

Contained use of genetically modified micro-organisms (GMOs). Recast

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The Commission presents a report on the experience of Member States with Directive 2009/41/EC on the contained use of genetically modified micro-organisms (recast) for the period 2006 – 2009. This report is based on a sixth series of Member States' reports.

Activities: to recall, contained use activities are classified into four classes: class 1 represents activities of no or negligible risk; classes 2, 3 or 4 represent activities of low, moderate or high risk, respectively.

Most contained use activities fell within class 1 or class 2. Significantly fewer class 3 and 4 activities were being carried out, but the number is increasing. Most activities were related to research but several serve commercial purposes such as the manufacture of diagnostics, or veterinary or medicinal products. On the whole, the Member States applied the Directive in a similar fashion. Differences arose as Member States enacted additional legislation in almost all areas covered by the Directive.

Problems with interpretation of the provisions: some Member States named topics which need further clarification, in relation with a necessary update of technical and scientific advancement and/or further harmonization on the European level.

- In Austria, Bulgaria, Cyprus, Estonia, Latvia, Lithuania, Malta, Portugal, Romania and Slovakia no specific problems with the interpretation of the provisions were reported. For the New Member States, in the majority of the cases the reason is the lack of activities due to the lack of notifications.
- Belgium, Czech Republic, Hungary and the Netherlands encountered problems in **assessing whether the application of certain new techniques resulted in a genetically modified organism** and fell within the scope of Directive 2009/41/EC. At the request of the Competent Authorities of Directive 2001/18/EC the Commission set up a New Techniques Working Group in October 2007 to assess a non-exhaustive list of techniques as to whether they result in the production of a genetically modified organism or microorganism as defined under Directives 2001/18/EC and 2009/41/EC. The outcome is expected to help to clarify whether certain new techniques result in genetically modified organisms and fall within the scope of Directive 2009/41/EC.
- The Netherlands, Spain, Hungary, Czech Republic, Belgium, Finland saw a need for **clarification of the scopes of Directive 2009/41/EC and Directive 2001/18/EC with respect to clinical trials.**

Other problems encountered in case of implementation of the Directive 2009/41/EC were the following:

- difficulties with the detection and identification of GMOs (Germany), lack of clarity of terminology (Germany, Finland);
- huge number of notifications of class 1 to be reviewed (Denmark), or huge number of inspections (Ireland);
- high number of notifications for viral vectors with low risk (United Kingdom) which created a significant administrative burden;
- difficulties in obtaining feedback from the users working with GMO/GMM (Spain). Member States proposed different measures such as including safe organisms in Part C of the Annex II of

the Directive 2009/41/EC (Slovenia), to set up a EU GMM Working Group focusing on research activities from the perspective of Directive 2009/41/EC, and to change the requirements for notifying class 2 activities (United Kingdom).

Clinical trials: the national reports showed that the **Member States addressed clinical trials in different ways**. Some Member States (Denmark and Finland) applied Directive 2009/41/EC on the contained use of GMMs, others (for example, Sweden) used Directive 2001/18/EC on the deliberate release of GMOs into the environment, and yet others applied other national legislation. Other Member States (Spain, UK) decide on a case-by-case basis whether a clinical trial is regarded as contained use or as a deliberate release. These differences stem from differences in the interpretation of annexes of Directive 2001/18/EC and Directive 2009/41/EC, in particular, as the latter Directive had not been specifically designed for clinical trials.

However, both Directives attribute the competence to regulate clinical trials with GM microorganisms essentially to the Member States, Directive 2009/41/EC by setting minimum standards leaving it up to the Member States to go beyond those minimum standards, and Directive 2001/18/EC by attributing the competence for authorising part B notifications to the Member States. Some Member States raise the point that further harmonization would be useful. However, most importantly, both Directives share as common objective a high level of protection so that, from a safety point of view, **further harmonisation at Union level is at present not a priority for the Commission**.