



EUROPEAN COMMISSION

*Brussels, 17.7.2014
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Dear President,

The Commission would like to thank the Assemblée nationale for its Resolution concerning the proposal for a Regulation of the European Parliament and of the Council on new psychoactive substances {COM(2013) 619 final} and the proposal for a 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 {COM(2013) 618 final}.

The Commission welcomes the fact that the Assemblée nationale shares its concerns about the growing availability and rapid spread of new psychoactive substances in the European Union. It agrees with the Assemblée nationale's view that EU-level action is necessary to clamp down on the spread of new psychoactive substances and that a stronger legal framework on new psychoactive substances is needed in the EU.

The Commission welcomes the positive opinion expressed by the Assemblée nationale regarding the possibility to introduce, under the proposed Regulation, EU-wide temporary restriction measures on new psychoactive substances that pose immediate risks to public health. These measures would ensure that consumers are protected from the harm caused by new psychoactive substances while the risks of these substances are assessed.

The Commission takes note of the Assemblée nationale's concern regarding the free movement of new psychoactive substances. The proposal for a Regulation, notably in Article 3, refers to the free movement of "new psychoactive substances and mixtures that have commercial and industrial use, and that are used for scientific research and development purposes". Under the Commission's proposal the marketing and sale of new psychoactive substances for the purpose of being consumed by people for their intoxicating effects would not be covered by the free movement principle.

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The Assemblée nationale expresses concern regarding the choice of legal base for the proposed Regulation – Article 114 of the Treaty on the Functioning of the European Union. The Commission believes that Article 114 is the most appropriate legal base for the proposed instrument, as it would enable reducing obstacles to trade for legitimate uses of new psychoactive substances. At the same time it would allow for their rapid and effective withdrawal from the market across the EU for harmful uses.

The proposed mechanism is a measure ensuring the establishment and functioning of the internal market, aimed at ensuring both the protection of public health and that of legitimate trade. Article 114 paragraph 3 foresees that "the Commission, in its proposal [for measures which have as their object the establishment and functioning of the internal market...] concerning health, safety and environmental protection and consumer protection, will take as a base a high level of protection, taking account in particular of any new development based on scientific facts [...]".

The Commission has conducted a thorough analysis of available information regarding new psychoactive substances before drafting the proposals and the Impact Assessment {SWD(2013) 319} accompanying them. This shows that roughly one fifth of the new psychoactive substances notified by the EU Member States have legitimate uses, for instance as active substances in medicines, in the high-tech or chemical industry, or are being researched for developing legitimate uses. The Impact Assessment also shows that divergent national restriction measures cause obstacles to licit trade, market fragmentation, an uneven level playing field, legal uncertainty for economic operators and difficulties for companies operating across the internal market or globally. These measures can also hamper research, hindering the development of legitimate uses of new psychoactive substances, including for medical and therapeutic purposes. Information from business and civil society organisations consulted during the preparation of the proposals support these findings.

The Commission believes that the proposals would provide flexibility to the EU Member States, enabling them to act to address national, regional or local problems. However, the degree of flexibility granted to the Member States, including the explicit possibility for Member States to maintain or introduce national measures on new psychoactive substances that are more stringent than the ones adopted by the Union, is an important issue, which is also being debated at the Council and which will be further addressed in the course of negotiations.

Unlike the Assemblée nationale, the Commission believes that it would not be appropriate to envisage the possibility to ban groups of new psychoactive substances that share chemical similarities, under the so-called "generic approach". During the preparatory work leading to the adoption of the legislative proposals, and in line with the Council Conclusions on new psychoactive substances of December 2011, the Commission examined the merits of a "generic approach", but concluded that it raises proportionality concerns. A "generic approach" would restrict the availability across the internal market of a large number of substances – even if some of them may not even be present on the market or may not have

psychoactive effects in humans. Wide generic bans at the EU level would, therefore, unduly restrict access to new substances for licit purposes and for research, with negative unintended consequences on economic activities. Moreover, the Commission considers that the implementation of a "generic approach" could be challenging. Bans on such a large number of substances would be technically difficult and expensive to enforce.

The points made above are based on the initial proposal presented by the Commission which is currently in the legislative process involving both the European Parliament and the Council at which your government is represented.

The Commission hopes that these clarifications address the concerns raised by the Assemblée nationale and looks forward to continuing the political dialogue in the future.

Yours faithfully,

*Maroš Šefčovič
Vice-President*