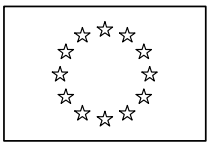

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 31.08.2004
SEC(2004) 1063

COMMISSION STAFF WORKING PAPER

ANNEX TO THE

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

{COM(2004)575 FINAL}

TABLE OF CONTENTS

ANNEX 1 : LIST OF IMPLEMENTING MEASURES ADOPTED IN 2002-2004 IN THE FRAMEWORK OF DIRECTIVE 2001/18/EC AND REGULATION 1830/2003

Relating to Part B of the Directive

– Council Decision 2002/813/EC of 3 October 2002 establishing, pursuant to Directive 2001/18/EC of the European Parliament and of the Council, the summary notification information format for notifications concerning the deliberate release into the environment of genetically modified organisms for purposes other than for placing on the market[1];

– Commission Decision 2003/701/EC of 29 September 2003 establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council a format for presenting the results of the deliberate release into the environment of genetically modified higher plants for purposes other than placing on the market[2];

Relating to Part C of the Directive

– Council Decision 2002/811/EC of 3 October 2002 establishing guidance notes supplementing Annex VII to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC[3];

– Council Decision 2002/812/EC of 3 October 2002 establishing pursuant to Directive 2001/18/EC of the European Parliament and of the Council the summary information format relating to the placing on the market of genetically modified organisms as or in products[4];

– Commission Decision 2004/204/EC of 23 February 2004 laying down detailed arrangements for the operation of the registers for recording information on genetic modifications in GMOs, provided for in Directive 2001/18/EC of the European Parliament and of the Council[5].

Relating to Part B and Part C of the Directive

– Commission Decision 2002/623/EC of 24 July 2002 establishing guidance notes supplementing Annex II to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC[6].

---

1 OJ L 280 , 18.10.2002, p. 62 – 83.
2 OJ L 254 , 8.10.2003, p. 21 – 2.
3 OJ L 280 , 18.10.2002, p. 27 – 3.
4 OJ L 280 , 18.10.2002, p. 37 – 6.
5 OJ L 65 , 3.3.2004, p. 20 – 2.
6 OJ L 200 , 30.7.2002, p. 22 – 3.

Relating to Regulation 1830/2003 on traceability and labelling

– Commission Regulation (EC) 65/2004 of 14 January 2004 establishing a system for the development and assignment of unique identifiers for GMOs[7]

LIST OF MEETINGS OF COMPETENT AUTHORITIES OF THE MEMBER STATES APPOINTED IN THE FRAMEWORK OF DIRECTIVE 2001/18/EC

– 19 June 2001, Stockholm

– 3 December 2001, Brussels

– 7 March 2002, Brussels

– 11 December 2002, Brussels

– 29 April 2003, Brussels

– 3 December 2003, Brussels

– 1 April 2004, Brussels

[7] OJ L 10 , 16.1.2004, p. 5-1.

ANNEX 2 : STATE OF TRANSPOSITION OF DIRECTIVE 2001/18/EC AS OF APRIL 2004

(Deadline for transposition: 17/10/2002)

Country	State of play as of April 2004
AU	Certain transposition measures received by Commission on 28/10/2002 but further transposition measures awaited.
BE	Draft measures sent to the Commission on 05/06/2003, yet to be adopted.
CY	Transposition measures communicated to Commission on 03/04/2004.
CZ	No communication to date.
DK	Transposition measures communicated to Commission on 7/11/2002.
DE	Draft implementing legislation notified to the Commission on 30/04/2004 in the context of Directive 98/34/EC. Implementing measures for transposition of Directive 2001/18/EC awaited.
EE	Transposition measures communicated to Commission on 26/02/2004.
EL	No communication.
ES	Directives 2001/18 and 98/81 have been transposed by the Law 9/2003 of 25/05/03 and the Royal Decree 178/2004 of 31 January 2004.
FI	Draft implementing legislation has been prepared but not yet adopted by Finnish parliament.
FR	Draft legislation implementing Directives 2001/18 and 98/81 to be adopted by the Parliament in 2004
HU	Transposition measures communicated to Commission on 16/03/2004
IE	Transposition measures communicated to Commission on 24/10/2003, legislation S.I.N°500 of 2003, which transposes Directive 2001/18/EC.
IT	Transposition measures communicated to Commission on 03/09/2003. The 'decreto legislativo n. 224 del 8 luglio 2003, pubblicato nella Gazzetta Ufficiale n.194 del 22 agosto 2003' transposes Directive 2001/18/EC on 29 September 2003.
LT	Transposition measures communicated to Commission on 20/02/2004.
LU	Certain transposition measures communicated to Commission on 02/02/2004. Final measures due in May 2004.
LV	No communication
NL	Draft legislation sent to the Commission for information on 02/07/2003 but has yet to go through the Dutch parliamentary process.
MT	Transposition measures communicated to Commission on 12/03/2004:
PL	Transposition measures communicated to Commission in March and April 2004.
PT	Directive implemented by 'Decreto Lei 72/2003' of 10/04/2003.
SE	Regulation implementing Directive 2001/18/EC adopted on 12/12/2002. The regulation should have entered into force the 17 January 2003.
SI	Transposition measures communicated to Commission on 16/04/2004
SK	Transposition measures communicated to Commission on 19/12/1003
UK	Transposition measures received by Commission on 18/10/2002 for England and on 19/03/2003 for Scotland, Wales and Northern Ireland.

ANNEX 3 : NUMBER OF APPLICATIONS FOR PART B AND PART C RELEASES

Table 1: Number of Part B Applications (by Type of GMO) under Directive 90/220/EEC and Directive 2001/18/EC as of 26 February 2004.

Type of Part B Application	**Member State**														
	AT	**BE**	**DE**	**DK**	**ES**	**FI**	**FR**	**GB**	**GR**	**IE**	**IT**	**NL**	**PT**	**SE**	**EU**
Directive 90/220/EEC															
Plants	3	119	119	39	181	18	501	211	19	4	273	136	12	64	1699
Other organisms	0	7	2	1	23	2	9	11	0	1	16	4	0	0	76
Total	*3*	*126*	*121*	*40*	*204*	*20*	*510*	*222*	*19*	*5*	*289*	*140*	*12*	*64*	*1775*
Since 17 October 2002 (Directive 2001/18/EC)															
Plants	0	1	15	0	47	1	17	4	0	0	2	3	0	4	94
Other organisms	0	0	0	0	1	0	0	3	0	0	0	1	0	0	5
Total	*0*	*1*	*15*	*0*	*48*	*1*	*17*	*7*	*0*	*0*	*2*	*4*	*0*	*4*	*99*
Total under both Directives															
Plants	**3**	**120**	**129**	**39**	**219**	**18**	**518**	**215**	**19**	**4**	**275**	**138**	**12**	**65**	**1774**
Other organisms	**0**	**7**	**2**	**1**	**24**	**2**	**9**	**14**	**0**	**1**	**16**	**5**	**0**	**0**	**81**
Total	***3***	***127***	***131***	***40***	***243***	***20***	***527***	***229***	***19***	***5***	***291***	***143***	***12***	***65***	***1855***

Table 2: Number of Part C Applications by Year as of March 2004									
Year	**Member State**								
	BE	**DE**	**DK**	**ES**	**FR**	**GB**	**NL**	**SE**	**EU**
1996	1	1		1	1			1	5
1997			1	1					2
1998	1	1					1		3
1999	1			1					3
2000		1		1			1		3
2001				1					1
2002		1				1			2
2003				1		1			2
2004				2		1	1		3
Total	3	4	1	8	1	3	3	1	24

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

Pre-application discussions

The opportunity for discussions between the notifier and the CA prior to the submission of an application varies significantly among MS. It should be noted that Directive 2001/18/EC neither provides for, nor prohibits, pre-application discussions and, as such, this is a national issue. It would appear that, in MS where CAs engage in full discussions of applications before the submission of the formal notification, the need to request further information from the notifier and thus the time and resources required to process the application are reduced. These discussions provide CAs with the opportunity to clarify requirements and provide industry with greater predictability.

Environmental risk assessment (ERA)

Commission Decision 2002/623/EC of July 2002 is an implementing measure which provides guidance for environmental risk assessment (ERA) in the framework of Annex II of Directive 2001/18/EC. The Directive, together with this Decision, stipulate stricter requirements for the ERA than those under Directive 90/220/EEC. In practice, some MS already imposed stricter requirements than necessary under Directive 90/220/EC and in these cases, Directive 2001/18/EC has not led to significant changes. However, a number of MS have had to increase their requirements in line with the new legislation, particularly in relation to indirect and delayed effects. This suggests that Directive 2001/18/EC has, or will, lead to a greater degree of harmonisation. However, there is insufficient experience at this stage to assess the degree of consistency among MS with regard to the requirements of the ERA.

Public information and consultation

The new Directive requires mandatory public consultation on all applications. Public information on Part B and Part C applications is available at http://gmoinfo.jrc.it.

For Part B releases, Article 9 of Directive 2001/18/EC requires MS to consult the public and, where appropriate, groups on the proposed deliberate release. The Directive allows for subsidiarity on this issue, stating only that MS shall lay down arrangements for this consultation, including a reasonable time-period, in order to give the public or groups the opportunity to express an opinion. Thus the specific arrangements are made at national level. These arrangements include websites, national newspapers and public hearings. Time periods for public consultation vary between 21-60 days among MS.

For Part C releases, Article 24 of the Directive requires the Commission to make the SNIF (the summary of notification) and the assessment report publicly accessible and foresees a period of thirty days for public consultation on each.

Given the recent nature of mandatory public consultations, some public interest groups and individuals have experienced difficulties in finding information and have raised concerns that the information made available may not be sufficient to develop an informed opinion. There are also concerns about how public responses are taken into account in the decision-making process, in particular, responses based on socio-economic and ethical factors, given that the Directive focuses on scientific assessment of applications.

In addition, the provision of information to the public on the location of releases is a cause of concern, given the possible malicious destruction of these crops and the ensuing costs for developers and growers of GMOs and possible effects on the overall market.

Antibiotic Resistance Marker (ARM) Genes

Article 4.2 of Directive 2001/18/EC states that MS and the Commission shall ensure that GMOs which contain genes expressing resistance to antibiotics in use for medical or veterinary treatment are taken into particular consideration when carrying out an environmental risk assessment, with a view to identifying and phasing out antibiotic resistance markers in GMOs which may have adverse effects on human health and the environment. This phasing out shall take place by 31 December 2008 in the case of GMOs authorised under Part B and by 31 December 2004 in the case of GMOs placed on the market according to Part C.

In order to ensure a common application of Article 4.2, the Commission has established a Working Group on ARMs with representatives of MS CAs. The Working Group will use the recent opinion of the European Food Safety Authority (EFSA) on this issue as a basis for developing clear and transparent criteria when assessing whether a specific ARM is to be considered harmful.

Implications for the diversity of European ecosystems

The risk assessment and authorisation process under Directive 2001/18/EC has been designed to reduce the potential for adverse consequences on the basis of scientific evaluation. For Part C releases, authorisation is given if the environmental risk assessment concludes that adverse effects are unlikely or that adverse effects, if any, on human or animal health or on the environment, can be avoided, in the context of the intended use, with the implementation of appropriate risk management measures. The requirement for post-market monitoring of effects is an important follow-up tool for identifying new or unanticipated effects.

For Part B releases, consent holders are required, at the end of a field trial with GM crops, to send a report to the CA with observations of any risk for human health or the environment. To date, general observations show that nothing unusual has been observed and/or there is nothing to suggest any risks.

Depending on the outcome of the risk evaluation of a field trial with a GM crop, CAs have imposed risk management measures such as the prevention of flowering, border rows and/or isolation distances to limit pollen flow. If deemed necessary, control of GM volunteer plants for one or more years after the end of the release has also been required. In general, national enforcement bodies regularly monitor whether consent holders comply with the imposed risk management measures. So far there have only been a few cases where consent holders have been found to be violating the conditions for risk management laid down in the consent. However, in none of these cases has this been reported to have resulted in harm to the environment.

Directive 2004/35/EC[8] on environmental liability with regard to the prevention and remedying of environmental damage was adopted in April 2004. This Directive is aimed at prevention and remediation of significant damage to water, land and protected species and habitats. Within this scope, a regime of strict liability is foreseen for environmental damage from GMOs, i.e. there is no requirement to demonstrate negligence or criminal damage. The Directive provides MS with a duty to order responsible operators to undertake preventive or remedial action, and a discretionary power to carry out the work themselves and then recover the costs from the operator. Nevertheless, in situations where an operator can demonstrate that the damage in question was the result of emissions or events explicitly authorised or where the potential for damage could not have been known when the event or emission took place, Member States may allow the operator not to bear the cost of remedial actions. The Directive specifically excludes civil liability for property damage or economic loss from, for example, adventitious presence of unwanted GM material/traits/species from neighbouring properties in crops or wild relatives.

Socio-economic implications

From 1997 to 2002, a steep decline occurred in the annual number of Part B notifications for field trials with GM crops in the EU. This decline may be due to the fact that the new regulatory framework was under development during this time, or due to fears of malicious damage following several such cases. It could also indicate a weakening of the European research base in this area.

Since the introduction of Directive 2001/18/EC, many industry representatives consider that the requirements under the Directive constitute a regulatory burden which substantially increases research and development costs, making it more difficult for small companies and public research institutes to bring products to the market and thus discouraging EU investment. In particular, the requirement to provide location details of field trials causes concern about the possible malicious destruction of these crops.

All deliberate releases of GMOs into the environment raise issues of *coexistence*. Regulation 1829/2003 has introduced an amendment to Directive 2001/18/EC (new Article 26a) which refers to possible national measures to avoid the unintended presence of GMOs in other products, as well as to Commission guidelines on coexistence. In this context, the Commission has already published a Recommendation on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming[9].

These developments have led to the adoption by some Member States of national measures on co-existence. The first measures of this type to be notified to the Commission aimed either at setting up GMO-free regions or at limiting (as much as possible) cultivation of GMOs by setting strict measures to be complied with at national/regional level. Based on legal and scientific considerations, and the case-by-case approach of the environmental legislation, the adoption of a blanket policy aimed at making a Member State or any particular part of it

---

8 OJ L 143 , 30.4.2004, p. 56 – 75.

9 Commission Recommendation of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the coexistence of genetically modified crops with conventional and organic farming.

'GMO-free' would not be acceptable when seeking to impose conditions that could not be justified in terms of protection of human health and the environment[10].

In December 2003 the Commission has recognised that, for the first time, the main principles laid down in the Commission's recommendation on co-existence have been taken into account in a notification, even though additional conditions were requested before the notification could be considered acceptable to the Commission[11].

Furthermore, under the new Regulations 1829/2003 and 1830/2003, GM food and feed will have to be labelled as GM except if they contain GM material in a proportion no higher than 0.9% and if this presence is adventitious or technically unavoidable. The Commission is also in the process of drafting a proposal establishing threshold levels for seeds where adventitious or technically unavoidable traces of authorised GMOs cannot be excluded, in accordance with Article 21.2 of Directive 2001/18/EC. Identical thresholds will then be adopted under the seed and other plant propagating material legislation.

Other socio-economic concerns include the possibility that the EU regulatory framework may have an adverse impact on producers in developing countries, the possibility of a brain-drain from Europe, of a decrease in scientific activity and of a reduction in interest by students to train in this publicly controversial research field, and finally the related possibility of a loss of competitiveness.

Use of simplified and differentiated procedures

Commission Decision 93/584/EEC[12] established the criteria for simplified procedures concerning the deliberate release into the environment of genetically modified plants pursuant to Article 6 (5) of Council Directive 90/220/EEC (Part B releases). Article 7 of Directive 2001/18/EC allows MS to use either differentiated or simplified procedures for certain GMOs for which sufficient experience has been gained. MS are divided in their use of, or preference for, simplified and differentiated procedures. Those that regularly used simplified procedures under Directive 90/220/EEC have retained their use under Directive 2001/18/EC. However, most CAs have allowed for both simplified and differentiated procedures under national legislation, as shown in Table 3.

---

10 c.f. Commission Decision 2003/653/EC of 2 September 2003, OJ L 230, p. 34-43.

11 c.f. Notification 2003/200/A under Directive 98/34/EC by the province of Carinthia (Austria) regarding Draft act on the regulation of precautionary measures for genetic engineering (Austrian designation: K-GtVG).

12 OJ L 279 , 12.11.1993, p. 42 – 43.

Industry supports the use of simplified procedures, citing reduced time and resources required and thus reduced costs. Simplified procedures are also suggested for 'stacks' of previously authorised GM products, combined by traditional breeding. However, there is currently limited experience with differentiated procedures and there is insufficient experience for industry to assess the impact of any shift towards differentiated procedures by MS.

Table 3: Use of Simplified and Differentiated Procedures

MS	AT	BE	DE	DK	ES	FR	GB	IE	IT	NL	PT	SE
Use of Simplified Procedures under Directive 90/220/EEC												
Never	X			X				X		X	X	X
Between 1 and 10 times												
More than 10 times		X	X		X	X	X		X			
Favoured Approach under Directive 2001/18/EC												
Retained use of simplified procedures	X		X	NA	X	X	X		X	NA		NA
Moved to use of differentiated procedures	X	X	X		X		X	X	X		X	

For Part C releases, Article 16 of Directive 2001/18/EC allows a CA, or the Commission on its own initiative, to make a proposal on criteria and information requirements to be met for the notification which would differ from the standard requirements set out under Article 13. Such a proposal would require the opinion of EFSA and would be adopted by comitology procedure. However, no proposal has as yet been submitted under this Article.

ANNEX 5 : SPECIFIC ISSUES RELATING TO PART C RELEASES.

The decision-making process

In general, stakeholders consider that Directive 2001/18/EC, as well as Regulation 1829/2003 on GM food and feed and Regulation 1830/2003 on traceability and labelling, facilitate the decision-making process. In addition, the defined time limits in the legislation should benefit the authorisation process.

Under Directive 90/220/EC, nine Article 16 cases were invoked by Austria, France, Luxembourg, Germany, UK and Greece to provisionally ban or restrict the placing on the market of individual GMOs authorised under that Directive. In December 2003, the Commission requested MS to consider their pending safeguard clauses under Directive 90/220/EEC and, if necessary, to re-submit them under Article 23 of Directive 2001/18/EC. Article 23 provides that any new or additional scientific evidence, which had not been previously examined, could be assessed and new measures taken if necessary. Austria and Greece have since submitted new evidence which has been forwarded by the Commission to EFSA for a scientific opinion. The Commission will take a Decision on the matter on the basis of this opinion.

Post-market monitoring and guidance

The majority of stakeholders consider that the requirements under Directive 2001/18/EC could be improved. Council Decision 2002/811/EC[13] of 3 October 2002 is an implementing measure which establishes guidance notes for monitoring in the framework of Annex VII to Directive 2001/18/EC. These guidance notes expand on the objectives and general principles for post-market monitoring of GMOs as well as on a general framework for the development of appropriate post-market monitoring plans. Reference is also made in the Decision to the possible need to complement the existing "framework with more specific, supplementary guidance on monitoring plans or checklists with regard to particular traits, crops or groups of GMOs".

Following discussion with MS CAs on this issue, the Commission established a Working Group with representatives of the MS CAs to develop specific, supplementary guidance for both case-specific and general surveillance monitoring, with a view to greater harmonisation.

[13] OJ L 280 , 18.10.2002, p. 27 – 36.