COMMISSION OF THE EUROPEAN COMMUNITIES

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SECOND REPORT FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT

on the experience of Member States with GMOs placed on the market under Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms.

{SEC(2007) 274}

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1. BACKGROUND AND SCOPE

On 17 October 2002, Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms (GMOs) and repealing Council Directive 90/220/EEC[1] became fully applicable.

According to Article 31.6 of this Directive, 'the Commission shall send to the European Parliament and the Council, in 2003 and thereafter every three years, a report on the experience of Member States with GMOs placed on the market under this Directive.'

The first report to the European Parliament and the Council was adopted by the Commission on 31 August 2004[2]. Subsequently, in accordance with Article 31.4 of Directive 2001/18/EC, 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 and a summary is included in Annex 1 to this second report to the European Parliament and the Council.

In order to deliver a comprehensive and balanced report to the European Parliament and to the Council, the Commission considers it appropriate

- to include experience not only with GMOs placed on the market under the Directive (Part C of the Directive) but also experience with GMOs for purposes other than placing on the market, i.e. research and development (Part B of the Directive) as well as

- to include contributions from other stakeholders such as industry/trade organisations, farmers' associations and environmental NGOs. A list of stakeholders who contributed is included in Annex 2.

The three-year reports from MS as well as contributions from other stakeholders thus form the basis of this second report to the European Parliament and to the Council.

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1 OJ L 106 , 17.4.2001 p. 1 – 39.

2 Available at http://ec.europa.eu/environment/biotechnology/index_en.htm

2. PLACING ON THE MARKET OF GMOS AS OR IN PRODUCTS (PART C OF THE DIRECTIVE)

Numbers of applications and authorisations

A total of 26 Part C notifications for GM plants was submitted under the Directive to eight MS (BE, DE, DK, ES, FR, NL, SE, UK) between 17 October 2002 and 17 October 2005. However, as of 18 April 2004, Regulation 1829/2003 on GM food and feed[3] became fully applicable. According to transitional arrangements set out in Article 46(3) of this Regulation, notifications submitted under Directive 2001/18/EC, which included feed use and for which an assessment report had not yet been provided, were transferred to the authorisation procedure under the Regulation. As a result of this exercise and following the withdrawal of a further three applications by the notifiers, thirteen applications remained under the Directive.

Out of these 13 applications, 5 products have been authorised under the Directive, as follows:

- **NK603 maize** from Monsanto Europe S.A [4],
- **MON863 maize** from Monsanto Europe S.A[5],
- **GT73 oilseed rape** from Monsanto Europe S.A[6],
- **1507 maize** from Pioneer Hi-Bred International INC and Mycogen Seeds[7], and
- **MON863 X MON810 maize** from Monsanto Europe S.A[8].

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3 Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed, OJ L 268 , 18.10.2003 p. 1 – 23.

4 Commission Decision 2004/643/EC of 19 July 2004 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (Zea mays L. line NK603) genetically modified for glyphosate tolerance. OJ L 295, 18/9/2004, p. 35-37. Final consent issued by Spain on 18/10/2004.

5 Commission Decision 2005/608/EC of 8 August 2005 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (Zea mays L., line MON 863) genetically modified for resistance to corn rootworm. OJ L 207, 10/8/2005, p. 17-19. Final consent issued by Germany, 9/2/2005.

6 Commission Decision 2005/635/EC of 31 August 2005 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of an oilseed rape product (Brassica napus L., GT73 line) genetically modified for tolerance to the herbicide glyphosate. OJ L 228, 3/9/2005, p. 11-13. This Decision was accompanied by Commission Recommendation 2005/637/EC of 16 August 2005 concerning the measures to be taken by the consent holder to prevent any damage to health and the environment in the event of the accidental spillage of an oilseed rape (Brassica napus L., GT73 line — MON-00073-7) genetically modified for tolerance to the herbicide glyphosate. OJ L 228, 3/9/2005, p. 19-20.

7 Commission Decision 2005/772/EC of 3 November 2005 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (Zea mays L., line 1507) genetically modified for resistance to certain lepidopteran pests and for tolerance to the herbicide glufosinate-ammonium. OJ L 291, 5/11/2005, p. 42-44. Final consent issued by the Netherlands, 16/3/2006.

8 Commission Decision 2006/47/EC of 16 January 2006 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (Zea mays L., hybrid MON 863 × MON 810) genetically modified for resistance to corn rootworm and certain lepidopteran pests of maize. OJ L 26, 31/1/2006, p.17-19.

Based on the three-year reports, 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. Some MS also referred to the authorisation process under Regulation 1829/2003 on GM Food and Feed[9] and enquired about the specific role of the competent authorities under Directive 2001/18/EC in this context. 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. The fees for notifications for placing on the market differ among MS and range from 0-50,000€ per application. Industry noted that this could influence the selection of the MS to which a company submits an application, especially in the case of small and medium enterprises. Farmers' organisations asserted the right of farmers to be able to choose whether or not to grow GM crops.

NGOs highlighted the current challenges of ensuring transparency and stakeholder involvement in the implementation of the Directive.

Details of all Part C releases are available at http://gmoinfo.jrc.it.

Traceability, Labelling and Thresholds

The general requirements for the labelling and traceability of GMOs under Directive 2001/18/EC (as well as for food and feed products produced from GMOs) have been elaborated in Regulation 1830/2003[10]. A specific report on the implementation of this Regulation was submitted by the Commission to the Council and to the European Parliament in May 2006[11].

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. One MS highlighted the need for thresholds for GMOs authorised under Part B of the Directive.

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 appropriate, proportionate renewal procedures to cover any remaining adventitious traces of these GMOs in order to ensure legal certainty following the expiry of consents.

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9 c.f. Articles 6 and 18 of the Regulation.
10 OJ 268, 18/10/2003, p.24-28
11 COM(2006)197 final, 10.5.2006

Post-market monitoring

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. Most MS supported the Working Group on Monitoring established by the competent authorities as the appropriate forum in which to address these issues.

NGOs reported that, as more GMOs are marketed, there would be a need for a more co-ordinated 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.

Sampling and detection

Commission Recommendation 2004/787/EC[12], on technical guidance for sampling and detection of genetically modified organisms, was developed to aid the implementation of Regulation (EC) No 1830/2003 on traceability and labelling. However, many MS have reported that the protocols included in this Recommendation are complex, time-consuming and expensive and that results are not in proportion to the time and expense involved.

Overall, MS expressed a clear wish for protocols that would reconcile the need for adequate sampling and detection with reasonable costs.

Industry reported that standard protocols to be developed should be harmonised with international testing methods, to be flexible and consistent with the practices currently used routinely by the seed, food and feed industries.

Farmers' organisations supported the use of GM DNA as the unit of measure for adventitious presence throughout the agricultural chain from seed to food and feed, to ensure consistency and to avoid litigation among stakeholders.

Antibiotic Resistance Marker Genes

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.

Further details from the individual MS three-year reports are available in Annex 1 of this report.

National safeguard clauses

Although not explicitly addressed by MS in their three-year reports, it is worth noting that, since the entry into force of the Directive, 6 MS (AT, DE, EL, FR, HU, LU) have maintained

[12] OJ L 348, 24/11/2004, p.18-26

provisional bans on 5 authorised GMOs under the provisions of Article 23 of the Directive. In each case, EFSA has found no reason to believe that the continued placing on the market of these GMOs would be likely to result in adverse effects to human and animal health or the environment under the conditions of their respective consents. Three of these GMOs are no longer commercialised by the companies concerned.

Since there are no scientific elements to justify national safeguard clauses on any of these products, the Commission, in accordance with its obligation under the EC Treaty, is in the process of requesting the MS concerned to withdraw their national measures prohibiting the sale of these products. In addition, the Commission intends to take the necessary measures to formalise the withdrawal from the market of the three GMOs that are no longer commercialised.

Scientific consistency and transparency of authorising Decisions

At the Environment Council of 26 June 2006, MS welcomed a series of measures proposed by the Commission to bring about practical improvements with a view to reassuring MS, stakeholders and the general public that Community decisions are based on high quality scientific assessments which deliver a high level of protection of human health and the environment. These measures aim at improving the scientific consistency and transparency for risk assessment and decision making procedures under the current legislative framework and are outlined in Annex 3 to this report.

3. RESEARCH AND DEVELOPMENT AND PURPOSES OTHER THAN PLACING ON THE MARKET OF GMOS AS OR IN PRODUCTS (PART B OF THE DIRECTIVE)

On numbers of applications

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, 4 applications were withdrawn, 23 applications were still pending as of October 2005[13], 191 consents were issued, and 27 applications were refused. The highest percentage of refusals was in Hungary where 14 out of a total of 21 applications were refused.

Details of all Part B releases are available at http://gmoinfo.jrc.it.

DE, FR and NL reported the destruction of field trials – in NL, 2 trials were partially destroyed; in FR, 19 of 56 planted trials were destroyed in 2003; and in DE, several cases of destruction were reported although the exact number is not known since, legally, applicants do not have to report destructions unless the authorisation requirements have been affected.

[13] The end of the reporting period for the Member State three-year reports (17 October 2002-2005)

The fees for Part B notifications differ among MS and range from 0-17,000€ per application. Industry noted that this could influence the selection of the MS to which a company submits an application, especially in the case of small and medium enterprises.

Farmers' organisations said that field trials were one of the means to maintain competitiveness in European research and agriculture.

Overall authorisation procedure

A majority of MS consider that the Directive has provided a more transparent and predictable regime within the EU. 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[14] on contained use whilst others apply Directive 2001/18/EC on deliberate release into the environment. Following a recent study, commissioned by the Commission, this issue will be discussed with the competent authorities appointed under both pieces of legislation in 2007.

In spite of opportunities to discuss the applications prior to submission, almost all competent authorities were required to seek additional information following submission, particularly in cases of new applications or applications for significantly larger field trials than previously authorised. This was cited as the biggest cause of delays in the process.

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.

Environmental risk assessment

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.

Public Consultation

A majority of MS provide a minimum of 30 days for public comments, using national and local newspapers, mailing lists, websites, registers and public hearings to provide access to applications by the public. Most MS provide the location of the field trial at the level of the municipality or townland rather than the exact location, in order to reduce the possibility of destruction of sites.

Public comments are forwarded to the scientific advisory committees set up by a majority of MS. The comments are also provided in the decision-making file forwarded to the relevant

[14] OJ L 117, 8/5/1990, p. 1-6

Ministers. A number of MS have found that public comments, when given, are too general in most cases to apply to specific cases.

Industry 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.

Further details from the individual MS three-year reports are available in Annex 1 of this report.

4. CONCLUSIONS

This report is specifically concerned with Directive 2001/18/EC and the deliberate release of GMOs into the environment. Eight Member States received applications for placing on the market of GMOs, and thirteen Member States received applications to conduct field trials for R&D purposes during the period October 2002-2005.

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.

Some Member States have called for more guidance on specific aspects of environmental risk assessment. 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.

Finally, 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.