BUENDIA SANGUINO Pilar (SG)

From:	FINER, Hannah <finerh@parliament.uk>
Sent:	Tuesday 12 November 2013 18:16
To:	SG NATIONAL PARLIAMENTS
Subject:	Reasoned Opinion of the House of Commons on COM(2013) 618 and COM(2013) 619
Attachments:	2013-11-12 Clerk of the House to the President of the European Commissio....pdf; Reasoned Opinion on regulation of new psychoactive substances.pdf; Chapter 8, 19th Report.pdf

Dear Sir/Madam,

Reasoned Opinion on documents No. 13857/13 (+ ADDS 1-2), a draft Regulation on new psychoactive substances and No. 13865/13 (+ ADDs 1–2), a draft Directive a draft Directive 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 drug

I enclose a letter from the Clerk of the House of Commons to the President. Also attached to this email are::

- the Reasoned Opinion
- the relevant extract from the Committee's Nineteenth Report of Session 2013-14 (HC 83-xviii). Please note that I have not included the text of the Annex as it replicates the Reasoned Opinion which is attached as a separate document.

Yours faithfully,

Hannah

Hannah Finer
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For information on the work of the Committee see:
http://www.parliament.uk/business/committees/committees-a-z/commons-select/european-scrutiny-committee/

HOUSE OF COMMONS

President of the European Commission
European Commission
Rue de la Loi 200
1049 Brussels
Belgium

By email: SG-NATIONAL-PARLIAMENTS@ec.europa.eu

12 November 2013

Dear Mr President,

EUROPEAN UNION DOCUMENTS NO. 13857/1 AND ADDENDA 1 AND 2, A DRAFT REGULATION ON NEW PSYCHOACTIVE SUBSTANCES, AND NO. 13865/13 AND ADDENDA 1 AND 2, A DRAFT DIRECTIVE AMENDING FRAMEWORK DECISION 2004/757/JHA OF 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 DRUG

On 11 November 2013, the House of Commons of the United Kingdom Parliament resolved as follows:

> That this House considers that the draft Regulation and draft Directive on the regulation of new psychoactive substances (European Union Documents No. 13857/13 and Addenda 1 and 2 and 13865/13 and Addenda 1 and 2) do not comply with the principle of subsidiarity, for the reasons set out in the annex to Chapter Eight of the Nineteenth Report of the European Scrutiny Committee (HC 83-xviii); and, in accordance with Article 6 of Protocol (No. 2) annexed to the EU Treaties on the application of the principle of subsidiarity and proportionality, instructs the Clerk of the House to forward this reasoned opinion to the Presidents of the European Institutions.

I enclose the relevant extract of the report.

Yours sincerely,

Robert Rogers

Sir Robert Rogers KCB, Clerk of the House of Commons
London SW1A 0AA T: 020 7219 1310/3758

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 drug[1]

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;

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[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]

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[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 Union[7] 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).

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[5] See pp. 44-5 of ADD 1.

[6] See p. 45 of ADD 1.

[7] Article 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.

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[8] See pp. 18-22 of ADD 1.

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

8 Regulation of new psychoactive substances

(a) (35324) 13857/13 + ADDs 1–2 COM(13) 619	Draft Regulation on new psychoactive substances
(b) (35325) 13865/13 + ADDs 1–2 COM(13) 618	Draft Directive amending 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 drug

Legal base	(a) Article 114 TFEU; co-decision; QMV (b) Article 83(1) TFEU; co-decision; QMV
Document originated	(Both) 17 September 2013
Deposited in Parliament	(Both) 25 September 2013
Department	Home Office
Basis of consideration	EMs of 8 October 2013
Previous Committee Report	None
Discussion in Council	No date set
Committee's assessment	Legally and politically important
Committee's decision	Not cleared; further information requested; recommended for a Floor of the House debate on the Reasoned Opinion before 13 November 2013

Background

Existing control measures for new psychoactive substances

8.1 Psychoactive substances affect the central nervous system and functioning of the brain, inducing changes in mood, perception and behaviour similar to those associated with the consumption of illicit drugs. They are often referred to as "legal highs" because they are marketed as licit alternatives to controlled drugs. The market in these substances is highly adaptable, responding rapidly to the imposition of new drug controls. Legal highs are usually sold through specialised shops or over the internet. Although their composition and effects are often unclear, they can be toxic, addictive, damaging to health and carry longer-term social risks (for example, because of the involvement of organised crime groups).

8.2 In 1997, the Council established a mechanism for Member States to exchange information, request a risk assessment and introduce EU-wide control measures and criminal penalties which Member States would implement through their domestic drugs

legislation.[19] The mechanism was strengthened by a Council Decision adopted in 2005 ("the 2005 Decision")[20] and its scope extended to all new psychoactive substances not already subject to international controls under United Nations Conventions on narcotic drugs and psychotropic substances.[21]

8.3 The 2005 Decision provides for Europol and the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) to produce a Joint Report on new psychoactive substances reported by Member States via an Early Warning System. The Council (acting by a simple majority of its members) may request a further assessment which would focus, amongst other things, on the health and social risks associated with the use of a new psychoactive substance, as well as the degree of involvement of organised crime networks. Following the risk assessment, the Commission or (if it chooses not to act) one or more Member States, may propose the introduction of EU-wide control measures. If endorsed by the Council (acting by a qualified majority), a Council Decision would require Member States to introduce control measures and criminal penalties, in accordance with their national law, within 12 months. The 2005 Decision makes clear, however, that:

> "Nothing in this Decision shall 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."[22]

8.4 The Commission published an assessment of the 2005 Decision in 2011[23] which concluded that changes were needed for three reasons:

- the procedure for introducing control measures only tackles one psychoactive substance at a time, making it difficult to take action on drugs composed of several substances, in a variety of combinations, and lengthening the time needed to decide whether EU-wide control measures/criminal sanctions are justified;
- the procedure is too reactive, lagging behind developments in the market, as substances submitted to control measures are rapidly replaced by new ones which have similar effects as a result of small changes to their chemical composition; and
- where EU control measures are justified, the Decision only provides for criminal sanctions but, in those cases where the public health implications are less clear-cut, lighter risk management options might be beneficial.

8.5 The Commission set out a number of options for revising the 2005 Decision which the Government described as "entirely sensible" and in line with measures being taken domestically to improve the UK's response to new psychoactive substances, such as enhanced forensic monitoring of new substances, and the introduction of temporary class drug orders and generic drugs legislation for groups of chemically related substances.

19 Joint Action 97/396/JHA, OJ No. L 167, 25.06.1997.

20 Council Decision 2005/387/JHA, OJ No. L 127, 20.05.2005.

21 The United nations Single Convention on Narcotic Drugs 1961 and the United Nations Convention on Psychotropic Substances 1971.

22 Article 9(3) of the 2005 Decision.

23 Council document 13074/11, (33045), HC 428–xxxv (2010–12), chapter 22 (7 September 2011).

8.6 Council Conclusions on new psychoactive substances agreed in December 2011 invited the Commission to propose changes to the 2005 Decision which should:

- seek to close gaps in the different types of laws used by Member States (drug control, medicines, and consumer protection legislation) to address new psychoactive substances;
- strengthen practical cooperation, the exchange of information, research and risk assessment, and improve monitoring of new psychoactive substances, with the EMCDDA as the leading body;
- address groups of hazardous substances;
- encourage Member States to develop fast-track procedures and impose temporary marketing restrictions for substances raising immediate concerns, pending completion of a risk assessment; and
- further streamline EU procedures and enhance cooperation between forensic and toxicological institutes.

8.7 The Council Conclusions also underlined the need for new legislation to "respect the division of competences between the EU and the Member States."[24]

Criminal penalties

8.8 A Framework Decision adopted by the Council in 2004 ("the 2004 Framework Decision") establishes minimum rules on the definition of offences linked to trafficking in illicit drugs and drug precursors and requires Member States to introduce criminal penalties. It only applies to drugs covered by United Nations Conventions on narcotic drugs and psychotropic substances, not to new psychoactive substances.

The UK's 2014 block opt-out decision

8.9 The 2005 Decision and 2004 Framework Decision are "Third Pillar" measures, adopted by unanimity under the procedures applicable to EU police and criminal justice measures before the Lisbon Treaty entered into force in December 2009. From 1 December 2014, all such measures will be subject to the full jurisdiction of the Court of Justice unless the UK exercises the right, conferred by the Lisbon Treaty, to opt out of them. The Government has notified its intention to opt out, and to rejoin a smaller number of measures which it considers are helpful in combating serious and organised crime. The 2005 Council Decision and 2004 Framework Decision are not included in the list of measures which the Government proposes to rejoin. They will therefore cease to apply to the UK from 1 December 2014, but the UK retains the right to participate in any replacement measures.

24 http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/jha/126879.pdf

EU competence in the field of drugs policy

8.10 There is no specific EU competence for drugs policy, but there are a number of provisions in the Treaty on the Functioning of the European Union (TFEU) that provide a basis for regulatory action. For example, harmonised rules to monitor and control trade in drug precursors within the EU (chemical substances with legitimate commercial uses that may be diverted into illicit drug production) are based on Article 114 TFEU, an internal market legal base, because their purpose is to prevent Member States adopting divergent national measures that would disrupt the licit trade in precursors and fragment the internal market.[25] Article 114(3) TFEU includes a requirement that measure affecting health, safety or consumer protection should "take as a base a high level of protection, taking account in particular of any new development based on scientific facts."

8.11 Whereas Article 114 TFEU provides for the approximation of Member States' laws, Article 168 TFEU on public health precludes harmonisation and envisages, instead, the adoption of incentive measures to protect and improve human health, which may include monitoring and early warning mechanisms to combat serious cross-border threats to health.

8.12 Illicit drug trafficking is one of the areas of crime listed in Article 83(1) TFEU on the grounds that it has a cross-border dimension and may need to be tackled on a common basis. Article 83(1) provides for the adoption of minimum rules on the constituent elements of drug trafficking offences and on criminal sanctions. Measures based on this Article are subject to the UK's Title V (justice and home affairs) opt-in or, if they build on elements of the Schengen *acquis*, the Schengen opt-out. The net effect is the same in both cases, enabling the UK to determine whether or not it wishes to participate in the measure.

Document (a) — the draft Regulation

8.13 The draft Regulation would repeal and replace the 2005 Decision. Unlike the 2005 Decision, it cites an internal market (Article 114 TFEU) legal base because, according to the Commission, 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."[26]

The main elements of the draft Regulation

8.14 There are a number of similarities between the draft Regulation and the 2005 Decision. It maintains the existing mechanism for exchanging information on new psychoactive substances, as well as the possibility to request a Joint Report (produced by the European Monitoring Centre for Drugs and Drug Addiction and Europol) on substances giving rise to concerns and to draw up a risk assessment as the basis for EU-wide control measures. There are, however, important differences:

25 See Council document 14514/12 (34286); see HC86–xvi (2012–13), chapter 9 (24 October 2012) and HC 86–xx (2012–13), chapter 26 (21 November 2012).

26 See p. 8 of the Commission's explanatory memorandum accompanying the draft Regulation.

- a new psychoactive substance must be notified by *several* Member States before any action is taken at EU level (Article 6);
- the Commission, rather than the Council, determines whether to commission a Joint Report (Article 6) and request a risk assessment (Article 7);
- the risk assessment report is submitted to the Commission, not the Council, and it is for the Commission to determine the level of health, social and safety risks that a new psychoactive substance presents (Article 7); and
- more rigorous deadlines are included to reduce delays in producing a Joint Report and risk assessment, and a broader range of stakeholders (including the European Chemicals Agency and European Food Safety Authority) are to be consulted (Articles 6 and 7).

8.15 Perhaps the most significant difference is that the principle of free movement is placed at the core of the draft Regulation. Article 3 provides that:

> "New psychoactive substances and mixtures shall move freely in the Union for commercial and industrial use, as well as for scientific research and development purposes."

8.16 The principle of free movement may be displaced, and market restrictions imposed, in the following circumstances:

- if a new psychoactive substance poses "immediate risks to public health" as a result of reported fatalities and severe health consequences "in several Member States" related to the toxicity of the substance, an immediate, temporary ban (valid for up to 12 months) must be imposed on the marketing of the substance to consumers. The ban would be introduced *before* the risk assessment has been completed (Article 9);
- in all other cases, market restrictions would be based on the outcome of the risk assessment, with the Commission determining the extent of health, social and safety risks associated with a new psychoactive substance and the type of restrictions that should apply (Article 10);
- if a new psychoactive substance presents low health, social and safety risks, no market restrictions may be introduced (Article 11);
- if a new psychoactive substance presents moderate health, social and safety risks, a permanent ban on marketing it to consumers must be imposed (Article 12); and
- if a new psychoactive substance presents severe health, social and safety risks, a ban on its production, manufacture and marketing (including importation to, or exportation from, the EU) must be imposed without undue delay (Article 13).

8.17 The introduction of market restrictions would be overseen by a Committee of Member State representatives under the so-called "examination procedure".[27] This procedure is intended to ensure that a draft implementing act cannot be adopted by the Commission if it is not supported by a qualified majority of Member State representatives.

8.18 Where Decisions introducing market restrictions have been adopted by the Commission, the draft Regulation includes safeguards to ensure that new psychoactive substances may still be used for authorised purposes. These include their use as active substances in human or veterinary medicinal products, or in other products provided that they cannot be recovered or abused, and their use for scientific research and development (Article 14). All new psychoactive substances on which a Joint Report has been produced will remain subject to monitoring by Europol and the European Monitoring Centre for Drugs and Drug Addiction (Article 15) and an updated risk assessment may be requested by the Commission in light of new information and evidence on the risks associated with a particular substance (Article 16).

8.19 The draft Regulation requires Member States to establish "effective, proportionate and dissuasive sanctions" for any breach of market restrictions introduced by the Commission (Article 17) and to ensure that an effective remedy is available for those whose rights are affected by the implementation of any such sanction (Article 18). It also requires Member States and the Commission to support the development, sharing and dissemination of information on new psychoactive substances and to facilitate cooperation with the European Monitoring Centre for Drugs and Drug Addiction, other relevant EU Agencies, and scientific and research centres (Article 20).

8.20 Member States remain free to adopt "technical regulations" on new psychoactive substances which are not subject to EU-wide market restrictions, but these must be communicated to the Commission under the procedures set out in Directive 98/34/EC.[28] The purpose of the notification procedure is to enhance market transparency and identify barriers to trade within the internal market. The Directive includes provision for technical regulations to be implemented immediately, without prior consultation, "for urgent reasons, occasioned by serious and unforeseeable circumstances relating to the protection of public health or safety [...] also for public policy, notably the protection of minors."[29] Even in cases where EU-wide market restrictions have been adopted, there is scope to exceed them provided the procedures and safeguards foreseen in Article 114(4) and (5) TFEU are respected.

The justification for EU action

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

27 The examination procedure is 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.

28 Directive 98/34/EC establishes a procedure for the provision of information on technical standards and regulations.

29 Article 9(7) of Directive 98/34/EC.

- decision-making procedures under the 2005 Decision are too slow and reactive to deal with the rapid emergence of new psychoactive substances in recent years and 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.

8.22 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."[30]

8.23 In terms of subsidiarity, 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 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."[31]

Document (b) — the draft Directive amending Framework Decision 2004/757/JHA

8.24 The purpose of the draft Directive is to extend the scope of the 2004 Framework Decision to include new psychoactive substances which present severe health, social and safety risks and are subject to permanent market restriction under Article 13 of the draft Regulation. The amendment is intended to ensure that the production and manufacture of

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

31 See p.45 of ADD 1, Impact Assessment.

all such substances, or the act of making them available on the market, is made a criminal offence in all Member States, and 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. An Annex to the draft Directive contains a list of substances which are already subject to EU-wide control measures and criminal penalties under the 2005 Decision.

8.25 As the legal base for the draft Directive is Article 83(1) TFEU, the UK's Title V opt-in applies.

The Government's view

Document (a) — the draft Regulation

8.26 The Minister for Immigration (Mr Mark Harper) recognises that new psychoactive substances present "a significant challenge", adding that "early identification and sharing of information is key to our understanding and response." He suggests that a further strengthening of the existing information exchange mechanism would "continue to complement the UK's own drugs early warnings systems which inform our public health messaging, legislation and enforcement responses."[32]

8.27 However, the Minister questions the Commission's choice of legal base for the draft Regulation and suggests that the proposal should cite a Title V (justice and home affairs) legal base. He notes that the 2005 Council Decision which it would replace is a justice and home affairs measure and continues:

> "Save for the graduated categorisation system proposed in the new measure, its operative provisions are very similar to Council Decision 2005/387/JHA. While the new measure is expressed in many places to harmonise the single market, it is clear that its main purpose is to control access to NPS [new psychoactive substances], mostly in a substantially similar manner to Council Decision 2005/387/JHA. The explanatory memorandum prepared by the Commission focuses on the risks to health and society arising from the misuse of NPS. The mischief at which the instrument is aimed is not barriers to trade arising from the internal market; it is the need for a coordinated, EU-wide approach to tackling emerging NPS.
>
> "Our own experience suggests that there is a very small legitimate trade in NPS, namely commercial and industrial use. For that reason, at this stage, we would question the basis of the Commission's assessment that NPS should be tackled by way of controls on the internal market pursuant to Article 114 TFEU. Our preliminary view is that there are good arguments that if the trade of NPS ought to be regulated at EU level, it should be pursuant to a measure under Title V TFEU, given the lack of evidence of legitimate NPS usage."[33]

32 See paragraph 21 of the Minister's Explanatory Memorandum.

33 See paragraphs 22–23 of the Minister's Explanatory Memorandum.

8.28 The Minister says that he will write with further details on the Government's position on the legal base. However, even if the Government maintains its preliminary view that a Title V legal base should be cited, the Minister suggests that the UK's Title V (justice and home affairs) opt-in Protocol would not apply because the draft Regulation is a Schengen measure, building on Article 76 of the 1990 Schengen Implementing Convention. Article 76 provides that Schengen States shall, "where necessary, and in accordance with their medical, ethical and practical usage, adopt appropriate measures for the control of narcotic drugs and psychotropic substances which in the territory of one or more contracting parties are subject to more rigorous controls than in their own territory, so as not to jeopardise the effectiveness of such controls." These measures should also apply to "substances frequently used in the manufacture of narcotic drugs and psychotropic substances."

8.29 EU measures which build on elements of the Schengen *acquis* in which the UK participates are subject to the Schengen Protocol, which takes precedence over the UK's Title V opt-in Protocol.[34] Under the terms of the Schengen Protocol, the UK is deemed to participate in a proposal building on a Schengen measure by which the UK already is already bound (in this case, Article 76 of the 1990 Convention), but has the right to opt out. If the UK wishes to opt out, it must notify the Council in writing within three months.

8.30 The Minister notes that the draft Regulation does not state that it is a Schengen-building measure, but that the UK intends to assert that it is and that the UK's Schengen opt-out applies. The Minister sets out the factors which are likely to be relevant in determining whether or not to participate in the draft Regulation:

- the introduction of a swifter process for assessing the risk of substances that cause EU-wide concern and for withdrawing from the market those that pose "severe" or "moderate" risks;

- the difficulty of "scientifically defining the thresholds between high, moderate and low" health, social and safety risks, and the implications of determining that a particular new psychoactive substance is low risk and does not warrant EU-wide action — the Minister adds that the UK's Advisory Council on the Misuse of Drugs undertakes its own risk assessment of new psychoactive substances;

- the potential to enhance effective law enforcement and judicial cooperation in tackling "a fast-paced market, cross-border activity and the role of the internet" through swifter EU-wide action — the Minister notes that the UK has already banned the majority of new psychoactive substances currently subject to EU-wide control measures; and

- the effectiveness of the calibrated approach set out in the draft Regulation, which envisages administrative and criminal sanctions, depending on the nature and extent of the market restriction imposed — the Minister adds that there will be associated enforcement (including forensic) costs.[35]

34 See Article 7 of Protocol No. 21 to the EU Treaties (the UK's opt-in Protocol).

35 See paragraph 25 of the Minister's Explanatory Memorandum.

8.31 Turning to the justification for EU action, the Minister notes that drug policy is "predominantly a competency of Member States" but that collective EU action "can be necessary to complement national approaches."[36] He does not express a view on the compliance of the draft Regulation with the principle of subsidiarity, adding that he will write with further information shortly. However, he considers that the proposal breaches the principle of proportionality to the extent that it "fetters the UK from adopting more stringent measures to control NPS." He continues:

> "In our view, it is vital for the UK, guided as necessary by EU expertise in NPS but not bound by it, to have a final say when deciding whether to exceed any minimum standards mandated by the EU. Where the UK proposes to take action unilaterally, it should not have to comply with Directive 98/34/EC. Whereas Council Decision 2005/387/JHA imposed minimum standards across the EU, this measure seeks to impose common standards across the EU. We do not consider the potential derogations contained in Article 114(4) or (5) of the TFEU to preserve sufficient autonomy for the UK in this challenging area. This level of EU control exceeds that which is required for the objectives of the Treaties to be achieved and therefore does not appear to comply with the principle of proportionality."[37]

8.32 Whilst acknowledging that the draft Regulation would not adversely affect fundamental aspects of the UK legal system, the Minister notes that it would be directly applicable in the UK (unless a UK Title V opt-in or Schengen opt-out applies) and would, as a result:

> "direct the UK Government and the UK Parliament on future legislative steps to take to limit or control the availability of NPS. At present, the drug control framework in the UK is made under the Misuse of Drugs Act 1971 and statutory instruments made thereunder and is a responsibility of the Home Secretary. This EU Regulation would place some limits and constraints on the Home Secretary's and the UK Parliament's freedom of action in this field."[38]

8.33 The Minister's Explanatory Memorandum indicates that the Government has no plans to undertake an impact assessment on the draft Regulation and makes no reference to consulting external stakeholders.

Document (b) — the draft Directive

8.34 The Minister notes that most harmful new psychoactive substances identified as being of concern at EU level under the 2005 Decision were already subject to control measures and criminal penalties under the Misuse of Drugs Act 1971. The UK has notified its intention to opt out of the 2004 Framework Decision, which the draft Directive would amend, as part of its 2014 block opt-out, and the Government does not propose to seek to

36 See paragraph 18 of the Minister's Explanatory Memorandum.

37 See paragraph 20 of the Minister's Explanatory Memorandum.

38 See paragraph 14 of the Minister's Explanatory Memorandum.

rejoin it. The Minister adds that "participation in any future NPS measure will need to be considered in light of the decision to opt out of the original measure."[39]

8.35 The Minister suggests that the draft Directive, like the accompanying draft Regulation, is a Schengen measure that builds on Article 71 of the 1990 Schengen Implementing Convention. Article 71 requires Schengen States to take "all necessary measures to prevent and punish the illicit trafficking in narcotic drugs and psychotropic substances", including administrative and penal sanctions, in accordance with United Nations Conventions.[40] The Government intends to assert that its right to opt out of the proposal under the Schengen Protocol applies.

8.36 The Minister expresses no view on the compliance of the draft Directive with the principle of subsidiarity and says he will write with further information shortly.

Conclusion

Questions for the Government

8.37 **The Minister's Explanatory Memoranda on these proposals raise many questions and provide few answers at this stage. This is disappointing given that the Government has already decided to opt out of the 2005 Decision (which the draft Regulation will replace) and the 2004 Framework Decision (which the draft Directive will amend) with effect from 1 December 2014 and might therefore be expected to have a clearer appreciation of the risks and benefits of EU action on new psychoactive substances and the introduction of EU-wide criminal offences and penalties.**

8.38 **Turning first to the draft Directive, we do not see how it would be legally possible for the UK to participate in an instrument — in this case, the draft Directive — which would amend a measure (the 2004 Framework Decision) which will cease to bind the UK from 1 December 2014. Whilst we understand that there are potential timing issues, if the draft Directive and Regulation are adopted and/or enter into force before 1 December 2014, we ask the Government whether it agrees with our understanding of the basic legal position.**

8.39 **We note that the Government considers that the draft Directive and draft Regulation are Schengen-building measures and that the UK's Schengen opt-out applies to both, regardless of the legal base cited. The Minister's Explanatory Memoranda refer to Articles 71 and 76 of the 1990 Schengen Implementing Convention as the source of the underlying Schengen obligations. We understand that these Articles are limited in scope to narcotic drugs and psychotropic substances covered by existing United Nations Conventions and so do not extend to new psychoactive substances. We ask the Government whether it shares our understanding of the scope of these Articles and to amplify its reasons for considering that the Commission's proposals (which concern new psychoactive substances that are *not***

39 See paragraph 21 of the Minister's Explanatory Memorandum.

40 These are the Single Convention on Narcotic Drugs 1961, the Convention on Psychotropic Substances 1971, and the Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances 1988.

subject to international control under the relevant UN Conventions) are Schengen-building measures.

8.40 **The Government's assertion that the draft Directive and draft Regulation are Schengen-building measures will have important implications for Denmark and for other non-EU States — Iceland, Norway, Switzerland and Liechtenstein — associated with the application and development of the Schengen *acquis*. We ask the Government whether it has consulted with these States and whether they consider that the Commission proposals are a development of the Schengen acquis.**

8.41 **With regard to the draft Regulation, the Government's reservations about the Article 114 TFEU (internal market) legal base appear to be based on a difference of view with the Commission on the scale of legitimate trade in new psychoactive substances. It is all the more surprising, given this difference of view, that the Government does not propose to carry out its own impact assessment or consult external stakeholders. We ask the Minister to explain why.**

8.42 **We note that the Government has not contested the use of an internal market legal base to regulate internal trade in drug precursors, or sought to assert that its Schengen opt-out applies.[41] We therefore also ask the Minister to explain why the Government considers that trade in drug precursors and new psychoactive substances should be regulated differently, and why Article 76 of the 1990 Schengen Implementing Convention is not also applicable to the trade in drug precursors, given that it expressly refers to "substances frequently used in the manufacture of narcotic drugs and psychotropic substances."**

8.43 **The Minister suggests that the draft Regulation should cite a Title V legal base. We ask him, accordingly, to identify which provisions of the draft Regulation establish specific obligations in the justice and home affairs field and which Title V Treaty Articles he considers should be cited as the legal base.**

8.44 **The Minister makes no reference to the conferral of significant implementing powers on the Commission, even though this is an important point of distinction with the 2005 Decision which vests political control in the Council. We ask the Minister whether he considers the conferral of implementing powers to be appropriate and proportionate.**

8.45 **We have consistently maintained that a unilateral assertion by the UK that its Title V (justice and home affairs) opt-in or Schengen opt-out applies undermines legal certainty. Whilst we recognise that the application of the Schengen Protocol is often less clear-cut than the UK's Title V opt-in, given that it is not dependent on the citation of a Title V legal base, we would nevertheless expect the Schengen origins of EU proposals to be set out in the recitals, not least as a means of clarifying their application to Denmark and non-EU Schengen associated countries. In the absence of any such recitals in the draft Regulation and Directive, we do not consider that it would be**

41 See Council document 14514/15; (34286); HC 86–xvi (2012–13), chapter 9 (24 October 2012) and HC 86–xx (2012–13), chapter 26 (21 November 2012).

appropriate to recommend a Schengen opt-out debate, but we will wish to debate both proposals once the Government has clarified is position on the issues we have raised.

Subsidiarity concerns

8.46 **It is particularly disappointing that the Government has been unable to provide an assessment of the subsidiarity implications of the draft Regulation and Directive. It is unreasonable to expect Parliament to come to an informed view on compliance with the subsidiarity principle within the timeframe required for a Reasoned Opinion under Protocol No. 2 to the EU Treaties without the benefit of an analysis by the Government.**

8.47 **Our preliminary view, however, is that the Commission has not demonstrated a sufficient justification for the scale of action proposed in the draft Regulation. Given the potential for cross-border trade in new psychoactive substances and the 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, we can see some advantage in harmonised EU rules. We nevertheless consider that the draft Regulation and Directive fetter Member State action to an unacceptable degree.**

8.48 **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.[42] 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.**

8.49 **There is little analysis in the Commission's Impact Assessment of the scope for Member States to act unilaterally, under Article 114(4) and (5), 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 than exists under the 2005 Decision. 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 draft Regulation or the imposition of additional constraints on Member States' freedom of action.**

8.50 **We also question whether the draft Regulation is proportionate and consider that it exceeds the scope for EU action set out in Conclusions on new psychoactive substances agreed by the Council in 2011. We note, with some concern, that the Commission rather than the Council is empowered to determine when to request a Joint Report and risk assessment on a new psychoactive substance, and to decide which type of market restrictions to apply. This is a significant departure from the 2005**

42 See pp. 18–22 of the Commission's Impact Assessment (ADD 1).

Decision, under which political control rests with the Council. We assume that the intention is to accelerate the decision making process but, for the reasons set out above, we consider that there are sound reasons for Ministers, represented in the Council and accountable to their national Parliaments, to decide what level of restrictions are justified.

8.51 **We conclude that the draft Regulation and Directive do not comply with the principle of subsidiarity and recommend that the House send the Reasoned Opinion annexed to this report to the Presidents of the Commission, Council and European Parliament following a debate on the Floor of the House.**

Annex: Draft Reasoned Opinion

Draft 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 drug[43]

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.

[43] Council documents 13857/13 and 13865/13; COM(13) 619 and COM(13) 618.