broadening the scope of this legislation; since this national legislation on illicit drug trafficking has to comply with the Framework Decision 2004/757/JHA on drug trafficking, the rules on the definition of offences and levels of sanctions defined in that EU instrument will consequently apply to the new psychoactive substance.

However, new psychoactive substances have a varying potential to pose risks and the decisions on them should be proportionate to those risks. **A more graduated choice of measures would therefore be appropriate**, in order to ensure that restriction measures underpinned by criminal sanctions are applied as **an instrument of last resort** to punish and deter behaviours that involve substances posing severe health, social and safety risks.

Decision-makers may be more likely to introduce restriction measures backed by criminal sanctions, when the only alternative would be to take no action on the substance at all, even if they have inconclusive evidence about its risks. This is because they would apply the precautionary principle.

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97 See footnote 5.

98 The Council Decision envisages the introduction of the restriction measures on substances foreseen by the UN Convention on Drugs, which only allow certain licit uses under very strict conditions.

99 If the Commission deems it not necessary to present an initiative on submitting the new psychoactive substance to control measures, one or more Member States may present such an initiative.

Restriction measures backed by criminal sanctions can be effective in reducing both the availability of substances that pose severe risks to individuals and to society, and the demand for such substances, because of their deterrent effect. They can be effective in particular if they are introduced in the early stages of a substance's 'use curve', when it emerges on the market[100], especially if they are accompanied by prevention measures. Criminal sanctions are more likely than administrative sanctions to be effective in the case of substances available on the black market. Therefore, a targeted use of criminal sanctions can be effective.

At the same time, criminal sanctions may sometimes have adverse consequences. One such consequence is that the trade in a substance **can move from the licit to the illicit market,** boosting the involvement of organised crime in this market and its revenues[101]. This is likely to happen in particular when users of the substance submitted to restriction measures are not convinced that the substance is harmful, because the measures were not based on a robust assessment of its risks. In this case, they are more likely to continue buying the substance, on the illicit market.

Effects of the introduction of restriction measures

1) Mephedrone in the UK

An annual online survey[102] among heavy users ("clubbers") showed that the submission of mephedrone to criminal law in the UK was **successful in reducing the availability of the substance in the market**, as last-month prevalence of use among "clubbers" decreased from 33.6% in 2010 to 25% in 2011. However, the supply of the substance shifted towards the black market: sale via drug dealers more than doubled (58%); price increased from €14.6 in 2010 to €24 in 2012, while perceived quality decreased (in 2010, quality was perceived to be excellent by 60% and good by 30%; in 2011 these percentages were respectively 7% and 32%, with 80% of users thinking that mephedrone had been mixed with other drugs; in 2012, 46% of respondents thought that quality worsened).

2) BZP in New Zealand

BZP was widely available and used in New Zealand before being subjected to drug control measures in 2008. Its availability dropped considerably following the introduction of these measures, but the substance is now reported to be available, again, on the black market. A study among frequent users showed that those who considered the availability of BZP to be '*very easy*' decreased from 98% in 2007 to 15% in 2008, and then increased again to 44% in 2009[103].

101 J. Birdwell, J. Chapman and N. Singleton, *Taking drug seriously – A Demos and UK Drug Policy Commission report on legal highs*, 2011.

101 J. Birdwell, J. Chapman and N. Singleton, *Taking drug seriously – A Demos and UK Drug Policy Commission report on legal highs*, 2011.

102 MixMag Magazine, Global Drug Survey, available at: http://www.mixmag.net/drugssurvey.

103 C. Wilkins and P. Sweetsur, 'The Impact of the prohibition of benzylpiperazine (BZP) "legal highs" on the availability, price and potency in New Zealand', presentation at the 6th Annual Conference of the International Society for the Study of Drug Policy, 30-31 May, Canterbury, UK.

The lack of options to restrict the availability of substances, besides restriction measures backed by criminal sanctions (or doing nothing) has as a result that the decisions taken at the EU level are not always proportionate to the risks posed by substances, and may therefore not be effective. In addition, the lack of proportionate and more graduated responses to the risks posed by substances makes it **difficult to address substances that have wide legitimate use** but that are harmful when used for recreational purposes. For instance, no action has been taken on GBL (see section 3.3.) under the Council Decision because this instrument does not enable a targeted restriction that does not **impede the substance's industrial uses**.

Member States consulted by the Commission for the preparation of the assessment of the Council Decision[104] pointed out that restrictions underpinned by criminal law should continue to be part of the answer to new psychoactive substances, but most of them argued that such measures are not always the most effective answer and therefore they should not be the only option. **A majority of Member States** indicated that the current lack of alternatives to criminal control measures, under the Council Decision, is inadequate and that a wider range of options (in particular market restriction measures underpinned by administrative sanctions) should be considered. Fourteen Member States would favour permanent market restrictions backed by administrative sanctions for substances found to pose moderate risks.

In addition, a large number of civil society and citizen stakeholders that took part to the public consultation, as well as respondents to the Eurobarometer survey (see section 2.2.1.), stressed that it is important to diversify away from a criminal justice focus on new psychoactive substances and to make a broader use of **consumer protection** approaches.

3.5. Who is affected by the problems and how?

Consumers are affected by the presence on the market of harmful new psychoactive substances. They can incur serious risks to their health, because of the harms caused by the recreational use of certain new psychoactive substances. These risks are heightened by the fact that these substances are often sold without sufficient or correct information about administration, dosage, intended effects, potential adverse side effects and interaction with other licit or illicit substances, including alcohol. Moreover, since some of the products presented as being new psychoactive substances – in particular those bought from street dealers – can also contain illicit drugs, users may face additional health and social risks, and may unintentionally break the law when possessing or using such substances.

Society at large is also affected, considering the fact that the frequent consumption of new psychoactive substances can affect social and family life, communities and the social fabric in the society. As with other licit and illicit psychoactive substances, their use can affect road safety and can play a role in violent behaviour and crime.

[104] See footnote 5.

Economic operators in the market for legitimate uses of new psychoactive substances are affected by the problem, because different restriction measures and requirements imposed by national authorities on specific substances lead to legal uncertainty, impede legitimate trade and may, therefore, disrupt business activities.

Public health institutions, and in particular emergency services, are affected because of the potential adverse health consequences that the consumption of certain new psychoactive substances may provoke, particularly considering the lack of information on their effects and lack of knowledge about effective treatments. Such services may not be equipped to deal with increasing numbers of users suffering from adverse health effects and are often unable to provide appropriate treatments.

Law enforcement authorities and the criminal justice system are also affected. The increasing availability of new psychoactive substances, and the submission to restriction measures backed by criminal law of large numbers of such substances, may be accompanied by some increase in organised criminal activity and may generate public nuisance. In addition, the difference in the legal status of substances that are a problem at the EU level can **jeopardise cross-border cooperation** (for instance, when a substance is submitted to restriction measures in the requesting state, but not in the requested one).

3.6. How would the problems evolve in the baseline scenario?

Assuming that the current framework will remain unchanged, the problems identified are **likely to get worse**.

The market for recreational use of new psychoactive substances is likely to grow. Although many factors determine the availability of new psychoactive substances (e.g. consumers' preferences and perceptions, price and channels of distribution), the rapid spread of substances in the EU internal market recorded in the past years is expected to continue for the mid-term future. Considering that the number of new psychoactive substances notified by the Member States tripled from 2009 to 2012 and that thousands of substances can potentially be manufactured at relatively low cost, the market will **possibly double by 2020**. The health and social costs associated with a growing availability and use of harmful new psychoactive substances would increase proportionally.

The market for legitimate uses of new psychoactive substances is also expected to grow, proportionally to the availability of such substances. Without a more effective EU instrument, replacing the **Council Decision,** that would enable faster and more proportionate responses to address an increasing number of new psychoactive substances, the problem will become worse. If no action is taken at the EU level, the adverse effects of individual national responses on legitimate trade and on consumer protection will continue and possibly intensify.

Member States will continue to follow their own approaches and certain may revise their national legislation on new psychoactive substances in the coming years to address this challenge. This will result in **growing discrepancies between national regulatory frameworks**, which may cause further displacement of harmful new psychoactive substances between the Member States, and may further hinder legitimate trade.

Furthermore, in the absence of proportionate measures to address new psychoactive substances at the EU level, a growing number of substances would be subject to criminal law measures, which are not always the most effective way to restrict the availability of substances and could have adverse effects. An additional undesirable side-effect would be the incrimination of many young people in respect of relatively minor offences, for possessing such substances. This would also place a larger burden on the criminal justice system, to investigate, prosecute and trial large numbers of such offences.

Finally, since the **involvement of organised crime** in the market for recreational use of new psychoactive substances may increase proportionally to the number of substances subjected to criminal law provisions, a further increase in the revenues of criminal networks and in violence associated with rivalling crime groups is expected, causing additional harms to society.

3.7. Right to act and subsidiarity

3.7.1. Legal basis

The EU's competence to act in the area of new psychoactive substances stems from four different provisions of the Treaty on the Functioning of the European Union (TFEU).

Article 114(1) TFEU 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 Member States which have as their object the establishment and functioning of the **internal market**. Article 114(3) TFEU, stipulates that the Commission should aim at ensuring a **high level of health, safety and consumer protection** in its proposals envisaged in paragraph 1 of Article 114 TFEU.

EU action on new psychoactive substances falls within the scope of action to improve the functioning of the internal market, because:

- It addresses obstacles to trade in the market for legitimate uses of new psychoactive substances, while enabling certain measures to be introduced to restrict the availability on the consumer market of those substances posing risks.

- It provides for a scientific assessment of the risks of substances, which is crucial for enabling a proportionate response, depending on the harms caused by each substance, thus mitigating the impact of restriction measures on legitimate trade.

- It addresses the lack of legal certainty for economic operators in this market, by reducing divergences between national approaches and harmonising the response given to substances causing concern at the EU level.

- It connects the market for legitimate uses in new psychoactive substances to the wider internal market, by tackling potential gaps between legislation on medicines, drug control, precursors, chemicals.

The EU also has the obligation to ensure a **high level of human health protection** in the definition and implementation of all EU policies (Article 168(1) TFEU) and to **protect the health, safety and economic interests of consumers** (Article 169(1) TFEU).

The aim of the envisaged proposals is to make use of the tools provided by the Lisbon Treaty to act rapidly to ensure that the legitimate trade in new psychoactive substances is not hindered and that the functioning of this market is improved while the health and safety of individuals are protected from potentially harmful new psychoactive substances, which cause concern at the EU level.

For this purpose, the EU should ensure that **effective and proportionate measures** are in place to reduce the availability and stop the dissemination of potentially harmful substances across the EU, and to submit those proven to cause harm to restriction measures, while avoiding that legitimate trade in such substances is impeded.

To tackle those new psychoactive substances that pose particularly high health, social and safety risks, the EU is empowered to bring such substances within the scope of **criminal law** provisions, subjecting them to the minimum rules on the definition of criminal offences and sanctions in the field of illicit drug trafficking. This stems from Article 83(1) TFEU.

3.7.2. Subsidiarity: Why the EU is better placed to take action

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 recreational use, 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 produces **knock-on effects** on other Member States (displacement of harmful substances) and hinders the operation of the internal market as far as legitimate trade in such substances is concerned. Moreover, the proliferation of diverse national regulatory regimes tackling these substances is likely to increase, further hampering legitimate trade. For these reasons, **EU action would ensure higher efficiency**.

(i) Necessity test

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 potentially harmful new psychoactive substances and by the proliferation of divergent national responses.

Therefore, EU-level action is necessary to ensure that harmful psychoactive substances, which cause EU-wide concern, can be identified and withdrawn from the market quickly in all Member States. EU action is also necessary to ensure an even level playing field and to reduce and to prevent the emergence of obstacles to legitimate trade resulting from Member State action.

(ii) EU value added test

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. Furthermore, EU-level decisions on restricting the availability of substances would increase legal certainty and reduce obstacles for economic operators in the market for legitimate uses, while **improving consumer protection across the EU**.

In addition, a robust EU-level mechanism addressing new psychoactive substances is likely to increase Member States' trust in the capacity of the EU to provide effective answers to this problem, thus **reducing the likelihood of unilateral Member State** action on substances causing cross-border concern and its adverse consequences on economic operators and consumers.

Action at the EU level would respect the **proportionality** principle by focusing only on those new psychoactive substances that raise concern at the EU level (see Page 5 for criteria). Member States would continue being responsible for addressing those substances that are a problem at local or national level.

4. OBJECTIVES

4.1. General, specific and operational objectives

General objectives	• 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.
Specific objectives	• 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.
Operational objectives	• To improve the quantity and quality of information and research on new psychoactive substances shared between EU and national authorities. • To increase the speed with which new psychoactive substances are identified, monitored and assessed, and with which decisions on harmful ones are taken. • To restrict the availability on the market for recreational use of new psychoactive substances that pose health, social and safety risks or that raise immediate public health concerns. • To ensure that restriction measures on new psychoactive substances do not hinder legitimate trade. • To ensure that restriction measures on new psychoactive substances are introduced that are proportionate to the risks that substances pose, in full compliance with fundamental rights enshrined in the Charter of Fundamental Rights of the EU (EU Charter).

4.2. Consistency of the objectives with EU and international policies

4.2.1. Consistency with EU policies and fundamental rights

The objectives are **in compliance with the horizontal policies** of the EU set in strategic documents, including the EU Drugs Strategy 2013-2020[105], the Stockholm Programme[106] and the Commission Communication "Towards a stronger European response to drugs"[107].

Any action of the EU must respect and observe the rights, freedoms and principles set out by the **EU Charter**. Member States must also respect them when implementing EU law. Considering the problems and objectives identified, EU action on new psychoactive substances will pursue the implementation of the right to health care (notably of a high level of human health protection, Article 35) and to consumer protection (Article 38), and respect 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), 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.

4.2.2. Consistency with the UN system

Action in the field of new psychoactive substances at the EU level is **fully consistent** with action at the UN level. This is because the Council Decision already includes provisions to prevent overlaps between the EU and the UN systems and to ensure their consistency. It foresees that all information available at the UN level should be used when the joint reports and risk assessments on substances are conducted at the EU level, and that no risk assessment shall be carried out on a substance when it is at an advanced stage of assessment at the UN level or has already been assessed and scheduled under the UN Conventions on Drugs.

105 Council Document 17547/12.
106 OJ C 115, 4.5.2010, p. 1-38.
107 COM(2011) 689 final.

5. POLICY OPTIONS AND THEIR IMPACTS

The Commission services have considered a **range of policy options** that could help achieve the objectives identified. These options were analysed, with the contribution of experts from various disciplines and on the basis of information received from stakeholders.

The policy options assessed have been grouped in four thematic clusters presenting viable policy alternatives, including the "status quo", to address the main problems identified:

(a) Improving knowledge of new psychoactive substances – non-legislative.

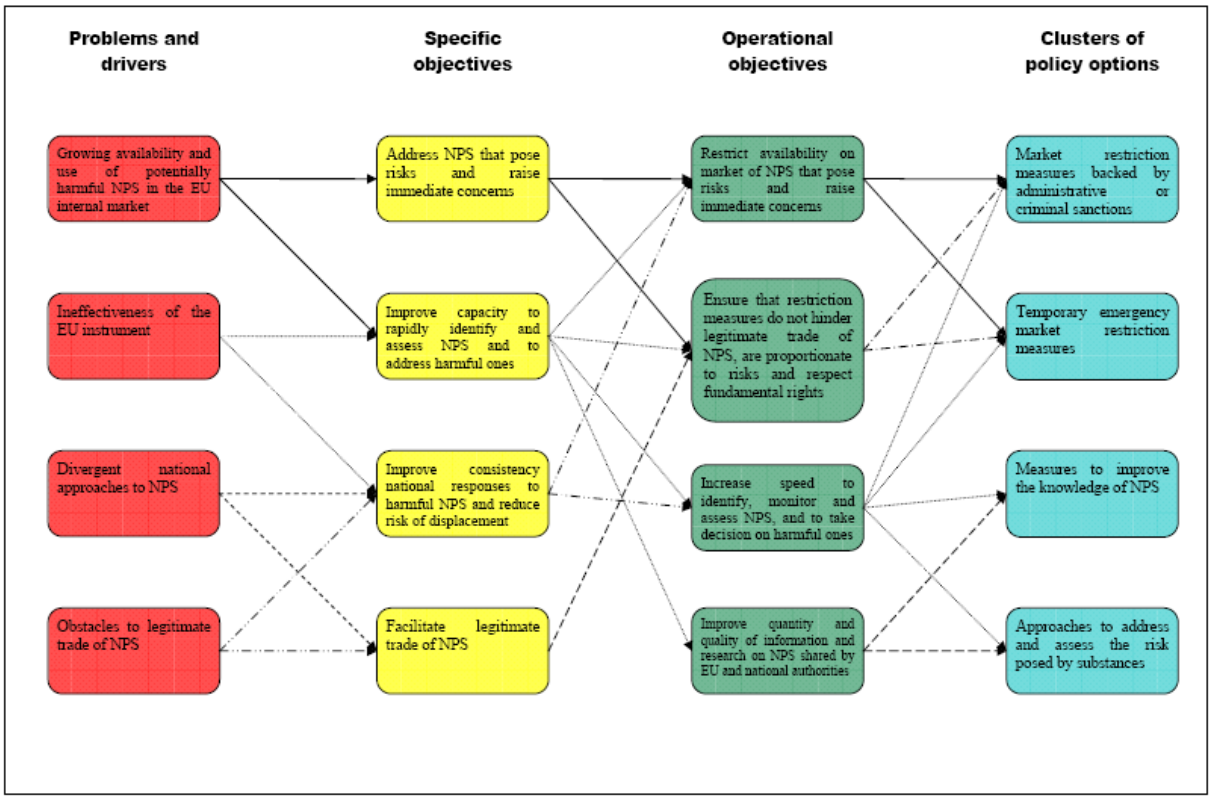
(b) Approach to address new psychoactive substances (individually or in groups) – both legislative and non-legislative.

(c) Temporary emergency measures - legislative.

(d) Decision on a new psychoactive substance - legislative.

Options in each cluster will be assessed and the preferred policy option will be composed of the best scoring option of each cluster.

Figure 5: Intervention logic



There are no strict links of dependency between options presented in each cluster, therefore all combinations of options are feasible. For this reason, it is not suitable to assess the impacts of predefined combinations of options, because this would exclude realistic and possibly more effective combinations.

5.1. Discarded options

On the basis of information available, feedback received from experts and a pre-screening of their feasibility, the following policy options were discarded:

5.1.1. Regulation of head shops and online shops

The option to regulate, at the EU level, the sale of new psychoactive substances for recreational use from head shops and online shops was discarded for reasons of **subsidiarity, stakeholder acceptability and usefulness**.

The market for recreational use of new psychoactive substances and the type of outlets for selling such substances to consumers differ strongly from a Member State to another, making a **"one size fits all" approach difficult**. At least eight Member States have reported to have taken drastic measures to close down head shops on their territory and those that do allow head shops use different approaches to regulating them. For example, in the Netherlands head shops operate on the basis of general conditions set out in the Dutch Food-and-Commodities Act. Under this, head shop owners cooperate closely with local and national authorities, with which they have regular exchanges on risk management, the monitoring of developments and trends in use of psychoactive substances.

Other Member States regulate head shops via general product safety instruments. For instance, in the UK, head shops are regulated on the basis of the General Product Safety Regulations of 2005, which require producers to place only safe products on the market (in line with existing EU laws on product safety), and of the Consumer Protection from Unfair Trading Regulations of 2008, which place an obligation on all businesses to trade fairly. This legislation prohibits making false or deceptive statements, omitting, hiding or providing unclear information which the average consumer needs in order to make an informed decision.

The decision by each Member State to accept or not head shops on its territory and the different ways in which those Member States that accept head shops regulate them are determined by political, cultural and social factors specific to each Member State. Therefore, the option to regulate head shops at the EU level **would not be likely to meet the acceptability** of Member States.

Moreover, the purpose of the measures is to identify, assess and quickly withdraw from the consumer market substances that are harmful, while reducing obstacles to legitimate trade, whatever the channel used for their retail. If a substance is subjected to restriction measures, it will be withdrawn from all retail outlets, including head shops and online shops. For this reason, EU-level rules specifically regulating head shops are **not useful** in achieving the objectives.

As far as the **internet** is concerned, this is a broader issue that goes beyond the online marketing or sale of new psychoactive substances. The issue touches on broader principles in the EU regarding the internet, where the need to ensure health and consumer protection has to be carefully balanced with the necessity to protect freedom rights and to provide proportionate procedures and adequate safeguards.

5.1.2. Market authorisation system for new psychoactive substances

The option to introduce at the EU level an authorisation system for new psychoactive substances was not considered appropriate, for reasons of **proportionality and Member States' acceptability**.

This option would entail a **registration and authorisation mechanism** at EU level, possibly similar to that established for medicines and implemented by the EMA in cooperation with national medicines authorities. This would require economic operators in the market for recreational use to prove that each substance brought on the market is safe, on the basis of a risk and safety assessment. Such a system would have to work on the basis of the principle of 'acceptable risk' for relatively safe products, which would require clear provisions for liability in case of undesirable effects. Substances authorised following such an EU-level procedure would be **labelled and sold under certain conditions**, possibly similar to those used for the sale of alcohol or tobacco (age limit of consumer, warning signs about possible health risks, for instance).

The development of such a mechanism at EU level was considered **disproportionate** in terms of costs and benefits and would be **unlikely to meet Member State acceptability**. Although certain categories of stakeholders would support such an option (several NGO representatives and individuals answering to the public consultation, and 15% of the respondents to the Eurobarometer, were in favour of regulatory rules and marketing conditions for new psychoactive substances similar to those applied to tobacco or alcohol), **Member State are unlikely to accept it**. Only two Member States, Romania and Poland, have systems under which producers must apply for an authorisation before placing a new psychoactive substance on the market. And no Member State applies specific regulatory rules for the marketing and sale of new psychoactive substances, as they do for tobacco or alcohol.

Instead, the vast majority of Member States have regulatory systems based on **withdrawing harmful new psychoactive substances** from the market for recreational use, and not on conditions for placing such substances on the market. While Member States support EU action to withdraw harmful new psychoactive substances from the market across the EU, they are unlikely to accept that the EU plays a role in placing such substances on the consumer market. For the same reason, recommending labelling conditions for new psychoactive substances placed on the market at Member State level was also not considered appropriate.

But general product safety rules, under the EU's General Product Safety Directive[108], apply anyway to new psychoactive substances. Under these rules, producers that place any products on the market must meet certain health and safety requirements.

5.1.3. Blanket ban on new psychoactive substances

The option to introduce a mechanism at the EU level that would permanently restrict the availability of all new psychoactive substances without assessing their risks (blanket ban) was also discarded. This is because restricting all such substances, even before they are launched on the market, without taking into account scientific evidence concerning the risks of each substance, would put a **disproportionate burden on economic operators**, as many substances that do not pose risks would be affected by the restriction measure.

An EU blanket ban on new psychoactive substances would impede legitimate trade. It would also hinder the development of legitimate uses of new psychoactive substances, because it would put undue burden on research on such substances. It would also have serious negative impacts on the freedom to conduct a business, which is enshrined in Article 16 of the EU Charter of Fundamental Rights. Such a restriction to a fundamental right would not be justified because it would be **disproportionate**. In particular, it would not constitute an appropriate measure to achieve the legitimate objective pursued, as it would negatively impact legitimate trade and the development of future legitimate uses of these substances.

Therefore, only gradated, calibrated policy options, where decisions on restrictions measures are taken proportionally to the risks of each substance, have been considered and assessed.

5.1.4. Discontinue EU action

The possibility to discontinue EU action, i.e. to repeal the Council Decision without replacing it with another instrument, was discarded. This is because the **problem is likely to grow** further, requiring even stronger EU-level action, and because the political request from Member States and public support for further action at the EU level indicate that this is not an option to be pursued.

Discontinuing EU action would mean relying on **horizontal instruments**, for instance on consumer protection, product safety, medicines or food legislation, to address, at the EU level, the spread of harmful new psychoactive substances. However, this **would not help achieve the objectives**. While these instruments, for instance the General Product Safety Directive, may occasionally help detect new psychoactive substances if such substances are notified through the Rapex system for dangerous products, they would not enable them to be systematically detected and addressed. In addition, only certain substances may, for instance, match the definition of "food", or could be considered "unauthorised medical products".

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[108] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety, OJ L 11, 15.1.2002, p. 4–17.

Only an instrument that targets new psychoactive substances specifically can ensure that these are systematically identified, monitored, assessed and that their availability on the market for recreational use is restricted through proportionate answers, depending on their actual risks and irrespective of their technical characteristics.

5.2. Assessment criteria

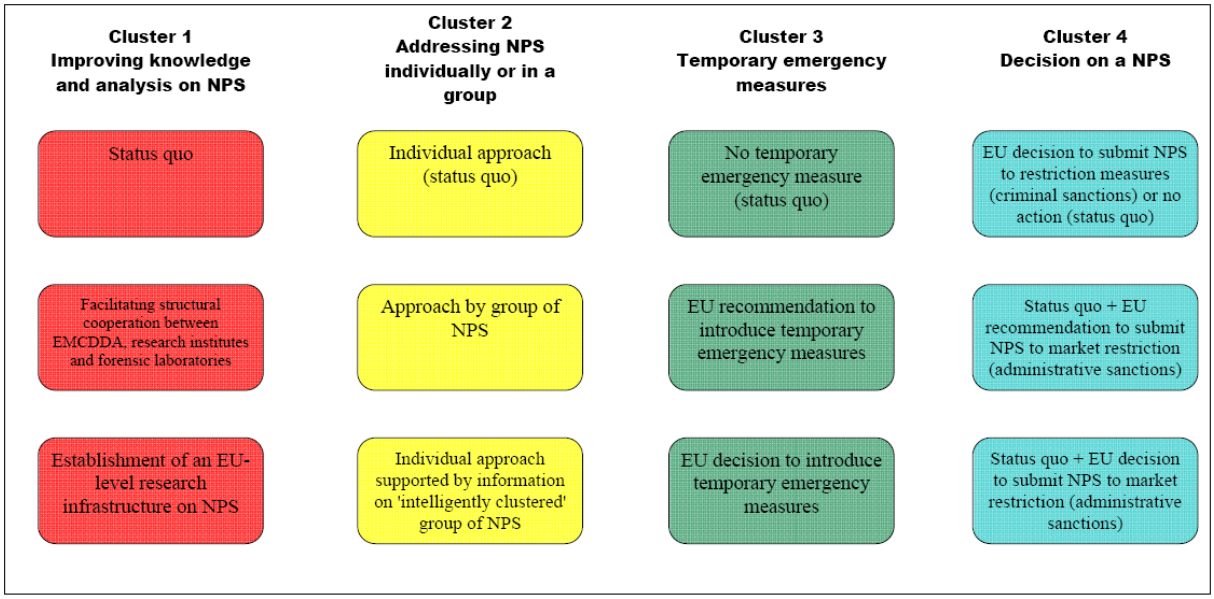
The assessment of the impacts of the policy option is based on a **multi-criteria approach** that includes: the effectiveness in achieving the relevant policy objectives; the economic, financial and social impacts, which also include the impacts on fundamental rights; proportionality and acceptability by stakeholders (Member States, market operators, experts). Environmental impacts are not assessed because they are likely to be marginal. Impacts on third countries are difficult to assess because, although one cannot exclude that the EU action may cause a displacement of harmful new psychoactive substances to third countries, it is not possible to establish a causal link because this would depend on many factors, including the policy implemented by third countries, their drugs market and the demand for the substances restricted at EU level.

The qualitative and quantitative assessment has been conducted on the basis of the data and information available to the Commission and provided by the Member States, EU agencies, experts and stakeholders. The **quantification of the costs is the best possible** considering the limited information available on the market for new psychoactive substances (see Annex 13 for details on methodology).

5.3. Overview of the options

The figure below presents an overview of all policy options that have been assessed in this report.

Figure 6: policy options



5.4. Cluster 1: improving knowledge and analysis on new psychoactive substances

The research and analytical capacities on new psychoactive substances need to be improved to enable their rapid identification and assessment, and the adoption of effective and sustainable measures to restrict, at the EU level, the availability of those posing health, social and safety risks. Improved knowledge and analysis about new psychoactive substances would also enable more effective and better calibrated prevention, treatment and harm reduction services to be designed and delivered, and would allow a better overview of legitimate uses of such substances.

This cluster aims at responding to the **problem** of inefficiency of the EU instrument in providing information on new psychoactive substances and on the risks that they pose. It would help achieve the **objectives** to improve the quality and quantity of information available at EU level and shared by Member States, and to improve the capacity to rapidly identify and assess new psychoactive substances. The options under this cluster are **non-legislative**.

5.4.1. Status quo

Member States share information, to the extent that it is available, on new psychoactive substances that they detect, by submitting to the EMCDDA and Europol, through the EWS, data on the chemical composition of substances, expected or reported effects, seizures. Member States are not obliged to submit this information. The agencies collate and analyse the information obtained from national authorities. When this information indicates that a new substance raises concern at EU level, the agencies may launch a joint report on it, requesting additional information. This joint report could lead to a risk assessment of the substance, which is also conducted on the basis of information available at national level, without conducting **tests** on the substance or specific prevalence studies, for instance.

Expected impacts	
Effectiveness in achieving the policy objectives	**High negative impact** because the available information will remain limited. This will not contribute to ensuring that risks are identified through a robust assessment, to improving the monitoring of the market and rapid identification of new substances, and will not help improve the quality and quantity of information and research that can be shared by authorities. Furthermore, existing resources do not enable conducting a risk assessment of several 'intelligently clustered' substances at the same time (see options cluster 2).
Economic and financial impacts	**No impact on the EU budget** because, although the expected increase in workload for the EMCDDA linked to growing availability of new psychoactive substances would require a 0.5 full-time equivalent (FTE), this should be covered through internal redeployment. No impact on other EU agencies. **No impact on Member States' budgets**.
Social impacts	**Low positive impact on public health and safety**, because it helps share information (although limited) among relevant health and law enforcement authorities throughout the EU about a substance present in the market.
Proportionality and acceptability by stakeholders	**Low acceptability**, because Member States request better support at the EU level, including more extensive and structured collection and dissemination of information on new psychoactive substances across the EU.

5.4.2. Facilitating structural cooperation between the EMCDDA, research institutes and forensic laboratories

Under this option, the EU provides financial support for structural cooperation between the EMCDDA, research institutes across the EU (including the Joint Research Centre – JRC) and networks of forensic laboratories (such as the European Network of Forensic Science Institutes). This cooperation, which includes institutes and laboratories covering various key fields of expertise, would support the EWS by responding to the **information needs identified by the EMCDDA** on specific substances, on trends and developments regarding the problem in general.

Activities supported under this option include: structural and standardised toxicology testing and data collection on emergency room data in Member States, investigative forensic analysis of substances including possibly synthesising reference samples, pre-clinical toxicology research, receptor and self-administration studies, the development of methods to collect epidemiological data (including the standardisation of survey methodologies, protocols and data collection methods), the development of effective prevention or treatment methods, dissemination of information and analysis about new psychoactive substances, the development of common criteria and guidelines for the proactive monitoring of the market (e.g. internet monitoring), which national authorities will be invited to implement voluntarily. As under the status quo, Member States will provide information through the EWS subject to its availability and their capacity, without any legal obligation.

These activities will support various stages, including the information exchange in the EWS, the preparation and drafting of the joint report, the risk assessment report, the monitoring of impacts of measures adopted on substances. This cooperation will be developed in **close cooperation with the EMCDDA**. It should be based on a competitive call, to reach out to the best available expertise across the EU.

Expected impacts	
Effectiveness in achieving the policy objectives	**High positive impact** because it will provide better and more extensive information on new psychoactive substances, their potential risks and trends of use. It will therefore contribute to improving the quality and quantity of information on new psychoactive substances and to providing more robust information on the market, including on legitimate uses, through proactive monitoring. It will increase the speed with which new psychoactive substances are identified and assessed, and will improve the overall efficiency and effectiveness of the mechanism. It will help make appropriate decisions on substances, proportionate to their risks.
Economic and financial impacts	**Medium negative impact on the EU budget**, because of its cost. This is likely to be €700,000 per year in 2014, 2015 and 2016, to establish it, and €400,000 per year for the period 2017-2020 (see Annex 13). The coordination of this structural cooperation network and the increase in workload due to the proliferation of new psychoactive substances would require 1 FTE at the EMCDDA, which should be covered through internal redeployment. No impact on other EU agencies. **No impact is expected on the Member States' budgets**, because it will not impose on them any obligation to collect additional information or to notify a new psychoactive substance that they detected.

Social impacts	**Medium positive impacts on health and safety**, because it will increase the capacity of health and law enforcement authorities to identify swiftly potential risks, therefore enabling a more rapid and more effective response to emerging substances, through adequate treatment, for instance.
Proportionality and acceptability by stakeholders	The measure will be **proportionate** because it will allow policy objectives to be achieved, without imposing additional burden on national authorities. **Medium acceptability**, due to stakeholders' support for developing EU-level research capacities on new psychoactive substances. Furthermore, the additional knowledge and analysis produced will also help Member States address more efficiently new psychoactive substances at national level. However, certain Member States may be reluctant to implement new voluntary EU guidelines on proactive monitoring of this market.

5.4.3. Establishment of an EU-level research infrastructure on new psychoactive substances

This option entails the establishment of a research infrastructure on new psychoactive substances in an existing EU agency (EMCDDA) or research facility (JRC). This structure will have the same tasks as those mentioned under the previous policy option with the difference that these tasks will be performed centrally, and not by linking existing institutes or centres that could perform such tasks. This option also entails setting up a laboratory for testing substances.

Expected impacts	
Effectiveness in achieving the policy objectives	Same as those identified under the previous option. However, this option may not provide the best results possible as expertise for conducting the various additional aspects cannot necessarily be concentrated at central EU level.
Economic and financial impacts	**High negative impact on the EU budget**. Assuming that this facility will be attached to the EMCDDA or JRC to ensure savings, its establishment is likely to cost €5.1 million and its running €1.4 million per year (see Annex 13). **No impact is expected on the Member States' budgets**.
Social impacts	Same as those identified under the previous option.
Proportionality and acceptability by stakeholders	The measure will be **disproportionate** because, while it will enable policy objectives to be achieved, it will entail important costs for the EU budget. **Low acceptability**, mainly due to the high cost for the EU budget.

5.5. Cluster 2: addressing new psychoactive substances individually or in a group

This cluster focuses on options for addressing new psychoactive substances, by assessing their risks (and subsequently adopting measures) either on individual substances or on groups of substances.

This cluster aims at responding to the following **problems and drivers**: inefficiency of the current EU instrument in providing information on new psychoactive substances and in producing a rapid response to new psychoactive substances. It would help achieve the **objective** to improve the capacity of the EU system to identify, assess and withdraw from the market harmful substances and the speed with which this would be done. The options covered by this cluster are both **legislative and non-legislative.**

5.5.1. Individual approach (status quo)

The Council Decision follows the individual approach. This means that the risks of each substance are addressed, at the EU level, taking into account its specific properties, effects and harms. Consequently, an EU decision on introducing restriction measures is made on the basis of the identified risks. Therefore, every time a new substance appears on the market, even if it is a variation of another one already assessed, it will need to be analysed separately and will be the subject of a specific decision on restriction.

Expected impacts	
Effectiveness in achieving the policy objectives	**Medium positive impact** because: on the one hand, it will help provide scientifically robust, precise and reliable information on the level of risks posed by each substance and will therefore help implement effective and proportionate responses; but on the other hand, it will not help improve the efficiency of the mechanism to identify, monitor and assess new substances, because addressing substances individually takes time. Consulted experts consider that the individual approach is the most scientifically robust mechanism for assessing new psychoactive substances. However, it is less effective in pro-actively addressing the emergence and potential risks of similar substances.

Economic and financial impacts	**No impact on the EU budget** because, although the expected increase in workload of the EMCDDA linked to the proliferation of new psychoactive substances would require a 0.5 FTE, this should be covered through internal redeployment (already addressed in cluster 1 option 2). No impact on other agencies. **No impact on the Member States' budgets** is expected. **Positive impact** on economic operators in the market for legitimate uses, because fewer substances, only those posing proven risks, will be submitted to restriction measures, and these measures will only cover the availability of substances for recreational use.
Social impacts	**No change relative to baseline**: existing benefits for public health and safety will continue because it provides robust evidence to inform health and law enforcement authorities about the risks posed by a substance and to justify the appropriate measures. On the one hand, **existing negative impacts on fundamental rights will remain**, notably on the freedom to conduct a business, because economic operators in the market for recreational use will not be permitted to market certain new psychoactive substances. However, such restrictions would be justified by the need to ensure a high level of protection of health and safety in the case of harmful substances. On the other hand, there will be **a positive impact compared to baseline** for economic operators in the market for legitimate uses, because their right to conduct a business will not be affected by the restriction measures.
Proportionality and acceptability by stakeholders	The measure will be **proportionate** because it allows policy objectives to be achieved, while addressing only substances that raise concerns at EU level. **Medium acceptability**, because this approach is currently implemented by the majority of Member States at national level, but at the same time Member States request a system that can better anticipate the emergence of substances.

5.5.2. Approach by group of substances

This option entails the monitoring and assessment of, and decision-making on, a group of similar substances. The group can be defined on the basis of substances' similar chemical structure (**generic approach**) or similar pharmacological effect (**analogue approach**).

Under this approach, the risk associated with a group is determined, in practice, following the assessment of one substance, whose results are then extended by analogy to the whole group (even if other substances from the group were not detected in the EU). A decision on possible restriction measures is taken on the entire group and will automatically apply to variations of restricted substances appearing on the market. That would mean, for instance, that when mephedrone was submitted to control measures, all cathinones that have a chemical structure or pharmacological effects similar to that of mephedrone would have been subjected to these restrictions as well.

However, not all substances belonging to a group present the same level of risk, despite chemical or pharmacological similarities[109].

[109] For instance, synthetic cannabinoids are chemically similar but not all of them are harmful to human health, and some have no psychoactive effect at all (feedback from forensic expert during the seminar on 1 March 2012).

Expected impacts	
Effectiveness in achieving the policy objectives	**Medium positive impact** because, on the one hand, it will help improve the EU capacity to quickly identify, monitor and assess new psychoactive substances; on the other hand, it will not facilitate the identification of the risks of each substance and the implementation of a response proportionate to these risks, since similar substances may pose very different risks[110] (this is also the reason why experts consider that this approach has scientific limitations). Restricting the availability of substances whose risk potential has not been proven could have **negative consequences**: • The availability of certain substances, which are used or have the potential to be used for legitimate purposes, could be unduly restricted, hindering their research and the development of legitimate uses. Business will be lost as a result. • The incrimination of large numbers of people who use or possess for personal use substances that have been submitted to restriction measures backed by criminal sanctions. Member States may face difficulties in effectively implementing restriction measures on many new substances at the same time that are similar in chemistry, as their identification will require sophisticated forensic testing. The measure would be effective for achieving the objective pursued, at the beginning, but its effectiveness would gradually deteriorate because it will become ever more difficult to enforce measures on many substances submitted to restriction measures.

[110] This concerns the "*principle of structure-activity relationship paradox*", which entails that similar molecules may not necessarily have the same biological effect, due to small but interdependent other differences on molecular level that may impact that effect.

Economic and financial impacts	**Low impact on the EU budget** because the EMCDDA will need to process and analyse additional information, on a greater number of substances. Combined with the expected increase in workload for the EMCDDA linked to growing availability of new psychoactive substances, this would require 1 FTE at the EMCDDA, which should be covered through internal redeployment (see cluster 1 option 2). No impact on other agencies. **Low negative impact on the Member States' budgets**, due to the likely increase in the quantity of information on groups of substances that they would share. However, Member States will not be obliged to collect additional data and will only be requested to share data already at their disposal. **Negative impact** on economic operators in the market for legitimate uses, because entire groups of substances, including substances whose risks have not been proven, will be submitted to restriction measures. Although these measures will only cover the availability of substances for recreational use, they will still impose an additional burden in relation to a wide number of substances and possibly hinder the emergence of future markets for substances that may have legitimate uses.
Social impacts	**High positive impact** on health and safety because potentially harmful substances with similar molecular structures could be identified and addressed very quickly, or even prevented from entering the market for recreational use. The likelihood that a substance submitted to restrictive measures would be quickly replaced by a variation would be reduced. **Negative impact on fundamental rights**, notably on the freedom to conduct a business, because economic operators may be prevented from marketing a new psychoactive substance for recreational use, even though its risks have not been proven, but only assumed on the basis of the analogy with risks posed by a similar substance. It will also hinder the emergence of future markets for legitimate uses of substances. This restriction would be only partially justified by the need to ensure a high level of protection of health and safety in the case of harmful substances. Consumers will in many cases not know whether they commit a drug-related offence as they might not know that the product that they buy is, in fact, a substance that was restricted.

Proportionality and acceptability by stakeholders	The measure will be **disproportionate** because it will go further than what is necessary to achieve the policy objectives. **Medium acceptability**, because Member States value the capacity of this approach to address rapidly similar substances at the same time and to anticipate developments, despite the disadvantages identified; however, only eight Member States currently implement a generic or analogue approach (Annex 12). **Economic operators may have concerns** because restriction measures on groups of substances may impede legitimate trade and the development of legitimate uses, as well as restricting the presence on the market for recreational use of a large number of substances whose risks have not been proven.

5.5.3. Individual approach supported by information on an 'intelligently clustered' group of substances

This option entails the monitoring, assessment and decision-making on individual new psychoactive substances, as under section 5.5.1, while also collecting the available information on other substances that are part of their group. This **'intelligent clustering'** of substances means that the Member States would provide to the EMCDDA and Europol, for analysis and dissemination, all information at their disposal on a new psychoactive substance and on a 'clustered group' of substances that have chemical similarity.

In this way, the future emergence of certain substances and their likely risks could be **anticipated**. The risks of a substance would still be assessed, and a decision on restricting its availability would still be made, individually. However, when necessary and appropriate, the Scientific Committee of the EMCDDA could conduct in parallel individual risk assessments of selected substances with a similar chemical structure or effects. A risk assessment report would be drawn up for each substance individually.

Expected impacts	
Effectiveness in achieving the policy objectives	**High positive impact** because it will help provide precise information on the level of risks posed by a substance, identify and implement effective and proportionate responses, improve the efficiency of the mechanism and the speed with which substances are identified, monitored and assessed, notably by helping to anticipate the emergence and potential risks of similar substances.
Economic and financial impacts	**No impact on the EU budget** because, although the expected increase in workload of the EMCDDA linked to the proliferation of new psychoactive substances would require a 0.5 FTE, this should be covered through internal redeployment (already addressed in cluster 1 option 2). No impact on other agencies. **Low negative impact** on the Member States' budgets, due to the likely increase in the quantity of information on groups of substances that they will share. However, Member States will not be obliged to collect additional data and will only be requested to share data already at their disposal. **Positive impact** on economic operators in the market for legitimate uses, because fewer substances, only those posing proven risks, will be submitted to restriction measures, and these measures will only cover the availability of substances for recreational use.
Social impacts	**Positive change** relative to baseline. Existing benefits for public health and safety will continue because it provides robust evidence to inform health and law enforcement authorities about the risks posed by a substance and to justify eventual restriction measures, while also providing some information on other potentially harmful substances that can emerge. On the one hand, **existing negative impacts on fundamental rights will remain**, notably on the freedom to conduct a business, because economic operators will not be permitted to distribute certain psychoactive substances for recreational use. However, such restrictions would be justified by the need to ensure a high level of protection of health and safety in the case of harmful substances. On the other hand, there will be **a positive impact compared to baseline** for economic operators in the market for legitimate purposes, because their right to conduct a business will not be affected by the restriction measures.

Proportionality and acceptability by stakeholders	The measure is **proportionate** because it allows policy objectives to be achieved, while only addressing substances that raise concerns at EU level. **High acceptability**, because it combines the positive elements of the individual approach, which is implemented by the majority of Member States at national level, with certain advantages of the approach by group of substances (implemented by eight Member States).

5.6. Cluster 3: temporary emergency measures

Temporary emergency measures would restrict the availability on the consumer market of those new psychoactive substances that, on the basis of the findings of the joint report and all other available evidence, are suspected to pose **immediate risks** to public health. This means that the harm to health that can be caused by the consumption of this substance and the potential scale of this harm requires rapid intervention by the public authorities, because it involves death and life-threatening injury in several Member States.

The decision to introduce temporary emergency measures would be made on the basis of the following **evidence**: 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; 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.

The temporary emergency measures would be in place pending the finalisation of the risk assessment of the substance. Following the risk assessment, and on the basis of all available evidence, the temporary measure would either be made permanent or would be discontinued (see cluster 4 below). The **restriction measures would only apply to the marketing and selling of the substance to consumers**, while commercial use will fall outside the scope of the restriction. Products on the consumer market that contain the restricted substance will be allowed only if they have been authorised on the basis of other existing legislation.

This cluster of options aims at responding to the following **problems and drivers**: increasing availability and use of potential harmful new psychoactive substances in the EU internal market; ineffectiveness of the EU instrument on new psychoactive substances to address harmful substances when they pose immediate risks to public health; differences in national approaches, which can cause displacement of substances and raise obstacles to legitimate trade.

It would help achieve the following **objectives**: to reduce the availability of harmful new psychoactive substances and thereby negative consequences on public health; to improve the capacity to rapidly withdraw from the consumer market substances that raise concerns; to improve consistency between national responses; to reduce the risk of displacement from one country to another, and; to reduce obstacles to legitimate trade. The options in this cluster are **legislative.**

5.6.1. No temporary emergency measures (status quo)

The status quo does not foresee the possibility to introduce temporary emergency measures across the EU to restrict the availability on the market of a new psychoactive substance causing immediate concern. A decision on whether to restrict or not the availability of a substance is taken only after the risk assessment is completed and this decision is permanent.

Expected impacts	
Effectiveness in achieving the policy objectives	**High negative impact** because it does not contribute to reducing the availability of substances that raise immediate concern and to improving the consistency of national responses to such substances. It can therefore lead to displacement of harmful substances between Member States due to differing national responses.
Economic and financial impacts	**No impacts** identified compared to baseline. The uncertainty caused by uncoordinated individual action, as Member States introduce temporary measures of different nature, covering different time-spans and involving various restrictions, will continue to impose uncertainty and costs on economic operators in the market for legitimate uses and to generate an uneven level playing field.
Social impacts	**No change relative to the baseline**. Risks to public health and safety will persist because new psychoactive substances that are suspected of posing immediate risks will continue to remain on the market until a final decision on their status is taken.
Proportionality and acceptability by stakeholders	The option is **not proportionate** because it provides measures that are not consistent with the suspected risks of substances. **Low acceptability**, because experts and Member States ask for faster action to tackle substances that raise immediate concerns.

5.6.2. EU recommendation to introduce temporary emergency measures

If the joint report drawn up by the EMCDDA and Europol, and other available evidence, show that a new psychoactive substance poses immediate risks to public health requiring rapid intervention by public authorities, the Commission would adopt a recommendation to the Member States to introduce temporary emergency measures to immediately withdraw it from the market and prohibit its distribution, sale, display or offering to consumers (industrial and scientific use will therefore not be affected as it would fall outside the scope of the restriction). This would allow the risk assessment of the substance to be conducted without consumers incurring possible risks to their health.

The marketing of substances for **legitimate uses will be allowed** also when the temporary restriction measure is in place: products on the consumer market that contain the restricted substance will be allowed only if they have been authorised on the basis of other existing legislation. The measure would be valid for one year.

The Commission will use the **evidence** referred to in section 5.6 to determine if a substance poses immediate risks to public health, requiring rapid intervention by public authorities through temporary emergency measures.

The Member States that choose to implement the recommendation would take the appropriate measures to ensure that non-compliance is sanctioned according to national law and would inform the Commission of national measures taken to implement the recommendation.

Expected impacts	
Effectiveness in achieving the policy objectives	The actual impact will depend on the level of implementation of the recommendation by the Member States. **The working assumption for the assessment of this option is that 14 Member States implement it**[111]. **Medium positive impact** because it will contribute to reducing the availability of potentially harmful substances; to increasing the consistency of national responses, thereby reducing the risk of displacement; to providing a swift and proportionate answer to the immediate concerns raised by a substance, while ensuring that sufficient time is available to assess its risks without consumers incurring risks to their health and safety. This option will help shorten the reaction time at the EU level to address the emergence of substances posing immediate risks. It will not disrupt legitimate trade because the restriction only applies to its sale to consumers. **The effectiveness is reduced because of the risk of displacement** of harmful substances from Member States that implement the recommendation to those that do not.

[111] This assumption is based on the fact that the 2011 assessment report on the functioning of the Council Decision shows that 14 Member States considered that a wider range of control options should be considered, including temporary controls and market regulation.

Economic and financial impacts	**Low impact on the Member States' budgets** because they already have mechanisms in place to implement the withdrawal from the market of dangerous substances and products, therefore any additional enforcement costs would be marginal. The administrative burden on the Member States will be limited because the only obligation will be to notify to the Commission the measures taken to implement the recommendation. (Annex 13 provides an estimate of the cost of enforcement, which, however, depends on the situation in the Member States). Infringements to temporary measures will be sanctioned through administrative fines at national level, which may partially contribute to cover the small costs of enforcement. It is impossible to quantify this impact because it is not possible to predict the level of non-compliance and the level of the administrative sanctions. **Negative impact on operators selling substances for recreational use** because the marketing of a substance will be forbidden for a limited time. However, **no impacts on economic operators in the market for legitimate uses**, because their activities will not be affected and could even be facilitated by a more consistent approach at EU level (although only temporarily). Since legitimate uses are regulated under other existing legislation, this option will not cause additional administrative costs to these market operators. These impacts are justified by the need to avoid risks to public health, as temporary measures will only be introduced if the joint report provides clear indications of **immediate concerns** requiring public authorities' intervention. If the complete risk assessment of a substance submitted to temporary measures does not confirm the initial indications that it poses immediate risks, the temporary emergency measure could have had unjustified negative impacts on economic operators in the market for recreational use. However, this risk is low because the Commission will only propose to introduce temporary emergency measures when the joint report provides clear indications of such risk.

Social impacts	**Medium positive impacts on public health**, because of the reduced likelihood that harmful substances will be available on the consumer market and consumed. This will also reduce the burden on public health authorities. However, it will be less effective in diminishing the availability of new psychoactive substances that are sold through the illicit market. **Negative (temporary) impacts on fundamental rights**, notably on the freedom to conduct a business and possibly on the right to property (the substance restricted cannot be marketed and could also be confiscated). However these are justified by the need to protect consumers from the possible risks posed by substances raising immediate concerns and are limited in time. Confiscation should only take place in the cases and under the conditions provided for by law (Article 17 of the EU Charter) and anybody subject to administrative sanctions must have a right to an effective remedy before a tribunal. **Positive impact compared to baseline** for economic operators in the market for legitimate uses because their right to conduct a business will not be affected by the restriction measures. This option will lead to a **medium reduction of health-related harms**.
Proportionality and acceptability by stakeholders	**This option scores well on proportionality** because it is commensurate with the indication of risk of a substance raising immediate concern and is limited in time, to reflect the need to produce decisive evidence on the actual harms caused by the substance. Moreover, it only addresses substances that raise concerns at the EU level and is not binding on Member States. **Medium acceptability**, as stakeholders have requested rapid responses to address harmful substances, and a majority of Member States have supported temporary measures during consultations[112]; however, experts question the effectiveness of recommendations to introduce temporary market restrictions. However, economic operators in the market for recreational use may oppose it because they see their business temporarily restricted.

[112] Member States have been consulted twice, during the evaluation of the Council Decision, and during the preparatory study for this impact assessment report.

5.6.3. EU decision to introduce temporary emergency measures

Compared to the previous option, this foresees that the temporary emergency measures will be binding on the Member States. As in the previous option, industrial and scientific use will fall outside the scope of the restriction measure, and the marketing of substances for **legitimate uses will be allowed** if products on the consumer market that contain the restricted substance have been authorised on the basis of other existing legislation.

Infringement of temporary emergency measures would entail administrative sanctions (e.g. fines, seizure, revocation of licence), which should be effective, proportionate and dissuasive, and determined at national level.

To ensure that the temporary emergency measures are in place swiftly, they will be introduced by the Commission through implementing acts, according to Article 291 TFEU, and will have direct effect. The Commission will base its assessment of whether the substance poses immediate risks to public health on the evidence referred to in section 5.6.

Expected impacts	
Effectiveness in achieving the policy objectives	**High positive impact** because it will: reduce the availability of potentially harmful substances and the risk of displacement; increase the consistency of national regulatory systems; provide a swift and proportionate answer to the immediate concerns raised by a substance, and; ensure that sufficient time is available to assess its risks without consumers incurring health, social and safety risks. This option will help shorten the reaction time at the EU level, to respond to the emergence of substances posing immediate risks. Moreover, it will not hinder legitimate trade.
Economic and financial impacts	**Economic impacts** are similar to the ones identified for the previous option, with the following differences: • Implementation costs will be low because Member States already have mechanisms in place to implement market withdrawal measures, but they will be higher in total than in the previous option because all Member States are compelled to implement the temporary measures. • Higher negative impact on operators in the market for recreational use because the restriction will apply in all Member States, but no impacts on operators in the market for legitimate use, because their activities will not be affected and could even be facilitated by a more consistent approach at EU level (although only temporarily). Since legitimate uses are regulated under other existing legislation, this option will not cause additional administrative costs to these market operators.

Social impacts	**Impacts on public health** are similar to the ones identified in the previous option but their effects are intensified by the fact that the EU decision will be implemented in all Member States. Impacts on fundamental rights are the same as the ones identified for the previous option. This option will lead to a **high reduction of harms** because of the reduced likelihood that harmful substances will be available on the consumer market and consumed. This will also reduce the burden on public health authorities. However, it will be less effective in diminishing the availability of new psychoactive substances that are sold through the illicit market.
Proportionality and acceptability by stakeholders	**This option scores well on proportionality** because it is commensurate with the indication of risk of a substance raising immediate concern and is limited in time, to reflect the need to produce decisive evidence on the actual harms caused by the substance. Moreover, it only addresses substances that raise concerns at the EU level. **High acceptability**, as stakeholders have requested rapid responses to harmful substances, and a majority of Member States have supported this measure during consultations. However, economic operators in the market for recreational use, who may see their business temporarily restricted, may oppose it. Economic operators in the market for legitimate uses will not be affected.

5.7. Cluster 4: decision on a new psychoactive substance

This cluster of options covers the type of decision that can be taken on a new psychoactive substance (no action or various restriction measures) after its risks were assessed. The restriction measures covered by this cluster are permanent, as opposed to the measures under the previous cluster, which are temporary. The restriction measures under the options considered in this cluster would affect to different extents the industrial, commercial and scientific uses of the substances and their availability on the internal market.

In order to determine what type of decision should be taken on a substance, the Commission will determine the substance's risk-level, taking into account the risk assessment report on the substance drafted by the EMCDDA's Scientific Committee and all other available evidence.

The Commission will take into consideration the following **criteria** in order to identify the level of risk of a substance:

– the harms 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;

– the social harms to the 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 harms;

– 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

Based on the information on the extent of the commercial and industrial use of the new psychoactive substance (including for scientific research and development purposes), as well as the evidence on harms, prevalence, patterns of use, availability to consumers and potential for diffusion of the substance and number of Member States affected, three levels of risk can be identified:

a) Low health, social and safety risk, which shall mean that, overall:

– the harms to health caused by the consumption of the new psychoactive substance associated with its acute and chronic toxicity, abuse liability and dependence-producing potential, are limited, as they provoke minor injury and disease, and minor physical or mental impairment;

– the social harms to the individuals and to society are limited, in particular regarding its impact on social functioning and public order, criminal activities associated with the new psychoactive substance are low, illicit profits generated by the production, trade and distribution of the new psychoactive substance and associated economic costs are non-existent or negligible;

– the risks to safety are limited, in particular there is a 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.

b) Moderate health, social and safety risk, which shall mean that, overall:

– the harms to health caused by the consumption of the new psychoactive substance associated with its acute and chronic toxicity, abuse liability and dependence-producing potential, are moderate, as they generally provoke non-lethal injury and disease, and moderate physical or mental impairment;

– the social harms to the individuals and to society are 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;

– the risks to safety are moderate, in particular with regards to a 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.

c) Severe health, social and safety risk, which shall mean that, overall:

– the harms to health caused by the consumption of the new psychoactive substance associated with its acute and chronic toxicity, abuse liability and dependence-producing potential, are life threatening, as they provoke death or lethal injury, severe disease, and severe physical or mental impairment;

– the social harms to the individuals and to society are 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 serious;

– the risks to safety are severe, in particular with regards to a 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.

This cluster of options will help respond to the following **problems and drivers**: increasing availability in the internal market of substances that cause harms; obstacles to legitimate trade and displacement of potentially harmful substances, caused by differences in national approaches; ineffectiveness of the EU instrument on new psychoactive substances.

It will help achieve the following **objectives**: to reduce the availability of harmful new psychoactive substances and thereby negative consequences on health and safety; to improve the capacity and speed to address harmful substances and introduce measures that are proportionate to the risks they pose, without hindering legitimate uses; to reduce the risk of displacement of substances. The options in this cluster are **legislative.**

5.7.1. EU decision to submit substances to restriction measures backed by criminal sanctions or no action (status quo)

Under the current instrument, on the basis of the results of the risk assessment from the EMCDDA's Scientific Committee, the Commission can either decide that a substance poses risks, and in this case it tables a legislative proposal to the Council requiring Member States to submit it to criminal law control measures, or it decides that it does not pose risks and it then presents a report justifying why control backed by criminal law is not necessary. It is not possible to identify different levels of risks. Once the legislative proposal is adopted by the Council, the Member States need to transpose the decision to submit the substance to control and criminal sanctions in their national legislation.

Submitting the substance to **criminal law control measures** entails that the Member States subject it to drug control measures and penalties as provided under their legislation by virtue of their obligations under the UN Conventions on Drugs. Since the national drug control legislation has to comply with Framework Decision 2004/757/JHA on drug trafficking, the rules on the definition of offences and levels of sanctions defined in that EU instrument will apply to the new psychoactive substance.

This means that, when conducted without right, 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, cultivation, possession or purchase of drugs with a view to conducting one of these activities will be considered a criminal offence, and the offender subjected to penalties that include deprivation of liberty. The purpose of criminal sanctions is to punish socially dangerous behaviours while deterring individuals from engaging is these same activities.

Under this option, only the exceptions for legitimate uses of the substance foreseen by the UN Conventions on drugs[113] are allowed.

Expected impacts	
Effectiveness in achieving the policy objectives	**Low positive impact** because, on the one hand, this option will: help reduce the availability of harmful substances; improve the consistency of national responses and reduce the risk of displacement of harmful substances; on the other hand, it does not ensure proportionality of response to the risks posed by a new psychoactive substance (no option is available to address substances that pose moderate risks, which would then either be submitted to a too strict regime - criminal law - or no action would be taken on them, leaving substances that pose risks on the market). It will not help ensure that restrictive measures do not hinder legitimate trade, because measures backed by criminal law put greater burden on economic operators. This would be particularly relevant in the case of substances posing low or moderate risk, and which have legitimate uses[114]. Since it does not distinguish between different levels of risks that a substance can pose, this option makes it more likely that substances are submitted to restrictive criminal measures, even if there is no evidence that they pose severe risk, than that no action is taken on them, on the basis of the precautionary principle. Submitting substances to criminal sanctions is effective and this option should, therefore, be used in a targeted way, for reducing the availability and demand of substances that pose severe risks and are available on the

[113] As explained in Annex 9, the scheduling of substances in analogy with the UN Conventions entails that legitimate uses are allowed only under strict conditions, depending on the health risk, potential for dependence and therapeutic usefulness of a substance, primarily for medicinal or research purposes, and – in case of synthetic substances – for industrial uses to the extent that end-products cannot be used to induce a psychoactive effect.

[114] Ibidem.

	black market. However, criminal sanctions are not effective when they are introduced without convincing supporting evidence or when are used for substances that do not pose severe risks. This is because, if users are not convinced that the substances are harmful to them, they would be more likely to continue buying them from the black market.
Economic and financial impacts	**No impact on the EU budget**. **No impact on the Member States' budgets** compared to the baseline because they already have systems in place to enforce criminal law measures on illicit drugs. However, the introduction of criminal law measures can lead to additional criminal justice costs (e.g. arrest, trial, prison) over time. **No impact on market operators compared to baseline**.
Social impacts	**No impacts on consumers' health and safety compared to baseline**. At present, this option restricts the availability of harmful new psychoactive substances, reducing, thereby, the burden for health and law enforcement authorities. **No change relative to baseline on negative impacts on fundamental rights**, notably on the freedom to conduct a business and on the right to property, which are justified on the basis of the need to ensure a high level of protection of health and safety. Continued negative impact on the principles of legality and proportionality of criminal offences and penalties. In cases where sanctions apply, there is a need to ensure that the fundamental rights to an effective remedy and to a fair trial, presumption of innocence and right to defence, and the principles of legality and proportionality of criminal offences and penalties, are respected. Confiscation should only take place in the cases and under the conditions provided for by law.
Proportionality and acceptability by stakeholders	This option raises **proportionality concerns** because it foresees measures based on criminal law that can be too rigorous for substances that pose medium risks. **Low acceptability**, because most Member States require more proportionate responses, matching the risks posed by each substance (underpinned by either administrative or criminal measures). However, certain Member States would prefer to have the option of criminal law only.

5.7.2. Status quo plus EU recommendation to submit substances to market restriction measures backed by administrative sanctions

This option entails that **the EU has three alternatives for action**, proportionally to the level of risk posed by a new psychoactive substance (see definitions of levels of risk in section 5.7):

a) EU decision to submit a substance to restriction measures backed by criminal sanctions, as in the status quo, if it poses **severe** health, social and safety risks. Member States would need to transpose the decision. Pending the transposition and implementation of the criminal law provisions by the Member States, the substance would be withdrawn from the market across the EU (underpinned by administrative law).

b) EU recommendation to submit a substance to restriction measures backed by administrative sanctions, if it poses **moderate** health, social and safety risks. In this case, the Commission would recommend to the Member States to immediately withdraw the substance from the market and prohibit its distribution, sale, display or offering to consumers (industrial and scientific use will therefore not be affected as it would fall outside the scope of the restriction). Member States would be free to decide whether to implement the recommendation and to introduce administrative sanctions for their infringement.

c) *No action*, if the substance poses **low** health, social or safety risks.

In order to determine which of the alternatives for action presented above is suitable for a substance on which a risk assessment report was drafted by the EMCDDA's Scientific Committee, the Commission will assess the substance's risk-level, taking into consideration the risk assessment report and all other available evidence.

The Commission will base its assessment of the level of risk of the substance on the **criteria** presented in section 5.7.

As in the case of the status quo, submitting the substance posing severe risks to criminal law control measures shall mean that the Member States subject the substance to drug control measures and criminal penalties as provided under their legislation by virtue of their obligations under the UN Conventions on Drugs. Since the national drug law legislation has to comply with Framework Decision 2004/757/JHA on drug trafficking, the rules on the definition of offences and levels of sanctions defined in that EU instrument will apply to the new psychoactive substance. Only the legitimate uses foreseen by the UN Conventions on Drugs would be allowed (see section 5.7.1).

For substances posing moderate risk, their marketing for **legitimate uses will be allowed** when a consumer market restriction measure is in place: products that contain the restricted substance can be placed on the consumer market, but only if they have been authorised on the basis of other existing legislation.

To ensure that the restriction measures would be in place swiftly, the decision to submit a substance to market restriction measures for substances posing severe risks would be taken by the Commission through an implementing act, according to Article 291 TFEU.

Expected impacts	
Effectiveness in achieving the policy objectives	The actual impact will depend on the level of implementation of the recommendation (b), in case of moderate risk level. **The working assumption for the assessment of this option is that 14 Member States implement it[115].** **Medium positive impact** on: reducing the availability of harmful substances; guaranteeing a response proportionate to the risks that substances pose; achieving better consistency and coordination across Member States, and; reducing the risk of displacement and obstacles to legitimate trade. The risks of displacement of harmful substances from Member States that implement the recommendation to those that do not, would continue to exist. The possibility to introduce market restriction measures backed by administrative sanctions on substances that pose moderate risk at the EU level, next to introducing criminal sanctions on substances posing severe risks, is likely to improve the effectiveness of both types of restriction measures in reducing availability and use of substances. Moreover, it would reduce the adverse consequences that the introduction of restriction measures backed by criminal sanctions on substances that do not pose severe risks would have (as described in 5.6.1.). The introduction of EU-wide immediately applicable market restriction measures on substances posing severe risks (pending the introduction of the necessary criminal law provisions by the Member States) would enable **swifter action** due to the use of implementing acts. Moreover, it would further increase the effectiveness of the EU action, as it will ensure that the substance is not available on the market during the period of transposition of criminal law provisions. However, this positive effect would be more limited if the substance becomes available on the black market.

115 See footnote 111.

Economic and financial impacts	**No impact on the EU budget**. **Low impact on the Member States' budgets** because they already have mechanisms in place to withdraw from the market dangerous substances and products, and to enforce criminal law measures on illicit drugs. **Small additional costs needed to enforce the recommendation** (b) will be offset by reductions in costs related to criminal justice, as fewer substances are expected to be subjected to restriction measures backed by criminal law. The administrative burden on the Member States[116] would be limited to the notification to the Commission of the measures taken to implement the EU recommendation (b) or the EU decision (a). Infringements to market restriction measures (and possibly to criminal law measures as well) would be sanctioned through fines at national level, which may partially contribute to cover any additional costs of enforcement. It is impossible to quantify this impact because it is not possible to predict the level of non-compliance with the market restriction measures and the level of the administrative sanctions imposed. **Negative impact on economic operators in the market for recreational use**, because they will no longer be able to market a new psychoactive substance submitted to restriction measures. This is justified by the social and health benefits of the restrictions, but cannot be quantified because it depends on various factors, including prevalence and price. **Positive impacts on economic operators in the market for legitimate uses**, because: • their activity for substances posing moderate risks will not be affected by the restriction measure and may even be facilitated by a more consistent approach at EU level; • for substances posing severe risks, specific legitimate uses allowed for illicit drugs will be possible, but will need to be authorised, and additional legitimate uses may be allowed, if specifically authorised under EU law. However, the need to obtain authorisation would cause limited additional administrative costs to market operators.

[116] Annex 13 provides an estimate of the cost of enforcement, which depends on the Member State.

Social impacts	**Medium positive impact on health and safety**, because harmful new psychoactive substances would no longer be available on the market. Negative impacts on **fundamental rights**, notably on the freedom to conduct a business and on the right to property. However, these are justified on the basis of the need to ensure a high level of protection of health and safety. **Positive impact compared to baseline** for economic operators in the market for legitimate uses, because their right to business will not be affected by the restriction measures for substances posing moderate risks, and is comparable to baseline (or potentially better, see impacts above) for substances posing severe risks. Positive impact on the principles of legality and proportionality of criminal offences and penalties. In cases where sanctions apply, there is a need to ensure that the fundamental rights to an effective remedy and to a fair trial, presumption of innocence and right to defence, and the principles of legality and proportionality of criminal offences and penalties, are respected. Confiscation should only take place in the cases and under the conditions provided for by law. This option would lead to a **medium reduction of health-related harms.**
Proportionality and acceptability by stakeholders	This option **scores well on proportionality**, because it allows for the achievement of the objective, without going further than what is necessary for this purpose. It offers a choice of alternative measures tailored to the level of risk of substances raising concerns at the EU level. **Medium acceptability**, because, although the majority of the Member States clamour a larger set of alternative responses, proportionate to the risks of substances, experts question the effectiveness of recommendations to introduce market restriction measures.

5.7.3. Status quo plus EU decision to submit substances to market restriction measures backed by administrative sanctions

As in the previous option, this entails that **the EU has three alternatives for action**, proportionally to the level of risk posed by a new psychoactive substance (see definitions of levels of risk in section 5.7):

a) EU decision to submit a substance to restriction measures backed by criminal sanctions, as in the status quo, if it poses **severe** health, social and safety risks. Member States would need to transpose the decision. Pending the transposition and implementation of the criminal law provisions by the Member States, the Commission will withdraw the substance from the market across the EU (this decision, underpinned by administrative law, will have direct effect, no transposition needed).

b) EU decision to submit a substance to restriction measures backed by administrative sanctions, if it poses **moderate** health, social and safety risk. In this case, the Commission will withdraw the substance from the market and prohibit its distribution, sale, display or offering to consumers only (commercial and scientific use will therefore not be affected as it would fall outside the scope of the restriction); this decision would have direct effect, no national transposition needed.

c) No action, if the substance poses **low** health, social or safety risk.

In order to determine which of the alternatives for action presented above is suitable for a substance on which a risk assessment report was drafted by the EMCDDA's Scientific Committee, the Commission will assess the substance's risk-level, taking into consideration the risk assessment report and all other available evidence. The Commission will base its assessment of the level of risk of the substance on the **criteria** presented in section 5.7.

As under the status quo, submitting the substance posing severe risks to **criminal law** control measures means that the criminal offences and the levels of sanctions defined by the EU Framework Decision 2004/757/JHA would apply and that the legitimate uses foreseen by the UN Conventions on Drugs would be allowed (see section 5.7.1).

Infringement to the EU-level market restriction measures would entail administrative sanctions (e.g. fines, seizure, revocation of licence), which would be determined at national level and should be effective, proportionate and dissuasive. The trade in these substances for **legitimate uses,** such as production of medicines, research or industrial production, will be allowed and products on the consumer market that contain the restricted substances will also be allowed if they have been authorised on the basis of other existing legislation.

To ensure that the appropriate restriction measures would be implemented swiftly, they would be introduced by the Commission through implementing acts, according to Article 291 TFEU.

Expected impacts	
Effectiveness in achieving the policy objectives	**High positive impact** on: reducing the availability of harmful substances; increasing the speed with which decisions on harmful new psychoactive substances are taken; guaranteeing a proportionate response to the risks posed by each substance, achieving better consistency and coordination across Member States, and; reducing the risks of displacement. This option enables **much swifter action** on new psychoactive substances, due to the use of implementing acts for the adoption of EU decisions, which will have direct effect. The positive impacts of introducing market restriction measures backed by administrative sanctions on substances posing moderate risks and on substances posing severe risks (pending the introduction of the necessary criminal law provisions by the Member States) have been analysed in the previous option.

Economic and financial impacts	**Economic impacts** are similar to those identified for the previous option, with the following differences: • Enforcement and implementation costs will be low because Member States already have mechanisms in place to withdraw substances from the market, but will be higher than in the previous option because all Member States have to implement the market restriction measures. • Higher negative impact on economic operators in the market for recreational use, because all Member States will apply restriction measures. However, very low impacts on operators in the market for legitimate uses of substances posing moderate risks, because their activity will not be affected and will be even facilitated by a more consistent approach towards restriction measures at EU level.
Social impacts	**Impacts on health and safety** are similar to the ones identified in the previous option. However, their effects are intensified by the fact that the EU decision on market restriction measures backed by administrative provisions for substances posing moderate risks is binding. **Impacts on fundamental rights** are similar to those identified in the previous option. This option will lead to a **high reduction of health-related harms**.
Proportionality and acceptability by stakeholders	This option **scores well on proportionality**, because it enables objectives to be achieved without going further than what is necessary for this purpose. It offers alternative measures tailored to level of risk of substances raising concerns at the EU level. **High acceptability**, since the majority of Member States consulted expressed a preference for a more extensive set of alternative responses that are proportionate to the risk of substances. However, certain Member States could prefer to have the option of criminal law only.

6. COMPARISON OF OPTIONS AND IDENTIFICATION OF THE PREFERRED OPTION

6.1. Comparison of impacts of the policy options

This chapter presents the comparison of the impacts of the policy options, to identify the best combination. The impacts of each option are rated against the status quo, which is rated 0 for facilitating the comparison. The scale used for the assessment of the options is the following:

Symbol	Meaning
- - -	High negative impact
- -	Medium negative impact
-	Low negative impact
0	No impact
+	Low positive impact
+ +	Medium positive impact
+ + +	High positive impact

The identification of the preferred combination of options will be based on the analysis of the expected impacts, paying particular attention to the effectiveness in achieving the objectives and the economic and social impacts (including impacts on fundamental rights).

Cluster 1: improving knowledge of new psychoactive substances

Options	Effectiveness in achieving the policy objectives	Economic and financial impacts	Social impacts	Proportionality and acceptability by stakeholders
Status quo	0	0	0	0
Facilitating structural cooperation between the EMCDDA, research institutes and forensic laboratories	+ +	-	+ +	+
Establishment of an EU research infrastructure for new psychoactive substances	+ +	- - -	+ +	-

The option to facilitate structural cooperation between the EMCDDA, research institutes and forensic laboratories is the preferred option because of its positive impacts on the achievement of the objectives and the smaller cost to the EU budget compared to an EU research infrastructure.

Cluster 2: addressing new psychoactive substances individually or in a group

Options	Effectiveness in achieving the policy objectives	Economic and financial impacts	Social impacts	Proportionality and acceptability by stakeholders
Individual approach (status quo)	0	0	0	0
Approach by group of substances	0	-	-	0
Individual approach supported by information on an 'intelligently clustered' group of substances	+	0	+	+

The individual approach supported by information on an 'intelligently clustered' group of substances is the preferred option because it combines the positive impacts on the achievement of relevant policy objectives and social impacts, without raising costs for the EU and national budgets.

Cluster 3: temporary emergency measures

Options	Effectiveness in achieving the policy objectives	Economic and financial impacts	Social impacts	Proportionality and acceptability by stakeholders
No temporary emergency measures (status quo)	0	0	0	0
EU recommendation to introduce temporary emergency measures	+ +	- -	+	+ +
EU decision to introduce temporary emergency measures	+ + +	- - -	+ +	+ + +

The possibility for the EU to introduce binding temporary emergency measures stands as preferred option because it allows for a better protection of public health, it ensures high consistency of approaches across the EU and a more rapid response.

Cluster 4: decision on a new psychoactive substance

Options	Effectiveness in achieving the policy objectives	Economic and financial impacts	Social impacts	Proportionality and acceptability by stakeholders
EU decision to submit substances to criminal law control measures or no action (status quo)	0	0	0	0
Status quo plus EU recommendation on market restriction measures	+ +	- -	+ +	+ +
Status quo plus EU decision on market restriction measures	+ + +	- - -	+ + +	+ + +

The possibility for the EU to decide on submitting a substance to either restriction measures backed by administrative sanctions or to restriction measures backed by criminal sanctions, or to take no action, depending on the level of risk of the substance at issue, is the one that scores best. Compared to the status quo, it is more effective in providing a swifter and more proportionate response to the risks posed by new psychoactive substances; compared to the alternative option, it ensures higher consistency of approaches across the EU and consequently reduces the risk of geographical displacement and the likelihood of obstacles to legitimate trade in the EU internal market.

6.2. The preferred policy option

The mechanism for addressing new psychoactive substances will include the following legislative and non-legislative components:

(1) supporting structural cooperation between the EMCDDA, research institutes and forensic laboratories (cluster 1, option 2);

(2) individual approach to addressing substances in an 'intelligently clustered' group, which will include information on the groups to which they belong and the possibility, when appropriate, to conduct individual risk assessments on a group of substances with a similar chemical structure (cluster 2, option 3);

(3) binding temporary emergency measures at the EU level restricting the availability of a new psychoactive substance that raises immediate public health concerns, requiring prompt action by the authorities. The temporary measures would be introduced following the EMCDDA-Europol joint report, and only if the risk cannot be addressed otherwise (cluster 3, option 3);

(4) EU action to restrict the availability of a substance, as appropriate proportionally to its risks: a) EU decision to submit the substance to restriction measures backed by criminal sanctions in case of severe risk (market restriction measures would be in place pending the adoption of implementing measures by the Member States); b) EU decision to submit the substance to consumer market restriction measures backed by administrative sanctions in case of moderate risk; c) no action in case of low risk (cluster 4, option 3).

No alternative combinations of options have been suggested by consulted stakeholders. The overall impacts of the preferred policy option will be the following:

Expected impacts	
Effectiveness in achieving the policy objectives	**High positive impacts**, as it helps achieve the policy objectives, in particular: to improve the capacity to identify, assess and take decisions on harmful new psychoactive substances and on those that raise immediate concerns, and the speed with which such decisions would be made; to reduce the availability of harmful new psychoactive substances and thereby negative consequences on health and safety; to introduce measures that are proportionate to the risks of new psychoactive substances, do not hinder legitimate uses and respect fundamental rights; to improve consistency of national responses on substances, therefore reducing the risk of displacement of harmful substances and improving conditions for legitimate trade. This option enables **much swifter action** on new psychoactive substances, due to the use of implementing acts for introducing EU-wide market restriction measures (in addition, the restriction measures, backed by administrative sanctions, have direct effect), and helps shorten the reaction time to respond to the emergence of substances posing immediate risks through temporary emergency measures. Although it is assumed that there will be an increase in the number of substances addressed at the EU level, it is not possible to quantify this increase because it depends on developments in the market for recreational use of new psychoactive substances and consumer preferences. Compared to the baseline, the possibility to introduce restriction measures backed by administrative sanctions next to criminal law measures is expected to **strengthen the effectiveness of both type of restriction measures** and to further reduce the availability of harmful substances. Because it would reduce the risk that criminal sanctions would be introduced on substances posing low or moderate risk, it would also mitigate the possible adverse effects that the introduction of criminal sanctions in such cases can have (involvement of organised crime in the market for recreational use, burden on national criminal justice systems).

Economic and financial impacts	**Costs to the EU budget** are of about €3.7 million during the period 2014-2020 (the additional work generated by the increase in the number of new psychoactive substances that are expected to be notified to the EMCDDA, and the coordination of the structural cooperation between the EMCDDA, research institutes and forensic laboratories, would require 1 FTE at the EMCDDA, which should be covered through internal redeployment). No impacts on other agencies. **Costs to the Member States' budgets** are low because they already have mechanisms in place to implement temporary or permanent restriction measures for the withdrawal from the market of dangerous substances and products, and to enforce criminal law measures on illicit drugs. Moreover, in the case of restriction measures backed by administrative sanctions, Member States will not have to bear the additional costs related to criminal justice. This will lead to savings in comparison to the current situation. The **administrative burden is limited** because Member States will only have to share information at their disposal (no obligation to collect new information or to notify detected new psychoactive substances) and notify national measures taken to implement EU decisions. **Medium negative impact on economic operators** in the market for recreational use, because market restriction measures will not allow them to place the substances at issue on the consumer market; these impacts are justified and balanced by the wider social and health benefits. The overall negative impact on these economic operators will be smaller than that of measures under the status quo, because the measures envisaged will be more proportionate to the risks of substances and more targeted. **Positive impact** on economic operators in the market for legitimate uses, because fewer substances, only those posing proven risks, will be submitted to restriction measures. Moreover: • their business involving substances posing moderate risks will not be affected by the restriction measures because they do not apply to the business to business trade; • for substances posing severe risks, specific legitimate uses allowed for illicit drugs will be possible, but will need to be authorised, and additional legitimate uses may be allowed, if specifically authorised under EU law. However, the need to obtain authorisation would cause limited additional administrative costs to market operators. **Legitimate uses** will be facilitated by a more consistent and clearer approach at the EU level. Since legitimate uses are already regulated under other legislation, this option will cause limited additional administrative costs to these market operators.

Social impacts	**High positive impact on public health and safety**, because the availability of harmful new psychoactive substances in the EU internal market is likely to be reduced and the sharing of information on them is likely to be increased. Restrictions to **fundamental rights**, notably on the freedom to conduct a business and the right to property, are justified on the basis of the need to ensure a high level of protection of health and safety from harmful substances. There are **positive fundamental rights impacts on economic operators in the market for legitimate uses**, because their right to conduct a business will not be affected by the restriction measures in case a substance poses moderate risk, or is comparable to baseline for substances posing severe risks. The preferred option will have positive impacts on the principles of legality and proportionality of criminal offences and penalties. In cases where sanctions apply, there is a need to ensure that the fundamental rights to an effective remedy and to a fair trial, presumption of innocence and right to defence, and the principles of legality and proportionality of criminal offences and penalties, are respected. Confiscation should only take place in cases and under the conditions provided for by law.
Proportionality and acceptability by stakeholders	The preferred option **scores very well on proportionality**, because it allows policy objectives to be achieved without going further than what is necessary for this purpose. It tailors the restriction measures to the level of risk posed by substances and does not unduly restrict legitimate trade. **Good acceptability**, because economic operators in the market for legitimate uses will not be unduly affected by the restriction measures and because the option responds to the call of a majority of Member States for a more graduated set of options to address substances (although certain Member States could still prefer having only criminal law measures to tackle new psychoactive substances). Moreover, the consultations conducted during the assessment of the current instrument show that a majority of Member States support the introduction of temporary emergency measures, that they are in favour of reducing the major gaps in the evidence-base underpinning decisions on new psychoactive substances, and that they support the combination of the positive elements of the individual approach with certain advantages of the approach by group of substances through 'intelligent clustering'.

The preferred policy option **strikes the right balance** between the need to protect individuals and society from the health, social and safety risks posed by the use of new psychoactive substances, on one hand, and the need to reduce obstacles to legitimate trade in these substances and to prevent the emergence of such obstacles, on the other hand. It has **very positive impacts on reducing harm to public health and safety**, because it enables the rapid withdrawal of harmful substances from the market, while also facilitating legitimate trade in the internal market.

By providing for a **more graduated and better calibrated set of options** that are proportionate to the levels of risks of substances and that do not unduly hinder legitimate uses, the envisaged measures make both types of restriction measures (backed by administrative or by criminal sanctions) more effective, while reducing their negative impact on economic operators in both the market for recreational use and on the one for legitimate uses, and on consumers.

In addition, the preferred option will help reduce market fragmentation, the risk of uneven level playing field for economic operators and will help increase legal certainty in the internal market, by clarifying how restriction measures will apply in the case of dual-use substances.

It will also help tackle in a more **predictable, consistent way** new psychoactive substances that raise EU-level concern. The preferred option is likely to help **pre-empt divergent national action** on new psychoactive substances raising cross-border concerns. This is because an EU-level mechanism that is able to anticipate better the spread of harmful new psychoactive substances, to ensure a robust assessment of their risks and to provide faster responses to protect consumers, without impeding legitimate trade, is likely to reduce the need for individual Member State action, and related adverse effects.

In addition, this option helps **better connect the market for legitimate uses** of new psychoactive substances with the broader internal market. This is because it facilitates the closure of gaps between drug legislation, on the one hand, and medicines legislation or legislation regulating specific markets (primarily REACH) on the other hand, by improving and clarifying the connection between these legislations. Moreover, it clarifies the **applicability of the provisions of Directive 98/34/EC[117] to national technical regulations prohibiting the placing on the market of new psychoactive substances on which the Union has not acted yet.** The result is that legitimate trade in new psychoactive substances will be facilitated, dual-use new psychoactive substances will be better integrated in the internal market, and the functioning of the market in other products, which are manufactured using new psychoactive substances, will be improved.

These **positive impacts clearly outweigh the costs** to the EU and Member State budgets, as well as the negative impacts on economic operators caused by the restriction measures.

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117 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.

While any restriction measures, at EU or national level, could have certain unwanted **consequences** – for instance that substances subjected to restrictions may be replaced with possibly even more harmful substances or that criminal groups may take over the market for a substance in certain countries if users still want to buy it from the black market – the envisaged measures **help prevent and address better** such consequences, because they provide more effective and refined responses.

The preferred option will **markedly improve the EU's capacity** to produce and share information and analysis on new psychoactive substances, to anticipate developments and provide adequate responses. It will **significantly increase the speed of reaction** to address new psychoactive substances at the EU level. This improved capacity will also enable the EU to better address the production of new psychoactive substances outside the EU, through political dialogue, cooperation programmes and projects with third countries.

Figure 7: Comparative timeline of the current Council Decision with the envisaged mechanism on new psychoactive substances

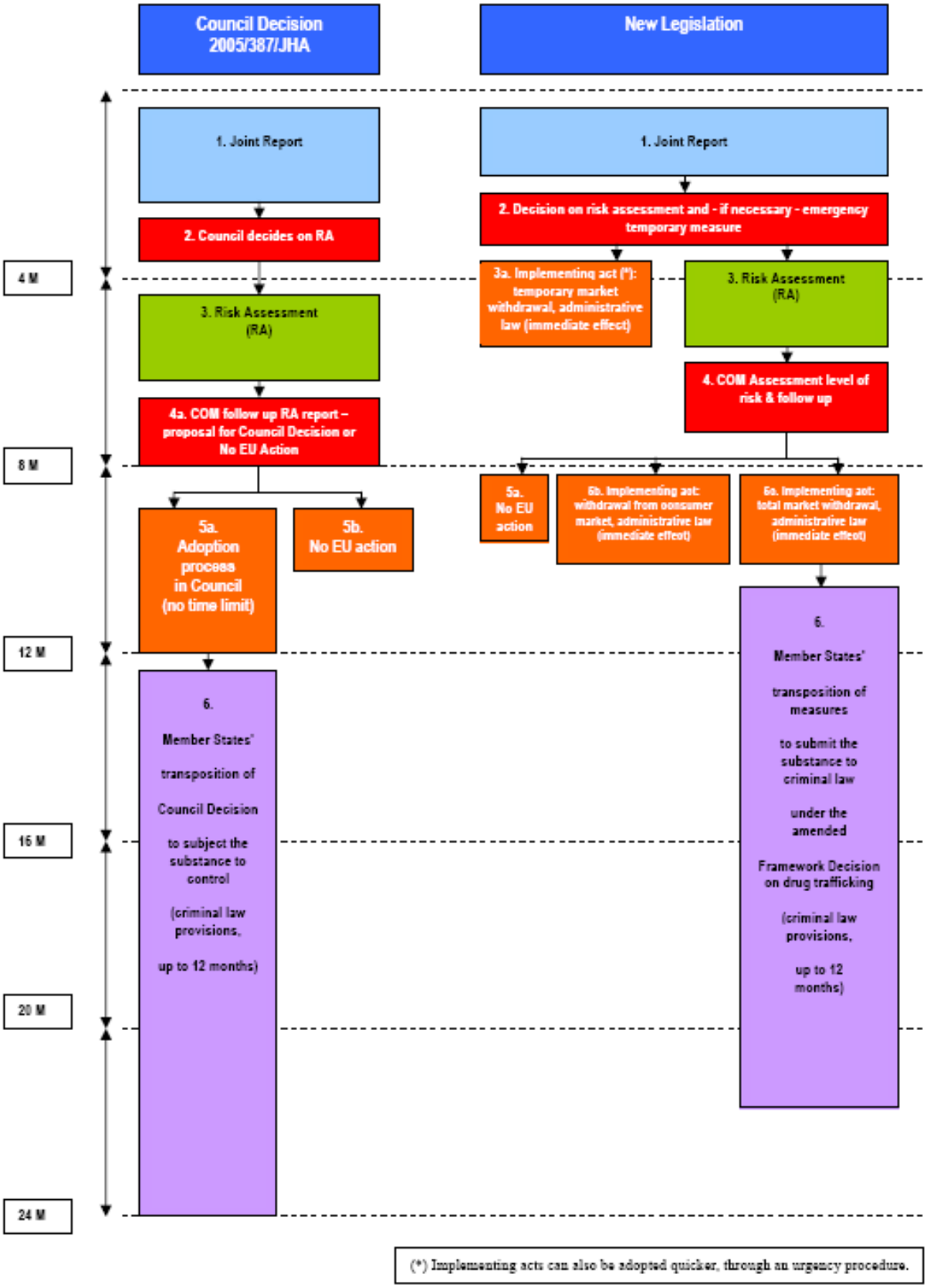

Figure 7 shows that, compared to the current instrument, the future mechanism will ensure a **much faster response to new psychoactive substances** (times are calculated from the start of the joint report on a substance). This is because of three main reasons:

a) Temporary emergency measures, on substances that cause immediate public health concern, can be **introduced at an early stage** (via implementing act), before the completion of a full risk assessment report: after just **six months** (see 3a. on the right column), and after only four months in case the implementing act through which the measures are introduced is adopted following the urgency procedure. This will dramatically shorten the time of first reaction to new psychoactive substances posing immediate concern.

The possibility of adopting early temporary emergency measures does not exist under the current instrument, which only enables permanent measures to be introduced, after the completion of the risk assessment. At the moment when a temporary emergency measure is introduced (and in force) under the new system, a risk assessment on the substance would only be launched under the current instrument.

b) Decisions on permanent restriction measures will be **adopted faster** than under the current instrument - after around **ten months** (see 5b. and 5c. on the right column) (restriction measures are adopted after around 12 months under the current instrument, but the need to transpose them in national legislation may add another 12 months). This is because **implementing acts** would be used, under the new mechanism, for adopting these measures, and because the duration of the joint report will be reduced. In addition, the time needed for collecting information on substances may be reduced further in practice, because more data will be available and this data will be easier to access, due to the fact that the new measures will enhance the quantity and quality of information available about new psychoactive substances.

At the moment when the permanent market restriction measures adopted by the Commission under the new mechanism are in force pending the transposition of criminal law provisions by the Member States, under the current instrument the Council would still only be deciding on the adoption of control measures backed by criminal sanctions (5a. on the left; there is no time limit for the adoption of the Council decision on restriction measures, but this decision has been adopted after four months following the Commission proposal, so broadly 12 months after the start of the process, to which the time necessary for national transposition has to be added).

c) Certain measures adopted under the new mechanism (the temporary emergency measures and the permanent restriction measures backed by administrative sanctions) will be **immediately applicable** in the Member States, without the need for national implementation (they will be in force after **six and ten months** respectively, four months, if the urgency procedure for adoption of implementing acts is being used for temporary restrictions). Only restriction measures backed by criminal sanctions (5c. on the right) would need to be transposed by the Member States (within 12 months, but certain Member States are likely to transpose the measure faster if the substance raises serious concern). Under the current instrument, the restriction measures backed by criminal law are not directly applicable either and need to be transposed and implemented by the Member States within 12 months from the adoption of a decision by the Council (although Member States can anticipate EU decisions).

The preferred option **respects the principle of subsidiarity** because it only addresses new psychoactive substances that are a problem across the EU and leaves to the Member States the responsibility to deal with those that are a problem at local or national level. Member States will not need to modify their national legislation in order to implement the preferred option. The preferred option also **respects the principle of proportionality** because it does not go beyond what is necessary to achieve the objectives, by providing measures tailored to the level of risk of substances.

Member States would be able to apply national measures before the introduction of any EU-level measure **in full respect of the provisions of Directive 98/34/EC**, and to go further than what is foreseen by EU measures **in full respect of the provisions of Article 114 TFEU**. The introduction of such national measures would affect the effectiveness of the instrument in facilitating the functioning of the internal market for legitimate uses, but would not reduce its overall effectiveness as to the protection of the health of consumers (although it may cause geographical displacement). At the same time, an EU instrument that enables the Union to act fast and on more solid evidence about substances is likely to pre-empt divergent Member States' action.

In addition to the measures envisaged under the preferred option, **targeted prevention and harm reduction services** are essential for addressing the recreational use of new psychoactive substances, for preventing and reducing severe drug-related injury and harm, their effects on individuals' health and safety, and on society. The EU will continue to support, including through funding, the development of innovative prevention and harm reduction methods, adapted to new psychoactive substances.

7. MONITORING AND EVALUATION

The Commission shall ensure that a system is in place to monitor the implementation and to evaluate the functioning of the future instrument addressing new psychoactive substances. The EMCDDA and Europol shall produce an annual report that will monitor the implementation of the instrument. The report will provide:

- Information on new psychoactive substances notified (number of notifications; characteristics of substance; Member State that notified; legitimate uses; availability on the internet);
- Information on the joint reports and risk assessments conducted;
- Information on new psychoactive substances subjected to restriction measures at the EU and national level (implementing an EU instrument or following national procedures);
- Information on health alerts issued (including on notified and documented health adverse effects of substances) and follow-up given by responsible authorities;
- Information on national restriction and control measures on new psychoactive substances;
- Information on the synergies and overlaps with other EU and UN mechanisms.

Most of this information is already collected by the two agencies via the EWS. Information on substances subjected to restriction measures at national level, which is not collected under the current system, will be provided by the national authorities to the Commission, which will inform the EMCDDA and Europol.

The Commission will evaluate the implementation, functioning, effectiveness, efficiency, utility and added value of the future mechanism on a regular basis. This evaluation shall also include an assessment of the effectiveness of the restriction measures introduced on the basis of the instrument. The Commission shall initiate an evaluation of the instrument every five years, submit the result to the European Parliament and the Council, and propose amendments, if necessary.

Annex 1 – Overview of mechanism and timeframe of the Council Decision 2005/387/JHA

Phase	What	Who	Timeframe	Output	Article
1.	Notification of new psychoactive substances; data on manufacture, trade, use	Member States via Reitox National Focal Points and Europol National Units	**Ongoing**	Information is transmitted through EWS to Member States, Commission and EMA	4
	Assessment of information on new psychoactive substance	EMCDDA and Europol		Decision to develop EMCDDA-Europol joint report	
	Joint report: data collection	Member States EMCDDA/ Europol/ EMA	**6 weeks**	Data from all Member States, EU institutions; preliminary scientific data	5(1) to 5(4)
	Presentation of joint report	EMCDDA/ Europol	**4 weeks**	Joint report presented to Council and Commission	5(5)
	Decision on need for and possibility of risk assessment	Council (at request of Commission or at least ¼ of Member States)	**4 weeks** after reception of joint report by Commission or Council	Decision by Council	6(1)

2.	Risk assessment[118]	EMCDDA Scientific Committee (plus Commission, Europol, EMA and external experts)	**12 weeks** after notification by Council of decision to conduct a risk assessment	Risk assessment Report	6(2)-6(3) 7
	Proposal on making new psychoactive substance subject to control measures	Commission	**6 weeks** after receipt of risk assessment Report	Proposal for Council Decision OR Commission report justifying why control is not necessary	8(1)
3.	Decision on Commission proposal	Council	**Unspecified**	Decision to control or not the substance	8(2), 8(3)
	Implementation of possible Council Decision to control the new psychoactive substance	Member States	**52 weeks** after publication of the Council Decision in the Official Journal	Member States submit substance to criminal law provisions under their laws by virtue of obligations under the UN Drug Conventions	

Annex 2 – Results of the surveys conducted in the context of the external study

A total of 252 stakeholders have been consulted in all Member States, the EU and internationally. These included the following:

- Personal and telephone interviews with European Commission and EU agencies officials, as well as European umbrella associations working in relevant fields;
- An online survey with National Focal Points (NFPs) from the Reitox network of the EMCDDA and Europol National Units (ENUs);
- Telephone and face-to-face interviews and online surveys with relevant national authorities in Member States, such as Ministries of Justice and of Health, law enforcement authorities (police, customs), public health institutes, NGOs working in the field of prevention or user support, forensic institutes, academics;

[118] The risk assessment report includes a description of the substance, including medical value; health and social risks; involvement of organised crime, information on seizures and manufacture, on any assessment of the substance in the UN system; a description of control measures applicable to the substance in the Member States; options for control and their possible consequences.

- An online user survey launched in the Member States consulted through the case studies, in three languages (English, German and Polish);
- An online industry survey launched among industry representatives;
- Telephone interviews with relevant international organisations and representatives from third countries.

The findings have been included in the relevant sections of the Impact Assessment report.

Level of stakeholder consultation	Types of stakeholders consulted	Total number of completed interviews	Comments (e.g. outstanding interviews/ online survey responses etc.)
EU level	EU agencies (EMCDDA, EMA, Europol, EFSA, ECHA)	6	
	EU associations (e.g. EURAD, EFPIA, UTRIP)	3	
	NFPs (Reitox network) (responses: AT, BG, CR, CY, CZ, DE, DK, EE, EL, FI, FR, HU, IT, LT, LV, MT, NL, NO, PT, RO, SE, SK, TR, UK)	24	6 (BE, ES, IE, LU, PL, SI)
	ENUs (responses: BG, DK, FR)	3	24 (all MS except for BG, DK, FR)
Total number of completed EU interviews/ survey responses – 42			

Level of stakeholder consultation	Types of stakeholders consulted	Total number of completed interviews	Comments (e.g. outstanding interviews/ online survey responses etc.)
MS level	Up to three interviews per MS: - National authorities (e.g. Ministries of Justice, or other law enforcement bodies such as police, and customs); - Ministries of Health, or public health institutes; - NGOs or academics.	64 interviews/ online survey responses. 13 MS fully completed i.e. all three stakeholders participated in an interview/ online survey (e.g. BE, BG, CZ, EL, ES, FI, FR, HU, IT, LU, NL, SI, UK)	9 MS (CY, DE, IE, LV, MT, PL, RO, SE, SK) nearly completed (two out of the three stakeholders participated in an interview/online survey). AT, DK, EE, LI, PT partially completed (only one of the stakeholders participated in interview/online survey).
	Interviews with head shops including traders' associations (the latter were also consulted through an online survey).	2 interviews (1 UK head shop, and 2 wholesaler in NL)	The majority of head shops contacted in CZ, DE, DK, ES, FR, HU, IT, NL and UK did not wish to contribute.
	Case studies in 6 MS – DE, FI, NL, PL, RO and UK 5-6 interviews per MS: - EWS correspondent; - Forensic institutes; - Customs officials; - Youth/user support organisations; - Law enforcement authority	24 personal interviews/ average of 5 interviews per MS	DE, UK and FI customs consulted only, as contacts were not received for the rest of the case study MS
	Online user survey responses launched in the majority of case study MS.	104 user responses received by 9 March 2012.	
Total number of completed MS interviews/ survey responses – 90			
International level	International organisations (e.g. UNODC, INCB, WHO)	3	
	Third Countries (response received from NZ)	1	Unable to organise interviews with representatives from Australia, Canada and the US after multiple attempts.
Total number of completed international interviews/ survey responses – 4			
Total number of interviews/ survey responses completed in the study – 252			

Annex 3 – Overview of the replies to the public consultation

A public consultation containing three questions on drugs policy was carried out in 28 October 2011 - 3 February 2012. The consultation aimed at gathering the opinion of individuals and stakeholders that have an interest in shaping EU drugs policy. The consultation was designed to help the European Commission identify areas where its actions could bring most added value in drugs policy.

The three questions on which the Commission asked the public to reflect on were:

1) What actions should the EU take to prevent the production of illicit drugs and their smuggling to and within the EU?

2) What regulatory measures should the EU develop to contain the spread of new psychoactive substances?

3) How can the EU help improve the availability, accessibility and quality of drug prevention, treatment and harm reduction services in the Member States?

The Commission received 205 contributions to the consultation from a variety of respondents, including governments, EU agencies and bodies, non-governmental organisation, citizens and others.

Each of the contributors was categorised in one of the following three groups of stakeholders:

1. Governments (regional and national), EU agencies and EU bodies.

2. Non-Governmental Organisations, institutes, private companies[119] and other types of organisations.

3. Citizens.

[119] 'Private company stakeholders' were added to the grouping of NGOs, Institutes and other organisations as they were few in number and of little qualitative value.

In total, 205 contributions to this public consultation were submitted and a total of 158 valid contributions have been evaluated from the following stakeholders:

Stakeholder type	**Number of valid contributions**
Governments (regional and national), EU agencies and bodies	10
Non-governmental organisations	37
Institutions/ organisations (national)	8
Citizens	103

70 contributions were received to question 1, 134 to question 2 and 132 to question 3.

In relation to **question 1 "What actions should the EU take to prevent the production of illicit drugs and their smuggling to and within the EU?"**, the main comments received were the following

Some government and law enforcement stakeholders call for an increase in cooperation and intelligence sharing between the Member States. In particular, coordination of operations between police, custom and border authorities to prevent the production and smuggling of illicit drugs should be improved. Constant monitoring of new production processes and of new smuggling routes and techniques is also crucial to prevent the production of illicit drugs and their smuggling, according to certain government and NGO stakeholders.

Drug trafficking affects the stability and socio-economic development of the EU. A couple of NGO stakeholders argue that to reduce the production of illicit drugs and their smuggling, the EU should not solely focus on reducing the overall amount of drugs produced but also on increasing political stability and security in source and transit states.

A number of governmental, NGO and citizen stakeholders call for improved border controls and improved cooperation between police, border and custom authorities to tackle cross-border drug trafficking, as this remains one of the largest enforcement challenges in the EU. Member States should allow Europol, Eurojust, EUROSUR and FRONTEX to make full use of their mandate in order to help prevent the production of illicit drugs and their trafficking towards and within the EU. One NGO stakeholder suggests that, in order to reduce drug smuggling, the EU should allocate funds specifically to border areas to discourage local populations from becoming involved in high profit drug trafficking.

Strengthening bilateral agreements and continued cooperation with producer and transit countries, third countries and other international organisations would help reduce drug smuggling and drug production, argue several government, NGO and citizen stakeholders.

One government stakeholder proposes creating forensic profiles of the cutting agents used by drug smugglers to provide intelligence to target the producers of illicit drugs and trace their provenance. Another government stakeholder argues that a more comprehensive data collection system concerning drug supply and drug supply reduction would help improve intelligence and highlight the most effective methods to tackle drug production. Another idea is to use prison services and correctional institutions to gather intelligence on drug production and smuggling. These facilities are an underused source as they have access to convicted drug offenders who may be able to provide the latest information regarding trafficking routes and smuggling methods.

Several NGOs point out that, to prevent the production of illicit drugs and their smuggling, the EU needs to realise that law enforcement is just one component of drug policy. They argue that public health, social, and educational policies are needed for a coherent and effective policy.

Several government stakeholders welcome the European Commission's upcoming proposal for *'stronger EU legislation on confiscation, recovery of criminal assets and mutual recognition of freezing and confiscation orders'*. Citizens suggest that it would be more effective to improve targeting of high-level drug dealers and drug smuggling organisations in order to seize larger amounts of criminal assets. Some citizens argue that if drug smuggling and production were a less profitable business, it would affect the amount of illicit drugs entering the EU. The seized drug trafficking assets could be reallocated to Member State budgets for treatment programmes and harm reduction services.

A few government and EU bodies and an advocacy NGO stakeholder call for improving the definition of drug trafficking offences and for providing a more detailed breakdown of penalties. Stronger obligations to adapt drug trafficking legislation are necessary as definitions and sentences can vary between Member States. One NGO stakeholder argues that the current perception of inconsistent rules allows drug traffickers and smugglers to move their businesses around Member States to evade harsher penalties and sentences. A number of legal advocacy NGO stakeholders argue that Member State judicial cooperation needs improving to effectively prosecute drug traffickers.

In addition, certain government, advocacy NGOs and citizen stakeholders urge the EU to consider more proportionality concerning the levels of sentences for drug users and user-dealers and to consider alternatives to incarceration (e.g. treatment and rehabilitation programmes) for minor drug offenders. One NGO stakeholder suggests funding re-employment programmes and forcing drug dealers to complete community service to help dissuade them to smuggle illicit drugs.

Several advocacy NGO stakeholders argue that in order to reduce the production and smuggling of drugs, there needs to be a decrease in the demand for drugs. Several citizens suggest focusing on high-level drug dealers and organised crime organisations and on effectively seizing their assets. Producing and smuggling illicit drugs is a hugely profitable enterprise but if the assets of larger drug traffickers are confiscated, it would become a less profitable business.

Many citizens call for the decriminalisation of all illicit drugs. The legal regulation by Member States of illicit drugs would reduce trafficking and production. Concerning cannabis, one advocacy NGO and most citizens state that the best way to tackle the production and trafficking of the substance is to make it legal. Many citizens state that current efforts to eliminate drug supply and demand are ineffective.

Lastly, one government stakeholder urges an increase in the monitoring and evaluation of supply-side action in EU Member States.

In relation to **question 2 "What regulatory measures should the EU develop to contain the spread of new psychoactive substances?"**, the main comments received were the following:

Government agencies and other EU bodies

The majority of stakeholders agree that regulatory measures are essential to contain the spread of new psychoactive substances and to enhance cooperation between Member States, as law enforcement measures are no longer the sole focus of anti-drugs policies. Three stakeholders suggest using alternative legislation such as consumer regulations, trading standards, healthcare regulations and food safety legislation to regulate new psychoactive substances.

Six stakeholders agree that the **EWS** is an effective network for exchanging information, but risk assessments and forensic testing need to be quicker. Currently procedures to control and identify new psychoactive substances are too complicated. The swift emergence of new psychoactive substances means any regulatory tools need quick enforcement.

Four stakeholders suggest stronger regulations **concerning precursors and pre-precursor**s:

- Introduce temporary scheduling of precursors and pre-precursors to allow time for more thorough risk assessments.
- Descriptions in regulatory measures of pre-precursors should be generic to enable the proactive scheduling of new psychoactive substances and to keep up with this rapidly changing market.
- Once the risks of a new psychoactive substance are established, the Council could decide to remove it from the scheduling.
- New regulatory measures for new psychoactive substances should in no way affect the legitimate trade of pharmaceutical products and precursors.

Five stakeholders referred to the effects of the existing divergence of national legislation on new psychoactive substances and to the fact that drug producers and traffickers are allegedly using loopholes in different Member States' legislations to produce and distribute new psychoactive substances legally throughout Europe.

Concerning **new legislative proposals**, one stakeholder stipulates that the EU should not rely on existing UN legal definitions of drugs but undertake academic research and create an EU list of definitions. Moreover, the European Commission should take into consideration the *ne bis in idem* principle when drafting its proposal. One stakeholder urged the Commission to consider if the precautionary principle would be adequate for addressing new psychoactive substances.

Two stakeholders highlight the problem of the **internet (online head shops)** in the supply of new psychoactive substances. Stakeholders call for more robust internet legislation, which would work in conjunction with international regulations to monitor and quickly close online shops.

Non-Governmental Organisations, Civil Society and citizens (137 contributions)

Twenty-nine stakeholders suggest that if any additional regulations are required for new psychoactive substances they should be health, trade or consumer protection oriented and not criminal law approaches. Numerous stakeholders support the idea to legally regulate new psychoactive substances, following the models used for regulating alcohol and tobacco.

Eight stakeholders state that faster analysis, more thorough risk assessments and enhanced cooperation across Member States are still necessary.

Five stakeholders suggest introducing an EU-wide list of banned precursors for these substances, temporary bans for new psychoactive substances, making it illegal to consume or sell them – the bans can be lifted once risk assessments are completed, reviewing all existing bilateral agreements concerning precursors and verifying if strengthening them would be more beneficial than introducing new legislative proposals on new psychoactive substances.

One stakeholder suggests creating national laboratories and emergency departments across Member States to deal exclusively with new psychoactive substances and produce additional research to better understand the problem and better contain the spread of new psychoactive substances.

Six stakeholders argue that a crucial tool to contain the spread of new psychoactive substances is to create stringent legislation regarding the **internet (online head shops**). Other stakeholders point out to the risk of displacement and the need for better coordination of Member States' legal frameworks, as once a head shop closes in one Member State it can simply reopen in another Member State or neighbouring country.

Five stakeholders highlight the issue of border control, stressing that traffickers smuggle easily psychoactive substances across borders and throughout the EU. Certain stakeholders suggest tightening border controls, using the full remit of existing international treaties, and increasing the involvement of Europol, CEPOL and Eurojust to address this problem.

Scientifically proven educational programmes would help contain the spread of new psychoactive substances, argue six stakeholders. Young people need clear facts concerning illicit drugs as honest information campaigns appear to be more successful than the negative "don't take drugs" information campaigns. Several stakeholders recommend increasing the use of social networking sites to target educational drug information at young people.

Annex 4 – National surveys on use and prevalence of new psychoactive substances

Between 2009 and 2011, surveys on use and prevalence of new psychoactive substances were carried out in a number of Member States. These surveys were mostly carried out amongst young people or "at risk" groups such as Internet users and nightclub-goers. Of the surveys that looked at a range of ages, it was evident that use was greater among younger people. However, the methods, sample and volume of people surveyed were different in each Member State, so the data are not comparable.

In the Czech Republic, the National Monitoring Centre for Drugs and Drug Addiction surveyed internet users in 2011: 4.5% of respondents aged 15-34 signalled that they had tried new psychoactive substances before. In addition, research into drug use in the nightlife sector was undertaken in 2010 which indicated that lifetime use of mephedrone was at 3.8%, of piperazines at 2.6%, and Spice at 3.3%.

In Germany, a 2009 epidemiological addiction survey suggested that the 12 month prevalence of "Spice" products is 0.4%. Usage is higher among younger age groups - e.g. lifetime use among the 18-20 age group is 1.9%, 1.8% among the 21-24 age group and 1.0% amongst the 25-29 group, compared with a 0.3% lifetime usage amongst the 30-39 year olds and 0.1% amongst those aged 40-49. In the groups up to age 64 years, 12 month prevalence is 0%.

In Ireland the National Advisory Committee conducted a Drugs Prevalence Survey (2010/2011) among a sample of 15-64 year olds, which found that 3.5% of the 7,669 surveyed in Ireland and Northern Ireland had taken new psychoactive substances within the last year. This included 6.7% of 15-34 year olds, but only 1.0% of the 35-64 year olds surveyed.

In Poland, a sample of young people (number of respondents not specified) were surveyed in 2008 and in 2010. In 2008, 3.5% of the young people surveyed had tried new psychoactive substances – in 2010 the percentage had risen to 11.4% of those surveyed. Of the 2010 figure, 7.2% had tried new psychoactive substances in the last 12 months and 1.1% in the last 30 days.

In Slovakia the survey carried out in 2011 by the National Monitoring Centre found that 5% of students from primary and secondary schools used "legal highs".

According to the Spanish State Survey on Drug Use in Secondary Schools (ESTUDES) undertaken in 2010 lifetime prevalence for the consumption of new psychoactive substances amongst 14 to 18 year olds was 0.7% - of these, 0.6% had consumed the new psychoactive substances in the last 12 months and 0.5% in the last 30 days.

In addition, surveys were carried out in Bulgaria among school children (in 2011) and university students (2010), and in Latvia a European School Survey on Alcohol and Other Drugs was undertaken in 2011.

Annex 5 – Estimation of the scale of the markets for and social costs related to new psychoactive substances

1) The markets for new psychoactive substances

a) Scale of the retail market for recreational use of new psychoactive substances

The scale of the market for recreational use of new psychoactive substances is difficult to estimate and varies from one country to another. Limited information is available on the prevalence of use and market data (e.g. import, export, distribution, sales). So far there are no systematic studies available that estimate the global economic and social burden[120] of the use of new psychoactive substances on individuals and society.

One way of approaching this is to make a comparison with an existing, similar psychoactive substance for which more data is available, which could be used as reference for calculations. For the purpose of this Impact Assessment, estimations have been made by drawing a comparison with the illicit substance ecstasy (MDMA). This comparison is justified for the following reasons:

- A considerable number among new psychoactive substances are stimulant substances (e.g. mephedrone, BZP, *m*CPP, methylone), like ecstasy.
- Some of these substances have similar effects to those of ecstasy and are sometimes sold as (an alternative to) ecstasy or added as cutting agent in ecstasy tablets.
- Available information suggests that new psychoactive substances are used by a limited population of mostly young people, mostly during adolescence and early adulthood, often in association with experimentation and clubbing. The use of ecstasy shows similar patterns of use, even though it may be somewhat more widespread towards the upper end of young adulthood.
- Depending on the country and market, the unit prices may be similar and the distribution channels for ecstasy and new psychoactive substances may overlap.
- Ecstasy poses a health risk similar to that of many new psychoactive substances. The potential for dependence is limited and harms are mostly linked to acute toxicity due to overdose.

[120] The costs related to new psychoactive substances may entail costs directly related to the use of these substances, e.g. health costs (treatment, overdose, mortality, infectious diseases, intangible costs of addiction), productivity costs (loss due to early mortality, short term disability), or drug-induced crime. In addition, costs may relate to the responses to the problem, e.g. enforcement of laws, product safety inspections, prosecution, arrests and incarceration including loss of productivity due to the latter, as well as costs of demand reduction policies (Report on Global Markets 1998-2007, 2009).

Comparisons with a variety of other substances could be made, but as there is very limited information about the share of other substances in the consumer market, this would add complexity but not necessarily more information. Despite the fact that various illicit drugs have been available for a long time, the scale of this market is not well known, mainly because of its informal nature. In 2009 the study *"A Report on Global Illicit Drug Markets 1998-2007"*[121] tried to estimate the scale of the market of the most common illicit drugs, and the global economic burden and unit costs of drug of drug-related harms.

The study estimated the scale of the retail market for cannabis, cocaine, heroin and ecstasy, on the basis of available data. For ecstasy, the scale of the market (EU-25) was estimated to be between **€750 million and €6.2 billion**[122] (2005 price levels). This percentage includes a low and high percentage for underreporting of use[123] (20% vs. 50%). Given the fact that new psychoactive substances are technically legal until they are controlled or made subject to market restrictions, underreporting (e.g. due to stigma) may be less of a problem. Therefore, a high range for the market in new psychoactive substances is not provided. On the basis of this estimate, combined with the data available on prevalence and use of new psychoactive substances, a rough calculation on the scale of this market is made.

According to EMCDDA data[124], the lifetime prevalence of ecstasy in 2005 – the year for which the economic estimates were made - was 3% of EU adult population (15-64 years old) and the last-year prevalence was 0.9% (i.e. one third of the lifetime users). By 2009 lifetime prevalence increased to 3.2% while last-year use decreased to 0.7%, i.e. roughly one fifth of the lifetime users[125]. Also in 2009, life-time prevalence among 15-34 years-old Europeans was 5.5% and the last year prevalence 1.4%, about one-fourth of lifetime prevalence.

The Eurobarometer "Youth attitudes on drugs" from 2011 included a question on the lifetime use of *"legal substances that have similar effects to illicit drugs"*. Among the respondents, the lifetime use of these substances was on average 5% among 15-24 year olds from across the EU, ranging from 1% in Romania to 16% in Ireland. In analogy with ecstasy, it is assumed that last-year's prevalence represents a similar proportion among young people aged 15-24 as compared to that of ecstasy in the age group 15-34, i.e. 1.4% / 5.5% x 5% = 1.3%. Considering the fact that **last year prevalence** among young ecstasy users aged 15-34 was twice that of the adult population aged 15-64, it is roughly assumed that the **last year prevalence** of new psychoactive substances among the adult population is half of that of youth aged 15-24, i.e. 50% of 1.3% **= 0,65%.**

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121 Available at: http://ec.europa.eu/justice/anti-drugs/files/report-drug-markets-full_en.pdf.

122 Data on Romania and Bulgaria was not available.

123 Studies show that actual substance use may be underreported in household surveys (due to stigma). For ecstasy no estimates were available, but for cannabis and cocaine the study argued that this may be 20% respectively 50%.

124 EMCDDA, 2007 Annual Report on the state of drug problem in Europe, 2007.

125 EMCDDA, 2011 Annual Report 2011 on the state of drug problem in Europe, 2011.

According to the MixMag drug survey 2011, a survey among mostly young 'clubbers' in the UK (average age 25), most of whom use licit and illicit drugs on (highly) frequent basis, last year use of new psychoactive substances was less than 10% (for e.g. methylone, BZP, 2CI, MDPV, GBL, SPICE/MAGIC). For mephedrone, last year use was over 51%, though. The survey for 2012 gives a similar picture, while mephedrone use in the past year dropped to 30% in this group of frequent users.

The most recent estimate of the EU-27 population is around 502.500.000 people[126]. The adult population aged 15-64 represents around 67% of this total, or 336.675.000 million. As a consequence, the number of last-year users of new psychoactive substances in the adult population is estimated at 0.65% x 336.675.000 = ± **2.2 million**.

EMCDDA data from the 2011 Annual Report shows that between 2003 and 2009, the prevalence of ecstasy use in the 15-34-year old population did not increase in EU countries, while certain countries reported moderate decreases. Over the period 2004-2009, the retail price level of ecstasy has continued to fall or remained stable across Europe as a whole. Therefore the scale of the market ranges presented in the 2009 study on illicit drugs markets may still be valid. When adjusting the prevalence rate of ecstasy to that of new psychoactive substances, and including only the lower percentages for underreporting of use, the scale of the market for new psychoactive substances is calculated as follows:

$$\frac{\text{€750.000.000}}{\text{0,9}_{\text{(LYP ecstasy 2005)}}} \quad \text{X 0.65}_{\text{(LYP NPS 2011)}} \quad = \text{€542.000.000}$$

These estimates should be interpreted with caution for many reasons. The prevalence data from the Eurobarometer 2011 survey has limited statistical value, in particular if compared to more sophisticated and comparative methodologies used for the calculation of the prevalence of illicit drugs in Europe. The estimation compares different age groups of consumers, notably young adult users, of ecstasy (15-34 years old) and new psychoactive substances (15-24 years old). Furthermore, the data available for ecstasy and new psychoactive substances is collected in different years (2005, 2009 for ecstasy and 2011 for NPS). The country coverage is slightly different because the Eurobarometer covers the EU-27 while the illicit markets study does not cover Romania and Bulgaria. Finally, the estimate is a global calculation of the scale of the retail market and disregards differences in price and purity for ecstasy between countries, but also the wide range of substances covered under the term 'new psychoactive substances', each with specific price levels, purity and quantities consumed. Therefore the estimate should be used for indicative purposes only.

126 Eurostat, 20 March 2012.

b) Scale of the market for legitimate uses of new psychoactive substances

It is not possible to provide a reliable estimate of the scale of the EU market for legitimate uses of new psychoactive substances. This is because information is not collected systematically on the substances (and products) that have legitimate uses, on what are these uses, on the market operators involved, distribution, sale and retail, as well as on turnover.

However, the limited information available on this heterogeneous market indicates that the scale of this market is likely to be significant. The following elements justify such a conclusion:

- The potential number of substances with psychoactive effects that may be launched runs into the thousands; considering that at least one fifth of the substances notified to the EWS have legitimate uses (many more substances are likely to have such uses, but information on this has not been shared through the EWS), it can reasonably be assumed that the number of substances with legitimate uses will increase proportionally to the increase in the number of available new psychoactive substances on the market.

- An increasing number of substances notified to the EWS have been previously researched for medicinal or other commercial purposes in the past before being launched on the market for recreational use, showing the great potential for overlap between recreational use and therapeutic use. It can be assumed that this process will continue.

- Legitimate uses of new psychoactive substances used recreationally may be discovered as a result of appropriate scientific or industrial research. For instance, certain substances are being researched for use in drug substitution treatment. Considering the fact the new psychoactive substances can be similar to illicit drugs without necessarily having the adverse consequences on health that illicit drugs have, it can be reasonably expected that other new psychoactive substances may also be researched for drug substitution treatment in the future.

The three case studies of new psychoactive substances that have wide legitimate use presented in the report, notably GBL, 1,4-BDO and *m*CPP, clearly show that the size of the market for at least some of these substances can be considerable. According to the estimates of producers of GBL and 1,4-BDO, the markets for these substances are XXX.

2) Social costs of recreational use of new psychoactive substances

This annex provides an overview of the most common harms associated with the use of new psychoactive substances. In this area, too, data and information lacks. The calculations of social costs presented below are to a large extent based on a comparison with ecstasy.

In a recent study[127], an attempt was made to rank the various harms of licit and illicit psychoactive substances, including a number of new psychoactive substances. Figure 1.3 below shows various types of harms that may be associated with new psychoactive substances. The overview shows some similarity on potential harms between mephedrone and ecstasy (categories include: death, health damage, dependence, impairment of mental functioning, loss of relationships, injury and crime) and that the overall weighted scores representing the levels of harms incurred by users in association to these substances are lower than those identified for alcohol, heroin, cocaine and tobacco.

Figure 8: Overview of the harms caused by licit and illicit drugs

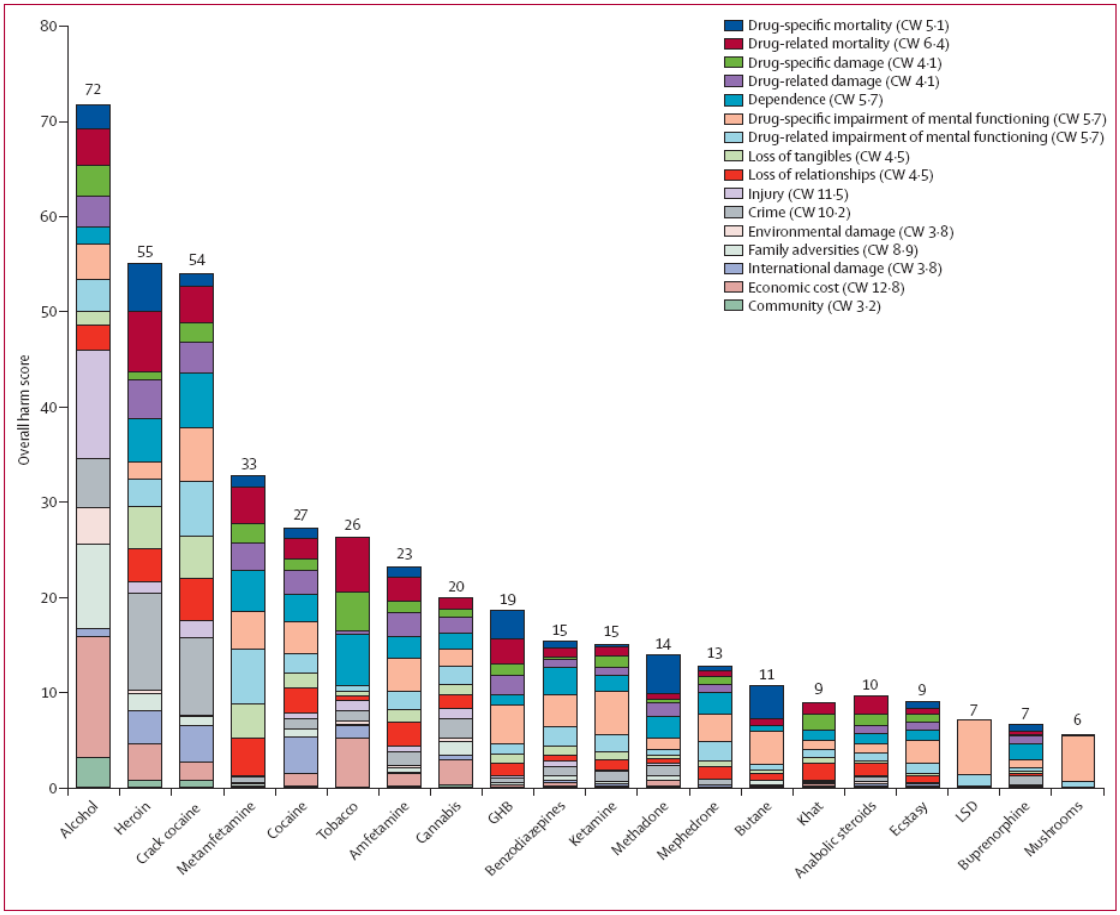

Figure 4: **Overall weighted scores for each of the drugs**
The coloured bars indicate the part scores for each of the criteria. The key shows the normalised weight for each criterion. A higher weight indicates a larger difference between the most harmful drug on the criterion and no harm. CW=cumulative weight. GHB=γ hydroxybutyric acid. LSD=lysergic acid diethylamide.

Source: D. Nutt et alii, "Drug Harms in the UK: a multicriteria decision analysis", available in: The Lancet, November 1, 2010; DOI: 10.1016/S0140-6736(10)61462-6.

127 D. Nutt et alii, "Drug Harms in the UK: a multicriteria decision analysis", available in: *The Lancet*, November 1, 2010; DOI: 10.1016/S0140-6736(10)61462-6.

Data available from EMCDDA does not suggest that the use of new psychoactive substances has to date resulted in major increases in treatment demand for these substances, or in important new trends in problematic drug use. However, there may be a delay in problems to occur and users of these substances may not have found yet their way to 'traditional' harm reduction and treatment services. There are signals from certain countries, e.g. Romania, that new psychoactive substances, such as mephedrone, may be injected by dependent users, causing potential risks for the spread of blood-borne infectious diseases. However, reliable and comparable data are not available.

The study mentioned above also argues that new psychoactive substances such as mephedrone, khat and mushrooms pose mostly risks to users and limited risk to others. It is therefore assumed - for the purpose of this Impact Assessment report - that the costs related to the use of harmful new psychoactive substances concern primarily health-related harms and to a lesser extent social harms (and within that category a relatively larger impact on social relationships, and lesser impact on crime and economic costs), as well as the costs of enforcing laws and the consequences of enforcement on public administration, economic operations and individuals.

The analysis of economic and social impacts of the various options presented in this Impact Assessment therefore mainly concerns impacts on **health and safety of consumers**, **impacts on economic operators** and **costs related to the level of implementation and enforcement related to the various options**, which are further developed underneath.

Figure 9: Licit and illicit drugs ordered by their overall harm score

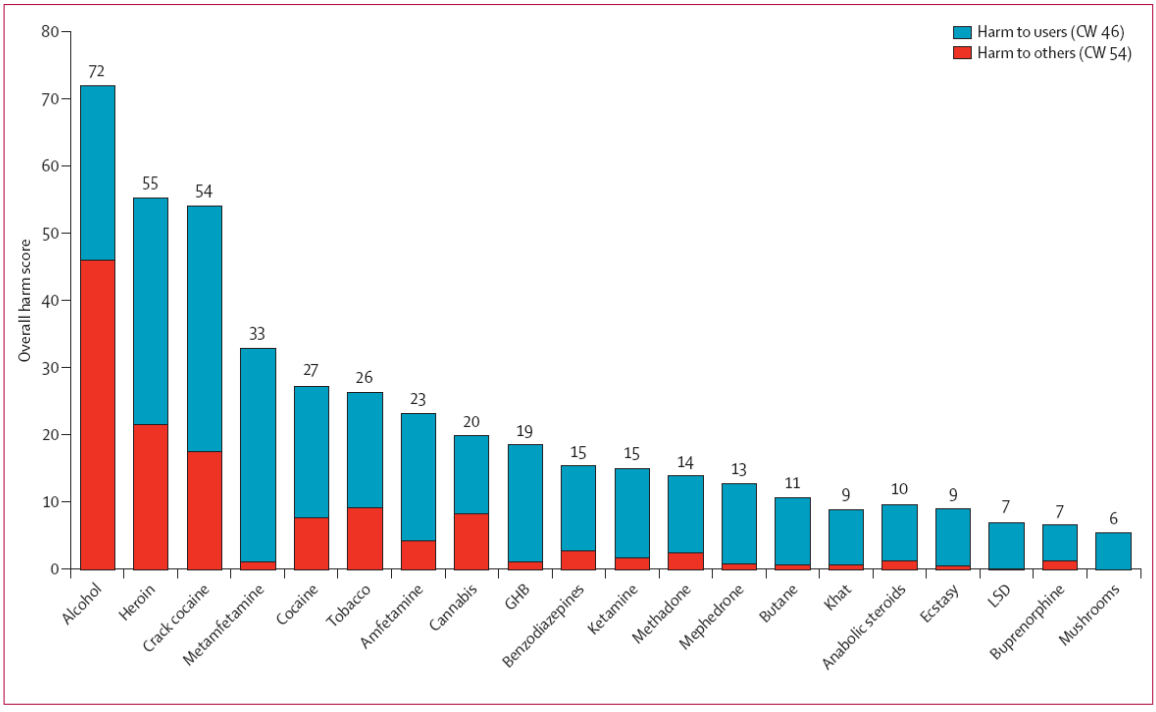

Figure 2: Drugs ordered by their overall harm scores, showing the separate contributions to the overall scores of harms to users and harm to others
The weights after normalisation (0–100) are shown in the key (cumulative in the sense of the sum of all the normalised weights for all the criteria to users, 46; and for all the criteria to others, 54). CW=cumulative weight. GHB=γ hydroxybutyric acid. LSD=lysergic acid diethylamide.

Source: D. Nutt et alii, "Drug Harms in the UK: a multicriteria decision analysis", available in: The Lancet, November 1, 2010; DOI: 10.1016/S0140-6736(10)61462-6

Cost of harm

In 2002, the UK Home Office report on the economic and social costs of class A drug use[128] assessed costs for various groups of users. For recreational users, the group mostly associated with the use of new psychoactive substances, the report identified an average **direct** health-related cost[129] per user of £60 (at 2000 price levels). Corrected for an average inflation of 2.25% per year, this equals £80 or €96 for current price levels. When applying this to the estimated number of users of new psychoactive substances in the EU (2.2 million users - last year prevalence), **the EU health-related costs of new psychoactive substances could be €211 million per year.** Also, whilst it is not possible to quantify, it can be assumed that there are productivity losses and arrests (for use of new psychoactive substances banned or when it is not clear whether the person has used an illicit or legal substance). These numbers are rough estimations and are only used for reference purposes in this Impact Assessment report. Prices presented concern UK figures, which are probably at the high end of the EU averaged.

3) Impacts on market operators

a) Impacts on operators in the market for legitimate uses

The variety of restriction measures on new psychoactive substances has a direct negative impact on economic operators in the market for legitimate uses of new psychoactive substances. This is because such measures can create obstacles to trade, generate legal uncertainty, market fragmentation, an uneven level playing field, and in some case may prevent companies from placing a substance on the market for legitimate purposes.

However, because of the limited information on the market and its scale, it is not possible to quantify this impact. The operators consulted in the context of this report were not able to provide a reliable quantification of the impact of the existing restriction measures on their business or on a specific substance. However, they consider that this impact is significant in some niche markets. In addition, because these substances are used for manufacturing other substances which are used for manufacturing a variety of products, restriction measures have a chain-reaction impact on various businesses and markets.

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128 Home Office Research, Development and Statistics Directorate, *The economic and social costs of Class A drug use in England and Wales, 2000*, 2002. Young recreational users are at risk from toxicity and overdose which exceptionally lead to death. In 2000, 20 ecstasy-related deaths were reported. The total social cost of each death was estimated at £ 1,144,890 in 2000. There is evidence of some causal association between productivity loss and recreational drug use but no data are available to estimate these effects. There is no evidence of impact on unemployment. There is no evidence of a causal relationship between acquisitive crime and younger recreational drug use, apart from acquisition/possession. The cost of a drug possession arrest is valued at £ 1,346.

129 Medical and ambulance costs, human costs (death) and loss of outputs (loss of productivity).

b) Impacts on operators in the market for recreational use

Although the size of the EU market of new psychoactive substances for recreational purposes is estimated at €542 million, important differences exist between Member States. One of the companies trading in "room odorisers" that was consulted for this report indicated that it had an annual turnover of approximately €1 million in this trade, with a 50% profit margin before taxation. This company claimed it was one of the two companies trading in the Dutch market. However, new psychoactive substances are not very popular in the Netherlands. It can be expected that in other countries, such as the UK and Ireland, similar companies would have a larger turnover. A report drawn up by the Irish authorities also indicated that certain head shops in the country had an annual turnover of €1 million.

The impact of measures restricting the production, trade and distribution of a new psychoactive substance depend on its share of the market. Mephedrone, which was submitted to control measures in 2010, had a relatively large market share, probably bigger than that of BZP when it was banned in 2008. BZP was also banned in New Zealand in 2007, after it achieved an estimated market value of 25-29 million NZ dollars (24 million tablets were sold every year, making it the fourth most consumed psychoactive substance in the country[130]). When it was controlled, its use decreased sharply, as it was replaced by new products.

Information received from a head shop owners association in Ireland[131] indicated that prior to government intervention which subjected a large number of new psychoactive substances to control measures and criminal sanctions, there were 100 head shops in the country with an average turnover of €200.000 to €400.000 per year, adding up to an estimated turnover of app. €20 million to €40 million per year. These shops typically sold 20 to 30 different types of 'legal highs' and employed over 500 staff. After the government intervention, 90% of shops were closed, and turnover for the remaining ten shops may have dropped dramatically by almost 95% to app. €1 million to €2 million. The existence of head shops and outlets selling new psychoactive substances has been reported in over ten EU Member States. However, the exact number of head shops or outlets in each country is unknown. In the Netherlands, it is estimated that the number of head shops is close to 100 nationwide.

The head shop owners association in Ireland has indicated that a more selective approach, restricting sale or controlling some new psychoactive substances would have had less impact on these businesses. This view is backed up by the association of Dutch head shop owners[132].

130 P. Reuter, *Options for regulating new psychoactive drugs: a review of recent experiences*, 2011.

131 Alternative Traders of Ireland, response to a stakeholder survey, April 2012.

132 Association National Platform Smart products, response to a stakeholder survey, April 2012.

4) Impacts on Member States

a) Impact on budget

Given the fact that new psychoactive substances can be sold freely on the consumer market until they are regulated or made subject to control measures, those substances sold over the counter through physical outlets and – normally – through websites are taxed with VAT, while legitimate businesses also pay income taxes and social security contributions. Prior to the intervention of the government in 2010, Irish head shops paid VAT (21%) and income tax. Based on the estimations of a turnover of €20 to €40 million per year, these shops paid € 3.5 million to €7 million on annual basis in VAT. In 2009, the overall average annual gross wage in Ireland was €39,772 per year. Assuming that jobs in head shops are paid below average and concern mostly single and younger staff, according to OECD figures[133] the average income for this group may equal 67% of €39,772 = €26.647. The tax wedge[134] for this group in 2009 was app. 22% of the gross annual salary, or €5.862 per worker. Assuming that the 500 staff were in full time jobs, the revenues for income tax and social security may have added up to 500 x €5.862 = €2.93 million per year.

The intervention in 2010 may therefore have reduced annual tax revenues for the Irish fiscal budget of € 3.15 million to €6.3 million in VAT revenues. Assuming that the reduction in the number of head shops and annual revenues would have affected the total number of employed staff in head shops in a similar way, the loss of revenues in terms of income tax and social security contributions may equal 90-95% of the situation prior to 2010, or €2.6 to €2.8 million per year. The total loss impact for the state budget of the government intervention in 2010 may therefore equal app. **€6 million** to **€9 million** per year.

The above is an example of the impact on Member State fiscal budget in case of a dramatic clampdown on retail outlets in one specific Member State. The impact on the budget of the restricted sale or control of one specific substance is likely to be smaller. In case of a substance with the prevalence of mephedrone, the impact may be considerable. In case of less prevalent substances, the impact will be smaller. At the same time, evidence also suggests that popular substances that shift to the illicit market often return at a higher price (in case of mephedrone in the UK, the price on the illicit market almost doubled compared to when the substance was legal). A popular, but controlled substance may therefore provide higher revenues to the illicit market.

b) Costs of implementation and enforcement

The implementation costs per substance for the enforcement of the temporary emergency measure, restriction measures backed by either administrative or criminal law are overall limited as use will be made of existing enforcement and information mechanisms.

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133 http://www.oecd.org/document/40/0,3746,en_33873108_33873500_45143016_1_1_1_1,00.html

134 Tax wedge: average income taxes plus employee and employer social security contributions minus cash transfers as a percentage of total labour costs.

The **additional cost** of restricting one additional substance will most likely be marginal and will vary per country, depending on the channels through which substances are sold and the number of shops. New psychoactive substances are sold through head shops, but in some countries also in bars and clubs or in herbal/health shops. In the national stakeholder survey conducted for this Impact Assessment, almost half of the Member States indicated that they had head shops[135]. In countries where drug control legislation is primarily used to restrict the market for or withdraw new psychoactive substances, existing inspection agencies may be attributed the task to implement decisions as presented under the policy options.

The Commission's standard cost model provides specific figures on the expenditure of public authorities for various tasks. The inspection or control of economic operators in the market for new psychoactive substances may – depending on the type of outlet and legal status of the substance – be the task of food/product safety inspectors, health sanitary inspectors or the police. Furthermore, in case of market withdrawal and import and export bans, customs and border guards will also be involved. The average unit cost for professionals in these areas is estimated at €32 per hour.

All EU Member States have food and safety inspectorates, medicines authorities, consumer safety agencies and police services in place. In case Member States need to introduce checks on their territory following a temporary or permanent market withdrawal, the enforcement costs will depend on the presence and number of head shops and other sales channels in a country. If inspections are conducted with four inspectors, including preparation time, visiting and reporting, such a check may cost 4 x 8 hours x €32 = €1,024 per shop. For the Netherlands, which has around 90 to 100 head shops, the enforcement cost would be approximately €82,160 to €102,400. The Polish crackdown in 2010 involved the simultaneous checking of 1,300 head shops, which may have required an estimated amount of €1,331,200. In Ireland, before 2010 (100 head shops) controls would have cost €102,400, while after 2010 this cost may be €10,240 on an annual basis (ten shops).

In case samples are taken from sale outlets, this may require further expenditure for forensic testing and reporting (between €100 and €150 per sample). In Poland, 12,000 samples were seized - 10 per shop - of which 8,000 were tested. The testing costs reached more than €8 million, but the Polish operation was exceptional and not representative for the EU situation.

[135] AT, BG, CR, DE, HU, IT, LV, NL, SI, UK and IE.

Table 10: Breakdown of additional costs for enforcement and inspections

Number of outlet in Member States	Cost of inspection in € (annual basis; € 1.024/ outlet)	Cost of inspection incl. samples in € (10 samples/ outlet; € 100/ sample)	Total cost of enforcement/inspection in € (annual basis)
10	10,240	10,000	21,240
50	51,200	50,000	106,200
100	102,400	100,000	212,400
500	512,000	500,000	1062,000

The above does not mean that these additional costs are incurred in full with the restriction or control of every new substance.

c) Costs of consequences of enforcement

If new psychoactive substances were all made illicit, this may have a considerable extra cost for law enforcement. The prevalence of use of illicit drugs is lower compared to that of licit substances like alcohol and tobacco, while the enforcement costs (policing, anti-trafficking) are high. Although new psychoactive substances have a different risk potential, when made illicit, the enforcement costs will be considerable, irrespective of their actual harms.

In 2009, approximately 912,416 arrests were reported in the EU for offences related to possession or use of cannabis, heroin, cocaine, amphetamines and ecstasy[136] while 169,608 arrests were reported for drug trafficking, production, selling. For ecstasy, 4,938 arrests were reported for trafficking and 11,191 arrests for use or possession - 16,129 arrests in total.

According to data from Eurostat and the European Commission for the Efficiency of Justice (CEPEJ) of the Council of Europe, a drug possession arrest is valued at £1,346 or €1,615 per case on average in the EU. Hence, cases brought to the prosecutor would cost approximately €26 million per year. Most cases for possession or use are dealt with through administrative sanctions. Reoccurring offenders may be prosecuted further. If 80% of the drug supply cases and 20% of the possession/use cases are followed by a court procedure (6,189 cases), at a rate of on average €6,000 per court case, this brings another €37 million in costs.

For drug supply offences no data exist on how many cases actually result in incarceration. If it is estimated that 20-30% of the cases going to court result in a prison sentence (1.857-3.095 cases), at a rate of €43.833 per incarceration per annum, this adds up to €54 to €81 million per year. For ecstasy, the cost of the criminal justice system may therefore be estimated at **€117 million** to **€144 million** per year.

136 EMCDDA Statistical Bulleting 2011.

These rough estimates are subject to many uncertainties. However, they give an indication of the possible cost of restriction measures on a prevalent new psychoactive substance. The prevalence of mephedrone was – in certain countries – almost equal to that of ecstasy. At the same time, a reduction of use would follow the introduction of restriction measures, which would offset some of these costs.

Annex 6 – Most frequently identified new psychoactive substances/"legal highs" on sale and prices in 2011

New psychoactive substance/'legal high'	Number of shops identified		Nature	Price for 10 g (EUR)
	July	January		
Kratom	128	92	Natural	6–15
Salvia	110	72	Natural	6–12
Hallucinogenic mushrooms	72	44	Natural	10–14
MDAI (aminoindane)	61	45	Synthetic	100–110
Methoxetamine (arylcyclohexylamine)	58	14	Synthetic	145–195
6-APB (benzofuran)	49	35	Synthetic	230–260
4-MEC (cathinone)	32	11	Synthetic	120–200
MDPV (cathinone)	32	25	Synthetic	115–239
Cactus	30	17	Natural	20–40 (plant)
Methiopropamine (thiophene)	28	5	Synthetic	115–130
5-IAI (aminoindane)	27	25	Synthetic	95–120
Dimethocaine (benzoate)	27	22	Synthetic	85–150
Methylone (cathinone)	26	17	Synthetic	76–130
5-APB (benzofuran)	23	6	Synthetic	250–330
AM-2201 (cannabinoid)	22	1	Synthetic	180–210
JWH-018 (cannabinoid)	20	5	Natural	200–230
JWH-250 (cannabinoid)	19	4	Natural	110–195
AMT (tryptamine)	19	13	Synthetic	230–460
MDAT (aminotetralin)	18	22	Synthetic	110–130
Mephedrone (cathinone)	18	23	Synthetic	120–200
JWH-122 (cannabinoid)	17	4	Synthetic	50–55 / 200–240
Ayahuasca (active principle DMT)	17	10	Natural	15–30 (kit)
4-FA (phenethylamine)	17	2	Synthetic	120–200
3,4-DMMC (cathinone)	16	3	Synthetic	90–200
Hawaiian baby woodrose (active principle lysergamides)	16	10	Natural	4–8 (10 seeds)
GBL (GHB related)	15	12	Synthetic	35–45 (½ litre)

Source: EMCDDA, Online sales of new psychoactive substances / 'legal highs': summary results from the 2011 multilingual snapshots, 2011

Annex 7 – Categories of adverse effects of substances' use

Category	Type	Example
Physical harm	Acute	Fatal poisoning, cardiac arrest
	Chronic	Psychosis, lung diseases
	Intravenous harm	Blood borne infections (HIV/ Hep)
Dependence	Intensity of pleasure	High pleasure encouraged repeated use; risk of tolerance
	Psychological dependence	High dependence potential, more difficult to withdraw
Social harms	Intoxication	Accidental damage
	Other social harms	Violence
	Health care costs	Emergencies, illnesses

Source: D. Nutt and alii, "Development of a rational scale to assess the harm of drugs of potential misuse", in: The Lancet, Vol. 369, n. 9566, p. 1047-1053

Annex 8 – List of new psychoactive substances that may have or have legitimate uses (as of 12 June 2012)

1. Medicines notified and monitored by the EWS

Zopiclone– notified by UK in May 2012: Zopiclone (ATC code N05C F01) is a non-benzodizepine hypnotic/sedative 'Z-drug' that belongs to the group of cyclopyrrolones. It is authorised as a medicinal product in the UK since 1993 and other EU Member States, such as France since 1987 to treat insomnia.

Glaucine – notified by UK in 2007: It is a plant derived substance, chemically related to the opioids and an Active Pharmaceutical Ingredient of the anti-tussive (i.e. used to suppress or relieve cough) medicinal product Glauvent which is manufactured and marketed in Bulgaria and perhaps in certain eastern European countries.

DXM – monitored since 2002: Dextromethorphan is the d isomer of the codeine analogue levomethorphan (a potent narcotic analgesic), but it has no analgesic properties. It is one of the active ingredients in many cold and cough medicines, such as Mucinex DM, Robitussin, NyQuil, Dimetapp, Vicks, Coricidin, Delsym, and others, including generic labels.

5-HTP – notified by DE in 2011: 5-Hydroxytryptophan (5-HTP), also known as oxitriptan (INN), is a naturally-occurring amino acid and chemical precursor as well as metabolic intermediate in the biosynthesis of the neurotransmitters serotonin and melatonin from tryptophan. It is marketed in many European countries for the indication of depression under names like Cincofarm, Levothym, Levotonine, Oxyfan, Telesol, Tript-OH, and Triptum.

Benzydamine – monitored since 2007: Benzydamine hydrochloride is reportedly a CNS stimulant and hallucinogen with local anaesthetic and analgesic properties, that is used as anti-inflammatory and pain reliever, and which can be bought without medical prescription in certain EU countries.

Pregabalin – notified by FI in 2009: Pregabalin is a prescription medicine (centrally authorised in the EU) marketed by Pfizer under the trade name Lyrica, used to treat several conditions, including neuropathic pain, epilepsy, and anxiety.

Phenazepam – notoified by DE in 2011: Phenazepam is a benzodiazepine not currently controlled under the UN Conventions, which was developed in the 1970s for the treatment of epilepsy, alcohol withdrawal syndrome, insomnia, and anxiety, and which is currently prescribed only in Russia and some countries of the former Soviet Bloc.

Phenibut – notified by SE in 2012: Phenibut is a derivative of the naturally occurring inhibitory neurotransmitter γ-aminobutyric acid (GABA) and, chemically, it has the parent structure of a phenethylamine. It was discovered and introduced into clinical practice in Russia in the 1960s for its anxiolytic and reported nootropic (cognition enhancing) effects. It acts as a GABA-mimetic at GABAB and to some extent at GABAA receptors. It also appears to be used as a food supplement or body building purposes.

Etizolam – UK – Dec 2011: Etizolam is a short-acting benzodiazepine marketed under the brand name Etilaam, Etizola, Sedekopan, Pasaden or Depas in some countries, which is used for the treatment of insomnia and anxiety disorders, and for which withdrawal symptoms have been documented. It has elimination kinetics between those of short-intermediate derivatives and ultra-rapidly eliminated benzodiazepines.

Ketamine – monitored since 1999: As an anaesthetic and analgesic, ketamine has a recognised unique therapeutic value in veterinary practice and, to a lesser extent, in human medicine.

GHB – monitored since 1998: Internationally controlled, a centrally authorised medicinal product at EU level (Xyrem).

2- Methoxyphenamine – UK – Nov 2011: 2- Methoxyphenamine acts as adrenergic beta receptor agonist and is used as a bronchodilator, marketed in some countries under a variety of different trades including Orthoxine and Casacol.

2. Substances with potential legitimate uses

Some of the substances below are based on modifications to known medicines or are metabolites of medicines.

1-Aminoindan – notified by FI in 2006: The anti-parkinsonian drug, rasagiline [N-propargyl-1-(R)-aminoindan; Azilect], is a secondary cyclic benzylamine and indane derivative, which provides irreversible, potent monoamine oxidase-B (MAO-B) inhibition and possesses neuroprotective and neurorestorative activities. A prospective clinical trial has shown that rasagiline confers significant symptomatic improvement and demonstrated alterations in Parkinson's disease progression.

Ostarine – notified by SE in 2011: Ostarine is a tissue-selective androgen receptor modulator (SARM), which is under development by GTx for the prevention and treatment of muscle wasting in patients with non-small cell lung cancer. It belongs to a novel class of androgen receptor targeting agents which exhibit in vivo activity for an androgenic and anabolic activity of a nonsteroidal ligand for the androgen receptor. These agents may be active alone or in combination with progestins or estrogens. They may be used for oral testosterone replacement therapy, male contraception, treating and imaging prostate cancer.

4-benzylpiperidine – notified by BG in 2011: 4-benzylpiperidine is a substituted piperidine, which acts as a monoamine dopamine-selective releaser and is expected to exhibit stimulant effects (piperidine is internationally controlled).

Ethylphenidate – notified by UK in 2011: Ethylphenidate belongs to the piperidine chemical class. It is a methyl analogue and a metabolite of methylphenidate, which can be formed via hepatic transesterification when ethanol and methylphenidate are coingested. Racemic methylphenidate hydrochloride is commercialised by Novartis under the name of Ritalin and used in the treatment of attention deficit hyperactivity disorder (ADHD).

3-amino-1-phenyl-butane – notified by BE in 2011: It is a metabolite and a precursor of Labetalol, an alpha/beta adrenergic antagonist which is used to treat high blood pressure and angina pectoris, and whose teratogenicity has been studied in animals. It is also a doping metabolite.

Etaqualone – notified by DK in 2009: Etaqualone is an analogue of the medicine methaqualone (internationally controlled). Methaqualone was developed in the 1960s and marketed mainly in France and some other European countries.

DMAA – notified by IE in 2010: DMAA is reported to be used as food dietary supplement and also as a nasal decongestant, treatment for hypertrophied or hyperplasic oral tissues and general purpose stimulant. The U.S. Food and Drug Administration issued in April 2012 warning letters to ten manufacturers and distributors of dietary supplements containing dimethylamylamine, more popularly known as DMAA, for marketing products for which evidence of the safety of the product had not been submitted to FDA. Also referred to as 1,3-dimethylamylamine, methylhexanamine, or geranium extract, the ingredient is in dietary supplements and is often touted as a "natural" stimulant.

Arecoline – notified by UK in 2010: Reported to be used as a veterinary purgative.

Desoxy-D2PM – notified by UK in 2010: 2-(Diphenylmethyl)pyrrolidine (desoxy-D2PM) is structurally related to desoxypipradrol (2-DPMP) and diphenylprolinol (D2PM) and therefore it is expected to exhibit stimulant effects. In turn, desoxypipradrol is a derivative of pipradrol, which is listed in Schedule IV of the 1971 UN Conventions. 2-(Diphenylmethyl)pyrrolidine is a chiral agent in NMR analysis and has been reported in certain 'body-building' products, and is commercially available from Sigma-Aldrich.

Camfetamine – UK – Nov 2011: Camfetamine is the N-methyl analogue of fencamfamine. Fencamfamine is a central nervous system stimulant which acts as a dopamine uptake inhibitor and increases locomotor activity. It was developed by Merck in the 1960s under the name of Reactivan® for the treatment of depressive day-time fatigue, lack of concentration and lethargy, in individuals with chronic medical conditions.

4-fluoroephedrine – notified by UK in 2012: 4-Fluoroephedrine is the 4-fluoro derivative of ephedrine – a sympathomimetic alkaloid of plant origin that increases the activity of noradrenaline on adrenergic receptors, and which is used as a stimulant and appetite suppressant.

1-ethynyl-cyclohexanol (ECX) – UK – Mar 2012: 1-Ethynyl-cyclohexanol (ECX) is a precursor and metabolite of Ethinamate (1-ethynylcyclohexanolcarbamate). Ethinamate is a short-acting carbamate derivative with mild sedative and hypnotic properties, used in the past to treat insomnia, which is under international control (Schedule IV of 1971 UN Convention).

ODT – DE – Jun 2009: ODT is a centrally acting synthetic opioid analgesic. It is a metabolite of tramadol and a potent μ-opioid agonist. Tramadol is a centrally acting synthetic opioid analgesic used for the treatment of moderate to severe pains, which was introduced in Germany in 1977.

CPCPP – AT – Sep 2007: CPCPP is possible that it is a metabolite of a medicinal product - the anti-depressant Nefazodone.

1-(3-chlorophenyl)piperazine (*m*CPP) – monitored since 2004: *m*CPP is used for neurochemical and psychiatric research and for the synthesis of trazodone and possibly several other related medicinal products. For this reason, although the EMCDDA and Europol produced a joint report on this substance, no risk assessment was conducted. *m*CPP is a metabolite of the psychoactive compound Trazodone, a serotonin modulator with sedative and antidepressant properties.

BZP – monitored since 1999: Human studies were carried out the 1970s to investigate BZP as a potential antidepressant drug. In veterinary, BZP has reportedly been marketed as a product for treatment of respiratory ailments in horses.

3. Plants

Kratom – monitored since 2007: Kratom (Mitragyna speciosa) is a 'traditional medicinal' leaf used in Southeast Asia. It contains many alkaloids including mitragynine (once thought to be the primary active), mitraphylline, and 7-hydroxymitragynine (which is currently the most likely candidate for the primary active chemical in the plant).

Salvia Divinorum – monitored since 2002: Salvia divinorum has been used traditionally in Mexico for healing and divination and became better known (available) in the early 1990's.

Kava – notified by UK in 2008: Kava is a banned substance in medicines and foods because of its hepatotoxicity.

Ibogaine – monitored since 2003: The hallucinogenic substance ibogain (12-methoxyibogamin) is extracted from plants, mainly Tabernanthe iboga. Ibogaine-containing preparations are used in traditional medicine and for ritual purposes in parts of Africa. It was first commonly advertised as having anti-addictive properties. In France it was marketed as Lambarene, a medical drug used for dieting.

4. Substances likely to have been researched for medicinal purposes

4-MTA – FR – Jan 2000: 4-MTA was originally synthesised as a potential antidepressant but at present it has no therapeutic use.

4-Methylamphetamine – BE – Dec 2009: 4-Methylamphetamine is a stimulant derivative of amphetamine, which was investigated in the past as an appetite suppressant and has serotonin, norepinephrine, and dopamine releasing properties.

AMT – monitored since 2001: AMT is a psychedelic amphetamine-tryptamine first developed in the 1960's for anti-depressant research, although it was never very successful as a prescription antidepressant.

Vanoxerine – BE – Apr 2007: Vanoxerine has been tested in clinical trials for treatment of cocaine addiction as it is believed to be a high affinity dopamine reuptake inhibitor.

JWH-015 – AT – Jul 2010: JWH-015 has been investigated in vitro as a novel therapeutic agent against non-small cell lung cancer (NSCLC).

CRA13 – DE – Jan 2011: CRA13 has undergone pharmacokinetics and safety human clinical trial phase I studies.

HU-331 – FR – Jan 2012: HU-331 has been researched for its high level of citotoxicity and low cardiotoxicity as an anticancer agent.

pFBT – FI – Dec 2008: pFBT is a synthetic-like derivative of cocaine, a tropane, which is reported to have stimulant and local anesthetic properties and seems to have been researched in the mid-1980's for potential neuroleptic activity.

5. Substances with other legitimate (chemical/industrial) uses

AM-694 – IE – Jul 2010: The radiolabelled isotop F(18) of AM-694 is used for mapping the distribution of CB1 receptors in the body.

AM-2233 – FI – Aug 2011: AM-2233 has been used as a selective radioligand for mapping the distribution of the CB1 receptor in the brain.

1-PEA – monitored since 2007: 1-PEA is a basic chiral amine, whose individual enantiomers are used for performing chiral resolution of acidic compounds by forming diastereomeric salts and as a chiral intermediate in synthesis.

Diphenylprolinol (D2PM) – UK – May 2007: Single stereoisomers of diphenylprolinol have been used on a large scale as chiral auxiliaries on an industrial scale.

TFMPP – monitored since 2001: TFMPP seems to be used as chemical intermediate in some syntheses. Some piperazine derivatives were originally evaluated as potential anthelminthic agents for the treatment of roundworm infestations in humans and animals, but were never developed. However, the parent compound piperazine is still licensed for this purpose.

Annex 9 - Information on the UN Drug Control Conventions

In case of a substance notified to the UN system under the **1961 Convention**, which covers **natural**, plant-based substances, the WHO assesses a) its potential to produce ill-effects in humans (e.g. toxicity) and b) its liability to abuse (potential for dependence). If the WHO finds that a substance has a risk potential similar to that of substances already listed under Schedules I or II of the Convention, it may recommend that the substance is scheduled accordingly. If the substance is part of a preparation with limited or no abuse, it may be recommended to schedule it under Schedule III of the Convention. If a substance has a risk potential similar to substances in schedule I or II, but that it also has no important therapeutic value, it may be recommended for listing under Schedule IV. The production, manufacture, import, export, trade in and possession of a substance under either Schedules IV, I and II of the Conventions is strongly restricted, while less strict rules apply for substances under Schedule III.

The UN system

Some 250 substances are listed in the Schedules annexed to the United Nations Single Convention on Narcotic Drugs (New York, 1961, amended 1972), the Convention on Psychotropic Substances (Vienna, 1971) and the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances (introducing control on precursors) (Vienna, 1988). The purpose of this listing is to control and limit the use of these drugs according to a classification of their therapeutic value, risk of abuse and health dangers, and to minimize the diversion of precursor chemicals to illegal drug manufacturers.

Narcotic drugs

Narcotic drugs are classified and placed under international control by the 1961 UN Single Convention on Narcotic Drugs, as amended in 1972. The Single Convention limits 'exclusively to medical and scientific purposes the production, manufacture, export, import, distribution of, trade in, use and possession of drugs' (art. 4c).

The annex to the 1961 Convention classifies narcotic drugs in four Schedules:

Schedules	**Harmfulness**	**Degree of control**	**Examples of listed drugs**
I	Substances with addictive properties, presenting a serious risk of abuse	Very strict; 'the drugs in Schedule I are subject to all measures of control applicable to drugs under this Convention' (art. 2.1)	Cannabis and its derivatives, cocaine, heroin, methadone, morphine, opium
II	Substances normally used for medical purposes and given the lowest risk of abuse	Less strict	Codeine, dihydrocodeine, propiram
III	Preparations of substances listed in Schedule II, as well as preparations of cocaine	Lenient; according to the World Health Organisation, these preparations present no risk of abuse	Preparations of codeine, dihydrocodeine, propiram

IV	The most dangerous substances, already listed in Schedule I, which are particularly harmful and of extremely limited medical or therapeutic value	Very strict, leading to a complete ban on 'the production, manufacture, export and import of, trade in, possession or use of any such drug except for amounts which may be necessary for medical and scientific research' (art. 2.5.b)	Cannabis and cannabis resin, heroin

Psychotropic substances

Psychotropic substances are placed under international control by the 1971 United Nations Convention on Psychotropic Substances. The objectives of this Convention are again to limit the use of these substances to medical and scientific purposes (arts. 5 and 7). While some psychotropic substances may have therapeutic value, they also present a dangerous risk of abuse.

The annex to the 1971 UN Convention on Psychotropic Substances also classifies substances in four Schedules:

Schedules	**Harmfulness**	**Degree of control**	**Examples of listed drugs**
I	Substances presenting a high risk of abuse, posing a particularly, serious threat to public health which are of very little or no therapeutic value	Very strict; use is prohibited except for scientific or limited medical purposes	LSD, MDMA (ecstasy), mescaline, psilocybine, tetrahydrocannabinol
II	Substances presenting a risk of abuse, posing a serious threat to public health which are of low or moderate therapeutic value	Less strict	Amphetamines and amphetamine-type stimulants
III	Substances presenting a risk of abuse, posing a serious threat to public health which are of moderate or high therapeutic value	These substances are available for medical purposes	Barbiturates, including amobarbital, buprenorphine
IV	Substances presenting a risk of abuse, posing a minor threat to public health with a high therapeutic value	These substances are available for medical purposes	Tranquillisers, analgesics, narcotics, including allobarbital, diazepam, lorazepam, phenobarbital, temazepam

Source: ELDD

The 1961 Convention also prescribes – in the case of substances for medical use – details for **labelling and packaging and advertisement**. The 1961 Convention allows certain exceptions for uses other than medical or scientific, including traditional uses (coca-leaves), the use of the cannabis plant for industrial purposes (fibre and seed, horticulture).

In case of a substance notified to the UN system under the **1971 Convention**, covering mainly **synthetic substances**, the WHO assesses a) its ability to produce a state of dependence, b) whether it has psychoactive effects, whether it has similar ill-effects or liability for abuse compared to substances already listed on Schedules I to IV of the Convention and subsequently assesses the degree to which the substance poses a public health or social problem, and its therapeutic value in medical treatments. On the basis of the recommendations made by the WHO, the UN system may decide to list the substance under Schedules I to IV of the Convention, which vary from very tight controls in Schedule I (licensing for very limited manufacture, trade and distribution; records; import and export licensing; prescription for supply or dispensing; provisions for criminal sanctions, etc.) to less stringent in Schedule IV (licenses for manufacture, trade and distribution; provisions for criminal sanctions).

The 1971 Convention also provides details for labelling and packaging and advertisement. It also allows other uses[137], but under strict conditions and requirements.

[137] Article 4: In respect of psychotropic substances other than those in Schedule I, the Parties may permit: a) The carrying by international travellers of small quantities of preparations for personal use; each Party shall be entitled, however, to satisfy itself that these preparations have been lawfully obtained; b) The use of such substances in industry for the manufacture of non-psychotropic substances or products, subject to the application of the measures of control required by this Convention until the psychotropic substances come to be in such a condition that they will not in practice be abused or recovered; c) The use of such substances, subject to the application of the measures of control required by this Convention, for the capture of animals by persons specifically authorized by the competent authorities to use such substances for that purpose.

Annex 10 – Procedures applied in the Member States for introducing measures on new psychoactive substances

Country	Duration of procedure for bringing new substance under control	Legal text produced
AT	6 months (due to "limit quantities" requirement)	Regulation of the Minister of Health
BE	About 1 year (standard procedure)	Royal Decree (for controlling new substances)
CY	6-12 months	Order of the Council of Ministers
CZ	Usually about 1 year	Law of Parliament
DK	2-3 days following recommendation of the National Board of Health	Regulation of the Ministry of Health and Prevention
DE	Standard listing: minimum 2 months (excluding preparations)	Standard procedure: Governmental Regulation
	Emergency listing: 1 week (excluding preparations)	Emergency procedure: Regulation of the Federal Ministry of Health
EE	Roughly 1 month	Regulation of the Minister of Social Affairs
EL	1-2 months (following notification from the National Focal Point)	Joint Ministerial Order of the Ministries of Health and Justice
ES	About 5-15 days for the Order's coming into force	Order of the Ministry of Health and Consumer Affairs
FR	Minimum 3 months	Decree of the Minister of Health
IE	Generic system: immediate / implicit control	Governmental Declaration Order
	Standard individual listing: about 1.5 months	

LT	National decision: 1-8 months	Decree or Order of the Ministry of Health
	If UN/EU decision: 1-2 months	
LU	Standard procedure: not used in practice	Grand-Ducal Decree
	Rapid procedure: 1-2 months	
LV	Neither the analogue system nor the individual listing system's standard procedure have yet been used in practice	Law amending the "Procedures for the Coming into force and Application of the Criminal Law" of Oct 2002
NL	Standard procedure: 3-6 months	Standard procedure: Order in Council
	Emergency procedure: 1 week (valid for 1 year)	Emergency procedure: Ministerial Regulation
PL	Standard procedure: minimum 9 months	Parliamentary Law (amending the Act of 29.07.2005 on counteracting drug addiction)
	Rapid procedure: about 6 months	
PT	Minimum duration of procedure: 1-12 months	Parliamentary Law (amending the Decree-Law 15/93)
RO	Approximately 4 months	Governmental Emergency Ordinance
SE	Standard procedure: 5-6 months	Governmental amendment to the Ordinance on the Control of Narcotic Drugs or Governmental amendment to the Ordinance on the Prohibition of Certain Goods Dangerous to Health
	Rapid procedure or international decision: immediate application	

SI	Approximately 2 months	(Governmental) Decree on completion of the Decree on the Classification of Illicit Drugs
SK	Standard procedure: at least 3 months	Parliamentary Law
	Rapid procedure: about 1 month	
UK	Generic system: immediate/ implicit control	Order in Council made by Her Majesty
	Standard individual listing: 2-3 months after opinion from the Advisory Council on the Misuse of Drugs	

Source: EMCDDA, Legal responses to new psychoactive substances, 2009

Annex 11 – Risk assessment mechanisms in the Member States

Reliance on EU RA	Use on ad-hoc basis	RA as part of general administrative practice	National RA in the main drug law
Belgium	Czech Republic	Latvia	Denmark
Greece	Ireland	Austria	Germany
Spain	Luxembourg	Romania	Estonia
Portugal	Poland	Slovakia	France
Bulgaria	Slovenia	Sweden	Netherlands
Malta	Croatia		UK
Slovakia			Finland
			Cyprus
			Hungary
			Lithuania

Source: EMCDDA, Legal responses to new psychoactive substances, 2009 and Early Warning System: National Profiles, 2012

Annex 12 – Approach on new psychoactive substances implemented by the Member States

Key: "X" denotes that the approach is currently implemented by the Member State; "*" denotes that the approach is currently being considered; "(*)" denotes that the approach is expecting to be considered in a short period of time

Member State	Type of legislation		
	Individual	Analogue	Generic
Austria	X	*	
Belgium	X		
Bulgaria	X	X	
Cyprus			X
Czech Republic	X		
Denmark	X		*
Estonia	X		
Finland	X		(*)
France	X		*
Germany	X		(*)
Greece	X		
Hungary	X		X
Ireland			X
Italy	X	X	
Latvia	X		
Lithuania	X		X
Luxembourg		X	

Member State	Type of legislation		
	Individual	Analogue	Generic
Malta	X		
Netherlands	X		
Poland	X	(*)	
Portugal			
Romania	X	(*)	
Slovakia	X		
Slovenia	X		
Spain	X		
Sweden	X		
United Kingdom			X

Source: results of the stakeholders' consultation and EMCDDA, Legal responses to new psychoactive substances, 2009

Annex 13 – Quantification of impacts

This annex presents a **detailed assessment and quantification** of the impacts of some options addressed in the impact assessment report. These impacts concern interventions concerning a substance, which has posed concerns at EU level. In the estimations, no account is taken of the fact whether a substance that is withdrawn from the market is immediately replaced by a similar one. Furthermore, the effect on health and safety (overdose, deaths, dependence, infections and crime) depends to a great extent to the type of substance that is being assessed, including its risk potential, its appeal to users, its method of administration.

Not all substances notified through the EWS are on the market at the same time or consumed in similar quantities. An EMCDDA briefing paper on online sales of new psychoactive substances[138] shows that, by July 2011, 26 substances were sold in 15 online shops or more, while 14 substances were sold in 25 online shops or more.

Reduction of health harms

The spread of certain psychoactive substances is sometimes referred to as an "epidemic". For certain substances that emerged in the past (e.g. heroin, crack cocaine) consumption rose sharply in the early stages, but then many light users desist while a small group become frequent and dependent users; the number of users may therefore decrease and level off when the susceptible population becomes smaller and certain adverse effects become known. Evidence suggests that prevention and enforcement may have some effect in the early outbreak of use of a new substance[139].

Mephedrone is presented as a case-study, because it was one of the most prominent new psychoactive substances in the EU market in recent years and was submitted to risk assessment and restriction measures at the EU level.

Recent studies suggest that the swift reaction of certain national authorities **had an impact on the overall levels of use** of mephedrone. The UK magazine *MixMag* annually conducts a drug survey among its readers, many of whom are regular clubbers and frequent users of psychoactive substances. In the table underneath, some of the trends regarding to mephedrone use among this atypical group of heavy users are presented, including 2010 data (before the substance was submitted to restriction measures in the UK).

Table 11 – Trends in mephedrone use among UK regular clubbers (MixMag drug survey)

Mephedrone use among clubbers	2010 (before ban)	2011 (after ban)	2012
Lifetime prevalence	42%	61%	N.A.
Last year prevalence	37.3%	51%	30%
Last month prevalence	33.6%	25%	N.A.

138 EMCDDA, *Online sales of new psychoactive substances / 'legal highs': summary results from the 2011 multilingual snapshots*, 2011.

139 European Commission, *A Report on Global Illicit Drug Markets 1998-2007*, 2009.

Nr. of days of use per month	4.5	2.7	N.A.
Price/ gram	€ 14.60	€ 23.10	€ 24.00
Availability	38% friend 33% online 24% dealer 5 % head shop	58% dealer 41% friend 1% website/ head shop	N.A.
Quality/ purity/ cut with something	60% excellent purity; 30% good; 8% fair; 2% poor 30% thought meph was cut with something	7% excellent purity; 32% good; 36% fair; 25% poor 80% thought meph was cut with something	49% thinks quality went down
Most common adverse effects after use			Agitation (23%), depression (41%), memory loss (24%), overheating (26%), extreme sweating (36%), teeth grinding (52%)

This shows that after the ban of mephedrone the last year prevalence for this substance among regular clubbers, which had initially peaked from 34% to 51%, declined to 30% in 2012, with the effect that the use of the substance was reduced. The 2011 survey also showed that the numbers of days of use in the past month dropped by 40% from 4.5 to 2.7 (from app. 54 to 32 days annually). Such a significant reduction among relatively heavy recreational users is likely to be reflected even stronger among the general population, who may also have less easy access to the substance. The survey also shows that the measures also had a significant effect on the sale through legitimate channels, i.e. head shops and internet, whose combined share dropped from 38% to 1% in less than one year.

However, restriction measures applied to a substance can have unintended consequences. The surveys do not reflect whether the reduction in the use of mephedrone has been compensated by increased use of other psychoactive substances, such as ecstasy or methylone. The involvement of criminal groups may increase – this is reflected in the doubling of sales of mephedrone through illicit drug dealers. The increase of the price per gram by 60% (from €15 to € 24) may reflect the market restructuring from licit to illicit. The price may fall again once this process has been finalised, as has been the case with other illicit substances.

Furthermore, the reports on strongly reduced purity or quality due to additions of cutting agents to the typical consumption dosages, may pose other, potentially serious health risks as the cutting agent is unknown and the (side-) effects of these newly added components may be equally or even more harmful than mephedrone itself. And as indicated earlier in this report, it has been suggested that during the peak in the use of mephedrone in the UK, a decrease in cocaine-related deaths occurred. If related to the increase in mephedrone use, this development could be seen as an unintended positive outcome of the use of mephedrone.

The conclusion is that a relatively fast response of authorities on certain new psychoactive substances may have a significant impact on their sale and availability on the legal market, and have an impact on health and social costs associated with it, although it is difficult to quantify these benefits. As the MixMag survey shows, heavy users reduced their use of the substance with on average 21 days (out of 54) per year, while the last year prevalence dropped with 20%. Data on the need for medical attention after the use of mephedrone were not available, but as the table above suggests, adverse effects following the use of mephedrone are experienced frequently. In the same MixMag survey, 2.5% of respondents mentioned that they had to seek medical attention after using synthetic cannabis products.

It can be expected that the differences in outcome for the reduction of health-related harms of new psychoactive substances will not show much difference when comparing the various relevant options. There may be a correlation between the options presented and the impact on social costs (criminalisation of certain behaviours, boost of illicit market in the substance).

Impact on economic operators in the recreational market

As indicated above, it is estimated that 10 to 15 new psychoactive substances are popular among consumers at any given time, although they may still differ considerably in terms of effects, risk potential and levels of use. When market restriction measures are introduced, backed by either administrative or criminal justice law, the consequence for economic operators is that the market in that specific substance is no longer accessible.

Mephedrone, which was very prevalent between 2008 and 2010, may have represented a share of 10-15% of the market for new psychoactive substances. Bringing it under control may have had a loss of income of approximately 10-15% of the total estimated market for new psychoactive substances in 2010-2011, therefore about €54 to €81 million**.** However, the number of new psychoactive substances that have a similar prevalence in the EU population is limited, and effects of measures on the market may be more likely in the range of 1-5% of the total market.

Impacts on economic operators in the market for legitimate uses

Measures restricting the production, trade and distribution of a new psychoactive substance will only affect the recreational use of these substances, since restrictions will not apply to the legitimate trade and use of a new psychoactive substance. Consequently, the measures will have no direct economic and financial impacts on market operators.

The production, distribution and use of new psychoactive substance for legitimate uses, for instance for producing a medical product or for industrial uses, is already regulated and addressed by relevant national or EU-level legislation. These set up various mechanisms for obtaining a licence or an authorisation to produce, trade or use the substance in that specific market. The cost of obtaining such authorisation is therefore not related to this instrument, but to the requirements of other existing relevant legislation. Overall, the restriction measures will not directly cause additional administrative costs to these market operators.

Assessment of options and quantification of impacts

Cluster 1 – improving knowledge of new psychoactive substances

The two alternative options compared to the status quo have the objective to increase the quantitative and qualitative information and analysis on new psychoactive substances notified through the Early Warning System, and to support the joint report and risk assessment processes. This will require initial investment in developing capacity and standard practices, a substance reference list, and training of experts in this area. After this initial investment phase, the maintenance costs would be reduced.

Option "Facilitating structural cooperation between the EMCDDA, research institutes and forensic laboratories"[140]

Funding component	**Activities (examples)**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
Enhancing forensic analysis of new psychoactive substances	Standardising analysis methods; enhancing collaboration; exchange of samples	100.000	100.000	100.000	50.000	50.000	50.000	50.000
Ad-hoc research on toxicology, pharmacology as part of JR/ RA (max 3 substances per year)	Laboratory testing of substances; including on toxicology, pharmacology, etc.	150.000	150.000	150.000	150.000	150.000	150.000	150.000
Pro-active research on specific (groups of) emerging NPS that do not yet pose EU level concern to better understand effects and properties	Laboratory testing of substances; including on toxicology, pharmacology	150.000	150.000	150.000	100.000	100.000	100.000	100.000
Development of a reference list on harms associated with licit and illicit psychoactive substances	Literature reviews; scientific panel; data collection; initial set up costs; updating the list (as of 2017)	75.000	75.000	75.000	30.000	30.000	30.000	30.000

140 These calculations have been based on expert opinion and on experiences with similar activities and projects funded under the Drug Prevention and Information Programme 2007-2013.

Development of standards and methods for monitoring, prevention and effective responses to the phenomenon of new psychoactive substances	Literature reviews; development of guidelines, of specific (rapid) survey protocols, of effective (emergency) information protocols, expert meetings	150.000	150.000	150.000	30.000	30.000	30.000	30.000
expert meetings to disseminate information	2 expert meetings (2x2 days) per year covering various tasks (EU and MS experts)	75.000	75.000	75.000	40.000	40.000	40.000	40.000
Total cost for the EU budget		**700.000**	**700.000**	**700.000**	**400.000**	**400.000**	**400.000**	**400.000**

Option "Establishment of an EU research infrastructure for new psychoactive substances" [141]

Funding component	**Cost type**	**2014**	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
Human resources (increase 3%/ year) – based on 2012 prices	1 research staff AD11	153.690	158.301	163.050	167.942	172.980	178.169	183.514
	4 lab and research staff AD 8	530.551	546.467	562.861	579.747	597.140	615.054	633.506
	2 support staff AST 3	114.456	117.890	121.426	125.070	128.822	132.686	136.667
Infrastructure and running costs lab (test materials/ etc)	Research equipment including: NMR spectrometer; high-resolution mass spectro-metry; GC-MS, and Ion Mobility Spectrometry (IMS); Thin Layer Chroma-tography (TLC) and a TLC MS	3.500.000	200.000	200.000	200.000	200.000	200.000	200.000

141 The infrastructural set-up components in this table have been based on the information provided through the preparatory study for this impact assessment (GHK Consulting, March 2012). All other costs have been based on the budget headings and staff composition in the budget of the EMCDDA for 2012-2013.

Buildings and operating expenditure (based on 2012 budget) – 2% increase/ year	Rental of buildings, ICT, movable property, administration, postal & telecom, social/ medical	157.100	160.242	163.447	166.716	170.051	173.452	176.921
Operational expenditure (based on 2012 budget) – 2% increase/year	Information, publishing, studies, missions	143.341	146.208	149.132	152.115	155.157	158.260	161.425
Procurement/ set up		500.000						
Total cost for the EU budget		**5.101.152**	**1.331.123**	**1.361.932**	**1.393.607**	**1.426.168**	**1.459.640**	**1.492.033**

Cluster 3: temporary emergency measures

Option "EU recommendation to introduce temporary emergency measures"

(a) Enforcement

The enforcement of a recommendation to introduce temporary emergency measures will have a limited impact on the Member States' budgets. This is based on the following assumptions:

– 14 Member States will implement the recommendation (new psychoactive substances represent a sizeable problem in roughly half of Member States, according to the 2011 Eurobarometer).

– One substance per year, which causes concern at the EU level, will be submitted to restriction measures.

– The enforcement cost of the restriction measures per substance per year depend on the existing national system for sanitary, food and product safety controls. The expenses related to the implementation of the temporary measure are therefore marginal and depend on the number of sales outlets for new psychoactive substance in the national territory.

(b) Harm reduction

It is estimated that the enforcement of the recommendation to introduce temporary emergency measures (in 14 Member States) will contribute to a reduction of health and social harms. It is not possible to quantify this reduction, but given the fact that the temporary measure is enacted in case of suspicions about the serious risk to health and safety posed by a specific substance, it can have **high** impact on the reduction of health-related harms; however, this is **likely to be reduced** because of the likely displacement of harmful substances between countries, because not all Member States are obliged and expected to introduce the restriction measure, since it is not binding.

Option "EU decision to introduce temporary emergency measures"

(a) Enforcement

The enforcement of a decision to introduce temporary emergency measures will have a limited impact on the Member States' budgets. This is based on the following assumptions:

– All Member States will introduce these measures.

– One substance per year, which causes concern at the EU level, will be submitted to restriction measures.

– The enforcement cost of the restriction measures per substance per year depend on the existing national system for sanitary, food and product safety controls. The expenses related to the implementation of the temporary measure are therefore marginal and depend on the number of sales outlets for new psychoactive substance in the national territory.

(b) Harm reduction

A decision to introduce temporary emergency measures will help reduce health and social harms. It is not possible to quantify this reduction, but given the fact that the measure is enacted in case of suspicion of serious risk to health and safety posed by a substance, the temporary measure can have high impact on the reduction of health-related harms.

Option "EU decision to submit substances to criminal law control measures or do nothing (status quo)"

(a) Enforcement

It is estimated that the enforcement of restriction measures backed by criminal law across the EU will have a maximum impact on the budgets of the Member States of **€117 to €144 million**. This is based on the following assumptions:

– All Member States will introduce the measures.

– One substance per year, which causes concern at the EU level, will be submitted to restriction measures.

– The enforcement cost of criminal law measures per substance per year involves arrests, prosecution, court cases and incarceration costs under the criminal justice system. The intensity of enforcement, and hence its cost, may vary depending on the type of substance, its prevalence and risk potential (also in terms of related crime). In analogy with the ecstasy market (see Annex 8), the maximum cost for the criminal justice system for a relatively prevalent substance is estimated to be between **€117 million and €144 million.**

(b) Harm reduction

It is estimated that submitting a prevalent new psychoactive substance to restriction measures backed by criminal law will help reduce health and social harms, although it is not possible to quantify this reduction. Because it can take a long time before such measures can be introduced, allowing a harmful substance to continue to be available in the market. For this reason, this option can have a **medium** impact on the reduction of health-related harms.

This option can have the following unintended consequences: increased health and social harms because a potentially harmful substance is not withdrawn quickly from the market and an increase of involvement of crime groups in the production and trade of the substance, after criminal law measures have been implemented. This involves additional risks because the quality and purity of the substance are likely to degrade after it becomes illicit.

Option "Status quo plus EU recommendation on permanent market restriction measures"

(a) Enforcement

It is estimated that the enforcement of this option will have an impact on the Member States' budgets of **less than €117 to €144 million**. This is based on the following assumptions:

– 14 Member States will apply the recommendations to introduce market restrictions while all will apply the criminal law measures.

– One substance per year, which causes concern at the EU level, will be submitted to restriction measures.

– The cost of implementing a recommendation to introduce market restriction measures is the same as for implementing a recommendation for temporary measures. The enforcement cost of the market restriction measures per substance per year depend on the existing national systems of sanitary, food and product safety controls. The costs related to the implementation of this option are therefore marginal and depend on the number of sales outlets for new psychoactive substance in the national territory.

– The maximum cost of implementing criminal law measures was estimated at between **€117 million and €144 million**. The possibility to introduce market restriction measures for those substances that do not pose high risks is likely to reduce the additional costs caused by the enforcement of criminal law measures.

(b) Harm reduction

It is estimated that the enforcement of the EU recommendation to introduce permanent market restriction measures (in 14 Member States) or of criminal law measures (in all Member States) can help reduce health and social harms. It is not possible to quantify this reduction, but given the fact that these restriction measures are enacted in case of moderate or serious concerns about the risk to health and safety posed by a specific substance, they could have a **high** impact on the reduction of health-related harms; however, this is **likely to be reduced** by the displacement of harmful substances between countries (since certain Member States would not apply the market restriction measures backed by administrative sanctions, which could not be binding) and by the risk of greater involvement of criminal group in the market.

Option "Status quo plus EU decision on permanent market restriction measures"

(a) Enforcement

It is estimated that the enforcement of this option will have a total impact on the Member States' budgets of **less than €117 to €144 million**, based on the following assumptions:

– All Member States will implement market restriction measures, whether backed by administrative or criminal law measures.

– One substance per year, which causes concern at the EU level, will be submitted to restriction measures.

– The cost of implementing a binding market restrictive measure (administrative) is bigger compared to that of a recommendation, because all Member States implement it. The enforcement cost of the market restriction measures per substance per year depend on the existing national system of sanitary, food and product safety controls in a country. The expenses related to the implementation of this option are therefore marginal and depend on the number of sales outlets for new psychoactive substance in the national territory.

– The cost of implementing criminal law measures was estimated at maximum between **€117 million and €144 million**. The possibility to introduce market restriction measures for those substances that not pose high risks is therefore likely to reduce the additional costs caused by the enforcement of criminal law measures

(b) Harm reduction

It is estimated that the enforcement of the EU decision to introduce permanent market restriction measures backed by either administrative or criminal law measures can help reduce health and social harms. It is not possible to quantify this reduction, but given the fact that the measures are enacted in case of moderate or serious risk posed by a substance, these measures could have a **high** impact on the reduction of health-related harms.