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COMMISSION STAFF WORKING DOCUMENT

Accompanying document to the

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

{COM(2007) 81 final}

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ANNEX 1

THREE-YEAR MEMBER STATE REPORTS TO THE COMMISSION ACCORDING TO ARTICLE 31.4 OF THE DIRECTIVE

(17 OCTOBER 2002-17 OCTOBER 2005)

SUMMARY REPORT

INTRODUCTION

Article 31.4 of Directive 2001/18/EC states that "**Every three years, Member States shall send to the Commission a report on the measures taken to implement the provisions of the Directive. This report shall include a brief factual report on their experience with GMOS placed on the market in or as products under this Directive**."

Article 31.5 states that "Every three years, the Commission shall publish a summary based on the reports referred to in [Article 31.4]".

Furthermore, Article 31.6 states that "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 timing of reporting requirements is therefore as follows:

17 October 2003 : 1st report from Commission to EP and Council (Article 31.6 and 31.7)[1]

17 October 2005 : 1st Member State reports to the Commission (Article 31.4)

Deadline not specified : Commission Summary report of MS reports (Article 31.5)

17 October 2006 : 2nd report from Commission to EP and Council (Article 31.6))

1. MEMBER STATE REPORTS

In July 2005, the Commission, following consultation with the Member States, circulated a questionnaire as a basis for Member States to fulfil their reporting obligations by 17/10/2005. All Member States except Portugal submitted a report. The Commission received the last Member State report in April 2006.

It should also be noted that, where questions implied the need for previous experience with Directive 90/220/EC, it was not necessary for the ten new Member States to reply to these questions.

The following is a summary of the Member State replies relevant to Directive 2001/18/EC, compiled by the Commission. Given that a specific report has been adopted on the implementation of Regulation 1829/2003[2], replies to questions concerning the Regulation have been excluded from this summary.

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1 COM(2004)575, adopted August 2004, available at http://europa.eu.int/comm/environment/biotechnology/

2 COM(2006) 626 final dated 25.10.2006

2. PART B: DELIBERATE RELEASE OF GMOS FOR ANY OTHER PURPOSE THAN PLACING ON THE MARKET

Directive 2001/18/EC on the deliberate release into the environment of GMOs introduced a number of key requirements in relation to Part B applications. Decision making on Part B releases takes place at the Member State level and is implemented through national legislation. Key requirements include:

clarifying and extending the scope of risk assessment requirements;

- mandatory public consultation on Part B applications;
- the introduction of differentiated procedures; and
- the phase-out of antibiotic resistance markers.

The questions set out aimed at gathering information on the experience of Competent Authorities in implementing these requirements.

Note that at the time of writing, Portugal had not submitted a report.

Changes in the Applications Process

1. How many applications (trials with plants and other trials) have been submitted in your Member State under Part B of Directive 2001/18/EC since 17 October 2002[3]? Of these applications, how many consents were issued? How many applications were refused? Of the consents issued, how many field trials reached completion (without being destroyed or interrupted)? Please provide lists with the details of all applications (notification number, short description, date of application, date of consent or refusal, beginning and end dates of field trials).

   Tables 1 and 2 present the numbers of Part B applications submitted per Member State since the Directive became fully applicable on 17 October 2002. Part B applications were submitted in 13 Member States, with the highest numbers submitted in Spain (89), France (54), Germany (25), Hungary (21), Sweden (18) and Netherlands (13). Twelve Member States did not receive any applications.

   Of a total of 245 applications received, 4 applications were withdrawn, 23 applications were still pending as of October 2005, 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.

[3] Since 1 May 2004 for the ten new Member States.

Details of all Part B releases are available at www.gmoinfo.jrc.it**.**

In SE, all field trials reached completion. However, in NL, DE and FR, destruction of field trials was reported – 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.

Table 1 : EU15 Part B Applications

	AT,EL, IE, LU	BE	DE	DK	ES	FI	FR	IT	NL	PT	SE	UK
Number of applications (plant and non-plant)	0	1 (plant) 2 (clinical trials)	25	1	89	2	42 (plant) 12 (clinical trials)	5	7 (plant) 6 (clinical trials)	-	16 (plant) 1 (clinical trial) 1 GMM	9
Consents		2	21		72	2	42	3	13		17	9
Refused		1			9		1					
Withdrawn			1	1	2							
Pending			3		6		11	2			1	
Total	0	3	25	1	89	2	54	5	13	-	18	9

Table 2 :EU10 Part B Applications

	CY	CZ	EE	HU	LT	LV	MT	PL	SK	SI
Number of applications (plant and non-plant)	0	1	0	21	0	0	0	4	0	0
Consents		1		7				2		
Refused				14				2		
Withdrawn										
Pending										
Total	0	1	0	21	0	0	0	4	0	0

2. Can you please outline the process that an applicant goes through when submitting an application for a Part B consent under your national legislation? Do you have a flow-chart available for this process?

All Member States have implemented application procedures for Part B consents in accordance with the provisions of the Directive, with individual differences depending on the organisational structures in place in each Member State. Explanations of the process, as well as flow-charts for a number of Member States, are available upon request from the individual Member State (see list of contact points attached).

3. Is there the potential for applicants to discuss their application prior to official submission? Please tick the relevant response.

All Member States provide opportunities for the applicant to discuss the application with the competent authority prior to submission.

4. How often do you need to seek additional information from applicants? Please tick the relevant response and add any comments you wish to make.

Despite the 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.

5. What is the biggest cause of delays in the process?

The need to request additional information was cited as the single biggest cause of delays in the process. Other specific causes of delays were challenges to decisions before the Courts (NL), the overall national context regarding GMOs (FR) and errors by the applicants such as being outside the scope of the Directive (PL).

6. Are there ways in which the delays could be shortened or prevented?

Various solutions to shortening or preventing delays have been proposed -- from issuing clearer guidance to applicants on what is required in the application, preparatory meetings and more frequent communication between the applicant and the competent authority, as well as earlier deposit of applications prior to the sowing season.

7. Have the requirements introduced by Directive 2001/18/EC provided for a more transparent and predictable regime within the EU?

A majority of MS consider that the Directive has provided a more transparent and predictable regime within the EU. FR expressed concerns about the homogeneity among MS given that the process is largely at the national level. NL referred to the issue of outcrossing from Part B trials which needed to be addressed. FR and NL also highlighted the different interpretations among MS on whether to apply the provisions of Directive 90/219/EC on contained use or Directive 2001/18/EC on

deliberate release for clinical trials on gene therapy. Harmonisation of gene therapy trials would require further discussion at EU level.

8. Has it provided industry with increased regulatory certainty?

Member States were divided about whether the system provides industry with more regulatory certainty – Spain, with the largest number of applications, highlighted procedural problems between the central government and Autonomous Communities as a source of difficulty for industry. A number of the EU10 MS have held workshops to provide industry with information on the process. FR pointed to the national context on GMOs and the increase in anti-GMO actions.

9. Is the time frame for decision making predictable?

Member States were divided on whether the timeframes for decision-making were predictable.

10. What aspects of implementation of the Part B process places the greatest burden on you as a Competent Authority? What could be done to improve the process?

Member States cited various aspects of the process which placed the greatest burden on their resources e.g. public and stakeholder consultation (BE, FR, IT, NL, UK), internal procedures and inspection activities (ES), appeal processes by both applicants and environmental organisations (NL), and the organisation of the evaluation work (IT). Several of the EU 10 MS cited a lack of capacity in their administrations which needed to be addressed.

11. Does the notifier have to pay a fee to introduce a notification under Part B of Directive 2001/18/EC? If yes, how much is this fee? Do you think that this fee affects the number of applications submitted in your Member State?

Table 3 EU15 fees for Part B applications

Member State	Fee	Effect on number of applications
AT	Depends on number of pages in application, plus notifier pays costs of public announcements and must provide proof for liability insurance to cover at least 4069.7€ per application.	
BE	1250€ per application. Under revision -- may rise to up to 5000€ plus 200€ per control analysis.	Reduced fee envisaged for non-commercial institutions.
DE	Range 2500-15000€. 75000€ in exceptional cases.	No effect seen.
DK	Depends on actual costs with maximum amount of DKK 150000.	
EL	3000€	No effect seen.

ES	Central government fee = 4525€. Autonomous Communities have individual fees.	Not known.
FI	3000€. Can be negotiated for restricted scope.	
FR	1525€ for new applications, 610€ for renewals. To be revised, up to a limit of 15000€.	
IE	3000€.	
IT	1549.37€. Currently under revision and will change in near future.	No known effect.
LU	Minimum fee 250€, maximum does not exceed 5,000€.	
NL	No fee.	
PT	--	
SE	Depends on the category of GMO. For plants, 38000 SEK for new applications, 15000 SEK for renewals, 112000 SEK for GMMs.	Universities complain about fees. For micro-organisms, the fee is not thought to affect the number of applications.
UK	ST£5000. For repeat releases, ST£2500.	No known effect.

Table 4 : EU10 fees for Part B applications

Member State	Fee	Effect on number of applications
CY	17,000€ new applications; 8500€ renewals, 10,200€ if additional information provided after initial application.	
CZ	Circa 670 €.	No known effect.
EE	Circa 20€	
HU	Table of varying fees according to type of activity. Range of 70000-300000 HUF.	
LT	No fee.	
LV	1469.4 LVL	
MT	No fee but under discussion.	
PL	3400 PLN for each decision. 5PLN stamp duty plus 0.5PLN per annex.	No known effect.

SK	770€	
SI	Applicant pays administrative processes expenses.	

Clarification of Environmental Risk Assessment Requirements

12. Has Directive 2001/18/EC led to any significant changes in what you require in the risk assessments?

Over half of the MS consider that the Directive has significantly increased requirements in relation to indirect effects and to delayed effects, while some MS (EL, FI, NL, SE, UK)) considered that there was no significant impact on risk assessment requirements.

13. Is clear guidance provided by the Commission on what is required in the environmental risk assessment?

Most MS consider that the Commission has provided clear guidance on what is required in the environmental risk assessment. FR added that it would appreciate details on aspects such as the level of detail required for different types of field trials e.g. depending on the number of hectares planted, the receiving environment, and long-term cumulative effects. For clinical trials on gene therapy, FR pointed to a lack of consistency between the annexes to the Directive and the Common Technical Document which has to be completed for such applications.

14. Is clear guidance available from the Commission on what are considered acceptable risks and what are considered unacceptable risks? In other words, have clear evaluation criteria been set for use in decision making?

Many MS (AT, BE, CY, DE, ES, FI, FR, MT, PL, SE, SI) would appreciate clearer guidance on what are considered to be acceptable and unacceptable risks, with specific criteria particularly in relation to risk management and to non-plant GMOs; more details on what are long-term effects; different information needed for different types of trials, different types of environment (FR); specific criteria for risk management (e.g. gene therapy clinical trials, antibiotic resistant markers, scale of trials, isolation distances) (ES).

15. How has clarification and strengthening of the environmental risk assessment requirements affected the length of time required to gain approval?

ES, LI, MT and SK considered that the length of time to gain approval had decreased, while HU and PL considered that it had increased. DK, FI, FR, IT, NL, SE and UK said that there had been no discernible impact.

16. How are the environmental risk assessment requirements communicated to potential applicants and other stakeholders?

Most MS use a combination of guidance documents, websites, meetings and seminars to communicate era requirements to potential applicants.

Public Consultation

For each Part B application, there is a mandatory requirement for public consultation to be held by the Competent Authority.

17. Can you please provide details of your Member State requirements under Directive 2001/18/EC in relation to public consultation and its timing for Part B applications? Do you consult at a national, regional or local level?

On public consultation, the 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. FR requests applicants to write a technical part of the application which is released to the public. BE provides a "public dossier" (vulgarised information, 3-5 pages) written by the applicant as well as the full notification (without confidential data) on the web and at the town hall of the city where the trial takes place. NL provides 6 weeks to comment on a draft decision and the public then has 6 weeks to appeal a decision. CZ organises a public hearing if negative public comments are received.

18. Can you please provide details on what information is provided to the public as part of the public consultation process (e.g. full application, location of field trials etc.)? What definition of location of field trials do you use?

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 prevent destruction of sites The UK generally provides a 4-figure national grid reference at the time of the public consultation process for crop trials. This is later released as 6 figures, although the individual farm is not identified. For clinical trials, the UK would usually release the names of the hospitals where the trial is taking place. IT and SE provide the exact location upon request. NL provides an area of 2X2 km on a topographical map of 1:25,000 and, for clinical trials, the address of the research institute of the hospital where the trials take place. FI provides the registration number of the property or farm on which the field trial is situated. CZ provides the exact location but not the maps on their website due to fears of destruction.

19. How are the results of the public consultation integrated into the final decision on whether or not to authorise a Part B release?

Public comments are forwarded to the scientific advisory committees set up by most MS. The comments are also provided in the decision-making file forwarded to the relevant Ministers. SE has so far found that public comments, when given, are too general in most cases to apply to specific cases. FR also has found that most public comments are at the level of general statements.

Simplified Procedures

Under Directive 2001/18/EC the simplified procedure is optional. The Directive also introduces the use of 'differentiated procedures' for certain categories of Part B releases.

20. How often have the simplified procedures under Directive 2001/18/EC been used within your Member State?

DE, ES, FR, NL and UK have used the simplified procedures provided under the Directive, mostly in cases of additional trial sites (DE) or for an event released in different locations or during several years (ES). Most other MS have not availed of these procedures.

21. Have you retained use of simplified procedures within national legislation or have you moved to the use of 'differentiated procedures'?

The same MS as above, as well as EL and IT, have retained the use of simplified procedures while AT, BE, FI and SE have moved to differentiated procedures in national legislation.

Antibiotic Resistance Markers

Directive 2001/18/EC requires the phasing out of Antibiotic Resistance Markers (ARMs) in GMOs that may have adverse effects on human health and the environment by 2008 for Part B GMOs.

22. Do you have any comments regarding implementation of Directive 2001/18/EC in relation to the phasing out of ARMs that may have adverse effects on human health and the environment in the EU?

All Member States agree on the need for more harmonised criteria for the phasing out of ARMs. The Opinion of the GMO Panel of the European Food Safety Authority (EFSA) dated 2 April 2004 and the document produced in December 2004 by the Working Group of the competent authorities and the Commission on ARMs for Part C notifications (ENV/04/27-REV) have been extremely useful for Member States. It is necessary to continue the work of this Working Group in order to ensure a common implementation of Article 4.2 of the Directive for Part B notifications and for genetically-modified micro-organisms. BE suggests that the different opinions of the Member States and EFSA on the classification of currently used antibiotics should be addressed in order to have an agreed document covering antibiotic use and therapy in all MS. This document would be a "risk management" classification of currently used antibiotics, covering the most critical situations in all MS, based on the EFSA opinion and subject to endorsement by the competent authorities of all MS

23. How have you applied Article 25 of Directive 2001/18/EC with regard to confidentiality to Part B applications? Which documents within the notification do you consider to be confidential?

MS which received notifications have applied the provisions of the Directive with a view to being as transparent as possible. Confidential information is usually indicated by the applicant with clear reasons for maintaining confidentiality, e.g. molecular characterisation of new traits. The competent authority accepts or rejects the confidential nature of the information, in consultation with the applicant

FR expressed the wish for harmonisation at EU level in order to avoid disparity in the application of the provisions by different MS[4]

In SE legislation, the decision not to disclose a certain piece of information cannot be taken beforehand. This decision is taken when there is a request to release the information. Whole documents cannot be considered to be confidential. Specific information in the documents, which would have a negative effect on the competitiveness of the applicant if they were disclosed, can be regarded as confidential. However, if there is a public interest in the information, and if this public interest is considered to be of greater importance than the negative impact on the applicant, the information may be released nonetheless.

When an applicant requests confidentiality, SE sometimes performs in depth investigations on, for example, what information is already publicly available in scientific literature and patent databases. The authority makes the final decision if any information should be confidential and may dismiss the applicant's arguments.

Certain information may never, according to Directive 2001/18/EC Article 25.4, be considered as confidential.

UK policy is to keep to an absolute minimum the material classified as confidential. Some parts of applications, concerning material to be patented, may be commercial in confidence and these will not be released to the public. Once the patent has been obtained UK would expect to be able to release details.

[4] Work is ongoing among the competent authorities and the Commission to arrive at a common understanding on how to apply the provisions of the Directive with a maximum of transparency and consistency.

PART C: Placing on the Market of GMOs as or in Products

Directive 2001/18/EC has introduced a number of new requirements in relation to the Part C approvals process, with the aim of providing a more harmonised, robust and transparent framework for the approval of GM products for the EU market. These requirements include in particular:

- a 10 year time limit on the duration of an approval;
- requirements for post-release monitoring;
- the phase-out of antibiotic resistance markers; and
- labelling and traceability requirements.

The questions set out aimed at gathering information on the experience of Competent Authorities in implementing these requirements.

Note that at the time of writing, Portugal had not submitted a report.

General Impact of 2001/18/EC on Part C Applications

24. How many applications have been submitted in your Member State under Part C of the Directive? How many have been (i) authorised, (ii) withdrawn, or (iii) are currently pending? Please provide a list with the notification number, short description, date of application/withdrawal/consent.

Table 5 : EU15 Part C Applications

	AT	BE	DE	DK	EL	ES	FI	FR	IE	IT	LU	NL	PT	SE	UK
- new	0	0	1	0	0	3	0	0	0	0	0	2	-	0	2
-updated from 90/220		3	3	1		6		1				2			1
pending		1		0		2		1				2		1	2
withdrawn		2				2									
transferred to 1829/2003			3	1		4									1
authorised			1			1						2			
Total	0	3	4	1	0	9	0	1	0	0	0	4	-	1	3

Table 6 : EU10 Part C applications

	CY	CZ	EE	HU	LT	LV	MT	PL	SK	SI
- new	0	0	0	0	0	0	0	0	0	0
-updated from 90/220										
pending										
withdrawn										
transferred to 1829/2003										
authorised										
Total	0	0	0	0	0	0	0	0	0	0

Details of all Part C releases are available at www.gmoinfo.jrc.it.

25. More generally, do you believe that implementation of Directive 2001/18/EC has helped restart the EU decision making process for Part C applications?

Most MS agree that the implementation of the Directive has helped to restart the Part C authorisation process, due to the added requirements for post-market monitoring and traceability and labelling. FR considered that the Regulations 1829/2003 (GM Food and Feed) and 1830/2003 (Traceability and Labelling) were necessary to re-start the decision-making process. ES commented that the issues of co-existence and thresholds are still impeding the process.

26. The Directive sets a maximum time limit of 10 years on Part C consents, although these can be renewed. How do you believe this provision will affect the number of applications coming forward?

MS were divided on the effect of the 10-year limit on the number of applications, half considering that there was no effect, and half having no opinion. NL said that there had been an increase in applications. FR said that the number of applications was affected more by the national context on GMOs than on the authorisation period.

27. Does the time limit make approval of Part C consents more acceptable to non-industry stakeholders within your Member State?

Again, half of the MS considered that the time limit made the Part C consents more acceptable to non-industry stakeholders, while the other half had no opinion. CY, FR, NL and UK commented that non-industry stakeholders remain largely negative towards authorisations.

28. Does the notifier have to pay a fee to introduce a notification under Part C of Directive 2001/18/EC? If yes, how much is this fee? Do you think that this fee affects the number of applications submitted in your Member State?

Table 6: EU15 Fees for Part C applications

Member State	Fee	Effect on number of applications
AT	Depends on number of pages in notification.	
BE	6200€ per notification. To be revised. Fee for new applications may rise to 15,200€	
DE	Range of 5000-30,000 € depending on size and effort required. 150,000€ in exceptional cases.	Not known
DK	Max is 200,000 Dkr	
EL	3000€	No effect seen.
ES	12,040€. Fee modelling under development.	Not known.
FI	6000€	
FR	1525€ for new applications, 610€ for renewals. To be revised, up to a limit of 15000€.	
IE	30,000€	No feedback.
IT	3098.74€. Currently under revision and will change in near future.	
LU		
NL	No fee	
PT		
SE	GM plants = 140,000 SEK For GM macrobial (nematodes, insects and Archnids) and microbial products the fee is diversified. The fee is regulated in KIFS 1998:8 and SFS 1998:942. 5000€ for every product	
UK	£12,000 UK	Public opinion has a greater deterrent effect than the fee.

Table 7: EU10 Fees for Part C applications

Member State	Fee	Effect on number of applications
CY	34000€ new application 25500€ for renewal 17000€ same product but different use 17000€ submission of additional information	No known effect.
CZ	Fee only applicable if final consent given – 1000€	No known effect.
EE	500 EEK (circa 32€)	No known effect.
HU	1. Authorization fee for gene technological modification of natural organisms (for each modification) 2. Authorization fee for establishing an institution for gene technological modification (for each institution) 3. Contained use of genetically modified organisms and the products made of genetically modified organisms 4. Intended release of genetically modified organism and products derived from genetically modified organisms (each modification and each place of release) 5. Deliberate release of genetically modified organism and products derived from genetically modified organisms (each modification) 6. Export and import of genetically modified organisms and the products derived from genetically modified organisms (each notification) 7. Transportation of genetically modified organisms and the products derived from genetically modified organisms (each notification)	70 000 HUF 260 000 HUF 135 000 HUF 300 000 HUF 250 000 HUF 180,000 HUF 70 000 HUF

LT	No fee.	
LV	2425.9 LVL	Possible effect.
Member State	Fee	Effect on number of applications
MT	Consent 46,587€; Amendment of notification 13,976€ -- these figures are not yet finalised.	Possible effect.
PL	5PLN stamp duty plus 0.5PLN per annex 3400 PLN per Decision	No known effect.
SK	30,000 SK (circa 770€	No known effect.
SI	Notifier pays administrative process expenses.	

29. Directive 2001/18/EC requires the phasing out of Antibiotic Resistance Markers (ARMs) in GMOs that may have adverse effects on human health and the environment by 31 December 2004 for Part C GMOs.

Do you have any comments regarding the implementation of Directive 2001/18/EC in relation to the phasing out of ARMs that may have adverse effects on human health and the environment for Part C GMOs in the EU?

Have you applied Article 4.2 of the Directive for some commercial GMOs in your Member State?

Many Member States, in particular those which have received applications, referred to the usefulness of the Opinion of the GMO Panel of the European Food Safety Authority (EFSA) dated 2 April 2004 and the document produced in December 2004 by the Working Group of the competent authorities and the Commission on ARMs for Part C notifications (ENV/04/27-REV). The document provides Member States with an additional guidance tool to be taken into account in the case-by-case risk assessment under Part C of Directive 2001/18/EC in order to ensure a common implementation of Article 4(2) of the Directive in all Member States. BE suggests that the different opinions of the Member States and EFSA on the classification of currently used antibiotics should be addressed in order to have an agreed document covering antibiotic use and therapy in all MS. This document would be a "risk management" classification of currently used antibiotics, covering the most critical situations in all MS, based on the EFSA opinion and subject to endorsement by the competent authorities of all MS.

In the second half of 2005, the Ministry of Agriculture in ES withdrew from the Spanish Register of Plant Commercial Varieties four modified varieties of maize, which include the event Bt-176, in accordance with Article 4.2 of Directive 2001/18/EC (Annex V). The Bt-176 event contains an ampicillin antibiotic resistance marker gene, which has been classified under group II by the GMO

Panel of the European Food Safety Authority (EFSA). The EFSA Opinion stated that although this antibiotic resistance gene was widely distributed in micro-organisms in the environment and although the presence of these antibiotic resistance genes in the genome of transgenic plants would have a minimal impact on human and animal health, these antibiotics were still used for therapy in human and veterinary medicine. For these reasons the use of ARMGs in group II should be restricted to field trial purposes and should not be present in GM plants to be placed on the market.

Since the authorization granted under Directive 90/220/EEC would be renewed before 17 October 2006, and although the marketing of these varieties would not imply risk for the public health or the environment, as confirmed by the EFSA opinion of July 8, 2004 [Bulletin (2004 78), 1-13], ES considered it suitable to apply the general principles applicable to the new requests in the frame of Directive 2001/18/CE.

DK stated that Statutory order 831 of 2/10/2002 provided that GMOs containing ARMs used in human and veterinary treatments could not be approved for field trials or for placing on the market.[5]

30. How have you applied Article 25 of Directive 2001/18/EC with regard to confidentiality to Part C applications? Which documents within the notification do you consider to be confidential?

MS which received notifications applied the provisions of Article 25 as transparently as possible after having consulted the applicant on a case-by-case basis. Most MS would appreciate further discussion on this issue.

The FR commission responsible for access to administrative documents (CADA) ruled that, where FR was the lead competent authority, only information relating to the process of obtention of the GMO or its marketing and which could have a negative effect on the competitive position of the company could be deemed confidential. For notifications where other MS took the lead, FR would respect the confidentiality decisions made by the other MS. FR expressed the wish for harmonisation of the Article 25 provisions at EU level, including rules for exchanging information among MS (see footnote 3).

UK aims to keep to an absolute minimum the material not available to the public and would only apply Article 25 to the intellectual property rights concerning a GM event

Reference should also be made to Question 23 relating to confidentiality.

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5 The conformity of this provision is being checked by the Commission legal service.

Traceability and Labelling

Directive 2001/18/EC establishes requirements for the labelling and traceability of GMOs and these are strengthened by Regulation 1829/2003 of the European Parliament and of the Council on genetically modified food and feed and Regulation 1830/2003 of the European Parliament and of the Council concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC.

31. What are your views as a Competent Authority on the workability of the systems set out in Directive 2001/18/EC and in Regulation 1830/2003 concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC ?

While many MS did not consider that they had enough experience with applications to give an opinion, some MS cited practical difficulties such as the analytical detection of GMOs in feed additives (DE); logistics along the production chain to certify that ingredients are GMO-free (BE, DE, MT); lack of clarity for the labelling and traceability of fermentation products produced using GMMs not present in the final product (EL); coordination among various Ministries (CZ, DK). ES proposed that an interpretative document would be useful in applying the legislation, both at national and at EU level. FR observed two problems: (i) on labelling, operators had difficulty understanding the links between Directive 2001/18/EC (Article 21 and Annex IV) and Regulation 1830/2003 (Article 4.6) and which provisions were to be applied, and (ii) on traceability, the fact that there are no seeds thresholds established for adventitious presence creates a legal void in the management of conventional seed lots which may contain adventitious presence of GMOs.

32. Have any specific issues arisen, for you as a Competent Authority, with regard to import of GMOs under Directive 2001/18/EC ?

A gap currently exists in knowledge of how to detect the adventitious presence of materials derived from GM crops that are cultivated in third countries, but that have not been approved yet in the EU. This is in part due to the fact that third countries are obliged to notify only those crops to the Biosafety Clearinghouse that are "living modified organisms" destined for export. There is a need to establish data resources on the GM crops that have been approved for cultivation in other countries, even if not for export, and the methods to detect these crops and their derived products.

33. Have you developed any measures within your Member State for the purposes of verification?

Measures reported include visits by control units in the regions for sampling and checks (DE); inspection checklists used by the National Food Administration (SE); access to laboratories by local authorities which enforce the legislation (UK); inquiries during controls on labelling, control, list and composition of ingredients and additives, vouchers, invoice, delivery note, technical forms (BE); controls throughout the chain, with specific in-depth controls for food and feed at two

levels – (i) the producer/importer of food and feed products for human consumption and animal feed and (ii) the producer/importer of food ingredients or raw material; also controls to check labelling of imported seed (FR); establishment of working group by relevant agencies (IE), development of analytical assays (FI); preparation of decree for national coordination of regional surveillance activities for implementation of Directive 2001/18/EC (IT); regular inspections (MT); membership of European Network of GMO Laboratories (CY, CZ); request by local control services for a "self-declaration" from importers that the imported material "contains" GMOs rather than "may contain" as well as guidelines to local and peripheral control services to discourage "GMO-free" labelling (EL). In Latvia, an annual programme for GM Food has been carried out since 2003, with 108 samples in 2004 and 100 samples in 2005, and an annual programme for GM feed has been carried out since 2004, with 11 samples in 2004 and 20 samples in 2005.

34. Do you have any comments to make about the thresholds in Regulation 1829/2003 on genetically modified food and feed with regard to the adventitious presence of GMOs for EU authorised materials and in relation to non-EU authorised materials in food and feed?

This question is addressed in the specific report on the implementation of Regulation 1829/2003[6].

35. Do you have any comments to make about Commission Recommendation 2004/787/EC on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003?

Most MS who replied to this question had difficulty with the Recommendation on the basis that the protocols are time-consuming and expensive and that comprehensive coverage was almost impossible to achieve. NL said that the results were not in proportion to the time and expense involved. Specific problems related to the lack of availability of reference material (DE); the wide choice of analytical methods available to control GMO positive maize samples (EL); the need for clarification on the unit for threshold values (BE, DE, FR)[7]; the need for a sampling plan for seeds and a more practicable protocol to suit the daily work of inspectors and authorities (AT), especially that of operators which use small amounts of ingredients or for control purposes at retail level (SE); the need for a database containing the genetic characterisation of all possible GMO events, not only authorised ones (ES); the need to address the practical difficulties of detecting hybrids versus a mixture of parental inbred lines, and the sampling and detection of mixtures of grains, flours or processed product (ES); difficulties with the large size of bulk samples and the number of incremental samples in the feed sector (EL).

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6 COM(2006) 626 final dated 25.10.2006

7 Note that the unit is defined in Commission Recommendation 2004/787/EC (O.J. L348, pp 18-26), sections V.4 and V.6 as "The results of quantitative analysis should be expressed as the percentage of GM-DNA copy numbers in relation to target taxon specific DNA copy numbers calculated in terms of haploid genomes."

On the issue of the unit for threshold values, DE said that there was a need to clarify whether weight, volume or DNA for threshold value should be used. A working group was currently evaluating the practicability of the Recommendation and preliminary results suggested that there would be a need to revise the Recommendation to make it more practicable. BE supported the unit of % weight for labelling thresholds for food and feed which would be compatible with related legislation. BE considered that the unit of haploid genomes used in the Recommendation would lead to different analytical results that would modify the thresholds of 0.5 and 0.9 GMO weight %. It would be necessary to study the impact of the adoption of the haploid genome unit instead of the weight percentage unit and to define conversion factors between the 2 units to reconcile analytical measures and threshold enforcement. FR noted that the provisions of the Recommendation were not mandatory for Member States but expressed regret that it had not been possible to produce a more consensual document which would have reconciled the need for adequate sampling and detection with reasonable costs.

SI noted that specific trait testing methods (detection, identification and quantification) of seed quality testing for GMO seeds has still not been adopted by ISTA.

36. In your opinion, is any further action or further regulation needed in relation to the adventitious presence of GMOs under Directive 2001/18/EC?

Several MS expressed the wish for further guidance, in particular to facilitate the life of control laboratories, inspectors and food operators e.g. on how operators are to verify adventitious presence; on harmonised evaluation criteria at EU level. UK and CZ called for clarification of thresholds for organic products and IT called for these thresholds to be as low as possible. ES pointed to the need for certified reference material to be available and for identification requirements to be adopted as soon as possible under the Cartagena Protocol in order to verify that imported GMOs are those that have been approved. NL called for thresholds to be set for GMOs which are not authorised in the EU, pointing to the fact that the adventitious presence of such GMOs is unavoidable in the light of bulk commodity trading and that a zero tolerance would be unworkable. Validated detection methods and authorized reference material would in these cases be extremely important. NL also called for thresholds to be established to cover outcrossing from Part B releases, pointing out that otherwise field trials could be in jeopardy. NL proposed that if the risks to human health and the environment for Part B trials were considered unacceptable then the application should not get a consent. However, if risks were deemed acceptable, then trace amounts of field trial material should be allowed in food and feed. A threshold would therefore be useful in this respect.

37. Do you have any comments to make about thresholds concerning the adventitious presence of genetically modified seeds in seed lots of non-genetically modified varieties?

Most MS which replied to this question emphasised the need for a legal instrument for the establishment of seeds thresholds (DE, BE, UK, AT, ES, FR), since it was very difficult to manage the labelling and traceability of conventional seed lots without such thresholds for adventitious presence. CY and LT said that the

thresholds should be set as low as possible, as a function of detection methods. IT pointed out that its experience with strict controls had reduced contamination of conventional seeds by GMOs from an average of 2% to 0.2% in less than 3 years SE replied that in the absence of specific seeds' thresholds, the standard for varietal purity in seed legislation was applied, if lower than 0.9%.

38. What additional measures do you believe should be put in place to support Directive 2001/18/EC and Regulations 1829/2003 and 1830/2003 (referred to above)?

The following additional measures or need for clarifications were proposed:

- ***harmonized obligations (to some extent) for coexistence of GM, conventional and organic crops (BE, ES, FR, PL);***
- ***guidance for determining whether contamination is adventitious or not (BE);***
- ***status of GMOs where approval has lapsed under the 10 year rule (UK);***
- ***adventitious presence of GMOs in widespread use in the rest of the world (UK);***
- ***regulation on GM thresholds for non-GM seeds (ES, SI);***
- ***liability aspects (ES, PL).***
- ***clear requirements to importer to identify or label GMOs in order to implement Regulation 1830/2003 (IT);***
- ***more information-sharing and cooperation among MS (inspection bodies and CAs) and Commission services (CZ);***
- ***detection methods for non-authorised GMOs (SI);***

Post-Market Monitoring

Part C applicants are required to supply a post-market monitoring plan setting out how the proposed releases will be monitored for unanticipated effects on the environment.

39. Will the provisions under Directive 2001/18/EC lead to new types of monitoring required or planned?

The majority of MS expect that new types of monitoring will be required/planned under the provisions of the Directive. Six MS expressed no opinion.

40. Given the guidance developed by the Commission, do you believe that the types of post-market monitoring that will be required will be consistent across the EU? If no, what would be needed to make them consistent?

Most MS agreed that there was a need for more consistency in post-market monitoring but that there would also always be a need for specific monitoring depending on the specific climate and natural environment in a Member State. Most MS also considered that the Working Group on Monitoring established by

the competent authorities was the correct forum in which to achieve more consistency. DE specified that consistency could be achieved by

- ***improvement of existing monitoring systems for GMO-related issues so that these systems could be used in general surveillance,***
- ***development of more specific EU-wide guidance on the main elements of general surveillance,***
- ***focusing post-market monitoring of the environment on European or internationally agreed protection goals,***
- ***setting up a network of the Competent Authorities to coordinate the implementation of EU-wide monitoring plans and to exchange experiences with their implementation and information about their results.***

ES said that general surveillance requirements (including liability aspects) should be more consistent across the EU and that common specific criteria for each GMO, developed via the Monitoring Working Group, could be used throughout the EU. ES nevertheless emphasised the need for a case-specific approach at national/regional level to take account of regional environmental conditions.

SE said that, once the necessary consistency had been achieved via the Monitoring Working Group, additional monitoring could be carried out by individual MS at its own expense.

NL replied that it would prove very difficult to obtain consistent monitoring plans across the EU given the large variation in environments and in opinions on what the monitoring should entail. Commission recommendations on monitoring, based on member state input, could be useful in this respect.

41. Is your Member State going to complete, in some cases, the monitoring and/or general surveillance plan that is planned by the applicant?

AT, CY, EE, IE, IT and LT affirmed their intentions to complete the applicants' monitoring plans, with AT emphasising the lack of detail in the monitoring plans. FR said that the general surveillance plans, carried out by the FR authorities concerning the impact of agriculture on the environment, would be adapted progressively as GMOs were authorised. NL, SE and UK said that they did not intend to, although NL and UK would be available to discuss issues further with the applicants. BE and DE had not yet decided on this aspect of monitoring.

ES replied that the Spanish Ministry for Environment had carried out, in the course of six years, some independent studies within the monitoring plan of the genetically modified varieties including Bt-176 and MON810 events, and that these studies were still ongoing. On the other hand, the Competent Authority of Spain was planning to carry out an independent study in order to determinate the possible impact from the use of tolerant plants to herbicides in the case of the cultivation of varieties was approved in the future.

42. Are there any issues concerning the development and implementation of case-specific post-market monitoring that you would like to see addressed?

A number of MS (DE, DK, ES, FI, SE) would like to see more practical guidelines issued for case-specific monitoring (CSM) and considered that the Working Group on Monitoring was the correct forum to provide these guidelines. CZ said that the target issues for CSM needed to be identified on a common basis for the EU. MT suggested that it should be obligatory for notifiers to take account of different situations in all MS.

AT said that, when a causal connection between an effect and a GMO had been established, case specific monitoring (CSM) was necessary to establish the extent of the effect. In most of the monitoring plans provided by applicants to date, the assumptions in the risk assessments were that all identified risks were considered to be "negligible". The task of a CSM would therefore be to confirm or reject these assumptions and thereby confirm or correct the extent of the effect (i.e. negligible or not). This had to be done even if the risk was considered to be negligible. However, no such CSM had to date been carried out by the applicants. IT said that general surveillance plans provided by the notifiers were not adequate as a management tool and that the assumptions made by the notifier in the risk assessment needed to be backed up by specific monitoring plans.

ES said that the Monitoring Working Group should continue to develop additional case-specific "checklists" for other kinds of GMOs (e.g. herbicide tolerant maize, GM cotton, etc.). It would also be necessary to elaborate plans and methods to monitor the potential adverse effects based on the generic checklist.

UK considered that it was too early to give a concrete answer to this question.

Another issue identified by SE was the question of economic responsibility for long-term monitoring of long-living species and in what forum this should be addressed.

43. Are there any issues concerning the development and implementation of general surveillance monitoring that you would like to see addressed?

DE and FI would also like to see more practical guidelines issued for general surveillance (GS) while NL and SE considered that the Working Group on Monitoring was the correct forum to provide such guidance. IT expressed concern about how GS could be carried out in practice by "usual operators" such as car/train drivers, ship pilots etc (IT). BE expressed concern about how competent authorities would be informed in practice when the first imports of authorised products would occur. In particular, BE posed the question of how the article, present in the authorisation decisions under Part C of Directive 2001/18, would be implemented in practice: "The consent holder shall be in the position to give evidence to the Commission and the CAs of the MS that the surveillance networks (…) collect the information relevant for the general surveillance of the product and that these networks have agreed to make available this information (…)."

CY said that the GS should be more detailed and prescriptive on preventive measures. MT said that some form of standardisation would be needed to reduce the variation among GS plans and that GS measures should cover all MS (and not cater only for the larger MS).

UK considered that it was too early to give a concrete answer to this question.

AT replied that the objective of General Surveillance was to identify adverse effects which were not accounted for in the environmental risk assessment. The monitoring plans submitted to date were too general and did not include a detailed monitoring strategy (including a sampling strategy for the detection of unintended effects). It was not clear how the applicants would comply with the requirements of the Directive when they only provided a "vague idea" of General Surveillance. The use of farmers' questionnaires which was proposed in many of the monitoring plans would not suffice to identify either subtle or even strong effects because farmers neither had the knowledge nor the resources to identify or monitor certain parameters with the according method in order to detect changes (e.g. abundance of certain pest or beneficial species, absence of a certain species etc.).

ES said that an EU-wide coordination of data resulting from post-market monitoring of GMOs was needed, for both GS and CSM (information networks, reporting activities, centralized registers, data bases, etc.)

44. Are there any issues concerning the boundary between case-specific monitoring and general surveillance monitoring which you would like to see addressed?

ES and FI considered that the boundary sometimes appeared unclear. ES, IE and SE consider that this is an issue for the Monitoring Group to address. UK considered that it was too early to give a concrete answer to this question.

DE quoted ACRE Guidance note 16, in which anticipated and unanticipated effects can be broken down into three separate categories as follows:

- ***Anticipated effects. Potential risks identified in the ERA as worthy of investigation via case-specific monitoring as well as those assessed as being extremely unlikely to occur and to cause harm.***

- ***Interactive or cumulative effects that are difficult or impossible to predict. Potential effects that are difficult to predict or assess fully in a single dossier and its risk assessment. e.g. effects that might arise as a result of an increase in the scale of cultivation and potential effects arising as a result of interactions between the GM crop and future varieties (GM and non-GM) that are released.***

- ***Unanticipated effects. Complete unknowns, i.e. potential effects not identified in the ERA, which can only be addressed by general surveillance.***

The main objective of case-specific monitoring (I) is to determine the significance of any adverse effects identified in the risk assessment. The assessment of risk should be based on Annex II of the Directive (2001/18/EC). General surveillance is not hypothesis driven and so it is primarily not conducted using directed

experimental approaches. However, robust scientific methodology should be applied and if necessary be developed.

AT considered that the boundary was already established in the risk assessment, in that CSM addresses risks that have been considered in the risk assessment, which means that, even if they are assumed to be negligible, they have been identified as "risks". GS addresses risks that have not been identified as such in the risk assessment.

Other Issues

45. Would you like to comment on any other aspects of the Directive or of other related legislation that would improve consistency and efficiency of the EU legislative framework for GMOs? If so, please add your comments below.

A number of issues have been highlighted for improvement[8], as follows:

- ***Urgent need to discuss practical implementation of procedures among all relevant institutions e.g. disagreements between MS and EFSA should be resolved at an earlier stage with respect to. Art 30 of Reg 178/2002 (DE, IT);***
- ***EU legislation on coexistence of GMOs with other crops (BE);***
- ***Thresholds of GM seeds in conventional seeds (BE);***
- ***Guidelines regarding the public information as required for the release of medicinal GMO for any other purpose than for placing on the market (clinical trials) would be welcome. Indeed, finding an acceptable compromise between the required public information on the one hand, and the privacy and/or medical secrecy on the other, is a very delicate process with important ethical issues (BE);***
- ***Concern about the transfer of the applications under Directive 2001/18/EC to Regulation 1829/2003 -- consultation according to article 6.4 and 18.4 of the Regulation is insufficient (ES, IT, PL);***
- ***Concern that all MS should implement the legislation on the basis of scientific evidence (UK);***
- ***Need for discussion on the way different MS regulate gene therapy (NL);***
- ***Accidental release needs to be examined more thoroughly in GS and CSM. Need better analytical methods, especially for compound feeds (CY);***
- ***Principle of proportionality should be applied with the PP (CZ).***

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8 All of these issues are discussed at the bi-annual meetings of the competent authorities, organised and chaired by the Commission. The objective of these meetings is to exchange information among Member States and the Commission in order to arrive at a common understanding on how to implement the provisions of the Directive.

- ***Need to extend expert groups to include EU 10 members (HU);***

- ***Need for better cooperation between Environment and Consumer and Health Protection Directorate-Generals in the Commission (SE);***

- ***Need technical guidance for sampling of particular plant parts for detection of GMOs, e.g in batch of Dianthus caryophyllus, which part of plant to be taken for sampling? What is the quantity of incremental samples etc? (LT);***

- ***Guidance on when animal tests/toxicological tests are required and on what tests are required for hybrids (MT).***

ATTACHMENT: List of Member State competent authorities dealing with Directive 2001/18/EC

Belgium

Institute of Public Health (IPH)
Federal Public Service (FPS) Health, Food Chain Security and Environment
Juliette Wytsmanstraat 14
B-1050 Brussels

FPS Health, Food Chain Safety and Environment
General direction Animaux, Végétaux et Alimentation
Division Denrées alimentaires et autres produits de consommation
Place Victor Horta, 40 Boîte 10
Bloc II - 7° étage
B-1060 Bruxelles

Czech Republic

Ministry of the Environment
Department of Environmental Risks,
Vrsovicka 65
100 10 Prague 10
Czech Republic

Denmark

Ministry of Environment
The Danish Forest and Nature Agency
Haraldsgade 53
DK-2100 Copenhagen ø

Germany

Federal Office of Consumers Protection and Food Safety
Dept. of Genetic Engineering
Taubenstrasse 42 - 43
DE-10117 Berlin

Bundesministerium für Verbraucherschutz, Ernährung und Landwirtschaft
Referat 222
Rochustrasse 1
DE-53123 Bonn

Estonia

Ministry of Environment
Nature Protection Department
Narva mnt. 7A - 329
15172 Tallinn
Estonia

The Jõgeva Plant Breeding Institute
Aamisepa 1
EE-alevik 48309, Jõgeva
Estonia

Greece

Ministry of Rural Development and Food
Directorate of Agricultural Policy and Documentation
Office 205
Acharnon 2 str.
GR-101 76 Athens

Spain

Ministerio de Medio Ambiente
DG de Calidad y Evaluacion Ambiental
Plaza San Juan de la Cruz s/n
ES-28071 Madrid

France

Ministère de l'Agriculture, de l'alimentation, de la pêche et des affaires rurales
Direction générale de l'alimentation
251, rue de Vaugirard
FR-75732 PARIS Cedex 15

Ministère de l'écologie et du développement durable
Bureau des Biotechnologies et des Installations agricoles et agro-alimentaires
Service de l'Environnement Industriel
Direction de la Prévention des Pollutions et des Risques
20, av de Ségur
FR-75302 Paris 07 SP

Ireland

Ministry - Department of the Environment, Heritage and Local Government
Environment Policy Section
Custom House
Dublin 1 - Ireland

EPA
P.O. Box 3000
Johnstown Castle Estate, Co. Wexford
Ireland

Italy

Ministero dell'Ambiente e della Tutela del Territorio
Direzione per la Protezione della Natura
via Capitan Bavastro 174
IT-00154 Roma

Cyprus

Ministry of Agriculture, Natural Resources and Environment
Department. Environment Service
Louki Akrita 1411, Nicosia
Cyprus

Latvia

Ministry of Agriculture
Food Surveillance Department
Food & Veterinary Service
Republikas laukums 2
LV-1981 Riga

Lithuania

Ministry of the Environment
GMO division
Nature Protection Dpt
A. Jakšto St 4/9
LT-01105 Vilnius

Luxembourg

Ministry of Health
Allée Marconi
L-2102 LUXEMBOURG

Hungary

Ministry of Agriculture and Rural Development
Budapest Kossuth square 11
HU-1055 Hungary
Hungary

Ministry of Environment and Water
Department of International Treaties for Nature Conservation
H-1121 Budapest, Költo u. 21
Hungary

Malta

Malta Environment and Planning Authority
Biosafety Co-ordinating Committee
Nature Protection Unit
Environment Protection Directorate
St. Francis Ravelin,
Floriana
(P.O. Box 200)
MT-Valletta CMR01
Malta

The Netherlands

Ministry of Housing, Spatial Planning and the Environment
Directorate-General for Environmental Protection
Directorate for Chemicals, Waste, Radiation Protection
Rijnstraat 8, P.O. Box 30945
NL-2500 GX The Hague

National Institute of Public Health and the Environment
Bureau GGO
RIVM, CSR
Antonie van Leeuwenhoeklaan 9
NL-3721 MA BILTHOVEN

Austria

Ministry of Health and Women - Dept IV/12
Radetzkystrasse 2
A-1030 Vienna

Ministry of Social Security and Generations
Radetzkystraße 2
AT-1030 Wien

Federal Ministry of Education, Science and Culture, Dept. BrGT
Rosengasse 2-6
A-1014 Vienna

Umweltbundesamt GesmbH
Spittelauer Lände 5
1090 Vienna
Austria

Poland

Chief Sanitary Inspectorate. Dept of food, nutrition and daily use objects hygiene
Dluga Str. 38/40
00-238 Warsaw, Poland
Poland

Ministry of the Environment
Department of Forestry, Nature Conservation and Landscape
52/54 Wawelska Street
00 - 922 Warsaw
Poland

Ministry of the Agriculture and Rural Development
Department of Plant Breeding and Protection
Wspolna Str. 30
00-920 Warsaw,
Poland

Slovak Republic

Ministry of the Enviroment of the Slovak Republik
Nam. L. Stura 1
812 35 Bratislava
Slovak Republic

Ministru of Agriculture
+421 (2) 5926 6567 / 66
+421 (2) 5296 6562

Slovenia

Ministry of the Environment and Spatial Planning - Environment Directorate
Biotechnology department
Dunajska cesta 48
SI-1000 Ljubljana

Ministry of Health
Sector for Food Safety and Health Suitability
Stefanova 5
SI-1000 Ljubljana

Ministry for Agriculture, Forestry and Food
Safety and quality of Food and Feed Section
Dunajska cesta 58
SI-1000 Ljubljana

Finland

Ministry of Social Affairs and Health - Board for Gene Technology
P.O. Box 33
Helsinki,
00023 Government, Finland

Sweden

Swedish Chemicals Inspectorate
Kemikalieinspektionen - Box 2
S-172 13 Sundbyberg
Sweden

Swedish Board of Agriculture
Crop Production Division
Vallgatan 8
SE -551 82, Jönköping

United Kingdom

Dept for Environment, Food and Rural Affairs
4/F6 Ashdown House
123 Victoria Street
UK-London SW1E 6DE
United Kingdom

ANNEX 2

LIST OF STAKEHOLDERS WHICH CONTRIBUTED TO THIS REPORT

Farmers' organisations

COPA-COGECA (Committee of Professional Agricultural Organisations in the EU
General Confederation of Agricultural Co-operatives in the EU),
Rue de Treves 61
B-1040 Brussels

LTO Netherlands,
PO Box 91,
NL-5000 MA Tilburg.

NGOS

Friends of the Earth
Helen.holder@foeeurope.org

Greenpeace European Unit,
Rue Belliard 199,
B-1040 Brussels.

British statutory conservation agencies
(Joint Nature Conservation Committee, English Nature, Scottish Natural Heritage and Countryside Council for Wales),
Biotechnology Advisory Unit English Nature,
c/o The Conntryside Agency,
1 Redcliff Street,
Bristol BS1 6NP,
U.K.

Industry/Trade Associations

FEFAC (Federation Europeenne de Fabricants d'Aliments Composes),
Rue de la Loi 223, Bte 3,
B-1040 Brussels.

OLEOSEM SEPROMA NTER (French seed industry),
Rue du Louvre 17,
F-75001 Paris

Europabio,
Av de l'Armee 6,
B-1040 Brussels.
Pioneer Overseas Corporation,
Av de Arts, 44,
B-1040 Brussels.

ESA European Seed Association,
Rue du Luxembourg, 23, bte 15,
B-1000 Brussels.

Groupe LIMAGRAIN (French agricultural cooperative),
Rue Limagrain, BP1,
F-63720 Chappes.

COCERAL (Comité du Commerce des céréales, aliments du bétail, oléagineux, huile d'olive, huiles et graisses et agrofournitures),
Rue du Trone 98,
B-1050 Brussels.

ANNEX 3

KEY ACTIONS PROPOSED BY THE COMMISSION TO THE COUNCIL IN 2006

Key Actions proposed by the Commission to the Council, June 2006

(a) EFSA to liaise more fully with national scientific bodies as a means to resolve diverging scientific opinions with Member States, in full compliance with the procedural modalities set out in the basic legislation

(b) EFSA to provide more detailed justification, in its opinions on individual applications, for not accepting scientific objections raised by national competent authorities

(c) EFSA to clarify which specific protocols should be used by applicant to carry out scientific studies (toxicology, animal) demonstrating safety, detailing for example, species and type of animals, numbers and duration of studies

(d) Commission to fully exercise its regulatory competences foreseen in the basic legislation to specify the legal framework in which EFSA assessment is to be carried out

(e) Potential long-term effects and bio-diversity issues to be addressed more explicitly and in line with the uses of the product, via adequate research and within the framework of monitoring plans, by applicants in their risk assessment for the placing on the market of GMOs and by EFSA

(f) To address specific risks identified in the risk assessment or substantiated by Member States by introducing on a case by case basis additional proportionate risk management measures in draft decisions to place GMO products on the market, as appropriate

(g) To establish, in any appropriate way, that, where in the opinion of the Commission, a Member State's observation raises important new scientific questions not properly or completely addressed by the EFSA opinion, the Commission may suspend the procedure and refer back the question to EFSA for further consideration