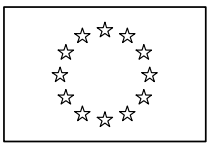

COMMISSION OF THE EUROPEAN COMMUNITIES

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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 and incorporating a specific report on the operation of parts B and C of the Directive

{SEC(2004) 1063}

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1. BACKGROUND

On 17 April 2001, 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] entered into force. This Directive became applicable as of 17 October 2002.

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.' It should be noted that this first report relates only to 15 Member States given that the reporting period in question ended prior to the date of entry for accession countries (1 May 2004). Subsequent three-year reports will, however, include these additional Member States.

According to Article 31(7) of this Directive, "when submitting this report in 2003, the Commission shall at the same time submit a specific report on the operation of part B and part C including an assessment of: (a) all its implications, particularly to take account of the diversity of European ecosystems and the need to complement the regulatory framework in this field; (b) the feasibility of various options to improve further the consistency and efficiency of this framework, including a centralised Community authorisation procedure and the arrangements for the final decision making by the Commission; (c) whether sufficient experience has accumulated on the implementation of part B differentiated procedures to justify a provision on implicit consent in these procedures and on part C to justify the application of differentiated procedures; and (d) the socioeconomic implications of deliberate releases and placing on the market of GMOs".

In July 2003, the Commission funded a study[2] to gather information from four groups of stakeholders (15 Member States (MS), industry and research organisations, public interest groups and farmers' organisations), as a basis for this report. The final report of the study is available upon request.

In the following sections, the overall state of implementation is described, the experience of stakeholders in implementing the Directive is summarised and issues requiring further action are identified.

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1 OJ L 106 , 17.4.2001 p. 1 – 39.

2 SBC (2004), 'Means to improve the consistency and efficiency of the legislative framework in the field of biotechnology', study contract number B4-3040/2003/359058/MAR/C4, carried out by Schenkelaars Biotechnology Consultancy (SBC), NL, in cooperation with Risk and Policy Analysts Ltd, UK, on behalf of the European Commission, April 2004.

2. OVERVIEW OF IMPLEMENTATION

The Commission convenes twice-yearly meetings with the competent authorities (CAs) of the MS in order to exchange views on specific implementation issues. Since April 2001, the date of entry into force of Directive 2001/18/EC, seven meetings have taken place. Working groups were established to develop the content of six implementing measures which have since been adopted by either the Commission or the Council in the framework of Directive 2001/18/EC. Two of these measures are specific to Part B of the Directive: (1) a standard format for summary notifications and (2) a standard format for reports on releases. Three are specific to Part C of the Directive: (1) a standard format for summary notifications; (2) guidelines for monitoring; and (3) the establishment of a register to record information related to genetic modifications. The sixth measure provides guidelines for environmental risk assessment concerning both Part B and Part C of the Directive.

Furthermore, Regulation 1830/2003[3] concerning the traceability and labelling of GMOs and the traceability of food and feed products produced from GMOs and amending Directive 2001/18/EC was adopted on 22 September 2003 and became fully applicable as of 15 April 2004. In the framework of this Regulation, and in relation to Article 19 of Directive 2001/18/EC, an additional implementing measure addressing the development and assignment of unique identifiers for GMOs was adopted on 14 January 2004.

Currently, additional working groups of CAs, chaired by the Commission, have been established to address specific issues such as herbicide resistance, Bt toxin, antibiotic resistance marker genes, post-market monitoring and ease of access to and exchange of information. In addition, as a result of the regular exchange of views among MS, the CAs have arrived at a common understanding on the implementation of specific articles of the Directive.

A full list of implementing measures and CA meetings is attached in Annex 1.

Regarding transposition of the Directive by the MS, it should be noted that, at the time of preparing this report, seven of the EU 15 MS and eight of the acceding countries had communicated transposition measures. Details are provided in Annex 2. The Commission has taken eight of the EU 15 States to court for non-transposition.

3. NUMBER OF APPLICATIONS FOR PART B AND PART C RELEASES

The number of Part B applications (by type of GMO) as of 26 February 2004 under Directive 2001/18/EC and its predecessor Directive 90/220/EEC[4] is presented in Annex 3, Table 1. Since the adoption of Directive 2001/18/EC, a slight increase in the number of summary notifications has occurred in France, Germany, Spain and the UK. In all other countries there has been a reduction or no change in the number of summary notifications.

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[3] OJ L 268, 18.10.2003, p. 24 - 28.

[4] OJ L 117 , 8.5.1990, p. 15 – 27.

Table 1 also highlights the fact that most experience with Part B applications has been with the authorisation of GM plants. Although a number of non-plant GMOs were authorised under Directive 90/220/EEC, very few have been authorised since Directive 2001/18/EC came into force.

Between January 2003 and March 2004, 24 Part C applications were submitted, as presented in Annex 3, Table 2. A number of these applications had originally been submitted under Directive 90/220/EEC (prior to 17 October 2002) and were complemented under Directive 2001/18/EC in accordance with Article 35 of the Directive. These applications are now at various stages of the authorisation process.

Although Part C of Directive 2001/18/EC covers all commercial releases, Regulation 1829/2003 on GM food and feed[5] now defines the procedures for placing GM food and feed (including crops for food or feed use) on the market. As of 18 April 2004 when the new Regulation became fully applicable, notifications submitted under Directive 2001/18/EC, concerning products for which feed use was included and for which an assessment report had not yet been provided, were to be transformed into applications under the new Regulation. Likewise, requests submitted under Regulation 258/97 on novel foods and novel food ingredients[6], for which the initial assessment report had not been forwarded to the Commission as well as for all cases in which an additional assessment report had been requested, were to be transformed into applications under the new Regulation. Henceforth, applications for GMOs for food and feed use will be authorised under this Regulation. Thus, in future, the number of applications under Part C of Directive 2001/18/EC may be reduced as a consequence of the evolving legislative framework in the field of biotechnology.

4. COMMON ISSUES RELATING TO THE OPERATION OF BOTH PART B AND PART C RELEASES.

A number of issues are common to the operation of both Part B and Part C releases. These include:

- Pre-application discussions
- Environmental risk assessment (ERA)
- Public information and consultation
- Antibiotic Resistance Marker (ARM) Genes
- Implications for the diversity of European ecosystems
- Socio-economic implications
- Use of simplified and differentiated procedures

Details of the experience to date with these issues are provided in Annex 4.

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5 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.

6 OJ L 43, 14.2.1997, p. 1.

5. SPECIFIC ISSUES RELATING TO PART C RELEASES.

Two specific issues relate to Part C releases, as follows:

- The decision-making process
- Post-market monitoring and guidance

Details of the experience on these two issues are provided in Annex 5.

6. IMPROVING THE CONSISTENCY AND EFFICIENCY OF THE LEGISLATIVE FRAMEWORK.

The previous sections identify areas in the operation of Part B and Part C of Directive 2001/18/EC where progress has been made and implementation is running smoothly, and where work is already underway to develop further guidance (e.g. on antibiotic resistance marker genes and on monitoring) and to address outstanding issues (e.g. transposition). This section identifies issues at this stage of implementation of the Directive where further action could be envisaged to improve the consistency and efficiency of the overall legislative framework.

The current authorisation process (in terms of forms and guidance) is focused on GM plants. GM medicines and GM animals are also under development and their authorisation will require consideration of different issues. In order to allow research organisations, industry as well as MS CAs to address these issues in a harmonised way, it will be necessary to develop **specific guidance on the risk assessment of non-plant GMOs.**

Research relating to the safety of field releases has been part of the EU research programmes in biotechnology for over 20 years[7]**. Further research sponsored by these programmes should be encouraged** in areas such as: rates of gene flow and introgression in relation to the adventitious presence of GMOs in (non-GM) seeds, food and feed; the efficacy of measures to limit pollen flow; and the environmental impact of different methods of conventional farming against which to compare the findings from GM crop growing.

Some stakeholders have requested **further guidance on the interaction between different pieces of legislation** and how these will work in practice. For example, although Article 12.2 of Directive 2001/18/EC clearly states that GMOs for medical use are excluded from Part C of Directive 2001/18/EC, industry stakeholders believe that it may be necessary to submit applications under both the Deliberate Release Directive and the medical authorisation procedures, based on their experience for Part B applications.

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[7] "A Review of Results: EC-sponsored research on safety of GMOS ",European Commission, 2001. Available at http://europa.eu.int/comm/research/quality-of-life/gmo/

Regarding the feasibility of a **centralised Community authorisation procedure**, industry stakeholders generally advocated this procedure. The experience of MS CAs with the centralised procedure under Regulation (EEC) No.2309/93[8] for the authorisation of medicinal products suggests that there is a need to clarify the obligations of the European Agency for the Evaluation of Medicinal Products (EMEA) when consulting national CAs, particularly with regard to the ERA. Experience has also shown that, for the purpose of cultivation, MS were not ready to accept the environmental risk assessment carried out by other MS, even if a common basis for such risks is foreseen in the Directive. As of 18 April 2004, Regulation 1829/2003 provides for a centralised procedure with the European Food Safety Authority (EFSA). In the light of experience to be acquired in the implementation of this Regulation, the Commission will consider the need for a centralised procedure under Directive 2001/18/EC.

7. CONCLUSIONS

This report is specifically concerned with Directive 2001/18/EC and the deliberate release of GMOs, although the wider legislative framework is also considered. The vast majority of GMOs that have been developed to date for deliberate release are transgenic crop plants, modified to be tolerant to certain herbicides or resistant to certain insect pests. Consequently, much of the available information and experience relates to GM crops.

Given that the Directive became fully applicable as of 17 October 2002, there is still relatively little experience of its implementation. The lack of transposition by a number of Member States also hinders implementation. Nevertheless, there is general agreement that the Directive, together with the recent Regulations on GM Food and Feed and Traceability and Labelling, help to increase confidence in the legislative framework and to increase the predictability of the decision-making process. In particular, increased requirements for the environmental risk assessment address the possible longer term, direct, indirect, delayed and cumulative effects on the environment and wildlife of releasing and using GMOs.

Currently, most concerns relate to the need for guidance in interpreting elements of the Directive such as post-market monitoring, the phasing out of antibiotic resistance marker genes which may have adverse effects on human health and the environment, and non-plant GMOs. In addition, guidance is required on the interaction of the various pieces of legislation. The Commission and Member States are already working on guidance for post-market monitoring and antibiotic resistance marker genes.

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[8] Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products**,** OJ L 214 , 24.8.1993, p. 1 – 21.