

# Mechanisms and Methods for Placing New Psychoactive Substances under Control<sup>1</sup>

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**Abstract.** The article deals with the international and national mechanisms used to place new psychoactive substances under control. The authors provide an overview of the systems in use in the United Nations and the European Union, as well as in many European and other states, to criminalize newly emerging psychoactive substances, as well as propose certain legislative changes that could be adapted in the European Union to make the procedures of criminalization more straightforward. The article also provides for an overview and analysis of legal formulations used to define new psychoactive substances in different European and other states: list approach, generic scheduling, blanket bans, regulation through the laws on consumer protection and health protection, establishing legal markets for new psychoactive substances.

**Keywords:** new psychoactive substances; criminalization; drug policy.

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## Naujų psichoaktyvių medžiagų kontrolės mechanizmai ir metodai

**Santrauka.** Straipsnis skirtas apžvelgti tarptautinius ir nacionalinius mechanizmus, naudojamus įtraukti naujas psichoaktyvias medžiagas į kontroliuojamų medžiagų ratą. Autoriai apžvelgia Jungtinėse Tautose, Europos Sąjungoje, Europos ir kitose valstybėse funkcionuojančias naujų psichoaktyvių medžiagų kriminalizavimo sistemas, taip pat siūlo tam tikrus teisinius būdus kaip kriminalizaciją Europos Sąjungoje padaryti paprastesne. Straipsnyje taip pat apžvelgiamos ir analizuojamos teisinės formuluotės, Europos ir kitose valstybėse vartojamos naujoms psichoaktyvioms medžiagoms apibrėžti: katalogo metodas, kriminalizacija pagal bendrus požymius, visaapimantys draudimai, reguliavimas pasitelkiant vartotojų teisių apsaugos ir sveikatos apsaugos teisės normas, teisinių rinkų naujoms psichoaktyvioms medžiagoms kūrimas.

**Pagrindiniai žodžiai:** naujos psichoaktyvios medžiagos, kriminalizacija, narkotikų politika.

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### Introduction

The legal definition of new psychoactive substances as a tool for criminalization and control of this rapidly changing phenomenon has been under consideration both in many European states and on the international scale since 1920s already (Madras, 2017). However, developments taking place in chemistry, biology, pharmacology and related fields during the latest decades have placed the issues under consideration on the forefront of the control and prevention of drug abuse. By the end of 2016, the European Monitoring Centre for Drugs and Drug Addiction monitored more than 620 new psychoactive substances on the European drug market (EMCDDA, 2017), up to December 2017, more than 800 substances have been reported to the United Nations Office on Drugs and Crime Early Warning Advisory (EWA) on New Psychoactive Substances by Governments, laboratories and partner organisations. However, up to March 2017, the United Nations Commission on Narcotic Drugs decided to place only 27 new psychoactive substances under international control (United Nations Office on Drugs and Crime, 2018).

Changes in the markets of new psychoactive substances are extremely rapid. NPS detected only a year ago are no longer present on the market, and the majority are currently limited to few countries and available for a short period of time.

All the aforementioned determines the needs to search for the most effective procedures and methods to criminalize newly emerging psychoactive

substances in a timely manner to be of importance. Although the theme has attracted some attention in literature, comprehensive analysis of legal attitudes adapted in different states is lacking and this article is aimed to fill the gap.

## 1. The Term and Notion of New Psychoactive Substances

The term and notion of new psychoactive substances has not been universally accepted in the literature. NPS include herbal substances (e.g. mushroom-based substances) or substances of synthetic origin (e.g. mephedrone) (Winstock et al., 2010). The term „new“ does not always mean that substances have been produced recently and for the first time (Chatwin et al., 2017). Accordingly, NPS are considered to be substances that have existed for decades, but have recently become available to a wider circle of users or have recently become popular. The dangers of NPS stem from the fact that they represent a legal substitute for traditional drugs, because their effect is similar to that of controlled psychoactive substances (Deluca et al., 2012). It is about the legal substitution of traditional drugs, because at the moment of selling or consuming NPS, they are not on the list of controlled substances, which is why the people who import, manufacture, distribute or consume new drugs cannot be prosecuted. They are sold in specialized shops, the so-called „head shops“ (Alexandrescu, 2017). One of the main reasons for the huge popularity and increasing number of NPS on the drug market is exactly the legal status of NPS, because distributors and users of new drugs do not risk being prosecuted and punished (Soussan et al., 2018).

However, it has been pointed out in the scientific literature that the term „legal highs“ is inappropriate for several reasons: 1) the status of NPS in relation to the regulations governing this area means only current legality, in other words, it is only a matter of time when new drugs will be added to the list of banned substances; 2) the adjective „legal“ can mislead drug users regarding the ban on substance use, if they have been added to the list of controlled substances; 3) dealers misuse this name because they use it for marketing purposes, emphasizing no prosecution risk for users; 4) this term is misleading regarding the harmful effects of NPS because it gives the illusion that new drugs are not dangerous because they are „legal“ (Corazza et al., 2013).

## 2. New Psychoactive Substances: International Mechanisms of Criminalization

Most of the known opioids are enlisted as narcotic or psychotropic substances in the Schedules of the 1961 Single Convention on Narcotic Drugs (as amended by the 1972 Protocol), and 1971 Vienna Convention on Psychotropic Substances as subject to measures of control of different scope (International Narcotics Control Board, 2016). These documents are often referred to in legal acts both on the EU and national level of Member States (European Council 2001; European Council, 2005; Código penal de España, 1967; Forskrift om narkotika, 2013). Taking into account that both conventions establish that the Schedules are to be modified by the Commission on Narcotic Drugs of the Economic and Social Council of the United Nations without a special ratification of the changes by the UN Member States (Single Convention on Narcotic Drugs, 1961; Convention on Psychotropic Substances, 1971), it could be considered as one of the first examples of a universal legislative process. It should however be noted that some Member States of the EU (e.g. Malta, the Netherlands) do provide for a separate national procedure for the changes of the UN and EU schedules to have effect in the respective Member States (Dangerous Drugs Ordinance, 1939; Opiumwet, 1928). Many EU Member States (e.g. Lithuania or Slovenia) provide for the same procedure indirectly, i.e. without giving a direct link to the UN conventions and EU council decisions (Lietuvos Respublikos narkotinių ir psichotropinių medžiagų kontrolės įstatymas, 2019; Zakon o proizvodnji in prometu s prepovedanimi drogami, 1999).

These national approaches adopted could raise some doubts whether they are not in contravention to the aforementioned conventions itself. For example, the 1961 Single Convention on Narcotic Drugs (as amended by the 1972 Protocol), establishes that decisions of Commission on Narcotic Drugs of the Economic and Social Council of the United Nations “become effective with respect to each Party on the date of its receipt of such communication” (Art. 3, para. 7). The 1971 Vienna Convention on Psychotropic Substances is slightly less rigid in this regard. Art. 2 para. 7 of the Convention establishes that every decision of the Commission on Narcotic Drugs to enlist a new substance in one of the schedules “shall become fully effective with respect to each Party 180 days after the date of such communication”, however acknowledges a right

of every State Party to avoid new obligations arising from a certain decision if a State Party “has transmitted to the Secretary-General a written notice that, in view of exceptional circumstances, it is not in a position to give effect with respect to that substance to all of the provisions of the Convention applicable to substances in that Schedule.”

The aforementioned provisions of the 1961 Single Convention on Narcotic Drugs (as amended by the 1972 Protocol), and 1971 Vienna Convention on Psychotropic Substances could be considered to create a system where new psychoactive substances in every state signatory to the conventions are criminalized by a decision of an international body – the Commission on Narcotic Drugs of the Economic and Social Council of the United Nations (at least in states that directly link their laws on narcotic drugs to the schedules established by the convention).

A similar procedure has been created inside the European Union. The Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances establishes that decisions to submit new psychoactive substance to control measures are to be made by the Council qualified majority acting on an initiative presented by the Commission. Some Member States also follow the attitude formulated towards recognition of new narcotic and psychotropic substances in the UN conventions. For example, the Narcotics Act of Finland establishes that “the term ‘psychoactive substance’ prohibited on the consumer market includes substances used for drug use which may be hazardous to health and which have been notified for surveillance pursuant to the Council Decision” (Huumausainelaki, 2008). However, most of the Member States still consider the aforementioned decisions by the European Council as a basis for a separate national regulation to be passed, e.g. the Lithuanian Law on Control of Narcotic and Psychotropic Substances does not provide no alternative procedure for a new psychotropic substance to be placed under measures of control apart through a formal decision of the Ministry of Health (Narkotinių ir psichotropinių medžiagų kontrolės įstatymas, 2019). Member States that establish a special “emergency” procedure also follow the rule that a national legal decision to enlist certain new psychotropic substance as a substance under legal control shall be adopted, e.g. the Latvian law on the order of legal circulation of narcotic and psychotropic substances and drugs establishes that the lists of narcotic

and psychotropic drugs are to be established by the Government; however, the Center for Prevention and Control Diseases is empowered to decide that the manufacture, acquisition, storage, transportation, transfer or distribution of new psychoactive substances that are not included in Latvia's lists of narcotic drugs, psychotropic substances and precursors and on which information from the European Early Warning System has been obtained or an opinion of a forensic authority on new psychoactive substances has been received, can be restricted or prohibited for 12 months (Likuma par narkotisko un psihotropo vielu un zāļu likumīgās aprites kārtību, 1998).

It could be considered in the framework of this article whether it would be feasible to formulate a proposal for a new EU regulation on the lists of new psychoactive active substances. For now, the lists adopted on the EU level are to be modified through Council Decisions. The Consolidated Version of the Treaty on the Functioning of the European Union, Article 288, does not establish a direct applicability of the Council decisions (Consolidated version of the Treaty on the Functioning of the European Union, 2008). The Court of Justice of the EU, however, has recognized that some decisions may have direct applicability; however, in cases when they refer to an EU country as the addressee only (Judgement 10 November 1992, Hansa Fleisch), this is not the case with the Council Decisions on new psychoactive substances. Therefore, it could be feasible to provide for a system where the new psychoactive substances are acknowledged to be controlled substances through a regulation instead of a council decision. The Consolidated Version of the Treaty on the Functioning of the European Union, Article 288, establishes that every regulation shall be binding in its entirety and directly applicable in all Member States (Consolidated version of the Treaty on the Functioning of the European Union, 2008). An example of a similar regulation could be drawn from the Commission Implementing Regulation (EU) 2015/1998 of 5 November 2015, laying down detailed measures for the implementation of the common basic standards on aviation security (Text with EEA relevance) that *inter alia* enlists articles that are prohibited to be carried into security restricted areas of airports (European Commission, 2015).

As mentioned above, the schedules established by the UN convention and EU council decisions also serve as a basis for lists of controlled narcotic and psychotropic substances established by national legal acts; however, the scope

of the national acts differ, i.e., there are certain substances that are placed under measures of control in some Member States of the EU only (EMCDDA, 2008). The differences could lead to some questions in regard of the basic EU principle of mutual recognition. However, norms established in the legal documents of the European Union preclude the application of the principle towards narcotic and psychoactive substances. E.g. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, Article 83 states that the Directive “shall not prevent the application of more stringent requirements laid down by Member States in respect of the wholesale distribution of narcotic or psychotropic substances within their territory”. Similarly, Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances, Article 9, states that “nothing in this Decision shall prevent a Member State from maintaining or introducing on its territory any national control measure it deems appropriate once a new psychoactive substance has been identified by a Member State”. Moreover, the European Commission, although acknowledging that the principle of mutual recognition in respect of narcotic and psychotropic substances is to be applied on a case by case basis, still has put forward a position that “when competent authorities of a Member State intend to adopt a decision that could prohibit the marketing of those substances lawfully marketed in another Member State on other than safety or health grounds, the Regulation (EC) No 764/2008 should apply. This is the case, for example, when a psychoactive substance lawfully marketed in another Member State is denied for reasons based on the denomination, size, composition, etc.”

The aforementioned norms shall be considered as a sufficient argument for a statement that opioids acknowledged to be narcotic or psychotropic substances in one Member State can still stay outside the scope of control measures directed to narcotic and psychotropic substances in other Member States. However, it should also be noted that the EU documents cited still use terminology “narcotic or psychotropic substances” towards substances that are acknowledged to be controlled substances in one of the Member States only. Taking into account that the same documents refer to narcotic and psychotropic substances as “classified as a narcotic or a psychotropic substance within the

meaning of the international conventions in force, such as the United Nations Conventions of 1961 and 1971” only, some clarifications would be necessary.

### 3. Legal Definitions of New Psychoactive Substances: List Approach and Its Alternatives

The term “new psychoactive substances” covers wider array of substances than uncontrolled opioids only. Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances denotes that “‘new psychoactive substance’ means a new narcotic drug or a new psychotropic drug in pure form or in a preparation”, “‘new narcotic drug’ means a substance in pure form or in a preparation, that has not been scheduled under the 1961 United Nations Single Convention on Narcotic Drugs, and that may pose a threat to public health comparable to the substances listed in Schedule I, II or IV”, and “‘new psychotropic drug’ means a substance in pure form or in a preparation that has not been scheduled under the 1971 United Nations Convention on Psychotropic Substances, and that may pose a threat to public health comparable to the substances listed in Schedule I, II, III or IV”. The Council Decision takes out from the scope of these terms a) substances currently listed in any of the schedules to the 1961 United Nations Single Convention on Narcotic Drugs, and the 1971 United Nations Convention on Psychotropic Substances, b) precursors in respect of which Council Regulation (EEC) No 3677/90 of 13 December 1990 laying down measures to be taken to discourage the diversion of certain substances to the illicit manufacture of narcotic drugs and psychotropic substances, and Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors provide for a Community regime. The Council Decision establishes that new psychoactive substances are to be brought under measures of control by the Council through the initiative of the Commission which in its own turn should be based on Risk Assessment Report of the EMCDDA. What should be noted in this respect is that the Council Decision adopts the same “list approach” similar to the one established by the 1961 United Nations Single Convention on Narcotic Drugs, the 1971 United Nations Convention on Psychotropic Substances, and most of the national laws related to drug trafficking of the Member States. Thus, it could be stated



that international, EU and national legal acts follow the same approach both towards traditional drugs and new psychoactive substances, i.e. that measures of control can be applied to these substances only in cases when they are formally acknowledged to be controlled before a certain person is found in possession of the substances.

It has been already acknowledged at least in the practice of law enforcement that the list approach is lacking, especially when applied to new psychoactive substances. The growth of the numbers of new psychoactive substances is accelerating. For example, there were only 85 substances listed in the schedules of the United Nations Single Convention on Narcotic Drugs in 1961, 250 substances listed in the schedules of the 1961 and 1971 conventions in 2013 (the lists have not been significantly expanded since then) (Corazza et al., 2017). While during the first 9 months of 2016 EMCDDA and Europol have issued 57 formal notifications of new psychoactive substances (NPS), 1 risk assessment report was submitted to the Council and the EC, and 5 EU Early-Warning Systems (EWS) Alerts and 3 EU Early-Warning Systems Advisories have been issued (General Secretariat of the Council. Standing Committee on Operational Cooperation on Internal Security (COSI), 2016).

Some Member States are searching for the ways to control new psychoactive substances that are not covered by the lists-based legal norms regulating narcotic and psychoactive substances. Several examples are worth mentioning.

The produced by the European Monitoring Centre for Drugs and Drug Addiction “New psychoactive substances in Europe: Legislation and prosecution — current challenges and solutions” states that: “Governments in Europe have responded in different ways to the challenges posed by the market in new psychoactive substances (NPS). Among these measures designed to reduce the availability and use of NPS, three broad and sometimes overlapping groups of legal responses can be identified. In the first group, existing laws that focused on consumer or health protection or medicines have been used. In the second group, drug laws have been modified, most commonly by introducing group definitions of substances under control. In the third group, innovative new laws have been developed to address these substances, in a few cases even defining a psychoactive substance by its effect rather than its chemical structure.” (EMCDDA, 2016).

#### 4. Generic Legislation on New Psychoactive Substances

Most of the Member States that deal with new psychoactive substances retain the “list approach” (analogue scheduling) to new psychoactive substances, establishing a more rapid procedure (ministerial orders instead of regulations passed by governments) for their inclusion in the lists only. However, the norms establishing “group definitions” (generic scheduling/generic bans) could count as a more promising practice. Generic bans are based on the structure of molecules of questionable substances and imply the prohibition of a group of psychoactive substances (Chatwin et al., 2017). This practically means that all substances originating from the same “molecular skeleton” are banned in this way (Kavanagh et al., 2014). In other words, generic bans criminalize those groups of substances that have the same chemical structures as the drugs that have already been banned (Hughes et al., 2017). The purpose of generic bans is to eliminate the basic weakness of the traditional approach of individual listing of new psychoactive substances (NPS), which can be reduced to the fact that the legislature, as a rule, loses a “time race” against drug dealers, who respond more quickly and distribute new drugs on a daily basis. Thus, all substances which have yet to emerge on the market of narcotic drugs are banned if their chemical composition is similar to that of banned drugs (chemical analogues) (Amsterdam et al., 2013).

The generic approach to problem solving has had some success in suppressing the drug market in Japan, particularly regarding simple chemical compounds whose number has been significantly reduced (e.g. naphthoylindoles – a class of synthetic cannabinoids and cathinones) (Kikura-Hanajiri, 2016). Some Member States of the European Union also base their drug policies on similar models. For example, the Austrian Law on New Psychoactive Substances establishes that “The Federal Minister or the Minister for Health may also define classes of chemical substances if this measure appears to be more appropriate than designation of individual new psychoactive substances” (Neue-Psychoaktive-Substanzen-Gesetz, 2019). A similar norm is established in the Polish Law on Counteracting Drug Addiction: “The Minister competent for health shall define by an ordinance a list of new psychoactive substances covering both these substances or groups of them” (Ustawa z dnia 29 lipca

2005 r. o przeciwdziałaniu narkomanii, 2005). The Estonian Act on Narcotic Drugs and Psychotropic Substances and their Precursors defines narcotic drugs and psychotropic substances as “substances and substances belonging to the groups listed in the lists established on the basis of subsection 31 (1) of this Act, as well as isomers, esters, ethers and salts of these substances, and medicinal products containing such substances”, as well as provides a legal definition of a group of narcotic drugs and psychotropic substances, namely “substances of the same general structural formula are substances of the list listed on the basis of subsection 31 (1) of this Act” (in this sense the Estonian Act seems kind of restrictive, i.e. group of narcotic substances could be understood only as a group of similar substances that are already included in the list individually) (Narkootiliste ja psühhotroopsete ainete ning nende lähteainete seadus, 1997). A seemingly similar approach can be found in the Danish Law on Narcotics, establishing that the term “drugs” denote inter alia “products of any kind [...] as well as processed forms of the relevant substances, drugs, plants and fungi, provided that the processing does not lead to a chemical change of the substances” (Forskrift om narkotika, 2013). The Lithuanian Law on Control of Narcotic and Psychotropic Substances (Art. 3) also provides that new psychoactive substances can be enlisted into the lists of controlled substances by their specific names or the group names of their derivatives (Lietuvos Respublikos narkotinių ir psichotropinių medžiagų kontrolės įstatymas, 2019).

This approach is a more promising one. However, some drawbacks should also be noted.

First, there is a lack of agreed criteria for the classification of narcotic and psychotropic substances. A set of criteria being applied covers the chemical structure of substances, their clinical use, their origin, sited of action of substances, action prototypes, behavioural effects of substances (Niesink, 1999). Many substances can be classified into more than one category under the same criteria applied: many drugs, while having similar chemical structures, have different pharmacological properties; many drugs have similar pharmacological properties, but different behavioural effects (Niesink, 1999), etc.

Second, chemical analogues do not always have the same effect as banned substances, because their effect depends not only on the chemical structure but also on the relationship with the receptor. For example, cocaine and atropine have the same chemical structure but different pharmacological effects

(cocaine causes severe psychoactive effects and, as such, is on the list of banned substances, while atropine is a drug widely used in medicine) (Amsterdam et al., 2013). Also, a cannabidiol (CBD) is a phytocannabinoid which has a similar chemical structure to that of a tetrahydrocannabinol (THC); however, it has psychotropic effects (antipsychotic effects – it reduces anxiety in patients), which are opposite from those of THC (de Mello Schier et al., 2012). Accordingly, generic bans may also encompass substances with no psychoactive effect. The consequences of the application of these regulations may be the prosecution of persons who manufacture, supply the market or use substances that are not drugs but rather medicines or related substances that do not have harmful properties of drugs. It appears that generic bans can be an obstacle to medical research aimed at finding new drugs for treating very serious diseases (Grob et al., 2011). This problem may be solved by enacting exemptions from generic bans on groups of compounds. However, this would require a complicated and expensive examination of a large number of complex chemical compounds, as well as time, which is a deficient resource in the fight against NPS. This would also mean the return to the individual consideration of each questionable substance, although the generic approach should represent a step forward in relation to the traditional NPS regulation. On the other hand, certain substances (synthetic cannabinoids - JWH-018, JWH-250, CP-59,540, CP-47,497) have a different chemical structure from the banned substances but the same psychoactive effect (a THC-like effect). This means that these substances should be banned by the individual listing of prohibited substances, which again brings us back to the traditional model despite all its flaws (Amsterdam et al., 2013).

Third, all new psychoactive substances are being created in order to bypass rigid characteristics of the substances under control. Thus, establishing the criteria of groups of substances instead of criteria (characteristics) of individual substances would only mean that persons engaged in production of new psychoactive substances shall seek for creation substances to avoid more general criteria. It is especially the case with the most complex chemical compounds that may have several hundred analogues; generic bans are not an instrument for a successful suppression of NPS (Amsterdam et al., 2013). Vice versa, it is difficult to assess the possible psychoactive effect of a substance which does not yet exist or does not exist on the market of narcotic drugs. For example, methedrone (also known as miaow-miaow) was banned in the United Kingdom

in 2010, even though there was no evidence of its harmful effects. It was subsequently found that mephedrone was one of the least harmful NPS, compared to alternatives to drug use (Nutt, 2011). Moreover, mephedrone had a positive impact on public health in this country. In 2009, it was found that deaths from cocaine had decreased. As an alternative to cocaine, users started consuming mephedrone, which reduced cocaine deaths. Therefore, care should be taken when banning substances with a psychoactive effect, and before reaching any decision; both the harmful effects and risks of their use should be taken into account, as well as the possible benefits. Caution is needed not only because of the possible benefits (e.g. customs revenues) from NPS the prohibition of which is being considered, but primarily because of the fact that an (un)justified ban on certain substances depends on whether their users and persons who are supplying the drug market will be prosecuted and punished.

Thus, last but not least, from the standpoint of the law, the greatest weakness of generic bans is that they raise certain question from the standpoint of the principle of legality, the fundamental principle on which criminal law rests. An average person should know what is punishable at the time of the commission of an offense, which is, with the application of generic bans, practically unachievable due to their complexity. Can an average citizen be expected to have knowledge of chemical compounds that is necessary for understanding generic bans? This opens up the problem of perpetrators invoking a mistake of law, that is, the misconception regarding the illegality of the act committed.

## 5. Blanket Bans of New Psychoactive Substances

Similar remarks apply to another group of solutions proposed – innovative new laws that have been developed to address these substances, in a few cases even defining a psychoactive substance by its effect rather than its chemical structure. Laws of some Member States (e.g. Austria) establish definitions of “psychoactive effects” based on the definition established in the Single Convention on Narcotic Drugs of 1961: “Central nervous system stimulation or depression, resulting in hallucinations or disturbances in motor function or thinking or behaviour or perception or mood” (Neue-Psychoaktive-Substanzen-Gesetz, 2019). Others formulate their own, sometimes more restrictive, definitions, e.g. the Portuguese law defines a psychoactive effect as an

effect “on the central nervous system, which may induce significant alterations in motor function as well as mental functions, namely reasoning, judgment and behaviour, often with delusional states, hallucinations or extreme euphoria, and may cause dependence” (Decreto-Lei n.º 54, 2013). However still these definitions usually serve as criteria to be followed for creation of lists of narcotic and psychoactive substances and not as alternatives to the lists. Thus, the doubts provided in regard of other two groups are applicable.

However, the fourth and the most promising group of solutions proposed should be considered. There are several states that establish that every psychoactive substance is considered under the measures of control except when a formal authorization from the government has been provided, so-called blanket bans.

The approach has been entrenched in the Psychoactive Substances Act 2016, passed by the Parliament of the United Kingdom, stating that:

- “(1) A person commits an offence if—
- (a) the person intentionally imports a substance,
  - (b) the substance is a psychoactive substance,
  - (c) the person knows or suspects, or ought to know or suspect, that the substance is a psychoactive substance, and
  - (d) the person—
    - (i) intends to consume the psychoactive substance for its psychoactive effects, or
    - (ii) knows, or is reckless as to whether, the psychoactive substance is likely to be consumed by some other person for its psychoactive effects.” (Psychoactive Substances Act, 2016).

A similar regulation could be found in the Romanian Law on combating operations with products susceptible to psychoactive effects, other than those provided by the normative acts in force, establishes:

- “(1) Operations with products that are susceptible to psychoactive effects shall be subject to authorization under the conditions established by this law.
- (2) Until authorization is obtained, it is forbidden to carry out operations with the product subject to authorization.
  3. A product is considered to be susceptible to psychoactive effects if it can reasonably be expected to cause psychoactive effects and if it is not used or could not be used for the purpose for which it has been produced.
  4. Reasonableness of the matter is to be assessed on however not limited to the following criteria:

- a) absence or insufficiency of data to determine the legal status of the product;
  - b) product characteristics, mainly composition, or lack of [medical] indication [for its use];
  - c) consumption, as a predictable purpose of the product;
  - d) the presentation of the product, its labelling, any warnings or instructions for its use, and any other indication or information relating thereto, or even its absence.
- (5) Authorization is also required if product operations are carried out by electronic means.” (Lege nr. 194, 2011).

The blanket bans model could be foreseen to gather momentum across the EU in the future. It is worth noting an elaborated definition of new psychoactive substances formulated by the European Commission in the Proposal for a regulation of the European Parliament and of the Council on new psychoactive substances, which reads: the European Union provide most detailed definition of new psychoactive substances: “new psychoactive substance means a natural or synthetic substance that, when consumed by a human, has the capacity to produce central nervous system stimulation or depression, resulting in hallucinations, alterations in motor function, thinking, behaviour, perception, awareness or mood, which is intended for human consumption or is likely to be consumed by humans even if not intended for them with the purpose of inducing one or more of the effects mentioned above, which is neither controlled under the 1961 United Nations Single Convention on Narcotic Drugs, as amended by the 1972 Protocol, nor the 1971 United Nations Convention on Psychotropic Substances; it excludes alcohol, caffeine and tobacco, as well as tobacco products within the meaning of Council Directive 2001/37/EC of 5 June 2001 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products”. It should be noted that similar attitudes can be supported by some EU legal acts in force that could act as precedents for the approach being considered. For example, actually analogical regulation exists in regard of firearms. Directive (EU) 2017/853 of the European Parliament and of the Council of 17 May 2017 amending Council Directive 91/477/EEC on control of the acquisition and possession of weapons, Art. 1, para. 1 establishes that ““firearm” means any portable barrelled weapon that expels, is designed to expel or may be converted to expel a shot, bullet or projectile by the action

of a combustible propellant, unless it is excluded from that definition for one of the reasons listed in Part III of Annex I. Firearms are classified in Part II of Annex I. An object shall be considered to be capable of being converted to expel a shot, bullet or projectile by the action of a combustible propellant if: (a) it has the appearance of a firearm; and (b) as a result of its construction or the material from which it is made, it can be so converted”.

The main advantage of blanket bans is that they criminalize all psychoactive substances without exception, both the current ones and the ones yet to emerge (Stevens et al., 2015). It seems that the legislature, by enacting blanket bans, has demonstrated its determination and managed to do what no one has achieved for several decades – to win the cat and mouse game with drug dealers who have always had an advantage in this game.

However, numerous objections to blanket bans arising from the PSA have been pointed out in the literature. The main problem is that blanket bans are vague, thus contradicting the principle of legality as one of the fundamental principles of criminal law. For example, the criminal legislation of the Republic of Serbia considers narcotic drugs to be only those substances that cause “pathological or functional changes in the central nervous system” (Zakon o psihoaktivnim kontrolisanim supstancama, 2010). Similarly, the 1971 Misuse of Drugs Act criminalizes those substances that have the capacity to induce harmful effects sufficient to create a social problem (Article 1, paragraph 2). Under the 2016 Act, any substance capable of producing a psychoactive effect in a person who consumes it is deemed a psychoactive substance. A psychoactive effect exists if a substance stimulates or depresses the central nervous system, affects the mental functioning or emotional state (Article 2, paragraphs 1 and 2 of the PSA). Therefore, it is not necessary for a substance to have negative effects on, or endanger, human health to be deemed a drug in the sense of this Act.

The concept of a psychoactive substance is determined using the term “psychoactive effect”. According to the Australian legislation, a “psychoactive effect” means: “a) stimulation or depression of the person’s central nervous system, resulting in hallucinations or in a significant disturbance in, or significant change to, motor function, thinking, behaviour, perception, awareness or mood; or (b) causing a state of dependence, including physical or psychological addiction” (Crimes Legislation Amendment (Psychoactive Substances and



Other Measures) Act, 2015). Accordingly, the psychoactive substance is considered to be “any substance that, when a person consumes it, has the capacity to induce a psychoactive effect” (Crimes Legislation Amendment (Psychoactive Substances and Other Measures) Act, 2015). The Australian legislation provides a more precise determination of a “psychoactive effect” because it means, among other things, “hallucinations” or a “significant disturbance”, that is, it is based on the harm caused to health. Yet, it is impossible to say that this definition of a “psychoactive effect” solves the problem surrounding the vagueness of blanket bans. For example, it is unclear what is meant by a “significant” disturbance. Interestingly, the 2016 PSA does not require any “significant” impact on mental functioning or emotional state. It is paradoxical that blanket bans pertain to drugs yet to emerge on the market, for it is impossible to say with certainty that drugs which have not emerged yet will cause inherent harmful effects to health (Barratt et al., 2017).

The vague definition of a “psychoactive effect” contained in the PSA leads to the dangers of applying the Act to the substances that do not induce harmful effects as traditional drugs do, or to substances that have negligible psychoactive effects. Blanket bans do not solve the problem of those NPS that are not sold as drugs, but rather as different products labelled “not for human consumption,” which has already been discussed in this article.

The scientific literature takes the view that a very broad application of the PSA and the violation of the principle of legality will not be prevented by enacting exemptions (Reuter et al., 2017). Additionally, it has been emphasized that screening techniques to determine a psychoactive effect are not reliable, because only clinical studies can provide accurate data on the psychoactive effect of a substance (Stevens et al., 2015). In spite of this, a psychoactive effect, according to the PSA, is determined after quick screening checks (Wadsworth et al., 2017). It should be emphasized that clinical studies require time (and significant costs), which represents a deficient resource in the effort of suppressing NPS.

Also, blanket bans may cause certain difficulties during the prosecution of drug-related offenders. The burden of proof is on the prosecution, which will face numerous difficulties in proving the subjective element of an offense, that is, that the perpetrator knew or suspected, or was obliged to know or to suspect that, in a certain case, it was a substance that produced psychoactive

effects (Stevens et al., 2015). Thus, the consequence of blanket bans is a criminal proceeding against drug dealers and drug users, which will last longer, resulting in significant additional costs.

## 6. Regulation of New Psychoactive Substances through Consumer Protection and Health Protection Laws

In some cases, it has been considered whether the issues raised by the principle of legality could be avoided through avoidance of criminalization of new psychoactive substances itself, leaning instead onto laws that deal with consumer protection and health protection. In this way dealing with new psychoactive substances would still be considered illegal however the regulation would be less rigid than applied towards narcotic drugs. Generally, these laws (health and consumer protection laws) are devoted to guarantee sufficient quality of services and products (including substances). Therefore, the application of the regulation to exempt a new psychoactive substance from the market would mean:

- a) the new psychoactive substance could be treated as a medicinal product and could circulate in the market under certain circumstances (thus, such an acknowledgement would carry in itself a certain part of recognition given to a new psychoactive substance and would burden inclusion of the new psychoactive substance in the list of controlled drugs afterwards), and
- b) the new psychoactive substance is precluded from circulation in the market due to the insufficient quality of it. When taking into account that the new psychoactive substances are usually defined as substances that provide an effect similar to the substances included in the lists of narcotic and psychotropic substances, this line of arguments would lead to an illogical conclusion that a certain NPS is precluded from circulation due to the fact that it produces insufficient psychoactive effect.

However, the judgment of the European Court of Justice in the Joined Cases C-358/13 and C 181/14 actually precludes this approach to be taken against new psychoactive substances. It can be stated that the judgment of the European Court of Justice mostly rests on definitional issues. The Court has stated that “the term ‘medicinal product’ [...] must be interpreted as not

covering substances [...] which are not such as to entail immediate or long-term beneficial effects for human health.” The same line of argument seems to be applicable to every application of consumer law towards new psychoactive substances. Several Member States (e.g. Denmark, the Czech Republic, Sweden) are still looking for a way to overcome effects of the ECJ judgment by specifically mentioning that the notions of narcotic and psychotropic substances used in their respective legal acts cover pharmaceutical products (Forskrift om narkotika, 2013; Zákon o návykových látkách a o změně některých dalších zákonů, 2017; Narkotikastrafflag, 1968). The same mode of thinking occurs in some countries outside Europe, e.g. Japan (Preedy, 2016). Following the arguments listed above, an approach taken by some countries (e.g. Austria, Finland, Ireland) to specifically exclude medicinal and pharmacological products from the application of drug related legal acts seems a more substantiated one (Neue-Psychoaktive-Substanzen-Gesetz, 2019; Huuhausainelaki, 2008; Criminal Justice (Psychoactive Substances) Act, 2010).

## 7. Establishing a Legal Market for New Psychoactive Substances

Finally, a new approach providing for certain legalization of new psychoactive substances should be considered. New Zealand is the first country to establish a legal market for new psychoactive substances by enacting the Psychoactive Substances Act 2013 (PSA) (Seddon, 2014). According to this approach, approval for the manufacture of NPS may be obtained from a competent state authority if manufacturers prove that the products carry a “low risk” of harm. Accordingly, if clinical trials in humans demonstrate that the use of a certain substance does not pose a significant risk to human health, then manufacturers may obtain approval for the manufacture and supply of NPS (Wilkins, 2014). Six criteria have been established to prove that the substance in question carries a “low risk” of harm: 1) toxicological effects; 2) risk to public health; 3) potential to cause death; 4) potential to create dependence; 5) likelihood of misuse; 6) appeal to vulnerable populations (Rychert et al., 2016).

In this way, New Zealand abandoned the policy based on the prohibition of NPS, which was followed by a number of weaknesses (a continuous emergence of new substances on the NPS market, a slow process of adding new substances

to the list of banned substances, etc.) (Meacher, 2013). One of the disadvantages of the NPS ban policy concerns the high costs of determining whether a particular substance should be added to the list of banned substances. Under the PSA, these costs are borne by manufacturers, rather than by government institutions (Wilkins, 2014). A key feature of this NPS regulation is the duty of manufacturers to prove that the substance they manufacture and put into circulation is safe regarding the preservation of health. Additionally, according to this concept, manufacturers are responsible for packaging and labelling substances whose production and putting into circulation is approved, providing the necessary information important for the safe use of these substances and paying a certain amount of money for each product put into circulation (Meacher, 2013). Thus, it aims to achieve a higher degree of the protection of users while at the same time limiting the number of new substances on the market. The limited use of substances is ensured by prescribing that the approved substances may be purchased solely by persons aged 18, at precisely determined retail shops, that is, by advertising bans; all products must have a label containing information on potential health risks, a list of ingredients, and contact details of the National Poisons Centre to obtain further information (Wilkins, 2014). It turns out that personal use of these substances will not constitute an offense. This solution represents a major change in drug policy because drug trafficking is a very serious crime in all modern legislation, while keeping drugs for personal use is also an offense in most countries (Akgul et al., 2017).

The legislature of New Zealand wanted to abandon the policy of banning NPS, which has many shortcomings. The main problem faced by law enforcement agencies in an attempt to suppress NPS is a *cat and mouse* game with drug dealers (Rychert et al., 2018). It is a fact that the ban on NPS cannot solve this problem, because each new drug on the list of banned psychoactive substances is quickly replaced with a similar substance that is not on the list (Winstock et al., 2010). Manufacturers of NPS slightly alter the molecular structure of the banned substance and thus produce a new substance similar in chemical structure and effects to the substance on the list of banned substances (Piggee, 2009; Stackhouse, 2013; Weingarten et al., 1988). Additionally, the starting point of this approach is that drug abuse will never be completely prevented. It follows that the “harm reduction philosophy” should be accepted (Wilkins et al., 2013).

The “interim regime” has been established to protect public health, because detailed regulations to regulate this matter have not yet been enacted by the competent authorities. Within this interim regime, it was foreseen to collect data on the potential harmfulness of substances whose production and supply was approved. However, the data was collected through anonymous phone calls. Due to the anonymity of the call, the issue of quality was raised (data providers did not often respond to key questions about the amount of substance they consumed, their health status, etc.) and the reliability of the data collected; this way of collecting data allowed manufacturers to make malicious calls in order to eliminate competing products from the market (Rychert et al., 2018).

During the temporary regime, the products containing a certain compound were withdrawn from the market, while the products containing the questionable substance were not. The explanation for this inconsistency is that the product quality on the market has oscillated, which had an impact on the harmfulness of products. In other words, one compound included in the product by one manufacturer may be harmful, yet it is perfectly safe in the product produced by some other manufacturer (Rychert et al., 2018).

The system that creates a legal market for NPS is based on the “low harm” of psychoactive substances. This term is vague because there is no generally accepted definition of what is meant by “low harm” when assessing new psychoactive substances (Wilkins et al., 2013).

It has already been mentioned that the limited use of NPS is ensured by prescribing that approved substances may be purchased solely by persons aged 18, at precisely determined retail shops. However, one of the managers in the industry that manufactures legal NPS interviewed within the study conducted on the consequence of applying the PSA reported that the consumers of 80-90% of these products represent teenagers aged 19, despite declarative statements that the marketing of the industry is not aimed at young people and people with low income (Rychert et al., 2016). Additionally, all industry managers interviewed during the survey confirmed that the prices of NPS legally sold were significantly reduced over time and the consumers were constantly looking for substances with a more potent psychoactive effect. The reason should be sought in the desire of industry to be competitive on the market and obtain a greater profit. The availability of legal NPS is being increased in this way, which was not the purpose of enacting the PSA. However, in spite of fi-

nancial losses, some retailers sold NPS at higher prices than their competitors to secure the status of a “responsible retailer” and a more responsible client base in which there would be no children or minors who would have to ask an adult to buy a NPS for them. Consequently, this creates another possibility of misusing the regulations pertaining to legal NPS: there is a possibility that children and minors will consume legal NPS despite the ban on purchase. Adults will continue to buy NPS in shops for them. Regarding consumers’ demands for more potent substances, it presents another challenge which the legal NPS market in New Zealand must face. The question arises as to whether the NPS industry will respect the regulations governing the composition of substances whose sale is approved or try to ignore the rules in order to meet customer demands and maximize profits.

Some authors believe that the legal sale of drugs (cannabis) will cause negative effects on public health (Pacula et al., 2014). According to them, the experience of alcohol and tobacco, which are legally sold, does not support the legalization of NPS, because when the manufacture and sale of questionable products is once approved, the subsequent prohibition or restrictive regulation is hardly feasible for legal, political, economic, psychological, and other reasons.

A fundamental problem that the 2013 PSA cannot solve is the legal sale of NPS despite the fact that the manufacture and sale of these products is not approved. In fact, various products containing psychoactive compounds will continue to be legally sold in specialized shops, and drug users will continue to buy and consume them even though they are labeled “not for human consumption”. The information “not for human consumption” enables the manufacturer and the retailer to avoid prosecution if the consumption of products caused harm to users’ health (Sathappan, 2014). In case of being prosecuted, their defense will be based on the claim that the user consumed the product willingly, despite the clear instruction “not for human consumption” on the package. Accordingly, although they are not sold or advertised as drugs, NPS can still be sold legally, but they will be labeled with a slang name which can be associated with drugs (Kavanagh et al., 2014). In this regard, it should be noted that unapproved NPS may be cheaper in the market, more potent and more appealing to customers because they have the status of a “forbidden fruit” (Wilkins et al., 2014).

## 8. Conclusions

The overview of mechanisms and methods of criminalization of new psychoactive substances presented in this article allows formulating certain propositions that could be discussed more thoroughly.

First, it is the view of the authors that certain legislative changes in regard of the control of new psychoactive substances could be made on the EU level. The Council Decision 2005/387/JHA establishes the competence of the European Council to submit new psychoactive substance to control measures by the qualified majority acting on an initiative presented by the Commission. However, it could be feasible to provide for a system where new psychoactive substances are acknowledged to be controlled substances through a regulation instead of a council decision. An example of a similar regulation could be drawn from the Commission Implementing Regulation (EU) 2015/1998 laying down detailed measures for the implementation of the common basic standards on aviation security (Text with EEA relevance) that *inter alia* enlists articles that are prohibited to be carried into security restricted areas of airports.

Second, the practice of many states has shown that the traditional “list approach” to criminalization of narcotic drugs is not sufficient to take action towards many new psychoactive substances due to the extremely rapid changes in composition of the substances under consideration. The practice to establish “group definitions” (generic scheduling) or defining a psychoactive substance by its effect rather than its chemical structure (blanket bans) are more promising, however do also suffer from some drawbacks. Alternative forms of legal regulation – covering new psychoactive substances by laws on consumer protection and health protection, as well as instances of establishment of legal markets for new psychoactive substances – are lacking in justification also. Thus, it could be generalized that no approach present in the laws overviewed in the article could be sufficient to address the issue of criminalization of new psychoactive substances in proper manner, and studies aimed to search for alternative ways of criminalization are necessary.

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