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NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on monitoring and controlling drug precursors and repealing Regulations (EC) No 273/2004 and (EC) No 111/2005 - Mandate for negotiations with the European Parliament

Delegations will find attached the Presidency compromise text with a view to obtaining a mandate for negotiations with the European Parliament on the above-mentioned proposal.

ANNEX

PUBLIC

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on monitoring and controlling drug precursors and repealing Regulations (EC) No 273/2004 and (EC) No 111/2005

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 33, 114 and 207 thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee[(1)],

Acting in accordance with the ordinary legislative procedure[(2)],

Whereas:

(1) The United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances adopted in Vienna on 19 December 1988 ('the UN Convention') is part of the worldwide effort to combat the production and trafficking of illicit drugs. The Union concluded the UN Convention by means of Council Decision 90/611/EEC[(3)].

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(1) OJ C [...], [...], p. [...]

(2) Position of the European Parliament of [date] (not yet published in the Official Journal) and decision of the Council of [date].

(3) Council Decision of 22 October 1990 concerning the conclusion, on behalf of the European Economic Community, of the United Nations Convention against Illicit Traffic in Narcotic

(2) Article 12 of the UN Convention requires the Parties thereto to take the measures they deem appropriate to prevent the diversion of substances which are included in the tables annexed to the Convention and used for the purpose of the illicit manufacture of drugs (drug precursors). The adoption of rules to monitor and control these drug precursors was implemented in the Union by Regulation (EC) No 273/2004 of the European Parliament and of the Council[4], regarding the control and monitoring measures within the internal market; and Council Regulation (EC) No 111/2005[5] on trade between the Union and third countries.

(3) The Evaluation of the Union drug precursor regulations[6] has shown that additional action with regard to designer precursors is necessary. Designer precursors are substances closely related to controlled drug precursors, with no known legitimate use, and which evade the controls set out in Regulations (EC) No 273/2004 and 111/2005. Those Regulations have been conceived to address the diversion of traditional drug precursors from licit channels towards the illicit manufacture of drugs, and do not include specific rules addressing designer precursors. The evaluation also pointed out to the need to take a holistic approach in regulating drug precursors, to ensure consistency with recent policy developments at Union level against drug trafficking. Recent developments include the EU Drugs Strategy and Action Plan, the adoption of Regulation (EU) 2023/1322[7] on the European Union Drugs Agency, the European Digital Strategy and the adoption of Regulation (EU) 2022/2399[8].

Drugs and Psychotropic Substances (OJ L 326, 24.11.1990, p. 56, ELI: http://data.europa.eu/eli/dec/1990/611/oj).

(4) Regulation (EC) No 273/2004 of the European Parliament and of the Council of 11 February 2004 on drug precursors (OJ L 47, 18.2.2004, ELI: http://data.europa.eu/eli/reg/2004/273/oj).

(5) Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the Community and third countries in drug precursors (OJ L 22, 26.1.2005, ELI: http://data.europa.eu/eli/reg/2005/111/oj).

(6) Report from the Commission to the European Parliament and the Council of 30.11.2020 - Evaluation of the EU drug precursors regulations (COM/2020/768 final).

(7) Regulation (EU) 2023/1322 of the European Parliament and of the Council of 27 June 2023 on the European Union Drugs Agency (EUDA) and repealing Regulation (EC) No 1920/2006 (OJ L 166, 30.6.2023, p. 6., ELI: http://data.europa.eu/eli/reg/2023/1322/oj).

(8) Regulation (EU) 2022/2399 of the European Parliament and of the Council of 23 November 2022 establishing the European Union Single Window Environment for Customs and amending Regulation (EU) No 952/2013 (OJ L 317, 9.12.2022, p. 1, ELI: http://data.europa.eu/eli/reg/2022/2399/oj).

(4) Drug precursor controls are a crucial component of drug supply reduction policy as outlined in the EU Drugs Strategy 2021-2025[9]. Furthermore, the EU Drugs Action Plan 2021-2025[10] highlights the need to address the challenge posed by designer precursors. Additionally, the 2023 EU Roadmap to fight drug trafficking and organised crime[11] stresses the need to set out innovative ways to speed up and broaden the current approach to regulating drug precursors in response to new methods of illicit drug production. Equally, as part of the new EU Drugs Strategy and EU Action Plan against drug trafficking, announced in Protect EU: a European Internal Security Strategy[12], the EU will boost operational efforts to stop the inflow of drug precursors, including designer precursors.

(5) Therefore, new rules on drug precursors should be adopted, to better address the developments in the illicit manufacture of drugs, and in particular, the proliferation of designer precursors. These new rules would also give effect to the obligations deriving from Article 12 of the UN Convention. This Regulation also aims to prevent circumvention by substitution with non-scheduled or designer precursors.

(6) In order to streamline current procedures and to reduce administrative burden, Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005 should also be merged into one Regulation. That should also facilitate the free movement of chemicals in the internal market. This Regulation should apply without prejudice to other Union legislation applicable to the substances contained in drug precursors covered by this Regulation, such as Regulation (EC)

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(9) Council Conclusions on the EU Drugs Strategy 2021-2025, 14178/20, 18 December 2020.

(10) Communication COM (2020) 606 final of 24.7.2020 from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions - EU Agenda and Action Plan on Drugs 2021-2025.

(11) Communication COM (2023) 641 final of 18.10.2023 from the Commission to the European Parliament and the Council on the EU roadmap to fight drug trafficking and organised crime.

(12) Communication COM (2025) 148 final of 1.4.2025 from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on ProtectEU: a European Internal Security Strategy.

No 1907/2006[14], Regulation (EC) No 1272/2008[15] or Regulation (EU) 2019/1148[16]. It should also apply without prejudice to the obligations of Member States to set out national rules on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking in accordance with Council Framework Decision 2004/757/JHA[17].
This Regulation should not apply to customs, police, armed forces and laboratories of competent authorities in the Member States when they are acting within the scope of their official duties, as the risk of diversion of drug precursors in such cases is minimal. The possession and use of drug precursors by pharmacies and veterinary dispensaries within the scope of their regular activities should also be exempt from the scope of the Regulation, as such operators are already subject to strict rules under Union and national legislation. Provision should be made for simplified formalities for specific external traders, such as pharmacies and dispensaries of veterinary medicinal products, to reduce the administrative burden for operators with a low risk profile.

(6a) This Regulation should only apply to mixtures and complex substances containing substances covered by the annexes to this Regulation if these substances can be easily used or extracted from these mixtures or complex substances by readily applicable or economically viable means. The same should apply to organisms containing such substances. To facilitate the tasks of competent authorities, the Regulation should set thresholds below which an extraction would not be considered readily applicable or economically viable. For mixtures, complex

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(14) Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, ELI: http://data.europa.eu/eli/reg/2006/1907/oj).

(15) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, ELI: http://data.europa.eu/eli/reg/2008/1272/oj).

(16) Regulation (EU) 2019/1148 of the European Parliament and of the Council of 20 June 2019 on the marketing and use of explosives precursors, amending Regulation (EC) No 1907/2006 and repealing Regulation (EU) No 98/2013 (OJ L 186, 11.7.2019,ELI: http://data.europa.eu/eli/reg/2019/1148/oj).

(17) Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking (OJ L 335, 11.11.2004, p. 8, ELI: http://data.europa.eu/eli/dec_framw/2004/757/oj).

substances and organisms containing substances above these thresholds, competent authorities are best placed to delimit on a case-by-case basis whether these substances can be easily used or extracted by readily applicable or economically viable means. In doing so, they may consider among other things the price of the mixture, complex substance or organism, the concentration of the scheduled substance and the procedure of extraction, including the presence of other substances that hinder extraction or their toxicity, the presence of substances that render further use in the illicit manufacture of drugs unfeasible, and the packaging size of the mixture, complex substance or organism.

(7) Scheduled drug precursors consist of or contain substances covered by the annexes to this Regulation. The annexes should include all the substances already covered by Regulation (EC) No 273/2004 of the European Parliament and of the Council and Council Regulation (EC) No 111/2005. Such substances are either covered by the UN Convention or are placed under control at Union level, in response to specific risks of diversion identified in the Union. To facilitate their free movement in the internal market and their external trade, harmonised rules should be set out to enable national authorities to control and monitor legitimate trade effectively, with a view to avoiding their diversion towards the illicit manufacture of drugs, without creating disproportionate administrative burdens. As is the case under the current rules, operators should continue to have the obligation to notify suspicious transactions. This is an important source of information for competent authorities to discover illicit activities. The obligation should be extended to significant disappearances and thefts, as such incidents could also indicate possible diversion towards the illicit manufacture of drugs. Similarly, operators should maintain their obligation to keep the documentation regarding transactions of scheduled drug precursors. To increase the possibility for competent authorities to gather evidence concerning illicit activities, the obligation to keep documentation should be extended to operators using scheduled drug precursors of the highest risk and the documentation should be kept for a longer period of time.

(8) This Regulation should lay down specific obligations for online marketplaces with respect to reporting suspicious transactions with scheduled drug precursors that take place on their websites or that use their computing services, once they have become aware of information leading to such a suspicion. The obligations on online marketplaces under this Regulation should not amount to a general monitoring obligation.

PUBLIC

(9) Category 1 drug precursors should be subject to strict control rules as they contain substances playing a key role in the illicit manufacture of drugs, but also with important legitimate uses which increases the risk of diversion from licit channels. Operators manufacturing, making available on the market, importing, exporting, performing intermediary activities, possessing or using such drug precursors should continue to be required to hold a licence, as this offers national authorities the possibility to make a thorough check of their legitimate intentions before the activity can be performed. Where fees are levied at national level for obtaining a licence, Member States should adjust such fees in order to safeguard the competitiveness of small and medium-sized enterprises within the meaning of Commission Recommendation 2003/361/EC[18]. The existing obligation of operators to verify that their customers also hold a licence should be maintained, as it proved to be an efficient way of verifying the reliability of such customers. However, the obligation to obtain customer declarations should no longer be maintained, as it leads to administrative burden without clear benefits in terms of facilitating the identification of suspicious transactions.

(9a) It is also important to maintain the existing obligation of operators trading in scheduled drug precursors to take adequate measures to secure premises, and to extend it to operators using such drug precursors, given their high risk of diversion. The appropriate measures to secure premises against unauthorised removal of drug precursors could depend, among other factors, on the category of the drug precursors, the size of the company, the quantity of drug precursors stored, the concentration of drug precursors or potential combinations thereof. Depending on those elements, adequate measures could include restricting access to the areas where the drug precursors are stored, physically securing the storage room, keeping records of accessing or handling of drug precursors, putting in place measures to prevent theft, or periodically checking the stock to identify disappearances.

[18] Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises, C(2003) 1422 (OJ L 124, 20.5.2003, pp. 36, ELI: http://data.europa.eu/eli/reco/2003/361/oj).

(10) Category 2 drug precursors are precursors which, even though frequently used in the illicit production of drugs, are traded in significant quantities in the internal market and external trade and have extensive legitimate uses. While the risk of diversion is significant, strict control measures need to be proportionate to avoid unnecessary burdens both for the industry and for the national authorities, with limited added value for the identification of suspicious activities. Therefore, operators' obligations to register their activities under this Regulation should be focused on substances with a higher risk of diversion and on the external trade, broadly in line with current practices. To reduce the administrative burden, obligations should be limited to registering their activities, without the requirement of approval by national authorities. In line with this risk-based approach, appropriate thresholds for registration in the internal market should be established.

(11) Category 3 drug precursors should be introduced to address the particularities and high risks for use in illicit drug production associated with designer precursors, which play a significant role in the illicit manufacture of drugs, as demonstrated by their high proportion in the number of seizures in the recent years, and do not have any known legitimate use other than research and innovation. Such precursors do not follow the traditional pattern of diversion from licit channels towards the illicit manufacture of drugs. In support of the fight against the production and trafficking of illicit drugs, it is therefore important, as a general rule, to ban them from: being made available on the market; import; export; intermediary activities; manufacturing; and their use or possession.

(12) However, as Category 3 drug precursors can be used in research and innovation and other legitimate uses may be discovered after the inclusion of various substances in the annex to this Regulation, it is important to set out rules allowing operators to perform activities with such precursors. Should small quantities of designer precursors be needed for research and innovation, operators should be required to file a prior notification to the competent authority in the Member State where they are established. That will encourage research and innovation by not imposing costly and lengthy formalities for transactions of low quantities and therefore low risk. Should operators need Category 3 drug precursors in higher quantities or for legitimate purposes other than research and innovation, they should then be required to obtain a licence in accordance with the provisions for Category 1 drug precursors, as the risks are similar.

PUBLIC

(12a) For those natural or legal persons that remain exempt from the obligations set out in this Regulation, it is encouraged to exercise due diligence. Carriers and other transporters acting solely in that capacity should remain exempt from licensing and registration requirements. They should nevertheless be encouraged to exercise due diligence proportionate to their role and activities, in particular to identify circumstances indicating a risk of diversion of drug precursors for the illicit manufacture of drugs.

(13) As new designer precursors can be easily created by modifying the chemical structure of substances placed under control, it is important that this Regulation is adapted to cater for the introduction of both a list of substances identified individually and of groups of substances identified in a generic way in Category 3 drug precursors. Whenever a group of substances is included in a generic way, an exemption list should be provided to exclude individual substances that are part of this group but for which a legitimate use other than research and innovation has been identified and which are not included in either Category 1 or Category 2 drug precursors.

(14) The requirement for obtaining import and export authorisations should be removed and replaced by quantity management, comprising quantity notification by operators and automatic verifications by customs authorities for import and export. That should reduce the administrative burden for external traders, whilst at the same time maintaining strict controls of drug precursors entering or leaving the customs territory of the Union and ensuring continued fulfilment of the UN Convention by the Union and its Member States.

(14a) In order to provide legal certainty to non-Union operators, and in line with the Union Customs Code, a provision should be put in place formalising and clarifying their drug precursor-related obligations under this Regulation, notably through the appointment of a single representative assuming full responsibility for these requirements. For importers, with the exception of external transit, and for exporters, this single representative may be the same as the one appointed indirect representative pursuant to Article 33 Regulation (EU) 2026/2108. Furthermore, this single representative may also be the same person undertaking the responsible officer obligations under this Regulation.

PUBLIC

(15) In accordance with Article 12(10) of the UN Convention, the effectiveness and practicability of pre-export notifications is fully recognised. However, exports to non-Member States participating in the Union Single Market and exports to countries where an international agreement waives the pre-export notification, should be exempt from the pre-export notification obligation.

(16) To enforce this Regulation effectively, it is important to enable competent authorities to request proof of licit purposes for drug precursors entering the customs territory of the Union.

(17) It is essential to step up efforts for raising the awareness of legitimate operators to the risks associated with non-scheduled precursors, to support them in identifying suspicious transactions and notifying them on voluntary basis. Thus, extensive information on drug precursors, including non-scheduled ones, and a tool to help determine the scope of scheduled designer precursors, will be made available through a Drug Precursors Information Repository.

(18) The Drug Precursors Information Repository should be developed, maintained, and kept up to date by the European Union Drugs Agency and should replace the existing Voluntary Monitoring List. The Repository should contain comprehensive information on scheduled and non-scheduled drug precursors, and their legitimate and illicit uses, to support operators in identifying suspicious transactions and Member States and the Commission in identifying new trends in the illicit production of drugs.

(19) Member States should organise regular training to raise awareness on the risks of diversion of drug precursors and the significant role which operators can play in the fight against the illicit manufacture of drugs. The Commission and the Agency should provide supportive measures related to the content of the training and awareness-raising actions to Member States.

(20) Mutual assistance between Member States and between Member States and the Commission should be reinforced, in particular by recourse to Council Regulation (EC) No 515/97[19].

[19] Council Regulation (EC) No 515/97 of 13 March 1997 on mutual assistance between the administrative authorities of the Member States and cooperation between the latter and the Commission to ensure the correct application of the law on customs and agricultural matters (OJ L 82, 22.3.1997, p. 1, ELI: http://data.europa.eu/eli/reg/1997/515/oj).

(21) To prevent the diversion of drug precursors towards the illicit manufacturing of drugs, competent authorities should be empowered to seize both scheduled and non-scheduled drug precursors, if there are reasonable grounds or evidence that the drug precursor is intended for illicit use.

(22) To ensure the correct application of this Regulation, Member States should lay down rules on penalties applicable for infringement of this Regulation, which should be effective, dissuasive and proportionate.

(23) Operators will no longer be obliged to submit annual reports, as it has not been proven to be the most efficient measure in the identification of suspicious activities, while being very burdensome for the industry. The current system of annual reporting should be replaced by a more streamlined digital and automated system. The relevant information should be available in the new electronic system. In addition, national authorities should still report, without delay, significant seizures of drug precursors. This would ensure that national authorities from other Member States can better target their controls.

(24) Following the Union's obligations of reporting in Article 12(12) of the UN Convention and Resolutions of the United Nations Economic and Social Council 1995/20 on measures to strengthen international cooperation to prevent diversion of substances included in table I of the UN Convention and used in the illicit manufacture of stimulants and other psychotropic substances and 49/3 strengthening systems for the control of precursor chemicals used in the manufacture of synthetic drugs, the Commission should draw up an annual report to be sent to the International Narcotics Control Board.

PUBLIC

(25) A centralised electronic system should be established to digitalise all the procedures set out in this Regulation. The system should allow operators to fulfil their obligations laid down in this Regulation and competent authorities to make their decisions on the implementation of this Regulation and perform their reporting obligations. The system should also facilitate the communication by the Commission of information requested under the UN Convention. The enforcement of legislation on drug precursors entering or leaving the Customs territory of the Union under this Regulation should be facilitated by the interconnection between that electronic system and the 'EU Single Window Environment for Customs'. In addition, the Commission should explore with the United Nations to possibly interconnect the electronic system with the United Nations system for the reporting of incidents with precursors or other tools, to avoid double reporting and facilitate the international cooperation. The Agency should have access to the information in the electronic system to facilitate the implementation of its mandate under Regulation (EU) 2023/1322 and the development and update of the Drug Precursors Information Repository.

(25a) In order to facilitate compliance by operators, in particular small and medium-sized enterprises, it is important to encourage the use of standardised electronic interfaces and forms.

(25b) In the electronic system it is important to ensure secure information exchange, data storage, protection against unauthorised automated extraction of data, and retention periods appropriate to the operational and regulatory objectives of this Regulation.

(26) Any processing of personal data under this Regulation should be carried out in compliance with the provisions of Regulation (EU) 2016/679[20] or Regulation (EU) 2018/1725[21] of the European Parliament and of the Council, within their respective scope of application.

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[20] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1, ELI: http://data.europa.eu/eli/reg/2016/679/oj).

[21] Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39, ELI: http://data.europa.eu/eli/reg/2018/1725/oj).

(27) In order to amend certain non-essential elements of this Regulation, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission to add or remove substances from the categories of drug precursors, where necessary as a matter of urgency. Given the particularities of designer precursors the Commission should have the possibility to add designer precursors also by including groups of substances, identified in a generic way and, where needed, to exclude individual substances part of such groups which have legitimate uses other than research and innovation and which are not to be included in a different category. However, the Commission should not add groups of substances in Category 1 or Category 2 drug precursors, unless this is necessary to fulfil the obligations under the UN Convention. In addition, the Commission should be empowered to amend non-essential elements set out in the annexes concerning licences, registrations, prior notifications, quantity management related to import and export, pre-export notifications, demonstration of licit purposes, determining the indicators for suspicion of intended use in the illicit manufacture of drugs, and reporting. It is of particular importance that the Commission carry out appropriate consultations during the preparatory work for the adoption of delegated acts, including at expert level and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[(22)]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.

(27a) When adopting delegated acts, it is important that the Commission ensures that the need to protect legitimate trade does not create regulatory gaps capable of being exploited for the illicit manufacture of drugs, including through the use of alternative substances, modified precursors, intermediates or non-scheduled drug precursors.

(27b) The Commission should make every effort to ensure that the delegated acts provided for in this Regulation enter into force sufficiently in advance of the application date of the relevant provisions in this Regulation to allow their timely implementation by Member States and operators.

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(22) OJ L 123, 12.5.2016, p. 1, ELI: http://data.europa.eu/eli/agree_interinstit/2016/512/oj.

(27c) A mechanism should be put into place for quantities exceeding the thresholds of Category 3 substances, where a demonstrable legitimate use is found. In such cases, temporary licences may be granted to operators by the Member State of establishment, when duly justified. The Member State should inform the Commission, the Agency, and other Member States. In parallel, it is appropriate that the Commission evaluates, without delay, the need to reclassify the substance into another category.

(28) Implementing powers should be conferred on the Commission in order to determine the implementing arrangements for the electronic system. These arrangements should include technical requirements and procedures for the implementation of the main obligations set out in this Regulation, such as obtaining a licence, filing a registration or prior-notification, or those linked to quantity notification and customs verification. These arrangements should also include the rules for the protection, safety and security of personal data. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[1].

(29) Since the objectives of this Regulation cannot be sufficiently achieved by the Member States and can therefore, by reason of the international and changeable nature of the trade in drug precursors, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in third paragraph of Article 5 of the Treaty on European Union. In accordance with the principle of proportionality as set out in that Article, this Regulation does not exceed what is necessary for reaching those objectives. This Regulation respects the fundamental rights and observes the principles recognised, in particular, by the Charter of Fundamental Rights of the European Union.

(30) Regulations (EC) No 273/2004 and 111/2005 should therefore be repealed.

(31) The application of this Regulation should be deferred with the time needed to establish the electronic system needed for its implementation.

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[1] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, pp. 13, ELI: http://data.europa.eu/eli/reg/2011/182/oj).

(32) Transitional arrangements should be set out to ensure the validity of documents issued under Regulation (EC) No 273/2004 and Regulation (EC) 111/2005 and to allow for the connection of the electronic system for competent authorities and customs systems, to guarantee legal certainty and ensure a smooth transition towards the new rules,

HAVE ADOPTED THIS REGULATION:

Chapter 1
General provisions

Article 1

Subject matter

1. This Regulation establishes harmonised rules for the monitoring and control of the making available on the market, import, export, possession, manufacturing and use of drug precursors and of intermediary activities involving drug precursors with a view to ensuring their free movement in the internal market while preventing their availability for the illicit manufacture of drugs and the proliferation of designer precursors.

2. This Regulation shall apply without prejudice to other provisions of Union legislation applicable to the substances in Annex I, Annex II and Annex III.

Article 2

Definitions

The definitions laid down in Regulation (EU) 2026/2108[2] for release for free circulation, temporary storage, temporary admission, inward processing, outward processing, transit, customs warehousing, free zone, re-export, re-export notification, importer, exporter, customs representative and carrier shall apply for the purposes of this Regulation.

[2] Regulation (EU) No 2026/2108 of the European Parliament and of the Council establishing the Union Customs Code and the European Union Customs Authority and repealing Regulation (EU) No 952/2013 (OJ, L, 2026/2108, 19.9.2026, ELI: http://data.europa.eu/eli/reg/2026/2108/oj).

PUBLIC

Where a term is defined both in this Regulation and in Regulation (EU) 2026/2108, the definition in this Regulation shall prevail.

For the purposes of this Regulation the following definitions shall apply:

(1) ‘drug precursor’ means a substance on its own, or a substance contained in a mixture, or a substance contained in another complex substance, or a substance contained in or produced by an organism, that can be used for the illicit manufacture of drugs;

(2) ‘drug’ means a drug as defined in Article 1, point 1 of Council Framework Decision 2004/757/JHA;[25]

(3) ‘scheduled drug precursor’ means a drug precursor consisting of or containing a substance covered by Annex I, Annex II or Annex III to this Regulation, unless it is exempted, in accordance with that Annex;

(4) 'non-scheduled drug precursor’ means a drug precursor which, although not containing or consisting of a substance covered by Annex I, Annex II or Annex III to this Regulation, but which is suitable for use in the illicit manufacture of drugs;

(5) ‘substance’ means a substance as defined in Article 3, point 1 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council;[26]

(6) ‘mixture’ means a mixture as defined in Article 3, point 2 of Regulation (EC) No 1907/2006;

(7) ‘organism’ means an organism as defined in Article 2(1) of Directive 2001/18/EC;

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[25] 11.2004, p. 8, ELI: http://data.europa.eu/eli/dec_framw/2004/757/oj).

[26] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006, pp. 1, ELI: http://data.europa.eu/eli/reg/2006/1907/oj).

(8) ‘designer precursor’ means a drug precursor which is a substance or a mixture containing a substance which is closely related to a substance covered by Annex I or Annex II, which may readily be converted to or substituted for those precursors, and which does not have any known legitimate use except for research and innovation purposes;

(9) ‘medicinal product' means a medicinal product as defined in Article 1, point (2) of Directive 2001/83/EC;[27]

(10) ‘veterinary medicinal product' means a veterinary medicinal product as defined in Article 4(1) of Regulation (EU) 2019/6;[28]

(11) ‘making available on the market' means any supply of a drug precursor for distribution or use on the Union market in the course of a commercial activity, whether in return for payment or free of charge;

(12) ‘use’ means use as defined in Article 3, point 24 of Regulation (EC) No 1907/2006;

(13) 'import' means the entry of drug precursors, having the status of non-Union goods, into the customs territory of the Union, including their temporary storage or placement under a customs procedure;

(14) ‘export’ means the exit of a drug precursor from the customs territory of the Union, including re-export of non-union goods, and any customs procedure resulting in Union goods leaving the customs territory of the Union, except for internal transit;

(15) *[deleted]*

(16) *[deleted]*

(17) *[deleted]*

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(27) 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 (OJ L 311, 28.11.2001, p. 67, ELI: http://data.europa.eu/eli/dir/2001/83/oj).

(28) Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43, ELI: http://data.europa.eu/eli/reg/2019/6/oj).

(18) *[deleted]*

(19) *[deleted]*

(20) *[deleted]*

(21) *[deleted]*

(22) *[deleted]*

(23) *[deleted]*

(24) ‘provider of an online marketplace’ means a provider of an online platform within the meaning of Article 3, point (i), of Regulation (EU) 2022/2065[(31)] that allows consumers or operators to conclude distance contracts with traders for the sale of scheduled drug precursors;

(25) ‘intermediary' means any natural or legal person arranging the purchase, sale or supply of drug precursors between two parties, or acting on behalf of at least one of those parties for that purpose where the goods will subsequently be imported or exported without taking these drug precursors into their possession or taking control of the carrying out of such transaction; this definition shall also apply to any activity involving the purchase and sale or supply of drug precursors without those precursors being introduced into the Union customs territory;

(26) ‘operator’ means any natural or legal person, manufacturing, making available on the market, possessing or using drug precursors or any external trader of such precursors;

(27) 'external trader' means any importer, exporter, or intermediary involved in the import, export, purchase, sale or supply of drug precursors;

(31) Regulation (EU) 2022/2065 of the European Parliament and of the Council of 19 October 2022 on a Single Market For Digital Services and amending Directive 2000/31/EC (Digital Services Act) (OJ L 277, 27.10.2022, p. 1, ELI: http://data.europa.eu/eli/reg/2022/2065/oj).

PUBLIC

(28) 'name of a substance covered by Annex I, Annex II or Annex III' means either the name of the substance as listed in Annex I, Annex II or Part I, of Annex III to this Regulation for substances identified individually, or the International Union of Pure and Applied Chemistry (IUPAC) name of the substance identified in a generic way, followed by the name of the generic group, as stated in this Regulation;

(29) *[deleted]*

(30) *[deleted]*

(31) *[deleted]*

(32) *[deleted]*

(33) 'ultimate consignee' means any natural or legal person in the country of final destination to whom imported or exported scheduled drug precursors are delivered; this person may be different from the end-user;

(34) 'suspicious transaction' means any transaction concerning drug precursors for which there are reasonable grounds for suspecting that the drug precursors concerned are intended for the illicit manufacture of drugs;

(35) 'seizure' means the temporary prohibition of the transfer, destruction, conversion, disposal or movement of drug precursors or temporarily assuming custody or control of drug precursors;

(36) 'International Narcotics Control Board' means the Board established by the Single Convention on Narcotic Drugs, 1961, as amended by the 1972 Protocol;

(37) 'the Agency' means the European Union Drugs Agency established by Regulation (EU) 2023/1322 of the European Parliament and of the Council[32];

(38) 'CAS No' means the Chemical Abstracts Service registry number which is a unique numeric identifier specific to each substance and its structure;

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[32] Regulation (EU) 2023/1322 of the European Parliament and of the Council of 27 June 2023 on the European Union Drugs Agency (EUDA) and repealing Regulation (EC) No 1920/2006 (OJ L 166, 30.6.2023, p. 6, ELI: http://data.europa.eu/eli/reg/2023/1322/oj).

(39) ‘CUS code’ means the number assigned to a substance in the European Customs Inventory of Chemical Substances (ECICS);

(40) ‘transhipment’ means the transhipment of drug precursors within the meaning of Article 1(39) of Commission Delegated Regulation (EU) 2015/2446;

(41) ‘research and innovation’ means any small-scale scientific experimentation, analysis or chemical research carried out under controlled conditions aimed at acquiring theoretical knowledge, or know-how relating to products, technologies or processes;

(42) ‘business premises’ means any building, facility, site or land under the control of an operator at a distinct physical location and used for any activities falling within the scope of this Regulation;

(43) ‘manufacturing of a drug precursor’ means any process by which a drug precursor is produced, including by synthesis, conversion or extraction, by any means, from a mixture, another complex substance, an organism, or any part thereof.

Article 3

Scope

1. This Regulation shall apply to:

(a) scheduled drug precursors;

(b) mixtures, complex substances and organisms containing scheduled drug precursors, which shall be subject to the same requirements as for the scheduled drug precursors they contain, except if:

(i) the scheduled drug precursor cannot be easily used or extracted by readily applicable or economically viable means; or

(ii) the scheduled drug precursor is below the concentration threshold set out in Annex I, Annex II or Annex III and, where applicable, does not meet the special conditions set out in Annex I, Annex II or Annex III;

(c) *[deleted]*

2. This Regulation shall also apply to non-scheduled drug precursors unless the condition in paragraph 1, point (b)(i) is met.

3. This Regulation shall not apply to the following operators:

   (a) customs, police, armed forces and official laboratories of competent authorities in so far as these operators act within the scope of their official duties;

   (b) pharmacies and dispensaries of veterinary medicinal products possessing or using Category 1 or Category 2 drug precursors in accordance with Article 5, within the scope of their regular activities.

4. This Regulation shall not apply to:

   (a) making available on the market, possession or use of medicinal products or veterinary medicinal products;

   (b) import, export or intermediary activities with medicinal products or veterinary medicinal products except export of those listed in Part II of Annex II;

   (c) medicinal products listed in Part II of Annex II carried by private individuals taken out of the Union where those products are intended for their personal use. Upon request individuals may be asked to provide supporting evidence.

Article 4

Internal market

Unless otherwise provided for in this Regulation or in other legal acts the Union, Member States shall not prohibit, restrict or hinder making available on the market of scheduled drug precursors by operators complying with this Regulation for reasons falling within the field approximated by this Regulation.

Member States may retain or adopt more stringent measures related to the monitoring of the legitimate trade of non-scheduled drug precursors provided that those measures meet an overriding requirement in the public interest, are appropriate for securing the attainment of the objective which they pursue and do not go beyond what is necessary to attain it.

Article 5

Categories of scheduled drug precursors

1. Scheduled drug precursors shall belong to one of the following categories:

   (a) Category 1 drug precursors: substances covered by Annex I;

   (b) Category 2 drug precursors:

      (i) substances covered by Part I (Category 2A) or Ia (Category 2B), of Annex II; or

      (ii) medicinal products and veterinary medicinal products containing substances covered by Part II, of Annex II;

   (c) Category 3 drug precursors: substances covered by Annex III that have no known legitimate use except research and innovation at the moment of their scheduling. The substances covered by Annex III shall be either listed individually or identified in a generic way by listing groups of drug precursors . Individual drug precursors included in such a group that have a legitimate use other than research and innovation and that are not included in Annex I or Annex II, shall be exempted from Category 3 and listed in Part II, Section 2, of Annex III.

2. Mixtures, complex substances and organisms containing substances covered by Annex I above the concentration threshold set out in that Annex, and in addition containing substances covered by Annex II or Annex III shall be subject to the requirements for Category 1 drug precursors.

3. Mixtures, complex substances and organisms containing substances covered by Annex III above the concentration threshold set out in that annex, and in addition containing substances covered by Annex II shall be subject to the requirements for Category 3 drug precursors.

4. Scheduled substances covered by Annex I or Annex II, which are also identified in a generic way in Part II, Section 1, of Annex III shall be subject to the requirements for Category 1 or, respectively, Category 2 drug precursors.

PUBLIC

Chapter 2

Obligations of operators

SECTION 1

COMMON PROVISIONS

PUBLIC

Article 6

Obligation of cooperation

1. Operators shall provide accurate, complete and up-to-date information to the competent authorities of the Member State concerned when fulfilling their obligations under this Regulation.

2. Operators shall, further to a request, provide competent authorities with the information and documentation necessary to demonstrate that they fulfilled their obligations based on this Regulation, without delay, in a machine-readable and structured way, using open standards, transferred through a secure communication channel without vendor lock-in.

3. Operators shall cooperate with those authorities, upon request, on any action taken to address the risks of diversion of scheduled drug precursors towards the illicit manufacture of drugs.

Article 7

Documentation and Records

1. Operators who make available on the market, import or export scheduled drug precursors and intermediaries who perform activities with scheduled drug precursors shall keep commercial documents for each transaction, which will include the following information:

   (a) the name of the substance covered by Annex I, Annex II or Annex III, or, in the case of a mixture, complex substance or organism, their name and the name of the substance covered by Annex I, Annex II or Annex III, contained in the mixture, complex substance or organism; for import, export or intermediary activities, the name shall be followed by the term 'DRUG PRECURSOR';

   (b) the quantity of the substance covered by Annex I, Annex II or Annex III and the unit of measurement used

   (ba) in the case of a mixture, complex substance or organism, the quantity and unit of measurement and, where available, the percentage of any substance covered by Annex I, Annex II or Annex III contained therein;

   (c) the names and addresses of the other operators involved in the transaction; and

   (d) commercial documentation shall specify where available the CAS number and the CUS code of the scheduled substance, in order to enable automated identification.

2. Operators shall keep the documentation referred to in paragraph 1 for a period of 5 years from the end of the calendar year in which the transaction took place.

Article 8

Provision of information on suspicious transactions, disappearances and thefts

1. Operators shall report to the competent authorities immediately suspicious transactions, significant disappearances and thefts of scheduled drug precursors. Where providers of online marketplaces become aware of any information regarding suspicious transactions, significant disappearances, and thefts of scheduled drug precursors, they shall immediately report that information to the competent authorities.

PUBLIC

2. For the purposes of paragraph 1, operators and providers of online marketplaces shall provide any available information, such as:

(a) the name of the substance covered by Annex I, Annex II or Annex III;

(b) the quantity of the substance;

(c) the names and addresses of the operators involved in the supply chain.

Article 8a

Single representative for external trade

With the exception of the cases covered by Article 24, external traders established outside the Union shall appoint a single representative established within the Union, who shall assume full responsibility for the requirements of this Regulation.

Article 8b

[Moved from Article 14]

Securing premises

Operators shall take adequate measures to secure business premises against the unauthorised removal of scheduled drug precursors.

PUBLIC

SECTION 2

CATEGORY 1 DRUG PRECURSORS

PUBLIC

Article 9

Licence

1. Without prejudice to paragraph 7, operators shall obtain a licence from the competent authorities of the Member State in which they are established before they manufacture, make available on the market, import, export, perform intermediary activities, possess or use Category 1 drug precursors in quantities exceeding the quantity thresholds set out in Annex I over one calendar year. In the case of external traders established outside the Union, the single representative shall obtain the licence from the competent authorities of the Member State where the single representative is established. This obligation shall not apply to:

   (a) direct customs representatives, carriers and other transporters acting solely in that capacity;

   (b) Category 1 drug precursors which are transhipped, placed under temporary storage, stored in a free zone, or leaving the customs territory of the Union by a re-export notification;

   (c) external traders or their single representative in the case of the external transit procedure. Instead, they shall be subject to the obligations applicable under Article 15, unless a relevant valid licence already exists for those drug precursors.

2. When considering whether to grant a licence, the competent authorities shall take into account the conditions set out in Annex IV regarding the competence and integrity of the applicant. The licence shall be refused if there are reasonable grounds for doubting the suitability and reliability of the applicant or its responsible officer.

3. The licence shall include the information set out in Annex IV and shall be granted for a period not exceeding three years, unless the applicant requests it for a shorter time period.

4. The competent authorities may grant simplified licences for 10 years, subject to the conditions set out in Annex IV.

5. Licence holders shall obtain an update to the license granted in accordance with paragraph 1 in the instances provided for in paragraph 5 of Annex IV.

5a. The license holder shall inform the competent authority within 10 working days of any changes to information provided in the application for the initial license which are not covered by paragraph 5 of Annex IV.

6. The licence may be suspended or revoked by the competent authorities whenever the conditions under which the licence was granted are no longer fulfilled or where there are reasonable grounds for suspecting that there is a risk of diversion of scheduled drug precursors towards the illicit manufacture of drugs.

7. External traders that import, export, or perform intermediary activities with Category 1 drug precursors in quantities not exceeding the quantity thresholds set out in Annex I over one calendar year shall be subject to the obligations applicable under Article 15.

8. The competent authorities may require applicants to pay a fee for processing the application for a licence. Where a fee is levied, competent authorities shall adjust the level of the fee set for small and medium-sized enterprises. Such a fee shall be levied in a non-discriminatory manner and shall not exceed the cost of processing the application.

Article 10

Responsible officer

1. Applicants for the licence referred to in Article 9(1) shall appoint a responsible officer established in the Union empowered to represent them in matters relating to the application of this Regulation. Operators shall notify the relevant competent authorities within 10 working days of any modifications regarding the information of the responsible officer communicated pursuant to Annex IV.

2. The responsible officer shall be empowered to take all decisions needed to ensure that the activities performed by the operator comply with this Regulation.

3. The responsible officer shall cooperate with the competent authorities. The responsible officer shall be able to provide communication in an official language of the Member State where the licence is applied for, or in another language accepted by the competent authorities.

Article 11

Labelling

Without prejudice to labelling obligations under other Union law, operators making available on the market, importing, exporting, or performing intermediary activities with Category 1 drug precursors shall ensure that the name of the substance covered by Annex I is indicated on the packaging or its label, or, in case of products supplied in bulk, in the accompanying documents.

Article 12

Documentation for use or possession

1. Operators using or possessing Category 1 drug precursors shall keep documentation on their activities in accordance with Article 7(1).

2. The operators referred to in paragraph 1 shall keep the documentation for a period of 5 years from the end of the calendar year in which the specific drug precursor was possessed for the last time.

Article 13

Verification of operators

Operators shall make available on the market Category 1 drug precursors only after having verified that the other operators involved in such a transaction, who are required to hold a licence under this Regulation, hold a valid licence.

Article 14

[Moved to Article 8b]

PUBLIC

SECTION 3

CATEGORY 2 DRUG PRECURSORS

PUBLIC

Article 15

Registration

1. External traders engaged in import, export or intermediary activities involving Category 2 drug precursors shall register information on their activities with the competent authority in the Member State where they are established. For external traders established outside of the Union, this registration shall be made by the single representative with the competent authorities of the Member State where the single representative is established. This obligation shall not apply to:

   (a) direct customs representatives, carriers and transporters when acting solely in those capacities;

   (b) Category 2 drug precursors transhipped, placed under temporary storage, stored in a free zone, or leaving the customs territory of the Union by a re-export notification.

1a. Operators manufacturing or making available on the market Category 2A drug precursors exceeding the quantity thresholds set out in Annex II shall register information on their activities with the competent authority in the Member State where they are established.

2. The registration shall include the information set out in Annex V and shall be made for a period not exceeding three years.

3. By way of derogation from paragraph 2, a registration may be valid for 10 years, subject to the conditions set out in Annex V.

4. The operators referred to in paragraphs 1 and 1a shall update the information in the registration, as needed, in accordance with Annex V.

5. The competent authority in the Member State of establishment of the operator may order the operator to suspend or cease the activities covered by the registration, where the registration does not comply with this Regulation; the conditions declared are no longer fulfilled; or, where there are reasonable grounds for suspecting that there is a risk of diversion of the scheduled drug precursors towards the illicit manufacture of drugs.

6. The operators referred to in paragraphs 1 and 1a shall appoint a responsible officer in accordance with Article 10.

7. The external traders referred to in paragraph 1 shall ensure that the name of the substance covered by Annex II is indicated on the packaging or its label, or, in case of products supplied in bulk, in the documents accompanying them.

SECTION 4

CATEGORY 3 DRUG PRECURSORS

Article 16

General Prohibition

1. Except as provided for in Articles 17 and 18 the manufacturing, making available on the market, import, export, possession, use of Category 3 drug precursors, and performing intermediary activities involving such drug precursors is prohibited.

2. *[deleted]*

Article 17

Prior notification for research and innovation

1. By way of derogation from Article 16 operators may manufacture, make available on the market, import, export, perform intermediary activities, possess and use Category 3 drug precursors subject to the conditions set out in this Article.

PUBLIC

2. Operators intending to manufacture, make available on the market, import, export, possess, use, or perform intermediary activities involving Category 3 drug precursors for research and innovation in quantities not exceeding the maximum quantity threshold set out in Part I of Annex III shall notify their intended activities over a period of maximum six months to the competent authority in the Member State where they are established, at least 10 days before the notified activities take place. The notified activities may commence after expiry of that period, provided that the prior notification has been duly submitted, and the competent authority has not objected to their commencement on the grounds set out in paragraph 5. In the case of external traders established outside the Union, the single representative shall make the notification with the competent authorities of the Member State where the single representative is established.

2a. The prior notification obligation referred to in paragraph 2 shall not apply to:

(a) direct customs representatives, carriers and transporters when acting solely in those capacities;

(b) Category 3 drug precursors which are, for research and innovation purposes, transhipped, placed under temporary storage, stored in a free zone, or leaving the customs territory of the Union by a re-export notification.

3. The prior notification referred to in paragraph 2 shall include the information set out in Annex VI.

4. The competent authorities may request additional information and perform inspections to check the accuracy of the information provided, including the use of drug precursors for research and innovation.

5. The competent authority of the Member State of establishment of the operator may order the operator to suspend or cease the activities covered by the prior notification, where the prior notification does not comply with this Regulation; the conditions declared are no longer fulfilled; or, there are reasonable grounds for suspecting that there is a risk of diversion of the Category 3 drug precursor towards the illicit manufacture of drugs.

PUBLIC

Article 18

Licence for Category 3 precursors

1. By way of further derogation from Article 16, operators may manufacture, make available on the market, import, export, perform intermediary activities, possess or use Category 3 drug precursors for research and innovation in quantities exceeding the maximum quantity threshold set out in Part I of Annex III or for other legitimate use, provided they obtain a licence in accordance with Article 9(1), (2) and (3). Article 9(5), (6) and (8) shall also apply to that licence.

2. Where an operator obtains a licence for other legitimate use, such licence shall be valid for no more than 12 months and can be renewed once, except for in exceptional circumstances, for a period of no more than 12 months. Where such a licence for a Category 3 precursor is granted for other legitimate use, the Commission shall evaluate the need to amend this Regulation in accordance with Article 37(2).

Article 19

Additional obligations for Category 3 drug precursors

1. Operators referred to in Article 17 or Article 18 shall make available on the market Category 3 drug precursors only after having verified that the operators involved in the transaction have made a prior notification or hold a licence in accordance with Article 17 or Article 18 respectively.

2. Operators manufacturing, using or possessing Category 3 drug precursors subject to the conditions set out in Article 17 or Article 18 shall keep documentation on their activities in accordance with Article 12.

3. Operators referred to in Article 17 and Article 18 shall appoint a responsible officer in accordance with Article 10.

(b) *[deleted]*

PUBLIC

4. Operators manufacturing, making available on the market, importing, exporting or performing intermediary activities with Category 3 drug precursors in accordance with Article 17 and Article 18 shall ensure that the name of the substance covered by Annex III is indicated on the packaging or its label, or, in case of products supplied in bulk, on the accompanying documents.

SECTION 5

EXTERNAL TRADE

Article 20

Import

1. The importer shall notify the competent authority of the Member State of establishment of the total quantity of the intended imports for each substance covered by Annex I or parts I and Ia of Annex II over a specified time period before the first import, and updates thereof. The quantity of substances imported during that time period shall not exceed the quantities notified.

2. Paragraph 1 shall also apply for imports of drug precursors covered by Annex III, subject to the conditions set out in Article 17 or Article 18.

3. The information to be provided in accordance with paragraphs 1 and 2 is set out in Chapter 1, of Annex VII.

4. Where the drug precursors referred to in paragraph 1 and paragraph 2 are transhipped, in temporary storage, placed under inward processing, external transit, in customs warehousing, or stored in a free zone, paragraph 1 and paragraph 2 shall not apply. However, upon request from the competent authorities, the importer shall provide information regarding the quantities involved.

PUBLIC

Article 21

Pre-export notification

1. All exports of Category 1 drug precursors and exports of Category 2 drug precursors to certain countries of destination, as referred to in Chapter 2 of Annex VII, shall be preceded by a pre-export notification by the competent authorities of the Member State concerned to the competent authorities of the country of destination.

2. Exports of Category 3 drug precursors, subject to the conditions set out in Article 17 or Article 18, shall also be preceded by a pre-export notification, as set out in paragraph 1.

3. The pre-export notification shall be waived for exports from the Union to a third country or territory outside the customs territory of the Union where that third country or territory is also part of the Union single market or there is an international agreement between the Union and a third country or territory waiving the pre-export notification.

4. Operators shall provide the information set out in paragraph 2 of Chapter 2 of Annex VII to the competent authorities of the Member State of establishment.

5. In the pre-export notification referred to in paragraph 1 and 2, the competent authorities of the Member State concerned shall provide the competent authorities of the country of destination with the information listed in paragraph 2 of Chapter 2 of Annex VII concerning the intended export.

5a. The country of destination shall be allowed a period of 10 working days to reply, at the end of which the export operation may proceed, subject to Article 22(6), if no advice from the competent authorities of the country of destination is received indicating that this export operation might be intended for the illicit manufacture of narcotic drugs or psychotropic substances. The competent authority may extend this period upon a duly justified request from the country of destination. The competent authority shall inform the operator of the result of the notification.

6. The competent authority supplying such information shall require the competent authority in the country of destination receiving the information to keep confidential any trade, business, commercial or professional secret or any trade process referred to therein.

PUBLIC

7. Simplified pre-export notification procedures may be applied by the competent authorities under the conditions set out in Chapter 2, point 4, of Annex VII where they are satisfied that this will not result in any risk of diversion of scheduled drug precursors.

Article 22

Export

1. The exporter shall notify the competent authority of the Member State of establishment of the total quantity of the intended exports for each substance covered by Annex I or Annex II in a specified time period before the first export, and updates thereof. The quantity of substances exported during that time period shall not exceed the quantity notified.

2. Paragraph 1 shall also apply for exports of drug precursors covered by Annex III, subject to the conditions set out in Article 17 or Article 18.

3. The information to be provided in accordance with paragraph 1 and paragraph 2 is set out in Chapter 3 of Annex VII.

4. Where the drug precursors referred to in paragraph 1 or paragraph 2 are leaving the customs territory of the Union under the external transit procedure or by a re-export notification, paragraphs 1 and 2 shall not apply.

5. Whenever, under an agreement between the Union and a third country, an export requires that an import authorisation has been issued by the competent authorities of that third country for the drug precursor in question, that import authorisation shall be provided to the competent authorities in the Member State of establishment before the export can be done.

6. Following the notification referred to in Article 21(1) and Article 21(2), the competent authorities of the Member States may prevent the export if the competent authorities of the country of destination have raised an objection on the grounds, that the export may be intended for the illicit manufacture of drugs, that the consignee is not involved in the legitimate trade in drug precursors, or that the consignee does not hold the necessary authorisation for the scheduled drug precursors in question.

PUBLIC

Article 23

Customs verification

1. Where the importer is established within the Union, the operator holding the licence, registration, or prior notification as required under this Regulation, for the purposes of import, except for the external transit procedure, shall be the importer indicated in the customs declaration. Otherwise, Article 8a applies.

In the case of external transit procedure, the operator holding the registration, or prior notification as required under this Regulation, shall be the holder of the transit procedure indicated in the customs declaration. For holder of the external transit procedure established outside of the Union, this obligation shall be undertaken by the single representative as defined in Article 8a.

Where the exporter is established within the Union, the operator holding the licence, registration, or prior notification, as required under this Regulation, for the purposes of exports, shall be the exporter indicated in the customs declaration. Otherwise, Article 8a applies.

2. The importer, exporter or holder of a transit procedure as referred to in paragraph 1 shall provide or make available to customs authorities either: proof of possession of a valid licence as referred to in Article 9 or Article 18; registration as referred to Article 9(7) or Article 15; or prior notification as referred to in Article 17, including, where applicable, the proof of notification of quantities in accordance with Articles 20 and 22, and the information on the status of the notification referred to in Article 21(5a).

3. Customs authorities may release a substance for a customs procedure or re-export only after having verified as a minimum that a valid licence, registration, or prior notification exists, where those are required, and that the information on the status of the notification referred to in Article 21(5a) was provided.

4. In addition to paragraph 3, the customs authorities shall verify that the quantities are within the thresholds notified in Article 20 and Article 22 before releasing drug precursors for free circulation, temporary admission, end use, outward processing, export or re-export.

5. The release of the goods shall not be deemed to be proof of compliance with this Regulation or other Union legislation.

PUBLIC

6. The verification referred to in paragraph 3 and paragraph 4 shall be done electronically and automatically via the technical means for cooperation referred to in Article 35(5).

7. The Commission and the customs authorities may use the data included in the electronic system referred to in Article 35 of this Regulation for carrying out their duties pursuant to Union legislation, including risk management, customs controls and release to a customs procedure within the meaning of Regulation (EU) 2026/2108.

8. Paragraph 2, 3, and 4 shall not apply to drug precursors that are transhipped, placed under temporary storage, stored in a free zone, or when they are leaving the customs territory of the Union by a re-export notification.

9. Paragraph 4 shall not apply to drug precursors that are placed under customs warehousing, inward processing, or external transit procedure.

Article 24

Demonstration of licit purposes

Where a scheduled drug precursor enters into the customs territory of the Union for transhipment, temporary storage or storage in a free zone for licit purposes, the operator shall demonstrate those licit purposes in accordance with Chapter 4 of Annex VII, upon request by the competent authorities. This obligation shall also apply to a scheduled drug precursor leaving the customs territory of the Union by a re-export notification.

PUBLIC

Chapter 3
Awareness raising activities

PUBLIC

Article 25

The Drug Precursors Information Repository

1. By [OP please add date: *3 years after entry into force of this Regulation*] the Agency shall establish a Drug Precursors Information Repository ('Repository').

2. The Repository shall contain information on drug precursors, in particular:

   (a) general description of the substance and its physicochemical properties;

   (aa) where available, the CAS number and the CUS code;

   (b) information on legitimate uses and trade;

   (c) information on the use of the substance in the illicit production of drugs.

3. If substances are as a group of substances identified in a generic way in accordance with Article 37(1), the Repository referred to in paragraph 1 shall include an indicative list of the most relevant individual substances covered by the group of substances and a specific function allowing operators and competent authorities to check if a specific substance is to be considered as being part of the group where available the CAS number and the CUS code of the scheduled substance.

4. The information referred to in paragraph 2, points (a), (aa) and (b) and the specific function referred to in paragraph 3 shall be publicly available and free of charge.

5. The information referred to in paragraph 2, point (c) may be used by the Commission, the Agency and other Union bodies and the Member States to identify new trends in the illicit manufacture of drugs and determine appropriate measures.

6. The Agency shall maintain and keep the Repository up to date.

Article 26

Training activities

1. Member States shall ensure that the competent authorities responsible for the tasks concerned are provided with training, such as risk management training, to detect, in the course of their duties, scheduled or non-scheduled drug precursors that may be used in the illicit manufacture of drugs, and to react in a timely and appropriate manner to a suspicious activity.

2. Member States shall organise, at least once every two years, awareness-raising actions for operators who manufacture, make available on the market, import, export, or perform intermediary activities, possess or use drug precursors.

2a. For the training referred to in paragraph 1 and the awareness-raising actions referred to in paragraph 2, the Commission and the Agency shall provide the Member States with support as necessary.

3. Operators shall be responsible for providing information to their personnel on the obligations of the operators under this Regulation and for raising personnel awareness in this regard.

Chapter 4

Cooperation, control and reporting

Article 27

Administrative cooperation and designation of competent authorities

1. Each Member State shall designate the competent authority or authorities responsible for ensuring the application of this Regulation and shall inform the Commission, the other Member States and the Agency thereof.

2. For the purposes of applying this Regulation, the provisions of Regulation (EC) No 515/97 shall apply with the necessary adaptations. The competent authorities designated under paragraph 1 shall act as competent authorities within the meaning of Article 2(2) of Regulation (EC) No 515/97.

Article 28

Controls by competent authorities

1. Competent authorities shall carry out controls to determine if operators fulfil the obligations laid down in this Regulation. When there is reason to believe that a drug precursor might be diverted towards the illicit manufacture of drugs, the competent authority shall perform additional controls without undue delay.

2. The competent authorities shall respect the principles of confidentiality and of professional and commercial secrecy and shall protect personal data in accordance with Union and national law.

3. Member States shall ensure that the competent authorities have the resources necessary to ensure the proper administration of their tasks under this Regulation.

Article 29

Control of internal market

1. Controls by the competent authorities on scheduled drug precursors to determine compliance with this Regulation, shall include, as appropriate:
   a) requiring operators to provide any relevant documents, data or information on their activities on scheduled drug precursors and on the supply chain;
   b) carrying out unannounced inspections and physical checks on scheduled drug precursors;
   c) entering business premises of operators in order to obtain evidence to determine compliance with this Regulation;
   d) taking the measures foreseen in paragraph 2;
   e) taking appropriate measures in case of non-compliance with this Regulation, proportionate to the non-compliance identified, including suspending, revoking or limiting the scope of the licence, ordering the suspension or cessation of activities covered by a registration or prior notification, issuing warnings, or applying penalties in accordance with Article 31.

2. Competent authorities may seize scheduled drug precursors for up to 30 days subject to the conditions set out under national law, to verify the identification of the drug precursors and compliance with this Regulation.

3. The duration of the period referred to in paragraph 2 may be extended to a maximum of 90 days upon duly justified reason.

Article 30

Control of export and import

1. The competent authorities of each Member State shall prohibit the introduction of scheduled drug precursors into the customs territory of the Union or their departure from that territory, where there are reasonable grounds to suspect that the drug precursors are intended for the illicit manufacture of drugs.

2. The competent authorities of each Member State shall prohibit the introduction of non-scheduled drug precursors into the customs territory of the Union or their departure from that territory where there is sufficient evidence that those drug precursors are intended for the illicit manufacture of drugs.

3. Customs authorities shall only allow the release of the scheduled drug precursors referred to in paragraph 1, for the respective customs procedure or re-export after verifying their compliance with this Regulation.

4. The competent authorities may temporarily detain non-scheduled drug precursors for which there is suspicion that they are intended to be used in the illicit manufacture of drugs in accordance with the conditions laid down in national law pending verification of that suspicion.

5. The period of temporary detention referred to in paragraph 4 shall not exceed 30 days. The duration of the period may be extended to a maximum of 90 days upon duly justified reason.

PUBLIC

6. Competent authorities shall be empowered to carry out controls and monitor suspicious transactions during import and export involving scheduled or non-scheduled drug precursors, including:

   (a) obtaining information on any orders for or activities involving import and export of scheduled or non-scheduled drug precursors;

   (b) entering the business premises of operators in order to obtain evidence of irregularities;

   (c) establishing that a diversion or attempted diversion of scheduled drug precursors has taken place, and carry out follow up measures, where required.

7. When determining if there is suspicion that scheduled or non-scheduled drug precursors are intended to be used in the illicit manufacture of drugs, competent authorities shall use the indicators laid out in Chapter 5 of Annex VII. Should the indicators laid out in chapter 5, point 9 (b), of Annex VII be fulfilled the external trader importing, exporting, or performing intermediary activities with the non-scheduled drug precursor shall be required to prove that the drug precursor is destined for legitimate use.

8. For the purpose of preventing specific risks of diversion of drug precursors stored in free zones and under temporary storage as well as in other sensitive areas, such as customs warehouses, Member States shall ensure that effective controls are applied to activities carried out in these areas.

Article 31

Penalties

1 Member States shall lay down the rules on penalties applicable to infringements of the provisions of this Regulation and shall take all measures necessary to ensure that they are implemented.

2. The penalties provided for shall be effective, proportionate and dissuasive.

3. Member States shall notify the Commission of those rules and of any subsequent amendment affecting them.

PUBLIC

Article 32

Reporting obligation

The competent authorities shall report information on seizures of drug precursors and information on the implementation of this Regulation subject to the conditions set out in Annex VIII.

Article 33

Obligation of information

1. Where the information referred to in Article 32 concerns significant seizures of non-scheduled drug precursors, the competent authority shall notify the Commission, the Agency and other Member States within 5 working days after the competent authority becomes aware of the seizure.

2. The competent authority of a Member State shall inform the Commission, the Agency and the competent authorities of other Member States within 5 working days of receiving a request for a licence for a Category 3 drug precursor in accordance with Article 18.

Article 34

UN reporting

The Commission shall, in consultation with Member States, submit an annual report to the International Narcotics Control Board based on information provided by operators and competent authorities, subject to the conditions set out in Annex VIII.

PUBLIC

Chapter 5
Drug precursors electronic system

PUBLIC

Article 35

Electronic system

1. The Commission shall, by 31 December 2030, establish and maintain a centralised electronic system for the submission, storage, processing, decision-making, and exchange of information for the monitoring and control of drug precursors in accordance with this Regulation.

1a. Functionalities of the electronic system referred to in paragraph 1 may be implemented within the EU Customs Data Hub established by Article 35 of Regulation (EU) 2026/2108, in accordance with the provisions laid down in Title III of that Regulation.

2. The Commission shall establish the electronic system referred to in paragraph 1, in particular with the following functions:

   (a) To enable operators to:

      (i) register in the system in order to perform formalities set out in this Regulation;

      (ii) request a licence in accordance with Article 9 and Article 18;

      (iii) make the registration required by Article 9(7) and Article 15;

      (iv) file a prior notification in accordance with Article 17(2);

      (v) verify in accordance with Article 13 and Article 19(1) that other operators hold a licence or made a prior notification;

      (vi) notify quantities to competent authorities in accordance with Articles 20 and 22;

      (vii) provide information on pre-export notifications in accordance with Article 21(4) and be informed of the results of those notifications.

(b) To enable operators and providers of online marketplaces to report on suspicious transactions, disappearances or thefts in accordance with Article 8;

(c) To enable competent authorities to:

(i) issue, suspend or revoke a licence;

(ii) order operators to suspend or cease activities covered by a registration or a prior notification, in accordance with Article 15(5) or Article 17(5) respectively;

(iii) provide information in accordance with Article 32 and Article 33;

(d) facilitate the preparation of the report to the International Narcotic Control Board in accordance with Article 34, by the Commission in consultation with Member States.

3. *[deleted]*

4. *[deleted]*

5. The Commission shall make the electronic system referred to in paragraph 1 interoperable with the EU Customs Data Hub in accordance with Article 50 of Regulation (EU) 2026/2108, to the extent that its functionalities are not implemented within the EU Customs Data Hub in accordance with paragraph 1a.

6. The Commission shall, in accordance with applicable Union law and in cooperation with the United Nations, aim to interconnect the system referred to in paragraph 1 with the systems of the United Nations for incidents reporting or other United Nations systems for drug precursors. Before exchanging personal data with the United Nations or interconnecting the electronic system referred to in Paragraph 1, the Commission shall ensure that the transfer of personal data is in conformity with Regulation (EU) 2016/679 or Regulation (EU) 2018/1725, as applicable.

7. The Commission, the Agency, the competent authorities and the operators shall have access to the data in the electronic system needed for performing their tasks under this Regulation. Without prejudice to their obligation under this Regulation, the Commission, the Agency, the competent authorities and the operators shall respect the principles of confidentiality and professional secrecy and shall protect personal data in accordance with Union and national law.

PUBLIC

8. By [*OP please add date: 18 months after the entry into force of this Regulation*], the Commission shall adopt an implementing act establishing implementing arrangements for the development and operation of the electronic system, including procedural and technical modalities for the processing of data, and for the technical specifications and the procedures to be followed for the implementation of Articles 6, 8, 9, 13, 15, 17, 18, 19(1), 20, 21, 22, 23, 32, 33 and 34. Where functionalities of the electronic system are implemented within the EU Customs Data Hub in accordance with paragraph 1a, the implementing arrangements shall be developed in accordance with the provisions governing the EU Customs Data Hub in Regulation (EU) 2026/2108.

9. The implementing act referred to in paragraph 8 shall be adopted in accordance with the examination procedure referred to in Article 40(2).

Article 36

Data protection

1. The processing of personal data within the electronic system referred to in Article 35 shall be carried out in compliance with Regulation (EU) 2016/679 or Regulation (EU) 2018/1725, as applicable.

2. The processing of personal data under this Regulation shall take place solely for the purpose of monitoring and controlling drug precursors with a view to ensuring their free movement in the internal market while preventing their availability for the illicit manufacture of drugs and the proliferation of designer precursors. Any processing of personal data under this regulation shall be limited to what is necessary and proportionate in order to achieve its purpose.

2a. Personal data processed in the electronic system pursuant Article 35 may be stored no longer than is necessary for the processing of that data and in any event no longer than 10 years:

a) after the expiry of the licence, registration or prior notification; or

b) where the personal data is not linked to a licence, registration or prior notification, starting from the last interaction with the system by the data subject.

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In case of investigation by the competent authority of the Member State and judicial proceedings, this data may be kept for a period longer than 10 years if necessary for the purpose of those procedures.

3. Access to personal data shall be limited to duly authorised staff of the Commission and other Union bodies and competent authorities to the extent necessary for the performance of their tasks under this Regulation. Those Union bodies and authorities shall ensure the confidentiality and integrity of such data and protect them against unauthorised access, use or disclosure, in accordance with the applicable Union data protection rules.

PUBLIC

Chapter 6
Delegation of powers and committee procedure

Article 37

Delegation of power

1. The Commission is empowered to adopt delegated acts in accordance with Article 38 amending Annex I, Annex II and Annex III to adapt those Annexes to new trends in diversion of drug precursors or to align them with any amendment to the tables annexed to the UN Convention, by adding or removing substances and adapting existing entries. The Commission may only add substances identified individually to Annex I or Annex II, unless otherwise required to align those Annexes with the tables annexed to the UN Convention. The Commission may add substances in Annex III either identified individually or in a generic way. When adding substances in a generic way, the Commission shall clearly identify the group of substances and, if applicable, the individual substances which are to be exempted from the control and monitoring measures for scheduled drug precursors.

2. When a substance covered by Annex III has legitimate use other than in research and innovation, as reported in accordance with Article 33(2), where applicable, the Commission shall adopt a delegated act amending that Annex by removing the substance from Part I of that Annex and, as appropriate, including it in Annex I or Annex II or in the exemption list in Part II, Section 2 of Annex III.

2a. The Commission is empowered to adopt delegated acts in accordance with Article 38 laying down the exceptional circumstances referred to in Article 18.

3. When adopting delegated acts to add new substances in accordance with paragraphs 1 and 2, the Commission shall also indicate, as applicable, for the substances concerned:

(a) the concentration threshold for a substance in Annex I, II or III below which and, where appropriate, the special conditions under which a mixture, complex substance or organism containing that substance is excluded from the scope of this Regulation in accordance with Article 3(1), point (b)(ii);

(b) a quantity threshold during one calendar year below which the obligations set out in Article 9(1), first subparagraph, and in Article 15(1a) do not apply;

(c) a maximum quantity threshold which can be notified for use in research and innovation, in the conditions laid down in Article 17(2), as applicable.

The Commission shall adopt delegated acts amending Annex I, Annex II and Annex III to set up the thresholds referred to in the first subparagraph, points (a), (b) and (c), for substances already included in those Annexes.

4. To attain the objectives pursued by this Regulation, the Commission is empowered to adopt delegated acts in accordance with Article 38 amending Annex IV, Annex V, Annex VI, Annex VII, and Annex VIII to adapt the general conditions and other technical rules for:

(a) licences;

(b) registrations;

(c) prior notifications;

(d) quantity notifications for import or export;

(e) pre-export notifications;

(f) the indicators to determine the licit purposes of the transaction referred to in Article 24;

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(g) determining the indicators for suspicion on intention of use in the illicit manufacture of drugs as referred to in Article 30(7); and

(h) reporting obligations.

5. Where imperative grounds of urgency or overriding general interests concerning public health and security so require, the procedure provided for in Article 39 shall apply to delegated acts adopted pursuant to paragraphs 1 and 2 of this Article.

Article 38

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 37 shall be conferred on the Commission for a period of five years from [*OP please add date: the date of entry into force of this Regulation*]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 37 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State acting in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

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6. A delegated act adopted pursuant to Article 37 shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 39

Urgency procedure

1. Delegated acts adopted under this Article shall enter into force without delay and shall apply as long as no objection is expressed in accordance with paragraph 2. The notification of a delegated act to the European Parliament and to the Council shall state the reasons for the use of the urgency procedure.

2. Either the European Parliament or the Council may object to a delegated act in accordance with the procedure referred to in Article 38(6). In such a case, the Commission shall repeal the act immediately following the notification of the decision to object by the European Parliament or by the Council.

Article 40

Committee procedure

1. The Commission shall be assisted by the Drug Precursors Committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011 of the European Parliament and of the Council.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

PUBLIC

Chapter 7
Transition and final provisions

PUBLIC

Article 41

Review

By 5 years from the date of application of this Regulation, the Commission shall submit to the European Parliament and to the Council a report on the application of this Regulation. The report shall contain an assessment of how this Regulation is achieving its objectives.

Article 42

Repeal

1. Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005 are repealed.

2. References to the repealed Regulations shall be construed as references to this Regulation and read in accordance with the correlation table in Annex X.

Article 43

Transitional provisions

1. Licences, special licences, registrations and special registrations issued under Regulation (EC) No 273/2004 or Regulation (EC) No 111/2005 before [*OP please add date: 3 years after the date of entry into force of this Regulation*] shall be valid until their expiry date or until [*OP please add date: 4 years after the date of entry into force of this Regulation*] whichever is soonest.

2. Licences and special licences for which an application is made before [*OP please add date: 3 years after the date of entry into force of this Regulation*] based on Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005 shall be granted in accordance with those Regulations and be valid until maximum [*OP please add date: 4 years after the date of entry into force of this Regulation*].

3. Licences, special licences, registrations and special registrations issued under Regulation (EC) No 273/2004 or Regulation (EC) No 111/2005 which are valid in accordance with paragraphs 1 and 2 may be revoked or suspended pursuant to those Regulations. After *[OP please add date: 3 years after the date of entry into force of this Regulation]*, they may be revoked or suspended in accordance with this Regulation.

4. Import and export authorisations issued under Regulation (EC) No 111/2005 before [*OP please add date: 3 years after the date of entry into force of this Regulation*] shall be valid until their expiry date.

5. *[deleted]*

Article 44

[deleted]

Article 45

Entry into force and application

1. This Regulation shall enter into force on the twentieth day following that of its publication in t*he Official Journal of the European Union.*
2. It shall apply from 31 December 2030.
3. By way of derogation from paragraph 2, Article 25, Article 35(1), (2), (5), (8) and (9), Articles 37, 38, 39, 40 and 43 shall apply from [*OP please add: date of entry into force of this Regulation*].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*
[...]	*[...]*

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ANNEX I

Category 1 drug precursors

Category 1 drug precursors contain or consist of:

Substance	**CAS number**	**CN code**	**CUS code**	**Quantity threshold referred to in Article 9(1), first subparagraph**	**Concentration threshold in mixtures, complex substances and organisms referred to in Article 3(1), point (b)(ii)**	**Special conditions on mixtures, complex substances and organisms**
1-phenyl-2-propanone (BMK), also known as phenylacetone	103-79-7	2914 31 00	-	-	-	
3'-chloropropiophenone	34841-35-5	2914 79 00	-	-	-	
2-bromo-3'-chloropropiophenone	34911-51-8	2914 79 00	-	-	-	
4'-methylpropiophenone	5337-93-9	2914 39 00	-	-	-	

Substance	CAS number	CN code	CUS code	Quantity threshold referred to in Article 9(1), first subparagraph	Concentration threshold in mixtures, complex substances and organisms referred to in Article 3(1), point (b)(ii)	Special conditions on mixtures, complex substances and organisms
2-Bromo-4'-methylpropiophenone	1451-82-7	294 79 00	-	-	-	
3'-Methylpropiophenone	51772-30-6	2914 39 00	-	-	-	
2-Bromo-3'-methylpropiophenone	1451-83-8	2914 79 00	-	-	-	
4'-Chloropropiophenone	6285-05-8	2914 79 00	-	-	-	
2-Bromo-4'-chloropropiophenone	877-37-2	2914 79 00	-	-	-	
Phenyl-2-nitropropene	705-60-2	2904 20 00	-	-	-	

Substance	CAS number	CN code	CUS code	Quantity threshold referred to in Article 9(1), first subparagraph	Concentration threshold in mixtures, complex substances and organisms referred to in Article 3(1), point (b)(ii)	Special conditions on mixtures, complex substances and organisms
N-acetylanthranilic acid, also known as 2-acetamidobenzoic acid	89-52-1	2924 23 00	-	-	-	
Isosafrol (cis + trans)	120-58-1	2932 91 00	-	-	-	
3,4-methylenedioxyphenylpropan-2-one (PMK)	4676-39-5	2932 92 00	-	-	-	
Piperonal	120-57-0	2932 93 00	-	-	-	
Safrole	94-59-7	2932 94 00	-	-	-	
N-phenyl-1-(2-phenylethyl)piperidin-4-	21409-26-7	2933 36 00	-	-	-	

Substance	CAS number	CN code	CUS code	Quantity threshold referred to in Article 9(1), first subparagraph	Concentration threshold in mixtures, complex substances and organisms referred to in Article 3(1), point (b)(ii)	Special conditions on mixtures, complex substances and organisms
amine (ANPP)						
1-(2-phenylethyl)piperidin-4-one (NPP)	39742-60-4	2933 37 00	-	-	-	
N-phenyl-N-(piperidin-4-yl)propanamide (norfentanyl)	1609-66-1	2933 39 99				
4-piperidone	41661-47-6	2933 39 99	-	-	-	
1-boc-4-piperidone	79099-07-3	2933 39 99	-	-	-	
Ephedrine	299-42-3	2939 41 00	-	-	-	
Pseudoephedrine	90-82-4	2939 42 00	-	-	-	
Norephedrine	14838-15-4	2939 44 00	-	-	-	

Substance	**CAS number**	**CN code**	**CUS code**	**Quantity threshold referred to in Article 9(1), first subparagraph**	**Concentration threshold in mixtures, complex substances and organisms referred to in Article 3(1), point (b)(ii)**	**Special conditions on mixtures, complex substances and organisms**
Ergometrine	60-79-7	2939 61 00	-	-	-	
Ergotamine	113-15-5	2939 62 00	-	-	-	
Lysergic acid	82-58-6	2939 63 00	-	-	-	

The salts of the substances listed in this Annex, whenever the existence of such salts is possible and not being the salts of cathine.

The stereoisomeric forms of the substances listed in this category not being cathine, and their salts, whenever the existence of such forms is possible.

The CAS numbers and CN codes listed in this Annex do not constitute of exhaustive list of all possible salts and stereoisomeric forms.

ANNEX II

Category 2 drug precursors

Part I

Individually listed substances with a higher risk of diversion

Category 2A drug precursors contain or consist of:

Substance	**CAS number**	**CN code**	**CUS code**	**Quantity threshold referred to in Article 15(1a)**	**Concentration threshold in mixtures, complex substances and organisms referred to in Article 3(1), point (b)(ii)**	**Special conditions for mixtures, complex substances and organisms**
Red phosphorus	7723-14-0	2804 70 10	-			
Potassium permanganate	7722-64-7	2841 61 00 00	-			
Acetic anhydride	108-24-7	2915 24 00	-			
Phenylacetic acid	103-82-2	2916 34 00	-			
Anthranilic acid	118-92-3	2922 43 00	-			
Piperidine	110-89-4	2933 32 00	-			

The salts of the substances listed in this Part of the Annex, whenever the existence of such salts is possible.

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Part Ia

Individually listed substances

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Category 2B drug precursors contain or consist of:

Substance	CAS number	CN code	CUS code	Concentration threshold in mixtures, complex substances and organisms referred to in Article 3(1), point (b)(ii)	Special conditions for mixtures, complex substances and organisms
Hydrochloric acid	7647-01-0	2806 10 00	-		
Sulphuric acid	7664-93-9	2807 00 00	-		
Toluene	108-88-3	2902 30 00	-		
Ethyl ether	60-29-7	2909 11 00	-		
Acetone	67-64-1	2914 11 00	-		
Methylethyl ketone (MEK)	78-93-3	2914 12 00	-		

The salts of the substances listed in this Part of the Annex, whenever the existence of such salts is possible, with the exception of salts of hydrochloric acid and sulphuric acid.

Part II

Medicinal products and veterinary medicinal products

PUBLIC

Category 2 drug precursors also consist of the following medicinal products:

Products	**CN code**	**CUS code**
Medicinal products and veterinary medicinal products containing pseudoephedrine or its salts	3003 42 00 3004 42 00	-
Medicinal products and veterinary medicinal products containing ephedrine or its salts	3003 41 00 3004 41 00	-

ANNEX III

Category 3 drug precursors

PUBLIC

Part I

Individually listed substances

Category 3 drug precursors contain or consist of:

Group (1)[3]	Substance IUPAC[4]	Other names	CAS number	CUS code	Maximum quantity threshold for research and innovation referred to in Article 17 (2)	Concentration threshold in mixtures, complex substances and organisms referred to in Article 3(1), point (b) (ii)	Special conditions for mixtures, complex substances and organisms
AA	Methyl 2-phenyl-3-oxobutanoate	Methyl alpha-phenylacetoacetate , CN Code : 2918 30 00, MAPA	16648-44-5	-	-	-	-
AA	Ethyl 2-phenyl-3-oxobutanoate	Ethyl alpha-phenylacetoacetate, CN Code : Ex 2918 30 00, EAPA; ethyl 3-oxo-2-phenylbutanoate	5413-05-8	-	-	-	-
AB	2-methyl-3-phenyloxirane-2-carboxylic acid	CN Code : 2918 99 90, BMK glycidic acid	25547-51-7	-	-	-	-
AB	Methyl 2-methyl-3-phenyloxirane-2-carboxylate	CN Code : 2918 99 90	80532-66-7	-	-	-	-
AB	Ethyl 2-methyl-3-phenyloxirane-2-carboxylate	CN Code : 2918 99 90		-	-	-	-
AB	Propyl 2-methyl-3-phenyloxirane-2-carboxylate	CN Code : 2918 99 90		-	-	-	-

[3] AA: Propylbenzene derivatives, Oxobutanoate esters
AB: Propylbenzene derivatives, Glycidic acid and its esters

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AG: Propylbenzene derivatives, Amides
AK: Propylbenzene derivatives, Others
BA: 5-propyl-1,3-benzodioxole (dihydrosafrole) derivatives, Oxobutanoate esters
BB: 5-propyl-1,3-benzodioxole (dihydrosafrole) derivatives, Glycidic acid and its esters
CA: Piperidine derivatives, Anilinopiperidines

[4] Substance name according to the IUPAC nomenclature.

AB	Isopropyl 2-methyl-3-phenyloxirane-2-carboxylate	CN Code : 2918 99 90		-	-	-	-
AB	Butyl 2-methyl-3-phenyloxirane-2-carboxylate	CN Code : 2918 99 90		-	-	-	-
AB	isobutyl 2-methyl-3-phenyloxirane-2-carboxylate	CN Code : 2918 99 90		-	-	-	-
AB	Sec-butyl 2-methyl-3-phenyloxirane-2-carboxylate	CN Code : 2918 99 90		-	-	-	-
AB	Tert-butyl 2-methyl-3-phenyloxirane-2-carboxylate	CN Code : 2918 99 90		-	-	-	-
AG	3-Oxo-2-phenylbutanamide	Alpha-phenylacetoacetamide, CN Code : 2924 29 70, APAA	4433-77-6	-	-	-	-
AK	3-Oxo-2-phenylbutanenitrile	Alpha-phenylacetoacetonitrile, CN Code : 2926 40 00, APAAN	4468-48-8	-	-	-	-
AK	(1R,2S)-1-(4-chlorophenyl)-2-(methylamino)propan-1-ol	(1R,2S)-(-)-chloroephedrine, CN Code : 2939 79 90	110925-64-9	-	-	-	-
AK	(1S,2R)-1-(4-chlorophenyl)-2-(methylamino)propan-1-ol	(1S,2R)-(+)-chloroephedrine, CN Code : 2939 79 90	1384199-95-4	-	-	-	-
AK	(1S,2S)-1-(4-chlorophenyl)-2-(methylamino)propan-1-ol	(1S,2S)-(+)-chloropseudoephedrine, CN Code : 2939 79 90	73393-61-0	-	-	-	-
AK	(1R,2R)-1-(4-chlorophenyl)-2-(methylamino)propan-1-ol	(1R,2R)-(-)-chloropseudoephedrine, CN Code : 2939 79 90	771434-80-1	-	-	-	-

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AK	Diethyl 2-(2-phenylacetyl)propanedioate	Diethyl (phenylacetyl) propanedioate, CN Code : 2918 30 00, DEPAPD	20320-59-6	-	-	-	-
AK	Isopropylidene (2-(3,4-methylenedioxyphenyl) acetyl)malonate	CN Code : 2932 99 00, IMDPAM; 5-[2-(1,3-benzodioxol-5-yl)acetyl] -2,2-dimethyl-1,3-dioxane-4,6-dione		-	-	-	-
BA	Methyl 2-(2H-1,3-benzodioxol-5-yl)-3-oxobutanoate	Methyl 3-oxo-2-(3,4-methylenedioxyphenyl)butanoate, CN Code : Ex 2932 99 00, MAMDPA, methyl 2-(2H-1,3-benzodioxol-5-yl)-3-oxobutanoate	1369021-80-6	-	-	-	-
BB	3-(1,3-benzodioxol-5-yl)-2-methyl-oxirane-2-carboxylic acid	CN Code : 2932 99 00, PMK glycidic acid	2167189-50-4	-	-	-	-
BB	Methyl 3-(1,3-benzodioxol-5-yl)-2-methyl-oxirane-2-carboxylate	CN Code : 2932 99 00	13605-48-6	-	-	-	-
BB	Ethyl 3-(1,3-benzodioxol-5-yl)-2-methyl-oxirane-2-carboxylate	CN Code : 2932 99 00	28578-16-7	-	-	-	-
BB	Propyl 3-(1,3-benzodioxol-5-yl)-2-methyl-oxirane-2-carboxylate	CN Code : 2932 99 00		-	-	-	-
BB	Isopropyl 3-(1,3-benzodioxol-5-yl)-2-methyl-oxirane-2-carboxylate	CN Code : 2932 99 00		-	-	-	-
BB	Butyl 3-(1,3-benzodioxol-5-yl)-2-methyl-oxirane-2-carboxylate	CN Code : 2932 99 00		-	-	-	-
BB	isobutyl 3-(1,3-benzodioxol-5-yl)-2-methyl-oxirane-2-carboxylate	CN Code : 2932 99 00		-	-	-	-

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BB	Sec-butyl 3-(1,3-benzodioxol-5-yl)-2-methyl-oxirane-2-carboxylate	CN Code : 2932 99 00		-	-	-	-
BB	Tert-butyl 3-(1,3-benzodioxol-5-yl)-2-methyl-oxirane-2-carboxylate	CN Code : 2932 99 00		-	-	-	-
CA	N-phenylpiperidin-4-amine (4-AP)	CN Code: 2933 39 99	23056-29-3	-	-	-	-
CA	Tert-butyl 4-anilinopiperidine-1-carboxylate (1-boc-4-AP)	CN Code: 2933 39 99	125541-22-2	-	-	-	-

The stereoisomeric forms of the substances listed in this Part, whenever the existence of such forms is possible.

The salts of the substances listed in this part whenever the existence of such salts is possible.

PUBLIC

Part II
Groups of substances identified in a generic way

SECTION 1
GROUPS OF SUBSTANCES

SECTION 2
SUBSTANCES EXEMPTED IN ACCORDANCE WITH ARTICLE 5(1)(C) OR ARTICLE 37(2)

The following substances are exempt from the groups of substances included in Section 1 of this Part:

Substance (IUPAC)	Other Names	CAS	CUS code

PUBLIC

ANNEX IV

Licence referred to in Article 9 and Article 18

1. In order to obtain a licence pursuant to Article 9 or Article 18 of this Regulation, operators shall make an application to the competent authority through the electronic system referred to in Article 35 containing the following:

   (a) the name and contact details of the operator, as well as the single representative where applicable, including postal and electronic address, and telephone number, and tax identification number if available;

   (aa) where Article 8a applies, the details of the importer or exporter, as applicable, shall also be provided pursuant to Article 23(1);

   (b) for import and export activities, if applicable, the external trader's Economic Operators Registration and Identification (EORI) number referred to in Article 19 (1) of Regulation (EU) 2026/2108 as well as that of their single representative;

   (c) if applicable, the reference to status as Authorised Economic Operator or Trust and check trader issued under Chapter 4 of Title II of Regulation (EU) 2026/2108;

   (d) the name of the responsible officer appointed in accordance with Article 10 of this Regulation, its contact details, and a description of its position and tasks;

   (e) the addresses of the business premises where Category 1 or, if applicable Category 3 drug precursors are to be possessed, manufactured or used;

   (f) information showing that the adequate measures referred to in Article 8b have been taken;

   (g) the name, the CN code and where available the CAS number and CUS code of the substances covered by Annex I or Annex III, as applicable;

   (h) in case of mixtures, complex substances and organisms, their name and the maximum concentration of the substances covered by Annex I or Annex III contained therein, as applicable;

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(i) the quantity of each substance covered by Annex I or Annex III, as applicable, estimated to be manufactured, involved in transactions or to be used during a validity period requested for the licences, expressed per year;

(j) an exhaustive list of the envisaged type of activities referred to in Article 9(1), first subparagraph and their detailed description;

(k) when requesting a licence for Category 3 drug precursors in accordance with Article 18, a justification for exceeding the maximum threshold set out in Annex III and documents demonstrating the legitimate use;

(l) an extract from the registry of commerce, if applicable;

(m) a certificate of good conduct of the operator and of the responsible officer or a document showing that they offer the necessary guarantee for the proper conduct of the activities;

(n) proof of competence in dealing with Category 1 or, if applicable, Category 3 drug precursors, such as a copy of internal procedures on dealing with drug precursors, including notifying suspicious transactions; or other documents demonstrating experience in dealing with Category 1 or, if applicable, Category 3 drug precursors;

(o) the period for which the licence is requested unless an application is made for a simplified licence in accordance with Article 9(4);

(p) if applicable, the third country identification number (TCIN) of the importer, exporter, or holder of the external transit procedure.

2. Upon request from the relevant competent authority, the operator shall submit any relevant additional information.

3. The competent authority shall issue a licence through the electronic system referred to in Article 35 after performing documentary checks and, if this is deemed to be necessary, inspecting the business premises where Category 1 or, if applicable, Category 3 drug precursors are to be possessed, manufactured or used.

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4. In accordance with Article 9(2), the competent authority shall grant a licence if the operator demonstrates:

(a) competence in dealing with Category 1 or, if applicable, Category 3 drug precursors, including in identifying suspicious transactions, for instance by setting out internal procedures for dealing with Category 1, or, if applicable, Category 3 drug precursors, including notifying suspicious transactions, or otherwise showing experience in dealing with such drug precursors;

(b) integrity by the absence of any serious infringement or repeated infringements of legislation in the field of drug precursors and the absence of a record of any serious criminal offence.

In accordance with Article 9(4), the competent authority may grant a simplified licence for 10 years to pharmacies and dispensaries of veterinary medicinal products, importing or exporting Category 1 drug precursors, without inspecting the business premises. In such cases, the provision of the documentation referred to in Article 7 of this Regulation as well as the obligation to appoint a responsible officer set out in Article 10 of this Regulation shall not apply.

4. The licence shall be granted per Member State covering all activities for Category 1 or, if applicable, Category 3 drug precursors and all business premises in that Member State.

The licence shall not be transferable.

5. An operator shall obtain an update of the licence granted in accordance with point 3 before the:

(a) manufacture, make available on the market, import, export, perform intermediary activities, use or possess drug precursors covered by Annex I or Annex III, in quantities exceeding those estimated in the application for a period of one calendar year;

(b) manufacture, make available on the market, import, export, perform intermediary activities, use or possess drug precursors covered by Annex I or Annex III, other than those included in the initial licence;

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(c) undertake additional types of activities among the activities referred to in Article 9(1), first subparagraph, which have not been included in the initial licence;

(d) change or extend to new business premises.

The competent authority may decide to update the licence for the remaining period of validity based on documentary checks only.

5a. An operator shall notify the competent authority within 10 working days of any changes to information provided in the application for the initial license, which are not covered by paragraph 5 of this Annex.

6. The decision to refuse a licence in accordance with Article 9(2) or to revoke or suspend an existing licence in accordance with Article 9(6) shall be communicated through the electronic system referred to in Article 35, shall be motivated and subject to appeal under the conditions set out in the national law.

7. The operator may request the renewal of a licence in accordance with point 1, for a period of up to three years. The competent national authority may decide to renew a licence based on documentary checks only.

PUBLIC

ANNEX V

Registration of information pursuant to Article 9(7) and Article 15

1. The registration pursuant to Article 9(7) or Article 15 of this Regulation shall be made through the electronic system referred to in Article 35 and shall include the following:

   (a) the name and contact details of the operator, as well as the single representative where applicable, including postal and electronic address, and telephone number, and tax identification number if available;

   (aa) where Article 8a applies, the details of the importer, exporter, holder of the external transit procedure, as applicable, shall also be provided pursuant to Article 23(1);

   (b) if applicable, the external trader's Economic Operators Registration and Identification (EORI) number referred to in Article 26 of Regulation (EU) 2026/2108 as well as that of their single representative;

   (c) if applicable, the reference to status as Authorised Economic Operator or Trust and check trader issued under Chapter 4 of Title II of Regulation (EU) 2026/2108;

   (d) the name of the responsible officer appointed in accordance with Article 10, its contact details, and a description of its position and tasks;

   (e) the addresses of the business premises where Category 2 drug precursors or Category 1 drug precursors, as applicable, are to be manufactured or stored;

   (f) the name, the CN code, the CAS number and CUS code of the substances as covered by Part I or Part Ia, of Annex II or of the products referred to in Part II, of Annex II, or of the substances covered by Annex I, as applicable;

   (g) in case of mixtures, complex substances or organisms, their name and the maximum concentration of the substances covered by Part I or Part Ia, of Annex II, or in Annex I, contained therein, as applicable;

   (h) the quantity of each substance covered by Annex II or Annex I, as applicable, estimated to be manufactured or involved in transactions during the validity period of the registration for each year;

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(i) an exhaustive list of the envisaged type of activities referred to in Article 9(7), Article 15(1), first subparagraph, or Article 15(1a), as applicable, and their detailed description;

(j) the period for which the registration is made, unless the registration is made in accordance with Article 15(3);

(k) if applicable, the third country identification number (TCIN) of the importer, exporter, or holder of the external transit procedure.

2. Pharmacies and dispensaries of veterinary medicinal products engaged in import, export or intermediary activities involving Category 2 drug precursors may file a registration for 10 years, in accordance with Article 15(3). In that case, the provision of documentation referred to in Article 7 of this Regulation as well as the obligation to appoint a responsible officer set out in Article 15(6) of this Regulation shall not apply.

3. An operator shall, in accordance with Article 15(4), update the information in the registration within 10 working days of any change requiring the operator to:

(a) make available on the market, import, export, or perform intermediary activities involving drug precursors covered by Annex I or Annex II, as applicable, in quantities exceeding those estimated in the initial registration for a period of one year;

(b) manufacture, make available on the market, import, export, or perform intermediary activities involving drug precursors covered by Annex I or Annex II, as applicable, other than those indicated in the initial registration;

(c) undertake additional activities;

(d) change or extend to new business premises.

4. The decision of a competent authority to order the suspension or cessation of the activity in accordance with Article 15(5) of this Regulation shall be communicated through the electronic system referred to in Article 35, motivated and subject to appeal under the conditions set out in the national law.

PUBLIC

ANNEX VI

Prior notification under Article 17(2)

1. The prior notification referred to in Article 17(2) of this Regulation shall be made through the electronic system referred to in Article 35 and shall contain at least the following:

   (a) the name and contact details of the operator, as well as the single representative where applicable, including postal and electronic address, and telephone number and tax identification number if available;

   (aa) where Article 8a applies, the details of the importer, exporter, holder of the external transit procedure, as applicable, shall also be provided pursuant to Article 23(1);

   (b) for import and export activities, if applicable, the external trader's Economic Operators Registration and Identification (EORI) number referred to in Article 26 of Regulation (EU) 2026/2108 as well as that of their single representative;

   (c) if applicable, the reference to status as Authorised Economic Operator or Trust and check trader issued under Chapter 4 of Title II of Regulation (EU) 2026/2108;

   (d) the name of the responsible officer appointed in accordance with Article 10 of this Regulation, its contact details, and a description of its position and tasks;

   (e) the addresses of the business premises where Category 3 drug precursors are to be possessed or used;

   (f) information showing that the adequate measures referred to in Article 8b of this Regulation have been taken;

   (g) the name, the CN code and where available the CAS number and CUS code of the substances as covered by Annex III to this Regulation;

   (h) the quantity of each substance covered by Annex III to this Regulation during the validity period of the prior notification;

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(i) in case of mixtures, complex substances or organisms, the name of the substance covered by Annex III to this Regulation contained therein, their quantity and maximum concentration;

(j) the date when the drug precursor is to be manufactured, made available on the market, imported, exported, subject to intermediary activities, possessed or used for the first time;

(k) an exhaustive list of the envisaged type of activities referred to in Article 17(1) of this Regulation and their detailed description;

(l) in the case of import and export activities, details of the transport arrangements, where applicable, such as the expected date of dispatch, method of transport, name of the customs office where the customs declaration is to be made and, where available at this stage, identification of the means of transport, itinerary, for exports; the expected point of exit from customs territory of the Union and the point of entry into the importing country and for imports; the expected date of arrival in the customs territory of the Union; where additional elements become available at a later moment, the operator shall update the prior notification;

(m) the names and contact details of the other operators to which the drug precursor is made available, imported, exported, or involved in the intermediary activities.

(n) a certificate of good conduct of the operator and of the responsible officer or a document showing that they offer the necessary guarantee for the proper conduct of the activities;

(o) an extract from the registry of commerce, if applicable;

(p) if applicable, the third country identification number (TCIN) of the importer, exporter, or holder of the external transit procedure.

PUBLIC

2. The prior notification shall be made available to customs authorities through the electronic system referred to in Article 35.

3. The decision of a competent authority ordering operators to suspend or cease activities covered by the prior notification in accordance with Article 17(5) shall be communicated through the electronic system referred to in Article 35, motivated and subject to appeal under the conditions set out in the national law.

PUBLIC

ANNEX VII

External trade (Articles 20 to 24 and 30)

Chapter 1

Import

PUBLIC

1. The following information shall be provided in accordance with Article 20:

(-a) The name and address of the importer, the exporters in the third country, and any other operators involved in the import operation or shipment, as well as the name and address of the ultimate consignees;

(a) the name, the CN code, and the CUS code of the substance covered by Annex I, Annex II, or Annex III or, in the case of a mixture, complex substance or an organism, its name the eight-digit CN code, and the name and CUS code of any substance covered by Annex I, Annex II or Annex III contained in the mixture, complex substance organism;

(b) the quantity of the substance and, in the case of a mixture, complex substance or organism, the quantity, and, if available, the percentage of any substance covered by Annex I, Annex II or Annex III contained therein;

(c) the reference to the licence referred to in Articles 9 or 18, the registration referred to in Article 15, or the prior notification referred to in Article 17.

(d) The quantity notified under Article 20(1) will be valid for a period of 180 calendar days.

1a. For transactions exempted under Article 20(4), the importer shall, upon a reasoned request, provide the competent authority with information regarding the quantities involved.

Chapter 2

Pre-export notification

2. The pre-export notification referred to in Article 21 shall contain at least the following:

(a) the names and addresses of the exporter, the importer in the third country, any other operator involved in the export operation or shipment, and the name and address of the ultimate consignee;

(b) the name of the substance covered by Annex I, Annex II or Annex III or, in the case of a mixture, complex substance or organism, its name and eight-digit CN code and the name of any drug precursor covered by the Annex, contained in the mixture, complex substance or organism;

(c) the quantity and weight of the drug precursor and, in the case of a mixture, complex substance or organism, the quantity, weight, and, if available, the percentage of any drug precursor contained therein;

(d) details of the transport arrangements, such as the expected date of dispatch, method of transport, name of the customs office where the customs declaration is to be made and, where available at this stage, identification of the means of transport, itinerary, the expected point of exit from customs territory of the Union and the point of entry into the importing country.

3. The certain countries of destination referred to in Article 21(1) to which a pre-export notification for the drug precursors covered by Annex II is required shall include all of the following:

(a) third countries with whom the Union has concluded a specific agreement on drug precursors;

(b) third countries which have requested to receive pre-export notifications in accordance with Article 12(10) of the UN Convention ;

PUBLIC

(c) third countries which have requested to receive pre-export notifications in accordance with Article 24 of the UN Convention .

(d) The lists of the countries of destination for export of the drug precursors covered by Annex II referred to in points (a), (b), and (c) shall be published on the Commission's website.

4. The competent authority may send a simplified pre-export notification, in accordance with Article 21(7), covering several export operations for a period of 180 calendar days.

5. The competent authority of the country of export shall supply the information specified in point 2 to the competent authority of the third country of destination.

6. The competent authority shall inform the country of destination accordingly and use the PEN-online system for this purpose.

Chapter 3
Export

7. The following information shall be provided in accordance with Article 22:

(-a) The name and address of the exporter, the importers in the third country, and any other operators involved in the export operation or shipment, as well as the name and address of the ultimate consignees;

(a) the name, CN code and CUS code of the substance covered by Annex I, Annex II or Annex III or, in the case of a mixture, complex substance or organism, its name and eight-digit CN code and the name and CUS code of any substance, as covered by Annex I, Annex II or Annex III contained in the mixture, complex substance or organism;

(b) the quantity of the substance and, in the case of a mixture, complex substance or organism, the quantity, and, if available, the percentage of any substance covered by Annex I, Annex II or Annex III contained therein;

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(c) the reference to the licence referred to in Articles 9 or 18, the registration referred to in Article 15, or the prior notification referred to in Article 17;

(d) for exports referred to in Article 22(5), a copy of the import authorisation issued by the country of destination.

(e) The quantity notified under Article 22(1) will be valid for a period of 180 calendar days.

7a. For transactions exempted under Article 22(4), the exporter shall, upon a reasoned request, provide the competent authority with information regarding the quantities involved.

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Chapter 4
Demonstration of licit purposes

8. The external trader shall provide information that the consignment has left the country of export in accordance with the national provisions in force adopted pursuant to Article 12 of the UN Convention to demonstrate the licit purpose of his transaction pursuant to Article 24.

For that purpose, the external trader may provide the reference to the licence referred to in Articles 9 or 18, the registration referred to in Article 15, or the prior notification as referred to in Article 17 to the competent authorities; or the import or export authorisation, or any other official document demonstrating the licit use of drug precursors by the operator from the third country, as the case may be.

Chapter 5

Indicators to determine if there is suspicion of intended use in illicit manufacture of drugs

PUBLIC

9. The following non-exhaustive list sets out indicators of intended use of drug precursors in the illicit manufacture of drugs:

   (a) the substances have not been correctly identified on the labels of the goods or consignment and have not been correctly declared to customs in accordance with Regulation (EU) 2026/2108, in particular as regards the description of the goods or the CN-codes;

   (b) the substances are included in the Drug Precursors Information Repository as drug precursors with no known legitimate uses.

ANNEX VIII

Reporting in accordance with Articles 32, 33 and 34

PUBLIC

1. In accordance with Article 32, the competent authorities shall provide information on:

   (a) total annual seizures of drug precursors;

   (b) the methods of diversion of drug precursors and illicit manufacturing of drugs, including information on stopped shipments and thefts;

   (c) information on administrative and law enforcement authorities responsible for regulating or enforcing national controls of drug precursors.

2. Member States shall provide the information referred to in point 1 and confirm the accuracy of the data provided, by 31 March at the latest, for the previous calendar year.

   Without prejudice to the first subparagraph, the competent authorities shall report significant seizures of drug precursors without delay.

3. The communication of information on seizures in accordance with point 1(a) shall include the following:

   (a) the name, and where available the CAS number and CUS code of the substances covered by Annex I, Annex II or Annex III, or the name as indicated in the Drug Precursors Information Repository referred to in Article 25, or the IUPAC name, as applicable;

   (b) if known, the origin, provenance and destination of the drug precursors;

   (c) the quantity of the substances, their customs status and the means of transport used, as applicable.

4. Significant seizures within the meaning of Article 33 and point 2 of this Annex cover seizures of significant quantities of scheduled drug precursors or non-scheduled drug precursors included in the Drug Precursors Information Repository, as applicable, or seizures of such drug precursors which point to organised crime taking place in more than one Member State, or seizures of newly discovered drug precursors.

5. Member States shall report the information referred to in point 1 in the electronic system referred to in Article 35.

6. The report referred to in Article 34 shall contain the following:

(a) *[deleted]*

(b) information on all seizures in the previous calendar year;

(c) information on the drug precursors used for the illicit manufacture of drugs and methods of diversion and illicit manufacture;

(d) information on quantities of scheduled drug precursors subject to legitimate trade for imports and exports in the previous calendar year;

(e) estimated needs for operators for the subsequent calendar year;

(f) information on administrative and law enforcement authorities responsible for regulating or enforcing national controls of drug precursors.

6a. The report referred to in Article 34 may contain information on quantities of scheduled drug precursors for legitimate trade and use in the internal market in the previous calendar year;

The information referred to in Paragraph 6(e) and Paragraph 6a shall be based on estimations done by operators requesting a licence for Category 1 drug precursors in accordance with Article 9 or Article 18, registering for manufacturing, making available on the market, import, export or intermediary activities in accordance with Article 15 or sending a prior notification for Category 3 drug precursors in accordance with Article 17.

The information referred to in point (d) shall be based on information provided by external traders as per their obligations under Articles 20 and 22.

The information referred to in points (b), (c) and (f) shall be based on the information provided by competent authorities in accordance with Article 32.

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ANNEX IX

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ANNEX X

Correlation table

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Part I
Correlation with Regulation (EC) No 273/2004

20.

Regulation (EC) No 273/2004	**This Regulation**
Article 1	Article 1
Article 2, point (a)	Article 2, point (3), Article 3(1), point (b)(i), Article 3(1), point (c), Article 3(3), point (c), Article 3(3), point (d)
Article 2, point (b)	Article 2, point (4)
Article 2, point (c)	Article 2, point (11)
Article 2, point (d)	Article 2, point (26)
Article 2, point (e)	Article 2, point (36)
Article 2, point (f)	-
Article 2, point (g)	-
Article 2, point (h)	Article 2, point (12), Article 2, point (26)
Article 2, point (i)	-
Article 3(1)	Article 10, Article 15(5), Article 19(3), point (a)
Article 3(2), first sentence	Article 9(1), first subparagraph
Article 3(2), second and third sentence	-
Article 3(3)	Article 13
Article 3(4)	Article 9(2)
Article 3(5), first and second sentences	Article 9(3)
Article 3(5), third sentence	Article 9(4)
Article 3(5), third sentence	
Article 3(6), (6a), (6b), (6c), (6d), (7)	-
Article 3(8)	Article 37(4)
Article 4	-

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Regulation (EC) No 273/2004	This Regulation
Article 5(1) and (2)	Article 7(1)
Article 5(3) and (4)	-
Article 5(5)	Article 7(2)
Article 5(6) and (7)	-
Article 6	-
Article 7, first paragraph	Article 11, Article 15(7), Article 19(4)
Article 7, second paragraph	-
Article 8(1)	Article 8
Article 8(2)-(4)	-
Article 9(1)	-
Article 9(2)	Article 25(2)
Article 9(3)	-
Article 10(1)	Article 29
Article 10(2)	-
Article 10(3)	Article 28(2)
Article 11(1)	Article 27(1)
Article 11(2)	Article 27(2)
Article 12	Article 31
Article 13(1)	Article 32
Article 13(2)	Article 37(4)
Article 13(3)	Article 34
Article 13a(1)(a)	Article 35(2), point (d)
Article 13a(1)(b)	Article 35(2), point (a)
Article 13a(1)(c)	-
Article 13a(2) and (3)	Article 36

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Regulation (EC) No 273/2004	This Regulation
Article 13a(4)	-
Article 13b	Article 36
Article 14(1)(a)	-
Article 14(1)(b)-(c) and (2)	Article 35(8)
Article 14a	Article 40
Article 15	Article 37(1)
Article 15a	Article 38
Article 16(1)	Article 31, third paragraph
Article 16(2)	-
Article 16(3)	Article 41
Article 17	Article 42
Article 18	Article 45

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Part II
Correlation with Regulation (EC) No 111/2005

20.1.

Regulation (EC) No 111/2005	This Regulation
Article 1, first paragraph	Article 1
Article 1, second paragraph	-
Article 2, point (a)	Article 2(3); Article 3(1), point (a), Article 3(1), point (b)(i); Article 3(1), point (c); Article 3(3), point (c); Article 3(3), point (d).
Article 2, point (b)	Article 2 (4)
Article 2, point (c)	Article 2 (13)
Article 2, point (d)	Article 2 (14)
Article 2, point (e)	Article 2 (25)
Article 2, point (f)	Article 2 (26)
Article 2, point (g)	Article 2 (30)
Article 2, point (h)	Article 2 (29)
Article 2, point (i)	Article 2 (33)
Article 2, point (j)	Article 2 (7)
Article 2, point (k)	Article 2 (36)
Article 3, first subparagraph	Article 7(1)
Article 3, second subparagraph, point (a)	Article 7(1), point (a)
Article 3, second subparagraph, point (b)	Article 7(1), point (b)
Article 3, second subparagraph, point (c)	Article 7(1), point (c)
Article 4, first sentence	Article 7(2)
Article 4, second and third sentences	Article 6(2)

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Regulation (EC) No 111/2005	This Regulation
Article 5	Article 11 Article 15(7); Article 19(4)
Article 6 (1), first sub-paragraph	Article 9(1), first subparagraph
Article 6 (1), second subparagraph	Article 9(2)
Article 6 (1), third subparagraph	Article 37(4)
Article 6 (2)	Article 9(6)
Article 7 (1) first subparagraph	Article 15(1), first subparagraph
Article 7 (1), second subparagraph	-
Article 7 (1), third subparagraph	Article 37(4)
Article 7 (2)	Article 15(5)
Article 8 (1)	Article 24
Article 8 (2)	Article 37(4)
Article 9 (1)	Article 8(1); Article 8(2)
Article 9 (2), first subparagraph	-
Article 9 (2), second subparagraph	Article 37(4)
Article 9 (2), third subparagraph	Article 35(8) and Article 35(9)
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Article 10 (2) (a)	-
Article 10 (2) (b)	Article 25
Article 10 (3)	-

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Regulation (EC) No 111/2005	This Regulation
Article 10 (4), first sentence	Article 33(1)
Article 10 (4), second sentence	-
Article 10 (5)	Article 37(1)
Article 11 (1), first subparagraph, first sentence	Article 21(1)
Article 11 (1), first subparagraph, second sentence	Article 37(4)
Article 11 (1), second subparagraph	-
Article 11 (2), first subparagraph	Article 21(5)
Article 11 (2), second subparagraph	Article 21(6)
Article 11 (3), first sentence	Article 21(7)
Article 11 (3), second sentence	Article 37(4)
Article 12 (1), first subparagraph	Article 22(1)
Article 12 (1), second subparagraph	-
Article 12 (1), third subparagraph	-
Article 12 (2)	-
Article 13	-
Article 14	-
Article 15 (a)	-
Article 15 (b)	-
Article 15 (c)	Article 22(6)
Article 15 (d)	Article 22(6)
Article 16	-

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Regulation (EC) No 111/2005	This Regulation
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Article 17, second subparagraph	-
Article 18, first sentence	-
Article 18, second sentence	-
Article 19	-
Article 20, first subparagraph	Article 20(1)
Article 20, second subparagraph	Article 20(4)
Article 21	-
Article 22	-
Article 23	-
Article 24	-
Article 25	Article 20(1)
Article 26 (1)	Article 30(1)
Article 26 (2)	Article 30(3)
Article 26 (3), introductory sentence	Article 30(6), introductory sentence
Article 26 (3), point (a)	Article 30(6), point (a)
Article 26 (3), point (b)	Article 30(6), point (b)
Article 26 (3), point (c)	Article 30(6), point (c)
Article 26 (3a), first subparagraph	Article 30(2)
Article 26 (3a), second and third subparagraphs	Article 33(1)
Article 26 (3b), introductory sentence	Article 30(6), introductory sentence
Article 26 (3b), point (a)	Article 30(6), point (a)

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Regulation (EC) No 111/2005	This Regulation
Article 26 (3b), point (b)	Article 30(6), point (b)
Article 26 (4)	Article 30(8)
Article 26 (5)	Article 9 (8)
Article 27, first sentence	Article 27(2)
Article 27, second sentence	Article 27(1)
Article 28, first sentence	Article 35(8)
Article 28, second sentence	Article 35(9)
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Article 30	Article 40
Article 30a	Article 37(1) Article 37(2)
Article 30b (1)	Article 38(1)
Article 30b (2)	Article 38(2)
Article 30b (3)	Article 38(3)
Article 30b (4)	Article 38(5)
Article 30b (5)	Article 38(6)
Article 31, first sentence	Article 31, first subparagraph
Article 31, second sentence	Article 31, second subparagraph
Article 32 (1)	-
Article 32 (2)	Article 37(4)
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Article 32a, points (a) and (b)	Article 35(1), Article 35 (2)
Article 32a (c)	-
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Regulation (EC) No 111/2005	This Regulation
Article 34, first subparagraph	Article 42(1)
Article 34, second subparagraph	Article 42(2)
Article 35, first subparagraph	Article 45, first paragraph
Article 35, second subparagraph, first sentence	Article 45, second paragraph
Article 35, second paragraph, second sentence	Article 45, third subparagraph
Article 35, second subparagraph, third sentence	-
Article 35, third subparagraph	Article 45, fourth subparagraph

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