

Reasoned Opinion of the House of Commons

Submitted to the Presidents of the European Parliament, the Council and the Commission, pursuant to Article 6 of Protocol (No 2) on the Application of the Principles of Subsidiarity and Proportionality.

concerning

a Draft Regulation of the European Parliament and of the Council on new psychoactive substances and a draft Directive of the European Parliament and of the Council amending Council Framework Decision 2004/757/JHA of 25 October 2004 laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking, as regards the definition of drug¹

Treaty framework for appraising compliance with subsidiarity

1. In previous Reasoned Opinions, the House of Commons has set out what it considers to be the correct context in which national parliaments should assess a proposal's compliance with subsidiarity. The House of Commons continues to rely on that context without restating it.

Proposed legislation

Purpose

2. The draft Regulation has a dual purpose: to reduce obstacles to legitimate trade in new psychoactive substances whilst also ensuring that appropriate and proportionate EU-wide restrictions are imposed on substances presenting moderate or severe health, social or safety risks. The draft Regulation seeks to achieve this dual purpose by:

- establishing the free movement of new psychoactive substances for commercial and industrial use, or scientific research and development purposes, as a core principle;
- strengthening the existing mechanism for exchanging information on new psychoactive substances, drawing on the expertise of Europol and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) to produce a Joint Report on substances notified by several Member States, and providing for a swifter risk assessment procedure;

¹ Council documents 13857/13 and 13865/13; COM(13) 619 and COM(13) 618.

- proposing a more graduated approach to the regulation of new psychoactive substances which seeks to distinguish between low, moderate and high risk substances and to introduce a more proportionate response at EU level, ranging from no market intervention to restrictions on consumer sales and, in the most severe cases, an outright ban accompanied by criminal sanctions;
- providing for the introduction of a temporary ban on consumer sales, prior to a risk assessment, if there is evidence to suggest that a new psychoactive substance poses immediate risks to public health in several Member States;
- ensuring that, where market restrictions have been introduced, new psychoactive substances may still be used for authorised purposes, for example, as active substances in medicinal or veterinary products or for scientific research and development;
- strengthening the monitoring of new psychoactive substances by Europol and the EMCDDA and promoting cooperation in research and analysis.

3. The draft Directive which accompanies the draft Regulation would amend a 2004 Framework Decision establishing minimum rules on the definition of offences linked to trafficking in illicit drugs and requiring Member States to introduce “minimum maximum” criminal penalties. The amendment is intended to ensure that the same criminal law provisions that currently apply to narcotic drugs and psychotropic substances under United Nations Conventions also apply to new psychoactive substances which have been assessed under the draft Regulation as presenting severe health, social and safety risks.

Operation

4. The draft Regulation is based on Article 114 TFEU — an internal market legal base — because the Commission says that its objective is to ensure that “trade in new psychoactive substances having industrial and commercial uses is not hindered and that the functioning of this market is improved, while the health and safety of individuals are protected from harmful substances which cause concern at the EU level.”² The draft Regulation would repeal and replace the existing regulatory framework for new psychoactive substances set out in Council Decision 2005/387/JHA. The 2005 Decision focuses exclusively on control measures which warrant the imposition of EU-wide criminal penalties and cites a justice and home affairs legal base.

5. The draft Regulation empowers the Commission (or Europol and the EMCDDA) to commission a Joint Report on a new psychoactive substance that gives rise to concerns across the EU. It authorises the Commission to determine whether a risk assessment is needed and whether, pending its completion, a temporary restriction on consumer sales is warranted because a substance poses immediate risks to public health. The Commission also determines the level of health, social and safety risks that a new psychoactive substance presents and the

² See p. 8 of the Commission’s explanatory memorandum accompanying the draft Regulation.

type of market restrictions to impose. In reaching a decision, the Commission acts under the supervision of a Committee of Member State representatives.³

6. The draft Directive is based on Article 83(1) TFEU which provides for the approximation of Member States' criminal laws and sanctions in cases where there is a clear cross-border dimension or a special need to take common action. It is the instrument through which Member States would be required to implement criminal sanctions following a decision by the Commission to impose a permanent market restriction on new psychoactive substances posing severe health, social and safety risks under Article 13 of the draft Regulation.

Subsidiarity

7. The Commission considers that there is a clear need for EU action for the following reasons:

- decision-making procedures under Council Decision 2005/387/JHA are too slow and reactive to deal with the rapid emergence of new psychoactive substances in recent years and the increase in the number of notifications made by Member States (which have tripled from 24 in 2009 to 73 in 2012);
- 80% of new psychoactive substances are reported by more than one Member State, demonstrating that there is a significant cross-border dimension;
- approximately one fifth of notified new psychoactive substances are used for legitimate purposes in industry, research, or as active substances in medicines; and
- divergent national approaches to new psychoactive substances can impede their legitimate use, divert trade in harmful substances from one Member State to another, and fragment the internal market.

8. The Commission suggests that the draft Regulation would increase legal certainty for economic operators and improve the functioning of the internal market whilst at the same time introducing a swifter, graduated and proportionate response to new psychoactive substances that takes into account the degree of health, social and safety risks associated with their consumption. It adds:

“Member States individually cannot solve the problem, since substances withdrawn from the market in one country can still be sold in neighbouring countries or over the internet, which renders national action ineffective. EU-level action would also have the benefit of alerting Member States to harmful substances that have emerged in other countries, helping them anticipate and address potential health threats.”⁴

³ See Articles 9, 12 and 13 of the draft Regulation. Decisions made under these Articles are subject to the examination procedure set out in Article 5 of Regulation (EU) No 182/2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers.

⁴ See p. 4 of ADD 1, Impact Assessment.

9. In its Impact Assessment accompanying the draft Regulation and Directive, the Commission sets out the two limbs of the subsidiarity test: the necessity test and the EU added value test.⁵ The Commission considers that action at EU level is necessary to ensure that new psychoactive substances causing EU-wide concern can be withdrawn from the market quickly in all Member States without disrupting legitimate trade. It suggests that EU action would also add value by improving the exchange of information between Member States, pooling scientific resources and analytical capacities and producing the evidence needed to develop the most effective responses. EU-level decisions restricting the availability of new psychoactive substances would enhance legal certainty, remove obstacles to legitimate trade, reduce the likelihood of unilateral Member State action and improve consumer protection across the EU. The Commission adds that Member States would “continue being responsible for addressing those substances that are a problem at local or national level.”⁶

Aspects of the draft Regulation and Directive which do not comply with the principle of subsidiarity

i) Failure to comply with essential procedural requirements

10. By virtue of Article 5 of Protocol (No 2) “any draft legislative act should contain a detailed statement making it possible to appraise compliance with the principles of subsidiarity and proportionality”. The requirement for the detailed statement to be within the draft legislative act implies that it should be contained in the Commission’s explanatory memorandum, which forms part of the draft legislative act and which, importantly, is translated into all official languages of the EU. The fact that it is translated into all official languages of the EU allows the detailed statement to be appraised for compliance with subsidiarity (and proportionality) in all the national parliaments of Member States of the EU, in conformity with Article 5 of Protocol (No 2). This is to be contrasted with the Commission’s impact assessment, which is not contained within a draft legislative act, and which is not translated into all the official languages of the EU.

11. The presumption in the Treaty on European Union⁷ is that decisions should be taken as closely as possible to the EU citizen. A departure from this presumption should not be taken for granted but justified with sufficient detail and clarity that EU citizens and their elected representatives can understand the qualitative and quantitative reasons leading to a conclusion that “a Union objective can be better achieved at union level”, as required by Article 5 of Protocol (No 2). The onus rests on the EU institution which proposes the legislation to satisfy these requirements.

12. For the reasons given below, we do not consider that the Commission has provided sufficient qualitative and quantitative substantiation in the explanatory memorandum of the necessity for action at EU level. This omission, the House of Commons submits, is a failure on behalf of the Commission to comply with essential procedural requirements in Article 5 of Protocol (No 2).

⁵ See pp. 44-5 of ADD 1.

⁶ See p. 45 of ADD 1.

⁷Article 5.

ii) Failure to comply with the principle of subsidiarity

13. We recognise that there is considerable potential for cross-border trade in new psychoactive substances and a risk that divergent national approaches might displace the health and social harms associated with their use from one Member State to another, or hinder legitimate trade. However, we consider that the draft Regulation and Directive fetter Member State action to an unacceptable degree.

14. The Commission acknowledges in its Impact Assessment that trade in new psychoactive substances for legitimate purposes is difficult to quantify as no comprehensive market information is available.⁸ Given this uncertainty, as well as the known risks associated with their recreational use, we do not consider that new psychoactive substances should necessarily be treated in the same way as other tradable commodities within the internal market. Divergent national rules cited by the Commission as an obstacle to legitimate trade, in our view, often reflect differing cultural and societal attitudes towards the regulation of drugs and psychoactive substances and are an important component of national strategies to manage and control drug use. The existing regulatory framework, set out in Council Decision 2005/387/JHA, recognises the legitimacy of different regulatory approaches at national level and expressly provides that the introduction of EU control measures shall not “prevent a Member State from maintaining or introducing on its territory any national control measure it deems appropriate once a new psychoactive substance has been identified by a Member State.”⁹

15. There is little analysis in the Commission’s explanatory memorandum and Impact Assessment of the scope for Member States to act unilaterally, under Article 114(4) and (5) TFEU, when faced with evidence of social or health harms which exceed the level of risk identified by the Commission when implementing market restrictions, but it seems clear that there would be far less flexibility under the draft Regulation and Directive than exists under Decision 2005/387/JHA. We do not consider that the Commission has produced sufficient evidence of disruption to legitimate trade, or displacement of the harmful effects of new psychoactive substances, to warrant market intervention on the scale envisaged in the proposed measures or the imposition of additional constraints on Member States’ freedom of action. The first limb of the subsidiarity test — that the proposed action cannot be sufficiently achieved by Member States — is not, therefore, met.

Conclusion

16. For these reasons the House of Commons considers these proposals do not comply with the principle of subsidiarity.

⁸ See pp. 18-22 of ADD 1.

⁹ Article 9(3) of Council Decision 2005/387/JHA.