Dear Chairman,


The Commission welcomes the fact that the House of Commons shares its concerns regarding new psychoactive substances and in particular regarding the “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”.

The Commission takes note of the conclusions of the House of Commons that the proposals do not comply with the principle of subsidiarity.

The Commission disagrees with that view. The Commission’s proposals are based on the acknowledgement that a Member State is better placed than the Union to address risks that are restricted to its national territory and that, in the case of a geographically contained risk, national action is more suitable.

National action can be sufficient in the case of substances whose risks are confined to the boundaries of one Member State and which do not spread further within the internal market. That is why the Commission’s proposals would enable Member State action to address a national, regional or local problem concerning new psychoactive substances. They allow Union action to complement national action on new psychoactive substances only where a substances poses Union-wide risks. Under the Commission’s proposals, action would only be taken at the EU level if a substance poses problems in several Member States and when the health, social and safety risks that it poses give rise to “concerns across the Union”.

Mr William Cash MP
Chairman of the European Scrutiny Committee
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There is a very strong case for taking action at the EU level to address the frequent emergence and the rapid spread of new psychoactive substances in the internal market. Since 1997, when the first EU instrument addressing new psychoactive substances was introduced, Member States have detected and shared information at EU level on more than 300 new psychoactive substances. In 2012 alone 73 new substances were detected across the EU. And in 2013 more than one new substance has been reported every week. Around 80% of the substances were reported by more than one Member State, which reveals the cross-border nature of the problem. Of these, 10 substances were subjected to control and criminal sanctions across the EU, because they posed Union-wide risks and national action alone could not effectively reduce their availability. In all cases, a scientific assessment showed that the risks were not confined to a specific country, but spread across the Union, causing severe health problems, including death, in several Member States. Consuming new psychoactive substances can be fatal. For instance, the substance 5-IT has reportedly killed 24 people in different EU Member States in just five months. Dealing effectively with these substances is a problem that requires a European response.

If Member States were to act individually in these cases, with no possibility to take EU-level action as the House of Commons seems to prefer, the death toll would have been higher. This is because Member States acting individually cannot reduce their availability effectively and sustainably in the internal market – as the trade in such substances would move to neighbouring countries - and cannot protect legitimate trade across the internal market – since disparate national responses cause fragmentation and obstacles to trade. Furthermore, trade in these harmful substances would have been displaced to countries less equipped to detect or withdraw them from the market rapidly.

Furthermore, the exchange of information on such substances alerts national authorities to potential public health problems, the risk assessment enables the pooling of scientific resources from across the Union, helping produce the evidence necessary to develop effective responses, and the swift adoption of EU-wide market withdrawal measures reduces the availability of harmful substances across the entire internal market, avoiding the emergence of safe havens. EU-level action on new psychoactive substances has clear added-value.

The Commission is convinced that, in compliance with the principle of subsidiarity, the proposals provide flexibility to the Member States. First, national, regional or local problems would be dealt with only by the Member States affected. Second, Member States are free to act in relation to any substance, until the Union has taken a decision. These would be taken in accordance with a procedure in which the agreement of a qualified majority of Member States is necessary. Third, under the Commission's proposals, EU-level restriction measures would only be introduced on substances that pose moderate or severe risks across the Union. Member States would remain competent to act in relation to low-risk substances.

Unlike the House of Commons, the Commission believes that there is sufficient evidence of disruption to legitimate trade and of displacement of the harmful effects of new psychoactive substances to justify the proposed action. New psychoactive substances circulate freely in the internal market, until and unless Member States or the Union subject them to restrictions measures.
The Impact Assessment (SWD(2013) 319) accompanying the proposals shows that divergent national restriction measures cause obstacles to trade, market fragmentation, uneven level playing field, legal uncertainty for economic operators and, more broadly, difficulties for companies operating across the internal market or globally. These measures can also hamper research, thus hindering the development of legitimate uses of new psychoactive substances, for medical and therapeutic purposes, for instance. The three case studies presented in the impact assessment report - the substances GBL, 1,4-DBO and mCPP - illustrate the negative consequences of unilateral national measures on legitimate trade. Information from business and civil society organisations consulted during the preparation of the proposals supports these arguments.

Moreover, in its Conclusions on new psychoactive substances of December 2011, the Council underlined the "necessity to ensure the protection of public health against the new threats posed by these substances, whilst avoiding the negative impact on the freedom of legal trade in industrial products and the development and availability of medicines".

The Commission considers that the proposals comply with the principle of subsidiarity and fulfil the procedural requirements set out in Protocol No 2 of the Treaty on the Functioning of the European Union on the application of the principles of subsidiarity and proportionality. The explanatory memoranda, the recitals and the articles of the proposals, as well as the Impact Assessment, contain detailed statements that allow national Parliaments and citizens to appraise the compliance of these proposals with the principles of subsidiarity and proportionality.

The Commission hopes that these comments address the concerns raised by the House of Commons in the Reasoned Opinion and looks forward to continuing our dialogue.

Yours faithfully,

\[Signature\]

Maros Šefčovič
Vice-President