EUROPEAN UNION

THE EUROPEAN PARLIAMENT **THE COUNCIL**

Brussels, 27 June 2023
(OR. en)

2022/0009 (COD)
LEX 2248

PE-CONS 16/1/23
REV 1

CORDROGUE 25
SAN 173
CODEC 548

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON THE EUROPEAN UNION DRUGS AGENCY (EUDA) AND REPEALING REGULATION (EC) No 1920/2006

REGULATION (EU) 2023/…
OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 27 June 2023

on the European Union Drugs Agency (EUDA)
and repealing Regulation (EC) No 1920/2006

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,

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

After consulting the Committee of the Regions,

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

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1 OJ C 323, 26.8.2022, p. 88.

2 Position of the European Parliament of 13 June 2023 (not yet published in the Official Journal) and decision of the Council of 27 June 2023.

Whereas:

(1) The European Monitoring Centre for Drugs and Drug Addiction (the 'EMCDDA') was established by Council Regulation (EEC) No 302/93[1]. That Regulation was recast in 2006 by Regulation (EC) No 1920/2006 of the European Parliament and of the Council[2].

(2) The EMCDDA was established to provide the Union, Member States and participating third countries with factual, objective, reliable and comparable information concerning drugs, drug addiction and their consequences at European level in order to help provide them with an overall view of that information for the purpose of informing policymaking and guiding initiatives to tackle drugs and, thus, giving such initiatives added value when, in their respective areas of competence, they take measures or decide on action to address the drugs phenomenon. The establishment and functioning of the EMCDDA has manifestly improved the availability of information on drugs and drug addiction, and their consequences, across the Union and internationally.

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1 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, p. 1).

2 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 (OJ L 376, 27.12.2006, p. 1).

(3) While its general objective is still valid and should be retained, Regulation (EC) No 1920/2006 no longer provides an adequate framework for addressing current and future drug challenges. Therefore, the mandate of the EMCDDA should be revised in order, amongst other things, to replace and strengthen it. The EMCDDA should be renamed the European Union Drugs Agency (EUDA) (the 'Agency'). Since substantial amendments to Regulation (EC) No 1920/2006 are needed to accommodate the common approach on Union decentralised agencies adopted on 19 July 2012 by the European Parliament, the Council and the Commission and to take account of the developments of the drugs phenomenon, in the interest of clarity and efficiency, that Regulation should be repealed and replaced by this Regulation.

(4) The main focus of Regulation (EC) No 1920/2006 was on health-related issues. While it is essential to maintain that focus, as health- and supply-related issues regarding the drugs phenomenon are intrinsically linked, it is also necessary to address drug supply in order to reduce the availability of drugs in the Union and curb drug demand and, thus, to contribute to addressing related safety and security concerns. In order to provide factual, objective, reliable, comparable and Union-wide significant data and analysis, the Agency should address the drugs phenomenon, taking an evidence-based, integrated, balanced and multidisciplinary approach to drugs, drug use, drug use disorders and addictions, prevention, treatment, care, risk and harm reduction, rehabilitation, social reintegration and recovery, drug markets and supply, including illicit production and trafficking, and other relevant drug-related issues and their consequences. The Agency's approach should incorporate human rights, gender and gender equality, age, health, health equity and social perspectives.

(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 area of drugs. It should cover the various facets of the drugs phenomenon and the solutions applied. In particular, the Agency should consider all aspects related to the protection and improvement of health, including physical and mental aspects, and the potential impact on public health. The Agency should also look into social aspects, including considerations linked to stigmatisation, marginalisation and the reintegration of people who use drugs. In doing so, the Agency should be guided by Union drug-related strategic documents.

(6) In pursuing its activities, the Agency should cooperate with other relevant Union bodies, offices and agencies within their respective mandates and should take account of their activities in order to avoid duplication. In particular, with due regard for their respective mandates, the Agency should cooperate with the European Union Agency for Law Enforcement Cooperation (Europol), established by Regulation (EU) 2016/794 of the European Parliament and of the Council[1], in order to ensure the collection of data, and the monitoring of trends, on drug supply, including illicit production and trafficking and other related crimes, on the use of new technologies and on new psychoactive substances. The Agency should also cooperate at international level with relevant authorities and bodies in third countries, in particular in candidate countries, and in support of Union and Member State action at the level of the United Nations. It is necessary that such cooperation comply with human rights norms.

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[1] Regulation (EU) 2016/794 of the European Parliament and of the Council of 11 May 2016 on the European Union Agency for Law Enforcement Cooperation (Europol) and replacing and repealing Council Decisions 2009/371/JHA, 2009/934/JHA, 2009/935/JHA, 2009/936/JHA and 2009/968/JHA (OJ L 135, 24.5.2016, p. 53).

(7) In order to attain maximum efficiency in addressing the drugs phenomenon, the Agency should have exchanges with relevant stakeholders and, in particular, with the scientific community, including academia, and civil society organisations, including organisations of people who use drugs and of communities affected by the consumption and sale of drugs or drug-related crime. Given the particular relevance of the experience of civil society organisations in the Agency's area of competence, the Agency should maintain cooperation on its activities with civil society organisations, such as those active in the relevant Commission expert groups on drugs composed of civil society organisations. The Agency should dedicate the necessary means to consult, exchange information and pool knowledge with those organisations, including in the area of new psychoactive substances. Where appropriate, the Agency should organise dedicated consultations on the topics within its mandate.

(8) With a view to disseminating reliable information on drugs and the drug situation, the Agency should engage in communication activities on topics within its mandate. However, communication to the wider public in the area of drugs can sometimes have unintended negative consequences. As part of its communication activities and where appropriate, the Agency should, therefore, consider disseminating its reports, including initial reports and risk assessment reports on new psychoactive substances, to the scientific community and civil society organisations with a view to minimising possible drug-related harm. Where the Agency is prevented from disseminating its reports, in particular due to the presence of classified or sensitive non-classified information, it could consider publishing summaries of those reports with a view to minimising possible drug-related harm.

(9) In its work, the Agency should pay due regard to poly-substance use because such use is becoming increasingly common.

(10) The Agency should develop its activities around three main areas of competence, namely monitoring, leading to better informed policies; preparedness, leading to better informed actions; and competence development, leading to stronger Union and Member State responses to the drugs phenomenon.

(11) The collection, analysis and dissemination of data should continue to be the main task of the Agency. When collecting, analysing or disseminating data, the Agency should comply with the legal framework on the processing of personal data and should not disseminate or transmit any data which would make it possible to identify individuals or small groups of individuals. Standard data are collected through national focal points, which should remain the primary data providers for the Agency. The Agency could also use additional sources and organise meetings of experts, including virtual meetings. In addition, closer to real-time data sources are increasingly available through innovative data collection methods. Therefore, the Agency should have access to relevant available data to obtain a holistic picture of the drugs phenomenon in the Union and the external factors influencing it. With a view to ensuring that each national focal point remain informed of the situation in its Member State, it should be informed on a regular basis of data concerning its Member State that are collected from additional sources of information and of the activities of the network of forensic and toxicological laboratories set up by this Regulation.

(12) The national focal points are key players in the Union's drug monitoring and reporting system. They collect information and produce comparable and scientifically sound data on the national drug situation, which feed 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 of developing relevant guidelines for their implementation. In addition, the national focal points participate in an early warning system and report on new trends in the use of existing psychoactive substances. It is therefore essential that the Agency and the national focal points have a mutually reinforcing relationship. The data requirements of the Agency should be mirrored in the national focal points. The national focal points 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 so as to avoid double reporting and duplication of efforts.

(13) It is necessary to establish the foundations of a relationship of mutual trust and continuous dialogue between the Agency and the national focal points, 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 to coordinated Union action in the field of drugs.

(14) With the aim of supporting effective Union action in the field of drugs and contributing to the work of the Agency, the national focal points should, *inter alia*, assume a coordinating role in activities related to ensuring coherent drug-related data collection and monitoring, communication with the Agency and promotion of evidence-based decision making, ensuring a cross-sectoral and comprehensive national view of the drug situation, including any relevant information on new trends and challenges, and contributing to the establishment of relevant indicators. In addition, and in line with national competence, the national focal points have a key role in promoting and supporting evidence-based decision-making, supporting systems of collaboration, assessing the information needs of relevant stakeholders and compiling an up-to-date inventory of national drug information sources.

(15) In order to facilitate and structure data collection and 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 and apply the appropriate digital solutions necessary for the performance of its tasks.

(16) In order to enable the Agency to make better use of the information available to it, for example to take 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 that of the EMCDDA.

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

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

(19) New psychoactive substances which pose public health and social risks across the Union should be adequately addressed. It is therefore necessary to monitor new psychoactive substances and, in order to enable a quick response, to maintain the early warning system set up under Regulation (EC) No 1920/2006. The provisions of that Regulation relating to the exchange of information on, and the early warning system for, new psychoactive substances, including initial reports and risk assessments on new psychoactive substances, were amended recently and should remain unchanged in this Regulation.

(20) Based on 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. Greater capacity to proactively and rapidly identify new threats and inform the development of counter-measures is urgently needed as the current dynamic nature of the drugs phenomenon means that related challenges can rapidly spread across borders.

(21) As dangerous substances and certain consumption patterns might lead to harm for health, the Agency should be able to issue alerts complementing and without prejudice to the relevant national alert systems. To support that function, the Agency should develop a European drug alert system which is accessible by national authorities. That system should facilitate the rapid exchange of information that might require rapid actions to safeguard health, social aspects, safety and security. The Agency should, under the conditions laid down in this Regulation, be able to develop an alert system to make information on identified risks available to people who use or potentially use specific drugs.

(22) 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 diversion and trafficking of drug precursors from legal channels to illegal drug production should be strengthened. To support that effort, the Agency should have a role in monitoring the diversion and trafficking of drug precursors and in assisting the Commission in the implementation of Union law on drug precursors.

(23) As there is a growing need for forensic and toxicological data and specialist expertise, matched by a need for better coordination between laboratories in the Member States, a network of forensic and toxicological laboratories knowledgeable in the area of drugs and drug-related harm should be set up. That network should enable the Agency to have access to relevant information, increase the Agency's capacities in that area and support knowledge exchange between the relevant laboratories in the Member States, without the Agency incurring the high costs of creating and running its own laboratory.

(24) The network of forensic and toxicological laboratories should be representative of the Member States in that each of them should be allowed 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, support the sharing of information between relevant laboratories and decrease the costs for individual laboratories.

(25) To further knowledge in the area covered by the mandate of the Agency and support Member States, the Agency should identify and finance relevant projects, such as the development of reference standards on new drugs, the elaboration of toxicological or pharmacological studies, the implementation of innovative approaches to research, and drug profiling. The projects that the Agency finances should be included in the Agency's consolidated annual activity report and be made public.

(26) The Agency will be in a position to access data and gain necessary scientific experience to develop and promote evidence-based interventions and best practices, to raise awareness about the adverse effects of drugs, prevention, risk and harm reduction measures, treatment, care, rehabilitation and recovery, and, where relevant, to take a gender-sensitive approach and to take into account the age dimension. The Agency should promote the implementation and updating of existing quality standards for drug prevention (European Drug Prevention Quality Standards) and 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), including how to reach high-risk populations.

(27) Given its Union-wide perspective, the Agency should be able to assess national measures and training, for example on prevention, including gender-sensitive and age-appropriate prevention, treatment, harm reduction, recovery and other related measures, in order to determine whether they reflect the latest scientific state of play and whether they have proven effective. A positive assessment of national measures could serve as a quality label.

(28) Considering that the Agency will be in a unique position at Union level that allows it to compare data and best practices, the Agency should be able to offer support, including, where so required by Member States, assisting with the 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 develop in those areas.

(29) International cooperation should be part of the core tasks of the Agency with responsibilities established in clear terms in order to allow it to fully engage in such activities and respond to requests from international organisations and other bodies and from third countries. The Agency should be able to offer adequate scientific and evidence-based tools for the development and implementation of the external dimension of the Union's drugs policy and for the important role of the Union at multilateral level, in accordance with the Treaties, as a means to ensure the efficient and coherent implementation of the Union's drugs policy internally and at international level. Work in that area should be based on an international cooperation framework developed by the Agency. The international cooperation framework should be in accordance with the Treaties and the Union priorities on international cooperation and guided by the relevant United Nations instruments. The Agency should revise the international cooperation framework on a regular basis in order to ensure that it adequately reflects international developments and priorities.

(30) In order to help Union funding for security and health research to develop its full potential and address what is required by a drugs policy, the Agency should assist the Commission in identifying key research themes and in 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 or in drawing up and implementing a Union framework programme, it should not receive funding from that programme and should take all necessary measures in order to avoid conflicts of interest. 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. Planned research and innovation activities should be set out in the single programming document containing the Agency's multiannual and annual work programme.

(31) The Commission and the Member States should be represented on the Management Board of the Agency to effectively supervise its work. The members and the alternate members of the Management Board should be appointed taking into account their relevant managerial, administrative and budgetary skills. Alternate members should act as members in the absence of the relevant members. Alternate members may also attend meetings in the presence of the relevant members without their presence entailing additional costs for the Agency and without taking part in the votes.

(32) The Management Board should be given the necessary powers, in particular to adopt the budget, the appropriate financial rules and planning documents, and the consolidated annual activity report. In order to ensure the independent functioning and integrity of the Agency, the Management Board should also adopt rules for the prevention and management of conflicts of interest in respect of its members, the members of the Executive Board, the members of the Scientific Committee, the members of a European Information Network on Drugs and Drug Addiction (the 'Reitox network'), seconded national experts and other staff not employed by the Agency. In so doing, it is important that the Agency give due consideration to the recommendations and guidelines on that matter, in particular those of the European Ombudsman and the Commission Guidelines on the prevention and management of conflicts of interest in EU decentralised agencies of 10 December 2013. The Management Board should exercise the appointing authority powers vis-à-vis the staff of the Agency, including the Executive Director.

(33) It is important that all parties represented on the Management Board endeavour to multiply perspectives and experiences represented in and contributing to its work, while ensuring the continuity of its work. All parties should aim to achieve gender-balanced representation on the Management Board.

(34) The Management Board should be assisted by an Executive Board to prepare its decisions. The Agency should be headed by an Executive Director. A Scientific Committee should assist the Management Board and the Executive Director with regard to relevant scientific matters.

(35) The Management Board should appoint the Executive Director following an open and transparent selection procedure organised and managed by the Commission. In line with the practice followed in the appointment of executive directors to the EMCDDA, the Commission should consider including a representative of the Management Board as an observer in the appointment procedure. The assessment by the Commission at the end of the initial five-year term of office of the Executive Director should include prior input from the Management Board on the performance of the Executive Director.

(36) It is important that the Agency be adequately resourced to carry out its tasks, objectives and responsibilities under this Regulation and be granted an autonomous budget reflecting its mission. 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 Court of Auditors should audit the Agency's accounts.

(37) In order to further support Member States and other stakeholders in understanding and addressing the drugs phenomenon, the possibility for the Agency to deliver additional services, beyond its core tasks laid down in this Regulation, against the payment of fees should be introduced. The method by which fees levied by the Agency are calculated should be transparent. The fees levied by the Agency should cover the full cost of providing the activities related to the services delivered, including staff and operational costs. Where fees have been levied in a financial year, the Agency's provisional accounts should be accompanied by a report on those fees. Such reports would also be subject to audit by the Court of Auditors. Fees should be set at a level that avoids a deficit or a significant accumulation of surplus and should be revised where that is not the case.

(38) The Executive Director should present the annual report of the Agency to the European Parliament and 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.

(39) Regulation (EC) No 1049/2001 of the European Parliament and of the Council[1] 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.

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[1] 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).

(40) Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council[1] 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)[2], to which the EMCDDA acceded, should apply to the Agency.

(41) The Agency processes data that require particular protection, in particular European Union Classified Information (EUCI) and sensitive non-classified information. The Agency should draw up rules on the confidentiality and processing of such information. The rules on the protection of EUCI should be consistent with Commission Decisions (EU, Euratom) 2015/443[3] and (EU, Euratom) 2015/444[4]. In accordance with those legal acts, the Agency should refrain from publishing sensitive data. It should also refrain from disclosing the confidential business information of third parties.

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

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1 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).

2 OJ L 136, 31.5.1999, p. 15.

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

4 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).

(43) The Agency should cooperate closely, in full compliance with fundamental rights, with relevant international organisations and other governmental and non-governmental bodies, including relevant technical bodies, from inside and outside the Union in the implementation of its work programme, in accordance with the relevant Treaty provisions and Member State competences, in particular to avoid duplication of work and to ensure access to all data and tools needed for carrying out its mandate.

(44) The Agency should replace and succeed the EMCDDA. It should therefore be the legal successor of all EMCDDA's contracts, including employment contracts, liabilities and properties. International agreements concluded by the EMCDDA before … [the date of application of this Regulation] should remain in force.

(45) Since the objective 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 (TEU). 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 that objective,

HAVE ADOPTED THIS REGULATION:

Chapter I

Objectives and tasks of the Agency

Article 1

Establishment of the Agency

1. This Regulation establishes the European Union Drugs Agency (EUDA) (the ‘Agency’).

2. The Agency replaces and succeeds the European Monitoring Centre for Drugs and Drug Addiction (the ‘EMCDDA’) 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 Lisbon, Portugal.

Article 3

Definitions

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

(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 to Council Framework Decision 2004/757/JHA[1];

(2) ‘new psychoactive substance’ means new psychoactive substance 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 substances or types of psychoactive substance, whether illicit or licit, in particular medicinal products, alcohol and tobacco, at the same time as the use of drugs or sequentially within a short period of time of the use of drugs;

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1 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).

(4) ‘drug precursor’ means a substance that is controlled and monitored in accordance with Regulation (EC) No 273/2004 of the European Parliament and of the Council[1] and with Council Regulation (EC) No 111/2005[2];

(5) ‘participating country’ means a Member State or a third country which has 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;

(7) ‘United Nations Drug Conventions’ means the United Nations Single Convention on Narcotic Drugs of 1961 as amended by the 1972 Protocol, the 1971 United Nations Convention on Psychotropic Substances and the 1988 United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances

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

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1 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).

2 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).

Article 4

General task of the Agency

1. The Agency shall:

(a) provide the Union and the 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, recovery, drug markets and supply, including illicit production and trafficking, and other relevant drug-related issues and their consequences; and

(b) recommend appropriate and concrete evidence-based actions on how to address, in an efficient and timely manner, the challenges relating to drugs, drug use, drug use disorders and addictions, prevention, treatment, care, risk and harm reduction, rehabilitation, social reintegration, recovery, drug markets and supply, including illicit production and trafficking, and other relevant drug-related issues and their consequences.

2. In carrying out its tasks, the Agency shall ensure full compliance with fundamental rights and data protection rules and shall take an evidence-based, integrated, balanced and multidisciplinary approach to the drugs phenomenon. That approach shall incorporate human rights, gender and gender equality, age, health, health equity and social perspectives.

Article 5

Specific tasks

1. In order to carry out the general task set out in Article 4(1), the Agency shall have the following specific tasks:

(a) monitoring tasks that include:

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

(ii) the dissemination of information, data and results of analyses pursuant to Article 6(5); and

(iii) the monitoring of the drugs phenomenon, encompassing the health, human rights, social, safety and security aspects thereof pursuant to Article 7;

(b) preparedness tasks that include:

(i) the exchange of information on, and the early warning system for, new psychoactive substances, including the preparation of initial reports and risk assessments pursuant to Articles 8 to 11;

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

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

(iv) the monitoring of developments related to the diversion and trafficking of drug precursors and contributing to the implementation of Union law on drug precursors pursuant to Article 14;

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

(c) competence development tasks that include:

(i) the development and promotion of evidence-based interventions, best practices and awareness-raising activities pursuant to Article 16;

(ii) the assessment of national measures pursuant to Article 17;

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

(iv) training pursuant to Article 19;

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

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

2. The Agency shall establish and coordinate, in consultation and cooperation with the competent authorities and organisations in the participating countries, the European Information Network on Drugs and Drug Addiction referred to in Article 32 (the 'Reitox network').

3. The Agency shall act in a transparent, objective, impartial and scientifically rigorous manner when carrying out the specific tasks set out in paragraph 1.

4. The Agency shall support, and improve coordination between, national and Union action in its areas of activity. The Agency shall facilitate the exchange 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, where appropriate.

6. In carrying out the specific tasks set out in paragraph 1, the Agency may:

(a) organise meetings of experts;

(b) set up ad hoc working groups; and

(c) finance projects, as necessary.

Where the Agency organises meetings, sets up working groups or finances projects under the first subparagraph, it shall keep the Reitox network informed.

7. In order to attain maximum efficiency in monitoring, assessing and responding to the drugs phenomenon, the Agency shall, in carrying out the specific tasks set out in paragraph 1, cooperate actively with relevant stakeholders, including:

(a) other relevant Union bodies, offices and agencies, within the limits of their mandates, in particular Europol, the European Union Agency for Criminal Justice Cooperation (Eurojust), established by Regulation (EU) 2018/1727 of the European Parliament and of the Council[1], the European Union Agency for Fundamental Rights, established by Council Regulation (EC) No 168/2007[2], the European Union Agency for Law Enforcement Training (CEPOL), established by Regulation (EU) 2015/2219 of the European Parliament and of the Council[3], the European Medicines Agency, established by Regulation (EC) No 726/2004 of the European Parliament and of the Council[4], the European Centre for Disease Prevention and Control, established by Regulation (EC) No 851/2004 of the European Parliament and of the Council[5], and the European Foundation for the Improvement of Living and Working Conditions (Eurofound), established by Regulation (EU) 2019/127 of the European Parliament and of the Council[6];

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1 Regulation (EU) 2018/1727 of the European Parliament and of the Council of 14 November 2018 on the European Union Agency for Criminal Justice Cooperation (Eurojust), and replacing and repealing Council Decision 2002/187/JHA (OJ L 295, 21.11.2018, p. 138).

2 Council Regulation (EC) No 168/2007 of 15 February 2007 establishing a European Union Agency for Fundamental Rights (OJ L 53, 22.2.2007, p. 1).

3 Regulation (EU) 2015/2219 of the European Parliament and of the Council of 25 November 2015 on the European Union Agency for Law Enforcement Training (CEPOL) and replacing and repealing Council Decision 2005/681/JHA (OJ L 319, 4.12.2015, p. 1).

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

5 Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for disease prevention and control (OJ L 142, 30.4.2004, p. 1).

6 Regulation (EU) 2019/127 of the European Parliament and of the Council of 16 January 2019 establishing the European Foundation for the improvement of living and working conditions (Eurofound), and repealing Council Regulation (EEC) No 1365/75 (OJ L 30, 31.1.2019, p. 74).

(b) other international bodies, offices and agencies, in particular the United Nations Office on Drugs and Crime (UNODC), the United Nations Economic and Social Council and the International Narcotics Control Board (INCB); and

(c) the scientific community and civil society organisations.

8. The Agency shall 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 specific tasks set out in paragraph 1. The Agency shall carry out communication activities in accordance with relevant communication strategies and dissemination plans adopted by the Management Board. The Agency may involve relevant stakeholders, including the scientific community and civil society organisations, in the development of those strategies and plans.

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 which have been communicated by the national focal points, which result from research, which are available from open sources, and which emanate from Union sources, non-governmental sources and competent international organisations and bodies;

(b) collect information and data needed in order to monitor poly-substance use and its consequences pursuant to Article 7(1), point (d);

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

(d) collect and analyse information and data on drug precursors and on the diversion and trafficking of drug precursors;

(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 with a view to ensuring greater uniformity of the measurement methods used by the Member States and the Union; the Agency may recommend compliance with such non-binding common standards;

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

2. The Agency shall collect relevant national data through the national focal points. Prior to collecting the data, the Agency and the national focal points shall discuss and agree on the national reporting package. The Agency may use additional sources of information for national data. Where the Agency uses such additional sources, it shall keep the national focal point concerned duly informed. The data collected shall, where possible, be disaggregated by sex and, where possible, by gender. Such data shall take into account the gender-sensitive aspects of drugs policy.

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 for the purpose of collecting, validating, analysing, reporting, managing and exchanging information and data, 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 analyses, conclusions and reports, including to the scientific community, civil society organisations and affected communities, including people who use drugs, with the exception of classified and sensitive non-classified information as referred to in Article 49;

(c) publishing, on the basis of data which it collects, a regular report on the state of the drugs phenomenon and emerging trends;

(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 of information on, and the implementation of, such standards and practices.

6. Where relevant, the Agency may disseminate information and data which have been disaggregated, in particular by Member State, sex, gender, age, disability and socio-economic status, in accordance with relevant Union law, in particular on data protection.

7. When disseminating information and data under paragraph 5, the Agency shall include references to the sources thereof.

8. The Agency shall not disseminate or transmit any information and data from which it is possible to identify individuals or small groups of individuals.

Article 7

Monitoring of the drugs phenomenon and sharing of best practices

1. The Agency shall monitor:

(a) the drugs phenomenon in the Union in a holistic manner, using epidemiological and other indicators, covering the health, human rights, social, safety and security aspects thereof, including the implementation of the applicable Union drug-related strategic documents;

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

(c) drug use, drug use disorders, drug addictions and related health risks, drug-related harm, risk behaviours associated with drug use and emerging trends in those fields;

(d) 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, and the implications for policies and responses;

(e) drug and poly-substance use and its consequences from an age and gender perspective, in particular its impact on gender-based violence;

(f) emerging trends in the drugs phenomenon in the Union and internationally in so far as they impact the Union; monitoring under this point shall include the monitoring of drug supply, including illicit production, trafficking and other related crimes and the use of new technologies, without prejudice to the mandates of other Union bodies, offices and agencies;

(g) 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;

(h) drug precursors and the diversion and trafficking of drug precursors;

(i) the implementation of Union and national drugs policies, including with a view to supporting the development and independent evaluation of such policies.

2. Based on its monitoring activities under paragraph 1, the Agency shall identify, support and, where appropriate, co-develop evidence-based best practices and innovative approaches. The Agency shall share such best practices and approaches with the Member States and facilitate the exchange of such best practices and approaches between them.

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

4. 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

The exchange of information on, and the 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. That 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 that 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 initial reports or combined initial reports 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 a majority of Member States considers that information on a new psychoactive substance collected in one or more Member States and shared with it or them gives rise to concerns that the new psychoactive substance might pose health or social risks at Union level, the Agency shall draw up an initial report on the new psychoactive substance.

   For the purposes of the first subparagraph, Member States shall inform the Commission and the other Member States of their wish that an initial report be drawn up. Where a majority of Member States has so informed the Commission, the Commission shall instruct the Agency accordingly and shall inform the Member States thereof.

2. An initial report as referred to in paragraph 1 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 might 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 to manufacture or extract it;

(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, and its use for scientific research and development purposes;

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

(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 an initial report as referred to in paragraph 1, the Agency shall use the 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 a new psychoactive substance. The national focal points shall provide such information within two weeks of receipt of such a request.

5. The Agency shall, without undue delay after it starts drawing up an initial report pursuant to paragraph 1, 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[1], Regulation (EC) No 726/2004 or Regulation (EU) 2019/6 of the European Parliament and of the Council[2];

(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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1 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).

2 Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC (OJ L 4, 7.1.2019, p. 43).

(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 in accordance with Article 112(1), point (c), of Regulation (EU) 2019/6;

(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[1].

Where information provided under the first subparagraph 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 it starts drawing up an initial report pursuant to paragraph 1, 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 on any use of the new psychoactive substance.

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[1] 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).

7. The Agency shall, without undue delay after it starts drawing up an initial report pursuant to paragraph 1, request the European Chemicals Agency, established by Regulation (EC) No 1907/2006 of the European Parliament and of the Council[1], and the European Centre for Disease Prevention and Control and the European Food Safety Authority, established by Regulation (EC) No 178/2002 of the European Parliament and of the Council[2], 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 agencies referred to in paragraphs 5, 6 and 7 of this Article shall be set out in working arrangements. Such working arrangements shall be concluded in accordance with Article 53(2).

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

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

[2] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

10. The Agency shall submit an initial report as referred to in paragraph 1 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 a similar chemical structure, it shall submit to the Commission and the Member States an individual initial report as referred to in paragraph 1 for each of those new psychoactive substances, 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 new psychoactive substance might 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 individual initial reports or 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 those new psychoactive substances might pose severe public health risks and, where applicable, severe social risks. The combined risk assessment shall be carried out by the Scientific Committee.

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

(a) available information on the chemical and physical properties of the new psychoactive substance or substances and the methods and the precursors used to manufacture or extract it or them;

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

(c) an analysis of the health risks associated with the new psychoactive substance or substances, in particular with respect to its or their 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 or substances, in particular its or their impact on social functioning, public order and criminal activities, and of the involvement of criminal groups in the manufacture, distribution and distribution methods, and trafficking of the new psychoactive substance or substances;

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

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

(g) other relevant information, where available.

4. The Scientific Committee shall carry out a risk assessment in order to assess the risks posed by the new psychoactive substance or group of new psychoactive substances. For each such risk assessment, 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 risk assessments as referred to in paragraph 4 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 pursuant to paragraph 1 or a combined risk assessment report pursuant to paragraph 2.

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 set out in paragraph 6 to allow for additional research and data collection to take place. Such a request shall contain information on the period of time needed to complete the risk assessment or combined risk assessment.

8. The Agency shall provide timely rapid risk assessments, in accordance with Article 20 of Regulation (EU) 2022/2371 of the European Parliament and of the Council[1], in the case of a threat as referred to in Article 2(1), point (b), of that Regulation, where the threat falls under the mandate of the Agency.

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[1] Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26).

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 Organization's 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 for that substance.

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 for that substance.

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, Regulation (EC) No 726/2004 or Regulation (EU) 2019/6;

(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 health and security threat assessment capability to identify at an early stage new developments of the drugs phenomenon that have the potential to impact negatively on health, social matters, safety or security in the Union and, by doing so, to help increase the preparedness of the relevant stakeholders to respond to new threats in an effective and timely manner.

2. The Agency may launch a health and security threat assessment on its own initiative based on an internal appraisal of signals arising from routine monitoring, research or other appropriate information sources. The Agency may also launch a health and security threat assessment at the request of the Commission or of a Member State, provided that the criteria set out in paragraph 1 are met.

3. A health and security 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. Where, following a health and security threat assessment, the Agency draws up a health and security threat assessment report, that report shall describe the identified threat, the current situation based on available evidence and the potential outcomes in the event of no action. The health and security threat assessment report shall set out options for preparedness and response that can be adopted to mitigate and to respond to the threat identified, including, where possible, evidence-based interventions on demand reduction, risk and harm reduction and recovery. The health and security threat assessment report may also contain potential follow-up measures. The Agency shall send the health and security threat assessment report to the Commission and, as appropriate, to the Member States.

5. The Agency shall cooperate closely with Member States, other Union bodies, offices and agencies and international organisations in carrying out a health and security 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 health and security threat assessment.

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

7. The Agency shall monitor the evolution of the situation and, where necessary, update the health and security threat assessments accordingly.

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 European drug alert system shall be complementary to the early warning system referred to in Article 8.

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 and of any information that might 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;

(g) social, safety and security risks;

(h) health measures implemented or intended to be taken at national level;

(i) measures other than health measures;

(j) 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 available from the early warning system referred to in Article 8 and other threat assessments undertaken in accordance with Article 12, from other Union bodies, offices and agencies and from international organisations, in particular the World Health Organization. The Agency shall take into account open source information and available information obtained through its data collection tools and from relevant stakeholders, including the scientific community and civil society organisations.

4. Based on the information and data received pursuant to paragraph 3, the Agency shall provide targeted rapid alert risk communications to the relevant national authorities, including the national focal points. The Agency may propose response options in such risk communications. Member States may consider such response options 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 enable the Agency to further analyse and assess risks referred to in paragraph 2 and of the actions implemented or measures taken following receipt of the rapid alert risk communications referred to in paragraph 4.

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 shall, if needed, develop an alert system to make information on a specific risk available, where appropriate, to people who use or potentially use specific drugs.

9. The Agency shall update its drug alerts, whenever necessary.

Article 14

Drug precursors

1. The Agency shall assist the Commission in monitoring developments related to the diversion and trafficking 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 Regulations (EC) No 273/2004 and (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 active in forensic and toxicological investigations of drugs and drug-related harm (the ‘network’).

2. The network shall act primarily as a forum for:

   (a) generating data and exchanging information on new developments and trends;

(b) organising training to enhance the competence of forensic drug and toxicology experts;

(c) supporting the implementation of quality assurance schemes; and

(d) supporting the further harmonisation of data collection and analytical methods.

The national focal points shall be informed on a regular basis, at least once a year, about the activities of the network. The national focal points shall have access to the information and data generated by the network.

3. Each Member State shall have the right to appoint to the network, through its representative in the Management Board, up to three laboratories specialising in forensic analysis, toxicology or other relevant fields related to drugs to act as national representative laboratories. The Agency may select additional laboratories or experts particularly active in forensic and toxicological investigations of drugs and drug-related harm 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 cooperate closely with existing networks and organisations active in the same areas as the network and shall take their work into account in order to avoid overlaps. The Reitox network shall be informed regularly, and at least once a year, about the work of the network.

6. The Agency shall chair the network and convene at least one meeting a 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, generated or collected by laboratories of the network, including, where necessary, for the analysis of new psychoactive substances.

8. The Agency shall identify and finance specific projects to further the work of the network, as appropriate and based on clear and transparent rules and procedures. The Agency shall establish those rules and procedures prior to identifying such projects.

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 of this Regulation, including Article 6(8) and Article 49.

Chapter IV
Competence development

Article 16

Evidence-based interventions, best practices and awareness raising

1. The Agency shall develop and promote evidence-based interventions and best practices with regard to, and raise awareness about, the adverse effects of drugs, prevention, treatment, care, risk and harm reduction, rehabilitation, social reintegration and recovery. Where relevant, the Agency shall take a gender-sensitive approach and take into account the age dimension. Evidence-based interventions, best practices and awareness raising activities may be adapted to the national context and implemented at national level and, whenever necessary, be targeted to specific groups.

2. Evidence-based interventions, best practices and awareness raising activities referred to in paragraph 1 shall be in accordance with human rights norms and the political orientation set out in the applicable Union drug-related strategic documents.

3. The Agency shall promote the implementation of existing quality standards for drug prevention and update them as appropriate. The Agency shall provide or support training pursuant to Article 19. The Agency shall develop, where appropriate, quality standards for risk and harm reduction, treatment, recovery, care and rehabilitation.

4. The Agency may offer support to Member States and shall, subject to their prior agreement, assist them in developing national interventions in the area of its mandate.

Article 17

Assessment scheme for national measures

1. At the request of a national authority of a participating country, the Agency shall assess 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 proven useful in addressing its declared objectives.

3. The Agency shall develop an assessment procedure. The Agency shall set out the assessment procedure in a transparent way in a standard operating protocol. The Management Board shall approve the standard operating protocol and any changes to it before the Agency applies it.

4. The Agency shall regularly inform the Management Board of the assessments it has undertaken pursuant to this Article.

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 accordance with the applicable Union drug-related strategic documents.

2. The Agency may offer support to Member States and shall, subject to their prior agreement, assist them in implementing their national drug policies, quality standards, best practices and innovative approaches. The Agency shall facilitate the exchange of information, including on relevant law and best practices, between national authorities and experts.

3. When it supports the evaluation of drugs policies, the Agency shall act independently and shall be guided by its scientific standards and an evidence-based approach.

Article 19

Training

The Agency shall, within the scope of its mandate and in coordination with other Union bodies, offices and agencies:

(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 the prior approval of 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(1);

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

(d) monitor developments of the international drugs phenomenon that might 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 and collected 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 the transmission of information under 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 substances to the UNODC and the World Health Organization;

(h) support third countries, in particular candidate countries, in developing their drug policies in accordance with the principles set out in the applicable Union drug-related strategic documents, including by providing support to the independent evaluation of their policies, and encourage those third countries to support the participation and involvement of civil society in the development, implementation and evaluation of drug policies.

2. The international cooperation framework referred to in paragraph 1, point (a), shall seek to further strengthen and support third countries' efforts to address drug issues in an evidence-based, integrated, balanced and multidisciplinary manner and in full compliance with human rights norms. That international cooperation framework shall take into account the relevant policy documents of the Union and consider the developments of the drugs phenomenon. It shall set out the priority countries or regions for cooperation and the key outcomes of the cooperation. It shall take into account the experiences of 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 expertise and provide technical assistance to third countries, in particular candidate countries, in accordance with the international cooperation framework referred to in paragraph 1, point (a).

Technical assistance shall focus, in particular, on setting up or consolidating national focal points, national data collection systems and national early warning systems and on the promotion of best practices in the fields of prevention, treatment, care, risk and harm reduction, rehabilitation, social reintegration and recovery, and subsequently assist in the creation and strengthening of structural links with the early warning system referred to in Article 8 and the Reitox network. The Agency may assess the national bodies of a third country where that third country so requests.

4. The Agency shall cooperate with international organisations and with third countries 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 and in drawing up and implementing the Union framework programmes for research and innovation activities that are relevant to achieve its general and specific tasks set out in Articles 4 and 5, respectively. The Agency shall pay due attention to intersectionality as a crosscutting principle in its research-related activities. Where the Agency assists the Commission in identifying key research themes or in 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 and specific tasks set out in Articles 4 and 5, respectively, 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 such research and innovation activities to the European Parliament, the Member States and the Commission in accordance with the security rules provided for in 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 the Health Emergency Preparedness and Response Authority, established by the Commission Decision of 16 September 2021[1].

4. The Agency may plan and implement pilot projects regarding matters covered by this Regulation.

5. The Agency shall take all necessary measures to avoid conflicts of interest in the implementation of the pilot projects referred to in paragraph 4. It shall make public information on its research projects, including demonstration projects. Such information shall include 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.

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[1] Commission Decision of 16 September 2021 establishing the Health Emergency Preparedness and Response Authority 2021/C 393 I/02 (OJ C 393 I, 29.9.2021, p. 3).

Chapter V
Organisation of the Agency

Article 22

Administrative and management structure

1. 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 30;

   (d) a Scientific Committee, which shall exercise the functions set out in Article 31; and

   (e) the Reitox network.

2. The members of the Agency's administrative and management structure shall not have any financial or other interests that could affect their impartiality. They shall act in the public interest and carry out their activities in an independent, impartial and transparent manner. They shall make an annual declaration of their interests, which may be accessible upon request.

Article 23

Composition of the Management Board

1. The Management Board shall be composed of:

   (a) one representative from each Member State, with the right to vote;

   (b) two representatives from the Commission, with the right to vote.

2. The Management Board shall also include:

   (a) two independent experts designated by the European Parliament, who are particularly knowledgeable in the field of drugs, 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 or 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 set out in Article 4(1), point (a), taking into account relevant managerial, administrative and budgetary skills. All parties represented on the Management Board shall make efforts to limit the turnover of their representatives in order to ensure continuity in the work of the Management Board. All parties shall aim to achieve gender-balanced representation 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 shall be renewable.

Article 24

Functions of the Management Board

1. The Management Board shall:

   (a) provide the general orientation for the Agency's activities;

   (b) adopt the draft single programming document referred to in Article 36 before its submission to the Commission for its opinion;

(c) having obtained the opinion of the Commission, adopt the Agency's single programming document by a majority of two-thirds of members with the right to vote;

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

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

(f) adopt the financial rules applicable to the Agency in accordance with Article 42;

(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 bodies, offices and agencies;

(i) adopt rules for the prevention and management of conflicts of interest in respect of its members, the members of the Executive Board, the members of the Scientific Committee and the members of the Reitox network, and of seconded national experts and other staff not employed by the Agency as referred to in Article 44, and shall publish annually on the Agency's website the declarations of interests of the Management Board members;

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

(k) approve the international cooperation framework referred to in Article 20(1), point (a), and the technical assistance programmes referred to in Article 20(3);

(l) approve the level of co-financing referred to in Article 33(5);

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

(n) adopt and make publicly available its rules of procedure, including rules for the prevention and management of conflicts of interest;

(o) in accordance with paragraph 2 of this Article, exercise, with respect to the staff of the Agency, the powers conferred by the Staff Regulations of Officials of the European Union (the 'Staff Regulations') on the appointing authority and by the Conditions of Employment of Other Servants of the European Union (the 'Conditions of Employment of Other Servants') on the authority empowered to conclude a contract of employment, laid down in Council Regulation (EEC, Euratom, ECSC) No 259/68[1], (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;

(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 29;

(r) appoint an accounting officer, subject to the Staff Regulations and the Conditions of Employment of Other Servants, who shall be independent in the performance of her or 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 31(6);

[1] OJ L 56, 4.3.1968, p. 1.

(u) take decisions following the assessment of the national focal points in accordance with Article 35;

(v) set the method for calculating fees and the way fees are paid in accordance with Article 38;

(w) ensure adequate follow up to findings and recommendations stemming from internal or external audit reports and evaluations and from investigations of the European Anti-fraud Office (OLAF), established by Commission Decision 1999/352/EC, ECSC, Euratom[1], and of the European Public Prosecutor's Office (EPPO), established by Council Regulation (EU) 2017/1939[2], as referred to in Article 48 of this Regulation;

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

(y) adopt working arrangements in accordance with Article 53.

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1 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).

2 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 setting out the conditions under which that 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 Executive Director 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 the right to vote. The Chairperson and the Deputy Chairperson shall be elected by a majority of two-thirds of the members of the Management Boards with the right to vote.

2. The Deputy Chairperson shall automatically replace the Chairperson if she or he is prevented from attending to her or 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 shall take part in the deliberations of the Management Board.

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, including representatives from civil society organisations, 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 35(6), Article 29(8) and Article 53(2), the Management Board shall take decisions by a majority of its members with the right to vote.

2. Each member with the right to vote shall have one vote. In the absence of a member with the right to vote, her or his alternate shall be entitled to exercise the 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 42 that are not reserved to the Management Board by this Regulation;

(b) ensure adequate follow up to the findings and recommendations stemming from internal or external audit reports and evaluations, and from investigations by OLAF and by EPPO, as referred to in Article 48;

(c) without prejudice to the responsibilities of the Executive Director, set out in Article 30, 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 for taking such provisional decisions 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 the 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 as an observer. 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. 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 in the Executive Board shall automatically expire on that date.

5. The Executive Board shall hold at least two ordinary meetings a 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 among its members. 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.

Article 29

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 Management Board shall appoint the Executive Director from a list of at least three candidates proposed by the Commission on the basis of an open and transparent selection procedure. The selection procedure shall include the publication of a call for expressions of interest in the *Official Journal of the European Union* and in other appropriate media. The Commission shall consult the Management Board on the draft call for expressions of interest. The Commission may include a representative of the Management Board as an observer in the selection procedure.

Before appointment by the Management Board to the post of Executive Director, the shortlisted candidates proposed by the Commission may be invited, without delay, to make a statement before the competent committee or committees of the European Parliament and answer questions from the committee members. After hearing the statement and the responses, the European Parliament may adopt an opinion setting out its views and submit it to the Management Board.

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 shall undertake an assessment that takes into account an evaluation of the Executive Director's performance, including prior input from the Management Board, and the Agency's future tasks and challenges.

5. The Management Board, acting on a proposal from the Commission that takes into account the assessment referred to in paragraph 4, may extend the term of office of the Executive Director once for a period of no more than five years.

The Management Board shall inform the European Parliament if it intends to extend the Executive Director's term of office. Before the Management Board takes a decision to extend the Executive Director's term of office, the Executive Director may be invited to make, without delay, a statement before the competent committee or committees of the European Parliament and answer questions from the committee members.

6. An Executive Director whose term of office has been extended shall 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 acting on a proposal from the Commission. The European Parliament and the Council shall be informed, in a manner that complies with the applicable confidentiality requirements, about the reasons for such a decision.

8. The Management Board shall reach decisions on the 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 the right to vote.

Article 30

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 her or his duties and shall neither seek nor take instructions from any government or from any other body.

3. The Executive Director shall report to the European Parliament on the performance of her or his duties when invited to do so. The Council may invite the Executive Director to report on the performance of her or 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 Agency's specific tasks set out 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 36 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 and 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 33(5), where such co-financing is to be granted to the national focal points;

(g) proposing to the Management Board the method for calculating fees and the way fees are paid in accordance with Article 38;

(h) preparing a follow-up action plan in relation to the conclusions of internal or external audit reports and evaluations, and to 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, where appropriate, by imposing effective, proportionate and dissuasive administrative penalties and by reporting any criminal conduct to the EPPO in accordance with Article 24 of Regulation (EU) 2017/1939 in respect of which the EPPO could exercise its competence;

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

(k) preparing the draft for the 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 post one or more liaison officers to the Union institutions and to relevant Union bodies, offices and agencies 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. Decisions to post liaison officers shall specify, in a manner that avoids unnecessary costs and a duplication of the administrative functions of the Agency, the scope of the activities to be carried out by the liaison officers.

7. Where called upon by the European Parliament or by the Council, the Executive Director shall attend, without undue delay, meetings organised by the European Parliament or the Council, as the case may be, on any subject related to the Agency's mandate.

Article 31

Scientific Committee

1. The Scientific Committee shall be composed of no less than seven and no more than 15 scientists appointed by the Management Board in view of their scientific excellence and their independence, following the publication of a call for expressions of interest in the *Official Journal of the European Union* and in other appropriate media. The Agency shall inform the competent committee or committees of the European Parliament of appointments to the Scientific Committee and about its work. The procedure for selecting members of the Scientific Committee 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. The parties involved in appointing members to the Scientific Committee shall aim to achieve gender-balanced representation 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 or 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, that there is a lack of independence on the part of a member and revoke the appointment of that member. The Management Board shall appoint a new member for the remaining term of office of that member in accordance with the ordinary procedure for the appointment of 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 considered 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 or the group of new psychoactive substances. 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 a 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 32

The European Information Network on Drugs and Drug Addiction

1. Through the European Information Network on Drugs and Drug Addiction (the 'Reitox network') the Member States shall contribute to the Agency's task of collecting and reporting consistent and standardised information on the drugs phenomenon across the Union. The Reitox network shall consist of the national focal points designated in accordance with Article 33 and a focal point for the Commission.

2. The Reitox network shall elect a Spokesperson and between one and three Deputy Spokespersons from among its members. The Spokesperson shall represent the Reitox network in relation to the Agency and shall be allowed to participate as an observer in the meetings of the Management Board.

3. The Reitox network shall hold at least one ordinary meeting a year. The Agency shall convene and chair the meetings. In addition, the Reitox network shall meet on the initiative of its Spokesperson or at the request of at least one-third of its members.

Article 33

National focal point

1. Each participating country shall designate a single national focal point, set up through appropriate national legal or administrative measures on a permanent basis and with a clear mandate. The designation of a national focal point and the appointment of the head of a 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 34(2). The head of the national focal point or an alternate shall represent the national focal point in the Reitox network.

3. National focal points shall be scientifically independent and ensure the quality of their data.

4. National focal points shall plan their activities in advance and shall have adequate budgetary and human resources allocated by national budgets and co-financed by the Agency in accordance with paragraph 5 of this Article to fulfil their mandate and carry out their tasks set out in Article 34(2), and shall have sufficient equipment and facilities to support their daily activities.

5. The core costs of the national focal point of each Member State shall be co-financed through a grant provided by the Agency provided that it complies with the conditions set out in paragraphs 1 to 4. In order to receive that 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. The Agency may provide additional funding to national focal points on an ad hoc basis for the participation in and delivery of specific projects.

6. The Agency shall assess national focal points in accordance with Article 35.

Article 34

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 achieving its general and specific tasks set out in Articles 4 and 5, respectively, thus contributing to coordinated Union action, each national focal point shall carry out the following tasks:

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

(b) collect relevant national data and information in the areas covered by Article 4 in accordance with 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 shall, wherever relevant, cooperate with experts and national organisations, the scientific community, civil society organisations and other relevant stakeholders active in the field of drugs policy;

(c) contribute to monitoring drugs and drug use and reporting thereon, including to international organisations;

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

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

(f) 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 and with information on possible measures related to health;

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

(h) 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;

(i) nominate, when requested by the Agency, national experts for specific discussions on 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 its activities to the Agency and other relevant stakeholders;

(l) implement quality assurance mechanisms to ensure the reliability of the data and information it obtains.

3. In accordance with their capacity, the national focal points shall monitor, analyse and interpret relevant information in the areas covered by Article 4. The national focal points shall provide that information and information on policies and solutions applied to the Agency.

4. The national focal points shall establish and maintain 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 pursuant to paragraph 2.

5. When collecting data pursuant to this Article, the national focal points shall ensure, where possible, that the data collected are disaggregated by sex or gender. The national focal points shall consider the gender-sensitive aspects of drugs policy when collecting and presenting data pursuant to this Article. The national focal points shall not transmit any data which would make it possible to identify individuals or small groups of individuals. They shall refrain from transmitting any information relating to specific individuals.

Article 35

Assessment of the national focal points

1. The Agency shall assess whether each national focal point, by carrying out the tasks set out in Article 34(2), contributes to the achievement of the tasks of the Agency. Such assessments shall not concern other functions of the body hosting the national focal point or the overall structure in which the national focal point is embedded.

2. The assessment referred to in paragraph 1 shall be based on relevant information to be provided by the national focal point. If necessary, the Agency may visit the national focal point.

3. The Agency shall present each assessment it carries out pursuant to paragraph 1 to the national focal point and national competent authority concerned. Assessments may include recommendations for carrying out the tasks set out in Article 34(2), set a timeline for their implementation and offer support from the Agency to national focal points for the purposes of capacity building.

4. Where recommendations, together with a timeline for their implementation, have been issued pursuant to paragraph 3, the national focal point concerned shall either inform the Agency that it has accepted the recommendations or, in the event of disagreement, provide the Agency with a written reasoned opinion.

5. The Agency shall inform the Management Board of the outcome of assessments carried out pursuant to paragraph 1 at its first meeting following the completion of the assessment by the Agency. In the event of disagreement between the Agency and the national focal point as referred to in paragraph 4 of this Article, the Agency shall submit the assessment, the recommendations and the timeline for their implementation for the approval of the Management Board at its next meeting by a majority of its members with the right to vote in accordance with Article 23. The representative of the Member State concerned shall not take part in that vote.

6. If, by the time specified in an assessment as referred to in paragraph 1, the national focal point does not fulfil the tasks set out in Article 34(2), the Management Board shall take a decision, at its first meeting following the time specified in the assessment by a majority of two-thirds of members with the right to vote, in accordance with Article 23, as to whether not to provide co-financing until the national focal point carries out the tasks set out in Article 34(2). The representative of the Member State concerned shall not take part in that vote.

7. The first assessment pursuant to paragraph 1 of each national focal point shall be carried out by the Agency by … [24 months after the date of application of this Regulation]. Thereafter, the Agency shall assess national focal points at regular intervals, as necessary.

Chapter VI
Financial provisions

Article 36

Single programming document

1. By 15 December of each year, the Management Board shall adopt a draft single programming document containing multiannual and annual programming and the documents listed in Article 32 of Commission Delegated Regulation (EU) 2019/715[1], 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. Where the Management Board decides not to follow elements of the opinion of the Commission or elements arising following the consultation of the European Parliament or of the Scientific Committee, it shall provide a justification. The Management Board shall forward the single programming document to the European Parliament, the Council and the Commission by 31 January of the following year.

[1] 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).

The Single Programming Document shall become final once the general budget of the Union has been definitively adopted and shall, if necessary, 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 multiannual 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.

Multiannual or annual programming shall include information about the implementation of the international cooperation framework referred to in Article 20(1), point (a), and the actions linked to that framework. It shall also include the Agency's planned research and innovation activities referred to in Article 21.

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 multiannual work programme shall set out overall strategic programming including objectives, expected results and performance indicators. It shall also set out resource programming, including the multiannual 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 multiannual and annual work programmes shall be prepared in compliance with Article 32 of Delegated Regulation (EU) 2019/715.

Article 37

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 Union;

(b) any voluntary financial contribution from the Member States;

(c) the fees paid for services rendered in accordance with Article 38;

(d) any financial contributions from the organisations and bodies and third countries referred to in Articles 53 and 54, respectively; and

(e) Union funding under indirect management or in the form of ad hoc grants in accordance with the financial rules applicable to the Agency and with the provisions of the relevant instruments supporting the policies of the Union.

4. The amount and origin of any revenue as referred to in paragraph 3, points (b) to (e), shall be included in the annual accounts of the Agency and clearly detailed in the annual report on the Agency's budgetary and financial management referred to in Article 41(3).

5. 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 33(5).

Article 38

Fees

1. The Agency may deliver upon request the following additional services:

(a) customised training;

(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, in particular candidate countries, pursuant to Article 20(3);

(e) other customised services rendered at the request of a participating country which require the investment of additional resources in the support of national activities.

The Agency shall charge fees for the delivery of services as referred to in the first subparagraph.

2. At the proposal of the Executive Director and after having consulted the Commission, the Management Board shall set, in a transparent manner, the method for calculating the fees and the way in which they are paid.

3. Fees shall be proportionate to the costs of the service delivered 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 shall be set at such a level as to avoid a deficit or a significant accumulation of surplus in the Agency's budget. If a significant positive balance in the budget, resulting from the provision of the services covered by fees, becomes recurrent, or if a significant negative balance results from the provision of the services covered by fees, the Management Board shall revise the method for calculating the fees in accordance with the procedure set out in paragraph 2.

5. Where applicable, the Agency shall include a report on the fees levied and their impact on the Agency's budget as part of the procedure for the presentation of accounts laid down in Article 41.

Article 39

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 the draft referred to in paragraph 1, adopt a provisional draft statement of estimates of the Agency's revenue and expenditure for the following financial year.

3. The provisional draft statement of estimates 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 statement of estimates to the Commission by 31 March.

4. The Commission shall send the statement of estimates of the Agency's revenue and expenditure to the budgetary authority together with the draft general budget of the Union.

5. On the basis of the statement of estimates of the Agency's revenue and expenditure, 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 of the Treaty on the Functioning of the European Union (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 Management Board shall adopt the Agency's budget by a majority of two-thirds of members with the right to vote. The budget shall become final once the general budget of the Union has been definitively adopted. Where necessary, the budget shall be adjusted accordingly.

9. Delegated Regulation (EU) 2019/715 applies to any building project likely to have significant implications for the budget of the Agency.

Article 40

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 41

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 the Court of Auditors.

2. 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.

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

4. On receipt of the Court of Auditors' observations on the Agency's provisional accounts pursuant to Article 246 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council[1], the Executive Director shall draw up the Agency's final accounts under her or his own responsibility and submit them to the Management Board for an opinion.

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

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

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

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

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[1] 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).

9. The Executive Director shall submit to the European Parliament, at the European Parliament'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 Regulation (EU, Euratom) 2018/1046.

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 42

Financial rules

The Management Board shall adopt the financial rules applicable to the Agency after consulting the Commission. The financial rules 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 43

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 the 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 comply with the Staff Regulations and the Conditions of Employment of Other Servants.

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 and the Conditions of Employment of Other Servants shall not apply to seconded national experts or other staff not employed by the Agency.

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

Protocol No 7 on the Privileges and Immunities of the European Union annexed to the TEU and to the TFEU shall apply to the Agency and its staff.

Article 46

Language arrangements

Council Regulation No 1[1] shall apply to the Agency.

Article 47

Transparency

1. Regulation (EC) No 1049/2001 shall apply to documents held by the Agency.

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

2. Regulation (EU) 2018/1725 of the European Parliament and of the Council[1] shall apply to the processing of personal data by the Agency.

3. The Management Board shall, within six months of the date of its first meeting after … [the date of application of this Regulation], establish measures for the application of Regulation (EU) 2018/1725 by the Agency, including those concerning the appointment of the Agency's data protection officer. Those measures shall be established after consultation of the European Data Protection Supervisor.

Article 48

Combatting fraud

1. In order to combat fraud, corruption and other unlawful activities, Regulation (EU, Euratom) No 883/2013 shall apply to the Agency.

2. The Agency shall accede to the Interinstitutional Agreement of 25 May 1999 concerning internal investigations by OLAF by ... [three months after the date 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.

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[1] 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).

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, with 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 Council Regulation (Euratom, EC) No 2185/96[1].

5. Without prejudice to paragraphs 1 to 4 of this Article, working arrangements and 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 the audits and investigations referred to in paragraphs 3 and 4 of this Article, in accordance with their respective competence.

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[1] 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 Decisions (EU, Euratom) 2015/443 and (EU, Euratom) 2015/444. The security rules of the Agency shall cover, *inter alia*, 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 with another Union body, office or agency within the framework of administrative arrangements. Administrative arrangements shall be subject to the authorisation of the Management Board after consultation of the Commission. In the absence of an administrative arrangement, any exceptional ad hoc release of EUCI to another Union body, office or agency 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.

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 Staff Regulations or Conditions of Employment of Other Servants.

Article 51

Evaluation and review

1. By … [five years after the date of application of this Regulation], and every five years thereafter, the Commission shall assess the Agency's performance in relation to its objectives, mandate, tasks and location in accordance with Commission guidelines. Such evaluations shall, in particular, address the possible need to modify the mandate of the Agency and the financial implications of any such modification. In its first evaluation, the Commission shall pay particular attention to the changes to the Agency's mandate and tasks introduced by this Regulation.

2. On the occasion of every second evaluation, the Commission shall also assess the results achieved by the Agency having regard to its objectives, mandate and tasks, including whether the continuation of the Agency is justified with regard to those objectives, mandate and tasks.

3. The Commission shall report to the European Parliament, the Council and the Management Board on the findings of evaluations under this Article. The findings of evaluations 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 bodies, in particular Union, governmental and non-governmental bodies, and with technical bodies competent in matters covered by this Regulation, within the framework of working arrangements concluded with such bodies, in accordance with the TFEU and the provisions on the competence of such bodies. Such working arrangements shall not cover the exchange of classified information.

2. The Management Board shall adopt working arrangements as referred to in paragraph 1 based on drafts submitted by the Executive Director and after the Commission's prior approval. Where the Commission expresses its disagreement with such working arrangements, the Management Board shall adopt them by a three-fourths majority of members with the right to vote.

3. The Management Board shall adopt 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, based on drafts submitted by the Executive Director and after informing the Commission.

4. The Agency shall publish working arrangements entered into pursuant to this Article on its website.

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 that 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, arrangements as referred to in the first subparagraph shall comply with the Staff Regulations.

Article 55

Cooperation with civil society organisations

1. The Agency shall maintain cooperation with relevant civil society organisations active in the fields covered by this Regulation at national, Union or international level for the purposes of consultation, the exchange of information and the pooling of knowledge through the involvement of those civil society organisations. To that end, the Agency shall designate a single contact point under the authority of the Executive Director to ensure the regular provision of information to civil society organisations on its activities, including by setting up a dedicated webpage or by other relevant means. The Agency shall allow civil society organisations to submit data and information relevant to its activities.

2. When considering specific topics, the Agency shall, where relevant, conduct dedicated exchanges with civil society organisations with relevant qualifications and experiences on the topic concerned.

3. Civil society organisations as referred to in paragraphs 1 and 2 shall be registered in the Transparency Register, established by the Interinstitutional Agreement of 20 May 2021 between the European Parliament, the Council of the European Union and the European Commission on a mandatory transparency register[1]. The Agency shall make the list of those civil society organisations public.

Article 56

Headquarters Agreement and operating conditions

1. The necessary arrangements concerning the accommodation to be provided for the Agency in the Member State in which the Agency has its seat, the facilities to be made available by that Member State and the specific rules applicable in that Member State to members of the Management Board, Agency staff, including the Executive Director, and members of their families shall be laid down in a Headquarters Agreement between the Agency and that Member State.

2. The Member State in which the Agency has its seat 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.

[1] OJ L 207, 11.6.2021, p. 1.

Article 57

Legal succession

1. The Agency shall be the legal successor in respect of all contracts concluded by, liabilities incumbent upon and properties acquired by the EMCDDA.

2. This Regulation shall not affect the legal force of agreements and arrangements concluded by the EMCDDA before … [the date of application of this Regulation].

Article 58

Transitional arrangements concerning the Management Board

1. The Management Board of the EMCDDA shall continue its work and functioning based on Regulation (EC) No 1920/2006 and the rules established thereunder until all representatives of the Management Board are appointed in accordance with Article 23 of this Regulation.

2. By … [9 months after the date of entry into force of this Regulation], the Member States shall notify the Commission of the names of the persons whom they have appointed as members and alternates of the Management Board in accordance with Article 23.

3. The Management Board established in accordance with Article 23 shall hold its first meeting by … [one month after the date of the application of this Regulation]. On that occasion, the Management Board may adopt its rules of procedures.

Article 59

Transitional arrangements concerning the Executive Director

1. The Director of the EMCDDA, appointed on the basis of Article 11 of Regulation (EC) No 1920/2006, shall, for the remaining period of her or his term of office, be assigned the responsibilities of Executive Director as provided for in Article 30 of this Regulation. The other conditions of her or his contract shall remain unchanged.

   If the term of office of the Director of the EMCDDA ends between … [the date of entry into force of this Regulation] and … [the date of application of this Regulation], and if that term has not already been extended under Regulation (EC) No 1920/2006, it shall be extended automatically until … [12 months after the date of application of this Regulation].

2. Where the Director appointed on the basis of Article 11 of Regulation (EC) No 1920/2006 is unwilling or unable to act in accordance with paragraph 1 of this Article, the Management Board 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 of the Executive Director in accordance with Article 29(2).

Article 60

Transitional arrangements concerning the national focal points

By … [11 months after the date of entry into force of this Regulation], the members of the Management Board shall provide the Agency with the name of the institutions designated as national focal points in accordance with Article 33(1) and the name of the heads of the national focal points. For that purpose, the members of the Management Board may send 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 of that Regulation.

Article 62

Repeal of Regulation (EC) No 1920/2006

1. Regulation (EC) No 1920/2006 is repealed with effect from … [the date of application of this 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 … [the date of application of this 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 … [12 months after the date of entry into force of this Regulation].

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

Done at Brussels,

For the European Parliament	*For the Council*
The President	*The President*

ANNEX

Correlation table

Regulation (EC) No 1920/2006	This Regulation
Article 1(1)	Article 1
Article 8	Article 2
–	Article 3
Article 1(2)	Article 4
Article 2	Article 5
Article 1(3) and (5), Article 2, points (a), (b) and (c)	Article 6
Annex I	Article 7
Articles 5a to 5d	Articles 8 to 11
–	Article 12
–	Article 13
–	Article 14
–	Article 15
–	Article 16
–	Article 17
–	Article 18
–	Article 19
Article 2(d)	Article 20
–	Article 21
–	Article 22
Article 9(1)	Article 23
–	Article 24

Regulation (EC) No 1920/2006	This Regulation
Article 9(2)	Article 25
Article 9(3)	Article 26
Article 9(1), third subparagraph	Article 27
Article 10	Article 28
Article 11	Articles 29 and 30
Article 13	Article 31
Article 5(1)	Article 32
Article 5(3)	Article 33
Article 5(2)	Article 34
–	Article 35
Article 9(4), (5) and (6)	Article 36
Article 14(1) to (4)	Article 37
–	Article 38
Article 14(5) to (9)	Article 39
Article 15(1)	Article 40
Article 15(2) to (9)	Article 41
–	Article 42
Article 18	Article 43
Article 18, fifth paragraph	Article 44
Article 17	Article 45
–	Article 46
Articles 6 and 7	Article 47
Article 16	Article 48
–	Article 49
Article 19	Article 50

Regulation (EC) No 1920/2006	This Regulation
Article 23	Article 51
–	Article 52
Article 20	Article 53
Article 21	Article 54
–	Article 55
–	Article 56
–	Article 57
–	Article 58
–	Article 59
–	Article 60
–	Article 61
Article 24	Article 62
Article 25	Article 63