New psychoactive substances: information exchange, early warning system and risk assessment procedure

2016/0261(COD) - 29/08/2016 - Legislative proposal

PURPOSE: to amend Regulation (EC) No 1920/2006 as regards information exchange, early warning system and risk assessment procedure on new psychoactive substances (NPS).

PROPOSED ACT: Regulation of the European Parliament and of the Council.

ROLE OF THE EUROPEAN PARLIAMENT: the European Parliament decides in accordance with the ordinary legislative procedure and on an equal footing with the Council.

BACKGROUND: new psychoactive substances can pose serious cross border threats to health which makes necessary to enhance monitoring, early warning and combating of those threats.

In 2015, 100 new substances were reported for the first time to the EU Early Warning System (EWS), bringing the total number of new substances monitored to **more than 560 – with more than 380 (70%) of these detected in the last five years** alone.

On 17 September 2013, the Commission put forward a package of two legislative proposals on new psychoactive substances: (i) a proposal for a Regulation on new psychoactive substances and; (ii) a proposed Directive amending Council Framework Decision 2004/757/JHA 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.

Inter-institutional negotiations of this legislative package have been ongoing for more than two years . The European Parliament adopted its legislative resolutions on 17 April 2014. The Council did not adopt a general approach on the proposals; during the examination of the proposals Member States expressed doubts concerning the choice of Article 114 of the Treaty on the Functioning of the European Union (TFEU) as the legal basis for the proposed Regulation.

In response to the **agreement by COREPER** on 6 April 2016 on a compromise approach proposed by the Netherlands Presidency of the Council to achieve the same objective of a swifter, more effective EU action on NPS, the Commission proposes targeted amendments of Regulation 1920/2006 integrating the draft provisions on early warning system and risk assessment procedure that were part of the 2013 Commission proposal for a Regulation on new psychoactive substances into the founding Regulation of the EMCDDA.

The proposal reflects the priorities set out by the European Agenda on Security adopted on 28 April 2015.

CONTENT: this proposal - based on Article 168(5) TFEU - seeks to amend Regulation (EC) No 1920 /2006 in order to **strengthen the EU early warning system and the risk assessment** and streamline procedures to ensure more effective and fast action.

In order to speed up the process, **deadlines are substantially shortened** compared to the current system based on Council Decision 2005/387/JHA.

For the purpose of swift and effective collection of information on NPS, the EMCDDA should conclude working arrangements with Europol, the European Medicines Agency, the European Chemicals Agency and the European Food Safety Authority without undue delay following the publication of the Regulation in the Official Journal.

This proposal also ensures a **participation of EUROPOL** in the early warning system and risk assessment procedure, in particular as input on the involvement of criminal groups in the manufacture and distribution of new psychoactive substances is concerned.

According to Article 23 of Regulation 1920/2006 the Commission may propose, if appropriate, and in the light of developments in respect of regulatory agencies on the basis of the next evaluation of the Centre further amendments to the EMCDDA founding Regulation

The following amendments to Regulation 1920/2006 seek to:

- clarify that tasks of the EMCDDA are information exchange and early warning on new psychoactive substances as well as risk assessment. The Centre also monitors all new psychoactive substances that have been reported by Member States;
- establish the respective roles of Member States, the EMCDDA and Europol in the process of exchange of information and early warning on new psychoactive substances;
- lay down the contents and the procedures for the drawing up and the transmission by the EMCDDA of an initial report on a new psychoactive substance. Europol, the European Medicines Agency, the European Chemicals Agency and the European Food Safety Authority are associated to the collection of information for an initial report;
- empower the Commission to request the EMCDDA to assess the risks of a new psychoactive substance on which an initial report has been drawn up. The proposal lays down the procedures for the risk assessment, which is to be conducted by the Scientific Committee of the EMCDDA, and for the drawing up and the transmission of a risk assessment report;
- detail circumstances in which no risk assessment is to be conducted on a new psychoactive substance.

BUDGETARY IMPLICATIONS: the subsidy for the Centre forms already part of the Union's budget. However, for the Centre to adequately deal with the growing number of requests related to information exchange on new psychoactive substances as well as with the proposed streamlined procedures for the EU early warning system and risk assessment procedure, an amount of **EUR 676 000 in total for the period 2017-2020** for the system development and an amount of **EUR 100 000 per year** to finance three additional contract agents will need to be added to the Centre's budget.