EUROPEAN
COMMISSION

Brussels, 12.1.2022
COM(2022) 18 final

2022/0009 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the European Union Drugs Agency

{SWD(2022) 8 final} - {SWD(2022) 9 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

Illicit drugs are a complex security and health problem that affects millions of people in the EU and globally. The European Drug Report 2021[1] points out that 83 million adults in the EU are estimated to have tried illicit drugs during their lives. In 2019, at least 5,150 overdose deaths occurred in the EU, with a steady increase every year since 2012, including among teenagers aged 15-19. The report also shows a deteriorating situation concerning the volumes of cocaine and heroin introduced in the EU, which is at an all-time high. Production of drugs, in particular synthetic drugs (amphetamines and ecstasy), takes place within the EU both for domestic consumption and for export[2]. The drug market is estimated at a minimum retail value of EUR 30 billion per year[3], and it remains the largest criminal market in the EU and a major source of income for organised crime groups[4].

Cannabis is the most commonly used drug. The use of heroin and other opioids continues to be most commonly associated with the more harmful forms of drug use. Crack cocaine is increasingly available; different illicit drugs are also becoming available in smaller doses or cheaper packages, considered more suited for home use. A rise in use of benzodiazepines[5] is also observed among high-risk drug users, prisoners and some groups of recreational drug users, potentially reflecting the high availability and low cost of these substances as well as pandemic-related mental health issues. Among people who use drugs, poly-substance use[6] is widespread having a detrimental impact on public health. Furthermore, increased availability of other drugs, particularly cocaine and some synthetic substances, is associated with increased levels of drug related violence and other crimes[7].

According to the latest studies[8], drug markets have been remarkably resilient to disruption caused by the pandemic. Not only were drugs production and trafficking largely unaffected but the pandemic also brought increased risks for marginalised populations. During the initial lockdowns related to the COVID-19 pandemic, some changes in routes and methods at wholesale level, as well as disruptions and some local shortages have been observed. Nevertheless, drug sellers and buyers have adapted to the new situation quickly, notably by increasing the use of encrypted messaging services, social media applications, online sources

---

1 European Monitoring Centre for Drugs and Drug Addiction (EMCDDA), European Drug Report 2021, European Drug Report 2021 | www.emcdda.europa.eu.

2 In 2019, more than 370 illegal drug production laboratories were dismantled in Europe; European Drug Report 2021.

3 EMCDDA/Europol, EU Drug Markets Report 2019, https://www.emcdda.europa.eu/2019/drug-markets.

4 See Transcrime, From illegal markets to legitimate businesses: the portfolio of organised crime in Europe, 2015, http://www.transcrime.it/wp-content/uploads/2015/03/OCP-Full-Report.pdf; Europol, Serious and Organised Crime Threat Assessment (SOCTA), 2021.

5 This includes the misuse of benzodiazepines diverted from therapeutic use or appearing as new benzodiazepines. 'New benzodiazepines' are defined as new psychoactive substances that contain a benzodiazepine core, and that are not controlled under the international drug control system.

6 The World Health Organisation defines poly-drug use as the use of more than one substance or type of substance by an individual consumed at the same time or sequentially within a short period of time. Source: https://www.who.int/substance_abuse/terminology/who_lexicon/en/.

7 EMCDDA/Europol, EU Drug Markets Report 2019, https://www.emcdda.europa.eu/2019/drug-markets.

8 EMCDDA, European Drug Report 2021; EMCDDA, Impact of COVID-19 on drug markets, use, harms and drug services in the community and prisons, April 2021 | www.emcdda.europa.eu.

as well as mail and home delivery services. The reduction in drug consumption seen during the initial lockdowns disappeared with the easing of restrictions on movement. As a result, by mid-2021, the levels of use of most drugs bounced back to pre-COVID levels or possibly even higher. Moreover, no decline in supply was noted. On the contrary, multi-tonne seizures of cocaine were reported in European ports in 2020 and early 2021, while cannabis cultivation and synthetic drug production within the European Union continued at pre-pandemic levels during 2020, with increasing numbers of cases involving cannabis adulterated with synthetic cannabinoids. While drugs services across Europe, including low-threshold services, drug consumption rooms, and residential and outpatient treatment services, returned to operation, they continue to be limited by strict COVID-19 measures in place and operate at reduced capacity.

These developments call for effective action at Union level. The EU Drugs Strategy 2021-2025[9] and the EU Drugs Action Plan 2021-2025[10] provide the strategic framework for this. The Strategy *inter alia* invites the Commission "*to present a proposal to revise the mandate of the EMCDDA [European Monitoring Centre for Drugs and Drug Addiction*[11]*] as soon as possible, to ensure that the agency plays a stronger part in addressing the current and future challenges of the drug phenomenon*"[12]. The current proposal delivers on this commitment.

In 2018/19, the Commission carried out the fourth evaluation of the Centre in line with the requirements of Regulation (EC) No 1920/2006[13]. It concluded that the Centre works overall well, but further improvements are possible in several areas, in particular in view of the developments of the drug phenomenon.

This finding has been further substantiated during regular contacts with the Centre and its stakeholders, which underlined an increasing disconnect between the complexity and rapid developments of the drug phenomenon and what the Centre's mandate provides for. Regulation (EC) No 1920/2006 does not reflect the current reality of the drug phenomenon and is out of step with the tasks the Centre needs to perform to address the current and future challenges of the drug phenomenon.

Therefore, this proposal provides for a **targeted revision** of the mandate of the European Monitoring Centre for Drugs and Drug Addiction, and seeks to strengthen its mandate in order to ensure that the future Agency can react effectively to new challenges, provide better support to Member States, and contribute to developments at the international level. Notably, the proposal aims to expressly cover poly-substance, i.e. other substance-based addictions when these substances are taken together with illicit drugs; to strengthen monitoring and threat assessment capabilities; to establish a laboratory to ensure that all forensic and toxicological information is available to the Agency; to reinforce the position of national focal points to ensure that they are able to provide relevant data; to establish the competence of the Agency to develop EU-level prevention and awareness raising campaigns as well as issue alerts in case particularly dangerous substances are available on the market. Finally, the proposal clarifies the role of the Agency in the international arena[14]. At the same time, the proposal will also adapt the institutional framework of the Agency to the common approach

9 OJ C 102I , 24.3.2021, p. 1.
10 OJ C 272, 8.7.2021, p. 2.
11 Regulation (EC) No 1920/2006 of the European Parliament and of the Council of 12 December 2006 on the European Monitoring Centre for Drugs and Drug Addiction (recast), OJ L 376, 27.12.2006, p. 1–13
12 EU Drugs Strategy 2021-2025, Strategic Priority 11, point 5.
13 COM(2019) 228.
14 For details, see the preferred option described below in Section 3.

of the European Parliament, the Council of the EU and the European Commission on decentralised EU agencies[15].

- **Consistency with existing policy provisions in the policy area**

This legislative proposal takes account of a wide range of EU policies in the area of internal security and public health.

When it comes to drugs policies, this legislative proposal takes account of the EU Drugs Strategy 2021-2025 and the related Action Plan. It also takes account of the amendment of Regulation (EC) No 1920/2006[16] as well as several acts to add substances to the definition of drugs under Council Framework Decision 2004/757/JHA[17].

This legislative proposal also takes account of cooperation of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) with other Union bodies, in particular the European Union Agency for Law Enforcement Cooperation (Europol)[18], the European Union Agency for Criminal Justice Cooperation (Eurojust)[19], the European Union Agency for Law Enforcement Training (CEPOL), the European Medicines Agency (EMA)[20], and the European Centre for Disease Prevention and Control (ECDC)[21], but also other EU decentralised agencies and bodies.

---

15 The common approach on EU decentralised agencies puts in place a comprehensive set of guiding principles to make the functioning of the EU's decentralised agencies more coherent, effective and accountable; see Joint Statement of the European Parliament, the Council of the European Union and the European Commission on decentralised agencies – Common Approach, 2012; https://europa.eu/european-union/sites/europaeu/files/docs/body/joint_statement_and_common_approach_2012_en.pdf.

16 Regulation (EU) 2017/2101 of the European Parliament and of the Council of 15 November 2017 amending Regulation (EC) 1920/2006 as regards information exchange on, and an early warning system and risk assessment procedure for, new psychoactive substances (OJ L 305, 21.11.2017, p. 1).

17 OJ L 335, 11.11.2004, p. 8. See also Directive (EU) 2017/2103 of the European Parliament and of the Council of 15 November 2017 amending Council Framework Decision 2004/757/JHA in order to include new psychoactive substances in the definition of 'drug' and repealing Council Decision 2005/387/JHA (OJ L 305, 21.11.2017, p. 12). Commission Delegated Directive (EU) 2019/369 of 13 December 2018 amending the Annex to Council Framework Decision 2004/757/JHA as regards the inclusion of new psychoactive substances in the definition of 'drug' (OJ L 66, 7.3.2019, p. 3); Commission Delegated Directive (EU) 2020/1687 of 2 September 2020 amending the Annex to Council Framework Decision 2004/757/JHA as regards the inclusion of the new psychoactive substance *N*,*N*-diethyl-2-[[4-(1-methylethoxy)phenyl]methyl]-5-nitro-1*H*-benzimidazole-1-ethanamine (isotonitazene) in the definition of 'drug' (OJ L 379, 13.11.2020, p. 55); Commission Delegated Directive (EU) 2021/802 of 12 March 2021 amending the Annex to Council Framework Decision 2004/757/JHA as regards the inclusion of the new psychoactive substances methyl 3,3-dimethyl-2-{[1-(pent-4-en-1-yl)-1*H*-indazole-3-carbonyl]amino}butanoate (MDMB-4en-PINACA) and methyl 2-{[1-(4-fluorobutyl)-1*H*-indole-3-carbonyl]amino}-3,3-dimethylbutanoate (4F-MDMB-BICA) in the definition of 'drug' (OJ L 178, 20.5.2021, p. 1).

18 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. 53–114).

19 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. 138–183).

20 Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1–33).

21 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. 1–11).

- **Consistency with other Union policies**

This legislative proposal takes account of other relevant Union policies that have been adopted or launched since the entry into force of Regulation (EC) No 1920/2006 on the European Monitoring Centre for Drugs and Drug Addiction (recast).

As regards innovation, this legislative proposal takes account of EU funding for drugs policy under Horizon 2020[22], the Internal Security Fund[23], the Drugs Policy Initiatives under the Justice Programme[24], the EU4Health Programme[25], and Horizon Europe[26].

As regards public health, this legislative proposal takes account of the establishment of an early warning and response system in relation to serious cross-border threats to health[27][28] and the proposals for the changes in the mandates of some of the above-mentioned agencies[29]. When considering cooperation with Union agencies and bodies, the proposal also considered the establishment of the European Health Emergency Preparedness and Response Authority (HERA)[30].

As regards the Agency's cooperation with third countries, this legislative proposal takes account of the Union's external policies.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

- **Legal basis**

Regulation (EC) No 1920/2006 of the Agency was based on Article 152 of the Treaty establishing the European Community, i.e. on the public health legal basis. This provision corresponds to Article 168 of the Treaty on the Functioning of the European Union (TFEU).

---

22 Regulation (EU) 2021/695 of the European Parliament and of the Council of 28 April 2021 establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013 (OJ L 170, 12.5.2021, p. 1–68).

23 Regulation (EU) No 513/2014 of the European Parliament and of the Council of 16 April 2014 establishing, as part of the Internal Security Fund, the instrument for financial support for police cooperation, preventing and combating crime, and crisis management and repealing Council Decision 2007/125/JHA (OJ L 150, 20.5.2014, p. 93–111). See also the Commission proposal for the Internal Security Fund for the next multiannual financial framework (COM(2018) 472 final).

24 Regulation (EU) No 1382/2013 of the European Parliament and of the Council of 17 December 2013 establishing a Justice Programme for the period 2014 to 2020 (OJ L 354, 28.12.2013, p. 73–83).

25 Regulation (EU) 2021/522 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014 (OJ L 107, 26.3.2021, p. 1–29).

26 COM(2018) 435 final.

27 Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1–15); see also the Commission proposal for a Regulation of the European Parliament and the Council on serious cross-border threats to health and repealing Decision No 1082/2013/EU, COM(2020) 727 final.

28 Commission Implementing Decision (EU) 2017/253 of 13 February 2017 laying down procedures for the notification of alerts as part of the early warning and response system established in relation to serious cross-border threats to health and for the information exchange, consultation and coordination of responses to such threats pursuant to Decision No 1082/2013/EU of the European Parliament and of the Council (OJ L 37, 14.2.2017, p. 23–27), which includes illicit drugs related threats.

29 For Europol, see COM(2020) 796 final; for the health agencies, see in general COM(2020) 724, and in more detail for EMA COM(2020) 725 and for ECDC COM(2020) 726.

30 The related inception impact assessment can be found under the following link: European Health Emergency Preparedness and Response Authority (HERA) (europa.eu).

Article 168(1), third subparagraph, TFUE reads: "*The Union shall complement the Member States' action in reducing drugs-related health damage, including information and prevention*". Article 168(5) TFUE provides that the European Parliament and the Council may adopt "*measures concerning monitoring, early warning of and combating serious cross-border threats to health*".

Addressing supply and drug market related issues supports reducing the availability of drugs in the EU and curbing drug demand and ultimately public health. The health and security dimensions of the drug phenomenon are intrinsically linked and cannot be addressed separately. Therefore, the content of this legislative proposal is covered by the public health legal basis and does not go beyond what is possible under that legal basis.

- **Subsidiarity (for non-exclusive competence)**

EU action to revise the mandate of the Agency is **necessary**.

The drug phenomenon affects all Europeans and is cross-border and multi-jurisdictional in nature, in particular when it comes to drug markets and organised crime. There are many common challenges across Member States, both on the health and security side, which need to be tackled. It is not possible to address the drug phenomenon only on a national or regional/sub-national level as drug trafficking is a transnational crime. Organised crime groups involved in drug trafficking exploit differences in regulatory and legal approaches across Member States. A problematic health or security pattern detected in a Member State very often appears in other Member States as well. National legislation or even the best national practice would not be able to address the cross-border aspects of the drug phenomenon. Due to this transnational character, there is thus a need for EU-level action.

This legislative proposal will lead to considerable **EU added value**. Adopting a targeted revision of the Agency's mandate, thereby enabling it to address current and future challenges, is in the interest of the EU, in particular in view of the recent deterioration of the drug situation in the EU characterised by the widespread availability of a diverse range of drugs of increasingly high purity or potency, supported by the misuse of innovation and technological developments, and leading to more complex patterns of use and an increasing impact on public health and security. The revision of the mandate of the Agency is part of the reaction of the EU to these developments.

As the evaluation showed, the Agency has an important added value compared to addressing the drug phenomenon solely at national level. Many of the phenomena are by nature cross-border, and increasingly global, and therefore cannot be addressed by a Member State alone. However, the current mandate of the Agency is limiting its action, the support it can give to Member States, and the role it can play internationally. The fact that, for example, the Agency's current mandate covers poly-substance use only to a limited extent, leads to a loss of the EU-level overview of the drug phenomenon, with data collected being fragmented or possibly non-existent. This would run contrary to the requirements of the EU's evidence-based policy-making in drugs policy, which relies on a neutral body to provide factual and objective data. The targeted revision proposed in this legislative proposal strengthens the Agency in crucial areas to enable it to address these common issues better.

The revision of current mandate would also contribute to a reduction of the administrative burden for and a simplification of administrative procedures in the Member States. Among the contributing factors to this are the proposed streamlining and centralisation of reporting obligations in the Member States through the national focal points, monitoring drug markets and maintaining an early warning system and drug alert system, organisation of training,

development of best practices, etc. This would lead to a reduction of administrative costs in the Member States. Another example is that better information would be available from the Agency for the benefit not only of the EU but also of the Member States. Member States on their own would not be able to collect and analyse data to the same extent as they lack either the knowledge or the resources, or the problem is a cross-border one. The latter element is also an argument for administrative simplification as no Member State could address those issues on their own and cooperating with numerous countries would lead to a high administrative burden.

- **Proportionality**

The proposal is **proportionate** as it is the only way for the necessary changes in the Agency's mandate to come about.

EU-level action does not intend to replace national actions or authorities nor to question their relevance. The drug phenomenon can only be addressed if all levels – EU, national and local – work together. The current proposal will not go beyond what is proportionate to tackle an EU-wide phenomenon.

When it comes to the possible new rules and responsibilities of the national focal points, it will remain for the Member States to decide exactly how they want to set up a national focal point. However, in order to ensure that the national focal points are in a position to provide to the EU-level what is necessary and to access the funding available at EU level, they should comply with a set of minimum requirements. Moreover, as the provision of the core data from the Member States to the Agency through the national focal points is the basis for the overall drug monitoring system, it is proportionate to set such minimum requirements.

- **Choice of the instrument**

Given that Agency's mandate is set out in Regulation (EC) No 1920/2006, the revision of its mandate has to take the form of a Regulation as well.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Stakeholder consultations**

The main stakeholder consultation for this proposal was undertaken as part of the evaluation of the Agency carried out in 2018/19. This process included an extensive stakeholder consultation, including a 12-weeks public consultation. The details of this stakeholder consultation are available in Annex III of the related Staff Working Document[31]. The Annex also includes a short summary of the outcomes of the public consultation. The synopsis report of the public consultation has been published as Annex 5 of the evaluation report[32].

In addition, the views of specific stakeholders, such as the Member States, the national focal points or other agencies, were adequately addressed through meetings and/or particular information requests.

Several discussions in view of the revision of the mandate of the Agency have taken place since the study of the consultant has been done, including discussions in the Management

[31] SWD(2019) 174.

[32] ICF, Final report – External evaluation of the EMCDDA, November 2018; link: https://op.europa.eu/en/publication-detail/-/publication/4eaca79c-72f6-11e9-9f05-01aa75ed71a1/language-en/format-PDF/source-search.

Board of the EMCDDA in December 2018 and June 2019, presentation of the evaluation results to the Horizontal Drugs Group in July 2019, presentation to the heads of national focal points in their meeting in May 2019.

In 2019 and 2020, several formal and informal meetings took place. This included informal meetings with different staff members of the Agency, the head of the national focal points, the Civil Society Forum on Drugs, and representatives of Member States.

More formal meetings were also organised by the Commission services. A virtual meeting with the core group of the Civil Society Forum on Drugs took place on 1 July 2020. The proposed revision of the EMCDDA mandate was also discussed at the Plenary meeting of the Civil Society Forum on Drugs on 8 October 2020. A discussion on the aspects related to the national focal points took place at the technical meeting of the Reitox network on 7 October 2020 and at the Head of National Focal Points meeting on 26 November 2020. A virtual informal workshop was organised for the members of the EMCDDA Management Board on 26 October 2020, which discussed the policy option and the main ideas for the preferred option.

During these exchanges, the need to adapt the EMCDDA regulation to the current challenges relevant to drugs, such as poly-substance use, and to ensure appropriate funding to the Agency were underlined. Participants called for further development of the monitoring, data collection and the assessment capacities of the Agency, as well as of its competence to initiate information campaigns and risk communication, strengthening its relationship with Member States' authorities, and in particular National Focal Points. The role of EMCDDA in relation with the international drug policy was also underlined and the need for proper forensic and toxicological laboratory capacity stressed as well.

- **Collection of data and use of expertise**

The Commission carried out an evaluation of the Agency with the support of a consultant in line with the requirements of Article 23 of Regulation (EC) No 1920/2006. The main outcomes of the evaluation were summarised in a Report from the Commission to the European Parliament and the Council[33] and an accompanying Staff Working Document[34]. The evaluation overall was positive as regards the five evaluation criteria (relevance, effectiveness, efficiency, coherence, EU added value), but also noted that improvements are possible in several areas. For example, the availability of more forward-looking products, the relationship with the scientific community and general practitioners, and general public awareness measures could be improved. The evaluation underlined as well the need to improve the provision of data, to address poly-substance use and to support to Member States in evaluating their national drug policies. The cooperation with third countries and international organisations could be further strengthened. The evaluation was inconclusive on the potential future broadening of the scope of the Agency to other licit and illicit substance and addictive behaviours[35].

The Agency provided expert input to the impact assessment and the legislative proposal in the course of its drafting, including estimates of the cost impacts of the different policy options.

33 COM(2019) 228.

34 SWD(2019) 174.

35 A summary of the main outcomes can also be found in Section 2.1 of the Impact Assessment.

- **Impact assessment**

In line with its "Better Regulation" policy, the Commission conducted an impact assessment.

A number of legislative and non-legislative policy options have been considered. Some policy options[36] were discarded at an early stage and were not subject to deeper analysis and assessment. Two policy options have been assessed in detail: they both have similar objectives but lead to a different level of impact in terms of costs, benefits and administrative burden.

– ***Policy option 4: Targeted revision - Delivering more value in drugs policy***

This option provides a thematic scope of action focussed on illicit drugs and targeted on deepening the evidence base on drug phenomena, while strengthening the Agency's monitoring and threat assessment capabilities to increase its ability to act and react to new challenges, including internationally. National focal points would need to be empowered to act as more effective intermediaries translating and implementing key inputs from the Agency at the national level. Under this policy option, the Agency would also gain agility in terms of responding to the needs arising in the drugs policy field through various tailored services for Member States. This option would bring an important reduction of administrative burden as well as simplification of procedures for Member States. It would also be more suitable as regards the necessary financial and human resource reinforcement.

– ***Policy option 5: Expansive revision - Focusing on diverse addictions***

This option provides a thematic scope of action expanded to cover addiction broadly, beyond drugs, and revamping the Agency's monitoring system based on applicable methodologies and indicators covering diverse addictions. The extended thematic scope on addictions would affect the body of data that would need to be provided by national focal points to the Agency, as well as the Agency's role as a hub for knowledge sharing. Finally, the involvement of the Agency in international cooperation would mainly be limited to the current drugs-related activities as other addictions do not have the same level of international and cross-border exposure. This option could result in possible overlaps with existing policies. It also raises questions over possible interference with national competencies and might be difficult from a subsidiarity perspective. It would also imply a serious increase of the financial and human resources necessary to the Agency to carry out its tasks.

Following a detailed assessment of the impact of the above mentioned policy options, the preferred option is policy option 4 leading to a **targeted revision** of the mandate. The main elements of this targeted revision are the following:

– The Agency's scope of action would be expanded to address poly-substance use, i.e. other substance-based addictions when these substances are taken together with illicit drugs. The revision should thus clarify what poly-substance use includes and in which conditions the concept can be applied. This limited widening of the mandate would necessitate the reporting of relevant data by the national focal points.

– The Agency's mandate would be expanded to explicitly address drug supply and drug market issues as this is an increasingly important dimension of the drug

[36] Policy option 0: Baseline scenario – Maintaining the current approach without changes; Policy option 1: Minimal revision - Stronger cooperation; Policy option 2: Dismantling of the Agency – Repeal of the founding Regulation; Policy option 3: Merging of the Agency with another EU body.

phenomenon and an EU Drugs Agency (EUDA) has to be able to fully address that dimension.

– The Agency's monitoring and threat assessment capabilities would be strengthened and the Agency would provide further support to the Member States to increase the impact of the Agency on the drug phenomenon and its ability to react to new challenges.

– A virtual laboratory, i.e. a network of laboratories combined with a competence centre in the Agency, would be established to ensure that more forensic and toxicological information is available to the Agency.

– The national focal points would be empowered to provide the relevant data to the Agency. The new Regulation would set minimum requirements for their set-up, which are then certified by the Agency. The mandate of the national focal points has to reflect the revision of the Agency mandate.

– The Agency would get the competence to act on its analysis and develop EU-level prevention and awareness raising campaigns as well as issue alerts in case particularly dangerous substances are available on the market.

– These elements would be complemented by strengthened cooperation with Member States, Union decentralised agencies and bodies, which is crucial, although would not deliver on its own on the objectives of this initiative.

– As regards the international dimension, the tasks of the Agency would be clarified to include in the mandate itself the relevant competencies.

This policy option is fully reflected in this legislative proposal. It would give the Agency the tools and capabilities to address all dimensions of the modern day drugs phenomenon.

In addition to revising the mandate of the Agency in substance, the legislative proposal will also adapt it to the common approach on decentralised EU agencies[37]. This has not been done yet as no substantive revision of Regulation (EC) No 1920/2006 has been undertaken since the agreement on the common approach in 2012. The adaptation to the common approach necessitates that many provisions regarding the institutional and governance rules of the Agency are expanded, even if the main content of these provisions remains the same. Adopting these new rules will bring the Agency's governance in line with the latest set of legislation on issues related to financial rules, data protection, combatting fraud and similar. It will also align the governance rules of the Agency to the ones of other EU decentralised agencies.

The main impacts of the current proposal are on the Commission and the Agency itself, and on national authorities. Linked to this, there would be possible impacts on simplification and/or administrative burden as demonstrated above[38]. The main economic impacts are on the EU budget, as regards the necessary increase of the EU contribution to the budget of the Agency, and to a much more limited extent on national budgets. Impacts on other stakeholders, in particular citizens/individuals and businesses, are limited and largely indirect through the better ability to tackle the drugs phenomenon in the EU.

---

37 See footnote 15.

38 See section on "Subsidiarity", page 5. No quantitative data is available regarding the simplification and burden reduction potential. The recent evaluation of the EU Drugs Strategy 2013-2020 concluded that there is no information available on the resources dedicated by Member States to drug-related issues. See Evaluation of the EU Drugs Strategy 2013-2020 and EU Action Plan on Drugs 2017-2020, SWD(2020) 150 final.

- **Fundamental rights**

The revision as such does not have any direct impacts on fundamental rights. The data collected by and for the Agency are statistical data, but do not include any personal data; therefore, Article 8 of the Charter of Fundamental Rights ("protection of personal data") is not affected. Other fundamental rights are not impacted either by the proposal.

It should be added, however, that the analysis of the Agency addresses important issues with possible implications for fundamental rights[39], even if the Agency does not decide on or manage itself such measures. In that sense, improving the functioning of the Agency could have positive indirect impacts on fundamental rights.

4. BUDGETARY IMPLICATIONS

This legislative proposal would have an impact on the budget and staff needs of the Agency as currently provided for in the Multiannual Financial Framework (MFF) and which are insufficient for the tasks the Agency should carry out to better address the drug phenomenon, including as regards drug markets and drug supply. It is estimated that an additional budget of around EUR 63 million and around 40 additional posts would be needed for the remainder of the period of the Multiannual Financial Framework (MFF) to ensure that the Agency has the necessary resources to enforce its revised mandate. The new tasks for the Agency proposed in this legislative proposal therefore require additional financial and human reinforcements compared to the resources earmarked in the adopted Multiannual Financial Framework 2021-2027, which provides for a 2% yearly increase of the EU contribution to the Agency. The budgetary impact of the additional financial resources for the EU Drugs Agency will be offset through a compensatory reduction from programmed spending under Heading 4[40] and should also stabilise the resource needs of the Agency over the period 2021-2027.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

The monitoring and evaluation of the Agency's mandate would largely be performed by the applicable mechanisms under this Regulation. Article 52 provides for an evaluation which assesses, in particular, the impact, effectiveness and efficiency of the Agency and of its working practices and may address the possible need to modify the structure, operation, field of action and tasks of the Agency, and the financial implications of any such modification. Further to this evaluation, the Commission will draw data through its representation in the Agency's Management Board meetings and its supervision, along with the Member States, of the Agency's work.

- **Detailed explanation of the specific provisions of the proposal**

Chapter I (Articles 1 to 5) includes the objectives and general tasks of the Agency. After setting out that the European Union Drugs Agency (EUDA) replaces the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) (**Article 1**) and defining the legal status and seat of the Agency **(Article 2)** as well as providing some definitions (**Article 3**), **Article 4** defines the objective of the Agency, which remains the same as in Regulation (EC) No 1920/2006. **Article 5** provides the overall tasks of the Agency around three main competence areas, which are detailed further in Chapters II to IV.

[39] For example, the work on alternatives to coercive sanctions, the work on minimum quality standards in drug demand reduction, best practices on treatment and harm reduction.

[40] For details, see the Financial Legislative Statement in Annex I.

Chapter II (Articles 6 and 7) clarifies the monitoring tasks of the Agency. **Article 6** defines what data the Agency has to collect and what actions they should undertake to have the most up-to-date information available for their analysis. It also defines the dissemination tasks of the Agency. **Article 7** sets out the main monitoring tasks of the Agency.

Chapter III (Articles 8 to 15) defines the early warning and risk assessment tasks of the Agency. **Articles 8 to 11** set out the rules on the information exchange on, the early warning system and the risk assessment procedure for new psychoactive substances. These provisions have not been changed compared to Articles 5a to 5d of Regulation (EC) No 1920/2006 (introduced through Regulation (EU) 2017/2101). The work undertaken by the Agency in this regard is the basis for the possible inclusion of a new psychoactive substance in the definition of 'drug' through a delegated directive under Council Framework Decision 2004/757/JHA. **Article 12** sets out the possibility for the Agency to develop threat assessments on new developments of the drug phenomenon that have a potential to impact negatively public health, safety and security. These threat assessments will help increase the preparedness of the EU to react to new threats and support other tasks of the Agency. **Article 13** builds on the information available from the EU Early Warning System, the threat assessments and other information from the Member States about the appearance of a serious direct or indirect drug-related risk. It provides for a European drug alert system, which facilitates the rapid exchange of information that may require rapid actions to be taken to safeguard public health, safety, or security. **Article 14** establishes competencies of the Agency in the area of drug precursors. Finally, **Article 15** sets up a network of forensic and toxicological laboratories (a "virtual laboratory").

Chapter IV (Articles 16 to 21) defines the tasks to be addressed as part of competence development. **Article 16** sets out the competencies of the Agency in relation to prevention. The Agency is already working in this area, e.g. through the development of a European Prevention Curriculum or through the Exchange prevention registry. This should be taken forward by enabling the Agency to develop cross-EU prevention programmes and campaigns, but also supporting Member States in preparing national campaigns. **Article 17** provides for an accreditation and certification procedure for national programmes, in particular national prevention, treatment, harm reduction and other related programmes. Such an accreditation or certification would give the national authorities or professional bodies the certainty that their programmes are in line with the latest scientific state of play and have been proven useful. **Article 18** empowers the Agency to provide support to the Member States, e.g. in the evaluation and development of their national strategies, but also in sharing innovative best practices or other relevant information. **Article 19** enables the Agency to provide training within the scope of its mandate, being it as a core or a supporting task, the latter of which could be provided subject to separate fees, if so decided. **Article 20** sets out the international cooperation and technical assistance activities of the Agency, which it should develop further. The provision also clarifies that international cooperation is part of the Agency's core tasks. **Article 21** provides a mandate to the Agency to be more active in the context of the EU research knowledge cycle. This should also include the Agency's involvement in the EU Innovation Hub for Internal Security[41].

Chapter V (Articles 22 to 34) sets out the rules on the organisation of the Agency. The rules are based on Regulation (EC) No 1920/2006. The changes introduced to the rules in this Chapter are due to the implementation of the common approach. The specificities of the Agency, such as the existence of a Scientific Committee or a network of national focal points, were kept, but have been adapted as appropriate.

[41] Council documents 12837/19, 12496/19, 7829/20.

Article 22 defines the structure of the Agency. **Articles 23 to 27** set out the composition, functions and the working methods of the Management Board. They are developed based on Article 9 of Regulation (EC) No 1920/2006, the rules of procedure of the Management Board of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and the common approach. **Article 28** sets out the rules for the Executive Board, which supports the Management Board and prepares its meetings. The basis for his provision is Article 10 of Regulation (EC) No 1920/2006, the rules of procedure of the EMCDDA Management Board and the common approach. **Article 29** sets out the responsibilities of the Executive Director and is based on Article 11 of Regulation (EC) No 1920/2006 and the common approach. **Article 30** sets out the rules for the Scientific Committee and is in line with Article 13 of Regulation (EC) No 1920/2006. Finally, **Articles 31 to 34** set out the rules for the Reitox network of national focal points and the national focal points themselves. The national focal points need to be strengthened in line with the revision of the Agency mandate and therefore the rules on the national focal points were expanded to set out their roles and responsibilities in more detail. The national focal points need to be empowered to act as a central body in the Member States for all drug-related data and should also get an appropriate role on national level. In order to be able to fulfil their role appropriately, their set-up should comply with certain minimum requirements, the compliance with which should be certified by the Agency. Beyond those minimum requirements, it is for the Member States to decide how to set up the national focal points within their national legal system.

Chapter VI (Articles 35 to 41) includes the financial provisions. **Article 35** sets out the rules on the Single Programming Document of the Agency, which includes the three-year planning as well as the work programme of the next year. This provision has been adapted to the latest financial regulations[42]. Changes in the financial provisions compared to Regulation (EC) No 1920/2006 are due to the implementation of the common approach and the currently applicable financial rules for EU decentralised agencies. The changes introduced as regards the budget procedures and the presentation of accounts and discharge are minor. The only new provision in this Chapter is **Article 37**, which would allow the Agency to charge fees for certain tasks, which are not part of the core tasks of the Agency. It will be up to the Agency to decide at a later stage, once this Regulation is applicable, whether it will use this option or not.

Chapter VII (Articles 42 to 44) includes the staff rules. Changes compared to Regulation (EC) No 1920/2006 are due to the implementation of the common approach and changes to the Staff Regulations and the Conditions of Employment of Other Servants (**Articles 42 and 44**)[43]. **Article 43** includes the staff rules applicable to the Executive Director.

Chapter VIII (Articles 45 to 63) includes general and final provisions. Changes compared to Regulation (EC) No 1920/2006 are due to the implementation of the common approach and adaptations to more recent legislation. The majority of these provisions was already included in Regulation (EC) No 1920/2006. This Chapter also includes transitional provisions **(Articles 58 to 61)** to enable a proper transition from the European Monitoring Centre for Drugs and Drug Addiction to the European Union Drugs Agency.

---

42 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. 1–38).

43 OJ L 56, 4.3.1968, p. 1.

2022/0009 (COD)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the European Union Drugs Agency

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 168(5) thereof,

Having regard to the proposal from the European Commission,

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

After consulting the European Economic and Social Committee[1],

After consulting the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure,

Whereas:

(1) The European Monitoring Centre for Drugs and Drug Addiction was set up by Council Regulation (EEC) No 302/93[3]. This founding act was recast in 2006 through Regulation (EC) No 1920/2006 of the European Parliament and of the Council[4].

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

(3) Whereas its general objective is still valid and should be retained, Regulation (EC) No 1920/2006 as such no longer fits for addressing the current and future drug challenges. Therefore, the mandate of the European Monitoring Centre for Drugs and Drug Addiction should be revised, including its replacement and renaming into "European Union Drugs Agency" ('the Agency'). Since substantial amendments to Regulation (EC) No 1920/2006 are needed to accommodate the common approach for Union decentralised agencies[5] and to take account of the developments of the drug

---

1 OJ C , , p. .

2 OJ C , , p. .

3 Council Regulation (EEC) No 302/93 of 8 February 1993 on the establishment of a European Monitoring Centre for Drugs and Drug Addiction (OJ L 36, 12.2.1993, L. 1).

4 Regulation (EC) No 1920/2006 of the European Parliament and of the Council of 12 December 2006 on the European Monitoring Centre for Drugs and Drug Addiction (recast) (OJ L 376, 27.12.2006, p. 1).

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

phenomenon, in the interest of clarity that Regulation should be replaced by a new Regulation.

(4) The main focus of Regulation (EC) No 1920/2006 was on health-related issues. However, addressing also drug markets and drug supply issues, is necessary to understand the impacts of the drug phenomenon on public health, reduce the availability of drugs in the Union and curb drug demand. Health- and supply-related issues are intrinsically linked. The Agency should therefore address the drug phenomenon more holistically.

(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 doing so, the Agency should be guided by relevant strategies and action plans adopted by the Union, in particular the applicable EU Drugs Strategy and Action Plan.

(6) In pursuing its activities, the Agency should cooperate with other Union agencies and bodies, in particular the European Union Agency for Law Enforcement Cooperation (Europol), the European Union Agency for Law Enforcement Training (CEPOL), the European Union Agency for Criminal Justice Cooperation (Eurojust), the European Medicines Agency (EMA), the European Centre for Disease Prevention and Control (ECDC), and the European Education and Culture Executive Agency (EACEA), and should take account of their activities in order to avoid duplication. Cooperation should also take place on an international level with relevant authorities and bodies in third countries and on the United Nations level.

(7) Poly-substance use, that is the concomitant use of one or more psychoactive substance or type of substance, whether licit or illicit, when those substances are taken together with drugs, is becoming increasingly common. Therefore, the Agency should address other substance-based addictions when those substances are taken together with drugs by developing monitoring systems that would consider, instead of focusing only on one substance, heroin for example, the important role played by concurrent or sequential use of other substances as well, such as non-controlled opioids or misused medications.

(8) The Agency should develop its activities around three main competence areas, i.e. monitoring, leading to better informed policies; early warning and risk assessment, leading to better informed actions; and competence development, leading to stronger Union responses to the drug phenomenon.

(9) The collection, analysis and dissemination of data should continue to be the main task of the Agency. The standard data is collected through the national focal points, which should remain one of the main data providers for the Agency. Additional, closer to real-time data sources are increasingly available through innovative data collection methods. Therefore, the Agency should have access to all data available to get a holistic picture of the drug phenomenon in the Union and the external factors influencing it.

(10) The data requirements of the Agency should be mirrored in the national focal points. They should be empowered within the Member States to receive all relevant data from the different national authorities. Data collection in the Member States should be streamlined as far as possible to avoid double reporting and duplication of efforts.

(11) In order to facilitate and structure data collection, information exchange, both qualitative and quantitative, and to support the establishment of an integrated and

interoperable monitoring system enabling real-time monitoring, the Agency should have an appropriate digital solution. This should allow for the automation of data and information management and exchange. Such solution should also facilitate the real-time monitoring of technology-enabled drug markets, including the darknet.

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

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

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

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

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

(17) As dangerous substances might lead to harm for public health, the Agency should be able to issue alerts. To support such a function, the Agency should develop a European drug alert system, accessible by national authorities. Such a system should facilitate the rapid exchange of information that may require rapid actions to safeguard public health, safety, and security. The Agency should be able to inform not only national authorities, but also potential users of these substances.

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

the Agency should have a role in monitoring the diversion and trafficking of drug precursors and assisting the Commission in the implementation of the Union drug precursors legislation.

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

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

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

(22) Since the Agency has access to data and the necessary scientific experience to develop and promote evidence-based prevention strategies, it should be involved in prevention work, in particular exchange of best practices and implementable research results in drug prevention, drug-related crime prevention and the prevention of drug-related harms, including the elaboration of quality standards for drug prevention (European Drug Prevention Quality Standards) or of a curriculum providing decision- and policy-makers with the knowledge about the most effective evidence-based prevention interventions and approaches (European Union Prevention Curriculum)

(23) Given its Union perspective, the Agency should be able to evaluate national measures and training, for example on prevention, treatment, harm reduction and other related measures, in view of their compliance with the latest scientific state of play and of their proven usefulness. Member States or relevant professional bodies should be given the possibility to use the accreditation or certification as a quality label for their work.

(24) Considering that the Agency has a unique position at Union level allowing it to compare data and best practices, the Agency should support evaluation and drafting of national drug strategies in a more structured way across Member States, in particular as regards policy development. 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 developed in these areas.

(25) The responsibilities of the Agency in the area of international cooperation should be defined in more clear terms in order to allow it to fully engage in such activities and respond to requests from third countries and bodies. The Agency should be able to contribute to the development and implementation of the external dimension of the

Union's drugs policy and the leadership role of the Union at multilateral level as a means to ensure the efficient and coherent implementation of the Union drug policies internally and at international level. In order that the Agency can allocate adequate levels of resources to this task, the work on international cooperation should be part of the core tasks of the Agency. It should be based on an international cooperation framework of the Agency, which should be in line with the Union priorities on international cooperation and should be revised on a regular basis to ensure that it adequately reflects international developments.

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

(27) The 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 continue assisting the Management Board and the Executive Director with regard to relevant scientific matters.

(28) The national focal points should be one of the main data providers to the Agency. It is necessary to set minimum requirements for their creation by Member States and their certification by the Agency. In order to guarantee the adequate functioning of the national focal points, they should be set up on a permanent basis, with a dedicated budget and a certain degree of independence in carrying out their function.

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

(30) Fees improve the funding of an agency and may be considered for specific issues that can be clearly separated from the core tasks of the agency. Any fees levied by the Agency should cover its costs for providing the respective services.

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

(32) Regulation (EC) No 1049/2001 of the European Parliament and of the Council[6] 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.

---

[6] 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).

(33) Regulation (EU, Euratom) No 883/2013 of the European Parliament and of the Council[7] 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)[8], to which the European Monitoring Centre for Drugs and Drug Addiction already acceded, should apply to the Agency.

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

(35) The Agency should cooperate closely with relevant international organisations, other governmental and non-governmental bodies and relevant technical bodies from inside and outside the Union in the implementation of its work programme, notably to avoid duplication of work and to ensure access to all data and tools needed for carrying out its mandate.

(36) The Agency replaces and succeeds the European Monitoring Centre for Drugs and Drug Addiction established by Regulation (EC) 1920/2016. It should therefore be the legal successor of all its contracts, including employment contracts, liabilities and properties acquired. International agreements concluded by the European Monitoring Centre for Drugs and Drug Addiction before the date of application of this Regulation should remain in force.

(37) Since the objectives of this Regulation, namely the establishment of an agency to address the drugs phenomenon, cannot be sufficiently achieved by the Member States but can rather, by reason of the scale and effects of the action, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives,

HAVE ADOPTED THIS REGULATION:

CHAPTER I

OBJECTIVES AND GENERAL TASKS OF THE AGENCY

Article 1

Establishment of the Agency

1. This Regulation establishes the European Union Drugs Agency ('the Agency').

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

---

7 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).

8 OJ L 136, 31.5.1999, p. 15.

Article 2

Legal status and seat

1. The Agency shall be a body of the Union with legal personality.

2. In each of the Member States, the Agency shall enjoy the most extensive legal capacity accorded to legal persons under national law. It shall, in particular, be able to acquire or dispose of movable and immovable property and be a party to legal proceedings.

3. The seat of the Agency shall be in Lisbon, Portugal.

Article 3

Definitions

For the purpose of this Regulation:

(1) 'drugs' means drugs as defined in Article 1, point 1, of Council Framework Decision 2004/757/JHA[9];

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

(3) 'poly-substance use' means the concomitant use of one or more psychoactive substance or type of substance, whether licit or illicit, when those substances are taken together with drugs;

(4) 'drug precursors' means substances that are controlled and monitored in accordance with Regulation (EC) No 273/2004 of the European Parliament and of the Council[10] and with Council Regulation (EC) No 111/2005[11];

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

(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[12], the United Nations Convention on Psychotropic Substances of 1971[13] and the United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988[14];

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

---

9 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).

10 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).

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

12 United Nations Treaty Series, vol. 976, No. 14152.

13 United Nations Treaty Series, vol. 1019, No. 14956.

14 United Nations, Treaty Series, vol. 1582, No. 27627.

Article 4

General task of the Agency

The Agency shall provide the Union and its Member States with factual, objective, reliable and comparable information, early warning and risk assessment at Union level concerning drugs, drug addiction, drug markets and their consequences, and to recommend appropriate and concrete, evidence-based actions on how to address the related challenges in a timely manner.

Article 5

Specific tasks

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

   (a) monitoring tasks that shall include:

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

      (2) the dissemination of information and data pursuant to Article 6(5); and

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

   (b) preparedness tasks that shall include:

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

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

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

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

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

   (c) competence development tasks that shall include:

      (1) the development, expansion and promotion of Union-wide prevention programmes and campaigns pursuant to Article 16;

      (2) the accreditation and certification of national measures pursuant to Article 17;

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

      (4) training pursuant to Article 19;

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

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

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

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

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

5. The Agency shall support the Commission, Member States and other relevant stakeholders, identified in the applicable Union strategies on drugs, in the implementation of those strategies, as appropriate.

6. In carrying out and implementing the tasks referred to in paragraph 1, the Agency may organise meetings of experts, set up ad hoc working groups and finance projects, as necessary.

7. In carrying out and implementing the tasks referred to in paragraph 1, the Agency shall cooperate actively with other Union decentralised agencies and bodies, in particular Europol, Eurojust, the European Medicines Agency, the European Centre for Disease Prevention and Control, civil society organisations and other relevant stakeholders, to attain maximum efficiency in monitoring, assessing and responding to the drugs phenomenon.

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

CHAPTER II

MONITORING

Article 6

Collection and dissemination of information and data

1. The Agency shall:

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

   (b) collect information and data needed for the monitoring of poly-substance use as referred to in Article 7(1), point (c);

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

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

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

(f) ensure improved comparability, objectivity and reliability of information and data at Union level by establishing indicators and common standards of a non-binding nature, compliance with which may be recommended by the Agency, with a view to ensuring greater uniformity of the measurement methods used by the Member States and the Union; in particular, the Agency shall develop tools and instruments to help Member States to monitor and evaluate their national policies and the Commission to monitor and evaluate Union policies.

2. The Agency shall collect relevant national data through the national focal points. It shall also cooperate closely with other national, European and international organisations and bodies that already have information of this kind.

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

4. The Agency may develop the necessary digital solutions through which information and data are managed and automatically exchanged.

If such digital solutions are developed, they shall:

(a) enable the automated collection of data, including open source information, while keeping the possibility of manual data provision available;

(b) apply artificial intelligence for data validation, analysis and automated reporting;

(c) allow for the computerised handling and exchange of information, data and documents.

5. The Agency shall disseminate information and data by:

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

(b) ensuring wide dissemination of its analysis, conclusions and reports;

(c) ensuring wide dissemination of reliable data, excluding sensitive non-classified and classified data, through publishing, on the basis of data which it gathers, a regular report on the state of the drugs phenomenon, including data on emerging trends;

(d) setting up and making available open scientific documentation resources and assisting in the promotion of information activities;

(e) providing information on quality standards, innovative best practices and implementable research results in the Member States and facilitating the exchange and implementation of such standard and practices.

6. The Agency shall not collect any data making it possible to identify individuals or small groups of individuals. It shall refrain from any transmission of information relating to specific individuals.

Article 7

Monitoring of the drug phenomenon

1. The Agency shall monitor:

(a) the drugs phenomenon in the Union holistically, through epidemiological and other indicators, covering the health, safety and security aspects, including the implementation of the applicable Union strategies on drugs;

(b) emerging trends in the drugs phenomenon in the Union and internationally as far as these impact on the Union; this shall include the monitoring of the use of new technologies for drug services or drug trafficking, and links to other crime areas, as relevant;

(c) poly-substance use and its consequences, in particular the implications for policies and responses arising from the interaction between the use of drugs with one or more psychoactive substance or type of substance, whether licit or illicit; including the increased risks of health and social problems, which may occur when drugs and other psychoactive substances are consumed at the same time or sequentially within a short period of time or when different substances are produced or sold together; the need to consider the common causes of drug use and addictions; and the implications for monitoring and exchange of best practices, which arise when policies and responses target multiple substances holistically;

(d) drug-related problems and the solutions applied, in particular the implementation of innovative best practices and research results;

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

(f) drug precursors and their trafficking and diversion;

(g) Union and national drugs policies, including in view of supporting their development and independent evaluation;

(h) Technology-enabled drug markets, in cooperation with Europol within their respective mandates.

2. Based on its monitoring activities, the Agency shall identify innovative best practices and develop them further. The Agency shall provide and share information on innovative best practices in the Member States and facilitate the exchange of such practices among the Member States.

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

CHAPTER III

PREPAREDNESS

Article 8

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

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

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

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

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

Article 9

Initial report

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

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

2. The initial report shall contain:

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

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

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

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

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

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

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

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

(i) other relevant information, where available.

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

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

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

(a) a medicinal product for human use or in a veterinary medicinal product that has obtained a marketing authorisation in accordance with Directive 2001/83/EC of the European Parliament and of the Council[15], Directive 2001/82/EC of the European Parliament and of the Council[16] or Regulation (EC) No 726/2004 of the European Parliament and of the Council[17];

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

(e) an investigational medicinal product as defined in Article 2, point (d), of Directive 2001/20/EC of the European Parliament and of the Council[18].

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

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

---

15 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).

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

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

18 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 the start of the drawing up of the initial report pursuant to the first paragraph, request the European Chemicals Agency, the European Centre for Disease Prevention and Control and the European Food Safety Authority to provide the information and data at their disposal on the new psychoactive substance.

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

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

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

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

Article 10

Risk assessment procedure and report

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

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

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

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

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

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

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

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

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

(g) other relevant information, where available.

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

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

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

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

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

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

Article 11

Exclusion from risk assessment

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

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

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

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

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

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

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

Article 12

Threat assessment and preparedness

1. The Agency shall develop a strategic general threat assessment capability to identify at an early stage new developments of the drugs phenomenon that have a potential to impact negatively on public health, safety and security and, through doing so, to help increase the preparedness of the relevant stakeholders to respond to new threats in a timely and effective manner.

2. The Agency shall set out a set of criteria to evaluate when to trigger a threat assessment.

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

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

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

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

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

Article 13

European drug alert system

1. The Agency shall set up and manage a rapid European drug alert system.

2. Member States shall immediately notify the Agency of any information relating to the appearance of a serious direct or indirect drug-related risk to human health, safety or security as well as any information that may be useful for coordinating a response whenever they become aware of such information, such as:

   (a) the type and origin of the risk;

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

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

   (d) analytical and toxicological data;

   (e) identification methods;

   (f) public health risks;

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

   (h) measures other than public health measures;

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

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

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

5. The Member States shall inform the Agency of any additional information at their disposal in order to further analyse and assess the risk as well as the actions implemented or measures taken following receipt of the notifications and information transmitted under the European drug alert system.

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

7. The Agency may open up participation in the European drug alert system to third countries or international organisations. That participation shall be based on

reciprocity and shall include confidentiality measures equivalent to those applicable in the Agency.

8. The Agency may develop an alert system through which it can directly reach and address people who use or potentially use drugs.

Article 14

Drug precursors

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

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

Article 15

Network of forensic and toxicological laboratories

1. The Agency shall set up a network of forensic and toxicological laboratories particularly active in the forensic and toxicological investigations of drugs and drug-related harms.

2. The network shall act primarily as a forum for generating data and information exchange on new developments and trends, organising training to enhance the competence of forensic drug experts, supporting the implementation of quality assurance schemes and supporting the further harmonisation of data collection and analytical methods.

3. Each Member State shall have the right to appoint, through its representative in the Management Board, two laboratories, one specialising in forensic analysis and one specialising in toxicology, as national representative laboratories to the network. The Agency may select additional laboratories or experts particularly active in the forensic and toxicological investigations of drugs and drug-related harms for specific projects.

4. The Joint Research Centre of the Commission shall be a member of the network and represent the Commission in the network.

5. The network shall closely cooperate with existing networks and organisations active in this area. The network referred to in Article 31 shall be informed regularly about the work of the network of forensic and toxicological laboratories.

6. The Agency shall chair the network and convene at least one meeting per year. The network may decide to create working groups, which may be chaired by members of the network.

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

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

9. The Agency shall create a database to store, analyse and make available the information and data collected or generated by the network.

CHAPTER IV

COMPETENCE DEVELOPMENT

Article 16

Prevention campaigns

1. The Agency shall design, develop and promote Union-wide programmes and campaigns for the prevention of drug-related problems and raising awareness of the adverse effects of drugs.

2. The programmes and campaigns referred to in paragraph 1 shall be in line with the political orientations set out in the applicable EU Drugs Strategy and Action Plan. They shall address important dimensions of the drug phenomenon, shall be targeted to specific groups and be informed by the Agency's collection of evidence and best practice.

3. The Agency shall develop and promote the implementation of quality standards for drug prevention and provide or support training pursuant to Article 19.

4. The Agency shall assist Member States in developing national prevention campaigns in the area of its mandate, including the development of prevention programmes aimed at the reduction of drug-related criminality and prevention of the exploitation of vulnerable individuals within the drug market.

Article 17

Accreditation and certification of national programmes

1. At the request of a national authority of a participating country or a relevant professional body, in cases where the participating country does not have any similar accreditation or certification body, the Agency shall provide accreditation and certification for national programmes in accordance with the standard operating protocol provided for in paragraph 3.

2. Before granting an accreditation or certification to a national programme, the Agency shall evaluate the programme and assess whether it complies with the latest scientific state of play and whether it has been proven useful to address its declared objectives.

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

   The standard operating protocol referred to in subparagraph 1 should contain at least:

   (a) specific conditions relating to the capacity and resources of the Agency to carry out the accreditation or certification procedure;

(b) the criteria according to which the national programme will be assessed in view of the accreditation or certification and which allow the verification of the conditions laid down in paragraph 2; programmes subject to an accreditation or certification shall include at least prevention, treatment, harm reduction, and other related subjects;

(c) the details of the accreditation or certification process carried out by the Agency, including designation of the documentation to be provided and the timeframe for the procedure;

(d) the conditions for restricting, suspending or withdrawing the accreditation or certification;

(e) the procedures for the resolution of appeals, including, where appropriate, legal remedies against accreditation decisions or the absence thereof.

Article 18

Support to Member States

1. At the request of a Member State, the Agency may support the independent evaluation of its drug policies and the development of evidence-based drug policies in line with the applicable Union strategies.

2. The Agency shall support the Member States in implementing their national drug strategies, quality standards and innovative best practices and it shall facilitate exchanges of information between national decision-makers.

3. In supporting policy evaluation, the Agency shall act independently and shall be guided by its scientific standards.

Article 19

Training

The Agency shall, within the scope of its mandate, in accordance with the staffing and budgetary resources at its disposal and in coordination with other Union decentralised agencies and bodies:

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

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

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

Article 20

International cooperation and technical assistance

1. The Agency shall:

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

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

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

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

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

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

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

(h) support third countries in developing their drug policies in accordance with the principles of the Union drug strategies, including through providing support to the independent evaluation of their policies.

2. The international cooperation framework referred to in paragraph 1, point (a), shall take into account the relevant policy documents of the Union and consider the developments of the drug phenomenon, in particular trafficking routes and drug production areas. It shall set out the priority countries or regions for cooperation and the key outcomes of the cooperation. The Agency shall evaluate and review the international cooperation framework regularly.

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

Technical assistance shall focus in particular on setting up or consolidating national focal points, national data collection systems and national early warning systems, and subsequently assist the creation and strengthening of structural links with the early warning system referred to in Article 8 and the network referred to in Article 31. If the third country so requests, the Agency may provide a certification for these national bodies.

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

Article 21

Research and innovation

1. The Agency shall assist the Commission and the Member States in identifying key research themes, drawing up and implementing the Union framework programmes

for research and innovation activities that are relevant to achieve its general task set out in Article 4. Where the Agency assists the Commission in identifying key research themes, drawing up and implementing a Union framework programme, the Agency shall not receive funding from that programme.

2. The Agency shall proactively monitor and contribute to research and innovation activities to achieve its general task set out in Article 4, support related activities of Member States, and implement its research and innovation activities regarding matters covered by this Regulation, including the development, training, testing and validation of algorithms for the development of tools. The Agency shall disseminate the results of that research to the European Parliament, to the Member States and to the Commission in accordance with Article 49.

3. The Agency shall contribute to and participate in the activities of the EU Innovation Hub for Internal Security, or any instrument that would replace it, in the framework of the research and innovation cycle.

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

5. The Agency shall make public information on its research projects, including demonstration projects, the cooperation partners involved and the project budget.

6. The Agency shall create a database to store, analyse and make available drug-related research programmes.

CHAPTER V

ORGANISATION OF THE AGENCY

Article 22

Administrative and management structure

The Agency's administrative and management structure shall comprise:

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

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

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

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

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

Article 23

Composition of the Management Board

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

2. The Management Board shall also include:

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

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

3. Each member of the Management Board shall have an alternate. The alternate shall represent the member in her/his absence.

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

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

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

Article 24

Functions of the Management Board

1. The Management Board shall:

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

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

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

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

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

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

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

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

(i) adopt rules for the prevention and management of conflicts of interest in respect of its members, the members of the Executive Board, Scientific Committee, and the European Information Network on Drugs and Drug Addiction (Reitox), as well as of seconded national experts and other staff not employed by the Authority as referred to in Article 44, and shall publish

annually on its website the declarations of interests of the Management Board members;

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

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

(l) approve the level of minimum co-financing referred to in Article 32(7);

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

(n) adopt its rules of procedure;

(o) in accordance with paragraph 2, exercise, with respect to the staff of the Agency, the powers conferred by the Staff Regulations on the Appointing Authority and by the Conditions of Employment of Other Servants on the Authority Empowered to Conclude a Contract of Employment[19] ("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 43;

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

(s) appoint the members of the Scientific Committee;

(t) approve the list of experts to be used to extend the Scientific Committee in accordance with Article 10(4);

(u) ensure adequate follow-up to findings and recommendations stemming from the internal or external audit reports and evaluations, as well as from investigations of the European Anti-fraud Office (OLAF) established by Commission Decision 1999/352/EC, ECSC, Euratom[20] and of the European Public Prosecutor's Office (EPPO) established by Council Regulation (EU) 2017/1939[21], as referred to in Article 48;

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

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

---

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

20 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).

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

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

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

Article 25

Chairperson of the Management Board

1. The Management Board shall elect a Chairperson and a Deputy Chairperson from among its members with voting rights. The Chairperson and the Deputy Chairperson shall be elected by a majority of two-thirds of the members of the Management Boards with voting rights.
2. The Deputy Chairperson shall automatically replace the Chairperson if she/he is prevented from attending to her/his duties.
3. The term of office of the Chairperson and the Vice-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 Vice-Chairperson shall be set out in the rules of procedure of the Management Board.

Article 26

Meetings of the Management Board

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

Article 27

Voting rules of the Management Board

1. Without prejudice to Article 24(1), points (c) and (d), Article 25(1), Article 43(8) and Article 53(2), the Management Board shall take decisions by majority of its members with voting rights.

2. Each member with voting rights shall have one vote. In the absence of a member with the right to vote, her/his alternate shall be entitled to exercise right to vote.

3. The Chairperson and Deputy Chairperson shall take part in the voting.

4. The Executive Director shall not take part in the voting.

5. The Management Board's rules of procedure shall establish more detailed voting arrangements, in particular the circumstances in which a member may act on behalf of another member.

Article 28

Executive Board

1. The Executive Board shall:

   (a) decide on those matters provided for in the financial rules adopted pursuant to Article 41 that are not reserved to the Management Board by this Regulation;

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

   (c) without prejudice to the responsibilities of the Executive Director, as set out in Article 29, monitor and supervise the implementation of the decisions of the Management Board, with a view to reinforcing supervision of administrative and budgetary management.

2. Where necessary, because of urgency, the Executive Board may take certain provisional decisions instead of the Management Board, in particular on administrative management matters, including the suspension of the delegation of the appointing authority powers and budgetary matters.

3. The Executive Board shall be composed of the Chairperson and the Deputy Chairperson of the Management Board, two other members appointed by the Management Board from among its members with the right to vote and two representatives of the Commission to the Management Board.

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

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

4. The term of office of members of the Executive Board shall be four years. The term of office of members of the Executive Board shall end when their membership of the Management Board ends.

5. The Executive Board shall hold at least two ordinary meetings per year. In addition, it shall meet on the initiative of its Chairperson or at the request of its members.

6. The Executive Board shall take its decision by consensus. If the Executive Board is not in a position to take a decision by consensus, the matter shall be referred to the Management Board.

7. The Management Board shall lay down the rules of procedure of the Executive Board, including the voting rules for its members.

Article 29

Responsibilities of the Executive Director

1. The Executive Director shall be responsible for the management of the Agency. The Executive Director shall be accountable to the Management Board.

2. Without prejudice to the powers of the Commission, of the Management Board and of the Executive Board, the Executive Director shall be independent in the performance of the duties and shall neither seek nor take instructions from any government nor from any other body.

3. The Executive Director shall report to the European Parliament on the performance of her/his duties when invited to do so. The Council may invite the Executive Director to report on the performance of her/his duties.

4. The Executive Director shall be the legal representative of the Agency.

5. The Executive Director shall be responsible for the implementation of the tasks assigned to the Agency as referred to in Article 5. In particular, the Executive Director shall be responsible for:

   (a) the day-to-day administration of the Agency;

   (b) preparing and implementing the decisions adopted by the Management Board;

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

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

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

   (f) proposing to the Management Board the level of minimum co-financing referred to in Article 32(7), if such co-financing is to be granted to the national focal points;

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

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

   (i) protecting the financial interests of the Union by applying preventive measures against fraud, corruption and any other illegal activities, without prejudicing the investigative competence of OLAF and EPPO, by effective checks and, if irregularities are detected, by recovering amounts wrongly paid and, where

appropriate, by imposing effective, proportionate and dissuasive administrative, including financial penalties;

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

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

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

6. The Executive Director shall decide whether it is necessary to locate one or more staff in one or more Member States for the purpose of carrying out the Agency's tasks in an efficient and effective manner. Before deciding to establish a local office, the Executive Director shall obtain the prior consent of the Commission, the Management Board and the host Member State(s) concerned. The decision shall specify the scope of the activities to be carried out at the local office in a manner that avoids unnecessary costs and duplication of administrative functions of the Agency. A headquarters agreement with the host Member State(s) concerned may be concluded.

Article 30

Scientific Committee

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

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

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

4. Where a member no longer meets the criteria of independence, she/he shall inform the Management Board. Alternatively, the Management Board may declare, on a proposal of at least one-third of its members or of the Commission, a lack of independence and revoke the person concerned. The Management Board shall appoint a new member for the remaining term of office in accordance with the procedure for ordinary members.

5. The Scientific Committee shall deliver an opinion where provided for in this Regulation or on any scientific matter concerning the Agency’s activities, which the Management Board or the Executive Director may submit to it. The opinions of the Scientific Committee shall be published on the Agency’s website.

6. For the purpose of assessing the risks posed by a new psychoactive substance or a group of new psychoactive substances, the Scientific Committee may be extended as deemed necessary by the Executive Director, acting on the advice of the chairperson of the Scientific Committee, by including experts representing the scientific fields relevant for ensuring a balanced assessment of the risks posed by the new

psychoactive substance. The Executive Director shall designate those experts from a list of experts. The Management Board shall approve the list of experts every four years.

7. The Scientific Committee shall elect a Chairperson and a Deputy Chairperson for the duration of the mandate of the Scientific Committee. The Chairperson may participate as an observer in the meetings of the Management Board.

8. The Scientific Committee shall meet at least once per year.

9. The list of members of the Scientific Committee shall be made public and shall be updated by the Agency on its website.

Article 31

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

1. The Agency shall have at its disposal the European Information Network on Drugs and Drug Addiction (Reitox network). The Reitox network shall consist of the national focal points designated in accordance with Article 32 and a focal point for the Commission.

2. The Reitox network shall hold at least one ordinary meeting a year. The meetings are convened and chaired by the Agency. In addition, it shall meet on the initiative of its Spokesperson or at the request of at least one-third of its members.

3. The Reitox network shall elect a Spokesperson and up to three Deputy Spokespersons from among its members. The Spokesperson represents the Reitox network towards the Agency and may participate as observer in the meetings of the Management Board.

Article 32

National Focal Point

1. Each participating country shall designate a single national focal point, set up on a permanent basis and with a clear mandate, through national legislation or any other legal act having similar effect. The designation of the national focal point and the appointment of the head of national focal point, as well as any changes to those appointments, shall be communicated to the Agency through the national member of the Management Board.

2. The responsible national authority shall ensure that the national focal point is entrusted with the tasks set out in Article 33(2). The head of the national focal point shall represent the national focal point in the Reitox network.

3. The head of the national focal point shall be independent from instructions from the responsible national authority in carrying out her/his function as head of the national focal point.

4. The national focal point shall plan its activities through an annual work plan.

5. The national focal point shall have in its budget a specific (annual) budget line or lines for drug-related monitoring and shall receive adequate support from decision-makers and adequate resources to carry out its tasks. In this regard, the participating country shall equip the national focal point with sufficient financial and human resources to fulfil its mandate and tasks, as referred to in Article 33(2), and have

sufficient equipment and facilities to support its daily activities. If the body hosting the national focal point is endowed with additional national tasks and obligations, additional human and financial resources shall be made available.

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

7. The national focal point shall be certified in this function by the Agency in accordance with Article 34.

Article 33

Tasks of the national focal points

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

2. The national focal points shall, as a minimum:

   (a) coordinate at national level the activities related to drug-related data collection and monitoring;

   (b) promote and support evidence-based decision-making at national level and participate in the national policy dialogues;

   (c) set-up or support national systems of collaboration between drug policy and other relevant policies, including in the law enforcement/security and health/social policy fields, involving the relevant stakeholders in the various areas;

   (d) collect, analyse and interpret in an objective manner at national level all relevant information on drugs, drug addiction, drug markets, drug supply and crime-related issues as well as on policies and solutions applied, needed for the Agency to comply with Article 6. In doing so, the national focal point shall bring together experience from different sectors – in particular health, justice and law enforcement – and cooperate with experts and national organisations active in the field of drugs policy;

   (e) monitor and report on drugs and drug use to the national authorities and contribute to reporting to international organisations;

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

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

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

(i) contribute to the establishment of relevant key epidemiological 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;

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

(k) present an annual report of activities to the Agency and the national stakeholders, including national decision-makers;

(l) compile an up-to-date inventory of national drug information sources;

(m) carry out peer-review processes and other quality assurance mechanisms to data input or output and apply quality control processes to ensure the reliability of the data and information obtained;

(n) assess the information needs of its national stakeholders, in particular its national decision-makers; and

(o) execute a communication strategy or carry out other activities to present its information to professionals or the general public.

3. The national focal point shall have the right to collect from other national authorities, bodies, agencies and organisations all the information it needs to carry out its tasks in accordance with paragraph 2. The national focal point shall maintain an extensive network of national partners and data providers for the collection of such information.

Article 34

Certification procedure for the National Focal Points

1. By *[OP please insert the date = 18 months after the entry into force of the Regulation]* at the latest, each national focal point shall apply for certification to the Agency.

2. The Agency shall certify each national focal point in its function as national focal point if it complies with the requirements set out in Article 32 and is entrusted with carrying out the tasks set out in Article 33.

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

3. The national focal point shall provide to the Agency all relevant information to prove that Articles 32 and 33 are complied with. If necessary, the Agency shall carry out a visit with the national focal point.

4. If a national focal point does not comply with the requirements set out in Article 32 or is not entrusted with carrying out the tasks set out in Article 33, the Agency shall provide a list of recommendations to the national focal point and certify the national focal point after a reassessment only once these recommendations are complied with.

CHAPTER VI

FINANCIAL PROVISIONS

Article 35

Single programming document

1. By 15 December of each year, the Management Board shall adopt a draft single programming document containing multi-annual and annual programming as well as all the documents listed in Article 32 of Commission Delegated Regulation (EU) 2019/715[22], based on a draft put forward by the Executive Director, after consulting the Scientific Committee, taking into account the opinion of the Commission, and in relation to multiannual programming after consulting the European Parliament. It shall forward it to the European Parliament, the Council and the Commission by 31 January of the following year.

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

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

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

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

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

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

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

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

Article 36

Budget

[22] 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).

1. Estimates of all revenue and expenditure for the Agency shall be prepared each financial year, corresponding to the calendar year, and shall be shown in the Agency's budget.

2. The Agency's budget shall be balanced in terms of revenue and of expenditure.

3. Without prejudice to other resources, the Agency's revenue shall comprise:

   (a) a contribution from the Union entered in the general budget of the European Union;

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

   (c) the fees paid for services rendered in accordance with Article 37; and

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

4. The expenditure of the Agency shall include staff remuneration, administrative and infrastructure expenses, and operating costs. The operating costs may include expenditure in support of the national focal points, as referred to in Article 32(7).

Article 37

Fees

1. The Agency may charge fees for the following:

   (a) training programmes;

   (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) certification of national bodies set up in third countries pursuant to Article 20(3);

   (e) other services falling within its mandate and rendered at the request of a participating country which require the investment of resources in the support of national activities.

2. At the proposal of the Executive Director, the Management Board of the Agency shall set the amount of the fees and the way in which they are paid.

3. Fees shall be proportionate to the costs of the relevant services as provided in a cost-effective way and shall be sufficient to cover those costs. Fees shall be set at such a level as to ensure that they are non-discriminatory and that they avoid placing an undue financial or administrative burden on stakeholders.

4. Fees should be set at a level such as to avoid a deficit or a significant accumulation of surplus in the budget. Should a significant positive balance in the budget, resulting from the provision of the services covered by fees, become recurrent, a revision of the level of the fees, or of the Union contribution, shall become mandatory. In case a significant negative balance results from the provision of the services covered by fees, a revision of the level of the fees shall become mandatory.

Article 38

Establishment of the budget

1. Each year, the Executive Director shall draw up a draft statement of estimates of the Agency's revenue and expenditure for the following financial year, including the establishment plan, and send it to the Management Board.

2. The Management Board shall, based on that draft, adopt a provisional draft estimate of the Agency's revenue and expenditure for the following financial year.

3. The provisional draft estimate of the Agency's revenue and expenditure shall be sent to the Commission by 31 January each year. The Management Board shall send the final draft estimate to the Commission by 31 March.

4. The Commission shall send the statement of estimates to the budgetary authority together with the draft general budget of the European Union.

5. On the basis of the statement of estimates, the Commission shall enter in the draft general budget of the Union the estimates it considers necessary for the establishment plan and the amount of the subsidy to be charged to the general budget, which it shall place before the budgetary authority in accordance with Articles 313 and 314 TFEU.

6. The budgetary authority shall authorise the appropriations for the contribution to the Agency.

7. The budgetary authority shall adopt the Agency's establishment plan.

8. The Agency's budget shall be adopted by the Management Board by a majority of two-thirds of members entitled to vote. It shall become final following final adoption of the general budget of the European Union. Where necessary, it shall be adjusted accordingly.

9. For any building project likely to have significant implications for the budget of the Agency, the provisions of Delegated Regulation (EU) 2019/715[23] apply.

Article 39

Implementation of the budget

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

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

Article 40

Presentation of accounts and discharge

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

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

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

3. 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.

4. On receipt of the Court of Auditors' observations on the Agency's provisional accounts pursuant to Article 246 of the Financial Regulation[24], the Executive Director shall draw up the Agency's final accounts under her/his own responsibility and submit them to the Management Board for an opinion.

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

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

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

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

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

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

Article 41

Financial rules

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

CHAPTER VII

STAFF

Article 42

General provision

1. The Staff Regulations and the Conditions of Employment of Other Servants and the rules adopted by agreement between the institutions of the Union for giving effect to

[24] 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).

those Staff Regulations and the Conditions of Employment of Other Servants shall apply to the staff of the Agency.

2. Where it engages staff from third countries following the conclusion of the agreements referred to in Article 54, the Agency shall, in any event, comply with the Staff Regulations and Conditions of Employment referred to in paragraph 1.

Article 43

Executive Director

1. The Executive Director shall be engaged as a temporary agent of the Agency under Article 2, point (a), of the Conditions of Employment of Other Servants.

2. The Executive Director shall be appointed by the Management Board, from a list of candidates proposed by the Commission, following an open and transparent selection procedure.

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 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 no more than five years.

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

7. The Executive Director may be removed from office only upon a decision of the Management Board acting on a proposal from the Commission.

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

Article 44

Seconded national experts and other staff

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

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

CHAPTER VIII

GENERAL AND FINAL PROVISIONS

Article 45

Privileges and immunities

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

Article 46

Language arrangements

The provisions laid down in Council Regulation No 1[25] shall apply to the Agency.

Article 47

Transparency

1. Regulation (EC) No 1049/2001 shall apply to documents held by the Agency.
2. The processing of personal data by the Agency shall be subject to Regulation (EU) 2018/1725 of the European Parliament and of the Council[26].
3. The Management Board shall, within six months of the date of its first meeting following the date of application of this Regulation, as referred to in Article 63, second subparagraph, establish measures for the application of Regulation (EU) 2018/1725 by the Agency, including those concerning the appointment of a Data Protection Officer of the Agency. Those measures shall be established after consultation of the European Data Protection Supervisor.

Article 48

Combatting fraud

1. In order to combat fraud, corruption and other unlawful activities, the provisions of Regulation (EU, Euratom) No 883/2013[27] shall apply to the Agency.
2. The Agency shall accede to the Interinstitutional Agreement of 25 May 1999 concerning internal investigations by the OLAF by six months from the day this Regulation comes into force, and shall adopt appropriate provisions applicable to all employees of the Agency using the template set out in the Annex to that Agreement.
3. The Court of Auditors shall have the power of audit, on the basis of documents and on the spot, over all grant beneficiaries, contractors and subcontractors who have received Union funds from the Agency.
4. OLAF and EPPO may carry out investigations, including 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

---

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

26 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).

27 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).

and procedures laid down in Regulation (EU, Euratom) No 883/2013 and Regulation (Euratom, EC) No 2185/96[28].

5. Without prejudice to paragraphs 1 to 4, cooperation agreements with international organisations and third countries as referred to in Articles 53 and 54, contracts, grant agreements and grant decisions of the Agency shall contain provisions expressly empowering the Court of Auditors and OLAF to conduct such audits and investigations, according to their respective competences.

Article 49

Protection of classified and sensitive non-classified information

1. The Agency shall adopt security rules equivalent to the Commission's security rules for protecting European Union Classified Information (EUCI) and sensitive non-classified information, as set out in Commission Decisions (EU, Euratom) 2015/443[29] and 2015/444[30]. The security rules of the Agency shall cover, among other, provisions for the exchange, processing and storage of such information.

2. The Agency may only exchange classified information with the relevant authorities of a third country or international organisation or share EUCI classified information with another Union body under the framework of Administrative Arrangements. Any such Administrative Arrangement shall be subject to the authorisation of the Management Board after consultation of the Commission. In the absence of such administrative Arrangement, any exceptional *ad hoc* release of EUCI to those authorities shall be subject to a decision by the Executive Director after consultation of the Commission.

Article 50

Liability

1. The Agency's contractual liability shall be governed by the law applicable to the contract in question.

2. The Court of Justice of the European Union shall have jurisdiction to give judgment pursuant to any arbitration clause contained in a contract concluded by the Agency.

3. In the case of non-contractual liability, the Agency shall, in accordance with the general principles common to the laws of the Member States, make good any damage caused by its departments or by its staff in the performance of their duties.

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

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

---

28 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).

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

30 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).

Article 51

Evaluation and review

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

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

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

Article 52

Administrative inquiries

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

Article 53

Cooperation with other organisations and bodies

1. The Agency shall actively seek to cooperate with international organisations and other, particularly Union, governmental and non-governmental bodies as well as technical bodies competent in matters covered by this Regulation, within the framework of working arrangements concluded with those bodies, in accordance with the Treaty on the Functioning of the European Union and the provisions on the competence of those bodies. Those working arrangements shall not cover the exchange of classified information.

2. Such working arrangements shall be adopted by the Management Board based on a draft submitted by the Executive Director and after the Commission's prior approval. Where the Commission expresses its disagreement with those working arrangements, the Management Board shall adopt them by a three-fourths majority of the members with a right to vote.

3. Amendments or changes to existing working arrangements, which are limited in scope and do not change the overall scope and intention of the working arrangements, or technical working arrangements with other technical bodies shall be adopted by the Management Board based on a draft submitted by the Executive Director and after prior information to the Commission.

Article 54

Cooperation with third countries

1. The Agency shall be open to the participation in its work of third countries that have entered into agreements with the Union to this effect.

2. Under the relevant provisions of the agreements referred to in paragraph 1, arrangements shall be developed specifying, in particular, the nature, extent and manner in which the third countries concerned are to participate in the work of the Agency, including provisions relating to participation in the initiatives undertaken by the Agency, financial contributions and staff.

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

Article 55

Consultation of civil society organisations

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

Article 56

Headquarters Agreement and operating conditions

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

2. The Agency's host Member State shall provide the best possible conditions to ensure the smooth and efficient functioning of the Agency, including multilingual, European-oriented schooling and appropriate transport connections.

Article 57

Legal succession

1. The Agency as established by this Regulation shall be the legal successor in respect of all contracts concluded by, liabilities incumbent upon and properties acquired by the European Monitoring Centre for Drugs and Drug Addiction as established by Regulation (EC) No 1920/2006.

2. This Regulation shall not affect the legal force of agreements and arrangements concluded by the European Monitoring Centre for Drugs and Drug Addiction as established by Regulation (EC) No 1920/2006 before *[OP please insert the date = 12 months after the entry into force of the Regulation]*.

Article 58

Transitional arrangements concerning the Management Board

1. The Management Board of European Monitoring Centre for Drugs and Drug Addiction as established by Regulation (EC) No 1920/2006 shall continue its work and functioning based on Regulation (EC) No 1920/2006 and the rules established

under that Regulation until all representatives of the Management Board are appointed in accordance with Article 23 of this Regulation.

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

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

Article 59

Transitional arrangements concerning the Executive Director

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

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

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

Article 60

Transitional arrangements concerning the national focal points

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

Article 61

Transitional budgetary provisions

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

Article 62

Repeal of Regulation (EC) No 1920/2006

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

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

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

Article 63

Entry into force

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

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

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

Done at Brussels,

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

LEGISLATIVE FINANCIAL STATEMENT

1. FRAMEWORK OF THE PROPOSAL/INITIATIVE

1.1. Title of the proposal/initiative

Proposal for a Regulation of the European Parliament and of the Council on the European Union Drugs Agency

1.2. Policy area(s) concerned

Policy area: Home Affairs

Activity: Security

12 10 03: European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)

1.3. The proposal relates to

☐ **a new action**

☐ **a new action following a pilot project/preparatory action**[74]

☒ **the extension of an existing action**

☐ **a merger of one or more actions towards another/a new action**

1.4. Objective(s)

1.4.1. General objective(s)

The general objective of the targeted revision of the founding Regulation is to ensure that the Agency is appropriately equipped to deal with the current and future challenges posed by drugs in the EU, enabling the agency to implement effective action in support to Member States efforts in this policy area.

EMCDDA operations demonstrate sound financial management, as the agency has a long historic record of excellent implementation of policy, with 99,9% budget implementation every year, fully in line with requirements on legality and regularity. Persons and institutions charged with management and governance of the agency receive a clean external audit report every year. Moreover, reporting and resolutions by the authority in charge, grant discharge to management in respect of implementation of the agency budget every year, confirming a consistently good performance of the agency under its current mandate.

Illicit drugs are a complex security and health problem that affects millions of people in the EU and globally. The situation is deteriorating, with volumes of cocaine and heroin introduced in the EU at all-time high. The use of benzodiazepines is also on the rise, potentially reflecting the high availability and low cost of these substances as well as pandemic-related mental health issues.

Production of drugs on the territory of EU Member States, in particular synthetic drugs (amphetamines and ecstasy) takes place for domestic consumption and for export. The drug market is estimated at a minimum retail value of EUR 30 billion per year, and it remains the largest criminal market and a major source of income for organised crime groups in the EU.

The Commission carried out an evaluation of the Agency[75] in 2019. It concluded, that there is an increasing disconnect between the complexity of the contemporary drug phenomenon and

[74] As referred to in Article 58(2)(a) or (b) of the Financial Regulation.

the Agency's founding regulation[76]. Therefore, the agency is out of step with tasks under its current mandate as it is insufficiently equipped to address requests made to it by its main stakeholders effectively. The agency has not received any additions to its resources other than the automatic correction of 2% in the recent past, except for a one-off addition of funding in the 2020 budget pursuant to the relevant legal/contractual obligations due to critical external variables. The number of staff in employment has been stable.

These developments call for effective EU level action. The EU Drugs Strategy 2021-2025 and the EU Drugs Action Plan 2021-2025 set out the strategic framework. The Strategy invites the Commission "to present a proposal to revise the mandate of the EMCDDA as soon as possible, to ensure that the agency plays a stronger part in addressing the current and future challenges of the drug phenomenon". The current proposal intends to deliver on this request, updating the current mandate as follows:

Current mandate		Specific objectives of the revised mandate	
- Collection and analysis of existing data - Improvement of data-comparison methods - Dissemination of data	>>	3) Establishment of a virtual forensic & toxicological laboratory 4) Strengthened role of REITOX National Focal Points.	1) Wider coverage of poly-drug use issues. 2) Enhanced capacity for threat assessment. 6) Enhanced capacity in supply and security issues.
- Cooperation with European and international bodies and organisations and with third countries	>>	7) Clarification of the international dimension	
- Information obligations	>>	5) Enhanced competence for information campaigns and risk communication	

1.4.2. Specific objective(s)

Defining seven specific objectives, the Commission sets out the logic of intervention in line with principles of budgeting in EU entities. The present legislative financial statement (LFS) is sound financial management as it presents the outcome of careful mapping of complementary resources with a view to extend the scope of agency activities.

1. Wider coverage of poly-drug use issues

Challenges arising from the interaction between the use of more than one psychoactive substance or type of substance are increasing, which requires appropriate policies and responses. These challenges include the increased risks of health and social problems, which may occur when psychoactive substances are consumed together with illicit drugs at the same time or sequentially within a short period of time. Similarly, it is important to address situations when different substances are produced or sold together and to consider the common causes of drug use and addictions, as well as the implications for monitoring and exchange of best practice targeting multiple substances holistically. The aim of this specific objective is thus to expand the Agency's scope of action to address other substance-based addictions when these substances are taken together with illicit drugs. The revision is also to provide a

[75] The fourth evaluation of EMCDDA, ref. COM(2019) 228.

[76] Regulation (EC) No 1920/2006 of the European Parliament and of the Council of 12 December 2006on the European Monitoring Centre for Drugs and Drug Addiction (recast)

better definition of poly-drug use and requires that national focal points provide the agency with relevant reporting, including data.

2. Enhanced capacity for threat assessment

The aim is to strengthen the Agency's monitoring and threat assessment capabilities, and its ability to react to new challenges. The revision will also allow the Agency to provide further support to Member States.

3. Establishment of a virtual forensic & toxicological laboratory

The aim is to establish a virtual laboratory, i.e. a specialist network of scientists and laboratories engaged in forensic and toxicological analysis. Sufficient laboratory and scientific competence and experience would still be needed in the Agency in order to steer the work of the virtual laboratory. A network of already existing national laboratories would be combined with a competence centre in the Agency, to ensure that all forensic and toxicological information is available to the Agency.

4. Strengthened role of REITOX[77] National Focal Points

The role of the Reitox network is currently set out in Article 5 of the founding Regulation. It is the interface between the Agency and the participating countries. The Reitox national focal points bring together the core data on drugs and drug addiction, as well as on policies and solutions applied. This is the basis for the key indicators and data used by the Agency. The Reitox network is the main source of information for the Agency. The Reitox National Focal points, however, sometimes face important challenges in terms of legal powers, human and financial resources, which are impacting on the quality and timing of the data provided. The aim is therefore to enable the National Focal Points to collect and provide the relevant data to the Agency. The revised founding Regulation will set minimum requirements for their set-up and certification by the Agency. The mandate of the national focal points has to reflect also the revision of the Agency mandate.

5. Enhanced competence for information campaigns and risk communication

The aim is to provide the Agency with the competence to act on its analysis and develop EU-level prevention and awareness raising campaigns as well as issue alerts in case particularly dangerous substances become available on the market.

6. Enhanced capacity in supply and security issues

The aim is to expand the Agency's mandate to also explicitly address drug supply and drug market issues, as this is an increasingly important dimension of the drug phenomenon. The future EU Drugs Agency shall be capable to act effectively in that dimension.

7. Clarification of the international dimension

Despite its international recognition as a centre of excellence and its active engagement on international issues, the founding Regulation does not define sufficiently the responsibilities of the Agency in this area. The Agency needs a clear mandate to analyse global developments and developments in third countries, which have the potential to affect the EU. With the drug phenomenon becoming increasingly global in its operation, a good understanding of the impacts of drug policies in third countries onto the EU markets is important. On issues, where the Agency has competences on an EU-level, it should also be able to contribute on an international level. It would contribute to the development and implementation of the external dimension of the EU's drugs policy and the leadership role of the EU at multilateral level. This should lead to reconsidering the current "ad hoc" and "project funding" approach, which puts obstacles to the Agency's performance and does not enable the EU to fully live

[77] Reitox is an abbreviation used for the European Information Network on Drugs and Drug Addiction

up to the expectations and political commitments of increased cooperation in the field of drugs with third countries. The aim is therefore to clarify the tasks of the Agency as regards the international dimension, to include in the mandate itself the necessary competencies.

1.4.3. Expected result(s) and impact

Specify the effects which the proposal/initiative should have on the beneficiaries/groups targeted.

Authorities in Member States, as well as the EU institutions, will be main beneficiaries of the reinforced functioning of the Agency. The revision of the founding Regulation would contribute to a reduction of administrative burden and a simplification of administrative procedures, in particular in the Member States. Amongst the contributing factors to this are the proposed streamlining and centralisation of reporting obligations in the Member States through the national focal points, monitoring drug markets and maintaining an early warning system and drug alert system, organisation of training, development of best practices, etc. This would lead to a reduction of administrative costs in the Member States. Another example is that better information would be available from the Agency for the benefit not only of the EU, but also of the Member States. Member States on their own would not be able to collect and analyse data to the same extent as they lack either the knowledge or the resources, or the problem is a cross-border one. The latter element is also an argument for administrative simplification as no Member State could address those issues on their own and cooperating with numerous countries would lead to a high administrative burden.

An extended mandate of the Agency will positively contribute to the economy and competitiveness on one hand and to law enforcement effort on the other. A renewed mandate will enable the Agency to implement activities that will help national authorities run better targeted drug prevention programmes and thereby, indirectly, will contribute to a more effective labour force (i.e. better drug prevention will reduce the labour-related incapacity linked to drug addictions). It will also contribute to law enforcement efforts in disrupting activities of organised crime groups. These are indirect impacts, which would be due to a better understanding of the drug situation. The direct economic impact is on the EU and national budgets.

The Agency will complement efforts by relevant stakeholders, in particular Member States' law enforcement authorities. The Agency will improve the analysis of drug supply in the EU based on better information on drug trafficking and production, thereby contributing to more effective law enforcement and supporting the internal security of the EU. In addition, improved access to best practices in the area of drug demand and other public health responses will be made to beneficiaries of the Agency's services. Moreover, the Agency will make relevant contribution to actions in support of the mental health policies in Member States.

The revision of the mandate would also have indirect environmental impact. Drug production on the territory of the EU Member States, in particular of MDMA (ecstasy) and (meth) amphetamines, has considerable negative impact on the environment, in particular when it comes to the dumping of the waste of drug production. Better knowledge regarding the production methods and precursor diversion would support the work of law enforcement in discovering illicit drug labs and subsequently in reducing environmental crime.

The work of the Agency tackles issues related to fundamental rights, e.g. the work on alternatives to coercive sanctions, the work on minimum quality standards in drug-demand reduction, best practices on treatment and harm reduction. In that sense, it is expected, that realignment of the functioning of the Agency shall have positive indirect impact in fundamental rights.

1.4.4. Indicators of performance

Specify the indicators for monitoring progress and achievements.

Number of publications which address substance-based addictions when these substances are taken together with illicit drugs in the context of poly-substance use.

Number of general threat assessments carried out by the Agency.

Virtual laboratory set up and involved in the regular work of the Agency.

Number of EU-level alerts issued.

Number of campaigns developed or their development supported.

Number of intelligence reports on supply-side issues provided to law enforcement authorities.

Number of notifications to the EU early warning system.

1.5. Grounds for the proposal/initiative

1.5.1. Requirement(s) to be met in the short or long term including a detailed timeline for roll-out of the implementation of the initiative

The Agency's scope of action shall be expanded to address other substance-based addictions when these substances are taken together with illicit drugs; the revision shall clarify the definition of poly-drug use. The targeted widening of the mandate shall enable the national focal points to provide the agency with complementary reporting, including data.

The Agency's mandate shall be expanded to explicitly address drug supply and drug market issues as this is an increasingly important dimension of the drug phenomenon and an EU Drugs Agency has to be able to fully address that dimension.

The Agency's monitoring and threat assessment capabilities would be strengthened and the Agency would provide further support to the Member States to increase the ability of the Agency to react to the drug phenomenon and to new challenges.

A virtual laboratory, i.e. a network of laboratories combined with a competence centre in the Agency, would be established to ensure that all forensic and toxicological information is available to the Agency.

The new Regulation shall set minimum requirements for the set-up of national focal points, which shall then certified by the Agency. The mandate of the national focal points shall reflect the revision of the Agency mandate.

The Agency shall have the competence to develop EU-level prevention and awareness raising campaigns as well as issue alerts in case particularly dangerous substances are available on the market.

As regards the international dimension, the tasks of the Agency would be clarified to include in the mandate itself the relevant competencies.

1.5.2. Added value of Union involvement (it may result from different factors, e.g. coordination gains, legal certainty, greater effectiveness or complementarities). For the purposes of this point 'added value of Union involvement' is the value resulting from Union intervention which is additional to the value that would have been otherwise created by Member States alone.

The drug phenomenon is affecting all Europeans and is cross-border, trans-continental and multi-jurisdictional in nature, in particular in the supply of drugs and the associated organised crime. Common challenges across Member States are numerous, both on the health and security side, which Member States may ever tackle effectively when acting in coordination. It is not viable to address the drug phenomenon at national or regional/sub-national level as drugs move across state borders and continents.

A problematic health or security pattern detected in a Member State very often appears in other Member States. National legislation or even the best national practice would not be able to address the cross-border aspects of the drug phenomenon. Due to this transnational character, there is a need for EU-level action.

1.5.3. Lessons learned from similar experiences in the past

This legislative proposal takes account of a wide range of EU policies in the area of internal security and public health. When it comes to drugs policies in the narrower sense, this legislative proposal takes account of the EU Drugs Strategy 2021-2025 and the related Action Plan. It also takes account of the amendment of Regulation (EC) No 1920/2006 as well as several acts to add substances to the definition of drugs under Council Framework Decision 2004/757/JHA. This legislative proposal furthermore takes account of cooperation[78] of the Agency with other Union bodies, in particular Europol, the European Union Agency for Law Enforcement Training (CEPOL), the European Medicines Agency (EMA), and the European Centre for Disease Prevention and Control (ECDC), as well as other EU agencies.

1.5.4. Compatibility with the Multiannual Financial Framework and possible synergies with other appropriate instruments

As regards innovation, this legislative proposal takes account of EU funding for drugs policy under Horizon 2020, the Internal Security Fund, the Drugs Policy Initiatives under the Justice Programme and the new Horizon Europe research programme. As regards public health, this legislative proposal takes account of the establishment of an early warning and response system in relation to serious cross-border threats to health and the proposals for the changes in the mandates of some of the above-mentioned agencies. It also considered the establishment of the European Health Emergency Preparedness and Response Authority (HERA). As regards the Agency's cooperation with third countries, this legislative proposal takes account of the Union's external policies.

1.5.5. Assessment of the different available financing options, including scope for redeployment

The EU contribution to the Agency has largely stayed stable in the MFF 2014-2020 despite an extended mandate following the adoption of the 2017 legislation on new psychoactive substances and the unavoidable rise of the Agency's operating costs.

The MFF 2021-2027 tables for a stable EU contribution to the Agency, with stable staff and an annual indexation of 2%.

The proposed revision intends to modernise the founding Regulation of the Agency, which has not been modified since 2006, and to clarify some of its existing provisions. It will also add new tasks, which are required in order to effectively address recent developments in drug markets policy. Indeed, the current mandate of the Agency does not reflect the current reality of the drug phenomenon. Therefore, the agency is out of step with tasks that an effectively functioning Agency is required to perform in addressing the challenges of the present day drug phenomenon and thereby effectively respond to requests made to it by its main stakeholders.

Since the proposal shall expand the Agency's mandate and will also clarify other tasks, hereby extending the Agency's capabilities under the terms of the treaties.

[78] For instance, the key drugs report at EU level - EU Drug Markets Report – is issued jointly by EMCDDA and Europol. Another example includes cooperation with relevant Justice and Home Affairs Agencies on training for drug law enforcement and judicial decision-makers or in the context of the risk assessment procedure for new psychoactive substances.

It is sound financial management to align the level of resources to a revised mandate. The proposal needs to be supported by additional financial resources and staff, compared to resources earmarked in the adopted Multiannual Financial Framework 2021-2027.

1.6. Duration and financial impact of the proposal/initiative

☐ **limited duration**

– ☐ Proposal/initiative in effect from [DD/MM]YYYY to [DD/MM]YYYY

– ☐ Financial impact from YYYY to YYYY

☒ **unlimited duration**

Implementation with a start-up period from 2024 to 2027, followed by full-scale operation.

1.7. Management mode(s) planned[79]

☐ **Direct management** by the Commission through

– ☐ executive agencies

☐ **Shared management** with the Member States

☒ **Indirect management** by entrusting budget implementation tasks to:

☐ international organisations and their agencies (to be specified);

☐the EIB and the European Investment Fund;

☒ bodies referred to in Articles 70 and 71;

☐ public law bodies;

☐ bodies governed by private law with a public service mission to the extent that they provide adequate financial guarantees;

☐ bodies governed by the private law of a Member State that are entrusted with the implementation of a public-private partnership and that provide adequate financial guarantees;

☐ persons entrusted with the implementation of specific actions in the CFSP pursuant to Title V of the TEU, and identified in the relevant basic act.

Comments

The baseline for the EU contribution to the European Union Drugs Agency's budget has been identified based on the adopted Multiannual Financial Framework 2021-2027, and on Fiche n°68[80].

To ensure optimal readability and transparency, the estimated financial impact of the legislative initiative includes only the resources needed in addition to the Agency's baseline EU contribution as set in the adopted MFF 2021-2027 (only the additional costs compared to the baseline are indicated, not the cumulative costs, unless clearly specified otherwise).

79 Details of management modes and references to the Financial Regulation may be found on the BudgWeb site: https://myintracomm.ec.europa.eu/budgweb/EN/man/budgmanag/Pages/budgmanag.aspx.

80 Working Document of the Commission Services on decentralised agencies and EPPO, 8 June 2020

2. MANAGEMENT MEASURES

2.1. Monitoring and reporting rules

Specify frequency and conditions.

The monitoring and reporting of the proposal shall follow principles outlined in the EMCDDA's Regulation[81], Financial Regulation[82] and in line with the Common Approach on decentralised agencies[83].

In particular, the Agency shall send each year to the Commission, the European Parliament and the Council a Single Programming Document (SPD) containing multi-annual and annual work programmes and resources programming. The SPD shall set out the objectives, expected results and performance indicators to monitor the achievement of objectives and results. The Agency shall submit a Consolidated Annual Activity Report to the management board. This report notably includes information on the achievement of the objectives and results set out in the SPD. The report shall be sent to the Commission, the European Parliament and the Council.

Moreover, the Commission shall regularly initiate an evaluation of the Agency's performance in relation to its objectives, mandate, tasks and location (every 6 years in the previous Regulation, every 5 years in the current proposal). The Commission shall forward the evaluation report to the European Parliament, the Council and the Agency's Management Board.

The 4th evaluation took place in 2018/19. It concluded that the Agency works overall well, especially as regards the five evaluation criteria (relevance, effectiveness, efficiency, coherence, EU added value), but that improvements are required in several areas, in particular in view of latest developments in the drug phenomenon. This last evaluation is one of the triggers of the present proposal, revising the Agency's mandate.

Further to this evaluation mechanism, the Commission will draw data through its representation in the Agency's Management Board meetings and its supervision, along with the Member States, of the Agency's work.

2.2. Management and control system(s)

2.2.1. Justification of the management mode(s), the funding implementation mechanism(s), the payment modalities and the control strategy proposed

Considering that the proposal impacts the annual EU contribution to the Agency, the EU budget will be implemented via indirect management.

Pursuant to the principle of sound financial management, the budget of the EMCDDA shall be implemented in compliance with effective and efficient internal control[84]. The EMCDDA is therefore

[81] Regulation (EU) 2017/2101 of the European Parliament and of the Council of 15 November 2017 amending Regulation (EC) No 1920/2006 as regards information exchange on, and an early warning system and risk assessment procedure for, new psychoactive substances. The European Monitoring Centre for Drugs and Drug Addiction was set up by Council Regulation (EEC) No 302/93. This founding act was recast in 2006 through Regulation (EC) No 1920/2006, which was amended through Regulation (EU) No 2017/2101 by integrating the rules as regards information exchange on, and an early warning system and risk assessment procedure for new psychoactive substances.

[82] Financial Regulation of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) - https://www.emcdda.europa.eu/system/files/publications/1013/financial-regulation-emcdda-Jun2019.pdf

[83] https://europa.eu/european-union/sites/europaeu/files/docs/body/joint_statement_and_common_approach_2012_en.pdf

[84] In line with the EMCDDA's Financial Regulation, Article 30 "Internal control of budget implementation"

bound to implement an appropriate control strategy coordinated among the various participants required by the EU financial regulation.

Regarding ex-post controls, the EMCDDA, as a decentralised agency, is subject to:

- internal audit by the Internal Audit Service of the Commission.

- annual reports by the European Court of Auditors, giving a statement of assurance as to the reliability of the annual accounts and the legality and regularity of the underlying transactions.

- annual discharge granted by the European Parliament.

- possible investigations conducted by OLAF to ensure, in particular, that the resources allocated to agencies are put to proper use.

As partner DG to the Agency, DG HOME will implement its Control Strategy on decentralised agencies to ensure reliable reporting in the framework of its Annual Activity Report (AAR). While decentralised agencies have full responsibility for the implementation of their budget, DG HOME is responsible for regular payment of annual contributions established by the Budgetary Authority.

Finally, the European Ombudsman provides a further layer of control and accountability.

2.2.2. Information concerning the risks identified and the internal control system(s) set up to mitigate them

The Agency implements internal control standards (ICS) and a specific Internal Control Framework (ICF), both deriving from the principles and guidelines laid down by the European Commission. The ICS and the ICF constitute the basis for assessing the effectiveness of the internal control system at the Agency.

The ICF consists of five interrelated components and 17 principles aimed at providing reasonable assurance in relation to the: 1. effectiveness, efficiency and economy of the operations; 2. reliability of reporting; 3. safeguarding of assets and information; 4. prevention, detection, correction and follow-up of fraud and irregularities; 5. adequate management of risks relating to the legality and regularity of the underlying transactions.

The risk management process is a central element in the system of internal control and a comprehensive risk identification and assessment exercise takes place regularly aimed at improving risk management at the Agency. The central risk register is updated regularly. This register identifies, for each area, the estimated risk level, impact and response; the mitigating measures currently in place; and the list of programmes, projects and actions that will contribute to reducing the outstanding residual risk levels. Risk assessment is carried out continuously at the Agency throughout the year, while a comprehensive analysis was performed by the managers in the context of preparing the single programming documents.

Moreover, the Agency's Single Programming Document must provide information on the internal control systems, while the Consolidated Annual Activity Report – or General Report of Activities - must contain information on the efficiency and effectiveness of the internal control systems, including as regards risk assessment. The 2020 Report indicates that the internal control system as a whole has been assessed as fully effective and functioning well.

As a decentralised agency, the EMCDDA's activities and operations are also controlled by, among others, the European Court of Auditors and the Internal Audit Service.

Finally, as partner DG of the Agency, DG HOME runs an annual risk management exercise to identify and assess potential high risks related to agencies' operations, including the EMCDDA. Risks

considered as critical are reported annually in DG HOME management plan and are accompanied by an action plan stating the mitigating actions.

2.2.3. Estimation and justification of the cost-effectiveness of the controls (ratio of "control costs ÷ value of the related funds managed"), and assessment of the expected levels of risk of error (at payment & at closure)

The ratio of "control costs/value of the related funds managed" is reported on by the Commission. The 2020 AAR of DG HOME reports 0.21% for this ratio in relation to Indirect Management Entrusted Entities and Decentralised Agencies, including the EMCDDA.

The European Court of Auditors confirmed the legality and regularity of the EMCDDA's annual accounts for 2020, which implies an error rate below 2%. There are no indications that the error rate would worsen in the coming years.

Moreover, Article 80 of the EMCDDA's Financial Regulation provides for the possibility for the Agency to share an internal audit capability with other Union bodies functioning in the same policy area if the internal audit capability of a single Union body is not cost-effective.

2.3. Measures to prevent fraud and irregularities

Specify existing or envisaged prevention and protection measures, e.g. from the Anti-Fraud Strategy.

The measures related to combating fraud, corruption and any other illegal activities are outlined, inter alia, in Article 16 of the Agency's Regulation and under Title X of the Agency's Financial Regulation.

The EMCDDA implements a specific anti-fraud strategy which reflects OLAF's methodology and guidance, in line with the Common Approach on EU decentralised agencies. The EMCDDA has started to review its Anti-fraud Strategy as a follow up to the revision performed by the European Commission of its own in 2019. The work is expected to be carried out over 2021.

The Agency also implements a specific policy for the for the prevention and management of conflicts of interest, which took into account the main recommendations addressed to agencies in this area by the European Parliament, the European Court of Auditors, the EU Ombudsman and the Commission's Internal Audit Service.

In its 2020 General Report of Activities, the Agency reports that there has been no cases of fraud since its creation. The degree of exposure of the EMCDDA to the risk of fraud can therefore be generally considered as relatively reduced.

Finally, as partner DG, DG HOME has developed and implemented its own anti-fraud strategy on the basis of the methodology provided by OLAF. Decentralised agencies, including the EMCDDA, fall within the scope of the strategy. In its 2020 AAR, DG HOME concluded that it had reasonable assurance that the anti-fraud measures in place were effective.

3. ESTIMATED FINANCIAL IMPACT OF THE PROPOSAL/INITIATIVE

3.1. Heading(s) of the multiannual financial framework and expenditure budget line(s) affected

- Existing budget lines

In order of multiannual financial framework headings and budget lines.

Heading of multiannual financial framework	Budget line	Type of expenditure	Contribution			
	Number	Diff./Non-diff.[85]	from EFTA countries [86]	from candidate countries[87]	from third countries	within the meaning of Article 21(2)(b) of the Financial Regulation
5	12 10 03	Diff./Non-diff.	NO	NO	NO	NO

85 Diff. = Differentiated appropriations / Non-diff. = Non-differentiated appropriations.

86 EFTA: European Free Trade Association.

87 Candidate countries and, where applicable, potential candidates from the Western Balkans.

3.2. Estimated impact on expenditure

3.2.1. Summary of estimated impact on expenditure

EUR million (to three decimal places)

Heading of multiannual financial framework	Number	Heading 5 –Security and Defence

European Union Drugs Agency			Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL**
Title 1:	Commitments	(1)					
	Payments	(2)					
Title 2:	Commitments	(1a)					
	Payments	(2a)					
Title 3:	Commitments	(3a)					
	Payments	(3b)					
TOTAL appropriations for the European Union Drugs Agency	Commitments	=1+1a +3a	14,137	15,634	16,376	16,784	**62,931**
	Payments	=2+2a +3b	14,137	15,634	16,376	16,784	**62,931**

Heading of multiannual financial framework	**7**	'Administrative expenditure'

EUR million (to three decimal places)

		Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL**
DG: HOME						
• Human Resources		0,152	0,152	0,152	0,152	0,608
• Other administrative expenditure		**0.110**	**0.110**	**0.110**	**0.110**	**0.440**
TOTAL DG HOME	Appropriations	0.262	0.262	0.262	0.262	**1.048**

TOTAL appropriations under HEADING 7 of the multiannual financial framework	(Total commitments = Total payments)	0.262	0.262	0.262	0.262	**1.048**

EUR million (to three decimal places)

		Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL**
TOTAL appropriations under HEADINGS 1 to 7 of the multiannual financial framework	Commitments	14,399	15,896	16,638	17,046	**63,979**
	Payments	14,399	15,896	16,638	17,046	**63,979**

3.2.2. Estimated impact on [body]'s appropriations

– ☐ The proposal/initiative does not require the use of operational appropriations

– ☒ The proposal/initiative requires the use of operational appropriations, as explained below:

The estimated financial impact of the legislative initiative includes only the resources needed in addition to the EMCDDA's baseline EU contribution (additional costs compared to the baseline – MFF 2021-2027).

Commitment appropriations in EUR million (to three decimal places)

Indicate objectives and outputs ⇩			Year **2024**		Year **2025**		Year **2026**		Year **2027**		**TOTAL**	
	Type[88]	Average cost	No	Cost	No	Cost	No	Cost	No	Cost	Total No	Total cost
SPECIFIC OBJECTIVE No 1 Wider coverage of poly-drug use issues												
- Output	Number of publications which address addictions beyond illicit drugs in the context of poly-substance use.			1.676		1.858		1.834		1.903		7.271
Subtotal for specific objective No 1				1.676		1.858		1.834		1.903		7.271
SPECIFIC OBJECTIVE No 2 Enhanced capacity for threat assesment												

[88] Outputs are products and services to be supplied (e.g.: number of student exchanges financed, number of km of roads built, etc.).

- Output	Number of general threat assessments carried out by the Agency.			1.838		2.053		3.035		3.142		10.068
Subtotal for specific objective No 2				1.838		2.053		3.035		3.142		10.068
SPECIFIC OBJECTIVE No 3 Establishment of a virtual forensic & toxicological laboratory												
- Output	Virtual laboratory set up and involved in the regular work of the Agency.			5,277		4,735		3,916		3,916		17.845
Subtotal for specific objective No 3				5,277		4,735		3,916		3,916		17.845
SPECIFIC OBJECTIVE No 4 Strengthened role of REITOX National Focal Points												
- Output	Number of EU-level alerts issued.			0.800		0.800		0.800		0.800		3.200
Subtotal for specific objective No 4				0.800		0.800		0.800		0.800		3.200
SPECIFIC OBJECTIVE No 5 Enhanced competence for												

information campaigns and risk communication												
- Output	Number of campaigns developed or their development supported.			0,200		1.069		1.138		1.176		3.583
Subtotal for specific objective No 5				0,200		1.069		1.138		1.176		3.583
SPECIFIC OBJECTIVE No 6 Enhanced capacity in supply and security issues												
- Output	Number of intelligence reports on supply-side issues provided to law enforcement authorities.			3.577		3.804		4.161		4.406		15.949
Subtotal for specific objective No 6				3.577		3.804		4.161		4.406		15.949
SPECIFIC OBJECTIVE No 7 Clarification of the international												

dimension												
- Output	Number of notifications to the EU early warning system.			0.769		1.314		1.490		1.440		5.014
Subtotal for specific objective No 7				0.769		1.314		1.490		1.440		5.014
TOTAL COST				**14,137**		**15,634**		**16,376**		**16,784**		**62,931**

3.2.3. Estimated impact on [body]'s human resources

3.2.3.1. Summary

– ☐ The proposal/initiative does not require the use of appropriations of an administrative nature

– ☒ The proposal/initiative requires the use of appropriations of an administrative nature, as explained below:

EUR million (to three decimal places)

	Year **2024**	Year **2025**	Year **2026**	Year **2027**	**TOTAL**
Temporary agents – Baseline (Draft Budget 2022)[89]	10.524	10.524	10.524	10.524	**42.095**
Temporary agents – Additional compared to the baseline (cumulative)	0.900	2.423	3.254	3.600	**10.178**
Temporary agents - TOTAL[90]	11.424	12.947	13.778	14.124	**52.273**
Contract staff – Baseline (Draft Budget 2022)	2.540	2.540	2.540	2.540	**10.160**
Contract staff – Additional compared to the baseline (cumulative)	-	0.037	0.261	0.485	**0.784**
Contract staff - TOTAL	2.540	2.577	2.801	3.025	**10.944**
Seconded National Experts– Baseline (Draft Budget 2022) – no additional SNE	0.078	0.078	0.078	0.078	**0.313**
TOTAL all staff	14.042	15.603	16.658	17.228	**63.530**

Staff requirements (FTE):

	Year **2024**	Year **2025**	Year **2026**	Year **2027**
Temporary agents – Baseline (Draft Budget 2022)	76	76	76	76
Temporary agents – Additional compared to the baseline (cumulative)	13	22	25	27

89 Staff levels indicated in Draft Budget 2022, with the assumption that staff will stay stable until 2024, calculated on the basis of the average staff unit costs to be used for LFS, indexed to the correction coefficient for Portugal (91,1**%**).

90 It is not possible at this stage to provide the detailed allocation between temporary agent – AD and temporary agents – AST. The costs estimates for staff have been made on the basis of the average costs for temporary agent, indexed to the correction coefficient for Portugal (91,1%).

Temporary agents - TOTAL	89	98	101	103
Contract staff – Baseline (Draft Budget 2022)	34	34	34	34
Contract staff – Additional compared to the baseline (cumulative)	-	1	6	7
Contract staff - TOTAL	29	38	40	41
Seconded National Experts– Baseline (Draft Budget 2022)	1	1	1	1

TOTAL	**119**	**137**	**142**	**145**

The human ressources necessary to implement the objectives of the new mandate have been estimated in cooperation with the EMCDDA. The estimates take into consideration the expected increase in workload as stakeholders make more use of the EMCDDA's services over time, as well as the time needed for the EMCDDA to absorb resources in order to avoid a situation where the agency would not be able to fully implement its EU contribution and commit appropriations in due time. The estimates also include the costs necessary to set up the virtual laboratory, including the starting one-off costs.

The staff needed for the revision of mandate is justified by persistent operational needs, in particular in the areas as detailed by the agency. The envisaged staff profiles added shall be engaged in operations and shall not represnet an increase in headcount in administration/overhead, thereby contribuitng to efficiency of operations:

a. ***Forensic and toxicological scientists/chemists:*** Needed for threat assessment, virtual laboratory, drug analysis, precursor analysis, profiling production sites deaths and poising etc.

b. ***Analysts with expertise in operational and strategic aspects of crime policing and security.*** This expertise is currently extremely limited within agency.

c. ***Strategic and operational analysts.*** Needed for developing international and geo-political analysis, threat assessment and early warning both within EU and in identifying external threats.

d. ***Data scientist, data modellers and data analysts***. Needed to manage analyse and present greater and more complex volume of data that would be collected by new tasks.

e. ***Policy support/political scientist***. Needed for enhanced support to policy and policy evaluation role.

f. ***Technical project managers***: To manage data collection contracts and research studies.

g. ***Trainers, curriculum development and capacity building experts***: To address enhanced role in training and building capacity within EU and externally.

h. ***ICT support database management*** etc. Increased capacity will be needed to support the envisaged databases, ICT infrastructure, system security, and stakeholder platforms, required to deliver the possible new capacities and competencies.

i. ***Artificial Intelligence Architect (IA) and Business Intelligence Analyst (BI)*** to assist developing and maintaining the EMCDDA digital platform and developing new solutions, machine learning and data analytics.

The total number of staff under the revised mandate by 2027 is proposed to be 145 - including 103 Temporary Agents, 41 Contract Agents and 1 Seconded National Expert. The total of 145 staff envisaged to work at the Agency by 2027 does not include staff hired on ad-hoc grant/delegation/contribution agreements, reported separately under section 4.3 of the EU budget. Recruitement dates are planned at mid-year. The amounts have been adapted accordingly: the costs of newly recruited staff have been estimated at 50% of the average costs for their recruitment year. The proposed addition in staff is deemed to increase efficiency of operations, since the number of administrative staff remains unchanged.

3.2.3.2. Estimated requirements of human resources for the parent DG

– ☐ The proposal/initiative does not require the use of human resources.

– ☒ The proposal/initiative requires the use of human resources, as explained below:

Estimate to be expressed in full amounts (or at most to one decimal place)

		Year **2024**	Year **2025**	Year **2026**	Year **2027**
• **Establishment plan posts (officials and temporary staff)**					
20 01 02 01 and 20 01 02 02 (Headquarters and Commission's Representation Offices)		1	1	1	1
20 01 02 03 (Delegations)					
01 01 01 01 (Indirect research)					
10 01 05 01 (Direct research)					
• **External staff (in Full Time Equivalent unit: FTE)**[91]					
20 02 01 (AC, END, INT from the 'global envelope')					
20 02 03 (AC, AL, END, INT and JPD in the Delegations)					
Budget line(s) (specify)[92]	- at Headquarters[93]				
	- in Delegations				
01 01 01 02 (AC, END, INT – Indirect research)					
10 01 05 02 (AC, END, INT – Direct research)					
Other budget lines (specify)					
TOTAL		**1**	**1**	**1**	**1**

The human resources required will be met by staff from the DG who are already assigned to management of the action and/or have been redeployed within the DG, together if necessary with any additional allocation which may be granted to the managing DG under the annual allocation procedure and in the light of budgetary constraints.

Description of tasks to be carried out:

91 AC = Contract Staff; AL = Local Staff; END = Seconded National Expert; INT = agency staff; JPD = Junior Professionals in Delegations.

92 Sub-ceiling for external staff covered by operational appropriations (former 'BA' lines).

93 Mainly for the EU Cohesion Policy Funds, the European Agricultural Fund for Rural Development (EAFRD) and the European Maritime Fisheries and Aquaculture Fund (EMFAF).

Officials and temporary staff	Represent the Commission in the Management Board of the Agency. Draw up Commission opinion on the annual work programme and monitor its implementation. Monitor implementation of the budget. Assist the Agency in developing its activities in line with EU policies, including by participating in experts meetings.
External staff	*No external staff foreseen*

Description of the calculation of cost for FTE units should be included in the Annex V, section 3.

3.2.4. Compatibility with the current multiannual financial framework

– ☐ The proposal/initiative is compatible the current multiannual financial framework.

– ☒ The proposal/initiative will entail reprogramming of the relevant heading in the multiannual financial framework.

Explain what reprogramming is required, specifying the budget lines concerned and the corresponding amounts. The proposal includes additional financial and human resources for EMCDDA compared to what is currently budgeted in the MFF proposal (Fiche N°68). The budgetary impact of the additional financial resources for EMCDDA will be offset through a compensatory reduction from programmed spending under Heading 4.

– ☐ The proposal/initiative requires application of the flexibility instrument or revision of the multiannual financial framework[94].

Explain what is required, specifying the headings and budget lines concerned and the corresponding amounts.

3.2.5. Third-party contributions

– ☒ The proposal/initiative does not provide for co-financing by third parties.

– The proposal/initiative provides for the co-financing estimated below:

EUR million (to three decimal places)

	Year **N**	Year **N+1**	Year **N+2**	Year **N+3**	Enter as many years as necessary to show the duration of the impact (see point 1.6)			Total
Specify the co-financing body								
TOTAL appropriations co-financed								

[94] See Articles 12 and 13 of Council Regulation (EU, Euratom) No 2093/2020 of 17 December 2020 laying down the multiannual financial framework for the years 2021 to 2027.

3.3. Estimated impact on revenue

– ☒ The proposal/initiative has no financial impact on revenue.

– ☐ The proposal/initiative has the following financial impact:

– ☐ on own resources

– ☐ on other revenue

– ☐ please indicate, if the revenue is assigned to expenditure lines

EUR million (to three decimal places)

Budget revenue line:	Appropriations available for the current financial year	Impact of the proposal/initiative[95]						
		Year **N**	Year **N+1**	Year **N+2**	Year **N+3**	Enter as many years as necessary to show the duration of the impact (see point 1.6)		
Article …….								

For miscellaneous 'assigned' revenue, specify the budget expenditure line(s) affected.

Specify the method for calculating the impact on revenue.

[95] As regards traditional own resources (customs duties, sugar levies), the amounts indicated must be net amounts, i.e. gross amounts after deduction of 20 % for collection costs.