Procedure file

Basic information

COD - Ordinary legislative procedure (ex-codecision procedure) Regulation	2022/0009(COD)
European Union Drugs Agency Subject 4.20.03 Drug addiction, alcoholism, smoking 7.30.30.04 Action to combat drugs and drug-trafficking 8.40.08 Agencies and bodies of the EU Legislative priorities Joint Declaration 2023-24	Procedure completed

Key players

European Parliament

Committee responsible	Rapporteur	Appointed
LIBE Civil Liberties, Justice and Home Affairs	S&D SANTOS Isabel Shadow rapporteur epp ZDECHOVSKÝ Tomáš renew europe. STRUGARIU Ramona FRANZ Romeo ECR KANKO Assita VANDENDRIESSCHE Tom ARVANITIS Konstantinos	20/04/2022
Committee for opinion	**Rapporteur for opinion**	**Appointed**
BUDG Budgets	epp HERBST Niclas	01/02/2022
ENVI Environment, Public Health and Food Safety	The committee decided not to give an opinion.	

Council of the European Union

European Commission

Commission DG	Commissioner

European Economic and Social Committee European Committee of the Regions	Migration and Home Affairs	JOHANSSON Ylva

Key events

12/01/2022	Legislative proposal published	COM(2022)0018	Summary
07/03/2022	Committee referral announced in Parliament, 1st reading		
01/12/2022	Vote in committee, 1st reading		
01/12/2022	Committee decision to open interinstitutional negotiations with report adopted in committee		
07/12/2022	Committee report tabled for plenary, 1st reading	A9-0289/2022	Summary
12/12/2022	Committee decision to enter into interinstitutional negotiations announced in plenary (Rule 71)		
14/12/2022	Committee decision to enter into interinstitutional negotiations confirmed by plenary (Rule 71)		
26/04/2023	Approval in committee of the text agreed at 1st reading interinstitutional negotiations	PE746.996 GEDA/A/(2023)002927	
12/06/2023	Debate in Parliament		
13/06/2023	Results of vote in Parliament		
13/06/2023	Decision by Parliament, 1st reading	T9-0226/2023	Summary
27/06/2023	Act adopted by Council after Parliament's 1st reading		
27/06/2023	Final act signed		
30/06/2023	Final act published in Official Journal		

Technical information

Procedure reference	2022/0009(COD)
Procedure type	COD - Ordinary legislative procedure (ex-codecision procedure)
Procedure subtype	Legislation
Legislative instrument	Regulation
Legal basis	Treaty on the Functioning of the EU TFEU 168-p5
Other legal basis	Rules of Procedure EP 165
Mandatory consultation of other institutions	European Economic and Social Committee European Committee of the Regions
Stage reached in procedure	Procedure completed
Committee dossier	LIBE/9/08091

Documentation gateway

Legislative proposal		COM(2022)0018	12/01/2022	EC	Summary
Document attached to the procedure		SEC(2022)0045	12/01/2022	EC	
Document attached to the procedure		SWD(2022)0008	12/01/2022	EC	
Document attached to the procedure		SWD(2022)0009	12/01/2022	EC	
Economic and Social Committee: opinion, report		CES0917/2022	18/05/2022	ESC	
Committee draft report		PE735.504	18/07/2022	EP	
Committee opinion	BUDG	PE732.800	01/09/2022	EP	
Amendments tabled in committee		PE736.535	20/09/2022	EP	
Committee report tabled for plenary, 1st reading/single reading		A9-0289/2022	07/12/2022	EP	Summary
Coreper letter confirming interinstitutional agreement		GEDA/A/(2023)002927	19/04/2023	CSL	
Text agreed during interinstitutional negotiations		PE746.996	19/04/2023	EP	
Text adopted by Parliament, 1st reading/single reading		T9-0226/2023	13/06/2023	EP	Summary
Draft final act		00016/2023/LEX	27/06/2023	CSL	
Commission response to text adopted in plenary		SP(2023)357	29/08/2023	EC	

Final act

Regulation 2023/1322
OJ L 166 30.06.2023, p. 0006 Summary

European Union Drugs Agency

PURPOSE: to strengthen the current mandate of the European Monitoring Centre for Drugs and Drug Addiction, transforming it into the European Union Drugs Agency.

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: the European Monitoring Centre for Drugs and Drug Addiction was set up by Council Regulation (EEC) No 302/93. This founding act was recast in 2006 through Regulation (EC) No 1920/2006 of the European Parliament and of the Council. However, this recast Regulation does not reflect the current reality of the drug phenomenon and is out of step with the tasks the Centre needs to perform to address the current and future challenges of the drug phenomenon.

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

Adopting a targeted revision of the Agencys mandate is part of the reaction of the EU to these developments.

CONTENT: the Commission proposes to strengthen the mandate of the European Monitoring Centre for Drugs and Drug Addiction and ensure that the future Agency can react effectively to new challenges, provide better support to Member States, and contribute to developments at the international level.

Establishment of the Agency

The proposal establishes the European Union Drugs Agency (EUDA) which will replace and succeed the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA). The new Agencys mandate should cover drug markets and drug supply issues which are necessary to understand the impacts of the drug phenomenon on public health, reduce the availability of drugs in the Union and curb drug demand.

Wider coverage of poly-drug use issues

The Agency should also expressly address poly-substance, i.e. other substance-based addictions when those substances are taken together with drugs by developing monitoring systems that would consider, instead of focusing only on one substance, heroin for example, the important role played by concurrent or sequential use of other substances as well, such as non-controlled opioids or misused medications.

Drug alert system

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

Virtual laboratory

The new mandate seeks to establish a network of forensic and toxicological laboratories, bringing together national laboratories. The network will foster information exchange on new developments and trends and will support the training of forensic drug experts.

Threat assessment capabilities

The proposal sets out the possibility for the Agency to develop threat assessments on new developments of the drug phenomenon that have a potential to impact negatively public health, safety and security. These threat assessments will help increase the preparedness of the EU to react to new threats and support other tasks of the Agency.

Information campaigns and supply and security issues

The Agency should be able to act on its analysis and develop EU-level prevention and awareness raising campaigns relating to illicit drugs, allowing the agency to act on the basis of the analysis it produces. The agency will also be able to support Member States in preparing national campaigns.

Moreover, the proposal aims to expand the Agencys mandate to also explicitly address drug supply and drug market issues. It seeks to improve the analysis of drug supply in the EU based on better information on drug trafficking and production, thereby contributing to more effective law enforcement and supporting the internal security of the EU. In addition, improved access to best practices in the area of drug demand and other public health responses will be made to beneficiaries of the Agencys services. Moreover, the Agency will make relevant contribution to actions in support of the mental health policies in Member States.

Research and innovation

The proposal provides a mandate to the Agency to be more active in the context of the EU research knowledge cycle. This should also include the Agencys involvement in the EU Innovation Hub for Internal Security.

International dimension

Under the new mandate, the Agencys role at international level is strengthened. Despite its international recognition as a centre of excellence and its active engagement on international issues, the founding Regulation does not define sufficiently the responsibilities of the Agency in this area. Therefore, the proposal aims to clarify the tasks of the Agency as regards the international dimension, to include in the mandate itself the necessary competencies.

Budgetary implications

This proposal would have an impact on the budget and staff needs of the Agency. It is estimated that an additional budget of around EUR 63 million and around 40 additional posts would be needed for the remainder of the period of the MFF to ensure that the Agency has the necessary resources to enforce its revised mandate.

European Union Drugs Agency

The Committee on Civil Liberties, Justice and Home Affairs adopted the report by Isabel SANTOS (S&D, PT) on the proposal for a regulation of the European Parliament and of the Council on the European Union Drugs Agency.

The committee responsible recommended that the European Parliament's position adopted at first reading under the ordinary legislative procedure should amend the proposal as follows:

As a reminder, the proposal seeks to replace and succeed the European Monitoring Centre for Drugs and Drug Addiction by transforming it into the European Union Drugs Agency (EUDA). This new Agency should react effectively to new challenges, provide better support to Member States, and contribute to developments at the international level. The new Agencys reinforced mandate should cover drug markets and drug supply issues which are necessary to understand the impacts of the drug phenomenon on public health, reduce the availability of drugs in the Union and curb drug demand.

Monitoring of the drug phenomenon and sharing of best practices

The report stressed that the Agency should monitor, inter alia, the following areas:

- the drugs phenomenon in the Union holistically, through epidemiological and other indicators, covering the public health, social and human rights, social reintegration, safety and security aspects;

- evidence-based best practices and innovative approaches to respond to the public health, social and human rights, safety and security aspects of the drugs phenomenon in the participating countries;

- emerging trends in the Union and internationally with respect to drug use, drug use disorders, drug addictions and related health risks and harm in so far as they impact the participating countries;

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

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

Health and security threat assessment and preparedness

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

Administrative and management structure

In the interests of transparency, Members called on the members of the Agencys administrative and management structure to avoid having any financial or other interests that could affect their impartiality. They should act in the public interest and carry out their activities in an independent, impartial and transparent manner, and make an annual declaration of their financial interests. All indirect interests which could affect their impartiality, including in the pharmaceutical industry, should be entered in a register that is held by the Agency and is accessible to the public upon request.

National focal points

The national focal points tasks have been extended. They should monitor, analyse and interpret relevant information in the relevant fields and should provide information on the policies and solutions adopted. They should consider the gender-sensitive aspects of drugs policy when collecting and presenting data.

Budget

The committee called for the Agency's budget to be balanced in terms of revenue and of expenditure. The Agency should be awarded an adequate budget to ensure sufficient staff and equipment in order to allow it to achieve the objectives and tasks set out in this Regulation. The Agency's revenue should also comprise Union funding under indirect management or in the form of ad hoc grants.

The amount and origin of any revenue should be included in the annual accounts of the Agency and clearly detailed in the annual report on the Agency's budgetary and financial management.

Fees

At the proposal of the Executive Director, the Management Board of the Agency should set the amount of the fees and the way in which they are paid in a transparent manner and after having consulted the Commission. Those fees shall cover only the human and financial costs associated with the provision of certain training programmes and the certification of national bodies set up in third countries, in particular candidate countries.

Members proposed for an annual external audit to be undertaken with regard to the fees collected by the Agency. The Agency should transmit the results of such audits to the European Parliament without delay.

Cooperation with civil society organisations

The report called for increased comprehensive involvement with civil society. Structured cooperation should be maintained with both relevant non-governmental and civil society organisations. The Agency should appoint a person within the Agency responsible for managing that cooperation, under the authority of the Executive Director. The names and the declared conflict of interests of stakeholders involved in its work on its website should be published according to Members.

European Union Drugs Agency

The European Parliament adopted by 592 votes to 12, with 23 abstentions, a legislative resolution on the proposal for a Regulation of the European Parliament and of the Council on the European Union Drugs Agency.

The European Parliament's position adopted at first reading under the ordinary legislative procedure amends the Commission proposal as follows:

General task of the Agency

In order to provide evidence-based, objective, reliable, comparable and meaningful data and assessment at EU level, the Agency will address the drugs phenomenon through an evidence-based, integrated, balanced and multidisciplinary approach to drugs, drug use, drug-related disorders and dependencies, prevention, treatment, care, harm reduction, rehabilitation, social reintegration and recovery, drug markets and supply, including illicit production and trafficking, and other relevant drug-related issues and their consequences.

The Agency's approach should integrate human rights, gender and gender equality, age, health, health equity and social perspectives.

Monitoring of the drugs phenomenon and sharing of best practices

According to the text, the Agency will monitor:

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

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

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

- poly-substance use and its consequences, in particular the increased risks of health and social problems, the social determinants of drug

use, drug use disorders and addictions, and the implications for policies and responses;

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

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

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

European drug alert system

The Agency will set up and manage a rapid European drug alert system, complementing and without prejudice to the relevant national alert systems. The European drug alert system will be complementary to the early warning system. The national focal points, in cooperation with the relevant national competent authorities, will immediately notify the Agency of any information relating to the appearance of a serious direct or indirect drug-related risk to health, social aspects, safety or security.

Administrative and management structure

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

The Management Board will include two independent experts appointed by the European Parliament. The Management Board will appoint the Executive Director on the basis of a list of at least three candidates proposed by the Commission in an open and transparent selection procedure.

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

National focal points

The national focal points must be scientifically independent and ensure the quality of their data. They will plan their activities and have sufficient budgetary and human resources allocated from national budgets and co-financed by the Agency to fulfil their mandate and sufficient equipment and facilities to carry out their day-to-day activities.

The National Focal Points provide the interface and facilitate interaction between the participating countries and the Agency. They will, inter alia, (i) contribute to the monitoring and reporting of drugs and drug use, including to international organisations; (ii) contribute to the exchange of information on new psychoactive substances and to the early warning system on them. The Agency will assess whether each National Focal Point, in carrying out its tasks, assists the Agency in fulfilling its missions.

Additional services

In order to further support Member States and other stakeholders in understanding and addressing the drugs phenomenon, the amended text introduces the possibility for the Agency to deliver additional services, beyond its core tasks laid down in this Regulation, against the payment of fees should be introduced. The method by which fees levied by the Agency are calculated will be transparent.

Lastly, the Agency will have to cooperate at international level with the competent authorities and bodies of third countries, in particular the candidate countries, and in support of the action of the Union and the Member States at United Nations level. This cooperation must comply with human rights standards.

European Union Drugs Agency

PURPOSE: to establish an agency to combat the drugs phenomenon, the European Union Drugs Agency (EUDA).

LEGISLATIVE ACT: Regulation (EU) 2023/1322 of the European Parliament and of the Council on the European Union Drugs Agency (EUDA) and repealing Regulation (EC) No 1920/2006.

CONTENT: the regulation establishes the European Union Drugs Agency (EUDA). The Agency replaces and succeeds the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) created in 1993.

The Agency will play a key role in the EU's response to the new health and safety challenges posed by illicit drugs. The Agency's headquarters will remain in Lisbon, Portugal.

General task

The Agency will:

- provide the Union and the Member States with factual, objective, reliable and comparable information, early warning and risk assessment at Union level concerning drugs, drug use, drug use disorders and addictions, prevention, treatment, care, risk and harm reduction, rehabilitation, social reintegration, recovery, drug markets and supply, including illicit production and trafficking, and other relevant drug-related issues and their consequences; and

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

The Agencys approach will incorporate human rights, gender and gender equality, age, health, health equity and social perspectives.

Observation and monitoring of the drugs phenomenon and sharing of best practices

The Agency will monitor:

- the drugs phenomenon in the Union in a holistic manner, using epidemiological and other indicators;

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

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

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

- emerging trends in the drugs phenomenon in the Union and internationally in so far as they impact the Union;

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

- drug precursors and the diversion and trafficking of drug precursors.

Based on its monitoring activities, the Agency will identify, support and, where appropriate, co-develop evidence-based best practices and innovative approaches.

Additional services

To further support Member States and other stakeholders in understanding and addressing the drugs phenomenon, the regulation introduces the possibility for the Agency to deliver additional services, beyond its core tasks, against the payment of fees should be introduced. The method by which fees levied by the Agency are calculated will be transparent. The fees charged by the Agency will have to cover the full costs of activities related to the services provided, including staff and operating costs.

International cooperation

The regulation strengthens the role of the Agency in the field of international cooperation. It instructs the Agency to actively seek ways of cooperating with international organisations. The Agency will engage third countries in its work.

ENTRY INTO FORCE: 1.7.2023.

APPLICATION: from 2.7.2024.

Transparency

STRUGARIU Ramona	Shadow rapporteur	LIBE	15/06/2022	EMCDDA
ARVANITIS Konstantinos	Shadow rapporteur	LIBE	15/06/2022	EMCDDA