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

2016/0261(COD) - 15/11/2017 - Final act

PURPOSE: to strengthen the EU's early warning system and risk assessment procedure for new psychoactive substances (NPS).

LEGISLATIVE ACT: Regulation (EU) 2017/2101 of the European Parliament and of the Council amending Regulation (EC) No 1920/2006 as regards information exchange on, and an early warning system and risk assessment procedure for, new psychoactive substances.

CONTENT: this Regulation amends Regulation (EC) No 1920/2006 in order to **strengthen surveillance** and improve the early warning system and to assess the health and social risks associated with new psychoactive substances. The Regulation shall take into account that **vulnerable groups**, especially young people, are particularly exposed to the risks associated with these new substances.

The main amendments adopted concern the following points:

Exchange of information, early warning system and risk assessment: each Member State shall ensure that its national focal point and Europol national units provide the **European Monitoring Centre for Drugs and Drug Addiction** (EMCDDA) with the necessary information they have on the NSPs.

The Centre, in cooperation with Europol, shall collect, collate, analyse and assess the information and communicate it in a timely manner to the national focal points and the Europol national units as well as to the Commission with a view to providing them with any information required for the purposes of early warning and for the purposes of allowing the Centre to draw up the initial report.

Initial report: where the Centre, the Commission or a majority of the Member States considers that information shared on a new psychoactive substance collected in one or more Member States gives rise to concerns that the new psychoactive substance may pose health or social risks at Union level, the Centre shall draw up an initial report on the new psychoactive substance.

The initial report shall allow the Commission to make an informed decision regarding the launch of the risk assessment procedure. Europol, the European Medicines Agency, the European Centre for Disease Prevention and Control, the European Chemicals Agency and the European Food Safety Authority shall be involved in collecting information for the preparation of the initial reports.

Risk assessment procedure and report: within **two weeks** of receipt of an initial report, the Commission may request the Centre to assess the potential risks posed by the new psychoactive substance and to draw up a risk assessment report. The Centre shall submit the risk assessment report or the combined risk assessment report to the Commission and the Member States within **six weeks** of receipt of the request from the Commission to draw up a risk assessment report. Following the risk assessment procedure, the Commission shall determine whether the new psychoactive substance in question should be included in the definition of ‘drug’ in accordance with the procedure provided for in Council Framework Decision 2004/757/JHA.

Exclusion from risk assessment: no risk assessment shall be carried out where the new psychoactive substance is at an advanced stage of assessment within the United Nations system.

No risk assessment shall be carried out where the new psychoactive substance is an active substance in a medicinal product for human use or in a veterinary medicinal product that has obtained a marketing authorisation.

ENTRY INTO FORCE: 22.11.2017.

APPLICATION: from 23.11.2018.