Combatting drugs: information exchange, risk-assessment and control of new psychoactive substances

2003/0215(CNS) - 11/07/2011 - Follow-up document

The Commission presents a report on the assessment of the functioning of Council Decision 2005/387 /JHA on the information exchange, risk assessment and control of new psychoactive substances. The assessment is a follow-up to the recommendation of the EU Drugs Action Plan 2009-2012 which requires the Commission to assess the functioning of this Council Decision and amend it, if necessary.

The assessment highlights the fact that the **market for new psychoactive substances has changed dramatically** in the past three years: there has been a significant increase in the number of substances detected, their variety and the diversification of their distribution channels.

Whilst the Council Decision on new psychoactive substances is certainly a useful instrument for tackling new substances at the EU level, in particular as it allows for an exchange of information among the Member States (early warning system), it appears from the assessment that it has three major shortcomings when it comes to submitting these substances to Europe-wide control measures:

Increase in new substances: the Decision is not able to tackle the large increase in the number of new psychoactive substances on the market, because it addresses substances one by one, through a lengthy process. In the past five years, Member States have notified 115 psychoactive substances through the information exchange mechanism set up by the Council Decision. While in the period 2005-2008 the number of new substances notified was stable at 10-15 a year, from 2009 there was a large increase in the number of notifications.

Many new psychoactive substances are in fact variations within a specific group of chemicals and are similar to substances controlled at national level. Some are products containing herbal and synthetic compounds that appear in various mixtures in different Member States. One example is Spice, a mixture containing herbs and synthetic cannabinoids that mimic the effects of cannabis. They are difficult to identify and regulate because of their diversity and the speed with which they are developed to replace those that are controlled.

Decision is reactive: substances submitted to control measures are quickly replaced with new ones with similar effects, often through small modifications of their chemical composition. Several Member States argue that the Decision prevents a comprehensive response, because as soon as a substance is submitted to control measures, a new one may be developed and easily marketed to replace it. It also makes it difficult to take action on drugs that are composed of several substances, in various combinations, each of which should be studied individually. This is why no action was taken at EU level on Spice.

Lack of alternative control measures: the Council Decision stipulates that, based on the findings of the risk assessment, the Council may decide on the submission of the substance to control measures and on the obligation to introduce criminal law measures. The lack of alternatives (i.e. measures other than criminal ones) mirrors the mechanism of the UN Conventions on illicit drugs. The risk assessments on BZP and mephedrone provided arguments for submitting the substances to control measures. Both concluded that the substances posed risks for health and society but acknowledged that there was limited scientific evidence on the acute and long-term effects on health and fatalities, on consumption patterns and on prevalence. In both cases the Council agreed to submit it to control measures, requiring Member States

to introduce criminal sanctions. In the case of BZP, the Council acknowledged that the risk assessment lacked conclusive evidence on the overall risks of the substance but it stated following the precautionary principle that it was necessary to take measures because of its risk to health.

A more effective instrument: subject to a further impact assessment, the Commission will examine the need for a more effective legal instrument. It will examine how to reconcile the need for a rapid response with enhanced risk assessment of substances. It will assess measures to extend the support for collecting toxicological and forensic information. The Commission sees the need for a **comprehensive response** at EU level to the frequent emergence and rising popularity of these substances. The key challenge is that they are manufactured and traded in a regulatory grey area, somewhere between drugs control, food safety, consumer protection, medicines and chemicals legislation. Authorities in many Member States are often unsure what legislation would tackle these substances most effectively.

Many substances that were notified by the Member States were not of EU-wide concern and were therefore dealt with at national level. Certain products, for instance Spice, raised concerns across several EU Member States, but were not dealt with at EU level because of the limited scope for action under the Council Decision to address such mixtures of substances. Several other substances that have raised public health concerns could probably have been tackled at EU level had the Council Decision offered 'lighter' risk-management options, in addition to criminal control measures.

The report stresses the importance of closing gaps between drugs control and other types of legislation, including food or product safety. In addition to criminal justice control measures, alternative risk management options would need to be assessed with a view to a faster response, at EU level, to the emergence of substances that raise concerns.

To improve understanding of the rapidly evolving market for new psychoactive substances, the Commission will examine ways of monitoring substances that are not submitted to risk assessment but that cause concern as well as those subjected to control measures.

Any legislative proposals on new psychoactive substances should be based on thorough and comprehensive analysis and debate. Therefore, **the European Parliament and the Council are invited to take part in the debate** on how EU legislation in this field could be made more effective. In the autumn, the Commission intends to present to the European Parliament and the Council, the main objectives and options for revising Council Decision 2005/387/JHA.

As legislation alone will not provide the complete answer to the complex challenge posed by new psychoactive substances, the Commission invites Member States to step up their efforts to improve the efficiency of drug information and prevention programmes, which should take into account the rising popularity of new psychoactive substances.