

SENATE OF THE REPUBLIC  
SEVENTEENTH PARLIAMENTARY TERM

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No 29

**RESOLUTION OF THE 12th STANDING COMMITTEE  
(Hygiene and Health)**

*(Rapporteur RIZZOTTI)*

*approved on 12 November 2013*

ON THE

**PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF  
THE COUNCIL ON NEW PSYCHOACTIVE SUBSTANCES (COM(2013) 619 FINAL)**

*under Article 144(1) and (6) of the Rules of Procedure*

**Communicated to the Presidency on 18 November 2013**

17TH PARLIAMENTARY TERM – DRAFT LEGISLATION AND REPORTS –  
DOCUMENTS DOC. XVIII, N. 29

The Committee,

having examined the Proposal for a Regulation of the European Parliament and of the Council on new psychoactive substances (COM(2013) 619 final),

noting that the legal basis indicated by the European Commission is Article 114 of the Treaty on the Functioning of the European Union, which concerns the approximation of Member State provisions relating to the establishment and functioning of the internal market;

noting that the stated aim of the proposal is to improve the functioning of the internal market regarding 'licit' uses of new psychoactive substances, by reducing obstacles to trade, preventing the emergence of such obstacles and increasing legal certainty for economic operators, while also reducing the availability of substances that pose risks through swifter, more effective and more proportionate EU action;

observing that the expression 'licit uses' is equivocal and open to a number of interpretations and applications and that in any case the use of such substances for indulgence or recreation could not be exempt from any form of control or consumer guarantee;

noting that the European Commission considers that the Member States alone are not in a position to reduce the problems caused by the distribution of harmful new psychoactive substances on the internal market and that uncoordinated national action risks producing adverse knock-on effects;

noting that the proposed Regulation would replace the existing basis for regulation in this field, namely Council Decision 2005/387/JHA, which is no longer considered adequate 'considering the scale and complexity of the problem', and that this legislative initiative is linked to a proposal for a Directive laying down minimum provisions on the constituent elements of criminal acts and penalties in the field of illicit drug trafficking;

stressing that, among the provisions to be repealed, Article 9(3) of Council Decision (2005/387/JHA) provides that a Member State must not be prevented from maintaining or introducing on its territory any national control measure it deems appropriate once a new psychoactive substance has been identified;

noting that since the proposed act is a Regulation, it would introduce rules of general application, binding in their entirety and directly applicable, which would have a substantial impact on existing national legislation on narcotics;

noting that the provisions in question would concern, in particular, only the new psychoactive substances that give rise to concerns at European level;

noting that the proposal, which provides for different categories of risk level to be attributed to different substances, may encourage the distribution of substances classified as posing 'moderate' or 'low' risks, and also excludes trafficking in such substances from the scope of criminal penalties;

whereas there is a lack of scientific evidence to justify firm conclusions on the degree of danger posed by new psychoactive substances;

stressing that it would be preferable to provide for a more prudent, dichotomous classification based on the presence or absence of risk, instead of the several graduated categories of risk provided for;

noting that the TFEU expressly provides that proposals under Article 114(1) must guarantee a high level of protection for health, safety and consumer protection;

noting that the choice to apply a graduated classification of the level of danger in the new substances is difficult to reconcile with the need to ensure the protection referred to above;

gives its opinion as follows:

unfavourable as regards the substance of the proposal, since it cannot agree with various aspects thereof, in particular:

- a) the provision for different categories of risk instead of a dichotomous distinction based simply on the presence or absence of risk;
- b) the preclusion of the adoption of restrictive measures for new psychoactive substances posing 'low' health, social and safety risks;
- c) failure 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;
- d) failure to provide for prior authorisation or registration for industrial use or use for scientific research of the new substances in order to prevent risks to public health in connection with possible clandestine human consumption;

favourable as regards the principle of subsidiarity, since the European Union is the best institutional level from which to ensure, in the sector concerned, protection of the correct functioning of the internal market, thereby avoiding the adoption at national level of divergent measures constituting an obstacle to trade and the development of possible industrial uses of the substances, 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;

unfavourable as regards the principle of proportionality, since the proposal includes measures that go beyond what is strictly necessary for the pursuit of the purposes specified, through measures which, in their current forms, would have a substantial impact on national legislation on narcotic substances.