



## EUROPEAN COMMISSION

Brussels, 13.03.2014  
C(2014) 1542 final

*Dear President,*

*The Commission would like to thank the Senato della Repubblica for its Opinion concerning the proposal for a Regulation of the European Parliament and of the Council on new psychoactive substances {COM(2013) 619 final}.*

*The Commission welcomes the fact that the Senato della Repubblica shares its concerns regarding the growing health, social and safety risks that new psychoactive substances pose in the Union. It further welcomes the view of the Senato della Repubblica that the proposal complies with the principle of subsidiarity, as the Union is best placed to ensure the protection of the correct functioning of the internal market, avoiding the adoption of national divergent measures that constitute an obstacle to legitimate trade and to the development of possible industrial uses of new psychoactive substances. The Commission takes note of the opinion of the Senato della Repubblica that the proposal complies with the subsidiarity principle "provided that this is without prejudice to the autonomy of the Member States with regard to the new substances that raise concerns at national level".*

*The Commission further takes note of the opinion expressed by the Senato della Repubblica regarding the compliance with the principle of proportionality, and in particular that the proposal includes measures that go beyond what is strictly necessary for the pursuit of the purposes specified.*

*Unlike the Senato della Repubblica, the Commission believes that the proposal does not, in content or form, exceed what is necessary to achieve its aim, and notably to reduce the health, social and safety risks posed by new psychoactive substances, and to avoid that different national restrictions hinder the legitimate trade and the development of new uses of these substances.*

*In the view of the Commission, the proposal complies with the proportionality principle because action would only be taken at the EU level if a new substance poses problems in several Member States and when its health, social and safety risks give rise to concerns across the Union. The Commission's proposal is 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*

*Mr Pietro Grasso  
President of the  
Senato della Repubblica  
Piazza Madama, 1  
IT – 00186 ROMA*

*more suitable. However, the Commission wants to reassure the Senato della Repubblica that it is aware that the degree of flexibility granted to Member States to address new psychoactive substances is a sensitive issue, which is also being debated at the Council, and which will be further addressed in the course of negotiations.*

*In addition, in compliance with the principle of proportionality, the proposal promotes a graduated approach, according to which restriction measures are proportionate to the level of health, social and safety risks that new psychoactive substances pose. This would ensure that Union action targets risks effectively while avoiding the introduction of unnecessarily severe restrictions that hinder legitimate activities.*

*The Commission takes note of the fact that the Senato della Repubblica disagrees with certain elements of the proposal and thanks it for the suggestions put forward.*

*As previously mentioned, the introduction of three categories of risks – low, moderate and severe – aims at providing a more proportionate response to the spread of new psychoactive substances, with restriction measures tailored to the risks that substances pose at Union level. The Commission believes that this is an important improvement on the existing mechanism, which applies instead a binary approach based on the determination of the presence or absence of risks. The graduated approach would facilitate quick action to withdraw harmful substances from the market and to prevent unjustified restriction of legitimate activities. During the consultations carried out by the Commission in the context of the assessment of the 2005 Council Decision on new psychoactive substances, published in 2011 {COM(2011) 430 final}, a large number of Member States criticised the current dichotomous approach and the lack of alternatives to criminal law measures.*

*In relation to substances posing low risks at Union level, the Commission would like to clarify that, although no EU-wide restriction measures would be introduced on such substances, Member States would be free to take any measure that may be justified at national level, depending on the risks that these substances pose in individual Member States.*

*In its Opinion, the Senato della Repubblica notes that the proposal "[fails] to provide for a prior determination of safety, with the burden of proof on the proposer, before psychoactive substances for human use can be placed on the market". The Commission would like to clarify that the aim of the proposal is to sanction and facilitate the free movement of new psychoactive substances only for legitimate industrial and commercial uses, and for research and development, and not for human consumption. The Commission's proposal continues applying the approach implemented since 1997 to new psychoactive substances at the EU level, notably to withdraw harmful substances from the market rather than to authorise their placing on the market under certain conditions. For these reasons, the Commission believes that the provision suggested by the Senato della Repubblica would not be suitable for this proposal.*

*The Senato della Repubblica also notes that the proposal does not "provide for prior authorisation or registration for industrial use or use for scientific research [...] in order to prevent risks to public health". The Commission shares the concerns of the Senato della Repubblica regarding the risks of diversion of new psychoactive substances from legitimate*

*to clandestine uses and would like to reassure the Senato that it will further explore this in the course of negotiations.*

*The Commission hopes that these comments address the concerns raised by the Senato della Repubblica in its Opinion and looks forward to continuing the political dialogue in the future.*

*Yours faithfully,*

*Maroš Šefčovič  
Vice-President*