Genetically modified organisms GMOs: deliberate release into the environment (repeal. Directive 90/220/EEC)

1998/0072(COD) - 05/03/2007 - Follow-up document

In accordance with the requirement in Article 31.6 of Directive 2001/18/EC, the Commission reports on experience of Member States with GMOs placed on the market under Directive. All Member States (MS) were required to submit three-year reports to the Commission for the period 17 October 2002 ? 17 October 2005, on the measures taken to implement the provisions of the Directive, including a brief factual report on their experience with GMOs placed on the market in or as products under the Directive. All MS except Portugal submitted their three-year reports to the Commission. The report also includes experience with GMOs for purposes other than placing on the market, i.e. research and development (Part B of the Directive) as well as contributions from other stakeholders such as industry/trade organisations, farmers' associations and environmental NGOs.

Placing on the market of GMOS as or in products (Part C of the Directive): a total of 26 Part C notifications for GM plants was submitted under the Directive to eight MS. However, following the introduction of Regulation 1829/2003/EC on GM food and feed, thirteen applications remained under the Directive. Out of these 13 applications, 5 products have been authorised, 4 from Monsanto. The majority of MS concur that the implementation of the Directive has helped to restore confidence in the authorisation process for the placing on the market of GM products. A number of MS have commented on the largely negative attitude of non-industry stakeholders towards new authorisations. Industry reported that, in its experience, the implementation of Directive 2001/18/EC has not helped to restore confidence in the EU decision making process for Part C applications and points in particular to the fact that no consents for cultivation have been issued since 1998.

On thresholds, MS reported difficulties with managing conventional seed lots which may contain adventitious presence of authorised GMOs, in the absence of seeds' thresholds for adventitious presence. Industry reported on the need to establish thresholds for authorised GMOs as well as for those not yet authorized in the EU, but which have already been approved for deliberate release in third countries. NGOs and some MS have demanded that thresholds be set at the level of detection of GM traces. Industry noted that many EU farmers are reluctant to grow GM varieties in many MS where large food processors, traders and retailers remain cautious about the use of GM material in the light of increasingly negative public opinion and of the costs associated with traceability. In addition, as first generation GMO products become obsolete and are no longer commercially marketed, industry has requested proportionate renewal procedures to cover any remaining adventitious traces of these GMOs in order to ensure legal certainty following the expiry of consents.

A majority of MS reported that there is a need for a more consistent approach to post-market monitoring while retaining the possibility for specific monitoring depending on the specific climate and natural environment in a MS. Several MS considered that monitoring plans submitted to date had tended to lack detail and a clear allocation of responsibilities. NGOs reported that, as more GMOs are marketed, there would be a need for a more coordinated approach with allocation of responsibility to an independent body rather than to the consent-holder alone, to carry out assessment of all monitoring and surveillance data relating to deliberate releases.

Many MS have reported that the protocols included in Recommendation 2004/787/EC on technical guidance for sampling and detection of genetically modified organisms are complex, time-consuming and expensive and that results are not in proportion to the time and expense involved.

Concerning the presence of antibiotic resistance marker genes, the majority of MS reported that the Opinion of the GMO Panel of the European Food Safety Authority (EFSA) dated 2 April 2004 has proven useful for the phasing-out of such genes. NGOs however have called for a new assessment of ARM genes to look solely at potential adverse effects on human health and the environment, without reference to their use by industry as a means to ensure the efficient selection of transgenic events in plants.

Research and Development (Part B of the Directive): 245 applications for the release of GMOs for purposes other than for placing on the market were submitted to 13 MS during the reporting period of 17 October 2002 ? 17 October 2005. The highest numbers of applications were submitted in Spain (89), France (54), Germany (25), Hungary (21), Sweden (18) and Netherlands (13). Twelve MS did not receive any applications. Of the total of 245 applications 191 consents were issued, and 27 applications were refused. The highest percentage of refusals was in Hungary. A majority of MS consider that the Directive has provided a more transparent and predictable regime. Concerns were expressed, however, about the lack of consistency among MS, given that the authorisation process is largely at the national level, and about the possibility of contamination of neighbouring crops from Part B trials. A number of MS also highlighted the specific issue of clinical trials on gene therapy, given that some MS currently apply the provisions of Directive 90/219/EC on contained use whilst others apply Directive 2001/18/EC on deliberate release into the environment. This issue will be discussed with the competent authorities appointed under both pieces of legislation in 2007.

Industry also called for greater harmonisation of Part B applications across the EU, citing differences amongst MS regarding data requirements, timelines and information to the public which decreased the predictability of the current system. Industry expressed particular concern about the timing of consents which were sometimes issued after the planting season.

A majority of MS considered that the Commission had provided clear guidance on what is required in the environmental risk assessment. Nevertheless a number of MS would appreciate additional guidance on what are considered to be acceptable and unacceptable risks and on long-term cumulative effects. Industry also called for more harmonisation of the environmental risk assessment requirements. NGOs pointed to the need for stronger guidelines for allergenicity testing.

Industry also expressed concern about the release of the exact location of field trials which often resulted in the harassment of farmers and ultimately in the destruction of the trials by anti-GM activists. This had clear adverse effects on biosafety research and on biotechnology product development in the EU. NGOs called for information of public interest to be easily and quickly accessible.

Conclusions: those Member States which have handled applications are generally positive about their experience with the implementation of the Directive, despite a number of technical issues which have yet to be adequately addressed such as a cost-effective and practical sampling and detection system, as well as greater consistency, more detail and better allocation of responsibilities in post-market monitoring measures.

Other stakeholders have tended to be less positive in their assessment of the Directive.

The Commission is committed to working with EFSA to further develop guidelines as part of an overall framework for risk assessment with a view to increasing the overall transparency of, and confidence in, the evaluation process. The majority of Member States would also welcome increased harmonisation on the process for Part B releases, including gene therapy trials, the definition of ?location? of field trials, additional guidance on environmental risk assessment and management measures to prevent contamination of neighbouring crops.

Lastly, the majority of Member States has emphasised the need for a legal instrument establishing seeds? thresholds, based on the difficulties they have experienced in managing the labelling and traceability of conventional seed lots without such thresholds for adventitious presence. The Commission is currently exploring various options in relation to this issue.