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RESOLUTION OF THE 12th STANDING COMMITTEE

(Hygiene and Health)

(Rapporteur: Maurizio ROMANI)

adopted at the sitting of 11 October 2016

ON THE

PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL AMENDING REGULATION (EC) NO 1920/2006 AS REGARDS INFORMATION EXCHANGE, EARLY WARNING SYSTEM AND RISK ASSESSMENT PROCEDURE ON NEW PSYCHOACTIVE SUBSTANCES (COM (2016) 547 FINAL)

pursuant to Article 144(1) and (6) of the Rules of Procedure

Sent to the President's Office on 17 October 2016

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The Committee,

having examined the Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 1920/2006 as regards information exchange, early warning system and risk assessment procedure on new psychoactive substances (hereinafter 'the Proposal for a Regulation');

having regard to the observations of the 14th Senate Committee;

having regard to the Government's report of 3 October 2016, drawn up pursuant to Article 6(4) and (5) of Law No 234 of 24 December 2012;

whereas the aim of the Proposal for a Regulation is to strengthen the early warning system and risk assessment within the European Union, reducing and simplifying their time frames and procedures in order to increase the responsiveness of legislation;

whereas the Proposal for a Regulation complies with the principles of subsidiarity and proportionality, taking into consideration both the cross-border nature of the market for new psychoactive substances and the trafficking thereof, and the fact that existing European Regulations can only be amended by the European institutions;

whereas the Proposal for a Regulation also provides added value for the European Union in terms of better health protection by strengthening monitoring, early warning and the ability to tackle new harmful psychoactive substances;

expresses a favourable opinion, with the following observations:

With regard to Article 1(2) of the Proposal for a Regulation, the possibility for States to provide the European Monitoring Centre for Drugs and Drug Addiction with information on emerging trends and consumption habits concerning traditional psychoactive substances, or on the appearance on the local illegal market of new, dangerous forms of already known and classified drugs - which would be eliminated under the aforementioned provision - should be maintained. Indeed, the prompt circulation of this crucial information, once checked by the European Monitoring Centre, could be of invaluable assistance to the networks of services operating nationally to provide timely, targeted responses to health-related emergencies;

Member States' ability to prohibit or monitor psychoactive substances abused locally or closely associated with the internal illegal market, either on their own initiative or faced with inaction on the part of European bodies, should be safeguarded (this is currently covered by Council Decision 2005/387/JHA of 10 May 2005 which, according to the explanatory memorandum to the Proposal for a Regulation, is to be replaced).

OPINION OF THE 14TH STANDING COMMITTEE

(EUROPEAN UNION POLICIES)

(Rapporteur: GINETTI)

4 October 2016

The Committee, having examined the proposal concerning risk assessment in relation to new psychoactive substances;

whereas:

the Proposal for a Regulation in question replaces Regulation (EC) No 1920/2006 of the European Parliament and of the Council of 12 December 2006 on the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA);

Article 1(1) of the Proposal proposes adding exchange of information, early warning system and risk assessment on new psychoactive substances to the functions of the Centre. To perform these new functions, the Centre will cooperate with Europol, the National Focal Points of the European information network on drugs and drug addiction (Reitox), the Europol National Units, and the European Commission;

Article 1(3) introduces the following new Articles to Regulation (EC) No 1920/2006: 1) Article 5a, which provides for an information exchange and an early warning system on new psychoactive substances, for which the Reitox National Focal Points and the Europol National Units will be responsible; 2) Article 5b, according to which the EMCDDA shall be required to draw up an 'initial report on the new psychoactive substance' where, based on the exchange of information and early warning system defined under Article 5a, the new psychoactive substance may pose health or social risks at the Union level; 3) Article 5c, which provides for the possibility that, within two weeks from the receipt of the initial report, the Commission may ask the Centre to assess the potential risks posed by the new psychoactive substance; (4) Article 5d, which sets out the cases in which no risk assessment shall be carried out.

having examined the Government's report issued on 3 October 2016 pursuant to Article 6(4) and (5) of Law No 234 of 24 December 2012,

states, for matters within its remit, that it does not object to the proposals, highlighting the following points:

the legal basis is Article 168(5) of the Treaty on the Functioning of the European Union (TFEU), on 'incentive measures designed to protect and improve human health and in particular (...) monitoring, early warning of and combating serious cross-border threats to health'.

In this regard, the two previous proposals put forward by the European Commission in 2013, namely the Proposal for a Directive including new psychoactive substances in the definition of 'drugs' and the Proposal for a Regulation introducing market restrictions on such substances, have not yet been finalised. The same applies to the discussions on the legal basis held at the Council, given that the Directive is based on Article 38 TFEU, which includes opt-outs for Denmark, the United Kingdom and Ireland, while the Regulation is based on Article 114 TFEU on the internal market, which presupposes the existence of a legal market for the above-mentioned substances.

Given the difficulties presented by the previous legal bases, changing it could facilitate the process of negotiation for this Proposal, which is seen as complementary to the Proposal for a Directive; the latter seeks to extend criminal penalties for drugs to cover behaviour associated with psychoactive substances.

The principles of subsidiarity and proportionality are respected, taking into account the cross-border nature of the market for new psychoactive substances and of the trafficking that may be associated with said substances. Moreover, in formal terms, any amendment to existing European Union Regulations (in this case, Regulation (EC) No 1920/2006) is the responsibility of the European institutions. The added value for the EU lies in the better protection of health through the strengthening of monitoring, early warning and the fight against new psychoactive substances.

In this regard, the committee supports the aim of the Proposal in question, which is to reduce the time frames for risk assessment concerning new psychoactive substances.

Moreover, the Committee considers it advisable to keep open the possibility of ensuring a police information channel, via Europol, separate from that for information obtained through the health system. Therefore, in Article 1(3) of the Proposal for a Regulation, in the first sentence of the first paragraph of the newly-added Article 5a, after the words 'the available information on new psychoactive substances', the words 'taking into account the two bodies' respective mandates' should be added.

The Committee also considers that the possibility, provided for by the current Article 9(3) of Council Decision 2005/387/JHA of 10 May 2005, for Member States to maintain or introduce on their territory any national control measure they deem appropriate once a new psychoactive substance has been identified by a Member State, should be maintained.