Assessment of legal definitions of opiates and new psychoactive substances

The project "NARCO-MAP: Improving knowledge on NPS and opiates trafficking in Europe" is aimed at two types of narcotic and psychotropic substances:

- new (novel) psychoactive substances, and
- opiates.

As it has been indicated in the Executive Project, these two categories significantly overlap, due to the fact, that synthetic opioids are usually included among New Psychoactive Substances. However, from a legal point of view these terms should be considered to be distinct due to different legal regulations of the substances.

The United Nations Office on Drugs and Crime (UNODC) denotes ***opiates*** as "naturally occurring alkaloids of the opium poppy (Papaver somniferum L.)"[1]. The term "opiates" usually does not cover the term "***opium***". The latter term has been defined by the United Nations Single Convention on Narcotic Drugs of 1961. The Convention states that ""Opium" means the coagulated juice of the opium poppy"[2], while "Opium poppy" means the plant of the species Papaver somniferum L."[3]. Although descriptions of opium provided in national laws of the EU Member States slightly differ (e.g. the Polish law describes opium as "concentrated milky juice of a poppy bag"[4], the Romanian law describes "raw opium" as a "latex thickened by partial dehydration harvested through carving of green capsule"[5]), the differences do

[1] United Nations Office on Drugs and Crime (UNODC). Terminology and Information on Drugs. Third edition. https://www.unodc.org/documents/scientific/Terminology_and_Information_on_Drugs-3rd_edition.pdf p.17.
[2] Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961. Art. 1, para. 1., p. (p)
[3] Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol amending the Single Convention on Narcotic Drugs, 1961. Art. 1, para. 1., p. (q)
[4] Ustawa z dnia 29 lipca 2005 r. o przeciwdziałaniu narkomanii. Art. 4. http://isap.sejm.gov.pl/Download?id=WDU20051791485&type=3
[5] Lege nr. 339 din 29 noiembrie 2005 privind regimul juridic al plantelor, substanţelor şi preparatelor stupefiante şi psihotrope. Articolul 2.

not raise any significant issue for consideration maybe apart a theoretical possibility to question the moment when criminal intent turns into a crime committed. Finally, the approach adopted by the UN Commission on Narcotic Drugs should be mentioned: "all preparations made direct from opium are considered to be opium (preparations). If the preparations are not made directly from opium itself but are obtained by a mixture of opium alkaloids (as is the case, for example, with pantopon, omnopon and papaveretum), they should be considered as morphine (preparations)."[6]

Although opium in the formally true sense of the word is not an alkaloid (opiate) in itself, it is feasible for the aims of the project to consider that the term "opium" is being encompassed by the term "opiates". The United Nations Office on Drugs and Crime (UNODC) considers the term "***opioid***" to be a generic one, denoting both "opiates and their synthetic analogues, which can be semi- or fully synthetic, with actions similar to those of morphine"[7]. It should be noted that morphine acts as an opioid agonist (mimics the effects of the opioid peptides)[8], while the term "opioids" is usually considered to cover both substances acting as agonists, antagonists or agonist-antagonist at opioid receptors[9] (G-protein coupled receptors with transmembrane domains for opioids as ligads)[10].

Most of the opioids are recognised as narcotic and psychotropic substances, although there are newly emerging forms of opioids (e.g. synthetic opioids) that are not yet controlled. For the sake of clarity, it would be preferable to restrict the term "opioids" only to substances that meet both legal and biological criteria: a) are controlled in all EU Member States and b) are natural, semi-synthetic or fully synthetic substances acting as agonists, antagonists or agonist-antagonists at opioid receptors.

---

http://www.ana.gov.ro/legislatie%20nationala/Legea%20339_2005%20priv%20regimul%20juridic%20al%20plantelor%20substantelor%20si%20preparatelor%20stupefiante%20si%20psihotrope.pdf

[6] List of Narcotic Drugs under International Control. Annex to Forms A, B and C (55 th edition, December 2016) (Yellow List). https://www.incb.org/documents/Narcotic-Drugs/Yellow_List/56th_Edition/YL-56th_edition_2017_EN.pdf

[7] United Nations Office on Drugs and Crime (UNODC). Terminology and Information on Drugs. Third edition. https://www.unodc.org/documents/scientific/Terminology_and_Information_on_Drugs-3rd_edition.pdf p.17

[8] Busse, G. D. (2006). Morphine. New York: Chelsea House Publishers. p. 40

[9] Hoskin, P. J., & Hanks, G. W. (January 01, 2007). Opioid Agonist-Antagonist Drugs in Acute and Chronic Pain States. Drugs, 41, 3, 326-344.

[10] Preedy, V. R. (2016). Neuropathology of drug addictions and substance misuse. Volume 3. S.l.: Elsevier Academic Press. p. 499

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[11]. These documents are often referred to in legal acts both on the EU[12] and national level of Member States (e.g. Spain[13], Denmark[14]). Taking into account that both conventions establish that the Commission on Narcotic Drugs of the Economic and Social Council of the United Nations can modify the Schedules without a special ratification by the UN Member States[15], the Schedules could be considered as one of the first examples of a universal legislative frameworks. It should be noted however that some Member States of the EU (e.g. Malta[16], the Netherlands[17]) specifically and many EU Member States (e.g. Lithuania[18] or Slovenia[19]) indirectly, i.e. without giving a direct link to the UN conventions and EU council decisions, do provide for a separate national procedure for the changes of the UN and EU schedules to have effect in the respective Member States.

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

[11] List of Narcotic Drugs under International Control. Annex to Forms A, B and C (55 th edition, December 2016) (Yellow List). https://www.incb.org/documents/Narcotic-Drugs/Yellow_List/56th_Edition/YL-56th_edition_2017_EN.pdf International Narcotics Control Board. List of Psychotropic Substances under International Control in accordance with the Convention on Psychotropic Substances of 1971 (Green List), New Version 2016, 27th edition. https://www.incb.org/documents/Psychotropics/greenlist/2016/V1604744_Eng.pdf

[12] Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances, Article 2; 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 71, para. 2., Art. 88. Para. 2, Art. 96. Para. 1

[13] e.g. Ley 17/1967, de 8 de abril, por la que se actualizan las normas vigentes sobre estupefacientes y adaptándolas a lo establecido en el convenio de 1961 de las Naciones Unidas. Artículo segundo. https://www.boe.es/buscar/doc.php?id=BOE-A-1967-5592;

[14] Forskrift om narkotika (narkotikaforskriften), § 4. https://lovdata.no/dokument/SF/forskrift/2013-02-14-199

[15] Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol. Art. 3; Convention on Psychotropic Substances, Art. 2 para. 5

[16] Dangerous Drugs Ordinance, Section 10. http://justiceservices.gov.mt/DownloadDocument.aspx?app=lom&itemid=8641&l=1

[17] Opiumwet (Wet van 12 mei 1928, tot vaststelling van bepalingen betreffende het opium en andere verdoovende middelen). Artikel 3a. http://wetten.overheid.nl/BWBR0001941/2017-05-25

[18] Lietuvos Respublikos narkotinių ir psichotropinių medžiagų kontrolės įstatymas, 3 straipsnis.

[19] Zakon o proizvodnji in prometu s prepovedanimi drogami (ZPPPD). 2. člen. https://www.uradni-list.si/glasilo-uradni-list-rs/vsebina/1999-01-5025?sop=1999-01-5025

submit new psychoactive substance to control measures are to be made by the Council qualified majority acting on an initiative presented by the Commission[20]. 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"[21]. However most of the Member States still consider the aforementioned decisions by the European Council as a basis for passing a separate national regulation, e.g. the Lithuanian Law on Control of Narcotic and Psychotropic Substances does not provide an alternative procedure for a new psychotropic substance to be placed under measures of control except through a formal decision of the Ministry of Health[22]. Member States that have a special "emergency" procedure in place also follow the rule that it should be preceded by a legal decision on a national level to enlist a certain new psychotropic substance as a substance under legal control. For example, the Latvian law on the order of legal circulation of narcotic and psychotropic substances and drugs provides for the lists of narcotic and psychotropic drugs to be established by the government[23]. However, the Center for Prevention and Control of Diseases is authorized to decide that the manufacture, acquisition, storage, transportation, transfer or distribution of new psychoactive substances, which 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[24].

It could be considered in the framework of the project whether it would be feasible to formulate a proposal for a new EU regulation on the lists of new psychoactive substances. Currently, the lists adopted on the EU level are modified through Council

[20] Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances. Art. 8. Para. 3
[21] Huumausainelaki, 3 §. http://www.finlex.fi/fi/laki/ajantasa/2008/20080373
[22] Narkotinių ir psichotropinių medžiagų kontrolės įstatymas, 4 str.
[23] Likuma par narkotisko un psihotropo vielu un zāļu likumīgās aprites kārtību. 3.pants. (2) https://likumi.lv/doc.php?id=40283
[24] Likuma par narkotisko un psihotropo vielu un zāļu likumīgās aprites kārtību. 4.pants. (2) https://likumi.lv/doc.php?id=40283

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[25]. The Court of Justice of the EU however, has recognized that some decisions may have direct applicability, however only in cases where they refer to an EU country as the addressee (Judgement 10 November 1992, Hansa Fleisch)[26], this is not the case with the Council Decisions on new psychoactive substances. Therefore, it would be feasible (it should be discussed within the project) to provide for a system where the new psychoactive substances become controlled substances through a regulation instead of a council decision. According to the Consolidated Version of the Treaty on the Functioning of the European Union, Article 288, every regulation shall be binding in its entirety and directly applicable in all Member States[27]. An example of a similar regulation could be drawn from the Commission Implementing Regulation (EU) 2015/1998 of 5 November 2015, which lay out 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[28].

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 in national legal acts, however the scope of the national acts differ, i.e there are certain substances that have placed under measures of control in some EU Member States only[29]. 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 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

[25] Consolidated version of the Treaty on the Functioning of the European Union. Article 288
[26] Summaries of EU legislation: The direct effect of European law. http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:l14547
[27] Consolidated version of the Treaty on the Functioning of the European Union. Article 288
[28] 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). Attachment 1-A.
[29] European Monitoring Centre for Drugs and Drug Addiction (EMCDDA). Substances and classifications table (31/10/2008). http://www.emcdda.europa.eu/html.cfm/index5733EN.html

by Member States in respect of the wholesale distribution of narcotic or psychotropic substances within their territory"[30]. 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"[31]. 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[32] should apply. This is the case, for example, in which a psychoactive substance lawfully marketed in another Member State is denied for reasons based on the denomination, size, composition, etc."[33].

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 controlled substances in one of the Member States only. Considering 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

[30] 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
[31] Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances, Article 9, para. 3
[32] Regulation (EC) No 764/2008 of the European Parliament and of the Council of 9 July 2008 laying down procedures relating to the application of certain national technical rules to products lawfully marketed in another Member State and repealing Decision No 3052/95/EC
[33] European Commission. Enterprise and Industry Directorate-General. Guidance document „The application of the Mutual Recognition Regulation to narcotic drugs and psychotropic substances". Brussels 1.2.2010. http://ec.europa.eu/docsroom/documents/5821/attachments/1/translations/en/renditions/native

Nations Conventions of 1961 and 1971"[34] only, some clarifications within the project would be necessary.

The issue that can be relevant to the goals of the project is the term "opioid" to be applied to substances (synthetic opioids) that are controlled in one or several Member States only, i.e. whether they should be denoted as opioids, or new psychoactive substances, or both. In fact, it could be noted that analogues to the opioids under control have been one of the first substances that have raised concern over new psychoactive substances, starting in 1920s already[35].

The term "new psychoactive substances" covers a 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"[36]. 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

[34] 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 71, para.2
[35] Madras B. K. The Growing Problem of New Psychoactive Substances (NPS). In: Baumann, Michael H, Richard A. Glennon, and Jenny L. Wiley. Neuropharmacology of New Psychoactive Substances (NPS): The Science Behind the Headlines. Springer, 2017. Print.P. 4
[36] Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances, Article 3

provide for a Community regime[37]. 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 turn should be based on the Risk Assessment Report by 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, in which they are formally put under control 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 number of new psychoactive substances register accelerating growth. 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[38] (the lists have not been significantly expanded since then). 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[39].

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.

[37] Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances, Article 2

[38] Corazza, Ornella, and Andres Roman-Urresterazu (eds.). Novel Psychoactive Substances Policy, Economics and Drug Regulation. Cham: Springer, 2017. p. xiv

[39] General Secretariat of the Council. Standing Committee on Operational Cooperation on Internal Security (COSI). Multilateral JHA Agencies Scorecard 2016. Annex to EU Justice and Home Affairs Agencies' cooperation in 2016 - Final report. Brussels, 16 December 2016. 15579/16. http://www.statewatch.org/news/2016/dec/eu-council-jha-agencies-rep-2016-15579-16.pdf

The report "New psychoactive substances in Europe: Legislation and prosecution — current challenges and solutions", produced by the European Monitoring Centre for Drugs and Drug Addiction 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, 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."

The aforementioned report of the EMCDDA presents overviews of all the free groups of approaches taken by different Member States (p. 9-12). However, it could be stated that the first two groups of approaches are insufficient to deal with the issue of new psychoactive substances in an effective way.

First, talking about the **laws that focus on consumer or health protection or medicines**. 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 ruled 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." [40]. The same line of argument seems to be applicable to every application of consumer laws towards new psychoactive substances. Several Member States (e.g. Denmark[41], the Czech Republic[42], Sweden[43]) are still looking for a way to overcome

[40] Judgment of the Court (Fourth Chamber) of 10 July 2014 (requests for a preliminary ruling from the Bundesgerichtshof — Germany) — Criminal proceedings against Markus D. (C 358/13) and G. (C-181/14) (Joined Cases C-358/13 and C 181/14). Para. 38 http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:62013CJ0358&from=LT

[41] Forskrift om narkotika (narkotikaforskriften), § 3. https://lovdata.no/dokument/SF/forskrift/2013-02-14-199

[42] Zákon o návykových látkách a o změně některých dalších zákonů, § 2. http://portal.gov.cz/app/zakony/zakonPar.jsp?idBiblio=46725&fulltext=&nr=167~2F1998&part=&name=&rpp=15

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. The same mode of thinking occurs in some countries outside Europe, e.g. Japan[44], also (although the ECJ judgment is not actual in these cases).

Generally, these laws (health and consumer protection laws) are devoted to guarantee sufficient quality of services and products (including substances). Therefore, 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 positive recognition of the new psychoactive substance and thus would burden inclusion of the new psychoactive substance in the list of controlled drugs afterwards), and
b) new psychoactive substance is precluded from circulation in the market due to insufficient quality. When considering that 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.

Following the arguments listed above an approach taken by some countries (e.g. Austria[45], Finland[46], Ireland[47]) to specifically exclude medicinal and pharmacological products from the application of drug related legal acts seems a more grounded one.

Second, regarding **group definitions** of 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

---

43 Narkotikastrafflag (1968:64), 8 §. https://www.riksdagen.se/sv/dokument-lagar/dokument/svensk-forfattningssamling/narkotikastrafflag-196864_sfs-1968-64
44 Preedy, Victor R. Neuropathology of Drug Addictions and Substance Misuse. Volume 2, Volume 2. London: Academic Press, an imprint of Elsevier, 2016. p.1056.
45 Neue-Psychoaktive-Substanzen-Gesetz, § 1. https://www.jusline.at/gesetz/npsg
46 Huumausainelaki, 3 §. http://www.finlex.fi/fi/laki/ajantasa/2008/20080373
47 Criminal Justice (Psychoactive Substances) Act 2010, Section 2. http://www.irishstatutebook.ie/eli/2010/act/22/enacted/en/html

procedure (ministerial orders instead of regulations passed by governments) for their inclusion in the lists only. However, the norms establishing "group definitions" (generic scheduling) could count as a more promising practice. 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"[48]. A similar norm is provided 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"[49]. 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"[50]. It also 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 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). 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 "[51].

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

First, there is a lack of agreed criteria for classification of narcotic and psychotropic substances. A set of criteria being applied covers chemical structure of substances,

[48] Neue-Psychoaktive-Substanzen-Gesetz, § 3. https://www.jusline.at/gesetz/npsg
[49] Ustawa z dnia 29 lipca 2005 r. o przeciwdziałaniu narkomanii, Art. 44b. http://isap.sejm.gov.pl/Download?id=WDU20051791485&type=3
[50] Narkootiliste ja psühhotroopsete ainete ning nende lähteainete seadus. § 2. https://www.riigiteataja.ee/akt/12851752
[51] Forskrift om narkotika (narkotikaforskriften), § 3. https://lovdata.no/dokument/SF/forskrift/2013-02-14-199

their clinical use, their origin, sited of action of substances, action prototypes, behavioural effects of substances[52].

Second, 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[53], etc.

Third, all new psychoactive substances are being created in order to bypass rigid characteristics of the controlled substances. Thus, establishing criteria of groups of substances instead of criteria (characteristics) of individual substances would only mean that persons engaged in production of new psychoactive substances will seek to create substances to avoid the more general criteria. Development of contemporary chemistry, biology and other sciences most probably will create "group definitions" only a temporary trump for new "legal highs" to emerge.

The same remarks apply to the third group of solutions proposed - **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**. Laws of some Member States (e.g. Austria[54],) establish definitions of "psychoactive effects" based on the definitions 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" [55]. Others formulate their own, sometimes more restrictive, definitions, e.g. the Portuguese law defines 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

[52] Niesink, Raymundus Johannes Maria. Drugs of Abuse and Addiction: Neurobehavioral Toxicology. Boca Ratón, Florida: CRC Press, 1999.P. 40
[53] Niesink, Raymundus Johannes Maria. Drugs of Abuse and Addiction: Neurobehavioral Toxicology. Boca Ratón, Florida: CRC Press, 1999.P. 40
[54] Neue-Psychoaktive-Substanzen-Gesetz, § 1, https://www.jusline.at/gesetz/npsg
[55] Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol. Art. 2, para. 4

dependence"[56]. However, 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.

Lastly, the fourth and the most promising group of solutions proposed should be considered. There are several states, which establish that every psychoactive substance is considered under the measures of control except when a formal authorization from the government has been issued. The Psychoactive Substances Act 2013 of New Zealand is being considered to be a forerunner of this approach. The act also establishes that:

"(1) A person must not, without reasonable excuse, import a psychoactive substance without a licence to import.

(2) A person who contravenes subsection (1) commits an offence and is liable on conviction,—

(a) in the case of an individual, to a term of imprisonment not exceeding 2 years:

(b) in the case of a body corporate, to a fine not exceeding $500,000."[57]

As the New Zealand Law Commission has stated, this approach effectively reverses the burden of proof from the government having to show products already on the market are unsafe to manufacturers having to prove products are safe before receiving the right to sell[58]. However, the definition provided in the New Zealand law seems to be too abstract, especially concerning the principle of *nullum crimen sine lege*. On the other hand, it should be noted that curbing new psychoactive substances is not limited to criminal punishments only. There are certain administrative and even civil and financial measures that are worth taking into account and thus both *nullum crimen* and *lex retro non agit* principles could be reserved only to a certain part of measures directed towards control of new psychoactive substances.

Still the European states adopting the aforementioned approach do provide more detailed definitions of new psychoactive substances.

---

[56] Decreto-Lei n.º 54/2013 de 17 de abril. Artigo 2.º. http://www.pgdlisboa.pt/leis/lei_mostra_articulado.php?nid=1903&tabela=leis

[57] Psychoactive Substances Act 2013. Section 25. http://www.legislation.govt.nz/act/public/2013/0053/latest/096be8ed812920cf.pdf

[58] Corazza, Ornella, and Andres Roman-Urresterazu. Novel Psychoactive Substances Policy, Economics and Drug Regulation. Cham: Springer, 2017. p. 66

The Romanian Law on combating operations with products susceptible to psychoactive effects, other than those provided by the normative acts in force, establishes that:

“"(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."[59]

A similar approach can be found in the Psychoactive Substances Act 2016, passed by the Parliament of the United Kingdom, which states 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

[59] Lege nr. 194 din 7 noiembrie 2011 (*republicată*) privind combaterea operaţiunilor cu produse susceptibile de a avea efecte psihoactive, altele decât cele prevăzute de acte normative în vigoare. Articolul 3

(ii) knows, or is reckless as to whether, the psychoactive substance is likely to be consumed by some other person for its psychoactive effects."[60]

It would be useful to consider whether an opposite regime could be applied to these substances: to establish that measures of control be applied to all substances corresponding to the general definition of new psychoactive substances except the ones excluded from the scope of the measures of control. In this context, 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, that reads: the European Union provides 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"[61].

It should be noted that such an attitude can be supported by some EU legal acts in force. For example, an 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

[60] Psychoactive Substances Act 2016. Section 8. https://www.legislation.gov.uk/ukpga/2016/2/pdfs/ukpga_20160002_en.pdf

[61] Proposal for a regulation of the European Parliament and of the Council on new psychoactive substances /* COM/2013/0619 final - 2013/0305 (COD) */

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"[62].

There are no conclusions and generalizations provided in the end of the text, because the text is intended as an instrument for discussion that hopefully will lead to conclusions of the project team instead of conclusions of the subjective conclusions of the author of the text.

[62] 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 (Text with EEA relevance.)