DIRECTIVE 2001/18/EC

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

QUESTIONNAIRE

June 2005

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".

Article 31.7 then specifies various aspects to be included in the Commission three-yearly reports to the European Parliament and Council.

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)
31 December 2005	Commission Summary report of MS reports (Article 31.5)
17 October 2006	2nd report from Commission to EP and Council (Article 31.6 and 31.7))

DRAFT QUESTIONNAIRE

In April 2005, the Commission circulated a draft questionnaire as a basis for Member States to fulfil their reporting obligations by 17/10/2005. Following comments from several Member States on the draft, version 2 is now attached.

The Commission invites MS CAs to comment on this draft by **24 June 2005** with a view to finalising the questionnaire before the summer break.

DEADLINE FOR COMMENTS: 24 June 2005

Contact Details

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

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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 below are aimed at gathering information on the experience of Competent Authorities in implementing these requirements.

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[2]? 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).

   There have not been submitted any applications (trials with plants and other trials) in Lithuania under Part B of Directive 2001/18/EC.

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?
   An applicant goes through the process determined in the order of the Minister of Environment *Regulation on GMOs Deliberate Release into the*

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

Environment, Placing on the Market **(Official Gazette 2004, No. 71-2487, in force since 1 May 2004). The overall objective of this order is to regulate usage and control requirements on GMOs and GMPs deliberate release into the environment in the Republic of Lithuania. This order has been prepared according to the requirements of the Directive 2001/18/EC of 12 March 2001 on the deliberate release into the environment of genetically modified organisms.**

According to the adopted detailed procedures, the applicant (natural or legal person), having intention to use GMOs, is obligated to receive written consent to execute deliberate release into the environment of GMOs for any other purposes than placing on the market. The applicant is obliged to submit an application to the Ministry of Environment along with the completely filled-in a special form of application both in written and digital formats, according to the provisions of Annex 1 of above-mentioned order.

The application should include the dossier supplying the information necessary for carrying out the environmental risk assessment of the deliberate release of GMOs (general information; information relating to GMOs; a plan for monitoring in order to identify effects of the GMOs on human health or the environment; a summary of the dossier; etc.), the environmental risk assessment and the conclusions, together with bibliographic reference and indications of the methods used.

The Ministry of Environment upon receipt of application for authorization for deliberate release into the environment of GMOs, scrutinizes the completeness of documents presented whether they fully confirm with the requirements stated in above-mentioned order and, in case of discrepancies, reasonably asks the applicant to submit lacking data or supplement information.

The Ministry of Environment acknowledges the date of receipt of the application and during the period of 10 days dispatches the application for authorization via E-mail and mail to the GMOs Steering Committee and the GMOs Experts Committee for submission of draft decision (during the subsequent 20 days period). The GMOs Steering Committee is a political advisory body, which consists of members appointed by the relevant state authorities, the subordinated organizations, non-governmental organizations, universities, scientific institutes. The GMOs Experts Committee is a consultative advisory body from scientific staff of various specializations.

The Ministry of Environment sends to the European Commission and other Member States a summary of application during 30 days period from its receipt.

The Ministry of Environment having considered and analyzed any observations and recommendations received from the GMOs Steering Committee, the GMOs Experts Committee, as well as findings from other Member States, responds in writing to the applicant (during 90 days of receipt of the application, but no longer than 120 days – waiting for lacking or additional information), that:

- **The Ministry of Environment has an opinion to grant the consent for deliberate release into the environment of GMOs for any other purposes than placing on the market, OR**

- **The Ministry of Environment has an opinion that deliberate release into the environment could not be granted, because of the reasoned objections. In that case the Ministry of Environment indicates concrete reasons for rejection of request and informs the European Commission on the decision taken.**

The applicant has right to start releasing GMOs into the environment under the conditions prescribed in the consent granted by the Ministry of Environment.
No consents for deliberate release of GMOs into the environment have been issued in the Republic of Lithuania until 1 October 2005.

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

Yes X No

Please explain your answer.

Prior to official submission of application for authorization for deliberate release of GMOs into the environment, there is the potential for applicants to discuss requirements for application. The Ministry of Environment upon receipt of application, scrutinizes the completeness of documents presented whether they fully confirm with the requirements stated in *the Regulation on GMOs Deliberate Release into the Environment, Placing on the Market* and, in case of discrepancies, reasonably asks the applicant to submit lacking data or supplement additional information. The detailed information about the requisite procedures are presented in the national GMO database http://gmo.am.lt and on the ministerial website www.am.lt.

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.

Almost always Quite often Almost never

If an applicant submitted incomplete or discrepant application, the Ministry of Environment can reasonably request the applicant to submit lacking data or supplement information according to the requirements of *the Regulation on GMOs Deliberate Release into the Environment, Placing on the Market.*

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

There have not been any cases of submitting the applications for authorization the deliberate release of GMOs into the environment.

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

No experience.

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

Yes X No Don't know

Please explain your answer.

As Lithuania has joined the European Union in May 2004, thus the general sector policy for GMOs safe usage and handling system is approximated to that of the European Union. Lithuania, as a new Member State, has no experience, however the defined exact requirements enable to regulate in efficient manner the experimental release of GMOs into the environment.

8. Has it provided industry with increased regulatory certainty?

Yes X No Don't know

Please explain your answer.

There had been organized several workshops for the different stakeholders (including industrial biotech companies) to introduce the regulatory requirements during the UNEP-GEF project on the Development of National Biosafety Framework for Lithuania. Furthemore the BEF (Baltic Environmental Forum) organized the workshops on:

- **"Genetically modified plants and their products";**
- **"Implementation of biosafety regulations";**
- **"Implementation and Enforcement of EC GMOs legislation – Handling Request and Enforcement Mechanisms", etc.**

9. Is the time frame for decision making predictable?

Yes X No Don't know

Please explain your answer.

Exactly determined time frame for decision-making and for additional information waiting is enough predictable according to the requirements defined in the Directive 2001/18/EC and accordingly in the national legislation.

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?

The greatest burden in implementation of the Part B under Directive 2001/18/EC is the absence of experience.

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?

Currently according to the national legislation the notifier has not to pay any fee to introduce a notification under Part B of Directive 2001/18/EC.

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? Please tick the relevant response.

Significantly increased the requirements in relation to direct effects
Significantly increased the requirements in relation to indirect effects
Significantly increased the requirements in relation to immediate effects
Significantly increased the requirements in relation to delayed effects
Has had no significant impact on risk assessment requirements

The Directive 2001/18/EC has had significant impact on risk assessment requirements in relation to direct, indirect, immediate and delayed effects. *The Order on Regulation of Risk Assessment on GMOs* (adopted by the order No. 681/689/525/753 of the Ministers of Environment, Health and Agriculture, and the Director of State Food and Veterinary Service) has been prepared taking into consideration the requirements of Directive 2001/18/EC and the 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. The order establishes the main principles, methods and performance procedures for the activities related to the risk assessment of GMOs and GMPs, consisted of GMOs, posed to the human and animal health, and environment.

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

Yes X No Don't know

The general principles and methodology for the environmental risk assessment are provided in Annex II of Directive 2001/18/EC and in the Commission Decision 2002/623/EC. The precautionary principle is taken into account in Directive 2001/18/EC, and environmental risk assessment should be carried out in accordance with this principle. EU legislation specifies what information is necessary for environmental risk assessment, which should be carried out by the notifier prior the release of GMOs into the environment.

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?

Yes X No Don't know

Please add any comments.

The Commission formulated a comprehensive and clear system for risk assessment. General and specific guidance on methodological evaluation criteria for potential environmental impact from the release of GMOs into the environment are listed in the Commission Decision 2002/623/EC.

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

Speeded up the process
Slowed down the process
Had no impact on the time required

Please add any comments.

Lithuania has considered the requirements for the environmental risk assessment along the lines of the Directive 2001/18/EC and the Commission Decision 2002/623/EC. The clear environmental risk assessment requirements lead to more effective and explicit evaluation of potential adverse effects of the GMOs, which may result from the deliberate release. However, due to the absence of practical experience Lithuania has not applied the environmental risk assessment requirements in decision-making yet.

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

***The Order on Regulation of Risk Assessment on GMOs* sets out the requirements of the environmental risk assessment. These requirements**

could be found through the national GMO database (or the Biosafety Clearing-House) and/or in the national Official Journal.
The applicant before submitting a notification to the Ministry of Environment has to provide the environmental risk assessment. The Ministry of Environment, upon receipt of the application for deliberate release of GMOs into the environment, without delay, but no later than 10 days informs and delivers the dossier to the GMOs Steering Committee and the GMOs Experts Committee requesting them to submit possible risk assessment posed by GMOs to human health and environment, and preliminary findings. The Ministry of Environment has to ensure that the potential adverse effects on human health and environment are assessed on a case-by-case basis.

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?

Lithuanian legislation on GMOs promotes public awareness and participation as an integral part of its regulatory framework. *The Order on Regulation on Public Information and Participation in Authorization of Consents for Use of GMOs* adopted by the Minister of Environment on June 11, 2003, was drafted taking into consideration Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters, the European Union Directive 2001/18/EC on the deliberate release into the environment of GMOs, and the European Union Directive 90/219/EEC on the contained use of GMOs in conjunction with Directive 98/81/EC amending Directive 90/219/EEC. The order applies for the parties (natural and legal persons, public institutions) involved in the process of information and participation during the notification and permitting to use GMOs. It declares the rights and duties of the notifier to inform public publicly announcing the intention to use GMOs, inviting to express and deliver comments on the application and preliminary decision taken on each specific case.
According to Article 4 of *the Order on Regulation on Public Information and Participation in Authorization of Consents for Use of GMOs* the Ministry of Environment has to organize the use, storage and availability of information about GMOs to the public through the internet database, undamaged the rights of confidential and intellectual information.
The Ministry of Environment, supported by the UNEP-GEF (UN Environmental Program – Global Environmental Facility) project, established the national GMO database. The main tasks of the national GMO database are to: transfer data into the system, store these data, process and present them, guarantee access to the data, but also restrict

access to confidential information. The GMO database (it could be found via Internet address: http://gmo.am.lt) contains the public available information on the following categories:

– National law and regulations;

– European Union legislation;

– Regional and International agreements;

– National Competent Authorities and Contact Points;

– Decisions taken on import, export and transit of GMOs;

– Notifications and Information on contained use of GMMs;

– Notifications and Information on consents issued for the deliberate release of GMOs into the environment or for the placing on the market;

– Roster of Experts;

– Other related information.

In the GMO database there is the section for the direct public opinion presentation. This database facilitates the implementation of better conditions for the public awareness raising, consultation and participation, facilitates the exchange of scientific, technical, environmental and legal information among national institutions and the public.

According to *the Order on Regulation on Public Information and Participation in Authorization of Consents for Use of GMOs*, the notifier has an obligation to inform public during the period of 10 days via different mass media about the fact of submission notification to the Ministry of Environment, the main scrutinized findings and about the fact of granted consent for deliberate release into the environment of GMOs in Lithuania.

The Ministry of Environment during the period of 10 days after the acceptance of decision concerning GMOs handling, publicizes via Internet and the national Official Journal the information on the consent issued for the deliberate release of GMOs into the environment. The public has right to make reasoned suggestions and comments, and submit to the Ministry of Environment within 40 days from the information submission about intention to use GMOs.

Information on GMOs regulation provided through the publication of leaflets, posters, articles in local and national press, and other informative materials ensure effective public awareness raising and consultation during the process of decision-making.

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?

The public has full right to receive freely announced information about the GMOs usage.

The following information is made available to the public:

1. The intention about the deliberate release of GMOs into the environment in the territory of Lithuania:

- **full application;**

- **location of field trials – the geographical location, the area of field trail, vectorial delimitation of field trail;**
- **intended date of the proposed release;**
- **environmental risk assessment.**

2. Primary findings of the Ministry of Environment concerning intentional release of GMOs into the environment.
3. Where, when, what and how the motivate suggestions or comments about GMOs is possible to submit.
4. Information on the consents issued for the deliberate release into the environment:
a) GMOs may be deliberate release into the environment and under which conditions;
b) GMOs may not be release into the environment.
5. In the emergency cases the Ministry of Environment informs the public.

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

The Ministry of Environment scrutinizes the motivated suggestions or comments concerning intentional release of GMOs into the environment and takes into consideration or explains why they were rejected.

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?

Never X
Less than 5 times
Between 5 and 10 times
More than 10 times

Lithuania has never been used the simplified procedures concerning the lack of sufficient experience on the deliberate release into the environment.

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

Retained use of simplified procedures

Moved to use of differentiated procedures X

Please comment on the reasons for this.

Lithuania has joined the European Union in May 2004, and the requirements of the Directive 2001/18/EC have been transposed to the national legislation. No experience.

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?

Lithuania endorses the phasing out of ARMs in GMOs that may have an adverse effect on human health and the environment, however it is not clear what ARMs are thought to be unacceptable, and what are not. The clarification would allow for industry and scientists to plan ahead.

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?

The national legislation on GMOs contains confidentiality provisions that apply equally to domestic and foreign producers of GMOs. The applicant has indicate the information in the applications that should be treated as confidential, provided that verifiable justification is given in such cases. Decision which information will be kept confidential is taken by the Ministry of Environment after consultation with the applicant.
Exemptions from the confidentiality clause include:

- **General description of GMO, name and address of the notifier, purpose of the release, location of the release and intended uses;**
- **Methods and plans for monitoring of GMOs and for emergency response;**
- **Environmental risk assessment.**

According to the above-mentioned *Order on Regulation on Public Information and Participation in Issuing of Consent for Use of GMOs* the public has full right to receive freely announced information about usage of GMOs enquiring what information would like to be given. It cannot be given in case the disclosure of it would offend its confidentiality and intellectual property rights.

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:

- 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.

Where questions imply the need for previous experience with Directive 90/220/EC, it is not necessary for the ten new Member States to reply to these questions.

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.

There have not been submitted any applications under Part C of Directive 2001/18/EC.

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?

Yes No **Don't know X**

Please give reasons for your answer.

No experience.

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?

No effect
Reduce the number of future applications
Increase the number of applications
Don't know X

Please give reasons for your answer.

No experience as no applications received.

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

Yes X No Don't know

The applicants will look more serious to GMOs risk assessment and monitoring.

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?

Currently the notifier has not to pay a fee to introduce a notification under Part C of Directive 2001/18/EC.

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?

Lithuania has not yet applied provisions of Article 4.2 of the Directive for some commercial GMOs.

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?

The national legislation on GMOs contains the same confidentiality provisions to both Part B and Part C applications.
The applicant has indicate the information in the applications that should be treated as confidential, provided that verifiable justification is given in such cases. Decision, on which information will be kept confidential is taken by the Ministry of Environment after consultation with the applicant.
Exemptions from the confidentiality clause include:

- **General description of the GMO, name and address of the notifier, purpose of the release, location of the release and intended uses;**
- **Methods and plans for monitoring of the GMOs and for emergency response;**
- **Environmental risk assessment.**

The public has full right to receive freely announced information about usage of GMOs enquiring what information would like to be given. It cannot be given in case the disclosure of it would offend its confidentiality and intellectual property rights.

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?

The systems set out in the Directive 2001/18/EC and in the Regulation 1830/2003 concerning traceability and labelling of GMOs and traceability of food and feed products produced from GMOs and amending Directive 2001/18/EC, are comprehensive and convenient for the application. The provisions for traceability ensure a high level of environmental and health protection and pave the way for a proper labelling system.

32. Have any specific issues arisen with regard to import or export of food and feed for you as a Competent Authority?

There have no any specific issues arisen with regard to import or export of GM food and feed.

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

The State Food and Veterinary Service is responsible for control of GM food and feed products imported from the third countries, as well as for control of GM food and feed products after placing on the market. The National Veterinary Laboratory (NVL) under the State Food and Veterinary Service has been designated as the reference laboratory for

GMOs testing in Lithuania. NVL has been accredited according to the EN ISO ITEC 17025 standard by German accreditation body DAP registration number (DAP-PL-3328.99). NVL currently has the capacity to screen maize and soy food and feed and their derivatives using accredited qualitative and quantitative (Real-Time) PCR methods.
Implemented GMOs detection methods:

- **Qualitative and quantitative detection of GMOs;**
- **Corn (Maximizer Bt176, Bt11, LibertyLink (T25) StarLink™, Roundup Ready™ GA21, YieldGard™ MON810, MON863, NK603);**
- **Soy (Roundup Ready and food products which contains GMOs, feedstuffs (GMOs screen));**
- **Rape (Falcon GS 40/90, GT73, MS8/RF3, MS1/RF1, Topas 19/2, Laurat, Trierucin).**

If imported equivocal soy, rape or maize food and feed products are not labelled, then samples from each consignment should be taken to identify the genetic modification. According the established requirements the compliance of these products, documental and physical inspection is accomplished.

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?

No comments.

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?

No comments.

36. In your opinion, is any further action or further regulation needed in relation to the adventitious presence of GMOs in food and feed?

No comments.

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?

It is important to acknowledge, that it is practically impossible to avoid the presence of genetically modified seeds in seed lots of non-genetically modified varieties. But contaminations in seed constitute a basis

contamination that is directly responsible for contaminations in the harvest. But it is important to include the contamination during the further processing of the harvest (e.g. in mills) or other processes during the production of food. In that case the risk exists that the threshold of 0.9 percent GMO contamination for 'GMO free' products will consequently be difficult to achieve. Therefore the permitted level for seed contamination must be set as low as possible.

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)?

Detection methods for non-authorised GMOs are needed.

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?

Yes X No Don't know

The development of national GMOs monitoring system depends upon provisions of *the Order on Regulation for Preparation of Monitoring Plan of GMOs after the Placing on the Market* according the Directive 2001/18/EC and the 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. No previous experience with the Directive 90/220/EC.

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?

The types of post-market monitoring that will be required will be consistent.

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

Yes X No Don't know

The national *Order on Regulation for Preparation of Monitoring Plan of GMOs after the Placing on the Market* describes the requirements for a post-monitoring plan. Applicants for consent to release must supply a dossier of prescribed information about the GMOs. This should include a detailed risk assessment of possible impact on human health and the environment, and the monitoring plan. The monitoring plan should be driven by and closely related to the risk assessment and hence should be proportionate to perceived risk identified in the environmental risk assessment. The monitoring plan should also incorporate general surveillance, which is intended to be used for longer-term observation and detection of unexpected developments.
The Government of Lithuania has approved the National Environmental Monitoring Program (NEMP) for plant, soil and water monitoring from 2005 to 2010. In new NEMP main responsibility should fall to Nature Protection Department of the Ministry of Environment, as it is established to deal with nature conservation issues – wildlife and natural flora conservation, designated areas strategy management.

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

No comments.

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

No comments.

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

No comments.

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.

The main attention is focused on sampling protocols of seed, other plant propagating material, food and feed lots in Commission recommendation 2004/787/EC. It is important to recognize, that cleanliness of seeds is crucial for preventing GMO spreading within European Community. However it is necessary to provide technical guidance for sampling of particular plant parts for detection of GMO. Recently there have been issued more and more consents for placing on market GM plants (e.g. *Nicotiana tabacum* or *Dianthus caryophyllus*) in European Community. Therefore it is necessary to provide guidance, which will facilitate sampling procedures from GM plants individuals (e.g. it is required to control batches of GMO from third countries on board. So if the consignment of GM *Dianthus caryophyllus* plants will arrive, it will be necessary to take samples from the lot. But there is no clear guidance which part of plant to take, what is the quantity of increment sample and etc.