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'A' ITEM NOTE

From:	Permanent Representatives Committee (Part 2)
To:	Council
No. prev. doc.:	9062/22
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the European Union Drugs Agency - General approach

INTRODUCTION

i) On 12 January 2022 the Commission presented a proposal for a Regulation of the European Parliament and of the Council on the European Union Drugs Agency[1].

ii) The aim of the proposal is to expand the current mandate of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) to ensure that the future Agency can react more effectively to new challenges, provide better support to Member States, and contribute to improving the situation at international level.

[1] 5304/22 + ADD 1 + ADD 2 + ADD 3 + ADD 4

In particular, the proposal aims to expressly cover poly-substance use; to strengthen monitoring and threat assessment capabilities with regard to both health and security; to set up a network of laboratories to make forensic and toxicological information available to the Agency; to reinforce the position of national focal points so that they can provide relevant data; and, lastly, to establish the competence of the Agency to develop evidence-based interventions and awareness-raising campaigns as well as to issue alerts where particularly dangerous substances become available on the market. The proposal also seeks to clarify the role of the Agency in the international arena and adapt the Agency's institutional framework to the joint approach of the European Parliament, Council and European to EU decentralised agencies.

iii) The proposal is based on Article 168(5) of the Treaty on the Functioning of the European Union (ordinary legislative procedure).

WORK IN OTHER INSTITUTIONS

iv) The European Parliament has not yet delivered its position on first reading. The file has been assigned to the Committee on Civil Liberties, Justice and Home Affairs (LIBE), and the rapporteur is Isabel Santos (S&D, PT).

v) The European Economic and Social Committee adopted an opinion at the plenary session on 18 and 19 May 2022.

vi) The Committee of the Regions decided not to issue an opinion on this proposal.

vii) One national parliament has issued an opinion on the application of the principles of subsidiarity and proportionality[2].

[2] 8455/22

WORK IN THE COUNCIL'S PREPARATORY BODIES

viii) The proposal was first presented by the Commission to the Horizontal Working Party on Drugs (HDG) on 13 January 2022. Following this initial general discussion, the HDG examined the proposal at its meetings on 2-3 February, 1-2 March, 6-7 April and 3-4 May 2022 under the French Presidency. The HDG reached an overall provisional agreement on the proposal, as set out in the Annex.

ix) During discussions in the HDG, Member States generally endorsed the level of ambition of the proposal, its general objectives and the need for swift adoption of the instrument. On the basis of the comments made by Member States during the negotiations within the HDG, the Presidency revised a number of provisions of the Commission proposal, in particular on the following points:

1) Clarification of the Agency's general task as described in Article 4, as well as the Agency's task of monitoring the drug phenomenon as defined in Article 7, in order to ensure a balanced approach and to cover all relevant aspects of the fight against the drugs phenomenon;

2) Clarification of the definition of poly-substance use;

3) Clarification of the role of the national focal points in relation to a number of specific tasks of the Agency throughout the text, ensuring that the national focal points are duly informed and involved in the work of the Agency;

4) Revising the Agency's prevention tasks, as referred to in Article 16, focusing on the need to develop and promote evidence-based interventions, good practices and awareness-raising;

5) Revising the Agency's tasks with regard to the national measures referred to in Article 17, focusing on the voluntary nature of the assessment of those measures;

6) Revising and clarifying the establishment, role and tasks of the national focal points, as referred to in Articles 32 and 33, ensuring that they support the Agency in effectively delivering its tasks thus contributing to coordinated Union action, while avoiding harmonisation and leaving it to the Member States to decide on the governance, structure or core tasks of the national focal points in relation to other national competent authorities;

7) Revising the provisions of Article 34 on the assessment of the national focal points, specifying the different stages of the procedure, including making recommendations and ensuring that the Agency offers appropriate support to the national focal point for capacity building;

8) Revising the provisions of Article 43 on the appointment, assessment and extension of the term of office or removal from office of the Executive Director of the Agency in order to ensure the appropriate role of the Management Board.

x) In view of the above, the Presidency considers that the text, as set out in the Annex to this note, presents a balanced compromise between the positions expressed by delegations and provides a solid basis for reaching a general approach. Changes to the text compared to the initial Commission proposal (5304/22) are indicated **in bold and underlined** and deletions are indicated by […].

xi) The (unanimous) support for the Presidency compromise was confirmed at the meeting of the Permanent Representatives Committee on 25 May 2022.

CONCLUSIONS

xii) The Council is therefore invited to reach a general approach on the text as set out in the Annex to this note, which will serve as a basis for negotiations with the European Parliament under the ordinary legislative procedure.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the European Union Drugs Agency

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 Article 168(5) thereof,
Having regard to the proposal from the European Commission,
After transmission of the draft legislative act to the national parliaments,
After consulting the European Economic and Social Committee[3],
After consulting the Committee of the Regions[4],
Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) The European Monitoring Centre for Drugs and Drug Addiction was set up by Council Regulation (EEC) No 302/93[5]. This founding act was recast in 2006 through Regulation (EC) No 1920/2006 of the European Parliament and of the Council[6].

(2) The European Monitoring Centre for Drugs and Drug Addiction was set up to provide factual, objective, reliable and comparable information concerning drugs, drug addiction and their consequences at Union level to provide the Union and the Member States with evidence to inform policymaking and guide initiatives to tackle drugs and thus give them added value when, in their respective areas of competence, they take measures or decide on action to address the drugs phenomenon.

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3 OJ C , , p. .
4 OJ C , , p. .
5 Council Regulation (EEC) No 302/93 of 8 February 1993 on the establishment of a European Monitoring Centre for Drugs and Drug Addiction (OJ L 36, 12.2.1993, L. 1).
6 Regulation (EC) No 1920/2006 of the European Parliament and of the Council of 12 December 2006 on the European Monitoring Centre for Drugs and Drug Addiction (recast) (OJ L 376, 27.12.2006, p. 1).

The [...] **establishment and functioning** of the European Monitoring Centre for Drugs and Drug Addiction **('the EMCDDA')** has manifestly improved the availability of information on drugs and drug addiction across [...] **the Union as well as internationally**.

(3) Whereas its general objective is still valid and should be retained, Regulation (EC) No 1920/2006 as such no longer [...] **provides an adequate framework** for addressing the current and future drug challenges. Therefore, the mandate of the European Monitoring Centre for Drugs and Drug Addiction should be revised, including **in order to provide for** its replacement**, reinforcement** and renaming [...] **as the** "European Union Drugs Agency" ('the Agency'). Since substantial amendments to Regulation (EC) No 1920/2006 are needed to accommodate the common approach for Union decentralised agencies[7] and to take account of the developments of the drug phenomenon, in the interest of clarity that Regulation should be replaced by a new Regulation.

(4) The main focus of Regulation (EC) No 1920/2006 was **placed** on health-related issues. [...] **While it is essential to maintain that focus**, addressing [...] drug supply [...] is **also** necessary [...] **in order to** reduce the availability of drugs in the Union and curb drug demand **and thus contribute to addressing links with other security threats**. Health- and supply-related issues **regarding the drug phenomenon** are intrinsically linked. [...] **In order to provide factual, objective, reliable, comparable and Union-wide significant data and analysis, the** Agency should [...] address the drug phenomenon [...] **taking a multidisciplinary approach in relation to drugs, drug use, drug use disorders and addictions, prevention, treatment, care, risk and harm reduction, rehabilitation, social reintegration and recovery, drug supply, including illicit production and trafficking, and other relevant drug related issues and their consequences**.

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7 Joint Statement of the European Parliament, the Council of the EU and the European Commission on decentralised agencies of 19 July 2012, https://european-union.europa.eu/sites/default/files/docs/body/joint_statement_and_common_approach_2012_en.pdf.

(5) The work of the Agency should be carried out with due regard to the respective powers of the Union and its Member States in the [...] **areas** of drugs **and the protection of health, particularly with a view to protect and improve human health and to combat the major cross-border health scourges. In particular, the Agency's mandate should include a comprehensive set of measures to support, coordinate or complement the actions of the Member States concerning monitoring, early warning of and combating serious cross-border threats to health posed by drugs, including, but not limited to adequate incentive measures**. It should cover the various facets of the drugs phenomenon and the solutions applied. In doing so, the Agency should be guided by relevant [...] Union **drug-related strategic documents**, in particular the applicable EU Drugs Strategy and Action Plan.

(6) In pursuing its activities, the Agency should cooperate with other **relevant** Union **bodies, offices and** agencies [...] **within their mandates** and should take account of their activities in order to avoid duplication. Cooperation should also take place on an international level with relevant authorities and bodies in third countries**, as well as in support of the Union's** and [...] **Member States' action at** the United Nations level.

(6a) In order to attain maximum efficiency in addressing the drugs phenomenon, it is also important for the Agency to maintain a close dialogue with the scientific community, civil society organisations, including organisations of people who use drugs, and other relevant stakeholders.

(7) Poly-substance use[...] is becoming increasingly common. Therefore, the [...] **Agency's work** should [...] **also pay due regard to** other substance-based addictions when those substances [...]**, whether licit or illicit, are consumed at the same time or sequentially within a short period of time** together with drugs [...].

(8) The Agency should develop its **coordinating and supporting** activities around three main competence areas, i.e. monitoring, leading to better informed policies; [...] **preparedness**, leading to better informed actions; and competence development, leading to stronger Union **and Member States'** responses to the drug phenomenon.

(9) The collection, analysis and dissemination of data should continue to be the main task of the Agency. **In carrying out this task, the Agency should pay particular attention to respecting the legal framework on the processing of personal data and should not collect any data making it possible to identify individuals or small groups of individuals.** The standard data is collected through the national focal points, which should remain [...] **primary** data providers for the Agency. Additional, closer to real-time data sources are increasingly available through innovative data collection methods. Therefore, the Agency should have access to [...] **relevant** data available to [...] **obtain** a holistic picture of the drug phenomenon in the Union and the external factors influencing it**, while keeping the national focal points informed**.

(10) **National focal points represent the cornerstone of the Union drug monitoring and reporting system. They collect information and produce comparable and scientifically sound data on the national drug situation which feeds into monitoring the situation across the Union. The national focal points are also key in the process of improving data collection methodologies and tools, and develop relevant guidelines for their implementation. In addition, the national focal points participate in the early warning system and report on new trends in the use of existing psychoactive substances and/or new consumption patterns involving combinations of psychoactive substances which pose a potential health risk. Moreover, they offer support in the production of different products of the Agency. It is therefore essential that the relationship between the Agency and the national focal points is a symbiotic and mutually-reinforcing one, and the** [...] data requirements of the Agency should be mirrored in the national focal points. They should be empowered within the Member States to receive all relevant data from the different national authorities. [...] **While avoiding any harmonisation measures and leaving the decisions as to the governance, structure or basic tasks of the national focal points in respect of other national competent authorities to the** Member States**, in line with the Treaties, the mandate of the Agency** should [...] **enable a streamlining of data collection in the Member States** as far as possible to avoid double reporting and duplication of efforts.

(10a) It is necessary to establish the foundations of a relationship of mutual trust and continuous dialogue between the Agency and the national focal points as main data providers to the Agency, based on a clear and effective functioning mechanism and a set of rules. The Agency should therefore be empowered to financially support the national focal points and contribute to their effective functioning, including by providing an assessment of each national focal point relating directly to its contribution towards a coordinated Union action in the field of drugs.

(11) In order to facilitate and structure data collection, information exchange, both qualitative and quantitative, and to support the establishment of an integrated and interoperable monitoring system enabling real-time monitoring, the Agency should [...] **develop** appropriate digital **solutions necessary for the performance of its tasks** [...]

(12) In order to enable the Agency to make better use of the information it has available, for example to issue more proactive measures such as threat assessments, strategic intelligence reports and alerts, and to enhance the Union's preparedness for future developments, the monitoring and analytical capacity of the Agency should be strengthened **as compared to the EMCDDA**.

(13) In order to improve the Union's preparedness, it is also necessary to have a holistic picture of the potential future developments of the drug phenomenon. To prepare itself and **better equip** policymakers for such future developments, the Agency should conduct regular foresight exercises taking into account megatrends, that is long-term driving forces that are observable now and will most likely have significant influence on the future, aiming at identifying new challenges and opportunities for responding to drug problems.

(14) The drug phenomenon is becoming [...] **increasingly** technology-enabled, as was shown again during the COVID-19 pandemic where a greater adoption of new technologies to facilitate drug distribution has been observed. It is estimated that about two-thirds of the offers on darknet markets are drug-related. Drug trading is using different platforms, including social media networks and mobile applications. This development is mirrored in responses to the drug phenomenon, with an increased use of **online interventions, including** mobile applications and e-health interventions. The Agency, together with other relevant Union agencies and avoiding duplication of efforts, should monitor such developments as part of its holistic approach to the drug phenomenon.

(15) New psychoactive substances which pose public health and social risks across the Union, should be **adequately** addressed**, including** at Union level. It is therefore necessary to monitor them and, to enable a quick response, to maintain the EU Early Warning System. The information exchange on and early warning system for new psychoactive substances, including the initial report and the risk assessment of new psychoactive substances has been amended recently and should remain unchanged.

(16) Based on the strengthened monitoring by the Agency and the experience gained in the risk assessment of new psychoactive substances, the Agency should develop general **health and security** threat assessment capabilities. A more proactive capacity to rapidly identify new threats and inform the development of counter-measures is urgently needed as the dynamic nature of the modern drug phenomenon means that related challenges can rapidly spread across borders.

(17) As dangerous substances **and dangerous consumption patterns** might lead to harm for public health, the Agency should be able to issue alerts **complementing and without prejudice to the relevant national alert systems**. To support such a function, the Agency should develop a European drug alert system, accessible by national authorities. Such a system should facilitate the rapid exchange of information that may require rapid actions to safeguard public health, safety, and security. [...]

(18) Drug precursors are substances necessary for the production of drugs such as amphetamines, cocaine and heroin. As illegal drug production in the Union is increasing, the prevention of trafficking and diversion of drug precursors from legal channels to illegal drug production should be strengthened. To support those efforts, the Agency should have a role in monitoring the diversion and trafficking of drug precursors and assisting the Commission in the implementation of the Union drug precursors legislation.

(19) As there is a growing need for forensic and toxicological data and specialist expertise, [...] **matched by** a [...] **requirement for better** coordination between laboratories in the Member States, it is necessary to set up [...] a network of forensic and toxicological laboratories knowledgeable in the area of drugs and drug-related harms. This [...] **network** should enable the Agency access to relevant information, increase its capacities in the area and support knowledge exchange between the relevant laboratories in the Member States, without incurring the high costs of creating and running its own laboratory.

(20) The network of forensic and toxicological laboratories should be representative of the Member States by allowing **each of** them to appoint [...] **up to three** laboratories to the network, covering toxicological and forensic expertise. In order to ensure the broadest coverage possible, experts from other laboratories relevant for the work of the Agency, including from the Customs Laboratories European Network, should also be given the possibility to participate in the network. Such cooperation would enable all laboratories involved to learn from each other across different domains.

(21) To further the knowledge in this area and support Member States, the Agency should **be mandated to** define and finance relevant projects, such as the development of reference standards on new drugs, the elaboration of toxicological or pharmacological studies, and drug profiling. Such an approach would support the sharing of information between relevant laboratories and would decrease the costs for individual laboratories.

(22) Since the Agency [...] **will be placed in a position to** access to data and **obtain** the necessary scientific experience to develop and promote evidence-based [...] **interventions,** best practices and [...] **raise awareness about adverse effects of drugs,** prevention, [...] **risk** and [...] **harm reduction measures, treatment, care, rehabilitation and recovery** including the [...] **promotion of the implementation and updating** of **existing** quality standards for drug prevention (European Drug Prevention Quality Standards) or of a curriculum providing decision- and policy-makers with the knowledge about the most effective evidence-based prevention interventions and approaches (European Union Prevention Curriculum)

(23) Given its Union**-wide** perspective, the Agency should be able to [...] **assess** national measures and training, for example on prevention, treatment, harm reduction and other related measures, in view of their compliance with the latest scientific state of play and of their proven usefulness. Member States [...] should be given the possibility to [...] **benefit, where they so decide, from** the [...] **assessment** as a quality label for their work.

(24) Considering that the Agency [...] **will be placed in** a unique position at Union level allowing it to compare data and best practices, the Agency should [...] **be mandated to offer support, including, where so required by Member States, as a means to assist with** evaluation and drafting of national drug strategies in a more structured way across Member States[...]. In addition, the Agency's role in providing training and support to Member States in the implementation of quality standards and good practices should be strengthened in light of the expertise it [...] **will be developing** in these areas.

(25) The responsibilities of the Agency in the area of international cooperation should be defined in [...] clear terms in order to allow it to fully engage in such activities and respond to requests from third countries and bodies. The Agency should be able to **offer adequate scientific and evidence-based tools to** contribute to the development and implementation of the external dimension of the Union's drugs policy [...] **in line with the Treaties** as a means to ensure the efficient and coherent implementation of the Union drug policies internally and at international level. In order [...] **to enable** the Agency [...] **to** allocate adequate levels of resources to this task, the work on international cooperation should be part of the core tasks of the Agency. It should be based on an international cooperation framework of the Agency, which should be in line with the **Treaties and the** Union priorities on international cooperation and should be revised on a regular basis to ensure that it adequately reflects international developments **and priorities**.

(26) In order to help Union funding for security **and health** research to develop its full potential and address the needs of drugs policy, the Agency should assist the Commission in identifying key research themes, drawing up and implementing the Union framework programmes for research and innovation that are relevant to the Agency's objectives. Where the Agency assists the Commission in identifying key research themes, drawing up and implementing a Union framework programme, it should not receive funding from that programme in order to avoid a potential conflict of interest. Finally, the Agency should participate in Union-wide initiatives addressing research and innovation to ensure that technologies necessary for its activities are developed and available for use.

(27) The **Agency's** Management Board should be assisted by an Executive Board to prepare [...] **the Agency's** decisions. The Agency should be headed by an Executive Director. A Scientific Committee should continue assisting the Management Board and the Executive Director with regard to relevant scientific matters.

(28) [...]

(29) The Agency should be properly resourced to carry out its tasks and granted an autonomous budget. It should be mainly financed by a contribution from the general budget of the Union. The Union budgetary procedure should be applicable as far as the Union contribution and any other subsidies chargeable to the general budget of the Union are concerned. The auditing of accounts should be undertaken by the Court of Auditors of the European Union.

(30) Fees improve the funding of an agency and may be considered for specific issues that can be clearly separated from the core tasks of the [...] **Agency. The** Agency should **thus be empowered to levy fees, which should be set out in a transparent manner and** cover its costs for providing the respective services.

(31) The Executive Director should present the annual report of the Agency to the European Parliament and to the Council. Furthermore, the European Parliament and the Council should be able to invite the Executive Director to report on the performance of her or his duties.

(32) Regulation (EC) No 1049/2001 of the European Parliament and of the Council[8] should apply to the Agency. The Agency should be as transparent as possible about its activities, without jeopardising the attainment of the objective of its operations.

(33) Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council[9] and the Interinstitutional Agreement of 25 May 1999 between the European Parliament, the Council of the European Union and the Commission of the European Communities concerning internal investigations by the European Anti-Fraud Office (OLAF)[10], to which the European Monitoring Centre for Drugs and Drug Addiction already acceded, should apply to the Agency.

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8 Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

9 Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999 (OJ L 248, 18.9.2013, p. 1).

10 OJ L 136, 31.5.1999, p. 15.

(34) In order to control and ensure the performance of the Agency and that its mandate allows it to carry out the necessary activities required by drug market and policy developments, an external evaluation of the Agency's work should be conducted on a regular basis and its mandate adapted accordingly, if needed.

(35) The Agency should cooperate closely with relevant international organisations, other governmental and non-governmental bodies and relevant technical bodies from inside and outside the Union in the implementation of its work programme, **in line with the relevant Treaty provisions and respecting Member States' own competence in this field,** notably to avoid duplication of work and to ensure access to all data and tools needed for carrying out its mandate.

(36) The Agency replaces and succeeds the European Monitoring Centre for Drugs and Drug Addiction established by Regulation (EC) 1920/[...] **2006**. It should therefore be the legal successor of all its contracts, including employment contracts, liabilities and properties acquired. International agreements concluded by the European Monitoring Centre for Drugs and Drug Addiction before the date of application of this Regulation should remain in force.

(37) Since the objectives of this Regulation, namely the establishment of an agency to address the drugs phenomenon, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale and effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in 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 go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

OBJECTIVES AND GENERAL TASKS OF THE AGENCY

Article 1

Establishment of the Agency

1. This Regulation establishes the European Union Drugs Agency ('the Agency').
2. The Agency shall replace and succeed the European Monitoring Centre for Drugs and Drug Addiction established by Regulation (EC) No 1920/2006.

Article 2

Legal status and seat

1. The Agency shall be a body of the Union with legal personality.
2. In each of the Member States, the Agency shall enjoy the most extensive legal capacity accorded to legal persons under national law. It shall, in particular, be able to acquire or dispose of movable and immovable property and be a party to legal proceedings.
3. The seat of the Agency shall be in Lisbon, Portugal.

Article 3

Definitions

For the purpose of this Regulation:

(1) 'drug[...]' means [...] **any of the following:**

(a) a substance covered by the 1961 United Nations Single Convention on Narcotic Drugs, as [...] **amended by the 1972 Protocol, or by the 1971 United Nations Convention on Psychotropic Substances;**

(b) any of the substances listed in [...] **the Annex** of Council Framework Decision 2004/757/JHA[11];

(2) 'new psychoactive substances' means substances as defined in Article 1, point 4, of Framework Decision 2004/757/JHA;

(3) 'poly-substance use' means the [...] use of one or more psychoactive substance or type of substance, whether [...] illicit[...] **or licit (in particular medicinal products, alcohol, tobacco),** when [...] **consumed at the same time or sequentially within a short period of time** with drugs;

(4) 'drug precursors' means substances that are controlled and monitored in accordance with Regulation (EC) No 273/2004 of the European Parliament and of the Council[12] and with Council Regulation (EC) No 111/2005[13];

(5) 'participating countries' means the Member States and third countries which have concluded an agreement with the Union in accordance with Article 54 **of this Regulation**;

(6) 'international organisation' means an organisation and its subordinate bodies governed by public international law, or any other body which is set up by, or on the basis of, an agreement between two or more countries;

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11 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).

12 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, p. 1).

13 Council Regulation (EC) No 111/2005 of 22 December 2004 laying down rules for the monitoring of trade between the [...] **Union** and third countries in drug precursors (OJ L 22, 26.1.2005, p. 1).

(7) 'United Nations Drug Conventions' means the United Nations Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol[14], the United Nations Convention on Psychotropic Substances of 1971[15] and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988[16];

(8) 'United Nations system' means the control mechanism system established by the United Nations Drug Conventions.

Article 4

General task of the Agency

The Agency shall provide the Union and its Member States with factual, objective, reliable and comparable information, early warning and risk assessment at Union level concerning drugs, drug [...] **use, drug use disorders and addictions, prevention, treatment, care, risk and harm reduction, rehabilitation, social reintegration and recovery, drug supply, including illicit production and trafficking, and other relevant drug related issues and their consequences, and** recommend appropriate and concrete, evidence-based actions on how to address the related challenges in [...] **an efficient and timely manner. In carrying out its tasks, the Agency shall take an evidence-based, integrated, balanced and multidisciplinary approach to the drugs phenomenon, incorporating a human rights, gender equality, public health and health equity perspective**.

14 United Nations Treaty Series, vol. 976, No. 14152.
15 United Nations Treaty Series, vol. 1019, No. 14956.
16 United Nations, Treaty Series, vol. 1582, No. 27627.

Article 5

Specific tasks

1. In order to implement the general task set out in Article 4, the Agency shall perform the following tasks:

(a) monitoring tasks that shall include:

(1) the collection **and analysis** of information and data pursuant to Article 6(1);

(2) the dissemination of information [...]**,** data **and results of analysis** pursuant to Article 6(5); and

(3) the monitoring of the drug phenomenon, encompassing [...] health**, social**, safety and security dimension, pursuant to Article 7.

(b) preparedness tasks that shall include:

(1) the information exchange on and early warning system for new psychoactive substances, including the preparation of an initial report and risk assessment, pursuant to Articles 8 to 11;

(2) **health and security** threat assessment and preparedness pursuant to Article 12;

(3) the establishment and operation of a European drug alert system pursuant to Article 13;

(4) monitoring the developments related to trafficking and diversion of drug precursors and contributing to the implementation of drug precursors legislation pursuant to Article 14;

(5) the establishment and operation of a network of forensic and toxicological laboratories pursuant to Article 15;

(c) competence development tasks that shall include:

(1) the development[...] and promotion of [...] **evidence-based interventions, best practices** and [...] **awareness raising activities** pursuant to Article 16;

(2) the [...] **assessment** of national measures pursuant to Article 17;

(3) support to Member States pursuant to Article 18;

(4) training pursuant to Article 19;

(5) international cooperation and technical assistance pursuant to Article 20;

(6) research and innovation activities pursuant to Article 21.

2. The Agency shall establish and coordinate, in consultation and in cooperation with the competent authorities and organisations in the participating countries, the network referred to in Article 31.

3. The Agency shall act in an objective, impartial and scientifically rigorous manner when carrying out and implementing the tasks referred to in paragraph 1.

4. The Agency shall **support and** improve coordination between national and Union action in its areas of activity and facilitate exchanges of information between decision-makers, researchers, specialists and those involved in drug-related issues in governmental and non-governmental organisations.

5. The Agency shall support the Commission, Member States and other relevant stakeholders, identified in the applicable Union [...] drugs **related strategic documents**, in the implementation of those [...] **strategic documents**, as appropriate.

6. In carrying out and implementing the tasks referred to in paragraph 1, the Agency may organise meetings of experts, set up ad hoc working groups and finance projects, as necessary**, keeping the Reitox network as referred to in Article 31 informed in a timely manner. When organising those meetings, the possibility of online meetings shall be considered**.

7. In carrying out and implementing the tasks referred to in paragraph 1, the Agency shall cooperate actively with other Union [...] **bodies, offices and** agencies [...] **within their mandates,** in particular Europol, Eurojust, **European Union Agency for Fundamental Rights, European Union Agency for Law Enforcement Training (CEPOL),** the European Medicines Agency, the European Centre for Disease Prevention and Control**, the European Foundation for the Improvement in Living and Working Conditions (Eurofound), scientific community**, civil society organisations and other relevant stakeholders, to attain maximum efficiency in monitoring, assessing and responding to the drugs phenomenon.

8. The Agency may engage in communication activities on its own initiative within its mandate. The allocation of resources to communication activities shall not be detrimental to the effective exercise of the tasks referred to in paragraph 1. Communication activities shall be carried out in accordance with relevant communication and dissemination plans adopted by the Management Board.

CHAPTER II
MONITORING

Article 6

Collection and dissemination of information and data

1. The Agency shall:

(a) collect [...] relevant information and data, including information and data communicated by the national focal points, resulting from research, available from open sources, and data emanating from Union, non-governmental sources and competent international organisations **and bodies**;

(b) collect information and data needed for the monitoring of poly-substance use **and its consequences** as referred to in Article 7(1), point ([...] **ac**);

(c) collect the available information and data from the national focal points [...]**, in cooperation with** Europol [...]**,** on new psychoactive substances and communicate that information to the national focal points and the Europol national units as well as to the Commission without undue delay;

(d) collect and analyse information and data on drug precursors, their diversion and trafficking;

(e) conduct and commission research and monitoring studies, surveys, feasibility studies, and pilot projects necessary to accomplish its tasks;

(f) ensure improved comparability, objectivity and reliability of information and data at Union level by establishing**, in cooperation with the national focal points,** indicators and **non-binding** common standards [...], compliance with which may be recommended by the Agency, with a view to ensuring greater uniformity of the measurement methods used by the Member States and the Union; [...]

(g) cooperate closely with relevant Union bodies, offices and agencies and international organisations and bodies, in particular Europol, UNODC and INCB, in order to facilitate the notification and avoid unnecessary burden for Member States.

2. The Agency shall collect relevant national data through the national focal points. **The national reporting package shall be previously discussed and agreed among the national focal points.** [...] **The Agency may** have **recourse to additional national sources of** information [...] **while keeping the national focal point informed in a timely manner**.

3. The Agency shall develop, within its mandate, data collection methods and approaches, including through projects with external partners.

4. The Agency [...] **shall** develop the necessary digital solutions through which information and data are **collected, validated, analysed, reported,** managed and [...] exchanged**, including in an automated manner**.

[...]

5. The Agency shall disseminate information and data by:

(a) making the information it produces available to the Union, the Member States and other interested parties, including as regards new developments and changing trends;

(b) ensuring wide dissemination of its analysis, conclusions and reports**, including to the scientific community, civil society, affected communities, including people who use drugs, excluding sensitive non-classified and classified data in accordance with Article 49 of this Regulation**;

(c) [...]

(d) setting up and making available open scientific documentation resources [...];

(e) providing information on quality standards, [...] **evidence-based** best practices**, innovative approaches,** and implementable research results in the Member States and facilitating the exchange and implementation of such [...] **standards** and practices.

5a. The Agency may also disseminate information and data disaggregated by Member State.

5b. When disseminating information and data, the Agency shall make a reference to the sources thereof.

6. The Agency **shall ensure, where possible, that the data collected is disaggregated by sex and that the collection and presentation of data considers the gender-sensitive aspects of drugs policy. It** shall not collect any data making it possible to identify individuals or small groups of individuals. It shall refrain from any transmission of information relating to specific individuals.

Article 7

*Monitoring of the drug phenomenon **and sharing of best practices***

1. The Agency shall monitor:

(a) the drugs phenomenon in the Union holistically, through epidemiological and other indicators, covering the health, **social,** safety and security aspects, including the implementation of the applicable Union [...] **drug-related strategic documents**;

(aa) evidence-based best practices and innovative approaches, regarding health, social, safety or security responses;

(ab) drug use, drug use disorders, drug addictions and related health risks and harms and risky behaviours as well as emerging trends in these fields;

(ac) poly-substance use and its consequences, in particular the increased risks of health and social problems, the social determinants of drug use, drug use disorders and addictions, as well as the implications for policies and responses;

(ad) drug and poly-substance use and their consequences from a gender perspective, in particular their impact on gender-based violence;

(b) emerging trends in the drugs phenomenon in the Union and internationally as far as these impact on the Union; this shall include the monitoring of **drug supply, including illicit production and trafficking and other related crimes as well as** the use of new technologies [...]**, in cooperation with Europol within their respective mandates**;

(c) [...]

(d) [...]

(e) in cooperation with Europol and with the support of the national focal points and the Europol national units, all new psychoactive substances that have been reported by Member States;

(f) drug precursors and their trafficking and diversion;

(g) **the implementation of the** Union and national drugs policies, including in view of supporting their development and independent evaluation[...]**.**

(h) [...]

2. Based on its monitoring activities, the Agency shall identify [...] **and support evidence-based** best practices and [...] **innovative approaches,** and share [...] **them with** the Member States and facilitate the exchange [...] **thereof** among [...] **them**.

2a. The Agency shall, in cooperation with the national focal points, develop tools and instruments to help Member States to monitor and evaluate their national policies and the Commission to monitor and evaluate Union policies.

3. The Agency shall undertake regular foresight exercises, taking into account the information available. It shall develop, on that basis, relevant [...] **scenarios** for the development of future drugs policy.

CHAPTER III
PREPAREDNESS

Article 8

Information exchange on, and early warning system for, new psychoactive substances

1. Each Member State shall ensure that its national focal point and its Europol national unit provide the Agency and Europol, taking into account their respective mandates, with the available information on new psychoactive substances in a timely manner and without undue delay.

   The information shall be related to the detection and identification, use and patterns of use, manufacture, extraction, distribution and distribution methods, trafficking, and commercial, medical and scientific use of, and potential and identified risks posed by, those substances.

2. The Agency, in cooperation with Europol, shall collect, collate, analyse and assess information on new psychoactive substances. It shall communicate this information in a timely manner to the national focal points, the Europol national units, and the Commission with a view to providing them with any information required for the purposes of early warning.

   The Agency shall draw up the initial report or the combined initial report pursuant to Article 9 based on the information collected pursuant to the first subparagraph.

Article 9

Initial report

1. Where the Agency, the Commission or the majority of Member States considers that information shared on a new psychoactive substance collected in one or more Member States gives rise to concerns that the new psychoactive substance may pose health or social risks at Union level, the Agency shall draw up an initial report on the new psychoactive substance.

For the purpose of the first subparagraph, Member States shall inform the Commission and other Member States of their wish that an initial report be drawn up. Where the majority of Member States is reached, the Commission shall instruct the Agency accordingly and shall inform the Member States thereof.

2. The initial report shall contain:

(a) a preliminary indication of the nature, number and scale of incidents showing health and social problems in which the new psychoactive substance may potentially be involved, and the patterns of use of the new psychoactive substance;

(b) a preliminary indication of the chemical and physical description of the new psychoactive substance and the methods and precursors used for its manufacture or extraction;

(c) a preliminary indication of the pharmacological and toxicological description of the new psychoactive substance;

(d) a preliminary indication of the involvement of criminal groups in the manufacture or distribution of the new psychoactive substance;

(e) information on the human and veterinary medical use of the new psychoactive substance, including as an active substance in a medicinal product for human use or in a veterinary medicinal product;

(f) information on the commercial and industrial use of the new psychoactive substance, the extent of such use, as well as its use for scientific research and development purposes;

(g) information on whether the new psychoactive substance is subject to any restrictive measures in the Member States;

(h) information on whether the new psychoactive substance is currently or has been under assessment within the United Nations system;

(i) other relevant information, where available.

3. For the purpose of the initial report, the Agency shall use information, which is at its disposal.

4. Where the Agency considers it necessary, it shall request the national focal points to provide additional information on the new psychoactive substance. The national focal points shall provide that information within two weeks of receipt of the request.

5. The Agency shall, without undue delay after the start of drawing up of the initial report pursuant to the first paragraph, request the European Medicines Agency to provide information on whether, at Union or national level, the new psychoactive substance is an active substance in:

   (a) a medicinal product for human use or in a veterinary medicinal product that has obtained a marketing authorisation in accordance with Directive 2001/83/EC of the European Parliament and of the Council[17], Directive 2001/82/EC of the European Parliament and of the Council[18] or Regulation (EC) No 726/2004 of the European Parliament and of the Council[19];

   (b) a medicinal product for human use or in a veterinary medicinal product that is the subject of an application for a marketing authorisation;

   (c) a medicinal product for human use or in a veterinary medicinal product whose marketing authorisation has been suspended by the competent authority;

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17 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).

18 Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p. 1).

19 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

(d) an unauthorised medicinal product for human use as referred to in Article 5(1) and (2) of Directive 2001/83/EC or in a veterinary medicinal product prepared extemporaneously by a person authorised to do so under national law in accordance with Article 10(1), point (c), of Directive 2001/82/EC;

(e) an investigational medicinal product as defined in Article 2, point (d), of Directive 2001/20/EC of the European Parliament and of the Council[20].

Where the information relates to marketing authorisations granted by Member States, the Member States concerned shall provide the European Medicines Agency with such information upon its request.

6. The Agency shall, without undue delay after the start of the drawing up of the initial report pursuant to the first paragraph, request Europol to provide information on the involvement of criminal groups in the manufacture, distribution and distribution methods, and trafficking of the new psychoactive substance, and in any use of the new psychoactive substance.

7. The Agency shall, without undue delay after the start of the drawing up of the initial report pursuant to the first paragraph, request the European Chemicals Agency, the European Centre for Disease Prevention and Control and the European Food Safety Authority to provide the information and data at their disposal on the new psychoactive substance.

8. The details of the cooperation between the Agency and the Union decentralised agencies referred to in paragraphs 5, 6 and 7 shall be governed by working arrangements. Such working arrangements shall be concluded in accordance with Article 53(2).

9. The Agency shall respect the conditions on use of the information, which are communicated to the Agency, including conditions on access to documents, information and data security and protection of confidential data, including sensitive data and confidential business information of third parties.

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20 Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ L 121, 1.5.2001, p. 34).

10. The Agency shall submit the initial report to the Commission and the Member States within five weeks of making the requests for information referred to in paragraphs 5, 6 and 7.

11. Where the Agency collects information on several new psychoactive substances that it considers to be of similar chemical structure, it shall submit to the Commission and to the Member States individual initial reports, or combined initial reports dealing with several new psychoactive substances, provided that the characteristics of each new psychoactive substance are clearly identified, within six weeks of making the requests for information referred to in paragraphs 5, 6 and 7.

Article 10

Risk assessment procedure and report

1. Within two weeks of receipt of an initial report as referred to in Article 9(10), the Commission may request the Agency to assess the potential risks posed by the new psychoactive substance and to draw up a risk assessment report, where there are indications in the initial report to believe that the substance may pose severe public health risks and, where applicable, severe social risks. The risk assessment shall be carried out by the Scientific Committee.

2. Within two weeks of receipt of a combined initial report as referred to in Article 9(11), the Commission may request the Agency to assess the potential risks posed by several new psychoactive substances with a similar chemical structure and to draw up a combined risk assessment report, where there are indications in the combined initial report to believe that the substances may pose severe public health risks and, where applicable, severe social risks. The combined risk assessment shall be carried out by the Scientific Committee.

3. The risk assessment report or combined risk assessment report shall contain:

(a) available information on the chemical and physical properties of the new psychoactive substance and the methods and the precursors used for its manufacture or extraction;

(b) available information on the pharmacological and toxicological properties of the new psychoactive substance;

(c) an analysis of the health risks associated with the new psychoactive substance, in particular with respect to its acute and chronic toxicity, abuse liability, dependence-producing potential, and physical, mental and behavioural effects;

(d) an analysis of the social risks associated with the new psychoactive substance – in particular its impact on social functioning, public order and criminal activities, and the involvement of criminal groups in the manufacture, distribution and distribution methods, and trafficking of the new psychoactive substance;

(e) available information on the extent and patterns of use of the new psychoactive substance, its availability and potential for diffusion within the Union;

(f) available information on the commercial and industrial use of the new psychoactive substance, the extent of such use, as well as its use for scientific research and development purposes;

(g) other relevant information, where available.

4. The Scientific Committee shall assess the risks posed by the new psychoactive substance or group of new psychoactive substances.

The Commission, the Agency, Europol and the European Medicines Agency shall each have the right to appoint two observers.

5. The Scientific Committee shall carry out the risk assessment on the basis of the available information and of any other relevant scientific evidence. It shall take into account all opinions held by its members. The Agency shall organise the risk assessment procedure, including identifying future information needs and relevant studies.

6. The Agency shall submit the risk assessment report or the combined risk assessment report to the Commission and the Member States within six weeks of receipt of the request from the Commission to draw up a risk assessment report.

7. Upon receipt of a duly reasoned request of the Agency, the Commission may extend the period for completion of the risk assessment or combined risk assessment to allow for additional research and data collection to take place. That request shall contain information on the period of time needed to complete the risk assessment or combined risk assessment.

8. The Agency shall also provide timely rapid risk assessments, in accordance with Article 20 of Regulation (EU) …/… on serious cross-border threats to health and repealing Decision No 1082/2013/EU, in the case of a threat referred to in point[...] (b) of Article 2(1) of that Regulation, where the threat falls under the mandate of the Agency.

Article 11

Exclusion from risk assessment

1. No risk assessment shall be carried out where the new psychoactive substance is at an advanced stage of assessment within the United Nations system, namely once the World Health Organisation Expert Committee on Drug Dependence has published its critical review together with a written recommendation, except where there are sufficient data and information available to suggest the need for a risk assessment report at Union level, the reasons for which shall be indicated in the initial report.

2. No risk assessment shall be carried out where, following an assessment within the United Nations system, it has been decided not to schedule the new psychoactive substance, except where there are sufficient data and information available to suggest the need for a risk assessment report at Union level, the reasons for which shall be indicated in the initial report.

3. No risk assessment shall be carried out where the new psychoactive substance is an active substance in:

(a) a medicinal product for human use or in a veterinary medicinal product that has obtained a marketing authorisation in accordance with Directive 2001/83/EC, Directive 2001/82/EC or Regulation (EC) No 726/2004;

(b) a medicinal product for human use or in a veterinary medicinal product that is the subject of an application for a marketing authorisation;

(c) a medicinal product for human use or in a veterinary medicinal product whose marketing authorisation has been suspended by the competent authority;

(d) an investigational medicinal product as defined in Article 2, point (d), of Directive 2001/20/EC.

Article 12

[...] ***Health and security threat*** *assessment and preparedness*

1. The Agency shall develop a strategic **evidence-based** general **health and security** threat assessment capability to identify at an early stage new developments of the drugs [...] **situation** that have a potential to impact negatively on [...] health**, social aspects**, safety [...] **or** security **in the Union** and, through doing so, to help increase the preparedness of the relevant stakeholders to respond to new threats in [...] **an efficient and** timely [...] manner.

2. [...]

A threat assessment may be launched by the Agency on its own initiative based on an internal appraisal of signals arising from routine monitoring, research or other appropriate information sources. A threat assessment may also be launched at the request of the Commission or of a Member State, if the [...] criteria **set out in paragraph 1** are met.

3. A threat assessment shall consist of a rapid evaluation of existing information and, where necessary, the collection of new information through the Agency's information networks. The Agency shall develop appropriate scientific rapid assessment methods.

4. The threat assessment report shall describe the identified threat, the current situation based on available evidence, the potential outcomes in the event of no action, and set out options for preparedness and response that may be adopted to mitigate the threat identified. It may also contain potential follow-up measures [...]. The threat assessment report shall be sent to the Commission and the Member States, as appropriate.

5. The Agency shall cooperate closely with **Member States,** other Union decentralised agencies and bodies, Union and international organisations in carrying out a threat assessment by involving them in the assessment as appropriate. Where the potential threat is already subject to an analysis under another Union mechanism, the Agency shall not carry out a threat assessment.

6. With the agreement of the Commission, the Agency shall conduct threat assessments on drug related threats emerging from outside the Union, which have the potential to impact [...] health, **social aspects,** safety [...] **or** security within the Union.

6a. The Agency shall, when needed, update the threat assessments and to monitor the evolution of the situation.

Article 13

European drug alert system

1. The Agency shall set up and manage a rapid European drug alert system**, complementing and without prejudice to the relevant national alert systems. The system is complementary to the Early Warning System on the new psychoactive substances, referred to in Articles 8-11**.

2. [...] **The national focal points, in cooperation with the relevant national competent authorities,** shall immediately notify the Agency of any information relating to the appearance of a serious direct or indirect drug-related risk to [...] health**, social aspects**, safety or security as well as any information that may be useful for coordinating a response whenever they become aware of such information, such as:

(a) the type and origin of the risk;

(b) the date and place of the event involving the risk;

(c) the means of exposure, transmission or dissemination;

(d) analytical and toxicological data;

(e) identification methods;

(f) [...] health risks;

(fa) social and security risks;

(g) [...] health measures implemented or intended to be taken at national level;

(h) measures other than [...] health measures;

(i) any other information relevant to the serious risk to health in question.

3. The Agency shall analyse and assess the available information and data on potential serious risks to [...] health and complement it with any scientific and technical information it may have available from the early warning system referred to in Article 8 and other threat assessments undertaken in accordance with Article 12, from other Union agencies and bodies and from international organisations, in particular the World Health Organisation. The Agency shall take into account information obtained through its data collection tools and from open source information.

4. Based on the information received pursuant to paragraph 3, the Agency shall provide targeted rapid alert risk communications [...] to the relevant national authorities, including the national focal points. Such risk communications [...] may propose response options, which Member States may consider as part of their preparedness planning and national response activities.

5. The [...] **national focal points, in cooperation with the relevant national competent authorities,** shall inform the Agency of [...] additional information at their disposal in order to further analyse and assess the risk as well as the actions implemented or measures taken following receipt of the notifications and information transmitted under the European drug alert system.

6. The Agency shall cooperate closely with the Commission and the Member States to promote the necessary coherence in the risk communication process.

7. The Agency may open up participation in the European drug alert system to third countries or international organisations. That participation shall be based on reciprocity and shall include confidentiality measures equivalent to those applicable in the Agency.

8. [...] **In close cooperation with the relevant national competent authorities, in particular the national focal points, the Agency** may develop an alert system [...] **to make information on the identified risk available to** people who use or potentially use **particular** drugs**, where appropriate**.

8a. The Agency shall update its drug alerts, whenever necessary.

Article 14

Drug precursors

1. The Agency shall assist the Commission in monitoring the developments related to the trafficking and diversion of drug precursors and in assessing the need to add to, remove from or change the category of listed scheduled and non-scheduled substances in relation to Regulation (EC) No 273/2004 and Regulation (EC) No 111/2005, including in identifying and assessing their licit and illicit uses.

2. The Agency shall prepare on its own initiative or at the request of the Commission a threat assessment report on drug precursors.

Article 15

Network of forensic and toxicological laboratories

1. The Agency shall set up a network of forensic and toxicological laboratories particularly active in the forensic and toxicological investigations of drugs and drug-related harms.
2. The network shall act primarily as a forum for generating data and information exchange on new developments and trends, organising training to enhance the competence of forensic drug **and toxicology** experts, supporting the implementation of quality assurance schemes and supporting the further harmonisation of data collection and analytical methods. **The national focal points shall be informed on a regular basis about the activities of this network and shall have access to the information and data generated by it.**
3. Each Member State shall have the right to appoint, through its representative in the Management Board, [...] **up to three** laboratories, [...] specialising in forensic analysis [...]**,** in toxicology **and in other relevant fields related to drugs**, as national representative laboratories to the network. The Agency may select additional laboratories or experts particularly active in the forensic and toxicological investigations of drugs and drug-related harms for specific projects.
4. The Joint Research Centre of the Commission shall be a member of the network and represent the Commission in the network.
5. The network shall closely cooperate with existing networks and organisations active in this area[...] **and shall take into account their work in order to avoid overlaps.** The network referred to in Article 31 shall be informed regularly**, and at least once a year,** about the work of the network of forensic and toxicological laboratories.
6. The Agency shall chair the network and convene at least one meeting per year. The network may decide to create working groups, which may be chaired by members of the network.

7. The network shall enable the Agency to have access to forensic and toxicological **data, produced or collected by the** laboratories **of the network**, including for the analysis of new psychoactive substances where this is needed.

8. The Agency shall define and finance specific projects to further the network, as appropriate and based on clear and transparent rules and procedures, which are defined by the Agency beforehand.

9. The Agency shall create a database to store, analyse and make available the information and data collected or generated by the network**, in accordance with the relevant provisions including Articles 6(6) and 49 of this Regulation**.

CHAPTER IV
COMPETENCE DEVELOPMENT

Article 16

[...]

Evidence-based interventions, best practices and awareness raising

1. The Agency shall [...] develop and promote [...] **evidence-based interventions, best practices** and [...] **raise** awareness [...] **about** adverse effects of drugs**, prevention, risk and harm reduction measures, treatment, care, rehabilitation and recovery. These interventions may be adapted to the national context and implemented at the national level and, whenever necessary, be targeted to specific groups**.

2. The [...] **interventions** referred to in paragraph 1 shall be in line with the political orientations set out in the applicable **Union drug-related strategic documents**[...].

3. The Agency shall [...] promote the implementation of **the existing** quality standards for drug prevention and **update them as appropriate, and** provide or support training pursuant to Article 19.

4. [...] **Upon their request, the** Agency shall assist Member States in developing national [...] **interventions** in the area of its mandate, including **in relation to** the [...] **prevention** of [...] **drug use, health related impacts and** the reduction of drug-related criminality and prevention of the exploitation of vulnerable individuals within the drug market.

Article 17

*[...] **Voluntary assessment scheme for** national [...] **measures***

1. At the request of a national authority of a participating country[...], the Agency shall provide [...] **an assessment of** national [...] **measures** in accordance with the standard operating protocol provided for in paragraph 3.

2. Before [...] **assessing** a national [...] **measure**, the Agency shall evaluate [...] **it** and [...] **analyse** whether it complies with the latest scientific state of play and whether it has been proven useful to address its declared objectives.

3. The Agency shall develop an [...] **assessment** procedure, which shall be set out in a transparent way by the Agency in a standard operating protocol. The Management Board of the Agency shall approve the standard operating protocol and any changes to it before its application.

[...]

3a. The Agency shall regularly inform the Management Board of the assessments it has undertaken.

Article 18

Support to Member States

1. At the request of a Member State, the Agency may support the independent evaluation of its drug policies and the development of evidence-based drug policies in line with the applicable Union [...] **drug-related strategic documents**.
2. The Agency [...] **may** support the Member States **at their request** in implementing their national drug [...] **policies**, quality standards [...]**,** best practices and **innovative approaches, and** it shall facilitate exchanges of information**, including on relevant legislation and best practices,** between national [...] **authorities and experts**.
3. In supporting policy evaluation, the Agency shall act independently and shall be guided by its scientific standards **and evidence-based approach**.

Article 19

Training

The Agency shall, within the scope of its mandate[...] and in coordination with other Union decentralised agencies and bodies:

(a) provide specialised training and curricula in areas of Union interest and relevance;

(b) provide training-related tools and support systems to facilitate Union-wide knowledge exchange;

(c) assist Member States in organising training and capacity building initiatives.

Article 20

International cooperation and technical assistance

1. The Agency shall:

(a) develop an international cooperation framework, to be approved by the Management Board subject to a prior approval by the Commission, which shall guide the activities of the Agency in the area of international cooperation;

(b) cooperate actively with the organisations and bodies referred to in Article 53;

(c) support the exchange and dissemination of Union best practices and implementable research results at international level;

(d) monitor developments of the international drug phenomenon that may pose a threat to or have implications for the Union through the monitoring and analysis of information available from international bodies, national authorities, research findings and other relevant information sources;

(e) provide data and analysis on the European drug situation in appropriate international meetings and technical fora, in close coordination with the Commission, and support the Commission and the Member States in international drugs dialogues;

(f) promote the incorporation of **all relevant** data on drugs [...] **covered by this Regulation,** gathered in the Member States or emanating from the Union into international monitoring and drug-control programmes, particularly those established by the [...] **United Nations** and its specialised agencies, without prejudice to Member States' obligations with regard to transmission of information under the provisions of the United Nations Drug Conventions;

(g) support the Member States in reporting the relevant information and providing the required analysis to the United Nations system, including the submission of all relevant data related to new psychoactive substance to the United Nations Office on Drugs and Crime and the World Health Organisation;

(h) support third countries in developing their drug policies in accordance with the principles of the **applicable** Union drug-[...] **related strategic documents**, including through providing support to the independent evaluation of their policies.

2. The international cooperation framework referred to in paragraph 1, point (a), shall take into account the relevant policy documents of the Union and consider the developments of the drug phenomenon[...]. It shall set out the priority countries or regions for cooperation and the key outcomes of the cooperation. **It shall also consider the experiences and activities undertaken by the Member States.** The Agency shall evaluate and review the international cooperation framework regularly.

3. The Agency shall transfer, at the request of the Commission and [...] **subject to** the approval of the Management Board, its know-how and provide technical assistance to third countries.

   Technical assistance shall focus in particular on setting up or consolidating national focal points, national data collection systems and national early warning systems **and the promotion of best practices in the fields of prevention, treatment, care, risk and harm reduction, rehabilitation and recovery**, and subsequently assist the creation and strengthening of structural links with the early warning system referred to in Article 8 and the network referred to in Article 31. If the third country so requests, the Agency may provide [...] **an assessment** for these national bodies.

4. Cooperation with third countries and with international organisations shall be carried out in accordance with Articles 53 and 54.

Article 21

Research and innovation

1. The Agency shall assist the Commission and the Member States in identifying key research themes, drawing up and implementing the Union framework programmes for research and innovation activities that are relevant to achieve its general task set out in Article 4. Where the Agency assists the Commission in identifying key research themes, drawing up and implementing a Union framework programme, the Agency shall not receive funding from that programme.
2. The Agency shall proactively monitor and contribute to research and innovation activities to achieve its general task set out in Article 4, support related activities of Member States, and implement its research and innovation activities regarding matters covered by this Regulation, including the development, training, testing and validation of algorithms for the development of tools. The Agency shall disseminate the results of that research to the European Parliament, to the Member States and to the Commission in accordance with Article 49.
3. The Agency shall contribute to and participate in the activities [...] **carried out** in the framework of the research and innovation cycle**, such as the EU Innovation Hub for Internal Security and European Health Preparedness and Response Authority**.
4. The Agency may plan and implement pilot projects regarding matters covered by this Regulation.
5. The Agency shall make public information on its research projects, including demonstration projects, the cooperation partners involved and the project budget.
6. The Agency shall create a database to store, analyse and make available drug-related research programmes.

CHAPTER V

ORGANISATION OF THE AGENCY

Article 22

Administrative and management structure

The Agency's administrative and management structure shall comprise:

(a) a Management Board, which shall exercise the functions set out in Article 24;

(b) an Executive Board, which shall exercise the functions set out in Article 28;

(c) an Executive Director, who shall exercise the responsibilities set out in Article 29;

(d) a Scientific Committee, which shall exercise the functions set out in Article 30;

(e) a European Information Network on Drugs and Drug Addiction (Reitox) in accordance with Article 31.

Article 23

Composition of the Management Board

1. The Management Board shall be composed of one representative from each Member State and two representatives from the Commission, all with voting rights.

2. The Management Board shall also include:

   (a) one independent expert particularly knowledgeable in the field of drugs designated by the European Parliament, with the right to vote;

   (b) one representative from each third country, which has concluded an agreement with the Union in accordance with Article 54, without the right to vote.

3. Each member of the Management Board shall have an alternate. The alternate shall represent the member in her/his absence **and may attend the meetings of the Management Board**.

4. Members of the Management Board and their alternates shall be appointed in light of their knowledge in the [...] **fields referred to in Article 4**, taking into account relevant managerial, administrative and budgetary skills. All parties represented in the Management Board shall make efforts to limit turnover of their representatives, in order to ensure continuity of the Management Board's work. All parties shall aim to achieve a balanced representation between women and men on the Management Board.

5. The Management Board may invite, as observers, representatives of international organisations with which the Agency cooperates in accordance with Article 53.

6. The term of office for members and their alternates shall be four years. That term may be renewable.

Article 24

Functions of the Management Board

1. The Management Board shall:

   (a) give the general orientations for the Agency's activities;

   (b) adopt the draft single programming document referred to in Article 35 before its submission to the Commission for its opinion;

   (c) adopt, having [...] **obtained** the opinion of the Commission, the Agency's single programming document by a majority of two-thirds of members entitled to vote in accordance with Article 23;

   (d) adopt, by a majority of two-thirds of members entitled to vote, the annual budget of the Agency and exercise other functions in respect of the Agency's budget pursuant to Chapter VI;

   (e) assess and adopt, by a majority of two-thirds of members entitled to vote, the consolidated annual activity report on the Agency's activities and send both the report and its assessment by 1 July each year to the European Parliament, the Council, the Commission and the Court of Auditors. The consolidated annual activity report shall be made public;

(f) adopt the financial rules applicable to the Agency in accordance with Article 41;

(g) adopt an anti-fraud strategy, proportionate to fraud risks taking into account the costs and benefits of the measures to be implemented;

(h) adopt a strategy for achieving efficiency gains and synergies with other Union decentralised agencies and bodies;

(i) adopt rules for the prevention and management of conflicts of interest in respect of its members, the members of the Executive Board, Scientific Committee, and the European Information Network on Drugs and Drug Addiction (Reitox), as well as of seconded national experts and other staff not employed by the [...] **Agency** as referred to in Article 44, and shall publish annually on its website the declarations of interests of the Management Board members;

(j) adopt the standard operating protocol referred to in Article 17(3);

(k) adopt the international cooperation framework of the Agency referred to in Article 20(1) and the technical assistance programmes referred to in Article 20(3);

(l) approve the level of [...] co-financing referred to in Article 32([...] **6**);

(m) adopt and regularly update the communication and dissemination plans referred to in Article 5(8), based on an analysis of needs;

(n) adopt its rules of procedure;

(o) in accordance with paragraph 2, exercise, with respect to the staff of the Agency, the powers conferred by the Staff Regulations on the Appointing Authority and by the Conditions of Employment of Other Servants on the Authority Empowered to Conclude a Contract of Employment[21] ("the appointing authority powers");

(p) in agreement with the Commission, adopt implementing rules for giving effect to the Staff Regulations and the Conditions of Employment of Other Servants in accordance with Article 110(2) of the Staff Regulations;

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21 Regulation (EEC, Euratom, ECSC) No 259/68 of the Council of 29 February 1968 laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Communities and instituting special measures temporarily applicable to officials of the Commission (OJ L 56, 4.3.1968, p. 1)

(q) appoint the Executive Director and, where relevant, decide on an extension of the term of office or on a removal from office in accordance with Article 43;

(r) appoint an Accounting Officer, subject to the Staff Regulations and the Conditions of Employment of other servants, who shall be totally independent in the performance of her/his duties;

(s) appoint the members of the Scientific Committee;

(t) approve the list of experts to be used to extend the Scientific Committee in accordance with Article [...] **30(6)**;

(ta) take decisions following the assessment of the national focal points in accordance with Article 34;

(u) ensure adequate follow-up to findings and recommendations stemming from the internal or external audit reports and evaluations, as well as from investigations of the European Anti-fraud Office (OLAF) established by Commission Decision 1999/352/EC, ECSC, Euratom[22] and of the European Public Prosecutor's Office (EPPO) established by Council Regulation (EU) 2017/1939[23], as referred to in Article 48;

(v) take all decisions on the establishment of the Agency's internal structures and, where necessary, their modification, taking into consideration the Agency's activity needs and having regard to sound budgetary management;

(w) authorise the conclusion of working arrangements in accordance with Article 53.

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22 Commission Decision 1999/352/EC, ECSC, Euratom of 28 April 1999 establishing the European Anti-fraud Office (OLAF) (OJ L 136, 31.5.1999, p. 20).

23 Council Regulation (EU) 2017/1939 of 12 October 2017 implementing enhanced cooperation on the establishment of the European Public Prosecutor's Office ('the EPPO') (OJ L 283 31.10.2017, p. 1).

2. The Management Board shall adopt, in accordance with Article 110 of the Staff Regulations, a decision based on Article 2(1) of the Staff Regulations and on Article 6 of the Conditions of Employment of Other Servants, delegating relevant appointing authority powers to the Executive Director and defining the conditions under which this delegation of powers can be suspended. The Executive Director shall be authorised to sub-delegate those powers.

Where exceptional circumstances so require, the Management Board may by way of a decision temporarily suspend the delegation of the appointing authority powers to the Executive Director and those sub-delegated by the latter and exercise them itself or delegate them to one of its members or to a staff member other than the Executive Director.

Article 25

Chairperson of the Management Board

1. The Management Board shall elect a Chairperson and a Deputy Chairperson from among its members with voting rights. The Chairperson and the Deputy Chairperson shall be elected by a majority of two-thirds of the members of the Management Boards with voting rights.
2. The Deputy Chairperson shall automatically replace the Chairperson if she/he is prevented from attending to her/his duties.
3. The term of office of the Chairperson and the [...] **Deputy** Chairperson shall be four years. Their term of office may be renewed once. If, however, their membership of the Management Board ends at any time during their term of office, their term of office shall automatically expire on that date.
4. The detailed procedure for the election of the Chairperson and the [...] **Deputy** Chairperson shall be set out in the rules of procedure of the Management Board.

Article 26

Meetings of the Management Board

1. The Chairperson shall convene the meetings of the Management Board.
2. The Executive Director of the Agency shall take part in the deliberations, without the right to vote.
3. The Management Board shall hold at least one ordinary meeting a year. In addition, it shall meet on the initiative of its Chairperson, at the request of the Commission, or at the request of at least one-third of its members.
4. The Management Board may invite any person whose opinion may be of interest to attend its meetings as an observer.
5. The members of the Management Board may, subject to its rules of procedure, be assisted at the meetings by advisers or experts.
6. The Agency shall provide the secretariat for the Management Board.

Article 27

Voting rules of the Management Board

1. Without prejudice to Article 24(1), points (c) and (d), Article 25(1)**, Article 34(4) and (4a)**, Article 43(8) and Article 53(2), the Management Board shall take decisions by majority of its members with voting rights.
2. Each member with voting rights shall have one vote. In the absence of a member with the right to vote, her/his alternate shall be entitled to exercise right to vote.
3. The Chairperson and Deputy Chairperson shall take part in the voting.
4. The Executive Director shall not take part in the voting.
5. The Management Board's rules of procedure shall establish more detailed voting arrangements, in particular the circumstances in which a member may act on behalf of another member.

Article 28

Executive Board

1. The Executive Board shall:
   (a) decide on those matters provided for in the financial rules adopted pursuant to Article 41 that are not reserved to the Management Board by this Regulation;
   (b) ensure adequate follow-up to the findings and recommendations stemming from the internal or external audit reports and evaluations, as well as from investigations of OLAF and of EPPO, as referred to in Article 48;
   (c) without prejudice to the responsibilities of the Executive Director, as set out in Article 29, monitor and supervise the implementation of the decisions of the Management Board, with a view to reinforcing supervision of administrative and budgetary management.
2. Where necessary, because of urgency, the Executive Board may take certain provisional decisions instead of the Management Board, in particular on administrative management matters, including the suspension of the delegation of the appointing authority powers and budgetary matters. **The conditions shall be set out in the rules of procedure of the Management Board.**
3. The Executive Board shall be composed of the Chairperson and the Deputy Chairperson of the Management Board, two other members appointed by the Management Board from among its members with the right to vote and two representatives of the Commission to the Management Board.

   The Chairperson of the Management Board shall also be the Chairperson of the Executive Board.

   The Executive Director shall take part in the meetings of the Executive Board, but shall not have the right to vote. The Executive Board may invite other observers to attend its meetings.

4. The term of office of members of the Executive Board shall be four years. The term of office of members of the Executive Board shall end when their membership of the Management Board ends.
5. The Executive Board shall hold at least two ordinary meetings per year. In addition, it shall meet on the initiative of its Chairperson or at the request of its members.
6. The Executive Board shall take its decision by consensus. If the Executive Board is not in a position to take a decision by consensus, the matter shall be referred to the Management Board.
7. The Management Board shall lay down the rules of procedure of the Executive Board, including the voting rules for its members.

Article 29

Responsibilities of the Executive Director

1. The Executive Director shall be responsible for the management of the Agency. The Executive Director shall be accountable to the Management Board.
2. Without prejudice to the powers of the Commission, of the Management Board and of the Executive Board, the Executive Director shall be independent in the performance of the duties and shall neither seek nor take instructions from any government nor from any other body.
3. The Executive Director shall report to the European Parliament on the performance of her/his duties when invited to do so. The Council may invite the Executive Director to report on the performance of her/his duties.
4. The Executive Director shall be the legal representative of the Agency.
5. The Executive Director shall be responsible for the implementation of the tasks assigned to the Agency as referred to in Article 5. In particular, the Executive Director shall be responsible for:
   (a) the day-to-day administration of the Agency;
   (b) preparing and implementing the decisions adopted by the Management Board;

(c) preparing the single programming document referred to in Article 35 and submitting it to the Management Board after consulting the Commission;

(d) implementing the single programming document and reporting to the Management Board on its implementation;

(e) preparing the Agency's consolidated annual activity report, presenting it to the Management Board for assessment and adoption;

(f) proposing to the Management Board the level of [...] co-financing referred to in Article 32([...] **6**), if such co-financing is to be granted to the national focal points;

(g) proposing to the Commission, after consulting the Management Board, the amount of fees in accordance with Article 37;

(h) preparing a follow-up action plan in relation to the conclusions of internal or external audit reports and evaluations, as well as investigations by OLAF and EPPO, as referred to in Article 48, and reporting on progress twice a year to the Commission and regularly to the Management Board and the Executive Board;

(i) protecting the financial interests of the Union by applying preventive measures against fraud, corruption and any other illegal activities, without prejudicing the investigative competence of OLAF and EPPO, by effective checks and, if irregularities are detected, by recovering amounts wrongly paid [...]**, and by reporting any criminal conduct in respect of which the EPPO could exercise its competence to the EPPO in accordance with Article 24 of Regulation 2017/1939 (EPPO Regulation)**;

(j) preparing an anti-fraud, and efficiency gains and synergies strategies for the Agency and presenting them to the Management Board for approval;

(k) preparing draft financial rules applicable to the Agency;

(l) preparing the Agency's draft statement of estimates of revenue and expenditure and implementing its budget.

6. The Executive Director [...] **may** decide [...] to locate one or more [...] **liaison officers to the Union institutions and to relevant Union bodies, offices and agencies,** in [...] **particular Europol,** for the purpose of carrying out the Agency's tasks in an efficient and effective manner. [...] **The** Executive Director shall obtain the prior consent of the Commission[...] **and** the Management Board [...]. The decision shall specify the scope of the activities to be carried out [...] **by** the [...] **liaison officers** in a manner that avoids unnecessary costs and duplication of administrative functions of the Agency. [...]

Article 30

Scientific Committee

1. The Scientific Committee shall consist of at most fifteen scientists appointed by the Management Board in view of their scientific excellence and their independence, following the publication of a call for expression of interest in the Official Journal of the European Union. The selection procedure shall ensure that the specialist fields of the members of the Scientific Committee cover the most relevant fields linked to the objectives of the Agency. **All parties shall aim to achieve a balanced representation between women and men in the Scientific Committee.**

2. The members of the Scientific Committee shall be appointed in their personal capacity for a four-year period, which shall be renewable once.

3. The members of the Scientific Committee shall be independent and shall act in the public interest. They shall neither seek nor take instructions from any government or from any other body.

4. Where a member no longer meets the criteria of independence, she/he shall inform the Management Board. Alternatively, the Management Board may declare, on a proposal of at least one-third of its members or of the Commission, a lack of independence and revoke the person concerned. The Management Board shall appoint a new member for the remaining term of office in accordance with the procedure for ordinary members.
5. The Scientific Committee shall deliver an opinion where provided for in this Regulation or on any scientific matter concerning the Agency's activities, which the Management Board or the Executive Director may submit to it. The opinions of the Scientific Committee shall be published on the Agency's website.
6. For the purpose of assessing the risks posed by a new psychoactive substance or a group of new psychoactive substances, the Scientific Committee may be extended as deemed necessary by the Executive Director, acting on the advice of the chairperson of the Scientific Committee, by including experts representing the scientific fields relevant for ensuring a balanced assessment of the risks posed by the new psychoactive substance. The Executive Director shall designate those experts from a list of experts. The Management Board shall approve the list of experts every four years.
7. The Scientific Committee shall elect a Chairperson and a Deputy Chairperson for the duration of the mandate of the Scientific Committee. The Chairperson may participate as an observer in the meetings of the Management Board.
8. The Scientific Committee shall meet at least once per year.
9. The list of members of the Scientific Committee shall be made public and shall be updated by the Agency on its website.

Article 31

European Information Network on Drugs and Drug Addiction (Reitox network)

1. [...] **Through** the European Information Network on Drugs and Drug Addiction (Reitox network) **the Member States shall contribute to the Agency's task of collecting and reporting consistent and standardised information on the drug phenomenon across the Union**. The Reitox network shall consist of the national focal points designated in accordance with Article 32 and a focal point for the Commission.
2. The Reitox network shall hold at least one ordinary meeting a year. The meetings are convened and chaired by the Agency. In addition, it shall meet on the initiative of its Spokesperson or at the request of at least one-third of its members.
3. The Reitox network shall elect a Spokesperson and [...] **at least one** Deputy Spokesperson[...] from among its members. The Spokesperson represents the Reitox network towards the Agency and [...] **shall** participate as observer in the meetings of the Management Board.

Article 32

National Focal Point

1. Each participating country shall designate a single national focal point, set up on a permanent basis and with a clear mandate, through **appropriate** national [...] legal [...] **or administrative measures**. The designation of the national focal point and the appointment of the head of national focal point, as well as any changes to those appointments, shall be communicated to the Agency through the national member of the Management Board.
2. The responsible national authority shall ensure that the national focal point is entrusted with the tasks set out in Article 33(2). The head of the national focal point shall represent the national focal point in the Reitox network. **In his or her absence, an alternate could represent the national focal point.**

3. The [...] national focal point shall be **scientifically** independent [...] **and ensure the quality of its data**.

4. The national focal point shall plan its activities [...]
[...] **ahead and** shall have [...] **the** adequate [...] **budgetary** and human resources to fulfil its mandate and tasks, as referred to in Article 33(2), and have sufficient equipment and facilities to support its daily activities.[...]

6. The national focal point [...] **shall** receive a [...] co-financing of its core costs through a grant provided by the Agency if [...] **it complies** with the conditions set out in paragraphs 1 to 6. In order to get this co-financing, the national focal point shall sign a grant agreement with the Agency on an annual basis. The level of [...] co-financing shall be proposed by the Executive Director, approved by the Management Board and regularly reviewed. Additional funding by the Agency to the national focal point can be provided on an ad hoc basis for the participation in and delivery on specific projects.

7. The national focal point shall be [...] **assessed** by the Agency in accordance with Article 34.

Article 33

Tasks of the national focal points

1. The national focal points shall form the interface **and support interactions** between the participating countries and the Agency.

2. **With a view to supporting the Agency in effectively delivering its tasks set out in Article 4, thus contributing to a coordinated Union action, the** [...] national focal points shall[...] **carry out the following activities**:

   (a) **for the purpose of communicating this data to the Agency,** coordinate at national level the activities related to drug-related data collection and monitoring;

   (b) [...]

   (c) [...]

   (d) collect[...] relevant **national data and** information [...] **in the areas covered in Article 4, as stemming from the national reporting package referred to in** [...] Article 6**(2), and transmit it to the Agency**. In doing so, the national focal point shall bring together experience from different sectors – in particular health, justice and law enforcement – and **may** cooperate with experts and national organisations**, the scientific community, civil society organisations and other relevant stakeholders** active in the field of drugs policy;

   (e) [...] contribute to reporting to international organisations;

   (f) support**, as appropriate,** the development of new epidemiological data sources to further the timely reporting of trends in substance use;

(g) support ad hoc and targeted data collection exercises in relation to new health and security threats;

(h) provide the Agency with information on new trends **and challenges** in the use of existing psychoactive substances or new combinations of psychoactive substances, which pose a potential risk to [...] health as well as information on possible measures related to [...] health;

(ha) contribute to the information exchange on, and early warning system for, new psychoactive substances, in accordance with Chapter III;

(i) contribute to the establishment of relevant [...] indicators and other relevant datasets, including guidelines for their implementation with a view to obtaining reliable and comparable information at Union level, in accordance with Article 6;

(ia) nominate, where appropriate, national experts for the discussions on the relevant indicators and for other ad-hoc and targeted data collection exercises;

(j) promote the use of the internationally agreed data collection protocols and standards to monitor drugs and drug use in the country;

(k) present an annual report of activities to the Agency**;** and [...]

(l) [...]

(m) [...] **implement** quality assurance mechanisms to [...] ensure the reliability of the data and information obtained[...]**.**

(n) [...]

(o) [...]

2a. If possible and depending on their capacity, the national focal points may also monitor, analyse and interpret relevant information in the areas covered in Article 4, as well as provide information on policies and solutions applied.

3. The national focal [...] **points** shall [...] **establish** the [...] **necessary cooperation with relevant** national **and regional** authorities, bodies, agencies and organisations [...] **for the collection of** the information [...] **they** need[...] to carry out [...] **their** tasks in accordance with paragraph 2. [...]

4. When collecting data pursuant to this Article, the national focal points shall ensure, where possible, that the data collected is disaggregated by sex and that the collection and presentation of data considers the gender-sensitive aspects of drugs policy. They shall not transmit any data making it possible to identify individuals or small groups of individuals. They shall refrain from any transmission of information relating to specific individuals.

Article 34

*[...] **Assessment of** the National Focal Points*

1. [...]

2. The Agency shall [...] **assess whether** each national focal point [...]**, by** carrying out the tasks set out in Article 33**(2), contributes to the delivery of the tasks of the Agency**.

The [...] **assessment** should not concern other functions of the body hosting the national focal point and the overall structure in which the national focal point is embedded.

The first assessment of all national focal points should be carried out by *[OP please insert the date = 36 months after the entry into force of the Regulation]* and thereafter at regular intervals, as necessary.

3. [...] **The assessment should be based on** relevant information [...] **shared by the national focal point.** If necessary, the Agency [...] **may** visit [...] the national focal point.

3a. Each assessment established by the Agency shall be presented to the respective national focal point and the competent national authority. The assessment may include recommendations for meeting the requirements set out in Article 32 and for carrying out the tasks set out in Article 33(2), including an offer of support from the Agency to the national focal point for capacity building.

3b. On this basis, the national focal point shall inform the Agency either of the acceptance of the recommendations and proposed actions, or, in case of disagreement with the recommendations, provide to the Agency its written reasoned opinion.

4. **The Agency shall inform the Management Board of the outcome of the assessment. In case of disagreement between the Agency and the national focal point, the Agency shall propose an action plan for** [...] a national focal point **to meet** [...] the requirements set out in Article 32 **and for** [...] carrying out the tasks set out in Article 33**(2) for the approval of the Management Board by a majority of two-thirds of members entitled to vote in accordance with Article 23** [...]

4a. If by the time specified in the action plan, the national focal point does not meet the requirements, the Management Board may decide by a majority of two-thirds of members entitled to vote in accordance with Article 23 that the Agency shall not provide co-financing to that national focal point for the following year.

CHAPTER VI
FINANCIAL PROVISIONS

Article 35

Single programming document

1. By 15 December of each year, the Management Board shall adopt a draft single programming document containing multi-annual and annual programming as well as all the documents listed in Article 32 of Commission Delegated Regulation (EU) 2019/715[24], based on a draft put forward by the Executive Director, after consulting the Scientific Committee, taking into account the opinion of the Commission, and in relation to multiannual programming after consulting the European Parliament. It shall forward it to the European Parliament, the Council and the Commission by 31 January of the following year.

   The Single Programming Document shall become definitive after final adoption of the general budget and if necessary shall be adjusted accordingly.

2. The annual work programme shall comprise detailed objectives and expected results including performance indicators. It shall also contain a description of the actions to be financed and an indication of the financial and human resources allocated to each action, in accordance with the principles of activity-based budgeting and management. The annual work programme shall be coherent with the multi-annual work programme referred to in paragraph 4. It shall clearly indicate tasks that have been added, changed or deleted in comparison with the previous financial year.

   Annual or multi-annual programming shall include the information about the implementation of the international cooperation framework referred to in Article 20 and the actions linked to this strategy.

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24 Commission Delegated Regulation (EU) 2019/715 of 18 December 2018 on the framework financial regulation for the bodies set up under the TFEU and Euratom Treaty and referred to in Article 70 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council, (OJ L 122, 10.5.2019, p. 1).

3. The Management Board shall amend the adopted annual work programme when a new task is given to the Agency.

   Any substantial amendment to the annual work programme shall be adopted by the same procedure as the initial annual work programme. The Management Board may delegate the power to make non-substantial amendments to the annual work programme to the Executive Director.

4. The multi-annual work programme shall set out overall strategic programming including objectives, expected results and performance indicators. It shall also set out resource programming including multi-annual budget and staff.

   The resource programming shall be updated annually. The strategic programming shall be updated where appropriate, and in particular to address the outcome of the evaluation referred to in Article 51.

5. The multi-annual and annual work programmes shall be prepared in compliance with Article 32 of Delegated Regulation (EU) 2019/715.

Article 36

Budget

1. Estimates of all revenue and expenditure for the Agency shall be prepared each financial year, corresponding to the calendar year, and shall be shown in the Agency's budget.
2. The Agency's budget shall be balanced in terms of revenue and of expenditure.
3. Without prejudice to other resources, the Agency's revenue shall comprise:
   (a) a contribution from the Union entered in the general budget of the European Union;
   (b) any voluntary financial contribution from the Member States;
   (c) the fees paid for services rendered in accordance with Article 37; and
   (d) any financial contributions from the organisations and bodies and third countries referred to in Articles 53 and 54, respectively.
4. The expenditure of the Agency shall include staff remuneration, administrative and infrastructure expenses, and operating costs. The operating costs may include expenditure in support of the national focal points, as referred to in Article 32(7).

Article 37

Fees

1. The Agency may charge fees for the following:
   (a) training [...] **pursuant to Article 19**;
   (b) certain support activities for Member States that have not been identified as a priority but could be beneficially conducted if supported by national resources;
   (c) capacity-building programmes for third countries, which are not covered by separate dedicated Union funding;
   (d) [...] **assessment** of national bodies set up in third countries pursuant to Article 20(3);
   (e) other services falling within its mandate and rendered at the request of a participating country which require the investment of resources in the support of national activities.
2. At the proposal of the Executive Director, the Management Board of the Agency shall set the amount of the fees and the way in which they are paid **in a transparent manner**.
3. Fees shall be proportionate to the costs of the relevant services as provided in a cost-effective way and shall be sufficient to cover those costs. Fees shall be set at such a level as to ensure that they are non-discriminatory and that they avoid placing an undue financial or administrative burden on stakeholders.
4. Fees should be set at a level such as to avoid a deficit or a significant accumulation of surplus in the budget. Should a significant positive balance in the budget, resulting from the provision of the services covered by fees, become recurrent, a revision of the level of the fees, or of the Union contribution, shall become mandatory. In case a significant negative balance results from the provision of the services covered by fees, a revision of the level of the fees [...] **may be applied**.

Article 38

Establishment of the budget

1. Each year, the Executive Director shall draw up a draft statement of estimates of the Agency's revenue and expenditure for the following financial year, including the establishment plan, and send it to the Management Board.
2. The Management Board shall, based on that draft, adopt a provisional draft estimate of the Agency's revenue and expenditure for the following financial year.
3. The provisional draft estimate of the Agency's revenue and expenditure shall be sent to the Commission by 31 January each year. The Management Board shall send the final draft estimate to the Commission by 31 March.
4. The Commission shall send the statement of estimates to the budgetary authority together with the draft general budget of the European Union.
5. On the basis of the statement of estimates, the Commission shall enter in the draft general budget of the Union the estimates it considers necessary for the establishment plan and the amount of the subsidy to be charged to the general budget, which it shall place before the budgetary authority in accordance with Articles 313 and 314 TFEU.
6. The budgetary authority shall authorise the appropriations for the contribution to the Agency.
7. The budgetary authority shall adopt the Agency's establishment plan.
8. The Agency's budget shall be adopted by the Management Board by a majority of two-thirds of members entitled to vote. It shall become final following final adoption of the general budget of the European Union. Where necessary, it shall be adjusted accordingly.
9. For any building project likely to have significant implications for the budget of the Agency, the provisions of Delegated Regulation (EU) 2019/715[25] apply.

[25] OJ L 122, 10.5.2019, p. 1.

Article 39

Implementation of the budget

1. The Executive Director shall implement the Agency's budget.

2. Each year the Executive Director shall send to the budgetary authority all information relevant for the evaluation procedures set out in Article 51.

Article 40

Presentation of accounts and discharge

1. By 1 March of the following financial year, the Agency's accounting officer shall send the provisional accounts to the Commission's accounting officer and to the Court of Auditors.

1a. By 31 March of the following financial year, the Commission's accounting officer shall send the Agency's provisional accounts, consolidated with the Commission's accounts, to the Court of Auditors.

2. By 31 March of the following financial year, the Agency shall send the report on the budgetary and financial management to the European Parliament, the Council and the Court of Auditors.

3. [...]

4. On receipt of the Court of Auditors' observations on the Agency's provisional accounts pursuant to Article 246 of the Financial Regulation[26], the Executive Director shall draw up the Agency's final accounts under her/his own responsibility and submit them to the Management Board for an opinion.

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26 Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1).

5. The Management Board shall deliver an opinion on the Agency's final accounts.

6. The accounting officer shall, by 1 July following each financial year, send the final accounts to the European Parliament, the Council, the Commission and the Court of Auditors, together with the Management Board's opinion.

7. The final accounts shall be published in the *Official Journal of the European Union* by 15 November of the following year.

8. The Executive Director shall send the Court of Auditors a reply to its observations by 30 September. The Executive Director shall also send this reply to the Management Board.

9. The Executive Director shall submit to the European Parliament, at the latter's request, any information required for the smooth application of the discharge procedure for the financial year in question, in accordance with Article 261(3) of the Financial Regulation.

10. On a recommendation from the Council acting by a qualified majority, the European Parliament shall, before 15 May of year N + 2, give a discharge to the Executive Director in respect of the implementation of the budget for year N.

Article 41

Financial rules

The financial rules applicable to the Agency shall be adopted by the Management Board after consulting the Commission. They shall not depart from Delegated Regulation (EU) 2019/715 unless such a departure is specifically required for the Agency's operation and the Commission has given its prior consent.

CHAPTER VII
STAFF

Article 42

General provision

1. The Staff Regulations and the Conditions of Employment of Other Servants and the rules adopted by agreement between the institutions of the Union for giving effect to those Staff Regulations and the Conditions of Employment of Other Servants shall apply to the staff of the Agency.
2. Where it engages staff from third countries following the conclusion of the agreements referred to in Article 54, the Agency shall, in any event, comply with the Staff Regulations and Conditions of Employment referred to in paragraph 1.

Article 43

Executive Director

1. The Executive Director shall be engaged as a temporary agent of the Agency under Article 2, point (a), of the Conditions of Employment of Other Servants.
2. The Executive Director shall be appointed by the Management Board, from a list of candidates proposed by the Commission[...] **involving, as observer, a representative nominated by the Management Board, on the basis of** an open and transparent selection procedure **following publication in the Official Journal of the European Union of a call for expressions of interest**.
3. For the purpose of concluding the contract with the Executive Director, the Agency shall be represented by the Chairperson of the Management Board.
4. The term of office of the Executive Director shall be five years. By the end of that period, the Commission**, after consultation of the Management Board,** shall undertake an assessment that takes into account an evaluation of the Executive Director's performance and the Agency's future tasks and challenges.

5. The Management Board, [...] **after consultation of** the Commission [...] **and taking** into account the assessment referred to in paragraph 4, may extend the term of office of the Executive Director once, for no more than five years.

6. An Executive Director whose term of office has been extended may not participate in another selection procedure for the same post at the end of the overall period.

7. The Executive Director may be removed from office only upon a decision of the Management Board [...] **after consultation of** the Commission.

8. The Management Board shall reach decisions on appointment, extension of the term of office or removal from office of the Executive Director on the basis of a two-thirds majority of its members with voting rights.

Article 44

Seconded national experts and other staff

1. The Agency may make use of seconded national experts or other staff not employed by the Agency. The Staff Regulations of Officials and the Conditions of Employment of Other Servants shall not apply to such staff.

2. The Management Board shall adopt a decision laying down rules on the secondment of national experts to the Agency.

CHAPTER VIII
GENERAL AND FINAL PROVISIONS

Article 45

Privileges and immunities

The Protocol on the Privileges and Immunities of the European Union shall apply to the Agency and its staff.

Article 46

Language arrangements

The provisions laid down in Council Regulation No 1[27] shall apply to the Agency.

Article 47

Transparency

1. Regulation (EC) No 1049/2001 shall apply to documents held by the Agency.
2. The processing of personal data by the Agency shall be subject to Regulation (EU) 2018/1725 of the European Parliament and of the Council[28].
3. The Management Board shall, within six months of the date of its first meeting following the date of application of this Regulation, as referred to in Article 63, second subparagraph, establish measures for the application of Regulation (EU) 2018/1725 by the Agency, including those concerning the appointment of a Data Protection Officer of the Agency. Those measures shall be established after consultation of the European Data Protection Supervisor.

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27 Council Regulation No 1 determining the languages to be used by the European Economic Community (OJ 17, 6.10.1958, p. 385).

28 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).

Article 48

Combatting fraud

1. In order to combat fraud, corruption and other unlawful activities, the provisions of Regulation (EU, Euratom) No 883/2013[29] shall apply to the Agency.
2. The Agency shall accede to the Interinstitutional Agreement of 25 May 1999 concerning internal investigations by the OLAF [...] from the day **of entry into force of** this Regulation [...], and shall adopt appropriate provisions applicable to all employees of the Agency using the template set out in the Annex to that Agreement.
3. The Court of Auditors shall have the power of audit, on the basis of documents and on the spot, over all grant beneficiaries, contractors and subcontractors who have received Union funds from the Agency.
4. OLAF and EPPO may **within the scope of their mandates** carry out investigations, [...] **which in regard to OLAF may also include** on-the-spot checks and inspections**,** with a view to establishing whether there has been fraud, corruption or any other illegal activity affecting the financial interests of the Union in connection with a grant or a contract funded by the Agency, in accordance with the provisions and procedures laid down in Regulation (EU, Euratom) No 883/2013 and Regulation (Euratom, EC) No 2185/96[30].
5. Without prejudice to paragraphs 1 to 4, cooperation agreements with international organisations and third countries as referred to in Articles 53 and 54, contracts, grant agreements and grant decisions of the Agency shall contain provisions expressly empowering the Court of Auditors and OLAF to conduct such audits and investigations, according to their respective competences.

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29 Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council of 11 September 2013 concerning investigations conducted by the European Anti-Fraud Office (OLAF) and repealing Regulation (EC) No 1073/1999 of the European Parliament and of the Council and Council Regulation (Euratom) No 1074/1999, (OJ L 248, 18.9.2013, p. 1).

30 Council Regulation (Euratom, EC) No 2185/96 of 11 November 1996 concerning on-the-spot checks and inspections carried out by the Commission in order to protect the European Communities' financial interests against fraud and other irregularities (OJ L 292, 15.11.1996, p. 2).

Article 49

Protection of classified and sensitive non-classified information

1. The Agency shall adopt security rules equivalent to the Commission's security rules for protecting European Union Classified Information (EUCI) and sensitive non-classified information, as set out in Commission Decisions (EU, Euratom) 2015/443[31] and 2015/444[32]. The security rules of the Agency shall cover, among other, provisions for the exchange, processing and storage of such information.
2. The Agency may only exchange classified information with the relevant authorities of a third country or international organisation or share EUCI classified information with another Union body under the framework of Administrative Arrangements. Any such Administrative Arrangement shall be subject to the authorisation of the Management Board after consultation of the Commission. In the absence of such administrative Arrangement, any exceptional *ad hoc* release of EUCI to those authorities shall be subject to a decision by the Executive Director after consultation of the Commission.

Article 50

Liability

1. The Agency's contractual liability shall be governed by the law applicable to the contract in question.
2. The Court of Justice of the European Union shall have jurisdiction to give judgment pursuant to any arbitration clause contained in a contract concluded by the Agency.
3. In the case of non-contractual liability, the Agency shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by its departments or by its staff in the performance of their duties.

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31 Commission Decision (EU, Euratom) 2015/443 of 13 March 2015 on Security in the Commission (OJ L 72, 17.3.2015, p. 41).

32 Commission Decision (EU, Euratom) 2015/444 of 13 March 2015 on the security rules for protecting EU classified information (OJ L 72, 17.3.2015, p. 53).

4. The Court of Justice of the European Union shall have jurisdiction in disputes over compensation for damages referred to in paragraph 3.

5. The personal liability of its staff towards the Agency shall be governed by the provisions laid down in the Staff Regulations or Conditions of Employment of other Servants.

Article 51

Evaluation and review

1. No later than *[OP please insert the date = five years after the date referred to in Article 63]*, and every 5 years thereafter, the Commission shall assess the Agency's performance in relation to its objectives, mandate, tasks and location in accordance with Commission guidelines. The evaluation shall, in particular, address the possible need to modify the mandate of the Agency, and the financial implications of any such modification.

2. On the occasion of every second evaluation, there shall also be an assessment of the results achieved by the Agency having regard to its objectives, mandate and tasks, including an assessment of whether the continuation of the Agency is still justified with regard to these objectives, mandate and tasks.

3. The Commission shall report to the European Parliament, the Council and the Management Board on the evaluation findings. The findings of the evaluation shall be made public.

Article 52

Administrative inquiries

The activities of the Agency shall be subject to the inquiries of the European Ombudsman in accordance with Article 228 TFEU.

Article 53

Cooperation with other organisations and bodies

1. The Agency shall actively seek to cooperate with international organisations and other, particularly Union, governmental and non-governmental bodies as well as technical bodies competent in matters covered by this Regulation, within the framework of working arrangements concluded with those bodies, in accordance with the Treaty on the Functioning of the European Union and the provisions on the competence of those bodies. Those working arrangements shall not cover the exchange of classified information.
2. Such working arrangements shall be adopted by the Management Board based on a draft submitted by the Executive Director and after the Commission's prior approval. Where the Commission expresses its disagreement with those working arrangements, the Management Board shall adopt them by a three-fourths majority of the members with a right to vote.
3. Amendments or changes to existing working arrangements, which are limited in scope and do not change the overall scope and intention of the working arrangements, or technical working arrangements with other technical bodies shall be adopted by the Management Board based on a draft submitted by the Executive Director and after prior information to the Commission.

Article 54

Cooperation with third countries

1. The Agency shall be open to the participation in its work of third countries that have entered into agreements with the Union to this effect.
2. Under the relevant provisions of the agreements referred to in paragraph 1, arrangements shall be developed specifying, in particular, the nature, extent and manner in which the third countries concerned are to participate in the work of the Agency, including provisions relating to participation in the initiatives undertaken by the Agency, financial contributions and staff.

   As regards staff matters, those working arrangements shall, in any event, comply with the Staff Regulations.

Article 55

Consultation of civil society organisations

The Agency shall maintain a close dialogue with relevant civil society organisations**, including organisations of people who use drugs,** active in the fields covered by this Regulation at national, Union or international level.

Article 56

Headquarters Agreement and operating conditions

1. The necessary arrangements concerning the accommodation to be provided for the Agency in the host Member State and the facilities to be made available by that Member State together with the specific rules applicable in the host Member State to the Executive Director, members of the Management Board, Agency staff and members of their families shall be laid down in a Headquarters Agreement between the Agency and Member State where the seat is located.
2. The Agency's host Member State shall provide the best possible conditions to ensure the smooth and efficient functioning of the Agency, including multilingual, European-oriented schooling and appropriate transport connections.

Article 57

Legal succession

1. The Agency as established by this Regulation shall be the legal successor in respect of all contracts concluded by, liabilities incumbent upon and properties acquired by the European Monitoring Centre for Drugs and Drug Addiction as established by Regulation (EC) No 1920/2006.
2. This Regulation shall not affect the legal force of agreements and arrangements concluded by the European Monitoring Centre for Drugs and Drug Addiction as established by Regulation (EC) No 1920/2006 before *[OP please insert the date = 12 months after the entry into force of the Regulation]*.

Article 58

Transitional arrangements concerning the Management Board

1. The Management Board of European Monitoring Centre for Drugs and Drug Addiction as established by Regulation (EC) No 1920/2006 shall continue its work and functioning based on Regulation (EC) No 1920/2006 and the rules established under that Regulation until all representatives of the Management Board are appointed in accordance with Article 23 of this Regulation.

2. By *[OP please insert the date = 9 months after the entry into force of the Regulation]*, the Member States shall notify the Commission of the names of the persons whom they have appointed as member and alternate of the Management Board, in accordance with Article 23.

3. The Management Board established in accordance with Article 23 shall hold its first meeting within one month of the entry into application of this Regulation. On that occasion it may adopt its rules of procedures.

Article 59

Transitional arrangements concerning the Executive Director

1. The Director of the European Monitoring Centre for Drugs and Drug Addiction appointed on the basis of Article 11 of Regulation (EC) No 1920/2006 shall, for the remaining period of her/his term of office, be assigned the responsibilities of Executive Director as provided for in Article 29 of this Regulation. The other conditions of her or his contract shall remain unchanged.

   If the term of office ends between the date of entry into force of this Regulation and the date of its application, and if that term has not been already extended under Regulation (EC) No 1920/2006, it shall be extended automatically until *[OP please insert the date = 24 months after the entry into force of the Regulation]*.

2. Should the Director appointed on the basis of Article 11 of Regulation (EC) No 1920/2006 be unwilling or unable to act in accordance with paragraph 1, the Management Board as referred to in Article 23 shall designate an interim Executive Director to exercise the duties assigned to the Executive Director for a period not exceeding 18 months, pending the appointment provided for in Article 43(2).

Article 60

Transitional arrangements concerning the national focal points

By *[OP please insert the date = 11 months after the entry into force of the Regulation]*, the member of the Management Board shall provide the Agency with the name of the institution, which was designated as national focal point in accordance with Article 32(1), and the name of the head of the national focal point. This can take the form of an e-mail confirming the current status quo.

Article 61

Transitional budgetary provisions

The discharge procedure in respect of the budgets approved on the basis of Article 14 of Regulation (EC) No 1920/2006 shall be carried out in accordance with the rules established by Article 15 thereof.

Article 62

Repeal of Regulation (EC) No 1920/2006

1. Regulation (EC) No 1920/2006 is repealed from [OP please insert the date = 12 months after the entry into force of the Regulation].

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

2. Internal rules and measures adopted by the Management Board on the basis of Regulation (EC) No 1920/2006 shall remain in force after *[OP please insert the date = 12 months after the entry into force of the Regulation]*, unless otherwise decided by the Management Board in the application of this Regulation.

Article 63

Entry into force

This Regulation shall enter into force on the day following that of its publication in the *Official Journal of the European Union*.

It shall apply from *[OP please insert the date = 12 months after the entry into force of the 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*