

Legal responses to new psychoactive substances in Europe: countries inside the REITOX network, Norway, and Türkiye

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Abstract

Introduction. The rapid proliferation of new psychoactive substances (NPS) presents a major challenge to drug control systems. Unlike traditional controlled substances, NPS are synthetic compounds engineered to bypass existing regulations, raising serious public health concerns due to their high potency and unpredictable toxicity. To support a coordinated European response, the REITOX (Réseau européen d'information sur les drogues et les toxicomanies) network brings together national focal points from EU Member States, Norway, Türkiye and the European Commission.

Objective. To provide a comparative overview of legislative frameworks and regulatory responses to NPS across REITOX Member Countries within the European Union.

Methods. We conducted a cross-national analysis of legal texts, procedures for scheduling new substances, and alignment with international and EU legislation. The role of the Early Warning System (EWS), coordinated by the European Union Drugs Agency (EUDA) and supported by the REITOX network, was also examined.

Results. The analysis revealed substantial variation among REITOX member states in legal approaches, timelines, and integration with EU-level mechanisms. REITOX focal points play a central role in information exchange and in supporting the EWS for early detection and coordinated responses to NPS-related threats.

Key words

- new psychoactive substances
- national legislations
- European Union Drugs Agency
- REITOX network
- NPS scheduling

INTRODUCTION

The proliferation of new psychoactive substances (NPS) [1] over the past two decades has become one of the most significant challenges for drug policy, public health, and regulatory systems in European Union [2, 3]. NPS are predominantly synthetic or semi-synthetic compounds, frequently derived through minor chemical modifications of controlled substances. These structural changes, often designed to circumvent existing drug laws, can produce compounds of unpredictable toxicity and markedly increased potency compared to their parent molecules [4]. In parallel, the digital ecosystem has become a significant driver of NPS dissemination, with online supply channels, including semi restricted areas of the deep web and anonymised dark web marketplaces, facilitating rapid, transnational distribution and accelerating the emergence of novel compounds. As a result, NPS use has been associated with acute

intoxications, overdose deaths, long-term neuropsychiatric sequelae, and substantial burdens on healthcare and forensic systems [5, 6].

According to the *European drug report 2025: trends and developments* [7], as of 2024, 1,000 NPS are currently under monitoring. A significant spike was observed in the years between 2012 and 2015, reflecting the initial surge in NPS emergence. Although the annual numbers have declined since then, the market remains active and dynamic. The largest group of NPS is represented by synthetic cannabinoids, which make up 28% of all monitored substances including new semi-synthetic derivatives with unpredictable pharmacological profiles. Synthetic cathinones, the second largest group of substances by number (18%), rank first in the EU in terms of quantity seized: 37 tonnes in 2023, up from 27 tonnes in 2022 and 4.5 tonnes in 2021. In 2024, one laboratory in Poland was dismantled, yield-

ing a seizure of about 800 kg. Of particular concern are new synthetic opioids, especially nitazenes: since 2019, at least 21 EU Member States have reported the presence of a nitazene in seizures as well as in acute intoxications and/or deaths. In Estonia and Latvia, for example, nitazenes made up 62 of 119, and 101 of 154, respectively, of drug-induced deaths in 2023. In 2024, seven new synthetic opioids were formally notified to the EU Early Warning System (EWS) [8], all of which were nitazenes, the highest number of nitazenes notified in a single year. These trends highlight a shift in the NPS phenomenon: the challenge is no longer characterised by the uncontrolled proliferation of numerous novel molecules, but by the emergence of fewer, highly potent and harmful compounds that present unprecedented risks to public health.

The global framework for drug control is established by the three United Nations international drug control conventions (1961, 1971, 1988), which provide a system of substance-by-substance scheduling. While these instruments guarantee legal certainty, their reliance on “positive lists” renders them structurally ill-suited to respond to the dynamic and adaptive nature of NPS. New analogues or derivatives not explicitly listed remain beyond control until formally scheduled, creating regulatory gaps that can be rapidly exploited by illicit producers and traffickers. Thus, although the UN treaties remain central to the international governance of narcotic and psychotropic substances, their mechanisms are insufficient to address the rapid evolution of the NPS market.

In response, the European Union has progressively developed a more adaptive regulatory framework to supplement international instruments. Since 1997, the EWS has served as the EU’s cornerstone mechanism for the detection, assessment, and control of emerging substances. Coordinated by the European Union Drugs Agency (EUDA) and supported by the REITOX (Réseau européen d’information sur les drogues et les toxicomanies) network of national focal points (30 national focal points of EU Member States, Norway, Türkiye, and the European Commission) [9], the EWS operates as a multi-layered surveillance and response system. It integrates toxicological data, forensic evidence, law enforcement information, and clinical case reports to enable a three-step process: early notification of new substances, scientific risk assessment, and, where appropriate, the adoption of EU-wide control measures.

The EU regulatory architecture has been further strengthened by recent legislative reforms. Regulation (EU) 2017/2101 [10] streamlined the risk assessment process, while Directive (EU) 2017/2103 [11] broadened the definition of “drug” within EU criminal law to explicitly include NPS. The most significant development, however, came with Regulation (EU) 2023/1322 [12], which expanded EUDA’s mandate, consolidating and upgrading its role as the successor to the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA). Under this regulation, EUDA has been tasked with developing predictive and preventive tools with the aim to reconcile the traditional trade-off between legal certainty and regulatory timeliness.

Despite these advances, significant heterogeneity persists among national legal responses to NPS within the REITOX member countries. Some countries rely on highly formalised legislative procedures, requiring parliamentary approval for each new scheduling decision. While these approaches ensure legal robustness and compliance with the principle of legality enshrined in Article 7 of the European Convention on Human Rights [13], they often result in delays of several months or even years before a new substance is brought under control. Conversely, other countries have adopted more flexible approaches, such as generic scheduling (covering groups of substances based on shared chemical structures), analogue provisions (extending control to substances with similar pharmacological effects), or emergency measures allowing temporary bans. These mechanisms provide speed and adaptability but may introduce legal ambiguities, raising concerns about enforceability and proportionality [14–18].

Against this background, the aim of this article was twofold. First, it seeks to provide a comparative overview of national legislative frameworks for the control of NPS across REITOX member countries, focusing on the instruments and procedures employed, the timelines for the inclusion of new substances, and the degree of alignment with EU-level mechanisms. Second, it aims to evaluate how divergent legal architectures affect the timeliness, robustness, and coherence of policy interventions. In doing so, it exposes structural weaknesses and considers opportunities for harmonisation, with the ultimate goal of supporting evidence-based and forward-looking policies that protect public health and the safety of European citizens against the evolving NPS phenomenon.

METHODS

This study is based on a comparative legal analysis of national frameworks governing the control of new psychoactive substances (NPS) across the Member States of the European Union (EU) and additional countries participating in the REITOX network.

The primary sources of data consisted of official legal texts at both national and EU levels, including criminal codes, drug control laws, ministerial decrees, and emergency measures. Where available, information was retrieved directly from government databases, national gazettes, or parliamentary archives. These were supplemented by secondary sources such as reports, policy briefs, and databases published by the EUDA and the former EMCDDA.

Given the multilingual nature of the data, many of the legal documents were originally available only in the official language of the respective country. In such cases, documents were translated into English for analytical purposes, either using official translations where provided or, when necessary, by the authors to ensure accurate comprehension and comparability across jurisdictions.

To facilitate systematic comparison, national control mechanisms were classified into three main categories: 1. relevant national legislative instruments: identification of current legal sources governing the control of narcotic substances and NPS, including primary leg-

- isolation, implementing decrees, and relevant sections of national penal codes;
2. timelines and procedures for NPS scheduling: evaluation of legislative pathways and the temporal dynamics involved in updating national controlled substance lists;
 3. substance classification systems: verification of the presence and structure of formal drug scheduling mechanisms.

This comparative approach enabled the identification of structural similarities and differences in national practices, as well as variations in the speed and flexibility of regulatory responses. Where available, informal data regarding risk assessment processes and institutional actors involved in decision-making were also incorporated to provide contextual depth.

RESULTS

Country-specific summaries of REITOX members, outlining the main legal instruments in force, the authorities responsible for scheduling decisions, and the modalities through which NPS are incorporated into national control lists, are presented in *Appendix A available online as Supplementary Material*. A comparative matrix on the national procedures is summarized in *Table 1* [19-110].

Data analysis has allowed to identify five major dimensions that shape the legal and operational landscape: the typology of national laws, the procedures and timelines for scheduling, the classification models used to define controlled substances, the scheduling systems and structures, and the mechanisms for transposing international standards and aligning with European Union legislation.

Typology of national law

A comparative analysis of the national legal framework reveals two main typologies for the control of NPS: integration into general drug legislation versus the adoption of NPS-specific legal instruments. In most REITOX member countries, NPS are regulated within broader narcotic and psychotropic drug control laws, often through periodic amendments to existing schedules or annexes (e.g., Italy, Poland, and Portugal). These frameworks typically do not distinguish NPS as a separate legal category but treat them under the same provisions as traditional controlled substances. In contrast, a limited number of jurisdictions (e.g., Germany) have established dedicated legislation for NPS, reflecting the unique challenges these substances pose. Such frameworks are designed to allow more flexible and timely responses through broader definitions, streamlined procedures, and mechanisms that can target entire groups of substances rather than single compounds.

Scheduling procedures

One of the central findings concerns the accuracy-speed trade-off. Countries relying on formal legislative scheduling, parliamentary processes or multi-step legal amendments, ensure high legal certainty and compliance with the principle of legality, but the extended timelines (often 6-12 months) hinder responsiveness to rapidly emerging substances. In contrast, administrative

decrees and executive measures enable swifter interventions (sometimes within weeks), mitigating immediate health threats but providing weaker legal durability and greater susceptibility to procedural challenges.

A third regulatory pathway consists of temporary control measures, applied in countries such as Hungary, Latvia, Lithuania, and the Netherlands. These measures, often lasting up to one year, function as legal “bridges” that allow substances to be regulated quickly while a full risk assessment is ongoing. Risk assessments themselves vary widely: in some countries (e.g., Bulgaria, Estonia, France, Lithuania, Norway, Slovakia) they are formally mandated; in others (e.g., Croatia, Czech Republic, Luxembourg, Poland, Portugal, Slovenia) they are *ad hoc*; while in jurisdictions such as Cyprus, Greece, Ireland, and Spain they are not required at all. These divergences introduce asymmetries in the scientific grounding of scheduling decisions.

Classification models

The legal classification of NPS can be broadly grouped into three models. The individual listing model, used by most countries (e.g., Italy, France, Germany, Spain), requires explicit identification of each substance by chemical name. This ensures clarity but is inherently reactive and often too slow. To overcome this, some jurisdictions have adopted generic classification systems (e.g., Ireland, Türkiye, Belgium, Hungary), which define families of compounds by core molecular structures and allow automatic inclusion of analogues. A third approach is the analogue control model, applied in countries such as Norway and Latvia, where substances may be regulated if chemically and pharmacologically similar to already scheduled compounds. Each model reflects a trade-off between legal certainty and flexibility, and several countries (e.g., Belgium, Germany, Italy, Ireland) adopt mixed approaches to maximise coverage.

Scheduling models

Most national frameworks rely on three criteria for classification: public health risk, potential for abuse, and possible therapeutic utility. Their normative translation, however, differs significantly. Some countries (e.g., Italy, France, Germany, Poland) adopt multiple schedules, allowing differentiated regulation from strict bans to restricted medical use. Others (e.g., Portugal, Norway, the Netherlands) adopt simplified or binary schedules, distinguishing mainly between licit and illicit substances. This heterogeneity influences prescribing practices, pharmaceutical traceability, thresholds for enforcement, and prevention strategies.

Transposition of international standards and harmonisation

All Member States are formally bound by UN Conventions, but mechanisms for transposing international decisions differ. In some jurisdictions (e.g., Italy, Germany, Poland), substances are incorporated with minimal delay – Italy even applying automatic inclusion via Presidential Decree 309/1990. In others, such as France, international listings are subject to national evaluation, taking into account domestic priorities and

Table 1
National legal frameworks and drug scheduling systems for new psychoactive substances (NPS) within the REITOX network

Country	Legal text	Drug scheduling
Austria	<ul style="list-style-type: none"> • <i>Suchtmittelgesetz (SMG)</i>: Federal Narcotic Substances Act, 1998. Main law regulating narcotic and psychotropic substances [19] • <i>Suchtgiftverordnung (SV)</i>: Narcotic Substances Ordinance: lists controlled narcotics [20] • <i>Psychotropenverordnung (PV)</i>: Psychotropic Substances Ordinance: covers controlled psychotropic drugs [21] • <i>Neue-Psychoaktive-Substanzen-Verordnung (NPSV)</i>: NPS Regulation and legal status [22] • <i>Suchtgift-Grenzmengenverordnung (SGV)</i>: Narcotic Threshold Quantities Ordinance [23] • <i>Psychotropen-Grenzmengenverordnung</i>: Psychotropic Threshold Quantities Ordinance [24] 	<ul style="list-style-type: none"> • The Suchtgiftverordnung (SV) and Psychotropenverordnung (PV) are structured into annexes (Anlagen) categorizing substances by their abuse potential and medical utility • New substances are added to the SV, PV, or Neue-Psychoaktive-Substanzen-Verordnung (NPSV) through ordinance amendments • Threshold quantities determining criminal or administrative liability are defined in the SGV and Psychotropen-Grenzmengenverordnung • These lists are maintained and updated by the Federal Office for Safety in Health Care (BASG) and published in the RIS (Rechtsinformationssystem)
Belgium	<ul style="list-style-type: none"> • <i>Royal Decree of 22 January 1998</i>: establishes lists of controlled psychotropic substances, regularly updated [25] • <i>Law of 24 February 1921</i>: primary legal foundation on drug control; frequently amended to adapt to evolving drug challenges. Act of 7 February 2014 expanded its scope to include psychotropic substances [26] • <i>Royal Decree of 6 September 2017</i>: introduces a generic system allowing the classification of entire groups of NPS based on chemical structure, ensuring faster regulatory response [27] 	<ul style="list-style-type: none"> • The scheduling framework legally binding through Royal Decrees (primarily the 1998 and 2017 instruments). These decrees are structured by: <ul style="list-style-type: none"> - specific listing (chemical name) - generic control (chemical group classification)
Bulgaria	<ul style="list-style-type: none"> • <i>Ordinance n. 1 of 1992</i>: classification and control measures for narcotic and psychotropic substances. Updated regularly via annexes • <i>Drugs and Precursors Control Act (1999)</i>: core legal framework for narcotic substances and precursors [28] • <i>Medicinal Products in Human Medicine Act: governs medicines containing controlled substances</i> [29] • <i>Penal Code, Art. 354a-354c</i>: criminalizes production, possession, and trafficking of illicit drugs 	<ul style="list-style-type: none"> • The controlled substances are listed in Annexes to Ordinance n. 1 of 1992 • Substances are classified in Schedules I-IV based on their medical use and risk profile • Updates are published in the State Gazette following proposal by the Ministry of Health
Croatia	<ul style="list-style-type: none"> • <i>Law on Combating Drug Abuse (Zakon o suzbijanju zlouporabe opojnih droga)</i>: core law regulating narcotic and psychotropic substances [30] • <i>Criminal Code (Kazneni zakon)</i>: penalizes production and trafficking. Possession for personal use is decriminalized (administrative sanction) [31] • <i>Health Protection Act</i>: addresses treatment and prevention [32] 	<ul style="list-style-type: none"> • The controlled substances are listed in annexes to the Act on Drug Abuse, grouped into categories based on risk and medical use
Cyprus	<ul style="list-style-type: none"> • <i>Narcotic Drugs and Psychotropic Substances Law (cap. 154)</i>: regulates narcotics and psychotropic substances and defines offenses related to trafficking and possession [33] • <i>The Suppression of Crime (Controlled Delivery and Other Special Provisions) (Amendment) Law of 1998</i>: provides mechanisms for controlled delivery of illegal drugs and other special provisions related to crime suppression [33] • <i>The Treatment of Convicted Users and Addicts Law, 2016</i>: focuses on treatment programs for individuals convicted of drug-related offenses [33] • <i>The Prevention and Suppression of Money Laundering Activities (Amendment) Law (n. 18(I) 2016)</i>: targets money laundering related to drug trafficking and other illegal activities [33] • <i>The Cultivation and Trade of Industrial Hemp Law of 2016</i>: regulates the cultivation and trade of non-psychoactive industrial hemp [33] • <i>The Road Safety (Amendment) Law of 2016</i>: includes regulations on drug use and road safety, specifically addressing driving under the influence of drugs [33] • <i>The Prevention of the Use and Dissemination of Drugs and Other Addictive Substances Law 2017</i>: focuses on preventing drug use and the dissemination of addictive substances through public health campaigns and national efforts [33] 	<ul style="list-style-type: none"> • The controlled substances are listed in annexes to the Narcotic Drugs and Psychotropic Substances Law, grouped into categories based on risk and medical use

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Table 1
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Country	Legal text	Drug scheduling
Czech Republic	<ul style="list-style-type: none"> • <i>Act n. 167/1998 Coll. on Addictive Substances</i>: main framework for drug scheduling and control of narcotic and psychotropic substances, including NPS. Amended in July 2023 to introduce new substance categories [34] • <i>Act n. 40/2009 Coll. (Criminal Code)</i>: article 283 and 284 criminalize unauthorized possession, manufacturing, and trafficking [35] • <i>Act n. 373/2011 Coll. on Specific Health Services</i>: regulates therapeutic treatment, prevention, and substitution treatment for addictions [36] • <i>Government Regulation n. 463/2013 Coll.</i>: contains the schedules of controlled substances (updated regularly; last update: 2024) [37] • <i>Act n. 65/2017 Coll. on Health Protection from Addictive Substances</i>: governs sale and advertising of alcohol, tobacco, e-cigarettes and includes preventive measures Amended twice in 2023 [38] • <i>Government Regulation n. 52/2024 Sb.</i>: effective March 6, 2024 includes substances such as HHC, HHC-O, and THCP [39] 	<ul style="list-style-type: none"> • The Czech Republic uses a five-group scheduling system under Government Regulation n. 463/2013 Coll. Substances are listed from Group I to V, based on scientific assessment of harm, dependence risk, and medical utility. While the law does not provide explicit definitions for each group, Group I typically includes substances without accepted medical use (e.g., heroin), whereas Groups II-V reflect decreasing levels of control and wider therapeutic application
Denmark	<ul style="list-style-type: none"> • <i>Consolidated Act n. 748/2008 on Euphoriant Substances</i>: establishes the legal basis for regulating psychoactive substances and empowers the Minister of Health to rapidly add new substances via executive orders [40] • <i>Executive Order n. 2446 of 12 December 2021 on Euphoriant Substances</i>: primary legal framework listing controlled substances in Denmark [41] • <i>Danish Penal Code (Straffeloven), Section 191</i>: addresses serious drug offenses, including large-scale trafficking and distribution [42] • <i>Danish Penal Code, Section 191a</i>: specifically targets serious doping offenses [42] 	<ul style="list-style-type: none"> • Five-tier classification system (Schedules A-E) for controlled substances: <ul style="list-style-type: none"> - List A: substances prohibited entirely - Lists B, D, E: substances permitted solely for medical or scientific purposes - List C: substances controlled in their unprepared form but not generally regulated when included in pharmaceutical preparations
Estonia	<ul style="list-style-type: none"> • <i>Act on Narcotic Drugs and Psychotropic Substances and Precursors thereof</i>: primary legal framework regulating controlled substances in Estonia. It outlines procedures for handling, inspection, and identification of narcotic drugs, psychotropic substances, and their precursors [43] • <i>Regulation n. 73 of the Minister of Social Affairs</i>: establishes the conditions and procedures for handling narcotic drugs and psychotropic substances for medical and research purposes, including maintaining records and reporting [44] 	<ul style="list-style-type: none"> • Estonia employs a scheduling system categorizing substances into six schedules, depending on their effect and misuse/dependence potential. This classification is detailed in Annex 1 of Regulation n. 73
Finland	<ul style="list-style-type: none"> • <i>Narcotics Act (373/2008)</i>: establishes the legal framework for controlling narcotic substances, including provisions for their manufacture, distribution, and possession [45] • <i>Government Decree on Substances, Preparations and Plants Considered as Narcotics (543/2008)</i>: lists substances classified as narcotics under Finnish law [46] • <i>Government Decree on Psychoactive Substances Prohibited on the Consumer Market (1130/2014)</i>: prohibits the sale and marketing of certain psychoactive substances not classified as narcotics but deemed harmful [47] • <i>Criminal Code of Finland, Chapter 50</i>: defines drug offences and associated penalties [48] 	<ul style="list-style-type: none"> • The scheduling system categorizing substances based on their potential for abuse and medical utility. The classification is detailed in the Government Decree on Substances, Preparations and Plants Considered as Narcotics (543/2008)
France	<ul style="list-style-type: none"> • <i>Law n. 70-1320 of 31 December 1970</i>: the first major drug law in France that established the prohibition of narcotic drugs [49] • <i>Code de la Santé Publique, specifically Book III, Title III, Chapter I</i>: establishes the legal framework for the classification, production, and control of narcotic drugs [50] • <i>Order of 22 February 1990</i> establishes the official list of controlled narcotic substances (regularly updated) [51] • <i>Law n. 2016-41 of 26 January 2016</i>: modifies the framework for penalties and enforcement concerning drug trafficking and use [52] 	<ul style="list-style-type: none"> • The substances are classified under the Public Health Code (articles L. 5132-1 et seq.). For instance, substances are categorized into Category 1 (which includes the most dangerous substances) and Category 2 (which comprises substances with a lower potential for abuse, but which remain under control)

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Country	Legal text	Drug scheduling
Germany	<ul style="list-style-type: none"> • <i>Narcotic Drugs Act (BtMG)</i>: governs the control of narcotic drugs, including licensing, prescription, import/export, and criminal penalties • <i>New Psychoactive Substances Act (NpSG)</i>: enacted in December 2016, this law prohibits the acquisition, possession, and sale of certain NPS, introducing generic controls over groups like phenethylamines and synthetic cannabinoids [53] • <i>Cannabis Control Act (CanG)</i>: effective from April 1, 2024, this act removed cannabis from the BtMG, regulating its use under a separate framework [54] 	<ul style="list-style-type: none"> • Germany employs a scheduling system under the BtMG, categorizing substances into three schedules: <ul style="list-style-type: none"> - Schedule I: non-marketable narcotics (e.g., heroin, MDMA) with no recognized medical use - Schedule II: marketable but non-prescribable substances, primarily for manufacturing purposes - Schedule III: marketable and prescribable narcotics under strict regulation
Greece	<ul style="list-style-type: none"> • <i>Ministerial Decisions</i>: specific substances are added to the controlled substances list through ministerial decisions. For example, mephedrone was added to Table A of the list of controlled substances included in Law 3459/06 • <i>Law 4139/2013</i>: primary legislation regulating the use and possession of addictive substances, replacing the earlier Law 3459/2006 [55, 56] 	<ul style="list-style-type: none"> • Greece employs a scheduling system categorizing substances into three tables: <ul style="list-style-type: none"> - Table A: substances with a high potential for abuse and no recognized medical use (e.g., heroin, LSD) - Table B: substances with a high potential for abuse but with recognized medical uses (e.g., morphine, methadone) - Table C: substances with a lower potential for abuse and recognized medical uses
Hungary	<ul style="list-style-type: none"> • <i>Act C of 2012 on the Criminal Code</i>: effective from 1 July 2013, this act covers offenses related to drug trafficking, possession, incitement of minors to use drugs, assisting production, precursors, NPS, and performance enhancement substances [57] • <i>Government Decree 66/2012 (IV. 2.)</i>: introduced on 3 April 2012, this decree allows for the rapid control of NPS through a formalized rapid assessment process. It created Schedule C for NPS, listing both individual substances and groups of chemical compounds [58] • <i>Ministerial Decree 55/2014 of the Minister of Human Capacities</i>: facilitates the inclusion of NPS into the controlled substances list following the rapid assessment process established by Government Decree 66/2012 [59] 	<ul style="list-style-type: none"> • Scheduling system include: <ul style="list-style-type: none"> - Schedule A: narcotic drugs with high abuse potential and no recognized medical use - Schedule B: psychotropic substances with recognized medical use but potential for abuse - Schedule C: new psychoactive substances (NPS), including both individual substances and groups of chemical compounds - Schedule D: precursors and other substances used in the production of narcotic drugs and psychotropic substances.
Ireland	<ul style="list-style-type: none"> • <i>Misuse of Drugs Acts 1977-2016</i>: this series of acts forms the primary legal framework for controlling drugs in Ireland. It regulates the importation, manufacture, trade, and possession of psychoactive substances [60] • <i>Misuse of Drugs Regulations 1988 (SI n. 328/1988)</i>: these regulations categorize controlled drugs into five schedules and outline the requirements for their handling [61] • <i>Criminal Justice (Psychoactive Substances) Act 2010</i>: this Act prohibits the sale, importation, and advertisement of psychoactive substances not already controlled under the Misuse of Drugs Acts [62] • <i>Misuse of Drugs (Amendment) Act 2015</i>: bill entitled an act to amend the Misuse of Drugs Act 1977; to confirm certain statutory instruments; and to provide for related matters [63] 	<ul style="list-style-type: none"> • The controlled drugs are categorized under five schedules in the Misuse of Drugs Regulations: <ul style="list-style-type: none"> - Schedule 1: substances with no recognized medical use and high potential for abuse - Schedule 2: substances with recognized medical use but high potential for abuse - Schedule 3: substances with less potential for abuse than Schedule 2 drugs - Schedule 4: substances with low potential for abuse - Schedule 5: preparations containing limited quantities of certain controlled drugs
Italy	<ul style="list-style-type: none"> • <i>Presidential Decree 309/1990 (Testo Unico delle leggi in materia di disciplina degli stupefacenti e sostanze psicotrope)</i>: primary legal framework regulating narcotic drugs and psychotropic substances in Italy. It outlines the classification of substances, penalties for offenses, and provisions for prevention and rehabilitation [64] • <i>Ministerial Decrees</i>: the Ministry of Health issues decrees to update the schedules of controlled substances, including the addition of new psychoactive substances (NPS). These decrees are published in the Official Gazette (Gazzetta Ufficiale) • <i>Law 16 May 2014 n. 79 (Conversion into law, with amendments, of Decree-Law n. 36 of March 20, 2014)</i>: urgent provisions concerning the regulation of narcotic drugs and psychotropic substances, prevention, treatment and rehabilitation of the relative states of drug addiction, as per Presidential Decree n. 309 of 9 October 1990, as well as the use of less onerous medicines by the National Healthcare Service [65] 	<ul style="list-style-type: none"> • The scheduling system classifies substances into five Tables: <ul style="list-style-type: none"> - Table I: substances with high abuse potential and no recognized medical use (e.g., heroin, LSD) - Table II: substances with high abuse potential but with recognized medical use (e.g., morphine, methadone) - Table III: substances with lower abuse potential and recognized medical use (e.g., codeine) - Table IV: preparations containing substances from Tables II and III in combinations that reduce abuse potential - Table medicinal products: medicinal products containing narcotic or psychotropic substances in minimal quantities

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Table 1
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Country	Legal text	Drug scheduling
Latvia	<ul style="list-style-type: none"> • <i>Law on the Procedures for the Coming into Force and Application of the Criminal Law (2002)</i>: governs the addition of controlled substances and criminal liability related to narcotics and psychotropics [66] • <i>Law on Procedures for the Legal Trade of Narcotic and Psychotropic Substances and Medicinal Products (2005, with amendments)</i>: establishes the legal framework for handling-controlled substances [66] • <i>Cabinet Regulation n. 428 (2009)</i>: lists controlled narcotic, psychotropic substances and precursors in Latvia [67] 	<ul style="list-style-type: none"> • Latvia classifies substances into four schedules: <ul style="list-style-type: none"> - Schedule I: particularly dangerous narcotic and psychotropic substances and associated plants - Schedule II: highly dangerous substances with medical and scientific uses - Schedule III: psychotropic substances with abuse potential - Schedule IV: precursors used in the manufacture of controlled substances
Lithuania	<ul style="list-style-type: none"> • <i>Law on the Control of Narcotic and Psychotropic Substances (1998, with amendments)</i>: establishes the framework for the classification, control, and regulation of narcotic and psychotropic substances in Lithuania [68] • <i>Criminal Code of the Republic of Lithuania</i>: specifies criminal offenses and penalties related to the illegal handling of narcotic and psychotropic substances • <i>Lithuanian Government's Decision (2005)</i>: regulates the control of precursors used in the illegal manufacture of drugs [69] • <i>Cabinet Resolution n. 1463 (2012)</i>: establishes the rapid response mechanism for controlling new psychoactive substances (NPS) by grouping substances with similar structures 	<ul style="list-style-type: none"> • Lithuania classifies substances into four schedules: <ul style="list-style-type: none"> - Schedule I: substances prohibited for medical use due to high potential for abuse and harm - Schedule II: substances used for medical purposes but considered highly dangerous - Schedule III: substances used for medical purposes with a lower potential for abuse - Schedule IV: substances used for medical or industrial purposes with the lowest potential for abuse
Luxembourg	<ul style="list-style-type: none"> • <i>Law of 19 February 1973</i>: governs the sale of medicinal substances and the fight against drug addiction [70] • <i>Law of 12 July 1996</i>: allows for an accelerated procedure to rapidly classify new substances deemed dangerous • <i>Grand Ducal Regulation of 19 February 1974</i>: details the classification of narcotic drugs and psychotropic substances [71] • <i>Grand Ducal Regulation of 30 July 2002</i>: implements measures for the control of drug precursors 	<ul style="list-style-type: none"> • Luxembourg classifies substances into schedules based on the UN Single Convention on Narcotic Drugs (1961) and the Convention on Psychotropic Substances (1971). The schedules are: <ul style="list-style-type: none"> - Schedule I: substances with high potential for abuse and no recognized medical use - Schedule II: substances with high potential for abuse but with some accepted medical uses - Schedule III: substances with less potential for abuse and accepted medical uses - Schedule IV: substances with low potential for abuse and widespread medical use
Malta	<ul style="list-style-type: none"> • <i>Dangerous Drugs Ordinance (cap. 101)</i>: governs control, import, export, sale, and possession of narcotic drugs [72] • <i>Medical and Kindred Professions Ordinance (cap. 31)</i>: controls psychotropic substances and professional practices related to medical use [73] • <i>Drug Dependence (Treatment not Imprisonment) Act (cap. 537)</i>: shifts focus from incarceration to treatment for drug-dependent individuals [74] • <i>Controlled Substances Regulations</i>: define registration, reporting, and licensing obligations for controlled substances 	<ul style="list-style-type: none"> • The classification appears in Schedules A, B, C, and D of the Dangerous Drugs Ordinance and associated regulations
Netherlands	<ul style="list-style-type: none"> • <i>Opium Act (Opiumwet)</i>: the foundational law governing drug control in the Netherlands. It distinguishes between Schedule I (hard drugs) and Schedule II (soft drugs) [75] • <i>Opium Act Directive</i>: provides guidelines for the enforcement of the Opium Act, including prosecutorial discretion and policy priorities [76] 	<ul style="list-style-type: none"> • The Opium Act classifies substances into two schedules: <ul style="list-style-type: none"> - Schedule I: hard drugs (e.g., heroin, cocaine, MDMA, amphetamines) - Schedule II: soft drugs (e.g., cannabis, hallucinogenic mushrooms)
Norway	<ul style="list-style-type: none"> • <i>Medicinal Products Act (Legemiddeloven)</i>: regulates the use and distribution of pharmaceuticals, including narcotic substances [77] • <i>Norwegian Penal Code (Straffeloven) Sections 231-232</i>: punishes the production, importation, exportation, possession, and trafficking of drugs [78] • <i>Regulation on Narcotic Substances (Narkotikaforskriften)</i>: provides the list of controlled substances and outlines the classification [79] • <i>Drug Reform (2022)</i>: the Norwegian Supreme Court decriminalized the possession of small amounts of drugs for personal use, emphasizing a health-based approach over criminal sanctions [80] 	<ul style="list-style-type: none"> • Classification system for controlled substances based on the risk they pose: <ul style="list-style-type: none"> - Class A: high-risk narcotics with no or very limited medical use (e.g., heroin, cocaine, amphetamines) - Class B: psychotropic substances and medicines with recognized medical use but significant abuse potential (e.g., benzodiazepines) - Class C: prescription medications with lower abuse potential • Substances not listed under these categories are regulated separately or remain uncontrolled unless specifically scheduled

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Table 1
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Country	Legal text	Drug scheduling
Poland	<ul style="list-style-type: none"> • <i>Act on Counteracting Drug Addiction (Ustawa o Przeciwdziałaniu Narkomanii, 2005)</i>: primary legal framework regulating the production, distribution, and possession of narcotic substances in Poland [81] • <i>Act on Counteracting Drug Addiction, Amendment (2011)</i>: amended provisions regarding the control and penalties for drug-related crimes [82] • <i>Regulation of the Minister of Health (2011)</i>: details the classification of psychoactive substances and their management [83] • <i>Regulation of the Minister of Health of 16 March 2017</i>: defines controlled substances and establishes conditions for import and export of narcotics and psychotropic substances [84] • <i>Regulation of the Minister of Health of 21 August 2019</i>: updates the list of new psychoactive substances (NPS) [85] 	<ul style="list-style-type: none"> • Poland classifies controlled substances under three categories based on their risk level: <ul style="list-style-type: none"> - Group I: narcotics with high potential for abuse (e.g., heroin, cocaine) - Group II: substances with moderate abuse potential (e.g., benzodiazepines, amphetamines) - Group III: prescription medications and substances with low abuse potential
Portugal	<ul style="list-style-type: none"> • <i>Decree-Law n. 15/93 (January 22, 1993)</i>: establishes the legal framework for controlling narcotic substances, including provisions for their manufacture, distribution, and possession [86] • <i>Regulation n. 111/2005 (article 7)</i>: Establishes the framework for the registration of operators in the controlled substances trade [87] • <i>Decree-Law n. 54/2013</i>: prohibits the production, export, advertisement, distribution, sale or simple dispensing of new psychoactive substances (NPS) named in the list accompanying the Decree Law and sets up a control mechanism for NPS [88] • <i>Ordinance n. 154/2013</i>: specifically addresses the control of NPS in Portugal, outlining which substances are prohibited [89] • <i>Decree-Law n. 254/2016 (October 16, 2016)</i>: focuses on harm reduction and the regulation of certain psychoactive substances • <i>Law n. 9/2023 (March 3, 2023)</i>: recent amendments to Decree-Law n. 15/93, incorporating new psychoactive substances (NPS) and bringing it into alignment with EU regulations [90] 	<ul style="list-style-type: none"> • Portugal uses a system that classifies substances based on their risk and medical utility. These substances are categorized into classes A, B, and C
Romania	<ul style="list-style-type: none"> • <i>Law n. 143/2000 on Combating Illicit Drug Trafficking and Consumption</i>: establishes the legal framework for preventing and combating illicit drug trafficking and consumption • <i>Law n. 522/2004</i>: amends and supplements Law n. 143/2000, introducing definitions such as “dependent consumer” and establishing integrated assistance programs [91] • <i>Government Emergency Ordinance n. 121/2006</i>: regulates the legal regime of drug precursors. Law n. 186/2007: approves Government Emergency Ordinance n. 121/2006 • <i>Law n. 194/2011</i>: addresses operations with products suspected to have psychoactive effects, other than those stipulated by existing legislation • <i>Joint Ministerial Order</i>: establishing mixed teams to control new psychoactive substances (2011) 	<ul style="list-style-type: none"> • Romania employs a scheduling system categorizing substances into three tables based on their potential for abuse and medical utility: <ul style="list-style-type: none"> - Table I: high-risk drugs with no medical use (e.g., heroin, cocaine) - Table II: risk drugs with limited medical use (e.g., cannabis, MDMA) - Table III: precursors and other substances medicinal products containing controlled substances
Slovakia	<ul style="list-style-type: none"> • <i>Act n. 139/1998 Coll.</i>: primary legislation regulating narcotic and psychotropic substances. It defines controlled substances and outlines penalties for drug-related offenses [92] • <i>Amendment (October 2013)</i>: allows the Minister of Health to temporarily add new psychoactive substances (NPS) to a controlled list for up to 3 years if there's reasonable suspicion of abuse and harmful effects • <i>National Anti-Drug Strategy 2021-2025 (Horizon 2030)</i>: approved by the Ministry of Health in 2021, aligning national drug policy with the EU Drugs Strategy 2021-2025 [93] 	<ul style="list-style-type: none"> • Five-tier classification system (Schedules A-E) for controlled substances: <ul style="list-style-type: none"> - List A: substances prohibited entirely - Lists B, D, E: substances permitted solely for medical or scientific purposes - List C: substances controlled in their unprepared form
Slovenia	<ul style="list-style-type: none"> • <i>Prevention of Illicit Drug Abuse and Treatment of Drug Addictions Act (1999)</i>: establishes the legal framework for preventing illicit drug abuse and providing treatment for drug addictions [94] • <i>Act on the Production of and Trade in Illicit Drugs (ZPPPD)</i>: governs the production and trade of illicit drugs, including penalties for violations [95] • <i>Decree on the Classification of Illicit Drugs (2000)</i>: lists substances classified as illicit drugs under Slovenian law [94] • <i>Resolution on the National Programme on Illicit Drugs 2023-2030</i>: adopted in June 2023, this strategy outlines Slovenia's approach to reducing and containing the harm caused by illicit drug use 	<ul style="list-style-type: none"> • Slovenia classifies controlled substances into three groups based on their risk and medical use: <ul style="list-style-type: none"> - Group I: extremely dangerous substances with no medical use (e.g., heroin, cocaine, THC/cannabis) - Group II: highly dangerous substances with recognized medical use (e.g., morphine, codeine) - Group III: moderately dangerous substances used medically (e.g., barbiturates, benzodiazepines)

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Table 1
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Country	Legal text	Drug scheduling
Spain	<ul style="list-style-type: none"> • <i>Law 17/1967</i>: modifies Law 25/1964 and establishes control over narcotic drugs [96] • <i>Royal Decree 2829/1977</i>: regulates the control of narcotic and psychotropic substances, aligning with international conventions [97] • <i>Criminal Code (Organic Law 10/1995)</i>: establishes penalties for drug trafficking and related offenses [98] • <i>Law 3/1996</i>: addresses drug control and treatment of drug addictions [99] • <i>Royal Decree 1675/2012</i>: updates the legal framework to include new psychoactive substances (NPS) [100] • <i>Organic Law 4/2015 on the Protection of Citizen Security</i>: addresses public safety, including provisions related to drug consumption and possession in public places [101] • <i>Código Penal – article 368</i>: penalizes trafficking, cultivation, and possession of drugs intended for sale [102] • <i>National Strategy on Addictions 2017-2024</i>: provides the strategic framework for addressing addictions, including illicit drugs, in Spain [103] • <i>Addictions Action Plan 2021-2024</i>: operational document implementing the National Strategy [104] 	<ul style="list-style-type: none"> • Spain uses a scheduling system that categorizes narcotic and psychotropic substances in accordance with UN conventions. These are published in official lists (not alphabetical or numerical classes) via Royal Decrees (RD), such as RD 2829/1977 and RD 1675/2012. The classification includes internationally controlled substances and emerging NPS, following recommendations from EU and international bodies
Sweden	<ul style="list-style-type: none"> • <i>Narcotic Drugs (Punishments) Act (SFS 1968:64)</i>: defines offenses and penalties related to narcotic drugs [105] • <i>Act on the Control of Narcotic Drugs (SFS 1992:860)</i>: establishes the framework for controlling narcotic drugs, including scheduling [106] • <i>Ordinance on the Control of Narcotic Drugs (SFS 1992:1554)</i>: supplements the 1992 Act, detailing the list of controlled substances [107] • <i>Act on Penalties for Smuggling (SFS 2000:1225)</i>: addresses penalties for smuggling narcotic drugs [108] 	<ul style="list-style-type: none"> • Sweden maintains official lists of controlled substances, updated regularly by the Medical Products Agency (Läkemedelsverket). These lists align with international conventions
Türkiye	<ul style="list-style-type: none"> • <i>Law n. 3298 on Narcotic Drugs (1986)</i>: specifically regulates opium and its derivatives, including cultivation, production, and distribution [109] • <i>Law n. 2313 on the Control of Narcotic Drugs</i>: establishes the framework for controlling narcotic drugs, including scheduling and classification [110] • <i>Turkish Penal Code (TPC)</i>: articles 188-192 define offenses and penalties related to narcotic drugs, including production, trade, and facilitation of drug use. Penalties range from 2 to 30 years imprisonment, depending on the severity of the offense 	<ul style="list-style-type: none"> • Türkiye maintains official lists of controlled substances, updated regularly by the Ministry of Health. These lists align with international conventions and are categorized without using alphabetical or numerical classes. The scheduling system includes both specific substances and generic groups to effectively control NPS

REITOX: Réseau européen d'information sur les drogues et les toxicomanies; HHC: hexahydrocannabinol; HHC-O: hexahydrocannabinol-o-acetate; THCP: tetrahydrocannabiphorol; MDMA: 3,4-methylenedioxymethamphetamine; LSD: lysergic acid diethylamide.

epidemiological trends. This discretion highlights the tension between regulatory harmonisation and national autonomy, often resulting in fragmented timelines for implementing international controls.

DISCUSSION

The comparative analysis reveals both areas of convergence and significant divergence among REITOX Member Countries, underscoring the complex interplay between national autonomy, international obligations, and supranational coordination. This heterogeneity forms the empirical basis for evaluating the regulatory trade-offs that shape both national and EU-level responses to the NPS phenomenon [111]. Recent developments in NPS markets highlight the urgency of addressing these regulatory disparities.

A substance swiftly scheduled in one country may remain legally accessible in another, creating “regulatory havens” that traffickers and online vendors can exploit. This patchwork of legal frameworks complicates cross-border enforcement and challenges the principle of equal health protection across Europe. Variations in scheduling speed and scope can result in uneven capacities among healthcare systems and public authorities to respond to NPS-related harms. Countries with slower legislative mechanisms may experience higher rates of acute intoxication and morbidity, while those with broader but less precise legal tools face challenges related to proportionality and legal certainty.

From a supranational perspective, these dynamics underscore the need for enhanced European coordination. While the EU Early Warning System provides a

structured platform for detection and risk assessment of NPS, its impact is limited by inconsistent national transposition. To address this, predictive and anticipatory tools – such as integrated forensic databases and real-time epidemiological monitoring – are urgently needed to align legal responses with the emergence of increasingly potent and toxic substances [112, 113].

The comparative findings presented suggest several policy directions. First, harmonisation between national frameworks and EU instruments is essential to reduce fragmentation. A stronger coordinating mandate for the EUDA could ensure consistent and timely translation of supranational risk assessments. Second, a multi-level governance strategy should be adopted, combining EU-level anticipatory instruments (e.g., generic definitions, analogue provisions), with national implementation tailored to local contexts. Third, integration of predictive tools (horizon scanning, predictive toxicology, algorithmic modelling) is critical to shift from reactive to proactive regulation.

Finally, reducing the exploitability of regulatory asymmetries by organised crime must remain a core priority, since criminal networks exploit jurisdictional gaps to market new compounds, undermining both public health and judicial coherence. Strengthening judicial cooperation, harmonising penalties, and enhancing cross-border enforcement are therefore indispensable.

Effectively regulating NPS in Europe requires a coherent, anticipatory, and multi-level governance framework. Building on comparative evidence, aligning national precision with EU-level agility, and embedding predictive tools into regulatory practice are essential steps to enhance resilience and safeguard public health against the evolving risks posed by NPS.

CONCLUSIONS

This comparative study demonstrates that regulatory responses to new psychoactive substances across Europe are shaped by deep divergences in legal instruments and implementation timelines. Such disparities result in uneven levels of protection for citizens, complicate law enforcement cooperation, and leave exploitable gaps for illicit markets. Although the European Union Drugs Agency, through the EU Early Warning System, provide important coordination platforms, their effectiveness remains inconsistent due to variable national transpositions.

Looking ahead, regulatory systems must evolve beyond reactive substance-by-substance listing mechanisms. The integration of predictive toxicology, artificial intelligence-assisted surveillance, and forensic-epidemiological databases would enable earlier identification of emerging

threats and more rapid implementation of binding measures. At the same time, a multi-level governance model – combining the legal rigour of national legislatures with the operational agility of EU instruments – appears essential to reduce fragmentation and uphold both legality and proportionality in enforcement.

This study is not without limitations: the analysis has focused primarily on legislative frameworks, without systematically assessing clinical outcomes or enforcement effectiveness. Future research should therefore explore how regulatory divergences translate into measurable health impacts and judicial practices, and how predictive tools can be operationalised across REITOX countries.

In conclusion, enhancing supranational coordination, embedding predictive capacities, and aligning national discretion with common European standards are critical steps to strengthen resilience against NPS. Only by moving from a reactive to a truly anticipatory model can ensure consistent public health protection, reduce the exploitability of legal loopholes by organised crime, and keep pace with the rapidly evolving dynamics of synthetic drug markets.

Authors' contributions

VA: conceptualization, investigation, writing – original draft, writing – review and editing; FPB: formal analysis, supervision; SP: writing – review and editing; GB: conceptualization, supervision, validation; SG: conceptualization, resources, supervision, writing – review and editing.

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The Authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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