



2022/0009(COD)

27.9.2022

AMENDMENTS

95 - 361

Draft report

Isabel Santos

(PE735.504v01-00)

European Union Drugs Agency

Proposal for a regulation

(COM(2022)0018 – C9-0010/2022 – 2022/0009(COD))

Amendment 95
Romeo Franz

Proposal for a regulation
Recital 2

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 96
Konstantinos Arvanitis

Proposal for a regulation
Recital 2

Text proposed by the Commission

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

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competence, they take measures or decide on action to address the drugs phenomenon. The **creation** of the European Monitoring Centre for Drugs and Drug Addiction has manifestly improved the availability of information on drugs and drug addiction across Europe.

competence, they take measures or decide on action to address the drugs phenomenon. The **work** of the European Monitoring Centre for Drugs and Drug Addiction has manifestly improved the availability of information on drugs and drug addiction across Europe **and internationally**.

Or. en

Amendment 97 Romeo Franz

Proposal for a regulation Recital 3

Text proposed by the Commission

(3) Whereas its general objective is still valid and should be retained, Regulation (EC) No 1920/2006 as such no longer fits for addressing the current and future drug challenges. Therefore, the mandate of the European Monitoring Centre for Drugs and Drug Addiction should be revised, including its replacement and renaming into “European Union Drugs Agency” (‘the Agency’). Since substantial amendments to Regulation (EC) No 1920/2006 are needed to accommodate the common approach for Union decentralised agencies⁴⁸ and to take account of the developments of the drug phenomenon, in the interest of clarity that Regulation should be replaced by a new Regulation.

⁴⁸ Joint Statement of the European Parliament, the Council of the EU and the

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⁴⁸ Joint Statement of the European Parliament, the Council of the EU and the

European Commission on decentralised agencies of 19 July 2012, https://european-union.europa.eu/sites/default/files/docs/body/joint_statement_and_common_approach_2012_en.pdf.

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Or. en

Amendment 98 **Konstantinos Arvanitis**

Proposal for a regulation **Recital 3**

Text proposed by the Commission

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⁴⁸ Joint Statement of the European Parliament, the Council of the EU and the European Commission on decentralised agencies of 19 July 2012, https://european-union.europa.eu/sites/default/files/docs/body/joint_statement_and_common_approach_2012_en.pdf.

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(3) Whereas its general objective is still valid and should be retained, Regulation (EC) No 1920/2006 as such no longer fits for addressing the current and future drug challenges. Therefore, the mandate of the European Monitoring Centre for Drugs and Drug Addiction should be revised, including its replacement, ***strengthening*** and renaming into “European Union Drugs Agency” (‘the Agency’). Since substantial amendments to Regulation (EC) No 1920/2006 are needed to accommodate the common approach for Union decentralised agencies⁴⁸***to reflect the balanced, evidence-based, integrated and multidisciplinary approach enshrined in the Union strategies on drugs*** and to take account of the developments of the drug phenomenon, in the interest of clarity ***and efficiency*** that Regulation should be replaced by a new Regulation.

⁴⁸ Joint Statement of the European Parliament, the Council of the EU and the European Commission on decentralised agencies of 19 July 2012, https://european-union.europa.eu/sites/default/files/docs/body/joint_statement_and_common_approach_2012_en.pdf.

Or. en

Amendment 99

Assita Kanko

Proposal for a regulation

Recital 3

Text proposed by the Commission

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Amendment

(3) Whereas its general objective is still valid and should be retained, Regulation (EC) No 1920/2006 as such no longer fits for addressing the current and future drug challenges. Therefore, the mandate of the European Monitoring Centre for Drugs and Drug Addiction should be revised, including its replacement, **reinforcement** and renaming into “European Union Drugs Agency” (‘the Agency’). Since substantial amendments to Regulation (EC) No 1920/2006 are needed to accommodate the common approach for Union decentralised agencies⁴⁸ and to take account of the developments of the drug phenomenon, in the interest of clarity that Regulation should be replaced by a new Regulation.

⁴⁸ Joint Statement of the European Parliament, the Council of the EU and the European Commission on decentralised agencies of 19 July 2012, https://european-union.europa.eu/sites/default/files/docs/body/joint_statement_and_common_approach_2012_en.pdf.

Or. en

Amendment 100

Romeo Franz

Proposal for a regulation

Recital 4

Text proposed by the Commission

(4) The main focus of Regulation (EC)

Amendment

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

No 1920/2006 was on health-related issues, ***which should continue to be the main focus and a priority for the Agency.*** However, addressing drug markets and drug supply, is **also** necessary to understand the impacts of the drug phenomenon on public health, reduce the availability of drugs in the Union and curb drug demand. Health- and supply-related issues ***regarding the drug phenomenon*** are intrinsically linked. The Agency should therefore address the drug phenomenon more holistically, ***by applying a multidisciplinary approach incorporating a human rights, gender equality, public and human health, health equity, sustainable development and social perspective in relation to drugs, drug use, drug use disorders and addictions, prevention, treatment, care, risk and harm reduction, rehabilitation, social reintegration and recovery, drug supply, including illicit production and trafficking, and other relevant drug-related issues and their consequences, including the potential unintended negative consequences associated with the implementation of policies and actions.***

Or. en

Amendment 101

Assita Kanko

Proposal for a regulation

Recital 4

Text proposed by the Commission

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

Amendment

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

should therefore address the drug phenomenon *more holistically*.

linked. *In order to provide factual, objective, reliable, comparable and Union-wide significant data and analysis,* the Agency should therefore address the drug phenomenon *in a multidisciplinary way, taking into account drug use, drug addictions, prevention, treatment, care, risk and harm reduction, rehabilitation, social reintegration and recovery, drug supply, including illicit production and trafficking, and other relevant drug related issues such as violence, criminality and their consequences.*

Or. en

Amendment 102

Konstantinos Arvanitis

Proposal for a regulation

Recital 4

Text proposed by the Commission

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

Amendment

(4) The main focus of Regulation (EC) No 1920/2006 was on health-related issues. However, addressing also drug markets and drug supply issues, is necessary to understand the impacts of the drug phenomenon *by applying a multidisciplinary approach incorporating a human rights, gender equality, public health, health equity, and social perspective in relation to drugs, drug use, drug use disorders and addictions, prevention, treatment, care, risk and harm reduction, abstinence-based recovery, rehabilitation, social reintegration, drug supply, including illicit production and trafficking, and other relevant drug-related issues and their consequences.*

Or. en

Amendment 103

Assita Kanko

Proposal for a regulation
Recital 4 a (new)

Text proposed by the Commission

Amendment

(4 a) The Agency, in cooperation with other Union bodies, offices and agencies, should also focus on and extend its activities to developing areas of cooperation with Member States regarding monitoring of drug trafficking, the illegal drugs markets and drug-related crime.

Or. en

Amendment 104
Romeo Franz

Proposal for a regulation
Recital 5

Text proposed by the Commission

Amendment

(5) The work of the Agency should be carried out with due regard to the respective powers of the Union and its Member States in the **area** of drugs. It should cover the various facets of the drugs phenomenon and the solutions applied. In doing so, the Agency should be guided by relevant strategies and action plans adopted by the Union, in particular the applicable EU Drugs Strategy and Action Plan.

(5) The work of the Agency should be carried out with due regard to the respective powers of the Union and its Member States in the **areas** of drugs **and the protection and improvement of public and human health**. It should cover the various facets of the drugs phenomenon and the solutions applied. In doing so, the Agency should be guided by **the evidence-based, integrated, balanced and multidisciplinary approach to the drugs phenomenon, which should include a gender equality and health equity perspective, as enshrined in** relevant strategies and action plans adopted by the Union, in particular the applicable EU Drugs Strategy and Action Plan.

Or. en

Amendment 105
Konstantinos Arvanitis

Proposal for a regulation
Recital 5

Text proposed by the Commission

(5) The work of the Agency should be carried out with due regard to the respective powers of the Union and its Member States in the area of drugs. It should cover the various facets of the drugs phenomenon and the solutions applied. In doing so, the Agency should be guided by relevant strategies and action plans adopted by the Union, in particular the applicable EU Drugs Strategy and Action Plan.

Amendment

(5) The work of the Agency should be carried out with due regard to the respective powers of the Union and its Member States in the area of drugs. It should cover the various facets of the drugs phenomenon and the solutions applied. In doing so, the Agency should be guided by ***and reflect the balanced, evidence-based, integrated and multidisciplinary approach enshrined in the*** relevant strategies and action plans adopted by the Union, in particular the applicable EU Drugs Strategy and Action Plan.

Or. en

Amendment 106
Romeo Franz

Proposal for a regulation
Recital 6

Text proposed by the Commission

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

Amendment

(6) In pursuing its activities, the Agency should cooperate with ***relevant*** Union bodies, ***offices and agencies, within their mandates and in full compliance with fundamental rights and data protection rules,*** and should take account of their activities in order to avoid duplication. Cooperation should also take place on an international level with relevant authorities and bodies in third countries and on the United Nations level. ***Cooperation should comply with the international human rights obligations of the Union.***

international level with relevant authorities and bodies in third countries and on the United Nations level.

Or. en

Amendment 107

Konstantinos Arvanitis

Proposal for a regulation

Recital 6

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 108

Ramona Strugariu, Fabienne Keller, Olivier Chastel, Hilde Vautmans, Maite Pagazaurtundúa, Michal Šimečka

Proposal for a regulation

Recital 6

Text proposed by the Commission

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

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Or. en

Amendment 109
Romeo Franz

Proposal for a regulation
Recital 6 a (new)

Text proposed by the Commission

Amendment

(6 a) In order to attain maximum efficiency in addressing the drugs phenomenon, the Agency should maintain a close and structured dialogue with the scientific community, healthcare professionals' organisations, academia, civil society organisations, including organisations of people who use drugs and the affected communities.

Or. en

Amendment 110
Konstantinos Arvanitis

Proposal for a regulation
Recital 6 a (new)

Text proposed by the Commission

Amendment

(6 a) In order to better address the drugs phenomenon, the Agency should maintain a close dialogue with the scientific community, civil society organisations and other relevant stakeholders.

Or. en

Amendment 111
Romeo Franz

Proposal for a regulation
Recital 7

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 112
Konstantinos Arvanitis

Proposal for a regulation
Recital 7

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 113
Konstantinos Arvanitis

Proposal for a regulation
Recital 9

Text proposed by the Commission

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

Amendment

(9) The collection, analysis and dissemination of data should continue to be the main task of the Agency. ***When collecting, analysing and disseminating data, the Agency should pay particular attention to respecting the legal framework on the processing of personal data and should not collect any data which would make it possible to identify individuals or small groups of individuals.*** The standard data is collected through the national focal points, which should remain one of the main data providers for the

Agency. Additional, closer to real-time data sources are increasingly available through innovative data collection methods. Therefore, the Agency should have access to all data available to get a holistic picture of the drug phenomenon in the Union and the external factors influencing it.

Or. en

Amendment 114

Romeo Franz

Proposal for a regulation

Recital 9

Text proposed by the Commission

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

Amendment

(9) The collection, analysis and dissemination of data should continue to be the main task of the Agency. ***When collecting, analysing and disseminating data, the Agency should pay particular attention to respecting the legal framework on processing of personal data and should not collect any personal data, nor any data which would make it possible to identify individuals or groups of individuals.*** The standard data is collected through the national focal points, which should remain one of the main data providers for the Agency. The Agency should have access to all data available to get a holistic picture of the drug phenomenon in the Union and the external factors influencing it.

Or. en

Amendment 115

Assita Kanko

Proposal for a regulation

Recital 9

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 116
Assita Kanko

Proposal for a regulation
Recital 9 a (new)

Text proposed by the Commission

Amendment

(9 a) The national focal points are key national players with respect to improving data collection methodologies and tools, and developing relevant guidelines for their implementation. In addition, the national focal points participate in the early warning system and report on new trends in the use of existing psychoactive substances and on new consumption patterns involving combinations of psychoactive substances which pose a potential health risk. Moreover, they provide training to persons dealing with prevention and offer support in the production of different products of the Agency.

Or. en

Amendment 117

Assita Kanko

Proposal for a regulation

Recital 10

Text proposed by the Commission

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

Amendment

(10) ***National focal points represent the cornerstone of the Union drug monitoring and reporting system. It is therefore essential that the relationship between the Agency and the national focal points is a symbiotic and mutually-reinforcing one and that*** the data requirements of the Agency ***are*** mirrored in the national focal points. They should be empowered within the Member States to receive all relevant data from the different national authorities. Data collection in the Member States should be streamlined as far as possible to avoid double reporting and duplication of efforts.

Or. en

Amendment 118

Romeo Franz

Proposal for a regulation

Recital 10

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 119
Romeo Franz

Proposal for a regulation
Recital 11

Text proposed by the Commission

(11) In order to facilitate and structure data collection, information exchange, both qualitative and quantitative, and to support the establishment of an integrated and interoperable monitoring system ***enabling real-time monitoring***, the Agency should have an appropriate digital solution. ***This should allow for the automation of data and information management and exchange. Such solution should also facilitate the real-time monitoring of technology-enabled drug markets, including the darknet.***

Amendment

(11) In order to facilitate and structure data collection, information exchange, both qualitative and quantitative, and to support the establishment of an integrated and interoperable monitoring system, the Agency should have an appropriate digital solution ***necessary for the performance of its tasks which should be in full compliance with fundamental rights and data protection rules.***

Or. en

Amendment 120
Konstantinos Arvanitis

Proposal for a regulation
Recital 11

Text proposed by the Commission

(11) In order to facilitate and structure data collection, information exchange, both qualitative and quantitative, and to support the establishment of an integrated and interoperable monitoring system enabling real-time monitoring, the Agency should ***have an appropriate digital solution. This should allow for the automation of data and information management and exchange. Such solution should also facilitate the real-time monitoring of technology-enabled drug markets, including the darknet.***

Amendment

(11) In order to facilitate and structure data collection, information exchange, both qualitative and quantitative, and to support the establishment of an integrated and interoperable monitoring system enabling real-time monitoring, the Agency should ***develop and apply the appropriate digital solutions required for the performance of its tasks, among others to facilitate real-time monitoring of technology-enabled drug markets, including the darknet.***

Amendment 121**Romeo Franz****Proposal for a regulation****Recital 12***Text proposed by the Commission*

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

Amendment

(12) In order to enable the Agency to make better use of the information it has available ***on the drug phenomenon, which encompasses the public health, social and human rights, and safety dimensions***, and to enhance the Union's preparedness for future developments, the monitoring and analytical capacity of the Agency should be strengthened.

Or. en

Amendment 122**Assita Kanko****Proposal for a regulation****Recital 14***Text proposed by the Commission*

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

Amendment

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

developments as part of its holistic approach to the drug phenomenon.

efforts, should monitor such developments as part of its holistic approach to the drug phenomenon.

Or. en

Amendment 123

Konstantinos Arvanitis

Proposal for a regulation

Recital 16

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 124

Romeo Franz

Proposal for a regulation

Recital 17

Text proposed by the Commission

(17) As dangerous substances might lead to harm for public health, the Agency should be able to issue alerts. To support such a function, the Agency should develop a European drug alert system, accessible by national authorities. Such a system should facilitate the rapid exchange

Amendment

(17) As dangerous substances might lead to harm for public health, the Agency should be able to issue alerts. To support such a function, the Agency should develop a European drug alert system, accessible by national authorities. Such a system should facilitate the rapid exchange

of information that may require rapid actions to safeguard public health, safety, and security. The Agency should be able to inform not only national authorities, but also potential users of these substances.

of information that may require rapid actions to safeguard public health, ***social and human rights***, safety, and security. The Agency should be able to inform not only national authorities, but also potential users of these substances.

Or. en

Amendment 125

Romeo Franz

Proposal for a regulation

Recital 19

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 126

Romeo Franz

Proposal for a regulation

Recital 21

Text proposed by the Commission

(21) To further the knowledge in this area and support Member States, the

Amendment

(21) To further the knowledge in this area and support Member States, the

Agency should define and finance relevant projects, such as the development of reference standards on new drugs, the elaboration of toxicological or pharmacological studies, and drug profiling. Such an approach would support the sharing of information between relevant laboratories and would decrease the costs for individual laboratories.

Agency should define and finance relevant projects, such as the development of reference standards on new drugs, the elaboration of toxicological or pharmacological studies, and drug profiling. Such an approach would support the sharing of information between relevant laboratories and would decrease the costs for individual laboratories. ***The projects that the Agency finances and the amounts invested in each project should be included in the Agency's annual working programme and be made public.***

Or. en

Amendment 127
Tomáš Zdechovský

Proposal for a regulation
Recital 21

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 128
Romeo Franz

Proposal for a regulation
Recital 22

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

(22) Since *the wide implementation of evidence-based interventions for demand as well as risk and harm reduction is essential to the objective of promoting public health and improving the well-being of communities and individuals*, the Agency *should have* access to data and *obtain* the necessary scientific experience to develop and promote evidence-based *and gender-sensitive interventions*, best practices and *awareness raising* in drug prevention, *risk and harm reduction, treatment, care, rehabilitation and recovery*, including the *promotion of the implementation and updating of existing* quality standards for drug prevention (European Drug Prevention Quality Standards) or of a curriculum providing decision- and policy-makers with the knowledge about the most effective evidence-based prevention interventions and approaches (European Union Prevention Curriculum), *as well as the research on and promotion of other demand reduction interventions such as psychosocial behavioural and medication-assisted treatment, rehabilitation and recovery services, and risk and harm reduction interventions, including innovative harm reduction interventions to reach high-risk populations.*

Or. en

Amendment 129
Tomáš Zdechovský

Proposal for a regulation
Recital 22

(22) Since the Agency has access to data and the necessary scientific experience to develop and promote evidence-based prevention strategies, it should be involved

(22) Since the Agency has access to data and the necessary scientific experience to develop and promote evidence-based *interventions, best practices, harm*

in prevention work, in particular exchange of best practices and implementable research results in drug prevention, drug-related crime prevention and the prevention of drug-related harms, including the elaboration of quality standards for drug prevention (European Drug Prevention Quality Standards) or of a curriculum providing decision- and policy-makers with the knowledge about the most effective evidence-based prevention interventions and approaches (European Union Prevention Curriculum)

reduction policies, and awareness rising and prevention strategies, it should be involved in prevention work, in particular exchange of best practices and implementable research results in drug prevention, drug-related crime prevention and the prevention of drug-related harms, including the elaboration of quality standards for drug prevention (European Drug Prevention Quality Standards) or of a curriculum providing decision- and policy-makers with the knowledge about the most effective evidence-based prevention interventions and approaches (European Union Prevention Curriculum)

Or. en

Justification

The policy of harm reduction is an important element of addressing addictions to drugs. It is, therefore, crucial to ensure that the strengthened EMCDDA will be enabled to on the basis of data and scientific experience develop and propose harm reduction policies to support the EU and the Member States in their efforts to address addictions.

Amendment 130 **Konstantinos Arvanitis**

Proposal for a regulation **Recital 22**

Text proposed by the Commission

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

Amendment

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

Amendment 131

Romeo Franz

Proposal for a regulation

Recital 23

Text proposed by the Commission

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

Amendment

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

Amendment 132

Konstantinos Arvanitis

Proposal for a regulation

Recital 23

Text proposed by the Commission

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

Amendment

(23) Given its Union perspective, the Agency should be able to evaluate national measures and training, for example on prevention, treatment, harm reduction, **abstinence-based recovery** and other related measures, in view of their compliance with the latest scientific state of play and of their proven **contribution**. Member States or relevant professional bodies should be given the possibility to

quality label for their work.

use the accreditation or certification as a quality label for their work.

Or. en

Amendment 133

Romeo Franz

Proposal for a regulation

Recital 25

Text proposed by the Commission

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

Amendment

(25) The responsibilities of the Agency in the area of international cooperation should be defined in clear terms in order to allow it to fully engage in such activities and respond to requests from third countries and bodies, **taking into account that international cooperation in the field of drugs should address the whole range of policy aspects of the drugs phenomenon, be guided by the Sustainable Development Goals, be in full compliance with international human rights obligations and be committed to gender equality.** The Agency should be able to **offer adequate scientific and evidence-based tools for** the development and implementation of the external dimension of the Union's drugs policy and the leadership role of the Union at multilateral level as a means to ensure the efficient and coherent implementation of the Union drug policies internally and at international level. In order that the Agency can allocate adequate resources to this task, the work on international cooperation should be part of the core tasks of the Agency. It should be based on an international cooperation framework of the Agency, which should be in line with the Union priorities on international cooperation and should be revised on a regular basis to ensure that it adequately reflects international developments **and fully complies with international human rights obligations, including gender**

Amendment 134
Konstantinos Arvanitis

Proposal for a regulation
Recital 25

Text proposed by the Commission

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

Amendment

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

Amendment 135
Romeo Franz

Proposal for a regulation

Recital 26

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 136

Konstantinos Arvanitis

Proposal for a regulation

Recital 26

Text proposed by the Commission

(26) In order to help Union funding for security research to develop its full potential and address the needs of drugs policy, the Agency should assist the Commission in identifying key research themes, drawing up and implementing the Union framework programmes for research and innovation that are relevant to the Agency's objectives. Where the Agency

Amendment

(26) In order to help Union funding for security **and health** research to develop its full potential and address the needs of drugs policy, the Agency should assist the Commission in identifying key research themes, drawing up and implementing the Union framework programmes for research and innovation that are relevant to the Agency's objectives. Where the Agency

assists the Commission in identifying key research themes, drawing up and implementing a Union framework programme, it should not receive funding from that programme in order to avoid a potential conflict of interest. Finally, the Agency should participate in Union-wide initiatives addressing research and innovation to ensure that technologies necessary for its activities are developed and available for use.

assists the Commission in identifying key research themes, drawing up and implementing a Union framework programme, it should not receive funding from that programme in order to avoid a potential conflict of interest. Finally, the Agency should participate in Union-wide initiatives addressing research and innovation to ensure that technologies necessary for its activities are developed and available for use.

Or. en

Amendment 137
Romeo Franz

Proposal for a regulation
Recital 27

Text proposed by the Commission

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

Amendment

(27) ***The Agency should have a Management Board, composed of two experts appointed by the European Parliament and representatives of the Commission and of the Member States. The Management Board should be responsible for overseeing the work of the Agency and*** should be assisted by an Executive Board to prepare its decisions. The Agency should be headed by an Executive Director ***who should be responsible for day-to-day management of the Agency.*** A Scientific Committee should continue assisting the Management Board and the Executive Director with regard to relevant scientific matters. ***When making their appointments, the Member States, the Commission and the European Parliament should ensure gender balance, in particular regarding the composition of the Management Board as a body. During a period of one year after ceasing to hold office, the former members of the Executive Board, including the its chairperson, should be prohibited from engaging in any gainful occupational***

activity with any entity where a conflict of interest exists or could be perceived to exist. The Executive Director should be appointed by the Management Board on the basis of a gender-balanced shortlist of candidates proposed by the Commission and after having obtained the consent of the European Parliament. The shortlisted candidates should be heard by the competent committee(s) prior to their approval by the Parliament. Full compliance with rules and principles on transparency and conflict of interests, particularly when engaging with stakeholders, should be ensured.

Or. en

Amendment 138
Konstantinos Arvanitis

Proposal for a regulation
Recital 27

Text proposed by the Commission

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

Amendment

(27) The Management Board should be assisted by an Executive Board to prepare its decisions. The Agency should be headed by an Executive Director. A Scientific Committee should continue assisting the Management Board and the Executive Director with regard to relevant scientific matters. *The importance of gender-balanced representation should be taken into account when appointing people to positions within the administrative and management structure of the Agency.*

Or. en

Amendment 139
Ramona Strugariu, Fabienne Keller, Olivier Chastel, Hilde Vautmans, Maite Pagazaurtundúa, Michal Šimečka, Malik Azmani

Proposal for a regulation
Recital 28

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 140
Konstantinos Arvanitis

Proposal for a regulation
Recital 29

Text proposed by the Commission

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

Amendment

(29) The Agency should be ***adequately*** resourced to carry out its tasks. ***That should be properly reflected in the multiannual financial framework with a dedicated and ambitious*** budget. ***The Agency*** should be mainly financed by a contribution from the general budget of the Union. The Union budgetary procedure should be applicable as far as the Union contribution and any other subsidies chargeable to the general budget of the Union are concerned. The auditing of accounts should be undertaken by the Court of Auditors of the European Union.

Or. en

Amendment 141

Ramona Strugariu, Fabienne Keller, Olivier Chastel, Hilde Vautmans, Maite Pagazaurtundúa, Michal Šimečka, Malik Azmani

Proposal for a regulation
Recital 29

Text proposed by the Commission

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

Amendment

(29) ***It is necessary to provide*** the Agency ***with the requisite human and financial resources to fulfill*** its tasks, ***objectives and responsibilities and to grant it*** an autonomous budget. It should be mainly financed by a contribution from the general budget of the Union. The Union budgetary procedure should be applicable as far as the Union contribution and any other subsidies chargeable to the general budget of the Union are concerned. The auditing of accounts should be undertaken by the Court of Auditors of the European Union.

Or. en

Amendment 142
Tomáš Zdechovský

Proposal for a regulation
Recital 30

Text proposed by the Commission

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

Amendment

deleted

Or. en

Justification

Please see justification of amendment to Article 37.

Amendment 143
Romeo Franz

Proposal for a regulation
Recital 30

Text proposed by the Commission

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

Amendment

(30) Fees improve the funding of an agency and may, ***to the extent such fees are duly justified and necessary***, be considered for specific issues that can be clearly separated from the core tasks of the agency. ***The method by which*** fees levied by the Agency ***are calculated should be transparent. The fees*** should cover ***the costs of the Agency*** for providing the respective services.

Or. en

Amendment 144
Ramona Strugariu, Fabienne Keller, Olivier Chastel, Hilde Vautmans, Maite Pagazaurtundúa, Michal Šimečka, Malik Azmani

Proposal for a regulation
Recital 30

Text proposed by the Commission

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

Amendment

(30) Fees improve the funding of an agency and may be considered for specific issues that can be clearly separated from the core tasks of the agency. ***The*** fees levied by the Agency ***shall be established through a transparent methodology in order to ensure a predictable budget and*** should cover its costs for providing the respective services.

Or. en

Amendment 145
Konstantinos Arvanitis

Proposal for a regulation

Recital 30

Text proposed by the Commission

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

Amendment

(30) Fees improve the funding of an agency and may be ***applied*** for specific issues that ***are*** clearly ***distinct*** from the core tasks of the Agency. ***The fee calculation method should be transparent and should ensure coverage of the respective Agency costs.***

Or. en

Amendment 146 Romeo Franz

Proposal for a regulation Recital 32

Text proposed by the Commission

(32) Regulation (EC) No 1049/2001 of the European Parliament and of the Council⁴⁹ should apply to the Agency. The Agency should be ***as*** transparent ***as possible*** about its activities, ***without jeopardising the attainment of the objective of its operations.***

Amendment

(32) Regulation (EC) No 1049/2001 of the European Parliament and of the Council⁴⁹ should apply to the Agency. The Agency should be ***fully*** transparent about its activities.

⁴⁹ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

⁴⁹ Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43).

Or. en

Amendment 147 Konstantinos Arvanitis

Proposal for a regulation Recital 35

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

(35) The Agency should *maintain a structured dialogue* with relevant *civil society* organisations.

Or. en

Amendment 148
Romeo Franz

Proposal for a regulation
Recital 35

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

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

Or. en

Amendment 149
Ramona Strugariu, Fabienne Keller, Olivier Chastel, Hilde Vautmans, Maite Pagazaurtundúa, Michal Šimečka, Malik Azmani

Proposal for a regulation
Recital 35 a (new)

(35 a) The Agency should establish close cooperation with experts on the ground and with relevant non-governmental and civil society organisations, recognising their important role in this field.

Or. en

Amendment 150

Romeo Franz

Proposal for a regulation

Recital 36

Text proposed by the Commission

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

Amendment

(36) The Agency replaces and succeeds the European Monitoring Centre for Drugs and Drug Addiction established by Regulation (EC) **No 1920/2006**. It should therefore be the legal successor of all its contracts, including employment contracts, liabilities and properties acquired. International agreements concluded by the European Monitoring Centre for Drugs and Drug Addiction before the date of application of this Regulation should remain in force.

Or. en

Amendment 151

Romeo Franz

Proposal for a regulation

Article 3 – paragraph 1 – point 3

Text proposed by the Commission

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

Amendment

(3) ‘poly-substance use’ means the **consumption** of one or more psychoactive substance or type of substance, whether illicit **or licit, in particular medical products, alcohol or tobacco, at**

drugs;

the same time or sequentially within a short period of time, together with drugs;

Or. en

Amendment 152

Konstantinos Arvanitis

Proposal for a regulation

Article 3 – paragraph 1 – point 3

Text proposed by the Commission

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

Amendment

(3) poly-substance use means the *simultaneous or short-interval sequential consumption* of one or more psychoactive *substances or types of substances, whether illicit or licit, indicatively medicinal products, alcohol or tobacco and* drugs;

Or. en

Amendment 153

Romeo Franz

Proposal for a regulation

Article 4 – paragraph 1

Text proposed by the Commission

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

Amendment

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

evidence-based, integrated, balanced and multidisciplinary approach to the drugs phenomenon, incorporating a human rights, gender equality, public and individual health and health equality, and social perspective.

Or. en

Amendment 154
Konstantinos Arvanitis

Proposal for a regulation
Article 4 – paragraph 1

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 155
Assita Kanko

Proposal for a regulation
Article 4 – paragraph 1

Text proposed by the Commission

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

Amendment

The Agency shall provide the Union and its Member States with factual, objective, reliable and comparable information, early warning and risk assessment at Union level concerning drugs **use, drug addictions, prevention, treatment, care, risk and harm reduction, rehabilitation, social reintegration and recovery, drug supply, including illicit production and trafficking, and other relevant drug related issues such as drug-related violence, drug criminality and drug trafficking** and their consequences, and recommend appropriate and concrete, evidence-based actions on how to address the related challenges in a timely manner.

Or. en

Amendment 156

Konstantinos Arvanitis

Proposal for a regulation

Article 5 – paragraph 1 – point a – point 1

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 157

Konstantinos Arvanitis

Proposal for a regulation

Article 5 – paragraph 1 – point a – point 2

Text proposed by the Commission

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

Amendment

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

Amendment 158

Romeo Franz

Proposal for a regulation

Article 5 – paragraph 1 – point a – point 2

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 159

Konstantinos Arvanitis

Proposal for a regulation

Article 5 – paragraph 1 – point a – point 3

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 160

Romeo Franz

Proposal for a regulation

Article 5 – paragraph 1 – point a – point 3

Text proposed by the Commission

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

Amendment

(3) the monitoring of the drug phenomenon, encompassing the public health, **social and human rights**, safety and security dimension, pursuant to Article

Amendment 161**Assita Kanko****Proposal for a regulation****Article 5 – paragraph 1 – point b – point 2***Text proposed by the Commission*

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

Amendment

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

Amendment 162**Konstantinos Arvanitis****Proposal for a regulation****Article 5 – paragraph 1 – point b – point 2***Text proposed by the Commission*

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

Amendment

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

Amendment 163**Romeo Franz****Proposal for a regulation****Article 5 – paragraph 1 – point b – point 2***Text proposed by the Commission*

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

Amendment

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

Amendment 164

Romeo Franz

Proposal for a regulation

Article 5 – paragraph 1 – point c – point 1

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 165

Konstantinos Arvanitis

Proposal for a regulation

Article 5 – paragraph 1 – point c – point 1

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 166

Romeo Franz

Proposal for a regulation

Article 5 – paragraph 4

Text proposed by the Commission

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

Amendment

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

organisations.

governmental organisations.

Or. en

Amendment 167

Konstantinos Arvanitis

Proposal for a regulation

Article 5 – paragraph 4

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 168

Ramona Strugariu, Fabienne Keller, Olivier Chastel, Hilde Vautmans, Maite Pagazaurtundúa, Michal Šimečka, Malik Azmani

Proposal for a regulation

Article 5 – paragraph 4 a (new)

Text proposed by the Commission

Amendment

4 a. The Agency shall develop a communication strategy and promote dialogue with non-governmental and civil society organisations in order to raise public awareness and actively disseminate information about its work.

Or. en

Amendment 169

Konstantinos Arvanitis

Proposal for a regulation
Article 5 – paragraph 7

Text proposed by the Commission

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

Amendment

7. In carrying out and implementing the tasks referred to in paragraph 1, the Agency shall cooperate actively with other Union ***bodies, offices and agencies within their mandates***, in particular Europol, Eurojust, ***the European Union Agency for Fundamental Rights, the European Union Agency for Law Enforcement Training (CEPOL)***, the European Medicines Agency, the European Centre for Disease Prevention and Control ***and the European Foundation for the Improvement in Living and Working Conditions (Eurofound)***, ***with other international bodies, offices and agencies, in particular ECOSOC and the UN Narcotics Board, and with the scientific community, academia***, civil society organisations, ***in particular the Civil Society Forum on Drugs, representatives of affected communities, including people who use drugs***, and other relevant stakeholders, to attain maximum efficiency in monitoring, assessing and responding to the drugs phenomenon.

Or. en

Amendment 170
Romeo Franz

Proposal for a regulation
Article 5 – paragraph 7

Text proposed by the Commission

7. In carrying out and implementing the tasks referred to in paragraph 1, the Agency shall cooperate ***actively*** with other Union ***decentralised*** agencies ***and bodies***, in particular Europol, Eurojust, the European Medicines Agency, the European Centre for Disease Prevention and Control,

Amendment

7. In carrying out and implementing the tasks referred to in paragraph 1, the Agency shall cooperate with other Union ***bodies, offices and agencies, within their mandates***, in particular ***the European Union Agency for Fundamental Rights***, Europol, Eurojust, ***the European Union***

civil society organisations and other relevant stakeholders, to attain maximum efficiency in monitoring, assessing and responding to the drugs phenomenon.

Agency for Law Enforcement Training (CEPOL), the European Medicines Agency, the European Centre for Disease Prevention and Control, ***and the European Foundation for the Improvement in Living and Working Conditions (Eurofound)***, ***and with the scientific community, academia***, civil society organisations, ***in particular the Civil Society Forum on Drugs, representatives of affected communities, including people who use drugs***, and other relevant stakeholders, to attain maximum efficiency in monitoring, assessing and responding to the drugs phenomenon.

Or. en

Amendment 171
Assita Kanko

Proposal for a regulation
Article 5 – paragraph 7

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 172
Konstantinos Arvanitis

Proposal for a regulation
Article 6 – paragraph 1 – point a

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 173

Konstantinos Arvanitis

Proposal for a regulation

Article 6 – paragraph 1 – point b

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 174

Romeo Franz

Proposal for a regulation

Article 6 – paragraph 1 – point b

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 175

Romeo Franz

Proposal for a regulation

Article 6 – paragraph 1 – point f

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 176

Romeo Franz

Proposal for a regulation

Article 6 – paragraph 3

Text proposed by the Commission

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

Amendment

3. The Agency shall develop, within its mandate, data collection methods and approaches.

Or. en

Amendment 177

Konstantinos Arvanitis

Proposal for a regulation

Article 6 – paragraph 4 – subparagraph 1

Text proposed by the Commission

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

Amendment

The Agency **shall** develop the necessary digital solutions through which information and data are managed and automatically exchanged. ***All such solutions shall be developed and implemented in a transparent, just, fair and equitable manner.***

Or. en

Amendment 178

Romeo Franz

Proposal for a regulation

Article 6 – paragraph 4 – subparagraph 1

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 179

Konstantinos Arvanitis

Proposal for a regulation

Article 6 – paragraph 4 – subparagraph 2

Text proposed by the Commission

If such digital solutions are developed, they shall:

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

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

(c) allow for the computerised handling

Amendment

deleted

and exchange of information, data and documents.

Or. en

Amendment 180

Romeo Franz

Proposal for a regulation

Article 6 – paragraph 4 – subparagraph 2

Text proposed by the Commission

Amendment

If such digital solutions are developed, they shall: *deleted*

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

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

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

Or. en

Amendment 181

Romeo Franz

Proposal for a regulation

Article 6 – paragraph 4 – subparagraph 2 – point a

Text proposed by the Commission

Amendment

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

Or. en

Amendment 182
Romeo Franz

Proposal for a regulation
Article 6 – paragraph 4 – subparagraph 2 – point b

Text proposed by the Commission

Amendment

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

Or. en

Amendment 183
Romeo Franz

Proposal for a regulation
Article 6 – paragraph 4 – subparagraph 2 – point c

Text proposed by the Commission

Amendment

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

Or. en

Amendment 184
Konstantinos Arvanitis

Proposal for a regulation
Article 6 – paragraph 5 – point b

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 185

Romeo Franz

Proposal for a regulation

Article 6 – paragraph 5 – point b

Text proposed by the Commission

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

Amendment

(b) ensuring wide dissemination of its analysis, conclusions and reports,
including to the scientific community, civil society and affected communities, including people who use drugs;

Or. en

Amendment 186

Tomáš Zdechovský

Proposal for a regulation

Article 6 – paragraph 5 – point e

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 187

Romeo Franz

Proposal for a regulation

Article 6 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5 a. Where relevant, the Agency may disseminate information and data disaggregated by Member State, gender,

age, race, ethnicity, disability and socio-economic status, in accordance with the relevant national legal framework and Union data protection law. When disseminating such information and data, the Agency shall make reference to the sources thereof.

Or. en

Amendment 188
Konstantinos Arvanitis

Proposal for a regulation
Article 6 – paragraph 5 a (new)

Text proposed by the Commission

Amendment

5 a. *Where relevant, the Agency may disseminate information and data disaggregated by Member State, gender, age, race, ethnicity, disability and socio-economic status, in accordance with the relevant national legal framework and Union data protection law. When disseminating such information and data, the Agency shall make reference to the sources thereof.*

Or. en

Amendment 189
Konstantinos Arvanitis

Proposal for a regulation
Article 6 – paragraph 6

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 190

Romeo Franz

Proposal for a regulation

Article 6 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

6 a. *The collection and dissemination of information and data pursuant to this Article shall be in full compliance with fundamental rights and data protection rules.*

Or. en

Amendment 191

Romeo Franz

Proposal for a regulation

Article 7 – title

Text proposed by the Commission

Amendment

Monitoring of the drug phenomenon

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

Or. en

Amendment 192

Konstantinos Arvanitis

Proposal for a regulation

Article 7 – title

Text proposed by the Commission

Amendment

Monitoring of the drug phenomenon

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

Or. en

Amendment 193
Konstantinos Arvanitis

Proposal for a regulation
Article 7 – paragraph 1 – point a

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 194
Romeo Franz

Proposal for a regulation
Article 7 – paragraph 1 – point a

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 195
Romeo Franz

Proposal for a regulation
Article 7 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

(a a) evidence-based best practices and innovative approaches, regarding health, social and human rights, and safety

responses, with particular attention to the impact of responses on affected population;

Or. en

Amendment 196
Konstantinos Arvanitis

Proposal for a regulation
Article 7 – paragraph 1 – point a a (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 197
Romeo Franz

Proposal for a regulation
Article 7 – paragraph 1 – point a b (new)

Text proposed by the Commission

Amendment

(a b) poly-substance use and its consequences, in particular the increased risks of health and social problems, as well as the social determinants of drug use, drug use disorders and addictions;

Or. en

Amendment 198
Romeo Franz

Proposal for a regulation
Article 7 – paragraph 1 – point a c (new)

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

Or. en

Amendment 199

Ramona Strugariu, Fabienne Keller, Olivier Chastel, Hilde Vautmans, Maite Pagazaurtundúa, Michal Šimečka, Malik Azmani

Proposal for a regulation

Article 7 – paragraph 1 – point b

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 200

Romeo Franz

Proposal for a regulation

Article 7 – paragraph 1 – point b

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 201
Konstantinos Arvanitis

Proposal for a regulation
Article 7 – paragraph 1 – point b

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 202
Konstantinos Arvanitis

Proposal for a regulation
Article 7 – paragraph 1 – point b a (new)

Text proposed by the Commission

Amendment

(b a) drug use, drug use disorders, drug addictions and related health risks and harm and emerging trends in those fields;

Or. en

Amendment 203
Romeo Franz

Proposal for a regulation
Article 7 – paragraph 1 – point c

Text proposed by the Commission

Amendment

(c) poly-substance use and its consequences, in particular the implications for policies and responses arising from the interaction between the use of drugs with one or more

deleted

psychoactive substance or type of substance, whether licit or illicit; including the increased risks of health and social problems, which may occur when drugs and other psychoactive substances are consumed at the same time or sequentially within a short period of time or when different substances are produced or sold together; the need to consider the common causes of drug use and addictions; and the implications for monitoring and exchange of best practices, which arise when policies and responses target multiple substances holistically;

Or. en

Amendment 204

Konstantinos Arvanitis

Proposal for a regulation

Article 7 – paragraph 1 – point c a (new)

Text proposed by the Commission

Amendment

(c a) 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;

Or. en

Amendment 205

Romeo Franz

Proposal for a regulation

Article 7 – paragraph 1 – point d

Text proposed by the Commission

Amendment

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

deleted

practices and research results;

Or. en

Amendment 206

Konstantinos Arvanitis

Proposal for a regulation

Article 7 – paragraph 1 – point d a (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 207

Romeo Franz

Proposal for a regulation

Article 7 – paragraph 1 – point g

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 208

Romeo Franz

Proposal for a regulation

Article 7 – paragraph 1 – point h

Text proposed by the Commission

Amendment

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

deleted

respective mandates.

Or. en

Amendment 209

Konstantinos Arvanitis

Proposal for a regulation

Article 7 – paragraph 2

Text proposed by the Commission

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

Amendment

2. Based on its monitoring activities, the Agency shall identify ***and develop*** innovative ***and evidence-based*** best practices, share ***them with*** the Member States and facilitate the exchange of such practices among ***them.***

Or. en

Amendment 210

Romeo Franz

Proposal for a regulation

Article 7 – paragraph 2

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 211

Assita Kanko

Proposal for a regulation
Article 7 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 212
Romeo Franz

Proposal for a regulation
Article 7 – paragraph 3

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 213
Konstantinos Arvanitis

Proposal for a regulation
Article 7 – paragraph 3

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 214

Romeo Franz

Proposal for a regulation

Article 8 – paragraph 2 a (new)

Text proposed by the Commission

Amendment

2 a. The information collected pursuant to paragraph 2 shall not contain any personal data or information that makes it possible to identify individuals or groups of individuals.

Or. en

Amendment 215

Konstantinos Arvanitis

Proposal for a regulation

Article 9 – paragraph 2 – point f a (new)

Text proposed by the Commission

Amendment

(f a) information on the health-related risks associated with the new psychoactive substances;

Or. en

Amendment 216

Romeo Franz

Proposal for a regulation

Article 9 – paragraph 3

Text proposed by the Commission

Amendment

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

3. For the purpose of the initial report, the Agency shall use information, which is at its disposal **pursuant to Article 8.**

Or. en

Amendment 217

Romeo Franz

Proposal for a regulation

Article 9 – paragraph 4

Text proposed by the Commission

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

Amendment

4. Where the Agency considers it necessary, it shall request the national focal points ***and the relevant stakeholders, including the scientific community, healthcare professionals, civil society organisations and affected communities,*** to provide additional information on the new psychoactive substance. The national focal points ***and the relevant stakeholders, where applicable,*** shall provide that information within two weeks of receipt of the request.

Or. en

Amendment 218

Konstantinos Arvanitis

Proposal for a regulation

Article 9 – paragraph 4

Text proposed by the Commission

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

Amendment

4. Where the Agency considers it necessary, it shall request the national focal points ***or the relevant stakeholders, including the scientific community, civil society organisations and affected communities,*** to provide additional information on the new psychoactive substance. The national focal points ***or the relevant stakeholders, as applicable,*** shall provide that information within ***three*** weeks of receipt of the request.

Or. en

Amendment 219
Konstantinos Arvanitis

Proposal for a regulation
Article 9 – paragraph 10 a (new)

Text proposed by the Commission

Amendment

10 a. Where appropriate, the Agency shall disseminate the initial report to the relevant stakeholders, including the scientific community, civil society organisations and affected communities, for awareness-raising purposes.

Or. en

Amendment 220
Romeo Franz

Proposal for a regulation
Article 10 – paragraph 3 – point c

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 221
Romeo Franz

Proposal for a regulation
Article 10 – paragraph 3 – point d

Text proposed by the Commission

Amendment

(d) an analysis of the social risks associated with the new psychoactive

(d) an analysis of the social risks associated with the new psychoactive

substance – in particular its impact on social functioning, public order and criminal activities, and the involvement of criminal groups in the manufacture, distribution and distribution methods, and trafficking of the new psychoactive substance;

substance – in particular its impact on social functioning, ***social marginalisation***, public order and criminal activities, and the involvement of criminal groups in the manufacture, distribution and distribution methods, and trafficking of the new psychoactive substance;

Or. en

Amendment 222
Romeo Franz

Proposal for a regulation
Article 10 – paragraph 3 – point f a (new)

Text proposed by the Commission

Amendment

(f a) available information on recommended evidence-based demand reduction and harm reduction responses to minimise the risks and harms associated with new psychoactive substances;

Or. en

Amendment 223
Konstantinos Arvanitis

Proposal for a regulation
Article 10 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

6 a. Where appropriate, the Agency shall disseminate the risk assessment report to the relevant stakeholders, including the scientific community, civil society organisations and affected communities, for awareness-raising purposes.

Or. en

Amendment 224
Romeo Franz

Proposal for a regulation
Article 10 – paragraph 8 a (new)

Text proposed by the Commission

Amendment

8 a. Where appropriate or upon request, the Agency shall disseminate the risk assessment reports to the European Parliament and to the relevant stakeholders, including the scientific community, healthcare professionals, civil society organisations and affected communities, for awareness-raising of the risks of a new psychoactive substance and recommended responses. In addition, summaries of all reports shall be publicly available on the Agency’s web portal.

Or. en

Amendment 225
Konstantinos Arvanitis

Proposal for a regulation
Article 12 – title

Text proposed by the Commission

Amendment

Threat assessment and preparedness

Health, security, inclusion, and social reintegration threat assessment and preparedness

Or. en

Amendment 226
Assita Kanko

Proposal for a regulation
Article 12 – title

Text proposed by the Commission

Amendment

Threat assessment and preparedness

Health and security threat assessment and

preparedness

Or. en

Amendment 227

Romeo Franz

Proposal for a regulation

Article 12 – title

Text proposed by the Commission

Threat assessment and preparedness

Amendment

Health threat assessment and preparedness

Or. en

Amendment 228

Konstantinos Arvanitis

Proposal for a regulation

Article 12 – paragraph 1

Text proposed by the Commission

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

Amendment

1. The Agency shall develop a strategic general **health, security, inclusion and reintegration** 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 aspects**, safety and security **in the Union** and, through doing so, to help increase the preparedness of the relevant stakeholders to respond to new threats in a timely and effective manner.

Or. en

Amendment 229

Romeo Franz

Proposal for a regulation

Article 12 – paragraph 1

Text proposed by the Commission

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

Amendment

1. The Agency shall develop a strategic **evidence-based** general **health** 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 and human rights**, safety and security and, through doing so, to help increase the preparedness of the relevant stakeholders to respond to new threats in **an efficient and** timely manner.

Or. en

Amendment 230

Assita Kanko

Proposal for a regulation

Article 12 – paragraph 1

Text proposed by the Commission

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

Amendment

1. The Agency shall develop a strategic **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, safety and security and, through doing so, to help increase the preparedness of the relevant stakeholders to respond to new threats in a timely and effective manner.

Or. en

Amendment 231

Romeo Franz

Proposal for a regulation

Article 12 – paragraph 2 – subparagraph 1

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 232

Romeo Franz

Proposal for a regulation

Article 12 – paragraph 2 – subparagraph 2

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 233

Romeo Franz

Proposal for a regulation

Article 12 – paragraph 4

Text proposed by the Commission

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

Amendment

4. The threat assessment report shall describe the identified threat, the current situation based on available evidence, the potential outcomes in the event of no action, and set out options for preparedness and response that may be adopted to mitigate ***and respond to*** the threat identified, ***including evidence-based interventions on demand and risk and harm reduction***. It may also contain potential follow-up measures to be adopted. The threat assessment report shall

be sent to the Commission and the Member States, as appropriate. ***Where appropriate or on request, the threat assessment report shall also be sent to the European Parliament.***

Or. en

Amendment 234
Konstantinos Arvanitis

Proposal for a regulation
Article 12 – paragraph 4

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 235
Assita Kanko

Proposal for a regulation
Article 12 – paragraph 5

Text proposed by the Commission

5. The Agency shall cooperate closely with other Union decentralised agencies and bodies, Union and international organisations in carrying out a threat

Amendment

5. The Agency shall cooperate closely ***with Member States and*** with other Union decentralised agencies and bodies, ***and*** Union and international organisations in

assessment by involving them in the assessment as appropriate. Where the potential threat is already subject to an analysis under another Union mechanism, the Agency shall not carry out a threat assessment.

carrying out a threat assessment by involving them in the assessment as appropriate. Where the potential threat is already subject to an analysis under another Union mechanism, the Agency shall not carry out a threat assessment.

Or. en

Amendment 236

Romeo Franz

Proposal for a regulation

Article 12 – paragraph 5

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 237

Konstantinos Arvanitis

Proposal for a regulation

Article 12 – paragraph 5

Text proposed by the Commission

5. The Agency shall cooperate closely with other Union ***decentralised*** agencies ***and bodies, Union*** and international organisations in carrying out a threat assessment by involving them in the assessment as appropriate. Where the potential threat is already subject to an analysis under another Union mechanism,

Amendment

5. The Agency shall cooperate closely with ***Member States,*** other Union ***bodies, offices and*** agencies and international organisations in carrying out a threat assessment by involving them in the assessment as appropriate. Where the potential threat is already subject to an analysis under another Union mechanism,

the Agency shall not carry out a threat assessment.

the Agency shall not carry out a threat assessment.

Or. en

Amendment 238

Romeo Franz

Proposal for a regulation

Article 12 – paragraph 6

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 239

Konstantinos Arvanitis

Proposal for a regulation

Article 12 – paragraph 6

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 240

Romeo Franz

Proposal for a regulation
Article 12 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

6 a. The Agency shall monitor new developments of the drugs phenomenon and, when needed, update threat assessments carried out in accordance with this Article.

Or. en

Amendment 241
Konstantinos Arvanitis

Proposal for a regulation
Article 12 – paragraph 6 a (new)

Text proposed by the Commission

Amendment

6 a. The Agency shall monitor the evolution of new developments of the drugs phenomenon as referred to in paragraph 1 and update the threat assessments accordingly.

Or. en

Amendment 242
Romeo Franz

Proposal for a regulation
Article 12 – paragraph 6 b (new)

Text proposed by the Commission

Amendment

6 b. Where appropriate, the Agency shall disseminate threat assessment reports to the relevant stakeholders, including the scientific community, healthcare professionals, civil society organisations and affected communities. Summaries of those reports shall be publicly available on the Agency's web portal.

Amendment 243

Romeo Franz

Proposal for a regulation

Article 13 – paragraph 2 – introductory part

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 244

Konstantinos Arvanitis

Proposal for a regulation

Article 13 – paragraph 2 – introductory part

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 245

Romeo Franz

Proposal for a regulation

Article 13 – paragraph 2 – point f a (new)

Text proposed by the Commission

Amendment

(f a) social and human rights risks,

Or. en

Amendment 246

Assita Kanko

Proposal for a regulation

Article 13 – paragraph 2 – point f a (new)

Text proposed by the Commission

Amendment

(f a) security risks

Or. en

Amendment 247

Konstantinos Arvanitis

Proposal for a regulation

Article 13 – paragraph 2 – point f a (new)

Text proposed by the Commission

Amendment

(f a) social risks;

Or. en

Amendment 248

Konstantinos Arvanitis

Proposal for a regulation

Article 13 – paragraph 2 – point f b (new)

Text proposed by the Commission

Amendment

(f b) security risks;

Amendment 249**Konstantinos Arvanitis****Proposal for a regulation****Article 13 – paragraph 3***Text proposed by the Commission*

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

Amendment

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

Or. en

Amendment 250**Romeo Franz****Proposal for a regulation****Article 13 – paragraph 3***Text proposed by the Commission*

3. The Agency shall analyse and assess the available information and data on potential serious risks to human health and complement it with any scientific and technical information it may have available from the early warning system referred to in Article 8 and other threat assessments

Amendment

3. The Agency shall analyse and assess the available information and data on potential serious risks to human health and complement it with any scientific and technical information it may have available from the early warning system referred to in Article 8 and other threat assessments

undertaken in accordance with Article 12, from other Union agencies and bodies and from international organisations, in particular the World Health Organisation. The Agency shall take into account information obtained through its data collection tools **and** from open source information.

undertaken in accordance with Article 12, from other Union agencies and bodies and from international organisations, in particular the World Health Organisation. The Agency shall take into account information obtained through its data collection tools, from open source information, **and via consultations with academia, civil society organisations and affected communities.**

Or. en

Amendment 251
Romeo Franz

Proposal for a regulation
Article 13 – paragraph 4

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 252
Romeo Franz

Proposal for a regulation
Article 13 – paragraph 8

Text proposed by the Commission

8. The Agency may develop an alert system through which it can directly reach

Amendment

8. The Agency, **in close cooperation with the relevant stakeholders, including**

and address people who use or potentially use drugs.

*the scientific community, civil society organisations and affected communities, and with the relevant national authorities, in particular the national focal points, may develop an alert system **to make information on a identified risk available** through which it can directly reach and address people who use or potentially use **particular drugs and relevant civil society organisations, where appropriate.***

Or. en

Amendment 253
Konstantinos Arvanitis

Proposal for a regulation
Article 13 – paragraph 8

Text proposed by the Commission

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

Amendment

8. ***In close cooperation with the relevant national authorities, in particular the national focal points, and with the relevant stakeholders, including the scientific community, civil society organisations and affected communities, the Agency shall develop an alert system to make information on identified risks available to people who use or potentially use particular drugs, where appropriate.***

Or. en

Amendment 254
Konstantinos Arvanitis

Proposal for a regulation
Article 15 – paragraph 2

Text proposed by the Commission

2. The network shall act primarily as a forum for generating data and information exchange on new developments and trends, organising training to enhance the

Amendment

2. The network shall act primarily as a forum for generating data and information exchange on new developments and trends, organising training to enhance the

competence of forensic drug experts, supporting the implementation of quality assurance schemes and supporting the further harmonisation of data collection and analytical methods.

competence of forensic drug **and toxicology** experts, supporting the implementation of quality assurance schemes and supporting the further harmonisation of data collection and analytical methods.

Or. en

Amendment 255

Romeo Franz

Proposal for a regulation

Article 15 – paragraph 2

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 256

Konstantinos Arvanitis

Proposal for a regulation

Article 15 – paragraph 3

Text proposed by the Commission

3. Each Member State shall **have the right to** appoint, through its representative in the Management Board, two laboratories, one specialising in forensic analysis and one specialising in toxicology, as national representative laboratories to the network. The Agency may select additional laboratories or experts

Amendment

3. Each Member State shall appoint, through its representative in the Management Board, two laboratories, one specialising in forensic analysis and one specialising in toxicology, as national representative laboratories to the network. The Agency may select additional laboratories or experts particularly active in

particularly active in the forensic and toxicological investigations of drugs and drug-related harms for specific projects.

the forensic and toxicological investigations of drugs and drug-related harms for specific projects.

Or. en

Amendment 257

Konstantinos Arvanitis

Proposal for a regulation

Article 15 – paragraph 5

Text proposed by the Commission

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

Amendment

5. The network shall closely cooperate with existing networks and organisations active in this area ***and shall take into account their work in order to avoid overlaps***. The network referred to in Article 31 shall ***in that respect be considered a strategic partner and shall*** be informed regularly, ***and at least twice a year***, about the work of the network of forensic and toxicological laboratories.

Or. en

Amendment 258

Romeo Franz

Proposal for a regulation

Article 15 – paragraph 5

Text proposed by the Commission

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

Amendment

5. The network shall closely cooperate with existing networks and organisations active in this area ***and shall take into account their work in order to avoid overlaps***. The network referred to in Article 31 shall be informed regularly, ***and at least once a year***, about the work of the network of forensic and toxicological laboratories.

Or. en

Amendment 259

Romeo Franz

Proposal for a regulation

Article 15 – paragraph 9

Text proposed by the Commission

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

Amendment

9. The Agency shall create a database to store, analyse and make available the information and data collected or generated by the network. ***The database of the Agency shall not contain any personal data.***

Or. en

Amendment 260

Romeo Franz

Proposal for a regulation

Article 16 – title

Text proposed by the Commission

Prevention campaigns

Amendment

Evidence-based interventions, best practices and awareness raising

Or. en

Amendment 261

Konstantinos Arvanitis

Proposal for a regulation

Article 16 – title

Text proposed by the Commission

Prevention campaigns

Amendment

Evidence-based interventions, best practices and awareness raising

Or. en

Amendment 262
Konstantinos Arvanitis

Proposal for a regulation
Article 16 – paragraph 1

Text proposed by the Commission

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

Amendment

1. The Agency shall develop and promote ***evidence-based interventions and best practices on prevention, risk and harm reduction, abstinence-based recovery, treatment, care and rehabilitation and*** awareness ***raising*** of the adverse effects of drugs. ***Such interventions, best practices and awareness raising shall be encouraged at the national context, implemented at the national level and targeted at specific groups.***

Or. en

Amendment 263
Romeo Franz

Proposal for a regulation
Article 16 – paragraph 1

Text proposed by the Commission

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

Amendment

1. The Agency shall design, develop and promote ***scientific, evidence-based and gender-sensitive interventions and best practices and raise*** awareness ***about prevention, risk and harm reduction, treatment, care, rehabilitation and recovery and*** the adverse effects of drugs.

Or. en

Amendment 264
Romeo Franz

Proposal for a regulation
Article 16 – paragraph 2

Text proposed by the Commission

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

Amendment

2. The ***interventions, best practices and awareness raising*** referred to in paragraph 1 shall be in line with ***the Union's international human rights obligations and*** the political orientations set out in the applicable EU Drugs Strategy and Action Plan. They shall ***ensure a balanced approach to demand reduction and harm reduction interventions, shall be adapted to the national context where necessary, shall be implemented at the national level, and may*** be targeted to specific groups.

Or. en

Amendment 265
Konstantinos Arvanitis

Proposal for a regulation
Article 16 – paragraph 2

Text proposed by the Commission

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

Amendment

2. The ***interventions, best practices and awareness raising*** referred to in paragraph 1 shall be in line with the political orientations set out in the applicable EU Drugs Strategy and Action Plan ***and shall ensure a balanced approach to demand reduction, harm reduction and abstinence-based recovery interventions.***

Or. en

Amendment 266
Konstantinos Arvanitis

Proposal for a regulation
Article 16 – paragraph 3

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 267

Romeo Franz

**Proposal for a regulation
Article 16 – paragraph 3**

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 268

Romeo Franz

**Proposal for a regulation
Article 16 – paragraph 4**

Text proposed by the Commission

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

Amendment

4. The Agency shall assist Member States in developing national ***gender-sensitive interventions*** in the area of its mandate, including ***in relation to the prevention of drug use and the related impact on health as well as the prevention of the exploitation of vulnerable***

within the drug market.

individuals within the drug market. ***Such interventions shall be tailored to the needs of individuals and affected communities.***

Or. en

Amendment 269

Konstantinos Arvanitis

Proposal for a regulation

Article 16 – paragraph 4

Text proposed by the Commission

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

Amendment

4. The Agency shall assist Member States in developing national ***interventions*** in the area of its mandate, including ***in relation to the prevention of drug use and the related impact on health***, drug-related criminality, and vulnerable ***groups or*** individuals.

Or. en

Amendment 270

Romeo Franz

Proposal for a regulation

Article 17 – paragraph 3 – subparagraph 2 – point b

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 271
Romeo Franz

Proposal for a regulation
Article 18 – paragraph 2

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 272
Konstantinos Arvanitis

Proposal for a regulation
Article 18 – paragraph 2

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 273
Konstantinos Arvanitis

Proposal for a regulation
Article 18 – paragraph 3

Text proposed by the Commission

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

Amendment

3. In supporting policy evaluation, the Agency shall act independently and shall be guided by its scientific standards *and an evidence-based approach*.

Amendment 274

Romeo Franz

Proposal for a regulation

Article 18 – paragraph 3

Text proposed by the Commission

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

Amendment

3. In supporting policy evaluation, the Agency shall act independently and shall be guided by its scientific standards ***and an evidence-based approach.***

Or. en

Amendment 275

Romeo Franz

Proposal for a regulation

Article 19 – paragraph 1 – introductory part

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 276

Konstantinos Arvanitis

Proposal for a regulation

Article 19 – paragraph 1 – introductory part

Text proposed by the Commission

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

Amendment

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

decentralised agencies and bodies:

Or. en

Amendment 277

Ramona Strugariu, Fabienne Keller, Olivier Chastel, Hilde Vautmans, Maite Pagazaurtundúa, Michal Šimečka, Malik Azmani

Proposal for a regulation

Article 20 – paragraph 1 – point b

Text proposed by the Commission

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

Amendment

(b) cooperate actively with the organisations and bodies referred to in Article 53 **and 55**;

Or. en

Amendment 278

Konstantinos Arvanitis

Proposal for a regulation

Article 20 – paragraph 1 – point f

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 279

Romeo Franz

Proposal for a regulation
Article 20 – paragraph 1 – point f

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 280

Ramona Strugariu, Fabienne Keller, Olivier Chastel, Hilde Vautmans, Maite Pagazaurtundúa, Michal Šimečka

Proposal for a regulation
Article 20 – paragraph 1 – point h

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 281

Tomáš Zdechovský

Proposal for a regulation
Article 20 – paragraph 1 – point h a (new)

Text proposed by the Commission

Amendment

(h a) as far as possible, and acting

within its mandate, provide data, analysis, and best practices to, and share the latest evidence-based policy recommendations with, the European Commission and the Member States, in as so far such date, analysis, best practices and policy recommendations concern European and national policies which address the phenomenon of addictions.

Or. en

Justification

Following the COVID-19 pandemic, there is a sharp increase observed in the number of European citizens struggling with various forms of addictions. To that end, European and Member States' cooperation on the topic of addictions is crucial going forward. With the expertise at the disposal of the EMCDDA, and with the strengthened mandate of the Agency in the future, the entity is well-placed to be involved on a more regular basis in general discussions at the EU and Member State level concerning the phenomenon of addictions. The Agency is well-positioned to when needed and when possible, offer its views and expertise on topics concerning addictions in general.

Amendment 282

Konstantinos Arvanitis

Proposal for a regulation

Article 20 – paragraph 2

Text proposed by the Commission

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

Amendment

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

activities undertaken by the Member States. The Agency shall evaluate and review the international cooperation framework regularly.

Or. en

Amendment 283
Romeo Franz

Proposal for a regulation
Article 20 – paragraph 2

Text proposed by the Commission

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

Amendment

2. The international cooperation framework referred to in paragraph 1, point (a), shall take into account the relevant policy documents of the Union and consider the developments of the drug phenomenon. It shall set out the priority countries or regions for cooperation and the key outcomes of the cooperation. The ***international cooperation framework shall also seek to support third countries' efforts to address drug issues in an evidence-based, integrated, balanced and multidisciplinary manner that is in full compliance with the Sustainable Development Goals and international human rights obligations and committed to gender equality.*** The Agency shall evaluate and review the international cooperation framework regularly.

Or. en

Amendment 284
Ramona Strugariu, Fabienne Keller, Olivier Chastel, Hilde Vautmans, Maite Pagazaurtundúa, Michal Šimečka, Malik Azmani

Proposal for a regulation
Article 20 – paragraph 2

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 285

Ramona Strugariu, Fabienne Keller, Olivier Chastel, Hilde Vautmans, Maite Pagazaurtundúa, Michal Šimečka

Proposal for a regulation

Article 20 – paragraph 3 – subparagraph 1

Text proposed by the Commission

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

Amendment

The Agency shall transfer, at the request of the Commission and with the approval of the Management Board, its know-how and provide technical assistance to third countries, ***in particular candidate and potential candidate countries, as well as the countries covered by the European Neighbourhood Policy.***

Or. en

Amendment 286

Konstantinos Arvanitis

Proposal for a regulation

Article 20 – paragraph 3 – subparagraph 2

Text proposed by the Commission

Technical assistance shall focus in particular on setting up or consolidating national focal points, national data

Amendment

Technical assistance shall focus in particular on setting up or consolidating national focal points, national data

collection systems and national early warning systems, and subsequently assist the creation and strengthening of structural links with the early warning system referred to in Article 8 and the network referred to in Article 31. If the third country so requests, the Agency may provide a certification for these national bodies.

collection systems and national early warning systems ***and the promotion of best practices in the field of prevention, risk and harm reduction, abstinence-based recovery, treatment, care and rehabilitation***, and subsequently assist the creation and strengthening of structural links with the early warning system referred to in Article 8 and the network referred to in Article 31. If the third country so requests, the Agency may provide a certification for these national bodies.

Or. en

Amendment 287

Romeo Franz

Proposal for a regulation

Article 20 – paragraph 3 – subparagraph 2

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 288

Ramona Strugariu, Fabienne Keller, Olivier Chastel, Hilde Vautmans, Maite Pagazaurtundúa, Michal Šimečka, Malik Azmani

Proposal for a regulation
Article 20 – paragraph 4

Text proposed by the Commission

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

Amendment

4. Cooperation with third countries and with international organisations shall be carried out in accordance with Articles 53, *54 and 55*.

Or. en

Amendment 289
Konstantinos Arvanitis

Proposal for a regulation
Article 21 – paragraph 1

Text proposed by the Commission

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

Amendment

1. The Agency shall assist the Commission and the Member States in identifying key research themes, drawing up and implementing the Union framework programmes for research and innovation activities that are relevant to achieve its general task set out in Article 4. ***In doing so, the Agency shall pay due attention to the gender dimension and apply intersectionality as a horizontal principle.*** Where the Agency assists the Commission in identifying key research themes, drawing up and implementing a Union framework programme, the Agency shall not receive funding from that programme.

Or. en

Amendment 290
Romeo Franz

Proposal for a regulation
Article 21 – paragraph 2

Text proposed by the Commission

Amendment

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

2. The Agency shall proactively monitor and contribute to research and innovation activities to achieve its general task set out in Article 4, support related activities of Member States, and implement its research and innovation activities regarding matters covered by this Regulation, ***while ensuring full compliance with fundamental rights, data protection, transparency and conflict of interest rules.*** The Agency shall disseminate the results of that research to the European Parliament, to the Member States and to the Commission in accordance with Article 49.

Or. en

Amendment 291
Romeo Franz

Proposal for a regulation
Article 21 – paragraph 5

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 292
Romeo Franz

Proposal for a regulation
Article 21 – paragraph 6

Text proposed by the Commission

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

Amendment

6. The Agency shall create a database to store, analyse and make available drug-related research programmes. ***The database shall not contain any personal***

data.

Or. en

Amendment 293

Romeo Franz

Proposal for a regulation

Article 22 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

The members of the Agency's administrative and management structure shall not have any financial or other interests that could affect their impartiality. They shall act in the public interest and carry out their activities in an independent, impartial and transparent manner, and shall make an annual declaration of their financial interests. All indirect interests which could affect their impartiality, including in the pharmaceutical industry, shall be entered in a register that is held by the Agency and accessible to the public upon request.

Or. en

Amendment 294

Konstantinos Arvanitis

Proposal for a regulation

Article 23 – paragraph 2 – point a

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 295

Ramona Strugariu, Fabienne Keller, Olivier Chastel, Hilde Vautmans, Maite Pagazaurtundúa, Michal Šimečka, Malik Azmani

Proposal for a regulation

Article 23 – paragraph 2 – point a

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 296

Romeo Franz

Proposal for a regulation

Article 23 – paragraph 2 – point a

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 297

Konstantinos Arvanitis

Proposal for a regulation

Article 23 – paragraph 3

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 298

Romeo Franz

Proposal for a regulation

Article 23 – paragraph 3

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 299

Ramona Strugariu, Fabienne Keller, Olivier Chastel, Hilde Vautmans, Maite Pagazaurtundúa, Michal Šimečka, Malik Azmani

Proposal for a regulation

Article 23 – paragraph 4

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 300

Romeo Franz

**Proposal for a regulation
Article 23 – paragraph 4**

Text proposed by the Commission

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

Amendment

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

Or. en

**Amendment 301
Romeo Franz**

**Proposal for a regulation
Article 23 – paragraph 5**

Text proposed by the Commission

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

Amendment

5. The Management Board may invite, as observers, representatives of international organisations with which the Agency cooperates in accordance with Article 53, ***as well as representatives from relevant civil society organisations***.

Or. en

**Amendment 302
Romeo Franz**

**Proposal for a regulation
Article 23 – paragraph 6**

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 303

Romeo Franz

Proposal for a regulation

Article 24 – paragraph 1 – point i

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 304

Romeo Franz

Proposal for a regulation

Article 24 – paragraph 1 – point l

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 305
Romeo Franz

Proposal for a regulation
Article 24 – paragraph 1 – point t

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 306
Konstantinos Arvanitis

Proposal for a regulation
Article 24 – paragraph 1 – point t

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 307
Romeo Franz

Proposal for a regulation
Article 28 – paragraph 2

Text proposed by the Commission

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

Amendment

2. Where necessary, because of urgency, the Executive Board may take certain provisional decisions instead of the Management Board, in particular on administrative management matters, including the suspension of the delegation of the appointing authority powers and budgetary matters. ***The conditions for doing so shall be set out in the rules of procedure of the Management Board. The***

rules of procedure of the Management Board shall be made public.

Or. en

Amendment 308

Romeo Franz

Proposal for a regulation

Article 28 – paragraph 4

Text proposed by the Commission

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

Amendment

4. The term of office of members of the Executive Board shall be four years ***with the possibility to be renewed once***. The term of office of members of the Executive Board shall end when their membership of the Management Board ends.

Or. en

Amendment 309

Tomáš Zdechovský

Proposal for a regulation

Article 29 – paragraph 5 – point g

Text proposed by the Commission

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

Amendment

deleted

Or. en

Justification

Please see justification of amendment to Article 37.

Amendment 310

Romeo Franz

Proposal for a regulation

Article 29 – paragraph 5 – point i

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 311

Konstantinos Arvanitis

Proposal for a regulation

Article 29 – paragraph 5 – point i

Text proposed by the Commission

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

Amendment

(i) protecting the financial interests of the Union by applying preventive measures against fraud, corruption and any other illegal activities, without prejudicing the investigative competence of OLAF and EPPO, by effective checks and, if irregularities are detected, by recovering amounts wrongly paid and, where appropriate, by imposing effective, proportionate and dissuasive administrative, including financial penalties, ***and by reporting to the EPPO any criminal conduct in respect of which the EPPO could exercise its competence in accordance with Article 24 of***

Amendment 312
Konstantinos Arvanitis

Proposal for a regulation
Article 29 – paragraph 6

Text proposed by the Commission

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

Amendment

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

Amendment 313
Isabel Santos

Proposal for a regulation
Article 29 – paragraph 6

Text proposed by the Commission

6. The Executive Director ***shall*** decide ***whether it is necessary to locate*** one or more ***staff in one or more Member***

Amendment

6. The Executive Director ***may*** decide ***to post*** one or more ***liaison officers at the Union institutions and at relevant Union***

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

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

Or. en

Amendment 314 **Romeo Franz**

Proposal for a regulation **Article 29 – paragraph 6**

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 315

Konstantinos Arvanitis

Proposal for a regulation
Article 30 – paragraph 1

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 316
Romeo Franz

Proposal for a regulation
Article 30 – paragraph 1

Text proposed by the Commission

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

Amendment

1. The Scientific Committee shall consist of at most fifteen scientists appointed by the Management Board in view of their scientific excellence and their independence, following the publication of a call for expression of interest in the Official Journal of the European Union ***and after the approval of the European Parliament. Gender-balance shall be ensured in that appointment.*** The selection procedure shall ensure that the specialist fields of the members of the Scientific Committee cover the most

relevant fields linked to the objectives of the Agency.

Or. en

Amendment 317

Konstantinos Arvanitis

Proposal for a regulation

Article 33 – paragraph 2 – point a a (new)

Text proposed by the Commission

Amendment

(a a) depending on their capacity, monitor, analyse and interpret relevant information in the areas covered by Article 4 and provide information on the policies and solutions applied;

Or. en

Amendment 318

Konstantinos Arvanitis

Proposal for a regulation

Article 33 – paragraph 2 – point d

Text proposed by the Commission

Amendment

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

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

Amendment 319

Romeo Franz

Proposal for a regulation

Article 33 – paragraph 2 – point d

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 320

Konstantinos Arvanitis

Proposal for a regulation

Article 33 – paragraph 2 – point h

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 321

Assita Kanko

Proposal for a regulation

Article 33 – paragraph 2 – point h a (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 322

Romeo Franz

Proposal for a regulation

Article 33 – paragraph 3

Text proposed by the Commission

Amendment

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

3. The national focal point shall **establish the necessary cooperation with relevant national and regional** authorities, bodies, agencies and organisations **for the collection of** information it needs to carry out its tasks in accordance with paragraph 2. The national focal point shall maintain an extensive network of national partners and data providers for the collection of such information.

Or. en

Amendment 323

Konstantinos Arvanitis

Proposal for a regulation

Article 33 – paragraph 3

Text proposed by the Commission

Amendment

3. The national focal point shall have

3. The national focal point shall have

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

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

Or. en

Amendment 324
Konstantinos Arvanitis

Proposal for a regulation
Article 33 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

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

Or. en

Amendment 325
Romeo Franz

Proposal for a regulation
Article 33 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. When collecting data pursuant to this Article, the national focal points shall ensure, where possible, that the data

collected is disaggregated by gender. The national focal points shall take into account gender-sensitive and intersectional aspects of drugs policy when collecting and presenting data pursuant to this Article. The national focal points shall not transmit any personal data or any data making it possible to identify individuals or groups of individuals.

Or. en

Amendment 326

Ramona Strugariu, Fabienne Keller, Olivier Chastel, Hilde Vautmans, Maite Pagazaurtundúa, Michal Šimečka, Malik Azmani

Proposal for a regulation Article 36 – paragraph 2

Text proposed by the Commission

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

Amendment

2. The Agency's budget shall be balanced in terms of revenue and of expenditure. *The Agency's budget shall be adequate to ensure sufficient staff and equipment in order to allow it to achieve its objectives and tasks as set by this Regulation.*

Or. en

Amendment 327

Tomáš Zdechovský

Proposal for a regulation Article 36 – paragraph 3 – point c

Text proposed by the Commission

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

Amendment

deleted

Or. en

Justification

Please see justification of amendment to Article 37.

Amendment 328

Isabel Santos

Proposal for a regulation

Article 36 – paragraph 3 – point c

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 329

Isabel Santos

Proposal for a regulation

Article 36 – paragraph 3 – point d

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 330

Isabel Santos

Proposal for a regulation

Article 36 – paragraph 3 – point d a (new)

Text proposed by the Commission

Amendment

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

supporting the policies of the Union;

Or. en

Amendment 331
Tomáš Zdechovský

Proposal for a regulation
Article 37

Text proposed by the Commission

Amendment

Article 37

deleted

Fees

1. The Agency may charge fees for the following:

(a) training programmes;

(b) certain support activities for Member States that have not been identified as a priority but could be beneficially conducted if supported by national resources;

(c) capacity-building programmes for third countries, which are not covered by separate dedicated Union funding;

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

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

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

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

administrative burden on stakeholders.

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

Or. en

Justification

The Commission proposes to enable the Agency to charge fees for "non-core services" (e.g. training and expertise provided to third countries etc.). This is a slightly unusual model as fee-charging agencies typically charge fees for core services (e.g. EMA licences, EBA supervisory services) and so the fee-based revenue becomes part of the agencies' core revenue stream, alongside the EU budget. Here, the idea is to enable EUDA to earn additional revenue in exchange for additional services, meaning it does not really ease pressure on the EU budget. Also, it is questionable how much resources (especially staff) would be used for these additional tasks – that would then be away from the core services the Agency is meant to provide. The proposed text lacks enough transparency and does not give the Parliament sufficient scrutiny over these non-core services, despite its key role in controlling the activities and budget of EU agencies. Should such proposal remain in a certain form, the Parliament should gain control over the process and ensure greater clarity, reporting and transparency.

Amendment 332

Konstantinos Arvanitis

Proposal for a regulation

Article 37 – paragraph 1 – introductory part

Text proposed by the Commission

1. The Agency may charge fees for the following:

Amendment

1. The Agency may charge ***third countries*** fees for the following:

Or. en

Amendment 333

Romeo Franz

Proposal for a regulation

Article 37 – paragraph 1 – point a

Text proposed by the Commission

Amendment

(a) training *programmes*;

(a) training *pursuant to Article 19*;

Or. en

Amendment 334

Konstantinos Arvanitis

Proposal for a regulation

Article 37 – paragraph 1 – point a

Text proposed by the Commission

Amendment

(a) training *programmes*;

(a) training *pursuant to Article 19*;

Or. en

Amendment 335

Konstantinos Arvanitis

Proposal for a regulation

Article 37 – paragraph 1 – point b

Text proposed by the Commission

Amendment

(b) *certain support activities for Member States that have not been identified as a priority but could be beneficially conducted if supported by national resources*;

deleted

Or. en

Amendment 336

Romeo Franz

Proposal for a regulation

Article 37 – paragraph 1 – point b

Text proposed by the Commission

(b) **certain** support activities for Member States that have not been identified as a priority but could be beneficially conducted if supported by national resources;

Amendment

(b) **necessary and duly justified** support activities for Member States that have not been identified as a priority but could be beneficially conducted if supported by national resources;

Or. en

Amendment 337

Ramona Strugariu, Fabienne Keller, Olivier Chastel, Hilde Vautmans, Maite Pagazaurtundúa, Michal Šimečka

Proposal for a regulation

Article 37 – paragraph 1 – point d

Text proposed by the Commission

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

Amendment

(d) certification of national bodies set up in third countries, **in particular candidate countries**, pursuant to Article 20(3);

Or. en

Amendment 338

Ramona Strugariu, Fabienne Keller, Olivier Chastel, Hilde Vautmans, Maite Pagazaurtundúa, Michal Šimečka, Malik Azmani

Proposal for a regulation

Article 37 – paragraph 1 – point e

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 339
Konstantinos Arvanitis

Proposal for a regulation
Article 37 – paragraph 1 – point e

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 340
Ramona Strugariu, Fabienne Keller, Olivier Chastel, Hilde Vautmans, Maite Pagazaurtundúa, Michal Šimečka, Malik Azmani

Proposal for a regulation
Article 37 – paragraph 2

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 341
Romeo Franz

Proposal for a regulation
Article 37 – paragraph 2

Text proposed by the Commission

2. At the proposal of the Executive Director, the Management Board of the Agency shall set the amount of the fees and

Amendment

2. At the proposal of the Executive Director, the Management Board of the Agency shall **in a transparent manner** set the amount of the fees and the way in

the way in which they are paid.

which they are paid.

Or. en

Amendment 342

Konstantinos Arvanitis

Proposal for a regulation

Article 37 – paragraph 2

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 343

Konstantinos Arvanitis

Proposal for a regulation

Article 37 – paragraph 4

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 344

Romeo Franz

**Proposal for a regulation
Article 37 – paragraph 4**

Text proposed by the Commission

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

Amendment

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

Or. en

**Amendment 345
Isabel Santos**

**Proposal for a regulation
Article 38 – paragraph 8**

Text proposed by the Commission

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

Amendment

8. The Management Board ***shall adopt the Agency's budget.*** It shall become final following final adoption of the general budget of the European Union. Where necessary, it shall be adjusted accordingly.

Or. en

**Amendment 346
Isabel Santos**

**Proposal for a regulation
Article 38 – paragraph 9**

Text proposed by the Commission

9. For any building project likely to have significant implications for the budget of the Agency, the provisions of Delegated Regulation (EU) 2019/715⁶⁶ apply.

⁶⁶ OJ L 122, 10.5.2019, p. 1.

Amendment

9. For any building project likely to have significant implications for the budget of the Agency, the provisions of ***the Commission*** Delegated Regulation (EU) 2019/715⁶⁶ apply.

⁶⁶ OJ L 122, 10.5.2019, p. 1.

Or. en

Amendment 347

Romeo Franz

Proposal for a regulation

Article 43 – paragraph 2

Text proposed by the Commission

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

Amendment

2. The Executive Director shall be appointed by the Management Board, from a ***gender-balanced*** list of candidates proposed by the Commission, following an open and transparent selection procedure ***and with prior approval by the European Parliament. Before that approval, the candidate selected by the Management Board for the post of Executive Director shall be heard by the competent committee(s) of the European Parliament. Where the European Parliament is of the opinion that the selected candidate does not sufficiently fulfil the requirements for the post, the open selection procedure shall recommence.***

Or. en

Amendment 348

Konstantinos Arvanitis

Proposal for a regulation

Article 43 – paragraph 2

Text proposed by the Commission

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

Amendment

2. The Executive Director shall be appointed by the Management Board, from a list of candidates proposed by the Commission, following an open and transparent selection procedure. ***Before appointment to a first term, the candidate selected by the Management Board for the post of Executive Director shall be invited, without delay, to make a statement before the European Parliament and answer questions put by its Members.***

Or. en

Amendment 349

Ramona Strugariu, Fabienne Keller, Olivier Chastel, Hilde Vautmans, Maite Pagazaurtundúa, Michal Šimečka, Malik Azmani

**Proposal for a regulation
Article 43 – paragraph 2**

Text proposed by the Commission

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

Amendment

2. The Executive Director ***shall be selected on the grounds of merit and documented high-level administrative, budgetary and management skills and*** shall be appointed by the Management Board, ***with the prior approval by the European Parliament***, from a list of candidates proposed by the Commission, following an open and transparent selection procedure, ***which shall respect the principle of gender balance.***

Or. en

Amendment 350

Romeo Franz

**Proposal for a regulation
Article 43 – paragraph 5**

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 351

Romeo Franz

Proposal for a regulation
Article 43 – paragraph 7

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 352

Romeo Franz

Proposal for a regulation
Article 47 – paragraph 3

Text proposed by the Commission

3. The Management Board shall, within six months of the date of its first meeting following the date of application of this Regulation, as referred to in Article 63, second subparagraph, establish measures for the application of Regulation (EU) 2018/1725 by the Agency, including those concerning the appointment of a Data Protection Officer of the Agency. Those measures shall be established after

Amendment

3. The Management Board shall, within six months of the date of its first meeting following the date of application of this Regulation, as referred to in Article 63, second subparagraph, establish measures for the application of Regulation (EU) 2018/1725 by the Agency, including those concerning the appointment of a Data Protection Officer of the Agency. Those measures shall be established after

consultation of the European Data
Protection Supervisor.

consultation of the European Data
Protection Supervisor ***and shall be made
public.***

Or. en

Amendment 353

Romeo Franz

Proposal for a regulation

Article 48 – paragraph 2

Text proposed by the Commission

2. The Agency shall accede to the Interinstitutional Agreement of 25 May 1999 concerning internal investigations by the OLAF ***by six months*** from the day this Regulation comes into force, and shall adopt appropriate provisions applicable to all employees of the Agency using the template set out in the Annex to that Agreement.

Amendment

2. The Agency shall accede to the Interinstitutional Agreement of 25 May 1999 concerning internal investigations by the OLAF from the day this Regulation comes into force, and shall adopt appropriate provisions applicable to all employees of the Agency using the template set out in the Annex to that Agreement.

Or. en

Amendment 354

Romeo Franz

Proposal for a regulation

Article 53 – paragraph 3 a (new)

Text proposed by the Commission

Amendment

3 a. Working arrangements entered into pursuant to this Article shall be made public on the Agency's website.

Or. en

Amendment 355

Romeo Franz

Proposal for a regulation

Article 54 – paragraph 1

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 356

Romeo Franz

Proposal for a regulation

Article 54 – paragraph 2 – subparagraph 1

Text proposed by the Commission

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

Amendment

Under the relevant provisions of the agreements referred to in paragraph 1, arrangements shall be developed specifying, in particular, the nature, extent and manner in which the third countries concerned are to participate in the work of the Agency, including provisions relating to participation in the initiatives undertaken by the Agency, financial contributions and ***their purposes, and staff. The arrangements shall ensure compliance with fundamental rights, data protection, transparency and conflict of interests rules.***

Or. en

Amendment 357

Romeo Franz

Proposal for a regulation

Article 54 – paragraph 2 – subparagraph 2

Text proposed by the Commission

As regards staff matters, those working arrangements shall, in any event, comply

Amendment

As regards staff matters, those working arrangements shall, in any event, comply

with the Staff Regulations.

with the Staff Regulations ***and shall be made public.***

Or. en

Amendment 358

Romeo Franz

Proposal for a regulation

Article 55 – paragraph 1

Text proposed by the Commission

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

Amendment

1. The Agency shall maintain a structured and close dialogue with relevant civil society organisations active in the fields covered by this Regulation at national, Union or international level. To that end, the Agency shall create an adequately funded mechanism for the systematic, regular and extensive consultation and exchange of information with civil society and community organisations working within the scope of the Agency's mandate. The mechanism shall be open to all interested and qualified stakeholders, including the EU Civil Society Forum on Drugs.

1a. The Agency shall appoint a focal point to manage the structured and close dialogue referred to in paragraph 1 under the authority of the Executive Director.

A representative selected by the EU Civil Society Forum on Drugs shall attend the sessions of the Management Board as an observer.

The names and the declared conflict of interests of stakeholders involved in the work of the Agency shall be made public on the website of the Agency.

Or. en

Amendment 359

Konstantinos Arvanitis

Proposal for a regulation
Article 55 – paragraph 1

Text proposed by the Commission

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

Amendment

The Agency shall maintain a ***structured*** dialogue with relevant civil society organisations active in the fields covered by this Regulation at national, Union or international level ***for the regular and extensive consultation and exchange of information with civil society organisations. The Agency shall appoint a focal point to manage that structured dialogue, under the authority of the Executive Director.***

Or. en

Amendment 360

Ramona Strugariu, Fabienne Keller, Olivier Chastel, Hilde Vautmans, Maite Pagazaurtundúa, Michal Šimečka, Malik Azmani

Proposal for a regulation
Article 55 – paragraph 1

Text proposed by the Commission

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

Amendment

The Agency shall ***closely cooperate with experts on the ground and non-governmental and*** with relevant civil society organisations active in the fields covered by this Regulation at national, Union or international level.

Or. en

Amendment 361

Konstantinos Arvanitis

Proposal for a regulation
Article 55 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

The structured dialogue referred to in the first paragraph shall be open to all interested and qualified stakeholders, and it shall include the EU Civil Society Forum on Drugs. To that end, appropriate and sustainable financial means and reinforced administrative support shall be made available to the EU Civil Society Forum on Drugs.

Or. en