

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

2007/0259(COD) - 20/12/2016 - Follow-up document

This Commission report examines the experience acquired by Member States in the framework of Directive 2009/41/EC of the European Parliament and of the Council on the contained use of genetically modified micro-organisms (recast) for the period 2009-2014.

The document presents a summary of the information provided by 26 Member States for each of the following aspects:

Operations and facilities: Most of the contained use operations carried out in the Member States, according to the information provided, fall within **Class 1** (zero or negligible risk) **or 2** (low risk). Few Class 3 or 4 operations (moderate and high risk) have been carried out.

Most of the operations were related to **research activities**, but several pursued commercial objectives, such as the manufacture of diagnostics and veterinary and human medicines.

Notification and approval systems: national systems differ slightly with regard to the competent authorities.

In many Member States, the competent authority for notification and approval is the ministry of the environment or environmental agencies. In others, these functions are performed by other ministries, acting alone or in collaboration with other authorities, such as the Ministry of Health or Research. Overall, the notifications were **processed within the deadlines** set by the Directive.

Accidents: few Member States (Finland, the Netherlands, Slovakia, Sweden and the United Kingdom) reported accidents. **Corrective actions** have been taken in the case of accidents with respect to operational processes and procedures, as well as installations used for contained use operations. The institutions concerned have made the necessary changes to prevent similar events from occurring in the future.

Inspections and enforcement measures: control procedures include regular annual inspections, unannounced inspections, first-time facilities checks, material sampling, and document and procedure checks.

Several problems were raised during inspections (e.g. inappropriate waste management, inaccurate documentation, ignorance of the latest genetic modification technologies, inadequate staff training, and inadequate signage). Where the inspections have identified situations requiring corrective action, the competent authorities must ensure that the notifiers take the necessary measures to make the necessary changes within the time limits laid down.

Problems in interpreting the provisions of the Directive: there are problems in some Member States, particularly with regard to the definition of genetic modification laid down in the Directive, notifications of genetic modifications resulting from the use of new techniques, the assessment of the various classes of GMMs, the "next contained use" operation and clinical trials under the Directive.

Several Member States pointed out that the large number of notifications, the demanding information requirements for each notification, the detailed reporting system and the complexity of the various procedures can create a **heavy administrative burden** for authorities and notifiers.

Public consultation and information: practically all Member States apply the provisions on public consultation and public information on the results of operations within the framework of the Directive. Some States, however, restrict public consultation to Classes 3 and 4 operations. Although the Internet is the most common means of communication, other means (seminars, meetings, brochures, etc.) are also used. Overall, no response was received through public consultations.

Waste disposal: Member States state that they treat waste management by class or by waste category. Only a few Member States (Belgium, Lithuania, Poland and Portugal) plan to inactivate all types of waste before disposal. Some Member States have disposal facilities dedicated to the inactivation of GM waste, while others use general waste treatment facilities.