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Accompanying the document

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TABLE OF CONTENTS

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT SUMMARY

Accompanying the documents

Proposal for a

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

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1. INTRODUCTION

The Impact Assessment covers measures aimed at reducing the availability in the internal market of new psychoactive substances that pose risks to consumers, while preventing the emergence of obstacles to legitimate trade.

New psychoactive substances ('legal highs') are natural or synthetic substances that act on the central nervous system and modify mental functions. Many such substances have or could have other uses (**'legitimate uses'**), for instance as active substances for medicines. New psychoactive substances are not subjected to control measures under the UN Conventions on drugs, unlike psychoactive substances such as cocaine or amphetamines ('illicit drugs').

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. **Council Decision 2005/387/JHA** set up an EU-wide system for exchanging information on such substances, managed by the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and Europol, for assessing their risks and for submitting them to control and criminal penalties across the EU. The 2011 Commission assessment concluded that the Council Decision does not enable an effective response to the challenge posed by new psychoactive substances.

2. PROBLEM DEFINITION

New psychoactive substances, which are used for various legitimate uses, are increasingly available in the internal market and are consumed by a growing number of people. The potential **risks** that these substances pose have prompted authorities to submit them to various restrictions, which can **hamper legitimate trade** and hinder the development of licit uses. The main causes of the problems are divergent national approaches to new psychoactive substances and the ineffectiveness of the EU instrument tackling such substances.

2.1. The market for new psychoactive substances

Between 1997 and 2012, Member States reported 290 new psychoactive substances. A large majority were notified by several Member States. The pace of notifications has increased drastically in recent years – from 24 in 2009 to 73 in 2012. The number of substances that could potentially emerge may run into the thousands.

2.1.1. The market for recreational use of new psychoactive substances

The **levels of use of new psychoactive substances for recreational purposes have increased** in recent years and use is predominant among young people. The 2011 Eurobarometer survey "Youth attitudes on drugs" found that 5% of young people in the EU reported having used such substances at least once in their life, with a peak of 16% in Ireland.

The number of people who have used new psychoactive substances the last year is estimated to **2.2 million** in the EU. The **internet and social networks** have facilitated their spread across the EU - the EMCDDA's snapshot surveys have recorded a four-fold increase in the number of online shops selling such substances between 2010 and 2012 (from 170 to 690).

In the past three years, specialised shops selling new psychoactive substances have opened up in at least 13 Member States. Such substances are also sometimes sold in petrol stations, video rental stores, sex shops or tobacconists. Companies producing these substances are based **outside the EU** (China and India) and adapt rapidly to restriction measures by offering alternative substances. The size of the market for recreational use of new psychoactive substances is estimated, through analogy with the market for ecstasy, to **€0.5 billion per year**.

2.1.2. The market for legitimate uses of new psychoactive substances

Many new psychoactive substances that are used recreationally have or could have various uses in the **industry** - examples include GBL (gamma-butyrolactone), 1-4 BDO (1,4-butanediol) and *m*CPP. However, comprehensive information is not available across the EU, because the collection of such data is not foreseen under the existing EU mechanism and Member States' authorities do not report such uses systematically.

Since 1997, the EMCDDA has received information on legitimate uses for around **a fifth of the substances notified**. This is a significant proportion and it may be underestimated, considering that these new substances are often not well known. It is assumed that the **size of the market for legitimate uses is considerable**, because of the number of psychoactive substances that are present on the market, that may yet be launched and because of their potential for 'dual' (recreational use and use in the industry).

2.2. Problem 1: Risks posed by the recreational use of new psychoactive substances

The recreational use of new psychoactive substances may cause **harms to the health and safety of consumers**, and can pose risks to and burdens on society. The most common **harms to health** include agitation, delirium, tachycardia, hypertension, fatal overdose, spread of blood borne infections (such as HIV or hepatitis C), psychiatric problems, dependence. The risks are higher when several new psychoactive substances are consumed together, and in combination with illicit drugs or alcohol. Lack of information on the administration of these substances heightens risks.

Because they may affect mental health and social functioning, the frequent use of new psychoactive substances can have a **negative impact on society**, adversely affecting family life and communities. The use of such substances may impair the ability to drive a car, and could lead to violent behaviour and crime. Organised crime is involved to a limited extent in this market, mostly in selling such substances alongside illicit drugs.

The **cost** of health-related harms of new psychoactive substances is estimated at €211 million per year and that of enforcing criminal law measures at €117 million to €144 million per year.

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

The restriction measures introduced by public authorities to curb the recreational use of new psychoactive substances can **impede legitimate trade**, by making it more difficult for economic operators to get access to such substances, thus causing loss of business. They can also make research more difficult, therefore hindering the development of new uses.

Restrictions vary from one Member State to another and from substance to substance. Depending on the type of legislation used, only certain uses are allowed at national level, and lack of compliance is sanctioned by administrative or criminal law. This leads to obstacles to trade, **fragmentation and an uneven level playing field**, and makes it difficult for companies to operate across the internal market.

Restriction measures may have a **chain-reaction impact** on economic operators, because these substances are often used in the production of other substances and goods. Since the market for new psychoactive substances is likely to grow, and Member States are likely to introduce further measures to curb their recreational use, **the obstacles to legitimate trade are expected to increase**.

2.4. Causes of the problem

The underlying causes of the problem are:

- Divergent national approaches: the **differences** between the Member States' laws and uncoordinated national action may have adverse effects on economic operators in the market for legitimate uses and on consumers.

- The **EU legislation on new psychoactive substances is ineffective**: the Council Decision is slow and reactive, it provides insufficient evidence to take appropriate and sustainable decisions on substances, and it lacks options for restriction measures.

2.5. Baseline scenario

If the current framework remains unchanged, the **problems are likely to become worse**. The market for recreational use is likely to grow and possibly double by 2020. The health and social costs associated with a growing availability and use of harmful substances would increase proportionally. The market for legitimate uses is also expected to grow, and the adverse effects of divergent national approaches and of ineffective EU legislation on legitimate trade will continue and possibly intensify.

3. ANALYSIS OF SUBSIDIARITY

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, while Article 114(3) TFEU requires the Commission to aim at ensuring a high level of health, safety and consumer protection in these proposals.

The EU 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**). To tackle those substances that pose severe risks, the EU is empowered to bring them within the scope of criminal law provisions on illicit drug trafficking (**Article 83(1) TFEU**).

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, and to ensure that divergent national approaches do not hinder legitimate trade. **EU-level action is necessary** to allow harmful new psychoactive substances to be identified and withdrawn from the market quickly in all Member States and to reduce and prevent the emergence of obstacles to legitimate trade resulting from Member State action.

4. POLICY OBJECTIVES

The main **policy objectives** of the EU action on new psychoactive substances are:

- 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.

The **specific objectives** are:

- 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.

5. POLICY OPTIONS AND ASSESSMENT

The policy options have been grouped in **four clusters**, including the "status quo". The following options have been discarded: regulation of specialised shops and of online shops;

introduction of an EU-level authorisation system for new psychoactive substances; introduction of a blanket ban; discontinuation of EU action.

5.1. Overview of the policy options

Cluster 1: improving knowledge and analysis on new psychoactive substances

This cluster presents options for strengthening EU-level research and analytical capacities on new psychoactive substances, to enable the EU to provide a more effective response.

(1) Status quo

EMCDDA and Europol only collate and analyse information on composition or expected effects of substances as submitted by the Member States.

(2) Facilitating structural cooperation between the EMCDDA, research institutes and forensic laboratories

The EU provides financial support for structural cooperation between the EMCDDA, research institutions, including the Joint Research Centre (JRC) and forensic laboratories across the EU, to support the information needs on specific substances, and to help produce and disseminate analysis about new psychoactive substances.

(3) Establishment of an EU-level research infrastructure

A research infrastructure is established in an existing EU research facility (JRC) or agency (EMCDDA). It would have the same tasks as those mentioned under option (2).

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

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

(1) Individual approach (status quo)

Each substance is monitored and assessed individually and a decision on whether or not to introduce restriction measures is taken on the basis of the specific risks that it poses.

(2) Approach by group of substances

Entire groups of similar substances are monitored, assessed and submitted to restriction measures. The group is defined on the basis of similar chemical structure (generic approach) or pharmacological effect (analogue approach).

(3) Individual approach supported by information on an 'intelligently clustered' group of substances

Each substance is monitored, assessed and submitted to restriction measures individually (as under option (1)), but information is collected on other substances from the same group. Therefore, the emergence of certain substances can be anticipated, but a risk assessment will be conducted on each individual substance.

Cluster 3: temporary measures

This cluster presents options for restricting temporarily the availability on the consumer market of new psychoactive substances suspected to pose **immediate risks to public health,** evidenced by reported fatalities and severe health consequences associated with their consumption, as well as the prevalence of use of the substances in several Member States. The restrictions are in place pending the risk assessment of substances and do not apply to their commercial and scientific use, or to products containing the substance that have been authorised under other EU legislation.

(1) No temporary measures (status quo)

Under the Council Decision, there is no possibility to introduce temporary measures across the EU. 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.

(2) EU recommendation to introduce temporary measures

The Commission issues a recommendation to the Member States to introduce temporary measures to immediately withdraw a substance from the market and prohibit its distribution, sale, display or offering to consumers (industrial and scientific use would fall outside the scope of the restriction). Member States that implement the recommendation take the appropriate measures to ensure that the substance is withdrawn from the market.

(3) EU decision to introduce temporary measures

Same as (2), but the measures are binding on the Member States. The decision to introduce them is taken by the Commission through an implementing act. Infringement of these measures would entail administrative sanctions, determined at national level.

Cluster 4: final decision on a new psychoactive substance

This cluster presents options for addressing the substance once a risk assessment is completed. The Commission identifies the level of health, social and safety risk that a substance poses - low, moderate or severe - and determines if and what type of restrictive measure should be introduced. It will take the following **criteria** into account: harms to health caused by the consumption of the substance (injury, disease, and physical and mental impairment); social harms to individuals and society (e.g. on social functioning, organised crime activities, illicit profits); risks to safety (spread of diseases, impact on road safety).

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

On the basis of the results of the risk assessment, the Commission tables a legislative proposal to the Council requiring Member States to submit the substance to criminal law control measures (national laws applicable to illicit drugs apply to the new psychoactive substance) or justifies why this is not necessary. Since national laws on illicit drugs have to comply with Framework Decision 2004/757/JHA on drug trafficking, the provisions of the Framework Decision apply to the new psychoactive substance subjected to control. Only the exceptions for legitimate uses of the substance foreseen by the UN Conventions on drugs are allowed.

(2) Status quo plus EU recommendation to submit substances to consumer market restriction measures backed by administrative sanctions

The Commission has three alternatives for action: if a substance poses low risks, no restriction is introduced; if it poses moderate risks, the Commission recommends to the Member States to withdraw the substance from the market and prohibit its distribution, sale, display or offering to consumers (commercial and industrial use, as well as scientific use, are not be restricted); if it poses severe risks, criminal law provisions apply as in the status quo.

(3) Status quo plus EU decision to submit substances to consumer market restriction measures backed by administrative sanctions

Same as (2), but if a substance poses moderate risks the Commission adopts a decision to submit it to restriction on the consumer market, instead of a recommendation, which will be binding and will be introduced through an implementing act.

5.2. Assessment of policy options

Cluster 1: improving knowledge of new psychoactive substances

The status quo does not help achieve the policy objectives. It has low positive impacts on public health and safety, and low acceptability by stakeholders. It does not entail any additional costs to the EU or the Member States.

Structural cooperation between the EMCDDA, research institutes and forensic laboratories has a high positive impact. It makes EU action more effective by generating evidence on the harms of new psychoactive substances. It requires EU budget funding of around €3.7 million in 2014-2020. It enjoys high stakeholder acceptability.

An EU research infrastructure has the same impacts but is disproportionate because it costs €5.1 million to set up and €1.4 million per year to run. It meets low stakeholder acceptability.

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

The individual approach (status quo) has medium positive impact on policy objectives. It does not improve the effectiveness of EU action, since it does not enhance the EU capacity to anticipate market developments, but it has positive impacts on health and safety by providing robust evidence on the risks of each substance. It has a positive impact on operators in the market for legitimate uses because only harmful substances are restricted. It enjoys good acceptability by stakeholders.

The approach by groups of substances has medium positive impact on policy objectives because it helps anticipate market developments and has positive impacts on health and safety, but it has a negative impact on fundamental rights and on operators in the market for legitimate uses, as restriction measures can be introduced on substances despite lack of evidence about their harms. It entails low costs for the EU and the Member States and enjoys good stakeholder acceptability.

The individual approach supported by information on an 'intelligently clustered' group of substances has a high positive impact on achieving policy objectives because it combines the advantages of both approaches presented above. It has high impacts on health and safety and

brings no additional costs to the EU and the Member States. It has positive impacts on operators in the market for legitimate uses and enjoys high stakeholder acceptability.

Cluster 3: temporary measures

The lack of temporary measures (status quo) has high negative impacts on the achievement of policy objectives, since substances that are likely to cause harm continue being available on the market. It has low stakeholder acceptability.

An EU recommendation to introduce temporary measures has a medium positive impact on policy objectives, because harmful substances are quickly taken off the consumer market. However, the risk of displacement remains, since not all Member States are likely to implement the recommendation. It entails limited costs to EU and Member State budgets (linked to implementation). Operators in the market for legitimate uses will see their activities facilitated by a common approach to certain substances across the EU. The negative impacts on the business and certain fundamental rights of operators for recreational use are justified. It is proportionate and enjoys good stakeholder acceptability.

The impacts of an EU decision to introduce temporary measures are similar but intensified because all Member States implement it. It is more costly than a recommendation, but more efficient in reducing the risk of displacement and on achieving positive impacts on public health. The activities of operators in the market for legitimate uses will be facilitated by a common approach on certain substances across the EU. It is proportionate and enjoys high stakeholder acceptability.

Cluster 4: final decision on a new psychoactive substance

The status quo has low positive impacts on achieving policy objectives because, although it helps improve the consistency of national action, it does not allow tackling substances posing medium risks in a proportionate way. It has negative but justified impacts on fundamental rights. It raises proportionality concerns and acceptability by stakeholders is low.

Adding to the status quo the possibility to adopt EU recommendations on consumer market restrictions has medium positive impacts on achieving the policy objectives, as it enables a response that is more proportionate to the harms of substances. However, the risk of displacement remains. It has medium positive impacts on the protection of health and safety, and low impact on EU and national budgets (linked to enforcement). It also has positive impacts on operators in the market for legitimate uses, because their activity would not be affected by the restriction measures (medium risks) and certain uses would be authorised even in the case of severe-risks substances. The negative impacts on fundamental rights and on the business of operators in the market for recreational uses are justified. It is proportionate to the risks that substances pose and enjoys stakeholder acceptability.

Adding to the status quo the possibility to adopt EU decisions introducing consumer market restriction measures has similar impacts, but these are intensified because the decision is binding on the Member States. It is more costly than the previous option, but also more efficient in reducing the risk of displacement and the negative impacts of harmful substances on health and safety. It is proportionate and enjoys high stakeholder acceptability.

6. PREFERRED POLICY OPTION

A comparative assessment of the impacts indicates that the following combination of legislative and non-legislative options would be the most effective in achieving the objectives:

(1) **Facilitating structural cooperation between the EMCDDA**, research institutes and forensic laboratories.

(2) **Individual approach supported by information on an 'intelligently clustered' group** of substances.

(3) **EU decision to introduce temporary measures**.

(4) **Status quo plus EU decision to submit substances to market restriction measures backed by administrative sanctions**.

The preferred option has **high positive impacts on public health and safety**. It enables swifter EU action, because temporary measures allow substances raising immediate concerns to be withdrawn from the consumer market earlier and it shortens the time needed for adopting restriction measures (through implementing acts), which are directly applicable.

The preferred option **markedly improves the EU's capacity to anticipate developments** and provide adequate responses to new psychoactive substances. It has positive impacts on operators in the market for legitimate uses. Although it has negative economic and fundamental rights impacts on operators in the market for recreational use, these are justified by the need to address the risks posed by substances, and counterbalanced by the positive impacts on economic operators in the market for legitimate uses.

The preferred policy option **strikes the right balance** between the need to protect individuals and society from the risks posed by the recreational use of new psychoactive substances and the necessity to reduce obstacles to legitimate trade and prevent the emergence of such obstacles. It also helps **better connect the market for legitimate uses of new psychoactive substances with the internal market**. By providing for a more graduated and better calibrated set of options, proportionate to the levels of risks, it reduces the negative impacts of restriction measures on economic operators and consumers. The positive impacts of this policy option outweigh the costs to the EU and Member State budgets.

This option respects the principle of **subsidiarity** because it only addresses those substances that raise problems across the EU and leaves to the Member States the responsibility to tackle those that are a local problem. It 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.

7. MONITORING AND EVALUATION

The EMCDDA and Europol will report annually on the implementation of the instrument. The Commission will evaluate regularly its implementation, functioning, effectiveness, efficiency and added value. It will initiate an evaluation of the instrument every five years and submit the result to the European Parliament and the Council, proposing amendments if necessary.