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From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
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To:	Mr Jeppe TRANHOLM-MIKKELSEN, Secretary-General of the Council of the European Union
No. Cion doc.:	SWD(2022) 9 final
Subject:	COMMISSION STAFF WORKING DOCUMENT EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT Accompanying the document Proposal for a Regulation of the European Parliament and of the Council on the European Union Drugs Agency

Delegations will find attached document SWD(2022) 9 final.

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COMMISSION STAFF WORKING DOCUMENT

EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT REPORT

Accompanying the document

Proposal for a Regulation of the European Parliament and of the Council

on the European Union Drugs Agency

{COM(2022) 18 final} - {SWD(2022) 8 final}

Executive Summary Sheet
Impact assessment on a proposal for a Regulation on the European Union Drugs Agency (revision of the mandate of the European Monitoring Centre for Drugs and Drug Addiction, i.e. of Regulation (EC) 1920/2006)

A. Need for action
Why? What is the problem being addressed?
The European Monitoring Centre for Drugs and Drug Addiction ('the Agency') was founded in 1993, with its founding Regulation recast in 2006 (Regulation (EC) 1920/2006). In 2018/19, the Commission carried out the latest evaluation (COM(2020) 228). The problem definition builds on the outcomes of the evaluation and addresses shortcomings raised by the Agency's main stakeholders. Whereas 25 years ago it was necessary to collect and analyse data to describe the drugs situation in Europe and its consequences, nowadays stakeholders need also real-time analysis about emerging challenges and advice on the best ways to address the fast evolving threats, such as new psychoactive substances entering the EU, which are more dangerous to (public) health and create also new security concerns. Policy-makers need more support and information to take informed choices and provide adequate responses. The Agency cannot provide sufficient support to Member States and the network of national focal points of the Agency (Reitox) is not used to its full potential. Finally, the international dimension of the Agency's work is insufficiently defined. For the implementation of the new EU Drugs Strategy 2021-2025, which takes an evidence-based approach to drugs policy, the information provided by the Agency is crucial.
What is this initiative expected to achieve?
The general objective of the initiative is to make sure that the Agency is fit for purpose and is appropriately equipped to deal with the challenges posed by drugs in the EU, leading to appropriate action and support by the EU and the Member States. The proposed revision of the mandate would be a targeted one. It should clarify the Agency's mandate as regards its scope of action (in particular the substances to address); increase its capacity to react faster and in a more targeted way to challenges and emerging threats; deepen the monitoring and analysis of the drug phenomenon; provide support to Member States; and clarify the international dimension of the work of the Agency.
What is the value added of action at the EU level?
The drug phenomenon is affecting all Europeans and is cross-border, and global, in nature. There are many common challenges, which apply across Member States, both on the drug demand and supply side. It is not possible to address the drug phenomenon only on a national level, as such an approach would lead to a fragmentation and Member States learn from each other by sharing experiences and best practices. EU action provides for an effective and efficient way to address these issues.
B. Solutions
What legislative and non-legislative policy options have been considered? Is there a preferred choice or not? Why?
The non-legislative policy option (further co-operation) and the dismantling or merging of the Agency were discarded from further analysis, as they would not address the problems identified. The preferred option is a targeted revision of the mandate. To address the request of some stakeholders to widen the scope of the Agency to other addictions, the question was analysed, but the impact assessment concluded that the Agency's main focus should remain on illicit drugs. However, poly-substance use should be better addressed. Drug supply and the drug markets should also be in the thematic scope of action of the Agency. In order to provide a more agile and

forward-looking analysis, the monitoring and threat assessment capabilities of the Agency should be further developed. To inform the public quickly and alert about threats present in several Member States, the Agency should support the development or develop itself information campaigns and EU-level alerts. In order to increase the Agency's information base, a specialist network of laboratories should be set up. The mandate of the national focal points should be strengthened to better use their capacities in support of the Agency and to mirror the changes to be introduced to the mandate of the Agency. Finally, the international dimension of the work of the Agency should be better clarified.

Who supports which option?

Main stakeholders, i.e. national and European policy-makers on drugs policy support – and even request – a strengthening of the Agency mandate. The new EU Drugs Strategy, adopted by the Council in December 2020, explicitly invites the Commission to present a proposal to revise the mandate as soon as possible. Some Member States having wider addiction strategies would like a broader mandate for the Agency. Other Member States have a drugs-only framework and would be happy with the current mandate accompanied by a clarification on poly-drug use. Setting minimum criteria for the national focal points might also be contentious with some Member States as they might consider it interfering with their prerogatives. However, these criteria would be needed to ensure a level playing field across Europe and ensure data provision to the Agency.

C. Impacts of the preferred option

What are the benefits of the preferred options (if any, otherwise main ones)?

The preferred option would contribute to better informed policies and actions; this would lead to more effective European (and national) responses to the drug phenomenon in the EU. This would be a major contribution for an effective and evidence-based response to the drugs phenomenon, both from a health and a security perspective. The mandate of the Agency would remain focussed mainly on monitoring, supporting the EU and its Member States, in line with the subsidiarity principle. Such a targeted revision of the Agency mandate would lead to better preparedness on European and national level as regards the growing new threats in the drugs area.

What are the costs of the preferred options (if any, otherwise main ones)?

The preferred option would require the reinforcement of the financial and human resources compared to the resources earmarked in the Multiannual Financial Framework (MFF) 2021-2027. It is estimated that an additional budget of around EUR 51 to 63 million and around 40 additional establishment posts would be needed for the new MFF period.

How will businesses, SMEs and micro-enterprises be affected?

There will be no direct impacts on businesses, SMEs and micro-enterprises. The revision might have positive indirect impacts through limiting the loss of manpower in the economy due to drug users not being able to work or provide work to their full abilities and through disrupting the income of the organised crime groups.

Will there be significant impacts on national budgets and administrations?

Although the preferred option would lead to an increase in tasks and responsibilities of the Agency, overall, the initiative would contribute to a reduction of administrative burden and a simplification of administrative procedures, in particular in the Member States. The main contributing factor is the proposed streamlining and centralisation of reporting obligations. Due to a lack of data on the available funds for drugs policy, it is not possible to quantify the impacts of simplification and burden reduction.

Will there be other significant impacts?

No.

D. Follow up

When will the policy be reviewed?

In line with the common approach, the Agency Regulation will include an external evaluation of

the Agency every 5 years.