New psychoactive substances

2013/0305(COD) - 17/04/2014 - Text adopted by Parliament, 1st reading/single reading

The European Parliament adopted by 507 votes 37 with 33 abstentions, a legislative resolution on the proposal for a regulation of the European Parliament and of the Council on new psychoactive substances.

Parliament's position in first reading following the ordinary legislative procedure amended the Commission position as follows:

Information exchange: to enable a more effective response to the rapid emergence and spread of new psychoactive substances across the Union, Parliament considered that the **information exchange mechanism (the 'Early Warning System') should be maintained and further developed**, in particular as regards to the collection and management of data on the detection and identification of new psychoactive substances.

The European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) should **issue health alerts to all Member States, through the system for rapid exchange of information** on new psychoactive substances if, on the basis of information received on a new psychoactive substances, this seemed to cause public health concerns. Those health alerts should also contain information regarding prevention, treatment and harm reduction measures that could be taken to address the risk of the substance. Information should include consumption and its patterns, **serious intoxication** or deaths, possible risks as well as the toxicity level, and data concerning manufacture.

Risk assessment: a risk assessment should be conducted if there were sufficient data available at Union level to suggest the need for a joint report of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and Europol.

Immediate risks to public health, and market restrictions: the proposal provided that the Commission should, by means of a Decision, prohibit the making available on the market to consumers of the new psychoactive substance if, based on existing information, it poses immediate risks to public health. The market restriction should not exceed a period of twelve months.

Members proposed that if the level of health, social and safety risks posed by the new psychoactive substance justified the introduction of permanent restriction measures, **the duration of the temporary market restriction may be extended by a further 12 months**, in the absence of permanent market restriction.

Low risks at Union level: the Commission should not adopt restriction measures on a new psychoactive substance if, based on the **existing evidence and on prescribed criteria**, it posed, overall, low health, social and safety risks at Union level.

However, where the decision to not adopt restriction measures on a new psychoactive substance that was considered to pose overall low health, social and safety risk at Union level was based on a partial or total lack of evidence, it should include an appropriate reference in the justification.

Parliament also stressed that **Members States should not be prohibited from introducing or maintaining the more stringent measures** regarding the specific risks the new psychoactive substance posed within their territory, independently of the classification of the substance by the Commission as posing low or moderate risks on the EU level.

A Member State willing to introduce a more stringent measure concerning the new psychoactive should immediately communicate the relevant draft laws, regulations or administrative provisions to the Commission and shall inform the other Member States.

Authorised use: decisions prohibiting the marketing of new psychoactive substance presenting a serious risk should not impede the free movement in the Union and the production, manufacture, making available on the market of **new psychoactive substances for scientific research and development purposes**, by duly authorised persons in establishments which were directly under the control of Member States' authorities or specifically approved by them.

For all of authorised uses, new psychoactive substances and products containing new psychoactive substances should include **directions for use**, including cautions, warnings and contraindications with other substances, to be either indicated on the label or included in the accompanying leaflet for the safety of the user.

Furthermore, Member States should take any appropriate measures to prevent the **diversion to the illicit market** of new psychoactive substances used for research and development purposes or for any other authorised uses.

Research, analysis, prevention and funding: the amended text provided that financial support and the necessary resources should be provided at Union and national level for the development, sharing and dissemination of information and knowledge on new psychoactive substances.

Moreover, the Commission and the Member States should promote the research into new psychoactive substances and ensure cooperation and coordination between networks at national and Union level in order to strengthen understanding of the phenomenon.

Prevention schemes as well as measures to raise awareness of the risks posed by psychoactive substances, such as **educational information campaigns** should be promoted.

Evaluation: the EMCDDA and Europol should report annually to the European Parliament, the Commission and Member States on the implementation of the Regulation. Five years after the entry into force of the Regulation and every five years thereafter, the Commission should:

- assess the implementation, application and effectiveness of this Regulation and publish a report. In this respect, the Commission, the EMCDDA and Europol should conduct post-risk assessments of new psychoactive substances;

- evaluate and if appropriate present a proposal for possible classification of groups of the new psychoactive substances in order to counteract the practise of bypassing the legislation in force by slight modifications of the chemical structure of the psychoactive substances.

The implementation reports should be published on a website and made publicly available.