

New psychoactive substances

2013/0305(COD) - 17/09/2013 - Legislative proposal

PURPOSE: to approximate the rules relating to new psychoactive substances that are of concern at Union level whilst ensuring a high level of health, safety and consumer protection.

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, which may have numerous commercial and industrial uses, as well as scientific uses, can pose **health, social and safety risks** when consumed by humans. Consumption of new psychoactive substances appears to be **increasing in Europe and use is predominant among young people**. According to the 2011 Eurobarometer "Youth attitudes on drugs", 5% of young people in the EU have used such substances at least once in their life, with a peak of 16% in Ireland, and close to 10% in Poland, Latvia and the UK.

During the past years, Member States have notified an increasing number of new psychoactive substances to the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA). **National restriction measures, which can vary depending on the Member State** and on the substance, lead to obstacles to trade in licit uses, fragmentation, an uneven level playing field and legal uncertainties for economic operators, and make it difficult for companies to operate across the internal market. They make research more cumbersome, hampering the development of new uses for these substances.

In this context, the case for swifter, more effective and more proportionate action on new psychoactive substances at EU level is compelling, considering the rapid changes in this market, which put national authorities under pressure to act.

The Commission Communication "[Towards a stronger European response to drugs](#)", adopted in October 2011, identified the spread of new psychoactive substances as one of the most challenging developments in drugs policy requiring a firmer EU response.

IMPACT ASSESSMENT: taking into account the results of impact assessment, the following solutions are preferred: (i) a more graduated and better targeted set of restriction measures on new psychoactive substances, which should not hinder the industrial use of substances; (ii) restriction measures should be introduced earlier; (iii) substances suspected to pose immediate public health risks should be subjected to temporary restrictions; (iv) restriction measures should be proportionate to a better determined level of risk of substances; (v) restriction measures should be introduced through a quicker procedure.

LEGAL BASIS: Article 114 of the Treaty on the Functioning of the European Union.

CONTENT: this proposed Regulation – which is intended to replace [Council Decision 2005/387/JHA](#) - aims at ensuring that **trade** in new psychoactive substances having industrial and commercial uses **is not hindered** and that the functioning of this market is improved, while the **health and safety of individuals are protected** from harmful substances, which cause concern at the EU level.

The proposal is accompanied by a [proposal for a 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.

The main elements of the proposal are as follows:

Exchange of information and temporary consumer market restrictions: this proposal sets up a robust system: (i) for exchanging rapidly information on new psychoactive substances emerging on the market, including on their commercial and industrial uses, for assessing the risks of substances that cause EU-wide concern and; (ii) for withdrawing from the market those substances that pose risks.

The substances suspected to pose immediate public health risk will be withdrawn from the consumer market temporarily, pending their risk assessment. Once the risk assessment is completed, measures will be taken proportionate to the risks of substances.

The proposal establishes the respective roles of Member States, the EMCDDA and Europol in the process of exchange of information on new psychoactive substances.

Low and moderate risks: according to the proposal, no restriction measures shall be introduced on new psychoactive substances posing low health, social and safety risks and provides a definition of low risks.

For substances posing moderate risks and permanent consumer market restrictions, they cannot be sold to consumers (except for uses specifically authorised, for instance by medicines legislation) but their trade is allowed for commercial and industrial purposes as well as for scientific research and development.

Severe risks: the proposal empowers the Commission to prohibit the production, manufacture, making available on the market, transport, importation or exportation of new psychoactive substances which pose severe health, social and safety risks, and provides a definition of severe risks.

New psychoactive substances posing severe risks will be subjected to **permanent market restriction**, covering both the consumer and commercial markets, and their use will only be possible for specifically authorised industrial and commercial purposes, as well as for scientific research and development. In addition, these substances will be subjected to EU criminal law provisions.

Sanctions: the proposal establishes the obligation for the Member States to lay down the rules on administrative sanctions applicable to infringements to market restriction, and to ensure that they are effective, proportionate and dissuasive.

BUDGETARY IMPLICATION: the proposal has no direct impact on the EU budget and does not create new tasks for the EMCDDA, Europol, the European Medicines Agencies, the European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA).