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on the European Union Drugs Agency

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TABLE OF CONTENTS

LIST OF ABBREVIATIONS 3

1. INTRODUCTION: POLITICAL AND LEGAL CONTEXT 4

1.1. Political context 4

1.2. Legal context 5

2. PROBLEM DEFINITION 6

2.1. Overview of the findings of the evaluation of the EMCDDA 6

2.2. What are the problems for action? 7

2.3. What are the problem drivers? 11

2.4. Who is affected and in what ways? 12

2.5. How will the problem evolve? 14

3. WHY SHOULD THE EU ACT? 15

3.1. Legal basis 15

3.2. Subsidiarity: Necessity of EU action 15

3.3. Subsidiarity: Added value of EU action 16

4. OBJECTIVES: WHAT IS TO BE ACHIEVED? 16

4.1. General objectives 16

4.2. Specific objectives 16

5. WHAT ARE THE AVAILABLE POLICY OPTIONS? 17

5.1. What is the baseline from which options are assessed? 17

5.2. Description of the policy options 18

5.3. Options discarded at an early stage 29

6. WHAT ARE THE IMPACTS OF THE POLICY OPTIONS? 35

6.1. Impacts on the European Union (EU bodies) and value-added 36

6.2. Impacts on national authorities 43

6.3. Impacts on simplification and/or administrative burden 45

6.1. Economic impacts 46

7. HOW DO THE OPTIONS COMPARE? 48

Specific objective 1: To increase the Agency's capacity to react faster and in a more targeted way to new challenges in the field of drugs, harms and addictions, and related threats 48

7.1. 48

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7.2. Specific objective 2: To deepen the monitoring and analysis of the drug phenomenon in Europe, both on the demand and supply side and their implications for health and security 50

7.3. Specific objective 3: To clarify the mandate of the Agency as regards what substances, behaviours and responses should be covered 51
7.4. Specific objective 4: To make the Agency more operational 52
7.5. Specific objective 5: To provide support to Member States in shaping and evaluating their drugs policies 53
8. PREFERRED OPTION 54
8.1. Summary of the preferred option 54
8.2. Explanation of the preferred option 55
8.3. Impacts of the preferred option on the EU budget 56
8.4. Scope for simplification and burden reduction 58
9. HOW WILL ACTUAL IMPACTS BE MONITORED AND EVALUATED? 59
OVERVIEW OF ANNEXES 61
ANNEX 1: PROCEDURAL INFORMATION 62
1. Lead DG, D*e*cide planning/CWP references 62
2. Organisation and timing 62
3. Consultation of the Regulatory Scrutiny Board 63
4. Evidence, sources and quality 68
5. Limitations 69
ANNEX 2: STAKEHOLDER CONSULTATION 70
1. Main stakeholder groups 70
2. Exception from the public consultation obligation 70
3. Inception Impact Assessment 71
ANNEX 3: WHO IS AFFECTED AND HOW? 74
1. Summary of benefits 74
2. Summary of costs 75
ANNEX 4: INTERVENTION LOGIC OF REGULATION (EC) 1920/2006 79
ANNEX 5: PROBLEM, DRIVERS, OBJECTIVES AND OPTIONS (INTERVENTION LOGIC OF THE CURRENT INITIATIVE) 80
ANNEX 6: SCHEMATIC OVERVIEW OF THE CONTRIBUTION OF THE POLICY OPTIONS TO THE SPECIFIC OBJECTIVES 81
ANNEX 7: RELEVANT DRUG-RELATED FIGURES 82

LIST OF ABBREVIATIONS

Term or acronym	*Meaning or definition*
CEPOL	European Union Agency for Law Enforcement Training
DG GROW	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs
DG SANTE	Directorate-General for Health and Food Safety
DG TAXUD	Directorate-General for Taxation and Customs Union
ECDC	European Centre for Disease Prevention and Control
EMA	European Medicines Agency
EMCDDA	European Monitoring Centre for Drugs and Drug Addiction (also referred to as 'the Agency')
ENFSI	European Network of Forensic Science Institutes
EU	European Union
Europol	European Union Agency for Law Enforcement Cooperation
EWS	EU Early Warning System on new psychoactive substances
Founding Regulation (of the Agency)	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.
HERA	European Health Emergency Preparedness and Response Authority
MAOC-N	Maritime Analysis and Operations Centre – Narcotics
MDMA	Methylenedioxy-methylamphetamine; commonly known as "ecstasy"
NPS	New Psychoactive Substances
Reitox	European Information Network on Drugs and Drug Addiction (*Réseau Européen d'Information sur les Drogues et les Toxicomanies*)
SMEs	Small and medium sized enterprises
TFEU	Treaty on the Functioning of the European Union
THC	Tetrahydrocannabinol
UN	United Nations
UNODC	United Nations Office on Drugs and Crime

1. INTRODUCTION: POLITICAL AND LEGAL CONTEXT

1.1. Political context

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. The report shows a deteriorating situation with the volumes of cocaine and heroin introduced in the EU at an all-time high. Production of drugs in particular synthetic drugs (amphetamines and MDMA) takes place within the EU for domestic consumption and for export.[2] The illicit 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].

Among people who use drugs, poly-drug use[5] is widespread. Cannabis is the most commonly used drug. The use of heroin and other opioids continue to be most commonly associated with the more harmful forms of drug use.[6] The European Drug Report 2021 observed a rise in use of benzodiazepines among high-risk drug users, prisoners and some groups of recreational drug users, potentially reflecting the high availability and low cost of these substances and pandemic-related mental health issues. This is having a detrimental impact on public health. Increased availability of other drugs, particularly cocaine and some synthetic substances, is associated with increased levels of drug related violence and other crimes.[7]

The European Monitoring Centre for Drugs and Drug Addiction ('EMCDDA'; 'the Agency') was founded in 1993[8] to address the escalating drugs problem in Europe at the time. The recast of the founding Regulation in 2006[9] kept the mandate of the Agency largely as it was, mainly making relevant institutional changes. The main substantive changes were the mandate for sharing and promoting evidence-based interventions ('best practices'), the inclusion of new psychoactive substances[10], and the transformation of the European Information Network on Drugs and Drug Addiction ('Reitox') network from a computer network to a network of national focal points. The revision of the legislation on new psychoactive substances in 2017 was the only other occasion when the founding Regulation

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1 EMCDDA, European Drug Report 2021, https://www.emcdda.europa.eu/edr2021.

2 In 2019, more than 370 illegal drug production laboratories were dismantled in Europe; European Drug Report (footnote 1).

3 See Annex 7, Figure 3.

4 The proceeds of organised crime within the EU are estimated at about €110 billion/year. 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 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. The concept carries the connotation of illicit use, though alcohol, nicotine, and caffeine are the substances most frequently used in combination with others in industrialized societies. Source: https://www.who.int/substance_abuse/terminology/who_lexicon/en/.

6 See Annex 7, Figure 1.

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

8 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.

9 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.

10 Council Decision 2005/387/JHA of 10 May 2005 on the information exchange, risk-assessment and control of new psychoactive substances, OJ L 127, 20.5.2005, p. 32.

was adapted. This revision integrated the main provisions of the three-step-approach of controlling new psychoactive substances into the founding Regulation.[11]

In 2018/19, the Commission carried out the fourth evaluation of the Agency in line with the requirements of the founding Regulation.[12] It concluded that the Agency works overall well, but further improvements are possible in several areas, in particular in view of the developments of the drug phenomenon.

As was shown by the evaluation and by the regular contacts with the Agency and its stakeholders, there is an increasing disconnect between the complexity of the drug phenomenon and what the Agency mandate provides for. The founding Regulation does not reflect the current reality of the drug phenomenon and is out of step with the tasks the Agency needs to perform to address the challenges of the drug phenomenon and the requests by its main stakeholders.

The drug phenomenon represents an integral element of the health and security challenges that Europe faces. With the drugs landscape developing constantly and new drugs regularly coming on the market, the drug phenomenon is becoming more complex and pervasive. This situation calls for an enhancement of the efforts at EU level.

In response, the Commission adopted the EU Agenda and Action Plan on Drugs 2021-2025 in July 2020.[13] On that basis, the Council adopted in December 2020 the new EU Drugs Strategy 2021-2025[14], which provides the overarching political approach and priorities for EU drugs policy for the next five years. It advocates a balanced, integrated, multidisciplinary and evidence-based approach to the drugs phenomenon. The Strategy *inter alia* 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.[15]

This impact assessment report prepares the ground for a **targeted revision** of the mandate of the Agency to address current and future challenges.

1.2. Legal context

The objective of the founding Regulation was to establish a European agency to provide the EU and its Member States with factual, objective, reliable and comparable information at European level on drugs and drug addiction and their consequences.[16]

In order to meet this objective, the key areas of activity of the Agency are defined in Article 2 of the founding Regulation as follows: collection and analysis of existing data; improvement of data comparison methods; dissemination of data; cooperation with European and international bodies and organisations as well as with third countries; information obligations; and exchange of information on, early warning system for, and risk assessment of new psychoactive substances.

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11 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, OJ L 305, 21.11.2017, p. 1.

12 COM(2019) 228.

13 COM(2020) 606.

14 OJ C 102I , 24.3.2021, p. 1; see for the related EU Drugs Action Plan 2021-2025, OJ C 272, 8.7.2021, p. 2.

15 Strategic Priority 11, point 5.

16 See the intervention logic of the current Regulation in Annex 4 of this report.

The Regulation sets out the priority areas of the activities of the Agency as follows:

1) monitoring the state of the drugs problem, in particular using epidemiological or other indicators, and monitoring emerging trends, in particular those involving poly-drug use;
2) monitoring the solutions applied to drug-related problems; providing information on best practices in the Member States and facilitating the exchange of such practices among them;
3) assessing the risks of new psychoactive substances and maintaining a rapid information system with regard to their use and also regarding new methods of using existing psychoactive substances;
4) developing tools and instruments to help Member States to monitor and evaluate their national policies and the Commission to monitor and evaluate European Union policies.

The core data is collected through the Reitox network. The remainder of the founding Regulation deals with the organisational set-up of the Agency and horizontal rules about its functioning.

2. PROBLEM DEFINITION

The problem definition set out in this section is the basis for the development of the intervention logic, which is shown in Annex 5.

2.1. Overview of the findings of the evaluation of the EMCDDA

The evaluation, supported by a study of a contractor[17], is positive as regards the five evaluation criteria, but notes that improvements are possible in several areas. These are set out in the Commission report on the evaluation[18] and in more detail in the accompanying Staff Working Document[19]. The main findings can be summarised as follows:

Relevance: The Agency's outputs correspond well to the needs expressed by stakeholders, including covering new topics. The relevance on national level is more limited than on European level as several Member States have wider addiction policies in place. The question on whether to broaden the mandate of the Agency to other addictions was assessed in detail, but the outcome was inconclusive. The evaluation concluded that there is scope for more engagement with the scientific community, practitioners and the public. It showed a need for more forward-looking products, identifying future trends and risks, to better support EU preparedness and response.

Effectiveness: The Agency is recognised as a centre of excellence in providing information on the drugs phenomenon not only in Europe but also internationally. The information produced by the Agency is considered factual, objective, reliable and robust, although comparability could be enhanced. The evaluation recognised the positive work of the Agency in monitoring the European drug situation, including through the EU early warning system. The Reitox network has a central role in the collection of information, even if quality varies

[17] 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.
[18] COM(2019) 228.
[19] SWD(2019) 174.

from country to country. The evaluation further assessed that poly-drug use is not sufficiently addressed. The activities undertaken at international level are compatible with the EU priorities as the Agency brings the EU's evidence-based policy-making about drugs monitoring to third countries, and thus helps improving the global understanding of the drugs phenomenon.

Efficiency: The evaluation concluded that the Agency uses the available human and financial resources efficiently. The budget of the Agency remained relatively flat over the evaluation period, at approximately EUR 16 million per year, although the Agency's output has grown considerably over the same period. The Agency is delivering the benefits envisioned in its mission at a reasonable cost. The evaluation identified scope for simplification and improvements, including on the use of information and communications technology and more targeted outreach to its main audiences, including online.

Coherence: The multiannual work programmes of the Agency were well aligned with the Agency's founding Regulation, the EU Drugs Strategy 2013-2020[20] and the European Agenda on Security[21]. The objectives and activities set out in the Agency's programming documents were coherent with the regulatory framework. The Agency's work was complimentary with the work of the EU institutions and agencies across the relevant strategic objectives. Although the Agency increased its focus on security issues, the evaluation concluded that more should be done on supply-side issues. A common theme across the interviewed stakeholder groups was the potential for the Agency to take an even more active role on the international stage.

EU added value: The EU-level overview of the drug situation provided by the Agency helped the Member States to improve their capacity to monitor and respond to the drug problems. A common methodology for data collection was considered as not achievable without the Agency. The Agency's engagement with national policy-makers and with practitioners could be improved. The Agency was considered the most effective option to carry out the tasks allocated to it. As regards the question of merging the EMCDDA with another EU agency or its termination, the answers during the consultation process were all negative.

2.2. What are the problems for action?

The drug phenomenon has changed considerably since the adoption of the Agency's current mandate through the recast of the founding Regulation in 2006. Whereas the worsening drug situation is a much wider problem, this impact assessment report only considers the limitations on the Agency due to the current mandate.

The main supporting evidence for the new challenges of the drug phenomenon, are the annual European Drug Reports[22] by the EMCDDA and the annual World Drug Report[23] by the UN Office on Drugs and Crime (UNODC). They show the developments from one year to the next and longer term trends. Another important source are the EU Drug Markets Reports[24], the third edition of which was published in autumn 2019 by the EMCDDA and Europol. Many other topical reports by the EMCDDA[25], partly together with other agencies, in particular Europol, and by international organisations, such as the UNODC and the

[20] OJ C 402, 29.12.2012, p. 1.
[21] COM(2015) 185.
[22] https://www.emcdda.europa.eu/publications-database_en?f%5B0%5D=field_series_type%3A404.
[23] https://www.unodc.org/unodc/en/data-and-analysis/wdr2021.html.
[24] https://www.emcdda.europa.eu/publications/joint-publications/eu-drug-markets-report-2019_en.
[25] References are included throughout this report to such topical reports of the Agency.

International Narcotic Control Board (INCB),[26] can provide further evidence on the development of the drug phenomenon.

Complexity of new drug phenomena lead to a disconnect with the existing Agency mandate

The Agency's monitoring – based on the current founding Regulation – is largely backward looking. The core data, related to the five currently defined key epidemiological indicators[27], is collected by the national focal points and provided by them to the Agency. This data is insufficient to cover new trends and developments as it covers only core data and comes with a time lag.[28] Additional data may be provided by ad hoc projects.[29] The analysis is published in the reports of the Agency, which are focussed on statistics and trends based on past developments. However, the modern drug phenomenon would necessitate more real-time and forward-looking analysis about emerging threats in order to anticipate developments, as identified by the evaluation, and to provide information on the best ways to address these new phenomena.

The current founding Regulation of the Agency is addressing illicit drugs, i.e. those controlled by the UN Drug Conventions[30] and those defined by Council Framework Decision 2004/757/JHA[31], and does not go beyond that to include other (substance-based or behavioural) addictions in its mandate. Several Member States have developed wider addiction strategies, often covering other (legal) substances, such as alcohol or tobacco, or even non-substance based addictions, such as gambling or compulsive gaming based on the logic that they are all addictions and share biological and behavioural characteristics.

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[26] For the UNODC, see in particular https://www.unodc.org/unodc/en/drug-prevention-and-treatment/index.html; https://www.unodc.org/unodc/en/data-and-analysis/drug-production-and-trafficking.html and https://www.unodc.org/unodc/en/data-and-analysis/drug-use.html. For the INCB, see in particular http://www.incb.org/incb/en/publications/incb-publications.html, including their annual report (www.incb.org/incb/en/publications/annual-reports/annual-report.html).

[27] The five key epidemiological indicators are: prevalence and patterns of drug use; problem drug use; treatment demand indicator; drug-related deaths and mortality; and drug-related infectious diseases.

[28] Annually reported statistical data typically has a delay. Data collected in a given year (N) requires time for collating and checking at national level. The EMCDDA allows 6 months for this process (N+6 months). National focal points submit their data in September/October of year (N+1). Once the data has been provided, the EMCDDA carries out a verification of the data and conducts an analysis, which is checked by the national focal points. This data and analysis is the basis for the drafting of the European Drug Report of year (N+2). For example, the European Drug Report of 2021 is largely based on data from 2019.

[29] See e.g. the wastewater analysis, https://www.emcdda.europa.eu/topics/wastewater, or hospital emergency data through the Euro-DEN network, https://www.emcdda.europa.eu/topics/hospital-emergencies_en.

[30] The UN Drug Conventions refer to the UN Single Convention on Narcotic Drugs of 1961, as amended by the 1972 Protocol, United Nations Treaty Series, vol. 978, No. 14152, the UN Convention on Psychotropic Substances of 1971, United Nations Treaty Series, vol. 1019, No. 14956; and the UN Convention against the Illicit Traffic in Narcotic Drugs and Psychotropic Substances of 1988, United Nations Treaty Series, vol. 1582, No. 27627.

[31] See the Annex of 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.

Country	Illicit drugs and NPS	Alcohol	Tobacco	Medicines	Behavioural addictions (e.g. gambling)	Doping
Belgium	Yes	Yes	Yes	Yes	No	No
Czech Republic	Yes	Yes	Yes	No	Yes	No
Germany	Yes	Yes	Yes	Yes	Yes	No
France	Yes	Yes	Yes	Yes	Yes	Yes
Cyprus	Yes	Yes	No	No	No	No
Lithuania	Yes	Yes	Yes	No	No	No
Luxembourg	Yes	Yes	Yes	Yes	Yes	No
Austria	Yes	Yes	Yes	Yes	Yes	No
Poland	Yes	Yes	Yes	Yes	Yes	No
Portugal	Yes	Yes	No	Yes	Yes	No
Sweden	Yes	Yes	Yes	No	No	Yes

Source: EMCDDA Papers: New developments in national drug strategies in Europe[32] (extract).

Furthermore, the current founding Regulation does not include drug precursors[33] in the Agency's scope of action. Drug precursors are relevant as their diversion is closely linked to the increasing production of synthetic drugs on the territory of the EU.[34]

The concept of poly-drug use was introduced with the recast of the founding Regulation. However, it has not been exploited sufficiently by the Agency, as shown by the evaluation. This is mainly due to the concept not being sufficiently clear and insufficient information being available as the national focal points do not have a mandate to collect data going beyond drugs. However, this would be needed to fill the concept with content.

Inadequate responses to new drug market challenges

Drug selling on online marketplaces, including on the darknet, social media platforms and mobile applications, is increasing, including during the height of the COVID-19 pandemic. These emerging marketplaces present new challenges. New technologies have facilitated the appearance of an online drug market as part of the darknet and on the "normal" internet. Equally, changing trafficking routes have caused a spill over effect into new areas. Drug selling is moving to closed groups or private chats, such as messaging applications, and is using other routes of getting drugs to the customer, for example through alleged food delivery couriers.[35] The Agency increased its collaboration with in particular Europol to better monitor these new marketplaces and to increase its understanding of the related challenges. In addition, drug production based in the EU is growing, in particular of MDMA (ecstasy) and increasingly for other amphetamine-type drugs. In recent years, laboratories for the production of other drugs have occasionally been detected in the Member States.[36]

Based on these new challenges, it can be concluded that a major shortcoming of the founding Regulation is that it does not include any references to the monitoring of drug markets or of drug supply. However, a thorough understanding of drug market and security issues is necessary for the Agency to provide a holistic picture to policy-makers. This was raised during the consultation for the 2018/19 evaluation, when several stakeholders mentioned supply-side issues as one element where further information from the Agency would be

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32 http://www.emcdda.europa.eu/system/files/publications/6402/20175662_TDAU17002ENN_PDF.pdf.

33 Drug precursors are substances that are controlled and monitored in accordance with Regulation (EC) No 273/2004 of the European Parliament and of the Council and with Council Regulation (EC) No 111/2005; these substances are chemicals that are primarily used for the legitimate production of a wide range of products, like medicine, perfumes, plastics, cosmetics etc. However, they can be misused for the illicit production of drugs.

34 Report from the Commission to the European Parliament and the Council, Evaluation of the EU drug precursors regulations, COM(2020) 768.

35 EMCDDA/Europol, EU Drug Markets – Impact of COVID-19, 2020. EMCDDA special report: COVID-19 and drugs – Drug supply via darknet markets, 2020; https://www.emcdda.europa.eu/publications/ad-hoc/covid-19-and-drugs-drug-supply-via-darknet-markets_en.

36 EU Drug Markets Report (footnote 7).

welcome.[37] Although Europol and the EMCDDA have started monitoring online drug markets, they do not have adequate tools and sufficient resources to develop appropriate responses.

Finally, the Agency has – based on the founding Regulation – a key responsibility in the monitoring of new psychoactive substances. However, it cannot do any of the analysis itself and has to rely completely on third parties, including on third-country agencies, for the forensic and toxicological examination, as it does not have laboratory capacities.

The Reitox network is not used to its full potential

The Reitox network has a very limited role based on Article 5 of the founding Regulation. It is the interface between the Agency and the participating countries[38]. The Reitox national focal points provide the core data on drugs and drug addiction, as well as on policies and solutions applied, to the Agency on an annual basis.

The evaluation concluded that the Reitox network is the main source of information for the Agency. Depending on the national context and situation, the position and outputs of the national focal points vary strongly, as the Regulation does not provide any details about their set-up and is not sufficiently clear on their rights and obligations on national and European level. The national focal points do not have access to all data required by the Agency for the key indicators as some other national authorities are reluctant to share relevant information.[39] Comparability of data could be further improved, as concluded in the evaluation.

Insufficient support to Member States

Several Member States have in the past asked for support, both for the evaluation and development of their national drug policies[40], as well as for their international activities, such as for the Agency to provide data to the UN[41] or to provide background information on the drug situation in the EU's neighbourhood[42]. The founding Regulation does not address these issues beyond requesting the Agency to develop relevant tools.

The evaluation concluded that Member States would be interested in more structural support in relation to evaluating and subsequently shaping national drug policies. Member States are not only interested in receiving data or comparing the national situation with the situation in other Member States, which is in the current mandate of the Agency, but to get concrete advice and support from the Agency, as they do not necessarily have all the relevant knowledge or capacity on their own.

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37 The need to do more work on supply-side issues was already raised by the previous evaluation in 2011/12; see Centre for Strategy and Evaluation Services (CSES), External Evaluation of the European Monitoring Centre for Drugs and Drugs Addiction, https://publications.europa.eu/en/publication-detail/-/publication/7d189e3b-f767-460b-b748-acf44d2daf9a/language-en/format-PDF/source-74343049.

38 In addition to the EU Member States, Norway and Turkey are members of the EMCDDA without voting rights.

39 Information provided by several focal points.

40 This was the case in 2015 for Germany, Ireland and Luxembourg, who asked for support in the evaluation of their drugs policies. Other Member States followed suit, e.g. most recently Portugal, where the evaluation of the national drugs strategy is on-going.

41 All Member States need to explicitly agree every year that the EMCDDA reports on their behalf the numbers and information related to the detection of new psychoactive substances, which are collected through the EU Early Warning System.

42 The rotating EU Presidencies regularly ask the Agency for updated information ahead of the formal EU drug dialogues.

The exchange of best practices on health and other demand side issues is too limited to be of real assistance for the Member States. National stakeholders expressed in the evaluation a need to move beyond the simple identification of best practices to supporting the implementation of evidence-based practices and the delivery of effective interventions, for example through training or accreditation schemes for such interventions.

The international dimension of the Agency is insufficiently defined

Analysing how international developments impact on the EU is becoming increasingly important due to the globalisation of the drug phenomenon. The tasks in the founding Regulation as regards international issues are mainly focussed on cooperation on a bilateral and multilateral level and are carried out on a case-by-case basis upon the request of the Commission. The same is true for the input the Agency is providing to the EU and to the Member States on the impact of drug policies in third countries on the EU markets.

UN bodies currently receive information directly from Member States, but also rely extensively on the Agency. Conversely, Member States provide information both to UN bodies and to the Agency. This creates risks of duplication of efforts and calls for better coordination, which was one of the conclusions of the evaluation.

2.3. What are the problem drivers?

The analysis of the evidence supporting the impact assessment, in particular the evaluation of the Agency, identified the following problem drivers:

The mandate of the Agency has not been adapted to the changes of the drugs phenomenon

The drugs phenomenon has changed considerably since the founding of the Agency in the early 1990s. It has become more complex and it now encompasses a broader range of illicit substances and drug-related behaviours. The drug market has become much more innovative, digitally enabled and globally connected. This means that new developments in both drug trafficking and drug use spread more rapidly than was previously the case.[43]

The Agency's EU Early Warning System[44] is monitoring currently more than 830 new psychoactive substances[45], of which 46 were identified for the first time in 2020.[46] The vast majority of these substances have appeared on the European market over the last 10 years. Whenever a new psychoactive substance is included in the list of drugs, the drug criminals develop a new substance by slightly altering the chemical composition.

Therefore, the demands on the Agency by its main stakeholders, in particular by the European and national policy-makers, have grown over time.[47] In the 1990s, no EU-level information to describe the drug situation and its consequences in an objective way was available and a related data collection system was missing. Nowadays, this is in place, but more sophisticated information, including real-time analysis about emerging threats and advice on the best possible ways to address those, is required.

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43 European Drug Report 2021 (footnote 1).

44 https://www.emcdda.europa.eu/publications/topic-overviews/eu-early-warning-system.

45 A new psychoactive substance (NPS) is defined as a new narcotic or psychotropic drug, in pure form or in preparation, that is not controlled by the UN Drug Conventions, but which may pose a public health threat comparable to that posed by substances listed in these conventions.

46 European Drug Report 2021 (footnote 1).

47 See EMCDDA, Looking back on 25 years of annual reporting on the drugs problem in Europe (2020), https://www.emcdda.europa.eu/publications/brochures/25-years-annual-reporting_en.

As the Agency mandate has not been revised since 2006 – and at the time only to a limited extent – the Agency is working based on an **outdated mandate** that is almost 30 years old. As explained above, there is an increasing disconnect between what Europe needs to address the drug phenomenon and what the Agency mandate provides for in legal terms. The founding Regulation does not reflect the current reality of the drug phenomenon and is out of step with the tasks the Agency needs to perform to address the related modern day challenges.

Multi-jurisdictional challenges due to new threats

Drug markets are cross-border by nature and many of the most commonly used drugs and precursors used in the EU are imported from third countries.

New security challenges stem from the growing involvement of organised crime groups in several criminal activities, such as drug trafficking, human trafficking, migrant smuggling, or financing of terrorist activities. Organised crime groups often use drug trafficking to obtain the cash needed for their other activities. These links have considerable impacts on the development of the drug phenomenon. Drug production based in the EU is growing and is driving greater levels of intimidation, corruption and violence within the EU and will lead to further challenges in the future. In addition, online trafficking of drugs is increasing.

Monitoring these developments is crucial for a better understanding of the drug phenomenon. However, the challenges related to these new threats cannot be addressed by any Member State on its own.

Evolving national policies lead to changing priorities

The importance given to the topic of drugs policy in the Member States changes over time. Member States shift their policies, whether in terms of health-orientation or security perspectives. Several Member States broadened their drugs strategies to a wider addiction approach over the last years. Such developments have significant impacts on the Agency as they lead to new needs and requests from its stakeholders, and ultimately to the need to refocus the priorities.

Recent developments in international drug policy

The drugs phenomenon is increasingly global and decisions taken in third countries can have considerable impact on the drug situation in the EU. This is rendering the EU's drug situation more and more intertwined with that of other countries and regions.[48] Work of the UN bodies in the drugs field increased over the last years, which lead to important recent developments in international drugs policy. An important impetus was the 2016 Special Session of the United Nations General Assembly on the World Drug Problem.[49]

2.4. Who is affected and in what ways?

The drug phenomenon is a far-reaching problem, which can affect everyone's life. The revision of the founding Regulation itself only has limited direct impact on some stakeholders, whereas other potential stakeholders, in particular citizens, would only indirectly be affected. This section sets out the most affected stakeholders and explains in

[48] For example, the decision by China to put a long list of fentanyl derivatives under control lead to less of these substances reaching the EU market.

[49] https://www.unodc.org/ungass2016/; for the Outcome Document of UNGASS 2016, entitled "Our joint commitment to effectively addressing and countering the world drug problem", see https://undocs.org/A/RES/S-30/1.

what ways they would be affected. In addition to its main stakeholders, the Agency itself would be affected by a proposal for the revision of its mandate.

Policy-makers on European and national level

The main stakeholders of the Agency are policy-makers on European and national level. Their primary need is information and evidence on which to base policy decisions and related actions.

As concluded by the evaluation, the Agency is more relevant to the needs of European than national policy-makers. On the national level, the relevance depends on the scope of national policies. The Agency is less relevant for those Member States that have a wider addiction policy, as the Agency would not be able to provide all necessary data. The availability of objective data is key for EU level policy-makers as it forms the basis of the EU's evidence-based policy-making in drugs policy.

Moreover, the relevance depends on the stage of development of national drug information systems. Member States with better-developed national drug information systems may rely less on the information available from the Agency. Nevertheless, national policy-makers rely on the Agency for cross-EU comparative analysis as this element cannot be covered by national systems.

If the Agency would not be able to address properly and in a timely manner the current and future challenges of the drugs phenomenon, the Agency would lose its relevance for policy-makers. Not collecting relevant data would have a negative impact as comparable data would not be available, would have to be gathered on an ad hoc basis or would not lend itself to identifying important new threats in a timely manner.

Scientific community

As regards the scientific community, the evaluation concluded that there is scope for greater engagement, although overall the needs of the scientific community were well addressed. Nonetheless, the Scientific Committee of the Agency has pointed out in its contribution that the Agency could provide added value by being more active and establishing greater synergies within the context of the EU research knowledge cycle.[50] This would include in particular helping to identify research gaps, helping or facilitating engagement with national scientific networks and experts, and ensuring the dissemination of research findings after a project finished and maintaining a registry of what has been funded, and more.

Practitioners

Practitioners rely on the Agency for information and for the exchange of best practices. The evaluation concluded that practitioners from the public health area appreciated the increased work on that pillar, in particular the focus on harm reduction and prevention. Several non-governmental (civil society) organisations underlined in their feedback to the inception impact assessment their appreciation for the work of the Agency and the need for a neutral scientific agency, and stressed that any change in the mandate of the Agency should not be to the detriment of its public health focus. In addition, the Agency is increasing its engagement with law enforcement practitioners, in particular through input into trainings of the European

[50] EU-ANSA agencies' engagement in the EU research knowledge cycle – An overview, https://op.europa.eu/en/publication-detail/-/publication/46ff56e9-12cb-11e8-9253-01aa75ed71a1/language-en/format-PDF/source-search.

Union Agency for Law Enforcement Training (CEPOL) and closer cooperation with Europol, although there is scope to do more in this area, as concluded by the evaluation.

The Agency itself

The Agency itself might suffer most if the mandate remains as it is. In practice, the Agency is interpreting its mandate already quite widely and is undertaking work, which is not explicitly covered by the current mandate. This is due to requests from its main stakeholders and necessitated by the developing drug landscape. However, such an approach has limits, in particular in view of the available human and financial resources, and the need to keep within the legal mandate.

2.5. How will the problem evolve?

Without any intervention, the problems identified in this impact assessment will persist or get worse over time. The drug phenomenon is constantly changing and will become even more complex. Unless sufficient and timely information on the real situation of the drug phenomenon is available, as regards public health, safety and security, there will be severe negative implications on EU and national level policy-making and ultimately on the responses afforded by public authorities. This would be exacerbated by the need for Member States to act unilaterally in the absence of an adequate EU-level solution, which would be particularly damaging as the drug phenomenon becomes more and more global.

The COVID-19 pandemic showed that drug criminals are able to adapt their illicit activities relatively easily and quickly to new circumstances, for example through virtual means (online markets, messaging applications, etc.) and reduced face-to-face interactions.[51] It is expected that these recent developments will have long-term impacts on drug markets.

By maintaining the status quo of the mandate, the Agency's capacity to address emerging and future challenges would continue to diminish. The tension between the reality of the drug phenomenon and the founding Regulation would increase further. Although the Agency adapted well to changes in the past, there are limits – set by the mandate, but in particular by financial and human resources – how far these adaptations can go. Adaptations are not only needed in relation to drug markets, which are not explicitly mentioned in the mandate of the Agency, but also in relation to health-related issues. The COVID-19 pandemic demonstrated that it is important to have the capacity to exchange information and experiences rapidly and to share best practices between Member States to learn from each other.[52]

Without a revised mandate, the Agency runs the risk of losing its added value, its relevance for stakeholders, and ultimately its status as a centre of excellence and as a model for other regions in the world.

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51 EMCDDA/Europol, EU Drug Markets – Impact of COVID-19, 2020. EMCDDA special report: COVID-19 and drugs – Drug supply via darknet markets, 2020; https://www.emcdda.europa.eu/publications/ad-hoc/covid-19-and-drugs-drug-supply-via-darknet-markets_en;.

52 EMCDDA trendspotter briefing – Impact of COVID-19 on drug services and help-seeking in Europe, 2020; https://www.emcdda.europa.eu/publications/ad-hoc/impact-of-covid-19-on-drug-services-and-help-seeking-in-europe_en.

3. WHY SHOULD THE EU ACT?

3.1. Legal basis

The founding Regulation 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).

Article 168(1) 3rd subparagraph reads: "*The Union shall complement the Member States' action in reducing drugs-related health damage, including information and prevention*". Article 168(5) 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, addressing supply-side issues is covered by the public health legal basis and does not go beyond what is possible under that legal basis.

Drugs are also referred to in Article 83 TFEU. Article 83(1) states that the European Parliament and the Council can adopt rules to "*establish minimum rules concerning the definition of criminal offences and sanctions in the areas of particularly serious crime with a cross-border dimension resulting from the nature or impact of such offences or from a special need to combat them on a common basis*". Illicit drug trafficking is one of the relevant areas of crime. However, Article 83 TFEU is not relevant for the current initiative as it does not intend to set such minimum rules.

3.2. Subsidiarity: Necessity of EU action

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

The drug phenomenon is affecting 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 drugs move around Europe. 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.

The action is **proportionate** as it is the only way that the necessary changes in the Agency's mandate can come about.

EU-level action does not intend to replace national actions or authorities or 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.

3.3. Subsidiarity: Added value of EU action

The EU added value of a revision of the Agency mandate will be considerable. 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. The revision of the mandate of the Agency is part of the reaction of the EU to these developments.

As the evaluation showed, and this is relevant also for the revision of the mandate, the existence of 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. The absence of the Agency would imply the loss of the EU-level overview of the drug phenomenon, as the data collected by Member States would be fragmented or possibly non-existent, with important consequences at national, EU and international level. 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. A targeted revision would strengthen the Agency in crucial areas to enable it to address these common issues better.

4. OBJECTIVES: WHAT IS TO BE ACHIEVED?

4.1. General objectives

The general objective of the proposal, i.e. the aim of a targeted revision of the founding Regulation, is:

- To have an Agency, which is appropriately equipped to deal with the current and future challenges posed by drugs in the EU, leading to efficient action and support for Member States.

4.2. Specific objectives

The specific objectives of the proposal are:

1) To increase the Agency's capacity to react faster and in a more targeted way to new challenges in the field of drugs, harms and addictions, and related threats;

2) To deepen the monitoring and analysis of the drug phenomenon in Europe, both on the demand and supply side and their implications for health and security;

3) To clarify the mandate of the Agency as regards what substances, behaviours and responses should be covered;

4) To make the Agency more operational; and

5) To provide support to Member States in shaping and evaluating their drugs policies.

5. WHAT ARE THE AVAILABLE POLICY OPTIONS?

5.1. What is the baseline from which options are assessed?

The baseline scenario is established by the founding Regulation of the Agency, i.e. Regulation (EC) No 1920/2006, and the current functioning of the Agency. The Agency's mandate is focussed on data collection, monitoring, harmonisation of data, analysis and publication of the outcomes of these exercises as regards (illicit) drugs, drug addiction and their consequences.

Areas of activity

The key areas of activity of the Agency are set out above. The "EMCDDA Strategy 2025"[53] attributed the activities and the tasks of the Agency to two main pillars, health and security. In addition, it defined four business drivers. The strategic objectives of the two main pillars reflect the priority areas set out by the founding Regulation.

While the Agency's focus is primarily on Europe, it works with partners in other world regions, exchanging information and expertise. The Agency cooperates with candidate and potential candidate countries as part of their accession process to the EU. Cooperation takes place based on bilateral agreements[54] or in the context of EU-funded projects[55]. Cooperation ranges from implementation of technical assistance projects to ad-hoc training or consultative support. Collaboration with European and international organisations in the drugs field is central to the Agency's work.

Reitox network

The Reitox network is the European information network on drugs and drug addiction. Members of the Reitox network are designated national institutions or agencies responsible for data collection and reporting on drugs and drug addiction ('national focal points' or 'national drug observatories'). The Reitox network links national drug information systems and is the main way in which the Agency exchanges data and methodological information on drugs and drug addiction in Europe. The financing of the national focal points is provided by the Member States, but is supported by a grant from the Agency.

Current monitoring system

The current monitoring system is based on the provision of data by the national focal points. It implies the collection of both quantitative data and qualitative information using different types of standardised data collection and reporting tools. The Agency collects data also from the projects it participates and through contracts with third parties. Different innovative data collection methods provide data on specific phenomena and closer to real time. Examples

[53] https://www.emcdda.europa.eu/system/files/publications/4273/2017.1998_EMCDDA_STRATEGY_2025_web-1.pdf.

[54] Working arrangements are in place with the Russian Federation, Ukraine, Moldova, Israel, Armenia, Georgia, Switzerland, Albania, Kosovo* and Serbia.
** This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.*

[55] See for the Western Balkan countries the projects financed by the Instrument for Pre-accession Assistance (IPA) (https://www.emcdda.europa.eu/about/partners/cc/ipa7_en) and for the European Neighbourhood Policy (ENP) area the EU4 Monitoring Drugs project (https://www.emcdda.europa.eu/topics/eu4md_en).

include wastewater analysis[56], hospital emergency data[57], analysis of data from drug checking facilities[58], and recent work to measure drug related violence[59].

In addition, the EU Early Warning System collects data on the detection of new psychoactive substances. The information is available in the European Database on New Drugs (EDND). The Agency itself does not conduct the forensic or toxicological analysis as it does not have a laboratory.

The Agency is the only body, which collects drug-related data on a European level. Contrary to other policy areas, Eurostat is not involved in the collection of data related to drug policy. Europol does not collect any data, but only has information from its operations. Such data would not be sufficient to provide an overview on European level on the developments of the drug phenomenon as it is focussed on specific issues. Finally, the EU health agencies only collect health-related data and not drug data.

Implementation of the founding Regulation

The main achievement of the establishment of the Agency is the availability of factual, objective, reliable and comparable information at European level concerning drugs and drug addiction. This information is the basis for the development of an integrated, balanced and evidence-based approach to EU drugs policy.

When it comes to the monitoring of the state of the drugs problem, the solutions applied to drug-related problems as well as to European and national policies, the Agency has published almost 400 scientific and institutional reports from 2013 to 2017. Among its flagship publications are the annual European Drug Report, including the country reports, the EU Drug Markets Report, published most recently in 2019, and the "Health and social responses to drug problems – A European Guide"[60].

The Agency has facilitated the exchange of best practices and of drug-related information through the participation of its staff in more than 1 500 events (contributions to conferences, policy fora, etc.). It has established an online best practice portal[61]. In addition, the Agency organises regular and frequent meetings with its stakeholders for the sharing of best practices.

In order to address, at least partially, new developments, the Agency is interpreting its mandate as widely as possible within the legal framework. As regards health-related issues and the best practice portal, it is regularly updated with new ways of providing support to people who use drugs and will develop further in this sense, also taking into account the experience gained during the COVID-19 pandemic. The Agency is monitoring the developments on the drug markets to a certain extent and in close cooperation with Europol. This wide interpretation is reaching its limits, including in relation to the available resources. The Agency cannot go beyond the legal framework as set out in the founding Regulation.

5.2. Description of the policy options

Non-legislative options

[56] https://www.emcdda.europa.eu/topics/wastewater.
[57] https://www.emcdda.europa.eu/topics/hospital-emergencies_en.
[58] https://www.emcdda.europa.eu/topics/drug-checking.
[59] https://www.emcdda.europa.eu/topics/drug-related-homicide_en.
[60] https://www.emcdda.europa.eu/system/files/publications/6343/TI_PUBPDF_TD0117699ENN_PDFWEB_20171009153649.pdf.
[61] https://www.emcdda.europa.eu/best-practice_en.

Policy option 0: Baseline scenario - Maintaining the current approach without changes

This option preserves the status quo and is described in Section 5.1. In this scenario, the current mandate, objectives, tasks, governance and organisation of the Agency would remain unchanged.

Policy option 1: Minimal revision - Stronger cooperation

Taking into account current cooperation between the Agency and various EU and UN bodies on various aspects of drug phenomena, cooperation on European level could be enhanced with, among others, Europol, the Maritime Analysis and Operations Centre – Narcotics (MAOC-N)[62], the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC), and on an international level with the United Nations Office on Drugs and Crime (UNODC). The envisaged reinforcement of the mandates of the relevant agencies would need to be taken into account. Furthermore, the creation of the European Health Emergency Preparedness and Response Authority (HERA)[63] could also provide an opportunity for fruitful cooperation with the Agency.

Stronger cooperation among the Member States themselves or between the Agency and the Member States, should also be pursued. However, this needs to remain within the competencies of the Member States and the Agency, or respective EU bodies.

This option would not lead to any legislative changes to the founding Regulation. The current mandate, objectives, tasks, governance and organisation of the Agency would remain unchanged.

Legislative options

Policy option 2: Dismantling of the Agency - Repeal of the founding Regulation

In line with the common approach on decentralised agencies[64], common and objective criteria should be used to assess the opportunity to dismantle agencies, when the mandate of an agency is thoroughly reviewed.

This option would effectively result in the repeal of the founding Regulation and ultimately the termination of the Agency.

Policy option 3: Merging of the Agency with another EU body

Further in line with the common approach on decentralised agencies[65], the possibility to merge the agency with another EU body should be considered.

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62 www.maoc.eu.

63 For Europol, see COM(2020) 796 final; for EMA, ECDC and HERA, see in general COM(2020) 724, and in more detail for EMA COM(2020) 725; for ECDC COM(2020) 726; and for HERA the inception impact assessment: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12870-European-Health-Emergency-Preparedness-and-Response-Authority-HERA-.

64 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.

65 Ibid. 65.

This option entails an assessment on whether merging the Agency with another EU body, such as Europol, the Maritime Analysis and Operations Centre – Narcotics (MAOC-N), the European Medicines Agency (EMA), the European Centre for Disease Prevention and Control (ECDC) or the European Health Emergency Preparedness and Response Authority (HERA) would be feasible. This would lead to the creation of a new body, absorbing the merging entities. The analysis takes into account the planned reinforcement of the mandates of the relevant agencies and the creation of HERA.[66]

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

The targeted revision option is a legislative option to amend/revise the founding Regulation and hence the Agency's mandate, by responding to the different issues outlined in the problem definition through a targeted degree of intervention in terms of: thematic scope of action for the Agency, the monitoring system, the Reitox network of national focal points, support to Member States, and international cooperation. The targeted revision option would be fully aligned with the strategic priorities covered by the EU Drugs Strategy 2021-2025.

Thematic scope of action

As the Agency was founded in early 1990s and the mandate has not been revised since 2006 – and at the time only to a limited extent – the Agency is working based on an outdated mandate that is almost 30 years old. This makes the thematic scope of action of the Agency a key intervention area. There is an increasing disconnect between the current reality of the drug phenomenon and what the Agency's mandate provides for in legal terms. The targeted revision option would deepen the efforts of the Agency in the drug area to address the key elements of the new drug phenomena – (i) other substance-based addictions when these substances are taken together with illicit drugs, i.e. poly-substance use; (ii) drug supply and drug market issues.

Firstly, the drug phenomena have become complex, now encompassing a broader range of substances, while the drug market has become much more innovative, digitally enabled and globally connected. Many problems related to illicit drug use are augmented with the simultaneous or sequential use of other psychoactive substances. For example, the combined use of heroin and alcohol increases the risk of overdoses. This is further exacerbated if different (illicit) drugs are used together. A better understanding of poly-substance use would help to better address the drug phenomena.

Secondly, the work of the Agency is – as previously explained – based on the two pillars, health and security. The recent evaluation concluded that the Agency could and should do more on supply-side issues. However, supply-side issues are not explicitly covered in the current mandate of the Agency. On the other hand, a drugs agency, which is not able to monitor supply-side issues, would ignore an important dimension of the drug phenomenon and would not be able to provide a holistic picture. Drug supply issues are intrinsically linked with the public health dimension of the Agency and, therefore, the Agency already managed to address some supply issues in its work.

Furthermore, the diversion and trafficking of drug precursors is a major input for drug production. The Agency is addressing drug precursors as a side issue in the context of drug market monitoring. The Commission collects data on diverted and trafficked drug precursors through a database hosted by the Directorate-General for Internal Market, Industry,

[66] See footnote 63.

Entrepreneurship and SMEs (DG GROW)[67] in line with the applicable precursor legislation[68]. The competent authorities nominated for this task by the Member States feed this database. The reporting is mandatory for a number of basic data elements, but Member States are invited to provide as much circumstantial information as possible. The information is then used by the Directorate-General for Taxation and Customs Union (DG TAXUD) for coordinating and sending the annual FORM D-reporting to the International Narcotics Control Board on behalf of the EU. The data is also provided to the Agency, which summarises the data and includes it in its regular reports. In order to get a better understanding of the situation of diversion and trafficking of precursors in the EU, the Agency should be in charge not only of analysing the data provided through the Commission's database, but collecting the relevant data should also be considered.

Monitoring system

The current monitoring system of the Agency is largely retrospective, dependent on established approaches and often comes with a considerable reporting time lag due to the data collection method. The targeted revision option would strengthen the Agency's monitoring and threat assessment capabilities to increase its ability to react to new challenges and have an increased impact on the drug phenomena. Therefore, the monitoring system under the targeted revision would no longer act as a passive observatory tool, but in addition to information gathering and analysis, the Agency would be able to act and react on its analysis.

Deepening the focus of the monitoring system on the drugs phenomena would entail the need to enhance it with capabilities for real-time and forward-looking analysis about emerging threats, in order to anticipate developments, as identified by the evaluation, and to provide information on the best ways to address these new phenomena. Both the health and the security angles would be addressed.

A crucial aspect of this enhanced monitoring system would be to ensure that the Agency is less reliant on third parties, including on third-country agencies, for forensic and toxicological examination. In this context, the Agency should develop **targeted laboratory capacities**. As the Agency does not have any laboratory capacities, it has to rely for the analysis of substances on the laboratories in the Member States and in third countries. Mechanisms to exchange forensic and toxicological data, knowledge and standards exist, but their operation is sporadic, on a bilateral basis or based on small EU funded projects. The laboratory of the Joint Research Centre (JRC) is supporting national laboratories in the analysis only on a case-by-case basis. This is financed and organised in the framework of the Customs Laboratory European Network. The 2018/19 evaluation identified a need to support the EU and its Member States' forensic and toxicological capacity.[69]

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[67] Database further to Article 13a of Regulation (EU) No 273/2004: https://webgate.ec.europa.eu/drugprecursors/index.cfm?fuseaction=dp.homepage.

[68] Regulation (EC) No 111/2005 on trade in drug precursors between EU and third countries, OJ L 22, 26.2.2005, p. 1; Regulation (EC) No 273/2004 on trade in drug precursors within the EU, OJ L 47, 18.2.2004, p. 1.

[69] The determination of the origin of drugs on the European market is becoming increasingly important when confronted with multiple cross-border drug-related threats. The EU relies on the Cocaine Signature Programme of the US Drug Enforcement Administration when it comes to cocaine profiling. Information gained from such analysis is highly useful for policy and decision-making at EU-level and for operational purposes. Significant EU funding was provided in the past to develop profiling methods for synthetic drugs, but the methods were later abandoned. A potential reason was that the success of the projects was framed in terms of their utility to help with the prosecution of cases rather than as a tool used to improve the strategic understanding of drug markets.

There are two variations of targeted laboratory capacities that were identified as possible solutions:

- First laboratory solution is a *reference laboratory* that would provide key services and support for EU-level priorities and specific projects. In this case, a choice would have to be made what scientific areas a reference laboratory could cover. The main elements of the laboratory capacities, such as information exchange, provision of reference material and access to specialised equipment, should be covered in any case.

- Second laboratory solution is a *virtual laboratory* that would act as a highly operational competence centre. In that case, the Agency would continue relying on existing laboratories in the Member States and the JRC[70]. These would work closely together in a virtual laboratory, i.e. a specialist network of scientists and laboratories engaged in forensic and toxicological analysis. The set-up of such a virtual laboratory could be inspired by the Reitox network or the European Network of Forensic Science Institutes[71]. Sufficient laboratory and scientific competence and experience would still be needed in the Agency to steer the work of the virtual laboratory.

In addition, to deepen the focus of the monitoring system on the drug phenomena in order to provide information on the best ways to address trends and threats relevant to the targeted thematic scope of action, the Agency should also gain the ability to react to new challenges and to act on its analysis. The existing cooperation between the Agency and EU bodies would need to be enhanced and reinforced, especially with Europol, Frontex and the Maritime Analysis and Operations Centre – Narcotics (MAOC-N) due to the new thematic scope of action, especially on drug supply and drug market issues. This will also support with the new monitoring capacities needed for the implementation of the EU Drugs Strategy. In this context, the Agency could develop the following types of products:

- **Alert system:** The Agency hardly has any tasks with an operational dimension as it currently is a mere monitoring centre with a strong scientific focus, in line with the founding Regulation. The only task of the Agency, which can be considered operational, is the EU early warning system. The Agency decides, based on certain criteria, to put a substance under intensive monitoring and to prepare an initial report. This is the basis for potential future control measures on European level. Under the EU early warning system, the Agency can issue alerts or advisories to the EU early warning network, informing its members about specific events or situations related to new psychoactive substances. Therefore, the existing system does not include an alert system, which could quickly inform people who use drugs about dangerous substances being on the market.

  The developments over the last years show that dangerous substances appear regularly. These can be new substances, of which the impacts are not known yet and, therefore, the danger of fatal or non-fatal overdoses are higher. These can be drugs, which are cut with dangerous substances, e.g. carcinogenic or toxic substances used as cutting agent. If the Agency gets information of such dangers, it passes it on to its networks, in particular the EU Early Warning System network. It then depends on the Member States' authorities on how they use the information received and if and how they inform the potentially affected users.

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70 https://ec.europa.eu/jrc/en/research-facility/open-access.

71 www.enfsi.eu. ENFSI, partly funded by the EU, works to improve the expertise, performance and quality of forensic science provision in Europe, in order to improve the administration of justice, however, it relies heavily on certain Member States with advanced capabilities.

Therefore, the Agency could be enabled to issue EU-level alerts or targeted warnings in case of such dangers. Such alerts could go to organisations, which support people who use drugs, be passed on to the media for further dissemination, be posted on relevant drug-related websites or fora, or be published in other ways, which would reach people who use drugs quickly. The exact way in which such an alert system could be set up would have to be defined by the Agency itself, in cooperation with the Member States and relevant civil society organisations.

- **Prevention and awareness campaigns:** The Agency supports the development of prevention programmes and shares experiences through its best practice portal. The Agency could get involved in developing cross-EU campaigns targeted e.g. at parents, teachers and local decision-makers, raising awareness of their prevention potential.

- **Risk analysis and intelligence reports:** The Agency could develop responses to supply-side topics and better address drug market issues by supporting national law enforcement authorities with risk analysis and intelligence reports to law enforcement authorities, in close collaboration with relevant EU bodies or agencies, especially Europol.

The Reitox network of national focal points

As the national focal points are the main data providers to the Agency, any changes in the Agency's monitoring system or the extent of its mandate have to be mirrored in their mandate as well. The scope of the national data collection needs to be clearly defined in the founding Regulation. While it is for the Member States to decide how a national focal point is set up, organised and with what means it is equipped, the mandate of the national focal points will have to reflect the revision of the Agency's mandate. The targeted revision would imply that data collection of national focal points on drug phenomena, particularly on poly-substance use would need to be improved to respond to the new thematic scope of action of the Agency. Furthermore, the targeted revision would empower national focal points to provide the relevant data to the Agency, and enable them to act as more effective intermediaries translating and implementing key messages from the Agency, nationally.

The targeted revision would focus on improving the data collection of the national focal points on the drug phenomena and enhancing their effectiveness and efficiency within their current set-up. The national focal points should assist the Agency in analysing and interpreting the national drug situation, and report and disseminate the Agency's products. In addition, being positioned as a central data hub, the national focal points could have a stronger (coordinating) role on national level as a service provider to national stakeholders and get additional specific assignments relevant in the national context.

Minimum requirements would be important to ensure the provision of high quality data from every Member State and to give some continuity and consistency to the national focal points. A **certification procedure** could verify the compliance with the minimum requirements. A certification solution could be implemented through a peer-to-peer review process. The peer pressure would result in a quasi-binding nature of the minimum requirements. As this would not be laid down in a binding decision of the Agency, there would not be any subsidiarity concerns with such an option. Another certification solution is to continue with the *status quo* of a voluntary certification procedure carried out by the Agency. The main downside of a voluntary certification system is that the minimum criteria would remain as recommendations without any binding nature.

Support to Member States

Currently, the Agency provides support to Member States on a demand basis. This mainly refers to the evaluation and shaping of national drug policy as well as the exchange of best practices or their implementation. However, the Agency could build on its core activities and strengths, and provide more support to Member States. The targeted revision option would position the Agency as a service provider to Member States offering tailored services based on the needs arising in the drugs policy field. New services would be introduced based on core strengths of the Agency and where it can leverage its data collection/monitoring/harmonization/analysis capabilities. Services such as accreditation and certification of (national) key intervention schemes, reporting of data on behalf of the Member States to the UN agencies, or training would be considered.

International dimension

The evaluation was clear on the potential for the Agency to increase its involvement on international issues. The recast of the founding Regulation in 2006 gave the Agency a more explicit role as regards cooperation with international organisations and third countries.[72] The Agency is quite active in the international arena, supporting the EU and its Member States in multilateral fora and in the cooperation with third countries. The Agency already carries out EU-financed projects in third countries, which contribute to improving national and regional responses to security and health threats in these countries/regions. The targeted revision option would clarify the role of the Agency in this area in order to improve the evidence base for EU drug policy-making, improve the outreach of the EU to third countries and contribute to the development and implementation of the external dimension of EU drugs policy.

The targeted revision would align the issues where the Agency has competences on an EU-level, with where it would be able to contribute on an international level. As the Agency's work would better reflect the EU's balanced, evidence-based, integrated and multi-disciplinary approach to drugs policy, it would be able to further act to promote this approach in third countries. The Agency would be given a clear mandate to participate in EU cooperation programes and to analyse global developments and developments in third countries, which have the potential to affect the EU. The expert input of the Agency would not only benefit the EU's international partners, but the EU itself. It would contribute to the development and implementation of the external dimension of EU drugs policy and the leadership role of the EU at multilateral level.

Policy option 5: Expansive revision – Focusing on diverse addictions

The expansive revision option is a legislative option to amend/revise the founding Regulation and hence the Agency's mandate, by responding to the different issues outlined in the problem definition by using the thematic scope of action as a starting point. The expansive revision option would broaden the efforts of the Agency away from the drug area and open up the scope of action to address a full thematic scope related to wide range of substance and behavioural addictions.

Thematic scope of action

The current thematic scope of action of the Agency refers to "drugs and drug addiction and their consequences"[73]. The founding Regulation itself does not define the terms further. Therefore, recourse has to be made to the definition of drugs in EU law. At the time of adoption of Regulation (EC) 1920/2006, Council Framework Decision 2004/757/JHA defined drugs with reference to the UN Drug Conventions and Joint Action 97/396/JHA of 16 June

[72] Article 2(d) of the founding Regulation.
[73] Article 1(2) of the founding Regulation.

1997 concerning the information exchange, risk assessment and the control of new synthetic drugs.[74] The definition was slightly adapted through Regulation (EU) 2017/2101.

Based on this definition, the thematic scope of action of the Agency covers (illicit) drugs. When revising the mandate, the question is whether it should be broadened to other (problematic) forms of substance use, including alcohol, tobacco, prescription medicines, and/or addictions not directly linked to substance use, such as gambling and compulsive gaming.

Alcohol and tobacco addictions are a serious health issue and lead to significant social and economic consequences. Addiction to prescription medicines is an increasing problem in the EU, and the possible magnitude of the problem can be seen in the opioid crisis in the US[75]. Behavioural addictions do not involve the use of substances, but can cover a wide variety of problematic behaviours, such as gambling, compulsive gaming, internet addiction, sex addiction, shopping addiction, and binge eating. Addictions are to some extent similar biologically and behaviourally, result in a similar compulsivity, and sometimes are addressed through similar policy approaches.

Licit and illicit markets involve different types of actors and have different types of problems. However, some consider the distinction arbitrary from a scientific point of view and the distinction can change over time.[76] Possible changes in the classification of a substance as licit or illicit have to be taken into account in any consideration on the future mandate. This is also relevant as regards low-THC[77] products and products containing cannabinoids, which are already on the market, or prescription drugs, which are misused widely in some areas of the world (e.g. opioid-based painkillers).

The stakeholder consultation during the 2018/19 evaluation revealed that while a majority of national stakeholders and Agency were largely in favour of broadening the scope to other addictions, other stakeholder groups (including EU-level stakeholders) were critical. The expansive revision option would have to address possible overlaps with existing policies on these addictions while building on areas that fit closely with the current activities of the Agency. It would also imply a serious increase of the financial and human resources necessary to the Agency to carry out its tasks.

Monitoring system

The current monitoring system of the Agency is largely built to monitor drug phenomena, mainly focused around drug use and related trends. Not only is the monitoring system largely retrospective, but it is dependent on established approaches. Therefore, the monitoring system of the Agency would have to be revised under the expansive revision based on the broad thematic scope of action, in order to provide analysis and information on the best ways to address applicable threats and trends covering not only the drug phenomena but also diverse addictions. While it would be relatively easy to extend some aspects of the current data collection system of the Agency to other substance-based addictions, in particular alcohol, tobacco and prescription medicines, collecting data regarding addictive behaviours would be more difficult as it requires different methodologies and studies.

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74 OJ L 167, 25.6.1997, p. 1.

75 https://www.whitehouse.gov/opioids/.

76 See e.g. related to cannabis, which has been liberalised in some areas of the world, such as Canada, Uruguay and some States in the US.

77 THC stands for tetrahydrocannabinol, which is the main psychoactive substance found in cannabis.

The existing cooperation between the Agency and other EU agencies would need to be enhanced and reinforced, especially with the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC) who do not specifically collect addiction-related data, but some of their data might be useful for a better understanding of addictions.

In addition, it has to be determined what tasks should be included to serve the monitoring system within this expansive scope of action, i.e. whether the Agency should integrate existing data into routine reporting; develop further the existing data collection regarding other addictions; monitor the health impacts of these addictions; and/or monitor all the consequences of these addictions. The assessment would have to address possible overlaps with existing policies on these addictions and should identify areas, which fit closely with the current activities of the Agency.

Since the monitoring system of the Agency requires updates in order to anticipate developments in the drug phenomena, as identified by the evaluation, for the Agency to be less reliant on third parties for forensic and toxicological examination, an **expanded laboratory solution** was identified. As previously mentioned, the Agency does not have any laboratory capacities, it has to rely for the analysis of substances on the laboratories in the Member States and in third countries. If the Agency would have its own centralized laboratory housed within the Agency itself, it would be able to work on and answer key strategic questions about the composition of drugs and drug markets. These questions often go unanswered due to lack of capacities on national and European level, especially as the laboratory of the JRC supports national laboratories only on a case-by-case basis within the Customs Laboratory European Network.

In addition to providing the Agency with an updated monitoring system that has the support of a developed laboratory, the expanded revision should include the different elements that would allow the Agency to react to new challenges and to act on its analysis. As outlined and described in the targeted revision option above, these are the **alert system, prevention and awareness campaigns, and risk analysis and intelligence reports**, and they would enable an operational response from the Agency on drug issues, in conjunction with the topics of diverse addictions.

The Reitox network of national focal points

As previously mentioned, the national focal points are the main data providers to the Agency. Therefore, any changes in the Agency's monitoring system have to be mirrored in their mandate, which is for the Member States to decide as well as how a national focal point is set up, organised and with what means it is equipped. Nevertheless, the expansive revision affects the mandate of the national focal points even more than the targeted revision, which will have to be taken into consideration.

Minimum requirements regarding the provision of high quality data from every Member State and to give continuity and consistency to the national focal points can be foreseen in the expansive revision option through a stronger certification option than the targeted revision or the current practice. Instead of continuing with the *status quo* of verifying the minimum requirements with the voluntary certification procedure carried out by the Agency, the expansive revision lays out a **mandatory certification** by the Agency. This would lead to a decision of the Agency as regards to compliance with the minimum requirements. In the case of non-compliance with the minimum requirements, the Agency could make recommendations on how these should be achieved, accompanied by a timetable. This solution could be considered as interfering with national competencies and might be difficult

from a subsidiarity perspective as not only the minimum requirements, but also the recommendations on how to implement them would be binding. However, this solution would respond to main weakness of the voluntary certification, which is that the recommendations cannot be enforced.

In addition, the expansive revision will increase the body of data to be provided by the national focal points to the Agency based on the expansive thematic scope of action covering diverse addictions. Therefore, the expansive revision would have to broaden efforts for collection of data across addictions. The majority of this data is already collected by the Member States based on EU legislation and/or because national strategies apply a wider addiction approach. However, clear rules on what data and information has to be provided by Member States through the national focal points to the Agency under this broader thematic approach, would need to be developed and established.

Support to Member States

In addition to the support the Agency currently provides to Member States such as support with evaluations and shaping of national drug policies or exchange of best practices, the expansive revision presents an opportunity to enhance and further expand the added-value to Member States. In addition to the services outlined in the targeted revision (i.e. accreditation, training), the expansive revision option would also build on the Agency's current role as an important hub for knowledge sharing, but with an increased thematic scope on diverse addictions. The best practice portal[78] is the best example of this. Key challenges for the EU, particularly on prevention and treatment, need the implementation of best practice standards and the transfer and adoption of best practice methods, which are laid out and discussed in the best practice portal. In the expansive revision, this role could be increased to include prevention and treatment of diverse addictions.

International dimension

The expansive revision would work towards clarifying the role of the Agency in this area mainly in terms of drug policy, as the drug phenomena topic is the most international topic within general addictions. The Agency already carries out EU-financed projects in third countries, which contribute to improving national and regional responses to security and health threats in these countries/regions. However, the Agency's envolvement is not garanteed to be consistent due to the setup of funding. Building on the solutions laid out in the targeted revision, the expansive revision should lead to providing the Agency with a sustanable budget for international activities, thus reconsidering the current "ad hoc" and "project funding" approach when participating in EU-financed projects in third countries, which impedes the Agency's performance and consistent involvement.

5.3. Options discarded at an early stage

In the course of the impact assessment exercise the following policy options were discarded at an early stage and thus were not subject to deeper analysis and assessment:

Policy option 0: Baseline scenario - Maintaining the current approach without changes

Keeping the baseline scenario in place would not address any of the problems and would not achieve the general objective of the proposed initiative. Section 2.5 sets out how the problem would evolve if no policy change would be implemented.

[78] See footnote 61.

Policy option 1: Minimal revision option - Stronger cooperation

This option would not achieve the general objective of the proposed initiative, although improving the cooperation between the Agency and the Member States and with other EU agencies is important.

Member States are interested in getting European-wide analyses of the drug phenomenon from the Agency and its support in the evaluation and shaping of their national drug policies. More cooperation among Member States themselves would not be able to address this, as they do not have the resources, capabilities or the competence to analyse the cross-border dimension of the drugs phenomenon.

An obvious candidate for further cooperation is Europol[79]. The two agencies are already cooperating on a number of issues, in particular when it comes to the early warning system and the development of reports on drug market issues. Potential overlaps in their tasks, in particular on drug markets, are addressed by a close cooperation of the two agencies, where each focusses on its strengths in the area. A further extension of the cooperation would be difficult as the EMCDDA's mandate does not refer to drug supply or drug market issues.

Another option would be the Maritime Analysis and Operations Centre – Narcotics (MAOC-N).[80] Enhancing and reinforcing the existing cooperation between MAOC-N and the Agency could involve sharing of data, intelligence analysis, and information on the substances seized. Further improving the cooperation between the two entities would be of benefit for both as MAOC-N would get additional strategic information, whereas the Agency could benefit from the operational knowledge of MAOC-N. However, there would be limits to what information MAOC-N would be able to share with the Agency due to the confidential nature of the information they hold.

As regards the European Medicines Agency (EMA)[81], the European Centre for Disease Prevention and Control (ECDC)[82] and the European Health Emergency Preparedness and Response Authority (HERA), the focus of cooperation would be on health issues. Looking at the mandates and the focus of these bodies, including of HERA[83], cooperation on drug-related issues would only be an ancillary task for them. Although ECDC and EMA look at serious cross-border health threats, their focus is on ensuring the functioning of the internal market and the general health security framework. Therefore, strengthened cooperation with these EU bodies would only address the objective of the proposed initiative to a limited extent.

Enhanced cooperation could be considered with the UN Office on Drugs and Crime (UNODC). The evaluation concluded that there are some overlaps between the work of the

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79 Existing working arrangements: https://www.emcdda.europa.eu/system/files/attachments/10200/Draft_Working_Arrangement_EMCDDA_Europol%20for%20MB_290618.pdf.

80 MAOC-N is an operational platform with the co-location of experienced law enforcement liaison officers and military attachés from six Member States (Spain, France, Ireland, Italy, Netherlands and Portugal) and the UK. Its main objective is to improve the cooperation in the fight against illicit drug trafficking by sea across the Atlantic Ocean and the Mediterranean Sea towards Europe and the West African Seaboard. The budget of MAOC-N is provided mainly by project grants from the Internal Security Fund – Police.

81 Existing working arrangements: https://www.emcdda.europa.eu/system/files/attachments/10204/Draft_Working_Arrangement_EMCDDA_EMA%20for%20MB_290618-1.pdf.

82 Existing working arrangements: https://www.emcdda.europa.eu/system/files/attachments/10396/Working_Agreement_EMCDDA_ECDC_4December.pdf.

83 See footnote 63.

Agency and UNODC, in particular in relation to the collection of drug-related data. It was suggested by consulted stakeholders that the Agency could support the Member States in their reporting to UNODC. The Agency's stakeholders identified further scope for increased cooperation on issues such as sharing best practices and adoption of common guidelines on data collection.[84] The remit of UNODC is global and, therefore, the emphasis of the two bodies is very different. Therefore, further strengthening the cooperation with UNODC would achieve the objectives of this initiative only to a limited extent.

The assessment of this non-legislative policy option leads to the conclusion that it would – on its own – not be able to achieve the general objective of the proposed initiative and would only to a very limited extent be able to address the problem drivers. However, cooperation with other agencies should be strengthened in any case in order to make full use of the complementarities outlined above. Addressing existing or potential future overlaps would be difficult in a non-legislative option and would have to be addressed from the outset in any (revised or new) working arrangements.

As policy option 1 is not able to address the problems set out in the problem definition nor to achieve the general and specific objectives of the proposed initiative, it will not be assessed further.

Policy option 2: Dismantling of the Agency - Repeal of the founding Regulation

According to the common approach, "*closing down an agency could be a solution for dealing with underperforming agencies unless the agency is still the most relevant policy option, in which case the Agency should be reformed*".[85]

The recent evaluation showed that the EMCDDA is considered not only on European level, but also internationally, as a centre of excellence. All stakeholders agreed during the evaluation that the termination of the Agency would have negative impacts and should be avoided. In the context of the recent discussions of the new EU Drugs Strategy in the Council's Horizontal Working Party on Drugs, all Member States were fully supportive of the work of the agencies involved and in particular stressed how much the Agency is needed to further EU drugs policy.

While at the first instance it would be policy-makers who would be affected by the termination of the Agency as they would not have access to EU-level information, ultimately, the general public would feel the impacts, albeit more indirectly. As there would be no obligation to collect the relevant data and no more centralised support, some countries would cease to collect the data. This would result in incomplete and fragmented data and imply the loss of the EU-level overview of the drug phenomenon.[86]

The exchange of best practice would be more difficult without a central organisation bringing the information and people together. The cessation of the Agency would undermine the possibility to design and implement drug policies and strategies based on objective and scientific evidence, both at EU and at national level. Closing down the Agency would have a negative impact on evidence-based policy-making.

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84 See footnote 19, p. 34.

85 Point 5 of the Common Approach (see footnote **Error! Bookmark not defined.**).

86 See footnote 19, p. 37/38; see the counterfactual case study in Annex 4 of the final report of the evaluation.

Based on the conclusions of the evaluation and the very good performance[87] of the Agency, it cannot be concluded that the Agency is underperforming. Such a conclusion would be contrary to the perception of stakeholders that the Agency in an important neutral voice providing factual, objective, reliable and high-quality data on drugs and dismantling it would cause serious issues for drug monitoring in Europe.[88]

The termination of the Agency would have negative consequences on the role of the EU at international and multilateral level, as it would diminish EU leadership in drugs policy, would likely negatively impact its ability to speak with one voice in international fora, and would lead to an incomplete picture of the situation of drugs in the EU, which would be contrary to the EU's interests.

The assessment considered alternatives to the Agency based on the analysis during the evaluation in view of their effectiveness in implementing EU drugs policy.

Allocating some of the tasks to the Commission services in cooperation with EU bodies (such as Europol, EMA, ECDC or HERA) or directly to these bodies would still ensure regular EU-level data collection and analysis. Attributing the tasks to the Commission would have two main disadvantages: a) the Commission might have to outsource some of the activities, which would lead to a loss of capacity and expertise in the mid- and longer term; and b) this loss of expertise might compromise the quality of the data analysis. Attributing the tasks to the mentioned EU bodies might limit the loss of expertise, but would create a fragmentation of the work and increase the coordination role to be played by the central services – which, at time of scarce human resources, would not be effective.

Another alternative would see the responsibility for monitoring the drug phenomenon reverting back to the Member States. The Member States would need to ensure that the collection of data continues among themselves with limited or no coordination at EU level. An agreement on common standards would be more difficult to reach, compromising the comparability of data. In addition, the reliability and impartiality of the information might suffer. Some Member States may decide not to take part in European data collection anymore.

The third alternative option would be to rely exclusively on the activities of international organisations, such as the UN Office on Drugs and Crime (UNODC), the World Health Organisation (WHO), the Council of Europe (in particular the Pompidou Group) or others. Although the collection of data would be coordinated by a central body (external to the EU), it would mean that the picture of the drugs phenomenon in the EU could be incomplete based on available world data as opposed to European data. In addition, the collection would be less relevant as it would not be targeted to the interests of the EU. This would lead to a loss of expertise and understanding of the influencing factors on the drug phenomenon in the EU. It would imply a loss of EU visibility on the global stage, given that the EU is seen as a model in terms of data collection and evidence-based drugs policy.

The dismantling of the Agency would imply the disinvestment of the EMCDDA budget of about EUR 16-17 million per year (if dismantled without replacement). If the tasks would be reallocated to another EU body, all or a large share of this budget would be needed in the receiving body and, therefore, the dismantling would lead to only limited budget savings for the EU. In case of a dismantling of the Agency without replacement on EU level, additional

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87 See the general reports of activities and the annual accounts; https://www.emcdda.europa.eu/publications-database?f[0]=field_series_type:472.

88 The feedback received on the inception impact assessment confirmed this view. Six (out of a total of 24) respondents stated that the dismantling of the Agency would lead to a serious threat for and weakening of the European drug monitoring system.

efforts and investments by national public authorities would be needed. This would likely lead to a higher total cost than the current solution. Unfortunately, very limited data is available as regards investments by Member States on drug policy.[89] Therefore, the real "costs of non-EU" cannot be estimated in a reliable way.

In conclusion, the assessment shows that the Agency is the most effective solution compared to the alternatives in achieving the objectives of EU drugs policy. The dismantling of the Agency would furthermore be in contradiction with the EU Drugs Strategy 2021-2025.

Policy option 3: Merging of the Agency with another EU body

According to the common approach, "*merging agencies should be considered in cases where their respective tasks are overlapping, where synergies can be contemplated or when agencies would be more efficient if inserted in a bigger structure*".[90]

The evaluation looked into possible overlaps and synergies with other organisations and concluded that there are hardly any overlaps. Stakeholders highlighted that the reason for the few overlaps is that the Agency is unique as a provider of an overview of the EU drug situation. The main overlap identified is with the UN Office on Drugs and Crime (UNODC) as regards data collection as both collect standard drug data, but at different times of the year, based on different definitions and in different formats.

As regards possible synergies between the Agency and other bodies, the evaluation showed that good cooperation is in place, many synergies are already exploited and that there is minimal duplication of work. Beyond the UNODC, stakeholders identified some unexploited synergies with the Commission, in particular with DG SANTE on health-related issues.

The potential to merge the EMCDDA with another EU body was not deemed desirable by stakeholders. There were no positive interview responses during the evaluation to the prospects of merging the EMCDDA with another EU agency. The primary reason was the very specific activities of the Agency.[91] For the same reason interviewees considered that such a merger would have a detrimental effect on the quality of the scientific outputs.

The potential candidates with whom the EMCDDA could be merged are, based on current cooperation levels, synergies and potential complementarities of work, Europol, MAOC-N, ECDC, EMA and HERA.

The Agency and Europol are cooperating closely on drug markets issues and on the EU early warning system for new psychoactive substances. Whereas Europol has operational information from law enforcement (in particular police) authorities, the EMCDDA has access to strategic information. The outcome of this work are several joint reports[92] and the involvement of the two agencies in each other's working groups. A merger of these two agencies might lead to a better understanding of drug market issues and the availability of additional information for law enforcement authorities on the functioning of drug markets. On the other hand, drug trafficking is for Europol one of many crime areas. Europol is large compared to the EMCDDA and the danger is that the drug-related issues would get lost

89 Evaluation of the EU Drugs Strategy 2013-2020 and EU Action Plan on Drugs 2017-2020, SWD(2020) 150 final.

90 Point 5 of the Common Approach (see footnote **Error! Bookmark not defined.**).

91 54% of all interviewed stakeholders expressed this view. In addition, almost all participants in the public consultation provided a clear negative answer to the potential closing or merging of the Agency with another body.

92 The joint flagship report is the EU Drug Markets Report (footnote 7).

among the many priorities of a merged agency. Furthermore, Europol reshuffles its priorities based on regular assessments. Only recently, due to the escalation of activities in the drug markets, Europol started to re-engage stronger on issues related to drug trafficking. The conclusion that a merger with Europol would not be beneficial for EU drugs policy does not change with the proposed revision of the Europol Regulation as it is focused on issues not addressing the problems identified in this impact assessment.[93] In addition, it is likely that a merged entity would focus mainly on drug market and crime issues and reduce the focus on health issues. This would not be in line with requests from stakeholders, in particular civil society and Member States, to continue the Agency's important work on public health issues.

The integration of MAOC-N with the Agency was considered because both organisations work on drug issues, have clearly complementary activities, are both located in Lisbon and because this could give the Agency an operational dimension. If MAOC-N would be integrated while keeping its specificities, it would allow for the continuation of the current working model of MAOC-N, which would ensure that the confidentiality and protection of the information exchanged, distribution of intelligence, and de-confliction would be kept separate. This could get the buy-in of the partner countries. Keeping a separate structure for MAOC-N within the Agency would lead however to considerable legal challenges as a hybrid governance model would be needed. Although a full inclusion of MAOC-N into the Agency would give the Agency a real operational dimension without raising the legal challenges of a hybrid governance model, it would most probably not be feasible as it would raise serious opposition from MAOC-N partners as the current functioning would not be feasible in a bigger structure. The integration of MAOC-N with the Agency could address the issue of financial sustainability of MAOC-N[94], but not the problems addressed in this impact assessment. Due to the specificities of the information held by MAOC-N, which can only be shared with the partner countries, the expected impact of giving the Agency a real operational dimension would not materialise.

The links between the Agency and EMA or ECDC are in relation to a limited number of health issues. The main common work strands with EMA are in relation to medicinal products and their potential misuse. The ECDC and the EMCDDA have a common interest in monitoring, communicating on, and preventing the spread of drug-related infectious diseases in Europe.[95] While ECDC analyses trends in these diseases across the whole population, EMCDDA focuses on specific drug-related risk groups such as injecting drug users. However, drug use as such is not a disease.

Merging with EMA or ECDC would have considerable downsides. It would lead to a loss of focus on drug-related issues due to the dilution in wider health aspects. This is particularly problematic in the aftermath of the COVID-19 pandemic, where the focus of these agencies will be on addressing the effects of the pandemic and bolstering the response to potential new pandemics in the future. As shown in practice during the pandemic, drug issues do not have the status of essential services and therefore are not in the core of general health considerations.[96] The current cooperation between EMCDDA, on the one hand, and EMA or

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93 COM(2020) 796 final. The three core issues addressed by the revision are the lack of effective cooperation between private parties and law enforcement authorities to counter the abuse of cross-border services by criminals; the big data challenge for law enforcement authorities; and gaps in innovation and research relevant for law enforcement.

94 This is however addressed to some extent with the renewed and increased support of the EU to the functioning of MAOC-N for the period 2022-2026.

95 See Proposal for a Regulation on serious cross-border threats to health, COM(2020) 727 final.

96 Closing remarks on the impact of the COVID-19 pandemic on the world drug situation – the European perspective, at the occasion of the United Nations Commission on Narcotic Drugs special event on the International day against drug abuse and illicit trafficking (26 June, Vienna),

ECDC, on the other hand, extends to the EU early warning system. For both agencies, Article 5b of the founding Regulation defines what information they should provide to the EMCDDA in case of the development of an initial report on a new psychoactive substance.[97] This kind of information is not available to EMCDDA and there is no intention to extend the Agency's mandate in these directions. Taking into account the proposed extensions of the mandates of EMA and ECDC as well as the intentions for the revision of the EMCDDA mandate as set out in the preferred option, there are no risks of overlaps regarding the data collection and/or analysis. In addition, the drug market related issues would likely not get the attention they deserve in a merged entity. Moreover, EMA is based on a regulatory logic, which does not fit with drug-related issues.

The mission for HERA is to strengthen the EU's preparedness and response in terms of medical countermeasures for serious cross-border threats to health. Based on the inception impact assessment[98], the main objective of the new EU body is to enable adequate EU preparedness via an EU level countermeasure management system that would allow rapid and equal access, availability, development and deployment of the most advanced medical countermeasures in the event of a health emergency. HERA should contribute to the Security Union, through improving the availability of countermeasures for preparedness and respond to intentional release scenarios and Chemical, Biological, Radiological and Nuclear (CBRN) threats. The specific focus of this new agency does not seem to lead to any complementaries or overlaps with the work of the EMCDDA.

No evidence is available that would indicate that addressing drug-related issues would be more efficient if the Agency would be merged with any of the aforementioned bodies. To the contrary, addressing these issues in a bigger structure of a merged entity includes the danger of dilution, i.e. that the drug topic would be marginalised and not addressed sufficiently. In addition, a merger with any of the aforementioned EU bodies would lead to a loss of balance between the health and security dimension in the new entity. Not having the balance between the two main pillars would be detrimental to EU drugs policy.

In case of a merger with another EU body or the shifting of the competences to one of them, human and financial resources would have to be transferred. Moreover, the transfer of undertaking would have to be carefully assessed as such a transfer of obligations can be quite expensive and time consuming. In addition, the simplification potential is quite small, as it would be mainly limited to the administration of the new entity vis-à-vis having these administrative functions in two agencies. Therefore, such a merger would not lead to relevant efficiency gains on the European level.

In conclusion, merging of the Agency with another EU body would be incoherent with the drug phenomenon in the EU, which necessitates stronger – not weaker – intervention at EU level. This option would fail to address the problems set out in the problem definition and would not help in achieving any of the general or specific objectives of the proposed initiative. Moreover, merging the Agency would be against the approach of the new EU Drugs Strategy 2021-2025, which explicitly asks for the Commission to present a proposal for a revision of the EMCDDA mandate. Therefore, this policy option will not be further assessed in the impact assessment.

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https://www.emcdda.europa.eu/system/files/attachments/13134/Speech-EMCDDA_Europol_Goosdeel_FINAL.pdf.

97 The working arrangements of the EMCDDA with the two agencies (see footnotes 81 and 82) were adapted to the update of this provision in 2018; see the related Commission opinions in C(2018)6815 (ECDC) and C(2018)6779 (EMA).

98 https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12870-European-Health-Emergency-Preparedness-and-Response-Authority-HERA-.

6. WHAT ARE THE IMPACTS OF THE POLICY OPTIONS?

This section analyses the impacts of the policy options 4: targeted revision and policy option 5: expansive revision. The main impacts are on the European Union (EU bodies) and on national authorities. Linked to this are possible impacts on simplification and/or administrative burden and economic impacts. The following sections of the report, assess the impact of the two package policy options defined in chapter 5.2.

When it comes to other impacts, those 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. In terms of impacts on the economy and competitiveness, social impacts, environmental impacts, and impacts on fundamental rights, the revision of the mandate of the Agency only has very limited and indirect impact. Therefore, these impacts will only be addressed below as far as relevant.

As regards *impact on the economy and competitiveness*, a revised mandate of the Agency would contribute positively through limiting the loss of manpower in the economy due to people who use drugs not being able to work or provide work to their full abilities, and through disrupting the income of organised crime groups. These are indirect impacts, which would be due to a better understanding of the drug situation. The only direct economic impact is on the EU and, depending on the option, national budgets.

An Agency, which would be better equipped based on a revised mandate, would help – together with Europol – to tackle drug supply in the EU based on better available information on drug trafficking and production, and thereby tackling crime and supporting the internal security of the EU. Another *social impact* of the revision would be improved access to best practices in the area of drug demand and other public health responses. In addition, based on the experience with drugs, the Agency could have an important contribution to actions in support of the mental health of users.

The revision of the mandate would have a certain indirect *environmental impact*. Drug production on the territory of the EU, in particular of MDMA (ecstasy) and (meth-)amphetamines, has considerable impacts 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 the illicit dumping of drug waste.

The revision as such does not have any direct *impacts on fundamental rights*. The data provided to the Agency are statistical data, but do not include personal data; therefore, Article 8 of the Charter of Fundamental Rights ("protection of personal data") is not affected. Other fundamental rights are even less impacted. It should be added, however, that the work of the Agency tackles important 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, improving the functioning of the Agency could have positive indirect impacts on fundamental rights.

None of the options proposed has *impacts on small and medium sized enterprises (SMEs)*.

6.1. Impacts on the European Union (EU bodies) and value-added

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

This option provides a thematic scope of action 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 messages from the Agency, nationally. Under this policy option, the Agency would also gain in agility in terms of responding to the needs arising in the drugs policy field through various tailored services for Member States.

Thematic scope of action

Such a targeted revision of the scope of action of the Agency would overall be coherent with EU policies. It would also allow a more holistic view on drugs issues by addressing both drug demand and drug supply in-depth, as well as the poly-substances angle of the drug phenomenon, without interfering with Member States' competencies, and therefore might be the most effective option of expanding the Agency mandate.

While targeting the thematic scope of action of the Agency more holistically on drug demand and supply, including poly-substance is relatively straight-forward, the issue of the Agency monitoring the diversion and trafficking of drug precursors requires further consideration. While it would strengthen the EU's response to drug precursors, as the Agency would be able to carry out a more thorough and complete analysis through triangulating drug precursor data with other drug supply indicators, in order to get a better understanding of the situation of diversion and trafficking of precursors in the EU, the Agency should be in charge not only of analysing the data provided through the Commission's database, but also to collect the relevant data. Probably the quickest way would be to transfer those parts of the current precursor database, which relate to the FORM D-reporting, from the Commission to the Agency, despite its limited scope. However, this could raise criticism from Member States as it would lead to a split of the database and potentially to the national authorities having to use different databases to report on international obligations. Another, possibly more sustainable option would be that the Agency uses its own tools to collect the relevant data. However, this would currently not be in line with the EU drug precursor legislation.

Monitoring system and support to Member States

The targeted revision would have the added value of closing the gap regarding the monitoring system for drugs, including for technology-enabled drug markets and responses. This would be beneficial for the EU, including its Member States, as it would allow for a full picture of the drug phenomenon in the EU. EU drug policy – and based on that, national drug policies – take an evidence-based approach. Therefore, a neutral body is needed to address drug-related issues and ensure a holistic monitoring system.[99] Without modern tools and methodologies for the detection and analysis of new phenomena, any drug information system would become increasingly blind to emerging threats and signals. This would affect the overall understanding of the drug phenomenon and might lead to the EU losing its leadership in international drug policy. The question is therefore not whether to have a more modern monitoring system in place or not, but who should implement it.

A modern monitoring system would form the basis for general threat assessments, which should identify at an early stage new developments of the drugs phenomenon. Such a capability is crucial in a fast-changing drug environment. Threats in one Member State or even in a third country can have major impacts on the drug market and services to be provided in another Member State – or the whole EU. Establishing an appropriate threat assessment

[99] See footnote 88.

capacity in the EU is therefore important for better understanding not only the threats themselves, but also the links between different phenomena and different markets. This would contribute further to an evidence-based EU drug policy and have considerable EU added value.

As for any suggestion that capabilities in the area of threat assessments are not needed on a European level, the answer is that the main threats deriving from new technologies are of a cross-border nature. No Member State on its own can carry out the monitoring and assessment of the potential threats, and Member States are themselves requesting these capabilities at the EU level.

When it comes to the support of Member States, the Agency provides such support upon request as regards evaluating or designing national drug policies. The Agency is supporting training initiatives, including the European Prevention Curriculum (EUPC).[100]

Although the Agency currently does not have the necessary data nor the resources nor the mandate to carry out this kind of monitoring and threat assessments or to expand its support to Member States, it would be well placed to develop such a capability. The Agency is already carrying out risk assessments for new psychoactive substances. It has done work on the monitoring of online market places, together with Europol, and is now involved in the related preparatory action[101].

Based on these experiences, the Agency could further expand its activities in these areas. Developing these capabilities further without addressing them in a revised mandate will be feasible only to a limited extent, as the Agency would need access to the relevant information, which is not covered by the data collection exercises based on the existing mandate.

An alternative would be to attribute such work to other EU bodies or an international entity. As regards EU bodies, the most obvious candidate for threat assessments and the monitoring of new technological developments would be Europol. The EMCDDA and Europol are cooperating in the monitoring of the darknet[102] and Europol provides input to the EU early warning system. However, if Europol would develop this capability, it would not cover the health side of the drug phenomenon. On the other hand, attributing this capability to one of the EU bodies in the health area (the ECDC, EMA or HERA) would not be sufficient either as the security dimension would then be under-represented.[103] As regards international organisations, neither the UN Office on Drugs and Crime nor the International Narcotic Control Board have the capacity or the resources to carry out the necessary actions, in particular if the main focus were to be on Europe. The practical experience of the past showed that these bodies are turning to the EU, including to the Agency, for such tasks. In addition, if they have to conduct new work, they would need financial support.

As none of the aforementioned agencies or organisations are addressing or will in the future address drug-related monitoring and threat analysis, there are no issues related to the coherence with the work of other agencies (or the Commission). In addition, coherence will

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100 https://www.emcdda.europa.eu/best-practice/european-prevention-curriculum_en.

101 The involvement of the EMCDDA in the Steering Committee for the preparatory action on darknet monitoring (General Budget of the European Union for the Financial Year 2020, item "18 02 77 04 Preparatory action — EU-coordinated Darknet monitoring to counter criminal activities", L 57, 27.2.2020, p. 1341) is important for identifying the appropriate tools to address such developments.

102 EMCDDA/Europol, Drugs and the darknet: perspectives for enforcement, research and policy, 2017; see also footnote 51.

103 See further arguments in section 5.3., which are also applicable here.

be ensured by a close cooperation of the Agency with these agencies and organisations, within their respective mandates.

Laboratory capacities

A centralised laboratory could produce or procure reference materials and then distribute them to the Member States, leading to significant savings and improving the capacities of Member States. Finally, a centralised laboratory could support laboratories in the Member States in areas requiring specialised expertise.

A reference laboratory would not allow for all the aforementioned benefits. However, it would give the Agency the possibility to provide key services to other laboratories and would alleviate some of the financial burdens from other (national) laboratories. This would be in particular true if the Agency could still provide reference materials to other European laboratories.

Lastly, a virtual laboratory would be the minimum option in this context. It would not allow for a centralisation of key laboratory functions in the Agency. The main impact of such an option would be the sharing of information and experience among relevant laboratories across Europe. The EU added value would be limited compared to the aforementioned options of having a "real" laboratory in the Agency, in whatever dimension.

Early warning and alerts

The Agency could be enabled to issue EU-level alerts or targeted warnings in case of various relevant dangers (e.g. quickly inform people who use drugs about dangerous substances being on the market). The main benefit of this being done directly by the Agency is the speed within which such information can be made available. In addition, Member States will usually not be aware of dangers, which originate in another Member State, but might spill over. As the EU early warning system could be an important basis of such alerts, the Agency seems to be well placed to prepare such alerts.

Prevention programmes and experience sharing

There is no coordination or exchange of experiences on such campaigns happening on a European level so far. Although the development of campaigns cannot follow a "one-size-fits-all-approach", the Agency could have an important supporting role for developing EU-level campaigns. Member States, national focal points and relevant other EU bodies would have to be closely involved.

The EU added value of the Agency supporting the development of prevention campaigns would be a common message across the EU on such issues. In addition, not all Member States have the capacity and/or knowledge to prepare such programmes or campaigns on their own and could benefit from the experience of the Agency. As the Agency would not develop such campaigns acting alone and would therefore not take this over from the Member States, there is no problem with the subsidiarity principle.

Developing targeted prevention and awareness campaigns as well as the possibility to issue alerts about dangerous substances would benefit the public health situation in the EU. People who use drugs and practitioners across the EU would benefit from more information.

It could be considered that Europol or the relevant EU health bodies are better placed to prepare such campaigns. However, no other EU agency has experience in addressing both the security and health dimensions of the drug phenomenon in their external communication.

Risk analysis and intelligence reports

In order to expand further on drug supply and drug market issues, the Agency would need to obtain the relevant data from the Member States. Based on such data and general threat assessments, the Agency could provide risk analysis and intelligence reports to law enforcement authorities. Close collaboration with Europol is essential.

It could be questioned whether it could not be for Europol alone to take such measures. The best results would be achieved if the strengths and available information of the Agency and Europol are put together. There is no intention to give to the Agency powers, which would be equivalent to Europol's, as Europol is operations-driven and the Agency focusses on data gathering and analysis.

The Reitox network of national focal points

The impact on the European level would be to have more and better quality information available. The availability of good data is key for the Agency to fulfil its mandate.

Although the available data improved since the previous evaluation[104], the 2018/19 evaluation concluded that further efforts are needed to ensure better comparability of data. If the national focal points would be further empowered by the revised mandate, it will be easier for them to get the necessary access to all relevant drug-related data and information. The national focal points would be in a position to ensure the implementation of the data quality standards.

Defining minimum requirements – and making sure that these are complied with (through the certification procedure) – would give assurance to the Agency and to the EU-level decision makers that the national focal points are able to comply with their tasks and obligations. Another impact on the European level would be the enhanced effectiveness and efficiency of translating and implementing key messages from the Agency, resulting in the national focal points acting as true intermediaries. Therefore, having strong national focal points in place adds value on EU-level.

International dimension

Further developing the role of the Agency in cooperation programmes, in particular as regards capacity building, would improve the outreach of the EU to third countries. One of the intentions of such programmes is to promote the EU's balanced, evidence-based, integrated and multi-disciplinary drugs policy in third countries.

The Agency does not have 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, a good understanding of the impacts of drug policies in third countries onto the EU is important. This would again improve the evidence base for EU drug policy-making.

The expert input of the Agency would not only benefit the EU's international partners, but the EU itself. It would contribute to the development and implementation of the external dimension of EU 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 impedes the Agency's performance and does not enable the EU to fully live up to the expectations and political commitments of increased cooperation between the Justice and Home Affairs agencies and priority third countries.

[104] See footnote 37.

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.

The reasons underpinning broadening the scope of action would be that addiction is an overarching health problem that should be addressed holistically; that the distinction between licit and illicit substances may to a certain extent be arbitrary; and that some Member States moved to broader addiction strategies in the preceding years.

The stakeholder consultation during the 2018/19 evaluation was inconclusive on the question whether the scope of action of the Agency should be broadened to other addictions. Whereas a majority of national stakeholders and Agency staff were largely in favour, other stakeholder groups (including EU-level stakeholders) were critical. Among those in favour of broadening the scope, alcohol was mentioned most frequently, while other substance-related addictions followed. There was less support to include behavioural addictions.[105]

Those Member States that apply at national level a broader addiction approach have an interest in the Agency broadening its scope to get access to the same quality data and analysis at EU level as they are accustomed to for drugs. They argue that broadening the scope of action would allow targeting risky behaviour instead of addiction to specific substances. Other Member States are more sceptical as they fear a weakening of the focus on drugs. They argue for a deepening of the efforts in the drug area, in view of the conclusions of recent reports that the drug phenomenon is worsening in the EU.[106]

The Agency has a well-functioning data collection system in place to collect standard data on drugs. Many surveys and data collection tools used on a national level to gather drug-related data already collect data on other substance-based addictions, in particular on alcohol and tobacco, even in Member States that do not apply a wider addiction approach. In addition, the Agency collects some data on other addictions through the European School Survey Project on Alcohol and Other Drugs (ESPAD).[107]

Monitoring the use of illicit substances is different from monitoring licit substances. Licit substances are subject to internal market rules. The harm and health consequences of alcohol or tobacco are well known and documented, whereas this is not always the case for drugs, especially for new synthetic drugs. When it comes to behavioural addictions, it could be difficult to draw the line between what should still be considered as being part of the scope of action and what should not be covered.

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105 For details see Annex 3 and Annex 4 of the final report of the evaluation (footnote 18). See also paragraph 25 of the European Parliament resolution of 17 December 2020 on the EU Security Union Strategy (2020/2791(RSP)), https://www.europarl.europa.eu/doceo/document/TA-9-2020-0378_EN.pdf.

106 Positions taken by Member States representatives in an informal workshop on the revision of the EMCDDA mandate on 26 October 2020 and previously during a discussion at the EMCDDA Management Board on the outcomes of the evaluation.

107 http://www.espad.org/.

Collecting certain data together and streamlining data collection will lead to economies of scale and cost efficiency. It would be relatively easy to extend some aspects of the current data collection system of the Agency to other substance-based addictions, in particular alcohol, tobacco and prescription medicines. There will be efficiency gains long-term from applying or adapting methodologies and indicators developed for drugs. Collecting data regarding addictive behaviours would be more difficult as it requires different methodologies and studies. In addition, behavioural addictions do not usually have a cross-border dimension and it could be questionable whether EU-level action would be appropriate.

Another question to be analysed is who would be best placed to collect such information.

On an international level, the UN Office on Drugs and Crime and the International Narcotic Control Board are already collecting some of the drug-related information, but their mandates do not go beyond illicit substances. Moreover, assigning the data collection to a UN body would reduce the focus on Europe, making available information less relevant for EU policy-making.

On a European level, both Eurostat and the Commission[108] collect some of the health-related data on substance-based addictions, however neither of them collects any drug-related data. The European Medicines Agency and the European Centre for Disease Prevention and Control do not specifically collect addiction-related data, but some of their data might be useful for a better understanding of addictions.

Analysing information across different addictions would help in getting a better understanding of the underlying commonalities of addictions. Based on its experience on drugs, the Agency could provide such services for other addictions. Comparability of data and sharing of best practices could be improved through the intervention of the Agency. This would help reaping synergies and help the EU and national policy-makers to have appropriate policy responses, applying a user-centric rather than a substance-centric perspective to addictions, and to better adapt to remaining differences. Therefore, it would be cost-efficient to increase the responsibilities of the Agency in areas, which fit closely with its current activities on drugs. Even going for the expansive option of broadening the mandate of the Agency to the monitoring of all addictions would be coherent with current EU policies as no other agency or the Commission are monitoring this across the EU. Some of these monitoring activities would interfere with national competencies (e.g. addictive behaviours, which do not have a cross-border dimension) and therefore could be problematic in terms of subsidiarity issues.

6.2. Impacts on national authorities

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

Targeting the thematic scope of action of the Agency holistically on the drug phenomena, including poly-substance use, and increasing the monitoring and threat assessment capabilities, would have similar impacts on national authorities as on the EU level. Missing information on latest developments means that national authorities are not able to react fast enough to new developments and threats. This reduces their preparedness. By looking into innovative health approaches, the Agency could provide drug services in the Member States with the latest available knowledge, which would ultimately benefit the drug users. Carrying out such research through the Agency would free capacities and resources in the Member

[108] For example the work of Directorate-General for Health and Food Safety on the facilitation of coordination and cooperation activities related to alcohol or the work of the European Medicines Agency regarding the pharmacovigilance of medications in the EU.

States. In addition, some developments, such as selling of drugs on the internet, do not fall under the responsibility of a single Member State as they are cross-border phenomena and therefore, by their nature, have to be addressed jointly.

When it comes to support of the Member States, national authorities can already use the available tools for the evaluation of their drugs policies.[109] However, further support is requested by the Member States for improving the effectiveness and quality of their drug policies and responses. When providing support, the Agency would have to take into account any national specificities.

Developing a competence centre in the Agency for policy and programme development and evaluation would alleviate a considerable burden from the Member States, leading to less demands and efforts on Member States' level. This is because it would allow them access to a major source of information and an independent third party's expert view. By working on national strategies, the Agency would – in return – gain additional expertise, which would benefit other Member States. As this would be a supporting function, which Member States can use, but which is not taking away any competencies from the Member States, there are no subsidiarity concerns to be addressed.

The Agency could be in charge of accreditation or certification of national prevention, treatment, harm reduction and other related interventions. The Agency – as a factual and objective expert – would be best placed to evaluate such interventions in view of their compliance with the latest scientific state of play and of their proven usefulness. Member States or relevant professional bodies could use the accreditation or certification as a quality label for their work. Alternatively, such accreditation or certification could remain with the Member States themselves, as far as such systems already exist. This option would necessitate more resources in the Member States as the centralisation effect would not apply and it would take away the neutral stance of the accreditation or certification.

Finally, the Agency could support Member States in the reporting to international organisations, in particular to the UN Office on Drugs and Crime (UNODC). This could contribute to reducing overlapping reporting obligations of the Member States to the Agency and UNODC. Data reporting is currently done for some data by different data providers and/or with different formats and/or based on different collection methodologies. Using the Agency as a coordination point for such reporting obligations, in particular in relation to the data the Agency is already collecting, would reduce the reporting burden on Member States.

A crucial element of the new monitoring system will be the laboratory capacities. An Agency-run laboratory will provide a platform for Member States' experts to exchange expertise and work on common projects. The main benefits for the Member States would be the availability of more information on drug markets and the reduction of costs. Cost reductions for the Member States would in particular derive from the fact that Member States would not need their own (full) laboratory capacities, whereas they would gain access to shared reference material and specialised equipment. Some of the analytical equipment needed is not readily available to authorities in the Member States as it can be prohibitively expensive. In other instances it may be available in certain research institutions, but with limited access by authorities. A centralised laboratory would free up capacities in existing Member State laboratories. The financial gains for Member States cannot be estimated, as the availability, size and capacity of laboratories differ considerably across Member States.

[109] "Evaluating drug policy: a seven-step guide to support the commissioning and managing of evaluations", www.emcdda.europa.eu/system/files/publications/4680/td0417390enn1.pdf, and the related website (www.emcdda.europa.eu/publications/topic-overviews/policy-evaluation).

Regarding the national focal points, in most Member States, they are hosted by a public authority or are a body mandated by the Member State to carry out the tasks provided for by the founding Regulation. In some Member States, the national focal points are well integrated into the national drug coordination system, whereas in others they are considered as mere European level data providers and lack visibility at national level, as the evaluation concluded. During the COVID-19 pandemic, some governments increased their recourse to the work and information available from the national focal points.[110]

A clearer definition of the tasks and responsibilities of the national focal point would benefit in particular the institution that is mandated as national focal point. It would allow the national focal point to become a central data hub and to access all the relevant data, so that it may provide a comprehensive overview on the national drug phenomenon to the Agency. It would clarify the workflows for all drug-related data in the Member States and strengthen the position of the national focal points in the national environment. If the national focal points could be recognised as a service provider not just for the Agency, but also for the national authorities, it would be of benefit to all Member States.

Establishing well-functioning and empowered national focal points is not solely about information. The innovative approaches, tools, trainings, etc. created by the collaboration with the Agency and within the Reitox network could be much better implemented on a national level, including with respect to follow-up and evaluation. Providing services creates new opportunities for data and information collections and hence a circle in which data provision and supporting services reinforce themselves. The sharing of best practices and the dissemination of information would be improved across Europe and as a consequence benefit the relevant authorities in the Member States.

In terms of impact on national authorities regarding the additional new tasks (i.e. early warning and alerts, prevention programmes and experience sharing, risk analysis and intelligence reports), the Agency's support to Member States could be in developing targeted national actions as messaging might be easier. The involvement of the Agency would ensure receiving input from a neutral EU-level organisation. The evidence-based approach provided by the Agency would lead to a more objective basis for developing interventions. The Agency would not take over any competencies here, but only support Member States.

When it comes to supply-side actions, the national authorities would be concerned as they would have to provide the relevant information to the Agency. Most of this information is provided only to Europol as part of operations. However, it might not always be accessible to the national focal points as there are no obligations to provide this information to them. The easiest way forward would be to streamline national data collection and clarify the data provision on the European level. In any case, it has to be ensured that these new responsibilities do not lead to a duplication of data provision efforts by national authorities. Finally, national law enforcement authorities would benefit from a stronger involvement of the Agency in drug-related cases. Having available well-informed risk analysis and intelligence reports is important for addressing drug-related criminality.

National authorities would not only benefit from streamlining of reporting obligations vis-à-vis UN organisations, but also from a better knowledge about global developments, which would have positive impacts on the development of their drug policies vis-à-vis third countries. It allows the national authorities to react quicker to potential threats coming from

[110] EMCDDA, EMCDDA national focal points' activities during the COVID-19 pandemic (2020); https://www.emcdda.europa.eu/system/files/publications/13442/NFPs_activities%20during%20C19_final.pdf.

outside the EU. An increased capacity of third countries to address their drug problems more effectively would benefit the Member States.

Policy option 5: Expansive revision – Focusing on diverse addictions

The main impact on national authorities in addition to what was outlined under the targeted revision, would be the need to provide additional data to the Agency. The majority of this data is already collected by the Member States based on EU legislation and/or because national strategies apply a wider addiction approach. If the scope of action of the Agency were extended to other addictions, the addressee of the data provided would have to change, e.g. from Eurostat or the Commission to the Agency.

6.3. Impacts on simplification and/or administrative burden

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

This option will have positive impacts on the administrative burden of national authorities as long as data provision regarding supply-side data is properly organised. Providing support to the Member States in addressing drug-related health and security threats would facilitate the work of the Member States as they would not have to do the analysis and development work.

Under this option, the availability of an improved monitoring system and better developed threat assessments would shift some of the analysis to the European level and therefore alleviate Member States' administrative burden. Centralising the analysis at the EU level would avoid duplication and lead to an overall simplification of procedures.

Strengthening the Agency's capacity to support Member States in the evaluation and shaping of national drug policies would add new tasks to the Agency's mandate, but would overall lead to a reduction of administrative burden in Member States. The same would be true if the Agency sets up a centralised accreditation or certification system for drug-related interventions. The centralisation of the reporting obligations to the UNODC, if this is made possible legally, would streamline reporting obligations and would reduce double reporting.

As regards a centralised laboratory on European level, it would enable streamlining the forensic and toxicological analysis across the EU. This would help reducing the burden on national laboratories, in particular as substances would only be analysed once instead of by several national laboratories. In addition, it would help streamlining administrative procedures for reporting of analytical results. However, having in place the laboratory of the Joint Research Centre (JRC), the potential for further simplification by establishing a laboratory in the Agency is limited. The high costs of a fully-fledged laboratory – and even of a reference laboratory – (see below) would be disproportionate to the added value these options would have.

The certification procedure for the compliance of the national focal points with the minimum requirements would be a new administrative task for the Agency. However, the additional burden would be limited as the Agency already has in place a voluntary process for national focal points to be certified. For the national focal points, it would require going through the certification procedure. This burden would be more relevant for those, which did so far not consider obtaining the voluntary certification. Adaptation to the new roles and responsibilities would represent an additional administrative burden during the implementation phase of the new legislation. However, this will lead to more streamlined and better organised data provision in the mid- and long-term and, therefore, the administrative burden would be overall reduced.

If the Agency would be able to support Member States in the reporting on international level, this could alleviate a separate reporting obligation from the Member States. Therefore, reinforcing the international dimension of the Agency would have a positive impact on reducing the administrative burden of national authorities.

Policy option 5: Expansive revision – Focusing on diverse addictions

Member States already collect most data on diverse addictions, and although more data would have to be provided to the Agency, the additional administrative burden for the Member States would be negligible. Centralising the data provision in one national entity and reporting to only one EU-level body would simplify national reporting procedures. However, this would only be feasible if clear data reporting obligations are set out in EU legislation and subsequently clear data flows are established in the Member States. As the Agency collects its data currently mainly through the Reitox network, the national focal points would have to be empowered to receive the relevant data from other competent national authorities. This centralisation would not only help the European data collection, it would also enable the Member States to get a better overview of the available information on addictions.

It has to be acknowledged that the benefits from streamlining reporting obligations will depend on how reporting is organised in the Member States. In some countries, the national focal points are already the main body involved in the collection of addiction-related data due to their integration in the responsible entity (e.g. ministry). In other countries, such obligations would lead to a need to reorganise data collection. Ultimately, the centralisation of data collection on addiction information would lead to cost-efficiency as duplications could be eliminated.

6.4. Economic impacts

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

While targeting the thematic scope of action on drug phenomena would have a minor direct economic effect, the main effect would be an increase of the resource needs of the Agency. The reduction of double reporting for the Member States would have a positive impact on the budgets of the reporting authorities.

The main direct economic impact would be on the EU budget as the Agency should receive a sufficient operational budget to develop or buy innovative monitoring tools, to develop the threat assessment capabilities and provide additional support to Member States. Sufficient IT resources would be needed. However, attributing these tasks to the Agency would lead to savings for the Member States as they could rely on the Agency to carry out the relevant monitoring activities.

Another main economic impact would be for a laboratory. Based on cautious estimations, establishing a fully-fledged laboratory would require approximately EUR 30 million. It would take between 5 and 7 years to reach its full capacity. Annual running costs would be around EUR 20 million. The setting up of a reference laboratory would take about 2-3 years to be fully operational, would cost approximately EUR 15-20 million to establish and have annual running costs of EUR 10-12 million. The costs for a "virtual laboratory" would be much lower and are estimated at around EUR 5-6 million a year, which would be needed for experienced staff, training, access to other laboratories and outsourcing of some of the work. However, to counterweight the high costs, a laboratory in the Agency would lead to a reduction of costs in the Member States as the relevant analyses would be done by the Agency.

The main economic impacts for developing the mandate of the national focal points further would be on the EU and national budgets. More tasks for the national focal points would mean that they need adequate resources. The national focal points are currently co-financed by the Agency with a fixed amount[111]. The Agency provides this amount to the national focal points from its budget as long as the respective Member State provides at least the same amount for the financing of the national focal point. The necessary resource increases could either come from the Member States themselves or the co-financing would have to be increased.

Policy option 5: Expansive revision – Focusing on diverse addictions

The main impact of extending the data collection would be on the resources needed for the collection of data, i.e. extension of the databases, increase of available staff to do the data processing and analysis, and an increased support to the national focal points to ensure that they have the capacity for providing this data. The move from one system to another might lead to an initial increase of administrative costs for some of the Member States. These should however be balanced out by the simplified procedures and the streamlined data collection system in the mid- to long-term.

Going beyond mere data collection and analysis to include other tasks currently undertaken for illicit substances, such as proposals for policy responses, development of specific intervention programmes, monitoring of treatment programmes, etc., would increase the resource needs. The resource needs will depend on what other addictions should be addressed by the Agency. Adding more than one substance to the scope of action would, however, not necessarily lead to a duplication or triplication of the costs.

Extending the mandate to comprehensive monitoring of other substance-based addictions or even all addictions (the maximum option for expanding the mandate) in relation to their health impacts is expected to come at a cost of between EUR 5 and 12 million per year depending on the width of the coverage. This is therefore excluded as an option, given the size of the cost in comparison to the overall budget of the Agency. The high additional costs would be due to the fact that new methodologies and systems would have to be established, in particular related to behavioural addictions.

Expanding the mandate to poly-substance use, and thereby addressing in a targeted way the main elements of other substance-based addictions, would come at an estimated cost of approximately EUR 1.5 million per year. If drug precursor monitoring would be fully covered by the Agency as well, e.g. following a revision of the drug precursor legislation, an additional EUR 1 million per year would be needed in the Agency. The costs for this expansion are relatively low as economies of scale could be applied in the Agency as many of the methodologies and responses applied to drugs are similar for other substance-based addictions and therefore this could be relatively easily integrated into the current routine reporting and monitoring.

7. HOW DO THE OPTIONS COMPARE?

This section compares the policy options for which the impacts are assessed in Section 6. The overall conclusion is that the **policy option 4: targeted revision** would be the best way forward to achieve the general objective of having in place an Agency, which would be appropriately equipped to deal with the current and future challenges posed by drugs in the EU, leading to efficient action and support for Member States. Both options contribute to the

[111] In the 2021 EMCDDA budget, this is a maximum of EUR 79 590 per year and national focal point.

achievement of more than one specific objective.[112] The tables comparing the options along the five specific objectives indicate the contribution to the achievement of these objectives from very positive (+++) to very negative (– – –).[113]

Unfortunately, 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.[114] Therefore, it is not possible to quantify the impact the evaluated options have on the Member States. These are therefore described only in qualitative terms.

7.1. Specific objective 1: To increase the Agency's capacity to react faster and in a more targeted way to new challenges in the field of drugs, harms and addictions, and related threats

The policy option, which would contribute to achieving this specific objective, are the following:

- Policy option 4: Targeted revision

Comparative assessment for specific objective 1		
	Policy option 4: Targeted revision	Policy option 5: Expansive revision
Impact on the EU (effectiveness)	+++	++
Impact on national authorities (effectiveness)	+++	++
Impact on simplification / administrative burden	+	–
Economic impacts (efficiency)	– –	– –

Further developing the current monitoring system and setting up appropriate threat assessment capabilities as well as improving the ability to react to the identified threats are key functions for increasing the EU's capacity to react faster and in a more targeted way to the challenges posed by the drug phenomenon. This would include the better coverage of the international issues. If these capabilities are given to the Agency, this would have to be accompanied by a strengthened role of the national focal points. Making available centralised European laboratory capacities would support the achievement of this specific objective.

Both policy options are coherent with existing EU policies or known policy initiatives. There are no other EU bodies, which carry out related actions. The assessment considered alternatives to the Agency, in particular Europol or the EU health bodies (the ECDC, EMA and HERA). The main reason why these are not better placed to provide the necessary

[112] See Annex 6 for an overview table.

[113] For the comparative assessment, the three main elements of policy option 4 are assessed separately as they may contribute differently to the specific objectives, in particular have very different economic impacts. This is not done for the other policy options as the impacts are not as diverging as for policy option 4.

[114] See footnote 89.

capabilities is that they would not be able to address the drug phenomenon in a holistic way. The focus would be either on security or on (public) health issues. In addition, those bodies have very particular and partly quite wide mandates, where the drug issue might be "lost" due to other priorities. Therefore, the Agency is best placed to develop the mentioned capabilities. Closer cooperation with these bodies would be beneficial as a complementary measure.

As regards the national level, the increased capacity of the Agency would benefit the preparedness in the Member States and, therefore, support their reactions to the developing drugs phenomenon. Due to the cross-border nature of the drug phenomenon, Member States need the support of an EU-level body, as they would not be able to do the necessary analysis in the same way due to missing data from other Member States. As the Agency is already working closely with Member States, through the Reitox network and through several working groups, it would be the best placed from that perspective.

The impact of the different policy options on the simplification and/or the administrative burden is overall positive. The main impact would come from the setting up of a laboratory in the Agency as this would help streamlining forensic and toxicological analysis across the EU and thereby reduce the related needs in the Member States. A similar impact could come from a new operational model for the national focal points as the streamlining of reporting obligations in the Member States could have a considerable positive impact. Streamlining the reporting obligations of the Member States and centralising them through the Agency would alleviate an important administrative burden from the Member States as it would reduce the double reporting of data. Supporting the Member States as regards prevention and awareness raising would lower the needs of Member States to be active in this area.

When it comes to the economic impact, the main impacts will be on the EU budget. As all options would lead to an increase in the activities of the Agency, further human and financial resources would be needed. The option, which would have the biggest impact on the EU budget, is the laboratory (see further in Section 7.2).

In order to achieve specific objective 1, EU-level legislation and action is needed. Member States might raise subsidiarity concerns when it comes to the role of the national focal points, and in particular to setting minimum requirements for their functioning, and as regards EU-level prevention and awareness raising campaigns or EU-level alerts. As regards the campaigns and alerts, these would be supporting actions for national level actions; however, if the relevant threat has a cross-border component, actions could be carried out on a European level. None of the options goes beyond what would be proportional for the achievement of the specific objective.

Setting out *minimum* requirements for the national focal points in EU legislation would provide them with more stability, making them less susceptible to political pressure and regular reorganisation. It would ensure a certain continuity and consistency in the functioning of the national focal points. However, the proposal does not intend to take over any functions from the Member States in this regard. Therefore, the measure is proportionate for the provision of high-quality data in the long-term. The certification of the compliance with the minimum criteria by the Agency is possible under the subsidiarity principle, or even necessary, to ensure a level-playing field across the EU

7.2. Specific objective 2: To deepen the monitoring and analysis of the drug phenomenon in Europe, both on the demand and supply side and their implications for health and security

The policy option, which would contribute to achieving this specific objective, is the following:

– Packaged policy option 4: Targeted revision

Comparative assessment for specific objective 2		
	Packaged policy option 4: Targeted revision	Packaged policy option 5: Expansive revision
Impact on the EU (effectiveness)	+++	+
Impact on national authorities (effectiveness)	+++	+
Impact on simplification / administrative burden	0	0
Economic impacts (efficiency)	+ to +++	–

Developing the current monitoring system, in particular in areas, which are new and innovative, is key if the EU wants to deepen the monitoring and analysis of the drug phenomenon. Making available centralised European laboratory capacities would strongly contribute to the development of a new and more modern monitoring system and would make the EU more independent in its forensic and toxicological analysis. However, this specific objective could not be achieved without a stronger position of and more data provided by the national focal points if the capabilities are developed in the Agency. Therefore, the data provision obligations need to be clarified.

Both policy options are coherent with existing EU policies or known policy initiatives. The Joint Research Centre (JRC) has laboratories, to which the Member States have access to and which are able to provide toxicological and forensic analysis of drugs, in particular new psychoactive substances. The Commission supports this. However, the JRC is not in a position to provide the necessary full laboratory services as detailed and resource-intensive investigations are needed for this work. Therefore, close cooperation with existing laboratories, in particular with the laboratory of the JRC, and existing networks, such as the European Network of Forensic Science Institutes, would have to be ensured.

Establishing laboratory capacities in the Agency would free up capacities on the national level and could support the national laboratories with reference material and provide access for them to specialised equipment, which are either expensive or not accessible easily. It would make the analysis data available to the Member States.

The impact of the different policy options on the simplification and/or the administrative burden is overall positive. The reasoning is the same as for specific objective 1 above.

When it comes to the economic impact, the main impacts will be on the EU budget. As all options lead to an increase in the activities of the Agency, further human and financial resources would be needed. The option, which has the biggest impact on the EU budget, is the

laboratory.[115] In order to have all relevant data available and become independent from third-country laboratories, a fully-fledged laboratory would be needed. A reference laboratory could be a good alternative option, but still comes with a high financial impact. The least expensive option is a virtual laboratory, as it does not necessitate the setting up of a physical laboratory in the Agency, but only staff with sufficient competence and experience. Although this would not achieve the independence of analysis within the EU, it provides for a good low-cost alternative to a "real" laboratory. Going for the maximum solution, a fully-fledged laboratory, would not be opportune in the current budgetary situation, even if it would have numerous benefits on a European level.

7.3. Specific objective 3: To clarify the mandate of the Agency as regards what substances, behaviours and responses should be covered

The policy options, which would contribute to achieving this specific objective, is the following:

- Packaged policy option 4: Targeted revision
- Packaged policy option 5: Expansive revision

Comparative assessment for specific objective 3		
	Packaged policy option 4: Targeted revision	Packaged policy option 5: Expansive revision
Impact on the EU (effectiveness)	+++	+++
Impact on national authorities (effectiveness)	+++	+++
Impact on simplification / administrative burden	+	+
Economic impacts (efficiency)	0	0

Clarifying the mandate of the Agency as regards the substances, behaviours and responses to be covered is necessary due to recent developments in several Member States, which moved to a wider addiction approach, and requests from stakeholders. Any changes in the mandate have to be mirrored in the mandate of the national focal points and appropriate data provision obligations.

Both policy options are coherent with existing EU policies or known policy initiatives.

Addressing substance-based addictions, i.e. alcohol, tobacco and prescription medicines, in their entirety might lead to overlaps with health-related legislation. Such data is collected and provided to Eurostat and/or the Commission, contrary to drug-policy data, which is solely provided to the Agency. On the other hand, the use of illicit and licit substances overlaps in three areas, where action might be useful in the context of poly-substance use. Firstly, poly-substance use leads to increased risks and public health impacts. Secondly, good practices and possible reactions to different addictions are similar and could be considered together. Thirdly, information and monitoring systems often tackle these addictions together as part of a holistic addiction approach.

[115] For the cost figures, see the economic impact section of policy option 4 (Section 6.2).

The main concern as regards behavioural addictions is on where to draw the line of what would be covered in a future-proof way (not too wide and not too restrictive). A wide coverage could lead to the scope of action becoming unmanageable for the Agency. In addition, as behavioural addictions only have limited cross-border risks, it might not be proportionate and in line with the subsidiarity principle to include behavioural addictions in a revised mandate.

In conclusion, addressing substance-based addictions as part of a more modern definition of poly-substance use appears to be the most appropriate option in view of coherence and proportionality considerations. Only those substances should be addressed in a new mandate for which the EU has competences. Data provision has to be addressed as the Agency would need additional data. In addition, it has to be ensured that this does not lead to duplication of data provision in the Member States. Some initial streamlining of data reporting flows might be needed in the Member States.

As several Member States already apply a broader addiction approach, they would benefit strongly from an increased involvement of the Agency in these areas. Other Member States, who still have a drugs-only policy, would also benefit from information regarding the links between different addictions. Therefore, clarifying the mandate as regards the substances to be covered would be beneficial on the national level.

The streamlining of reporting obligations across different addictions would have a positive impact in the mid- to long-term. Providing data to one entity only, which carries out the analysis in an integrated way, would lead to an overall reduction of administrative burden.

When it comes to the economic impact, the impact of packaged policy option 5 is expected to be neutral. On the one hand, adding the information collection and analysis regarding additional substances would lead to additional resources needs for the Agency. On the other hand, the streamlining of reporting obligations should lead to sufficient benefits to outweigh the additional costs, at least in the mid- to long-term. Moreover, the need for considerable additional resources in the Agency is a reason for not extending the mandate to all addictions.

7.4. Specific objective 4: To make the Agency more operational

The main policy options, which would contribute to achieving this specific objective, are the following:

- Packaged policy option 4: Targeted revision

Comparative assessment for specific objective 4		
	Packaged policy option 4: Targeted revision	Packaged policy option 5: Expansive revision
Impact on the EU (effectiveness)	+++	+
Impact on national authorities (effectiveness)	+++	+
Impact on simplification / administrative burden	0	0
Economic impacts (efficiency)	–	0

The Agency currently does not have any operational tasks. Empowering the Agency to take the necessary actions based on its monitoring and threat assessment would be a significant and important step for the Agency to respond in a more effective manner to the deteriorating drug situation in the EU. The basis for such work would be availability of all relevant information, which is why the mandate of the national focal points would have to mirror the decision taken at the EU level.

The new EU Drugs Strategy puts a stronger emphasis on prevention and security issues. Strengthening the Agency's capabilities as regards prevention campaigns, EU-level alerts and the provision of risk analysis and intelligence reports, and further develop its international work would be in line with the new Strategy. Both policy options are coherent with existing EU policies or known policy initiatives.

The Member States would benefit from the increased responsibilities of the Agency when it comes to the appropriate operational reactions to its monitoring and threat assessment work. As most of the threats regarding the supply dimension and deriving from dangerous substances are of cross-border nature, Member States are not able to address this appropriately on their own. As regards campaigns, Member States would be able to use the experience of the Agency and to learn from other experiences through the interaction in the Agency. This would overall lead to better informed campaigns. The proposed actions would not replace Member States actions, but complement them. Therefore, no subsidiarity concerns should emerge.

Neither policy options will have a major impact on the simplification and/or the administrative burden on European and national level. The new operational tasks would lead to a reduction of administrative burden in the Member States as they would have to put less work and efforts in these areas.

When it comes to the economic impact, the main impact will be on the EU budget. As all options would lead to an increase in the activities of the Agency, further human and financial resources for the Agency would be needed.

7.5. Specific objective 5: To provide support to Member States in shaping and evaluating their drugs policies

The main policy options, which would contribute to achieving this specific objective, are the following:

- Packaged policy option 4: Targeted revision

Comparative assessment for specific objective 5		
	Packaged policy option 4: Targeted revision	Packaged policy option 5: Expansive revision
Impact on the EU (effectiveness)	++	+
Impact on national authorities (effectiveness)	+++	++
Impact on simplification / administrative burden	0	0
Economic impacts	–	–

(efficiency)		

Providing more support to Member States on evaluation and shaping their drugs policies would be beneficial not only for the individual Member State but for the EU as a whole. It would enable the Member States to more efficiently deal with the challenges of the national drug phenomenon. On the other hand, with the Agency providing support, it would learn more about the national policies and could provide the learning from one Member State to another. It would lead to more information on national drug policies becoming available on a European level. The national focal points would need to be closely linked to this work as they would be one of the main sources for the Agency to understand the national context.

Both policy options are coherent with existing EU policies or known policy initiatives. There are no other EU bodies, which carry out the related actions or for which an extension of mandate is foreseen in this direction.

However, packaged policy option 4 has the biggest impact on the national level. If the Agency is mandated to provide support to Member States in the evaluation and the shaping of their national drug polices, it is evident that the national authorities will be the main beneficiaries of such a policy option.

This would lead to simplification and a reduction of the administrative burden in particular on the national level. On the contrary, not attributing the tasks to the Agency or attributing them only marginally would have a negative impact on national authorities as they would have to make sure on their own that drug-related interventions are in line with the scientific state of play.

When it comes to the economic impact, the main impact will be on the EU budget, due to limited extra requirements in terms of human and financial resources, whereas it would lead to cost savings on the national level.

Member States are evaluating and shaping their drug policies independently from each other. They might use the tools provided by the Agency, but no further development towards more support to the Member States would be possible without strengthening the Agency's mandate. There are no subsidiarity concerns as this policy option concerns a supporting competence and does not move any national responsibilities or competences to the EU level.

8. PREFERRED OPTION

8.1. Summary of the preferred option

Based on the impact assessment, the preferred option would be 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 other substance-based addictions when these substances are taken together with illicit drugs**, i.e. the revision is to provide a better definition of **poly-substance use**. This 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 phenomenon and an EU Drugs Agency has to be able to fully monitor 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 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 stronger **cooperation** with Member States and EU bodies, which is crucial, although would not deliver on its own on the objectives of this initiative.

- The **national focal points would be empowered to provide the relevant data** to the Agency. The revised founding 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.

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

8.2. Explanation of the preferred option

The future scope of action of the Agency would remain limited mainly to illicit drugs, but would address other substance-based addictions when these substances are taken together with illicit drugs. To that end, the new mandate should include a clearer and more modern definition of poly-substance use. The main factors for not fully including other substances or addictions in the mandate of the Agency are related to the need to have a clearly defined mandate, proportionality and cost considerations. The concept of poly-substance use should be integrated both in the data gathering on consumption of other addictive substances and in terms of policy responses into the reporting. A revised mandate should consider drug precursors in view of their impacts on drug markets and the potential efficiency gains if the analysis is done by the Agency.

The monitoring and threat assessment capabilities and the support functions for the Member States would be strengthened. The Agency is best placed to carry out these functions, as it would be an extension of current responsibilities. In addition, the Agency covers both pillars of the drug phenomenon already for many years, whereas the other options of EU bodies would lean either to the security or the health side. These capabilities would increase the impact of the Agency on the drug phenomenon and its ability to react to new challenges. Improving the monitoring capabilities would be the basis for any further work on threat assessment and providing support to the Member States.

The Agency would get the competence to act on its analysis and support the development of EU-level campaigns as well as provide alerts in case of specific threats being identified by the Agency.

As regards the laboratory capacities, the best option would be to set up a laboratory inside the Agency as it would allow for an independent EU-level analysis of illicit drugs. However, as the costs linked to the setting up and running of a laboratory are very high, the impact assessment opts for a more modest solution in the form of a virtual laboratory.

When it comes to the national focal points, the necessary adaptations to the new mandate of the Agency have to be implemented to mirror the changes in the Agency mandate. At the same time, minimum requirements for their set-up would be established to strengthen their position at national and European level. These minimum requirements would be certified by the Agency for each national focal point to ensure a level-playing field across Europe.

Finally, the international role of the Agency would be clarified in a revised mandate of the Agency. The Agency should not be restricted to EU-funded projects in third countries, but overall should develop the international dimension as part of its tasks, including through capacity-building projects.

Any of the policy options would not be able to address – on its own – the problems or problem drivers identified in this report. This combination of policy options contributes to better-informed policies, which in turn lead to better-informed actions and ultimately to stronger European (and national) responses to the developments of the drug phenomenon. This would be an important element on how to address the problems on the EU drug markets, both from a health as well as a security perspective. Stronger action and stronger cooperation is needed by all actors and a revised Agency would be central in these endeavours.

The preferred option adds considerable value at EU level, as it would allow for pooling resources in an EU-level agency instead of work being done in each Member State independently. Implementing the preferred option would avoid duplication of work in the Member States. In addition, several phenomena are cross-border and therefore no Member State could address them properly on its own.

All consulted stakeholders, in particular the European Parliament, the Member States and civil society, would support a strengthening of the Agency and the overall direction as proposed in the preferred option. The only element, which is expected to be subject to diverging opinions, is the scope of action of the Agency. Some Member States will argue for widening the Agency's scope of action further, whereas others will urge for caution and would prefer the Agency to remain focussed on illicit drugs only. The preferred option suggests a middle ground between these two positions.

8.3. Impacts of the preferred option on the EU budget

In 2014, the EU budget contribution and the number of staff in the authorised establishment plan[116] was reduced by approximately 5% and 10%, respectively, compared to the period before, in line with the overall request by the budget authorities to reduce EU staff. Since then, the EU contribution to the Agency budget remained stable with an annual contribution of approximately EUR 16 million[117], despite increased costs in line with the requirements of

[116] Information provided by the EMCDDA in January 2020 to the Commission in the context of the 2021 budgetary procedure.

[117] No changes in the authorised establishment plan, which provides for 76 authorised posts.

the EU Staff Regulation and a strengthened role of the Agency in the risk assessment procedure for new psychoactive substances.

The preferred option would require the reinforcement of the financial and human resources compared to the resources earmarked in the Multiannual Financial Framework (MFF) 2021-2027. The MFF 2021-2027 includes EUR 123.4 million (current prices) for the EU contribution to the EMCDDA over the whole MFF period, i.e. a 2% annual increase compared to the 2021 budget, and a stable number of authorised posts.

It is estimated that the preferred policy option would require an increase of the EU contribution to the Agency in the range of EUR 51 to 68 million over the period 2024-2027, with the coverage of poly-drug use issues representing approximatively EUR 7 million, supply and security issues representing EUR 16 million, enhanced threat assessment capacity representing EUR 10 million, the set up and functioning of a virtual laboratory representing approximately EUR 18 million, information campaigns and risk communication representing EUR 3.5 million, and the international dimension requiring EUR 5 million. Such an increase of the EU contribution would include an overall increase of staff of approximately 40 FTEs (full-time equivalents). The final proposal will be in this range and would correspond to the most cost-effective option.

Table 1: Additional appropriations needed for the revision of the Agency mandate based on the preferred option and attribution over the MFF period – EUR million

	2021	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**2021-2027**
EU contribution to EMCDDA MFF	16.6	16.9	17.3	17.6	18	18.3	18.7	**123.4**
Additional appropriations needed	*0*	*0*	*0*	**11-15**	**14-21**	**13-16**	**13-16**	**51-68**

Table 2: Estimated staff increase (projection) – Full-time equivalents

		2021	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**	**Projected variation 2021-2027**
Total staff – Based on Draft Budget 2021[118]		111	111	111	111	111	111	111	+0
Additional staff	**Variation**				**+14**	**+18**	**+5**	**+3**	**+ 40**

[118] All staff categories funded by EU contribution: temporary agents, contract agents, Seconded National Experts.

needed for revision[119]	Total staff				125	143	148	151	

The cost estimates presented in Annex 3 as well as the overall budget and number of posts are subject to budget availability. Any increase of the EU contribution to the Agency's budget resulting from a revision of the mandate would need to stay within the ceilings of Heading 5 of the MFF 2021-2027 and could be offset through a compensatory reduction from programmed spending under other Headings of the Union Budget.

By reducing the ambitions of the proposed initiative, the budget impacts could be lowered. This could be achieved by either not attributing a specific task to the Agency or by reducing the human and financial resources available for carrying out a specific task. In any case, the final proposal will not opt for the most expensive option, but will take into account the context of the MFF 2021-2027. Any of the options for securing the additional financial resources will remain within and compatible with the MFF 2021-2027. In addition, different possibilities for securing the necessary budget for the revision of the mandate are being considered ahead of making the proposal.

Depending on the outcome of the negotiations with DG Budget and the available resources, the ambition level of the proposed initiative will be modulated. This is why this impact assessment does not yet provide any concrete figures, but a range for the additionally needed appropriations. The estimated number for the staff increase is a minimum needed for the tasks considered under the preferred option. The new budget should allow for a re-balancing between the Agency's budget lines as currently the main weight is on Title 1 (staff costs), whereas only minor amounts are available for real operational tasks.[120]

In view of the considerable increase of the budget needs for the implementation of the preferred option, the revision should include the option for the Agency charging fees for certain services. Such services should be easily separable from the other services provided by the Agency. Examples could be the provision of targeted training and capacity building (on- and offline) or the accreditation and certification of certain interventions. Taking into account the limited resources dedicated to drugs policy in the Member States (as far as these figures are available), charging fees might have a prohibitive effect on using the services provided by the Agency. Therefore, a careful case-by-case assessment of the possible services, which could be subject to the payment of fees, would have to be carried out by the Agency together with the Commission. However, it would be premature to carry out such an assessment at this stage, as it is not clear whether the Agency would use this option. The assessment has to be done if and when the Agency decides in favour of this options. Fees are set – in line with the common approach for decentralised agencies – by the Commission.

8.4. Scope for simplification and burden reduction

The assessment of the impacts addressed the impacts on simplification and/or the administrative burden. Although the preferred option would lead to an increase in tasks and responsibilities of the Agency, overall, 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. The main contributing factor to this is the proposed streamlining and centralisation of reporting obligations in the Member States through the national focal points. This would lead, at least in the mid- to long-term, to a

[119] Temporary agents and limited number of Seconded National Experts.

[120] Title 3 of the Agency budget includes the amounts needed for the Reitox co-financing.

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 an argument for administrative simplification as no Member State could address those issues on their own and cooperating with numerous (neighbouring) countries would lead to a high administrative burden.

Unfortunately, it is not possible to quantify the burden reduction potential as concrete figures in this regard do not exist. 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.[121] This is an area where further research should be done, e.g. by the Agency.

9. HOW WILL ACTUAL IMPACTS BE MONITORED AND EVALUATED?

It will be essential that the implementation of the revised founding Regulation is closely monitored. New tasks will be added to the mandate of the Agency by the revision, while others will be clarified. The new functions will have to be closely assessed on a regular basis. Providing for a robust monitoring and evaluation mechanism is crucial to ensure that the envisaged beneficial effects of the revised founding Regulation materialise in practice.

The monitoring and evaluation of the revised mandate will largely be performed by the applicable mechanisms provided for in the founding Regulation. The founding Regulation includes the requirement on the Commission to initiate an evaluation every six years. A regular evaluation will be retained in the new regulation, but its periodicity will be adapted to the common approach for decentralised agencies. Therefore, an evaluation will take place in the future every five years. The next evaluation[122] will be too early to conclude already on the effects of the revision along the five better regulation requirements. However, that evaluation will be an opportunity to develop a robust baseline for future evaluations.

The Commission will monitor the performance of the Agency and the impacts introduced by the revision of the mandate through its participation in the Agency's bodies, i.e. in the Management Board, the Executive and Budget Committees and the Reitox network. The Agency is subject to the audit procedure of the annual accounts with the European Court of Auditors and the discharge procedure by the European Parliament. The Internal Audit Service is regularly undertaking audits of different aspects of the Agency's work.

In line with better regulation rules, the evaluation of the revised mandate will be based on a detailed programme for monitoring the outputs, results and impacts realised. The monitoring programme will set out the indicators and the intervals at which the necessary evidence will be collected. These indicators reflect and define the success of the policy options and will be measured on a yearly basis, based on the general report of activity of the Agency and the observations gained from the participation in the Agency's bodies. Overall success will be assessed as part of the first regular evaluation after the entry into force of the new mandate.

[121] See footnote 89.

[122] Based on the current founding Regulation, the next evaluation would take place in 2024.

The table below summarises tentative indicators[123] to monitor the achievement of specific objectives linked to the building blocks of the preferred policy option. It should be noted that some indicators contribute to measuring the achievement of more than one specific objective, but are only mentioned once.

Specific objective	Indicator
Specific objective 1: To increase the Agency's capacity to react faster and in a more targeted way to new challenges in the field of drugs, harms and addictions, and related threats	Number of general threat assessments carried out by the Agency Number of notifications to the EU early warning system
Specific objective 2: To deepen the monitoring and analysis of the drug phenomenon in Europe, both on the demand and supply side and their implications for health and security	New and innovative data collection methods developed and implemented Number of data sets collected through new and innovative data collection methods Virtual laboratory set up and involved in the regular work of the Agency
Specific objective 3: To clarify the mandate of the Agency as regards what substances, behaviours and responses should be covered	Number of additional standard data sets collected by the Agency on other addictions Number of publications which address addictions beyond illicit drugs in the context of poly-substance use Number of requests refused by the Agency going beyond its scope of action
Specific objective 4: To make the Agency more operational	Number of campaigns developed or their development supported Number of EU-level alerts issued Number of intelligence reports on supply-side issues provided to law enforcement authorities
Specific objective 5: To provide support to Member States in shaping and evaluating their drugs policies	Number of requests made by Member States Number of requests accepted by the Agency Number of accreditations/certifications of national intervention schemes

[123] It should be noted that these indicators do not include quantitative targets as they are dependent on external factors. In particular, they depend on the development of the overall drug phenomenon and future EU drug strategies. Success will have to be measures over time as for some indicators an upward trend and for others a downward trend on an annual basis would be considered successful. In some cases, zero would be a successful outcome as it would mean that sufficient information is available and intervention by the Agency was not needed (e.g. EU-level alerts).

OVERVIEW OF ANNEXES

Annex 1: Procedural information

Annex 2: Stakeholder consultation

Annex 3: Who is affected and how

Annex 4: Intervention logic of Regulation (EC) 1920/2006

Annex 5: Problem, drivers, objectives and options (intervention logic of the current initiative)

Annex 6: Schematic overview of the contribution of the policy options to the specific objectives

Annex 7: Relevant drug-related figures

ANNEX 1: PROCEDURAL INFORMATION

1. Lead DG, Decide planning/CWP references

Decide Planning	*Short title*	*Foreseen adoption*	*CWP Reference*
PLAN/2019/5417	Revision of the mandate of the European Monitoring Centre for Drugs and Drug Addiction	Q4 2021	---

2. Organisation and timing

Evaluation of the Agency

Article 23 of the founding Regulation provides for "*an external evaluation of the Centre every six years, to coincide with the completion of two of the Centre's three-year work programmes*". The fourth evaluation of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) was carried out in the period April to November 2018. The evaluation was conducted by a consortium lead by ICF Consulting Ltd., in collaboration with the Centre for the Study of Democracy (CSD) and Optimity Advisors. The final report on the evaluation was submitted to the Commission in the beginning of November 2018 and was published by the Commission.[124]

The Commission adopted a report about the evaluation, which was accompanied by a detailed Staff Working Document, in May 2019.[125] The report summarised the main results of the evaluation.

Inter-service Group (ISG)

- A new ISG, chaired by DG HOME, was set up in January 2020.
- The following Directorates-General (DGs) participated in the ISG: the Secretariat-General (SG), the Legal Service (LS), DG Human Resources (HR), DG Budget (BUDG), European Anti-Fraud Office (OLAF), DG Mobility and Transport (MOVE), DG Taxation and Customs Union (TAXUD), DG Internal Market, Entrepreneurship and SMEs (GROW), DG Research and Innovation (RTD), DG Health and Food Safety (SANTE), European Neighbourhood and Enlargement Negotiations (NEAR), International Partnerships (INTPA), Service for Foreign Policy Instruments (FPI), the Joint Research Centre (JRC); and the European External Action Service (EEAS).
- The ISG met for its first meeting on 12 February 2020. As a follow-up to this first meeting, the ISG had the opportunity to comment in writing on the inception impact assessment.

[124] See footnote 18.
[125] See footnote 19.

- Due to the restrictions imposed on face-to-face meetings by the measures taken to tackle the COVID-19-pandemic, the ISG was consulted in writing on Sections 1 to 5 of the draft impact assessment report between 15 and 24 June 2020. The comments received were taken into account and the structure of the report revised.

- The (virtual) ISG meeting held on 20 October 2020 discussed the complete draft impact assessment report (the minutes of the ISG meeting are included in the file submitted to the Regulatory Scrutiny Board). The comments received during the ISG meeting were taken into account in the final draft report.

- The revised draft of the impact assessment was sent to the ISG for written comments. The consultation took place from 15 to 19 February 2021. The comments received were taken into account.

3. Consultation of the Regulatory Scrutiny Board

The Regulatory Scrutiny Board received the draft version of the present impact assessment report on 18 November 2020. The draft impact assessment report was examined by the Regulatory Scrutiny Board on 16 December 2020.

The overall opinion of the Regulatory Scrutiny Board was negative.

In response, the Directorate-General for Migration and Home Affairs submitted a revised version of the draft impact assessment to the Regulatory Scrutiny Board on 14 April 2021 that addressed the comments made by the Regulatory Scrutiny Board in the following way:

Recommendations of the Regulatory Scrutiny Board	***Implementation of the recommendations into the revised impact assessment report***
Summary of findings	
(1) The report does not clearly demonstrate the problems that this initiative aims to tackle. It does not sufficiently differentiate between shortcomings of the current regulation and new drug challenges, for which the Agency could be part of the policy response. It does not provide an overall convincing and clear narrative that is coherent with the results of the preceding evaluation.	The revised impact assessment provides more contextual information throughout the document. It acknowledges that the current founding Regulation reached its overall objective and that the revision is a targeted one. It also provides the context within which the Agency works, i.e. the recent developments of the drug phenomenon, which are worrying. Strengthening the Agency and providing it with the necessary tools to help addressing the situation is one out of many measures to be taken to address the overall phenomenon. The explanations in the revised impact assessment have been streamlined to be clearer as regards their narrative.
(2) The presentation of policy options is overly complex and not sufficiently linked to the choices that policy makers should consider.	The revised impact assessment streamlined the policy options by combining several of the options and included options for the policy-makers, as regards other bodies to address the issues, clearer options where the only logical option is the

	Agency, etc.
(3) The report insufficiently assesses the added value and proportionality of some of the proposed measures. It is not specific enough about the options' simplification and cost reduction potential.	The revised impact assessment made an effort to provide more information on the added value and addressed proportionality issues further. However, we are not able to provide quantified data on the simplification and cost reduction potential of the different options as such data is not available (see the main body of the impact assessment, in particular Section 8.4.).
What to improve	
(1) The context section should better present the current mandate of the Agency. It should briefly explain its monitoring and data collection tasks, and their intended role in supporting EU and national anti-drugs policies.	The context section was updated to refer more to the issues requested by the Regulatory Scrutiny Board and less to the development of the Agency over time.
(2) Given the largely positive findings of the preceding evaluation, the report should be clearer on the evidence-base of the problem analysis. It should specify which problems stem from shortcomings of the current Regulation and which are the new issues that have emerged, for which new action by the Agency could be an element of the policy response. The problem analysis should clearly motivate the type and scale of agency changes that the options suggest. In doing so, the report should differentiate more clearly between the overall development of drugs challenges and the contribution the Agency could realistically make in tackling those.	DG HOME clarified already in the meeting of the Regulatory Scrutiny Board on 16 December 2020 that the revision is a targeted one. This was stated more clearly in the revised draft. Further information as regards the evidence-base for the evaluated options was included in the revised draft. This included a further differentiation between the shortcomings of the Regulation and the challenges stemming from the developments of the drug phenomenon. It was further clarified that the revision of the mandate would support addressing the challenges of the modern-day drug markets, without being *the* only element to address the drug challenges.
(3) The report should better explain the added value of the Agency compared to other data collection instances and bodies (national, EU and international). It should substantiate the need for extending the Agency's current mandate to develop threat assessment capacities, indicating the operational testing shortcomings across the EU. It should better argue the EU-added value of providing support to Member States. It should also substantiate the benefits of EU-level drug communication as	All elements addressed in this comment were further substantiated in the draft, by adding further explanations, despite the overall shortening of the text. When it comes to data collection, a comparison is not possible as the EMCDDA is the only body on EU-level collecting drug-related data. The only other bodies collecting similar data are UN-level bodies, such as the United Nationals Office for Drugs and Crime and the International Narcotic Control Board. However, their focus is much wider than Europe and specific European data

compared to more targeted communication at Member State, regional or local level.	would not be available anymore.
(4) The report should simplify the presentation of options and better link them to the main policy choices that policy makers should consider. It should present genuine alternatives for each of the key issues and assess and compare them more systematically. It should consider other combinations of (sub-) options under the preferred policy package, possibly differing in terms of ambition level, scope of action or budgetary implications.	The revised draft impact assessment packaged the different options into less, but clearer options. The main policy choices for policy-makers were better underlined and additional information included, as far as available.
(5) The report should further develop the REFIT dimension and the scope for simplification and cost reduction under the various options. As far as possible, it should provide quantitative estimates of foreseen cost reductions from centralising tasks (data collection, testing capacity, communication, etc.). It should specify for each task why the Agency would be more efficient in carrying it out than the Member States.	Further qualitative information was included into the revised impact assessment regarding the simplification potential of the various options. As explained in Section 8.4 of the revised draft, it is not possible to quantify the burden reduction potential as concrete figures in this regard do not exist. 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.
(6) The report should present a clearer and more convincing narrative. It should be shortened by avoiding repetitions and better focusing on the relevant information in the problem definition, options and impact sections.	The narrative was revised by shortening the text and in particular by taking into account the technical comments provided by the Regulatory Scrutiny Board ahead of the meeting. This lead to the streamlining of the text, deleting potential repetitions and focussing the text on the main elements.

Following the resubmission of the draft impact assessment, the Regulatory Scrutiny Board gave its positive opinion with reservations on 12 May 2021. The comments made by the Regulatory Scrutiny Board were addressed in the following way:

Recommendations of the Regulatory Scrutiny Board	***Implementation of the recommendations into the revised impact assessment report***
Summary of findings	
(1) The problem analysis does not sufficiently distinguish between the shortcomings of the Regulation and new challenges that may require a revision.	Further clarifications have been included in the text, in particular in Section 2, and the text was shortened.

(2) The intervention logic is not clearly set out.	The intervention logic is included in Annex 5, setting out the problem, the problem drivers, the general and specific objectives of the proposal as well as the policy options, which were analysed in the this impact assessment.
(3) The presentation of policy options is confusing and does not bring out clearly the available policy choices.	The text was further clarified.
(4) The report does not show the costs and benefits of individual options. It is unclear on how the preferred option aligns with the EU budget framework, and what the corresponding ambition level would be.	The benefits of the individual options, in particular as regards quantified benefits, cannot be provided as related data is not available. Therefore, the benefits were described in qualitative terms. The costs of the individual options are set out in Annex 3 and will be further detailed in the Legislative Financial Statement, which will accompany the proposal for a Regulation.
What to improve	
(1) The report should base the problem description more on the evaluation findings. It should distinguish between the shortcomings of the current Regulation and new challenges that may require a revision. It should also better differentiate between findings of the evaluation and other evidence gathered (e.g. through stakeholder consultations) that might change the evaluation's conclusions. The problem analysis should explain the current restrictions in the Agency's mandate relating to other substance-based addictions and polydrugs. It should discuss to what extent resource constraints have prevented extending the Agency's activities. It should also clarify the relationship and interaction with other data collection instances and European bodies to address potential overlaps. The problems 'insufficient support to Member States' and 'the need to develop EU-level prevention and awareness raising campaigns' should be substantiated with more robust evidence and critically assessed from a subsidiarity and EU added-value perspective.	Further clarifications have been included throughout the text to address the issues raised. This includes further information on the shortcomings of the current Regulation vis-à-vis the challenges of the modern-day drug phenomenon. However, as these are closely interlinked, the differentiation is not always possible. As regards data collection, please see the table above (first opinion), point 3; further information was included in the baseline (section 5.1).

(2) Based on a more coherent narrative, the report should present a clearer intervention logic. It should convincingly demonstrate how the options (and the measures contained therein) would deliver on the specific objectives and ultimately tackle the identified problem drivers. A clear visual presentation of the intervention logic should be included in the main text. Specific objectives should be expressed in more SMART terms, so that progress can be measured.	Further information was included in the impact assessment on the intervention logic. The visual presentation itself was left in the annex (Annex 5) due to the format of the intervention logic. The intervention logic should be read in conjunction with the intervention logic of the founding Regulation. It should be further developed by the first evaluation under the new Regulation, in particular as regards the SMART terms, as the final text of the Regulation depends on outcome of the legislative process (or even already by the last evaluation under the current founding Regulation, if this happens towards the end of the legislative process).
(3) The presentation of the policy options remains complex, confusing and geared towards the preferred option. On the one hand, some of the key options (e.g. scope of action, priority activity areas, new tasks) seem artificial and not really presenting alternatives. On the other hand, certain available choices (e.g. on scope, laboratory capacities, national focal points) are not clearly identified or sufficiently explained upfront. The report should therefore be revised to present genuine alternative options, possibly with different ambition levels (e.g. minimum, targeted or maximum revision), that could tackle either simultaneously all the identified problems (in case these are inter related) or by key problem area (in case these are independent). Following such a logic, the preferred option should be one of the options.	The text was further clarified to address the different ambition levels. The presentation of the policy options was restructured based on two ambition levels.
(4) The report should compare all options in terms of effectiveness, coherence and efficiency. This should allow to provide greater clarity on the (budgetary) costs and benefits of the alternative options, including those resulting from different implementation choices (e.g. expanding or merging the agency). In this context, it seems premature to discard a merger with another agency upfront, given the potential cost savings and overall	More information was added in relation to effectiveness, coherence and efficiency for all the policy options. A merger of the EMCDDA with another agency is – in line with the analysis in the impact assessment – not opportune. The recent developments of the drug phenomenon call for a stronger agency, not for a weakening of the situation, which would however happen in all the considered options for a merger. The potential cost savings would be minor as a

budgetary constraints.	merged agency would have to continue the majority of the tasks of the EMCDDA and would therefore need the related budget.
(5) The report should clarify how the preferred option is aligned with the EU multiannual financial framework 2021-2027 and be clear on what ambition level will be possible within this frame. It should further assess the potential of a charging fees option, by at least giving broad indications on potential costs and benefits and potential impact on the overall budget for this initiative.	This information will be presented – in line with the available templates – in the Legislative Financial Statement (LFS). The financial (and related human) resources are being discussed with DG Budget. The option of the Agency to charge fees for some of its tasks is merely an option at this stage, which should be enabled by a revised Regulation. It will be for the Agency to decide whether they will make use of this option in the future. Therefore, it would be premature to analyse this option in more detail in this impact assessment.
(6) The report should further develop the REFIT dimension by giving special consideration to simplification and burden reduction potential, quantifying it as far as possible.	See the table above (first opinion), point 3.
(7) The report should be further streamlined in order to have a more synthetic and focused presentation, bringing out a more convincing narrative. Relevant information should be presented where it belongs (e.g. description of options in the option section and not in the impact analysis). Annex 1 should provide a complete table indicating how all the suggestions of the Regulatory Scrutiny Board have been taken into account, including 'Box C – what to improve'.	The comments were fully taken into account when revising the impact assessment, including adding the comments from Box C of the first opinion in Annex 1 of the impact assessment.

4. Evidence, sources and quality

The main source of evidence was the outcome of the evaluation:

- Report from the Commission to the European Parliament and the Council, Evaluation of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) 2018, COM(2019) 228 final; and the accompanying Staff Working Document SWD(2019) 174 final.
- Evaluation of the EMCDDA – Final Report (https://op.europa.eu/en/publication-detail/-/publication/4eaca79c-72f6-11e9-9f05-01aa75ed71a1/language-en/format-PDF/source-search); Annex 3 (https://op.europa.eu/en/publication-detail/-/publication/598b184d-72f6-11e9-9f05-01aa75ed71a1/language-en/format-PDF/source-search) and Annexes 4 to 6 (https://op.europa.eu/en/publication-detail/-

/publication/604a15ae-72f6-11e9-9f05-01aa75ed71a1/language-en/format-PDF/source-search)

The previous evaluation of the EMCDDA in 2012 was used as background: https://op.europa.eu/en/publication-detail/-/publication/7d189e3b-f767-460b-b748-acf44d2daf9a/language-en/format-PDF/source-74343049.

The outcome of the final evaluation of the EU Drugs Strategy 2013-2020 and EU Action Plan on Drugs 2017-2020, SWD(2020) 150 final, https://ec.europa.eu/home-affairs/sites/homeaffairs/files/what-we-do/policies/european-agenda-security/20200724_swd-2020-150-commission-staff-working-document_en.pdf, has been taken into account.

Formal and informal stakeholder consultations as well as the feedback to the inception impact assessment: see Annex 2.

In addition, several publications of the Agency were used to provide information on the drug phenomenon, in particular

- The European Drug Report 2021; and
- The 3rd edition of the EU Drug Markets Report.

Other publications are quoted in the report as appropriate.

5. Limitations

The following limitations to the robustness of the impact assessment could be identified:

- Available data on national funding for drugs policy: as concluded in the final evaluation of the EU Drugs Strategy 2013-2020 and EU Action Plan on Drugs 2017-2020, very limited quantifiable data on spending on drugs policy is available at Member States level. This prevented the evaluation from making a sound assessment of the implementation costs for Member States brought by the Strategy. Furthermore, national financial estimates for the period of the 2017-2020 Action Plan are unavailable. Therefore, no quantifiable estimates on the benefits of the policy option on national level and the simplification and cost reduction potential could be made in this impact assessment. Recourse was made to a qualitative assessment.

- Data lag: The data referred to in the impact assessment is largely referring to 2018, only in limited cases to 2019, as there is a lag in the availability of data. This is linked to the way data is reported to and verified by the Agency.

- Intervention logic for Regulation (EC) 1920/2006: At the time of adoption of Regulation (EC) 1920/2006, no intervention logic was prepared. Therefore, the intervention logic used in this impact assessment is the one developed by the contractor for the 2018/19 evaluation of the Agency.

- Reduced possibility for informal outreach to stakeholders: Due to the COVID-19 pandemic, it was not possible to do as much outreach as originally planned. The meetings at the EMCDDA were cancelled as of mid-March 2020 and therefore no informal meetings in the margins could take place. The same is true for the Council's Horizontal Working Party on Drugs. This seriously limited additional (informal) exchanges for the preparation of the proposal, including for the impact assessment report.

ANNEX 2: STAKEHOLDER CONSULTATION

1. Main stakeholder groups

The main stakeholders of the Agency are:

- European-level and national policy-makers;
- Practitioners and professionals working in the drugs field; and
- Scientists and researchers.

2. Exception from the public consultation obligation

The main stakeholder consultation for this proposal was undertaken as part of the 2018/19 evaluation. This process included an extensive stakeholder consultation, including a 12-weeks public consultation. Details of this stakeholder consultation are available in Annex III of the Staff Working Document on the evaluation.[126] This 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.[127]

The public consultation as part of the external consultation received a limited number of contributions (147 in total), despite the considerable efforts by the Commission and even more by the Agency to advertise the public consultation. The low response rate was due probably to the rather technical nature of the issue, i.e. the evaluation of an agency with a very specific mandate. The technical nature of the evaluation was the reason why it was accepted that the public consultation questionnaire was translated from English only into five other EU languages and not into all official EU languages. It should be noted that almost half of the respondents were answering on behalf of organisations, the other half (55%) in their personal capacity. The latter group included inter alia members of the EMCDDA Scientific Committee and other people directly involved in the work of the Agency (despite answering on their own behalf, instead of on behalf of an organisation).

The public consultation for the evaluation contained some forward looking questions, in particular it asked questions about what other information would be usefully provided by the Agency, what other research domains should be addressed by the Agency to cover stakeholder needs, how the Agency could have greater impact, about future synergies with other agencies, and finally on how stakeholders see the future of the Agency within the evolving context of drugs policy. These questions were open-ended textual questions, which were mandatory to be completed. Despite the mandatory character of the questions, not all stakeholders had an opinion on these issues. Further information is available from the synopsis report, which was provided by the contractor (see Annex 5 of the final evaluation report).

The revision of the mandate of the EMCDDA was considered in internal discussions, including with the Secretariat-General, as consisting of rather "technical" changes[128], which

[126] See footnote 19.

[127] See footnote 17.

[128] The evaluation included in its conclusion recommendations for several such changes. Some of the changes need a revised legal framework to be implemented. For those actions, which can be addressed within the current mandate, the Agency developed an action plan to follow up on those recommendations (Doc EMCDDA/33/19; see point 5.3 of the minutes of the 60th Management Board meeting,

are very specific and public knowledge about the Agency itself is lacking (as most answers to the public consultation during the evaluation came from experts). In addition, a second public consultation on the same issues would be seen by many as a duplication of the previous one and therefore they would likely not participate again. Therefore, no further open public consultation was launched.

The main stakeholders, which will be directly concerned by the revision, would be the Member States and their national focal points due to higher reporting obligations. The other direct effects will be on the Agency itself. Other stakeholders would only be indirectly affected by having an Agency in place, which would be better equipped to deal with the future challenges posed by drugs in the EU.

Several discussions on the potential revision have taken place since the evaluation report was made available, e.g. discussion in the Management Board of the EMCDDA in December 2018 and June 2019, presentation to the Council's Horizontal Working Party on Drugs in July 2019, presentation to the heads of national focal points in their meeting in May 2019, etc. At all these occasions, the main conclusions of the evaluation were discussed.

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

More formal meetings were organised by DG HOME. 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 discussed at the plenary meeting of the Civil Society Forum on Drugs on 8 October 2020 (afternoon session). 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 meeting of the Heads of National Focal Points in November 2020.[129] 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 elements of the preferred option.

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

3. Inception Impact Assessment

The inception impact assessment was published for feedback on the Commission website for 8 weeks, i.e. from 4 June to 30 July 2020.[130]

Statistical information about the feedback received

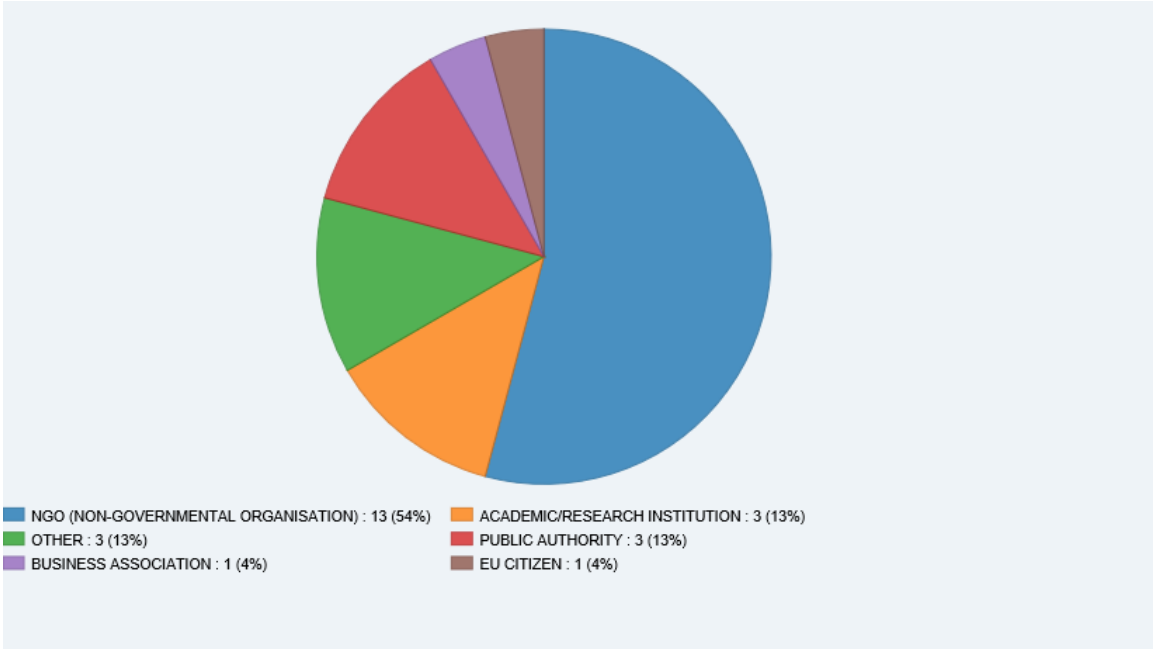
The publication of the inception impact assessment received 24 feedback responses. Non-governmental organisations submitted more than half of the answers (13 out of the 24 responses), with the other answers having been submitted by academic/research institutions (3), public authority (3), other (3), and one each from a member of the European Parliament (marked as submitted from a citizen) and from a business association. Europol forwarded an

https://www.emcdda.europa.eu/system/files/attachments/13078/EMCDDA_50_19_Final%20minutes%20MB%20meeting%2012-13%20December%202019_060320_COM_PT_signed%20uploaded.pdf).

129 As a follow-up to the meeting of the Heads of National Focal Points, the Reitox network submitted a position paper to the Commission.

130 https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/12432-Revision-of-the-mandate-of-the-European-Monitoring-Centre-for-Drugs-and-Drug-Addiction.

additional response, not recorded on the Commission website, from a national law enforcement agency.



20 out of 24 respondents accepted that their feedback is published with their personal information.

Eight out of 24 responses were submitted from Spain, four from Poland, three from Belgium, two from Romania, one each from France, Germany, Ireland, Mexico and US. In addition, two responses were submitted by international bodies/organisations.

Analysis of the feedback received

All respondents expressed general support to the work of the Agency and stressed the importance of the Agency being a neutral data provider. About half of the respondents (11) did not provide any input on the different policy options proposed in the inception impact assessment, but only provided a general statement of support for the work of the Agency.

The general comments focussed mainly on the direction the revision of the mandate should take. There was a strong voice for focussing the work of the Agency also in the future on health-related issues, harm reduction and related topics. Several respondents stressed the importance of the Agency to continue its data collection and monitoring tasks, being it for the issues they are already in charge or for an expanded mandate. This was linked in several cases to the request for additional resources for the Agency as a revision should not be to the detriment of the current (excellent) functioning of the Agency. Different suggestions were made as regards the issues to be addressed by the EMCDDA in the future. Drug supply issues were mentioned by several respondents as an area to work on, despite some mentioning that these are addressed already by other EU agencies (e.g. Europol). Overall, most respondents underlined the need for a balanced mandate. Several respondents suggested the widening of the scope of action to other (licit) substances and/or addictive behaviours. One respondent advocated the need to abandon the differentiation between illicit and licit substances.

From those making statements on the different policy options, six respondents provided very clear negative statements as regards policy options 2 and 3 (dismantle the Agency or merge with another agency). The main gist of the statements in this regard was that the dismantling

of the Agency would lead to a serious threat for and weakening of the European drug monitoring system as stakeholders heavily rely on the EMCDDA for data. One respondent stated that if a merger would be considered, it should be with the European Centre for Disease Prevention and Control as it has a health angle.

Those respondents (9), which addressed policy options 3 and 4, mentioned issues for the Agency to address in the future. These included *inter alia* new issues, including poly-substance use, internet trade in drugs, links to drug supply, research, precursors, role of the national focal points, international drug policy, and shaping and evaluation of national drug strategies. Respondents underlined the need to avoid overlaps and redundancies in case the mandate of the EMCDDA is expanded.

ANNEX 3: WHO IS AFFECTED AND HOW?[131]

1. Summary of benefits

The tables below summarise the costs and benefits for the **preferred option**. Given the limitations created by the lack of available data, the tables have been filled to the extent possible.

There is no quantified data available on the benefits of the different policy options (see the main text of the impact assessment report for explanations). Different benefits are included and explained in a qualitative way.

I. Overview of Benefits (total for all provisions) – Preferred Option		
Description	***Amount***	***Comments***
Direct and indirect benefits		
Better understanding of the drugs phenomenon in the EU	N/A	Updating the Agency mandate to equip it with the necessary means to deal with the current and future challenges posed by drugs in the EU would lead to a better understanding of the drugs phenomenon. If better information were available, it would be easier for the European and national level to react to developments. It would be easier to do so in a coordinated manner across borders, which is crucial as the drugs phenomenon was and increasingly is of cross-border nature, and would allow addressing new developments. Ultimately, the strengthened actions of the Agency would contribute to the health and security dimension of EU drugs policy.
Savings in administrative costs in the Member States	N/A	The streamlining of reporting obligations would lead to a reduction of administrative costs in the Member States, at least in the mid- to long-term. This has to be seen alongside the necessary increase of the EU contribution to the Agency. Unfortunately, due to a lack

[131] See Section 2.4., which describes who is affected and in what ways.

		of data, no quantified data is available on the possible savings in the Member States.
Drug demand and supply reduction	N/A	The ultimate goal of any revision of the Agency would be the contribution of its work to drug demand and supply reduction. The Agency cannot do this on its own, but the information it makes available leads to a better understanding of the drug phenomenon and availability of better intelligence. This is the evidence-base for EU drugs policy, which has as its strategic policy areas: drug supply reduction: enhancing security; drug demand reduction: prevention, treatment and care services; and addressing drug-related harms; underpinned by three cross-cutting themes in support of the policy areas (international cooperation; research, innovation and foresight; and coordination, governance and implementation).

2. Summary of costs

As regards the costs, no costs occur for citizens/consumers and businesses from the revision of the current initiative. The costs are on the administrations only and there mainly on the EU budget. Some costs might occur on national level. Such potential costs will be indicated in the table, however, without quantified cost estimates, as these are not available.

The cost estimates for the EU contribution to the Agency budget are based on the calculations provided by the EMCDDA, but have been verified by the Commission as regards them being in line with the actual operational needs of the preferred policy options. The estimates for staff costs have been calculated based on the current Commission average unit costs for human resources to which the correction coefficient for Portugal was applied.

The tables provide ranges for the different costs as the final costs depend on the choices made within the preferred policy option for the final proposal. The amounts are the additional costs needed over the period of the MFF 2021-2027. The cost estimates assume that the European Parliament and the Council adopt the new Regulation at the earliest in 2023, with implementation starting in 2024. The hiring of the majority of the new staff is spread over the initial two years in order to allow sufficient time for absorption. The annual amounts of recurrent costs refer to the financing needs once the Agency is fully up and running on the related tasks; therefore, the costs will be lower in the phase-in of the new mandate.

It is estimated that the preferred policy options would require an increase of the EU contribution to the Agency in the range of **EUR 51 to 68 million** over the period 2024-2027, including an overall increase of staff of approximately **40 FTEs** (full-time equivalents). These cost estimates are subject to budget availability. In any case, any increase of the EU contribution to Agency's budget resulting from a strengthening of the mandate would need to stay within the ceilings of Heading 5 of the MFF 2021-2027.

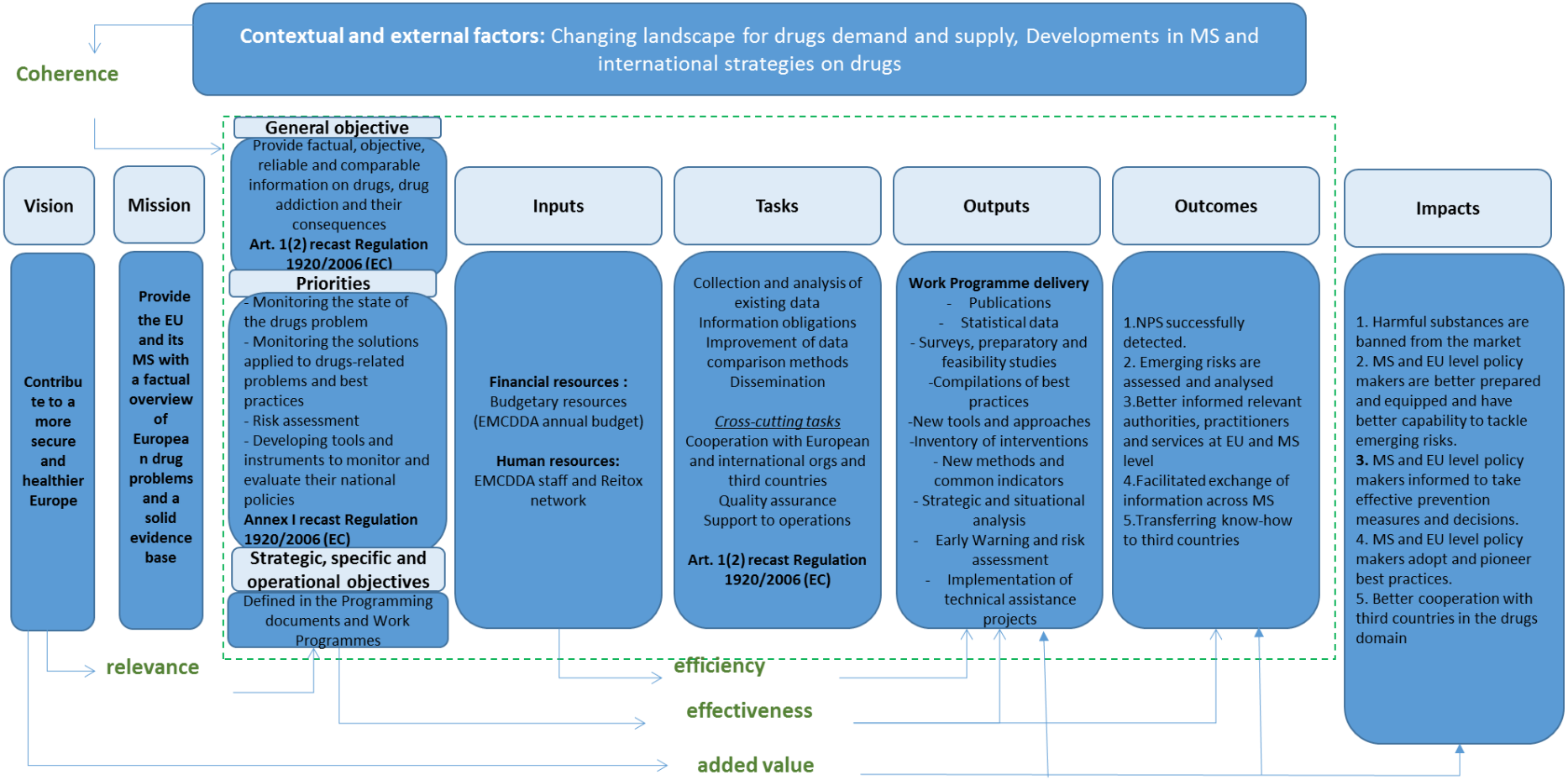
II. Overview of costs – Preferred option							
		Citizens/Consumers		Businesses		Administrations	
		One-off	Recurrent	One-off	Recurrent	One-off	Recurrent[132]
Thematic scope of action	Direct costs	N/A	N/A	N/A	N/A	Some IT-investments might be needed to extend the current data collection and monitoring system to other substances. However, these should not be major in view of the system already being in place and are integrated in the cost estimates of the recurrent costs.	*EU budget:* Approx. EUR 1.5 million/year (without drug precursors); with drug precursor monitoring, this would increase to about EUR 2.5 million/year (only in the final years of the MFF) → Overall impact on MFF 2021-2027: EUR 6-11 million *National budgets:* There might be some minor cost increases for Member States in case data for the substance-based addictions is not yet collected in the way needed. However, in the mid- to long-term the streamlining of reporting obligations will reduce these costs.
	Indirect costs	N/A	N/A	N/A	N/A	– – –	– – –
Monitoring	Direct costs	N/A	N/A	N/A	N/A	See above.	*EU budget:*

[132] The recurrent costs include staff costs.

system (except virtual laboratory) and support to Member States; national focal points							Approx. EUR 4.5-5.5 million/year → Overall impact on MFF 2021-2027: EUR 18-22 million If the co-financing of the national focal points would have to be increased, this would have an impact of up to EUR 2 million/year → Overall impact on MFF 2021-2027: EUR 7-9 million *National budgets:* No costs to be expected for the monitoring, threat assessments and support to Member States. However, strengthening the role of the national focal points will lead to an increase in their resource needs. It is up to the Member States on how much (additional) funds they will make available for the national focal points; therefore, the overall impact on national budgets cannot be calculated.
	Indirect costs	N/A	N/A	N/A	N/A	– – –	– – –
Virtual laboratory	Direct costs	N/A	N/A	N/A	N/A	As no physical laboratory is set up under the preferred option, no particular initial costs are needed, except for some	*EU budget:* Approx. EUR 4-5 million/year annual running costs; the staff ramp up will be longer than for the other tasks to ensure smooth budget

						possible IT investment.	absorption. → Overall impact on MFF 2021-2027: EUR 16-20 million *National budgets:* No costs to be expected
	Indirect costs	N/A	N/A	N/A	N/A	– – –	– – –
International dimension	Direct costs	N/A	N/A	N/A	N/A	No set-up costs to be expected.	*EU budget:* Approx. 1.5 million/year → Overall impact on MFF 2021-2027: EUR 4-6 million
	Indirect costs	N/A	N/A	N/A	N/A	– – –	– – –

ANNEX 4: INTERVENTION LOGIC OF REGULATION (EC) 1920/2006



Source: SWD(2019)174 final

ANNEX 5: PROBLEM, DRIVERS, OBJECTIVES AND OPTIONS (INTERVENTION LOGIC OF THE CURRENT INITIATIVE)

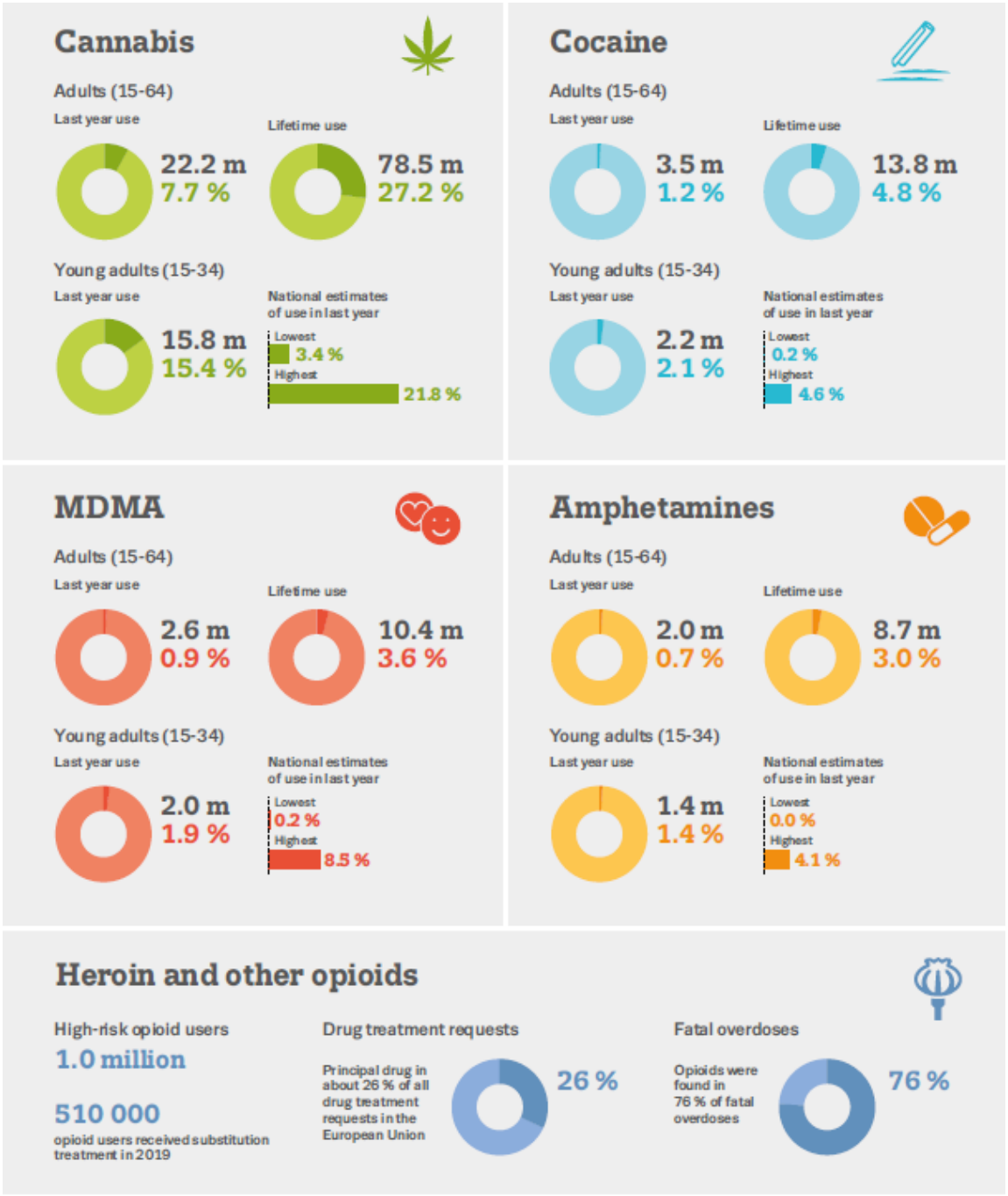
Problem	Problem drivers	General objective	Specific objectives	Policy options		Capacity to tackle the problem drivers
				Non-legislative	Legislative	
Complexity of new drug phenomena lead to a disconnect with the existing Agency mandate Inadequate responses to new drug market challenges The Reitox network is not used to its full potential Insufficient support to Member States The international dimension of the Agency is insufficiently defined	The mandate of the Agency has not been adapted to the changes of the drugs phenomenon Multi-jurisdictional challenges due to new security threats Evolving national policies lead to changing priorities Recent developments in international drug policy	To have an Agency, which is appropriately equipped to deal with the current and future challenges posed by drugs in the EU, leading to efficient action and support for Member States.	To increase the Agency's capacity to react faster and in a more targeted way to new challenges in the field of drugs, harms and addictions, and related threats; To deepen the monitoring and analysis of the drug phenomenon in Europe, both on the demand and supply side and their implications for health and security; To clarify the mandate of the Agency as regards what substances, behaviours and responses should be covered; To make the Agency more operational; and To provide support to Member States in shaping and evaluating their drugs policies.	Option 0: Baseline scenario: Maintaining the current approach without changes Option 1: Non-legislative & minimal revision option: Stronger cooperation	Option 2: Dismantling of the Agency: Repeal of the founding Regulation Option 3: Merging of the Agency with another EU body Option 4: Targeted revision – Delivering more value in drugs policy Option 5: Expansive revision – Focusing on diverse addictions	Option 0 would not achieve any of the specific objectives. Option 1 would achieve some of the specific objectives but would only to a very limited extent be able to address the problem drivers. Option 2 would not achieve any of the specific objectives and would seriously undermine EU drug policies. Option 3 would not achieve any of the specific objectives. Option 4 would achieve all specific objectives with a reasonable additional cost. Option 5 would achieve all specific objectives but at high additional costs.

ANNEX 6: SCHEMATIC OVERVIEW OF THE CONTRIBUTION OF THE POLICY OPTIONS TO THE SPECIFIC OBJECTIVES

	Specific objective 1: To increase the Agency's capacity to react faster and in a more targeted way to new challenges in the field of drugs, harms and addictions, and related threats	Specific objective 2: To deepen the monitoring and analysis of the drug phenomenon in Europe, both on the demand and supply side and their implications for health and security	Specific objective 3: To clarify the mandate of the Agency as regards what substances, behaviours and responses should be covered	Specific objective 4: To make the Agency more operational	Specific objective 5: To provide support to Member States in shaping and evaluating their drugs policies
Policy option 4: **Targeted revision**	X	X	X	X	X
Policy option 5: **Expansive revision**	X		X		X

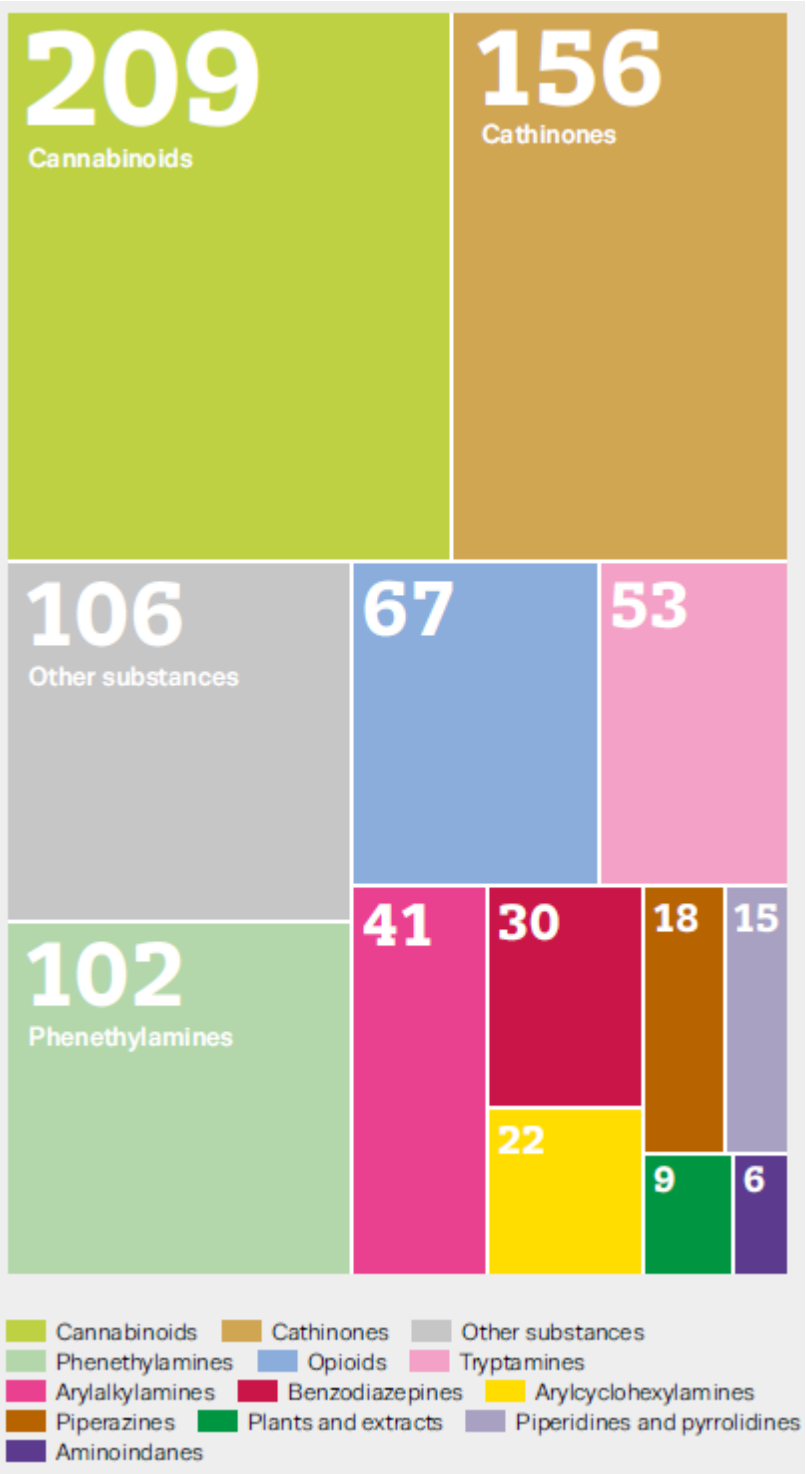
ANNEX 7: RELEVANT DRUG-RELATED FIGURES

Figure 1: Estimates of drug use in Europe



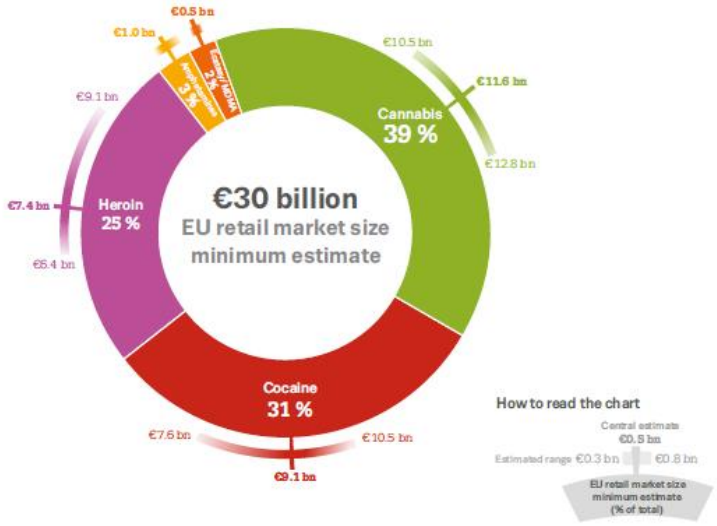
Source: European Drug Report 2021, p. 13.

Figure 2: Number of substances monitored by the EU Early Warning System by category



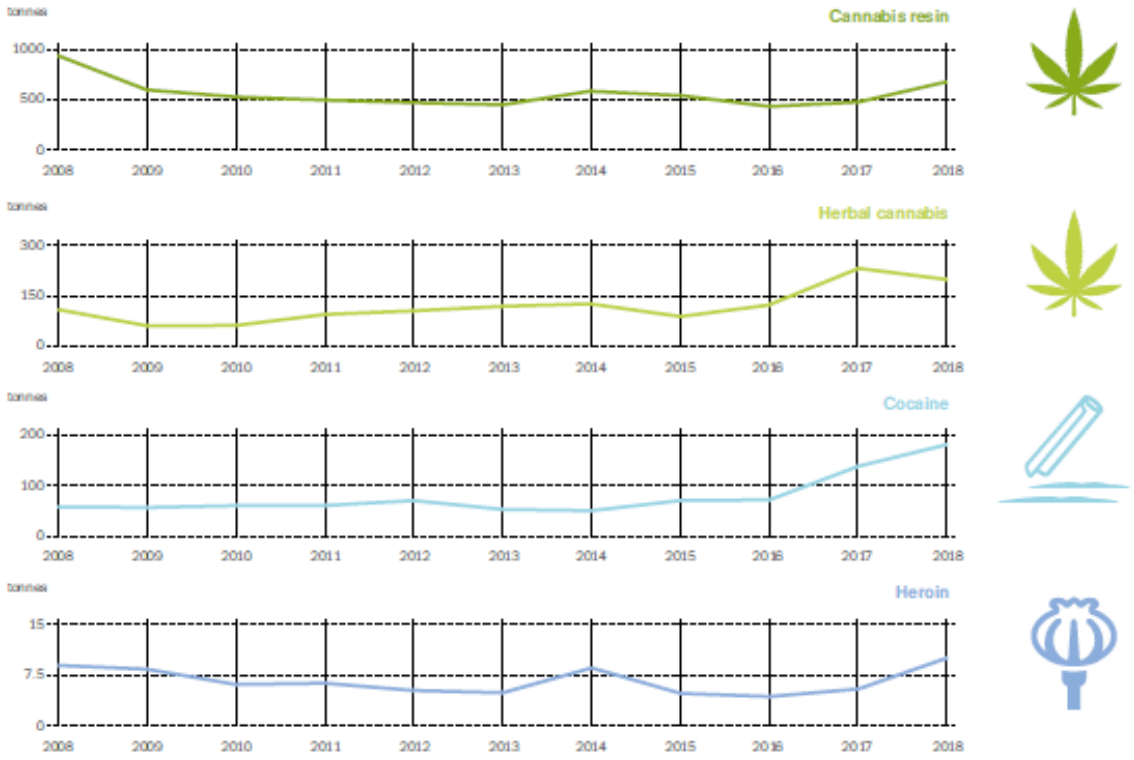
Source: European Drug Report 2021, p. 27.

Figure 3: Estimated retail value of the illicit market for the main drugs in the EU



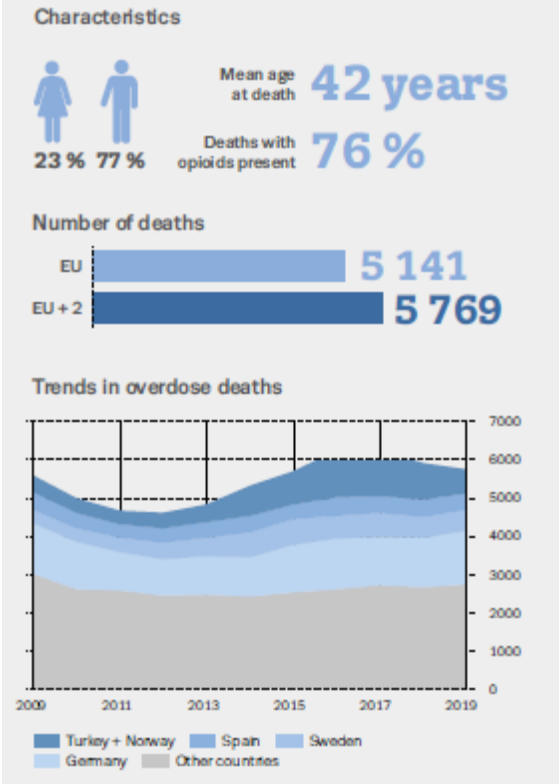
Source: EU Drug Markets Report 2019, Figure 1.1, p. 29.

Figure 4: Trends in quantities of cannabis, cocaine and heroin in the European Union



Source: European Drug Report 2020 – Key issues, Figure 2, p. 9, https://www.emcdda.europa.eu/edr2020.

Figure 5: Drug-induced deaths



Source: European Drug Report 2021, p. 41.