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AD HOC TECHNICAL EXPERT GROUP ON
RISK ASSESSMENT UNDER THE
CARTAGENA PROTOCOL ON BIOSAFETY
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SYNTHESIS OF INFORMATION RELATED TO RISK ASSESSMENT AND RISK MANAGEMENT RECEIVED IN INTERIM NATIONAL REPORTS ON IMPLEMENTATION OF THE CARTAGENA PROTOCOL ON BIOSAFETY

I. INTRODUCTION

1. At its second meeting in 2005, the Conference of the Parties serving as the meeting of the Parties to the Protocol, in paragraph 5 of decision BS-II/9, requested the Executive Secretary to compile the information on risk assessment and risk management submitted by Parties in their interim national reports, for inclusion in a synthesis report for consideration by the Ad Hoc Technical Expert Group on Risk Assessment established in paragraph 4 of the same decision.

2. A total of 44 interim national reports were received by the Executive Secretary, and almost all of these provided answers to the particular questions related to risk assessment and risk management (Articles 15 and 16).

3. Section II of this document presents the analysis of information submitted in the interim national reports with respect to Articles 15 and 16. Section III draws on the findings to make some general conclusions of relevance to the work of the Ad Hoc Technical Expert Group on Risk Assessment.

II. ANALYSIS

4. There were eight questions in the interim reporting format related to risk assessment and risk management. Responses to the first seven of these (questions 16 to 22) are summarized in table 1.

5. Question 23 of the interim national reporting format allows for provision of detailed information, and reads "Please provide further details about your responses to the above questions, as well as description of your country's experiences and progress in implementing Articles 15 and 16, including any obstacles or impediments encountered." Several Governments provided information in accordance with this question. Responses are annexed to this document. Details regarding aspects of national legislation dealing with risk assessment and risk management account for most of the information provided under question 23, although some information is also provided that explains responses to questions 16 to 22.

6. Results of the questionnaire must be interpreted carefully, taking into account the limited number of responses. First, less than one-third of Parties submitted interim national reports (44 out of a total of 125 Parties as of 1 October 2005). It is often difficult to generalize from small sample sizes, particularly when comparing responses within or among regions for which there were few submissions. Second, the reports vary in the amount of information provided, and many reports provided little additional information to support answers to the questions. Third, reporting countries were self-selecting, therefore results may be biased towards countries that were better able to prepare interim reports for any reason.

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Finally, the submissions highlight some weaknesses in the interim reporting format that appear to lead to ambiguous responses.

7. Results for questions 16 and 17 reveal that most reporting countries have not yet imported living modified organisms for intentional introduction into the environment. Among those who have imported living modified organisms for intentional introduction into the environment, risk assessments have been carried out in all but one case (question 16), and in most of those cases the Party of Import required the exporter to carry out the risk assessment (question 17) and required the notifier to pay for the risk assessment (question 18). However, it is not possible to generalize these results as they are based on a very small number of samples (only 12 Parties reported being Parties of Import).

8. Results for question 19 indicate that many reporting countries have established mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of the Protocol (Article 16.1). However, it is important to note that most of the positive responses come from the WEOG region (15 yes, 0 no) and the CEE region (9 yes, 3 no), whereas only about half of reporting countries from the other regions (Asia-Pacific, Africa, Latin America and the Caribbean) responded positively (8 yes, 7 no).

9. Many developing countries indicated under question 23 that they have draft national regulatory frameworks in place but that they have not yet been approved and implemented. It is not clear from the responses at what level of detail these frameworks provide for risk assessment and risk management measures.

10. Results for question 20 indicate that many reporting countries have adopted measures to prevent unintentional transboundary movements of living modified organisms (Article 16.3). However, once again the positive responses come mostly from the WEOG region (15 yes, 0 no) and the CEE region (10 yes, 2 no), while only about half of reporting countries from the other regions (Asia-Pacific, Africa, Latin America and the Caribbean) responded positively (7 yes, 8 no).

11. Results for question 21 indicate that most reporting countries endeavour to ensure that any living modified organism undergoes an appropriate period of observation before it is put to its intended use (Article 16.4). Again, however, the majority of positive responses came from the WEOG region and the CEE region, and the limited results reported from the other regions (Asia-Pacific, Africa, Latin America and the Caribbean) are mixed and inconclusive.

12. Question 22 asked whether a country has cooperated with others for the purposes specified in Article 16.5, namely to identify living modified organisms or traits which may have adverse effects on biodiversity, and to take measures to address such living modified organisms or specific traits. Responses indicate that most reporting countries from WEOG region (13 yes, 1 no) and CEE region (9 yes, 3 no) have undertaken such cooperation, whereas most reporting countries from other regions (Asia-Pacific, Africa, Latin America and the Caribbean) have not (2 yes, 12 no).

13. In addition to supplying supporting information or additional information related to questions 16 to 22, several countries noted that their national frameworks for biosafety were in a draft stage, not yet agreed and therefore not yet implemented. This may be considered an impediment to implementation of the operational provisions of the Protocol, including those related to risk assessment and risk management, although it is not clear how soon those countries would be able to operationalize the risk assessment and management provisions if they received a notification under Article 8.

III. GENERAL CONCLUSIONS

14. It is difficult to draw many specific conclusions from the limited number of interim national reports submitted. However, the submissions do give an indication of the range or responses, and it is possible to make a few preliminary general conclusions as follows:

(a) Few countries have imported living modified organisms for intentional introduction into the environment. Most of those countries that have imported living modified organisms for intentional introduction into the environment have required the exporter to carry out the risk assessment and have required the notifier to pay for the risk assessment;

(b) Mechanisms and measures to implement the risk assessment and risk management provisions of the Protocol are operational to a large extent in the WEOG and CEE regions, and to a lesser extent in Asia-Pacific, Africa, and Latin America and the Caribbean;

(c) Many CEE countries use the European Community legislation as their basis for risk assessment of living modified organisms, and are operationalizing EC Directives in that regard;

(d) Many developing countries seem to be at a stage where they have developed a draft framework for biosafety but are not yet at a stage of implementation.

Table 1. Responses to questions 16 to 22 of the interim national report on implementation of the Cartagena Protocol on Biosafety. Results are tabulated globally and by region, including Asia and the Pacific (A-P), Africa, Central and Eastern Europe (CEE), Latin America and the Caribbean (LAC) and Western Europe and Other States Group (WEOG). For each answer to each question, the responding countries are listed using the 2-letter country codes, and any comments made in the margins of those questions are shown. Country codes are listed at the bottom of the table.

		Global		WEOG		A-P		Africa		CEE		LAC	
		#	%	#	%	#	%	#	%	#	%	#	%
16.	If you were a Party of import during this reporting period, were risk assessments carried out for all decisions taken under Article 10? (Article 15.2)												
a)	yes	11	26	5	31	1	25	1	14	3	25	1	25
	at (yes, as involved in the procedure acc. To dir. 2001/18/ac), dk, fr (imports were for experimental purposes, see q6 and q8), id, Mx (please see q23), pl, ro, sk, za, es, gb,												
b)	no (please clarify below)	1	2	0	0	1	25	0	0	0	0	0	0
	Kh (no, because the law is not in place to regulate LMO releases)												
c)	not a Party of import	31	72	11	69	2	50	6	86	9	75	3	75
	al, dz, be, bz, bg, cm, cu, eg, ee, et, eur, fi, de, hu, ir, ie, it, jp, lv, lt, ml, nl, no, pt, md, kn, si, se, ch, tg, ua,												
17.	If yes, did you require the exporter to carry out the risk assessment?												
a)	yes - in all cases	9	23	4	31	1	25	1	14	3	25	0	0
	dk, fr, id, pl, ro, sk, za, es, gb,												
b)	yes - in some cases (please specify the number and give further details below)	1	3	0	0	1	25	0	0	0	0	0	0
	Kh (exporter has to provide document related to RA of such LMOs check. Cambodia may ask experts to review)												
c)	No	2	5	1	8	0	0	0	0	0	0	1	34
	At, Mx												
d)	not a Party of import	27	69	8	61	2	50	6	86	9	75	2	66
	al, dz, be, bz, bg, cm, cu, eg, ee, et, eur, fi, de, hu, ir, it, jp, lv, lt, ml, no, md, si, se, ch, tg, ua,												
18.	If you took a decision under Article 10 during the reporting period, did you require the notifier to bear the cost of the risk assessment? (Article 15.3)												
a)	yes - in all cases	7	28	1	17	2	100	1	20	3	33	0	0
	kh, id, lv, pl, ro, za, gb,												
b)	yes - in some cases (please specify the number and give further details below)	3	12	2	33	0	0	0	0	1	11	0	0
	Be, lv, se												
c)	no	15	60	3	50	0	0	4	82	5	56	3	100
	al, dz, at (n/a), bz, cu (n/a), eg (n/a), ee, et(?), lv, lt, ml, mx, sk, es, ch (n/a),												

19.	Has your country established and maintained appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of the Protocol? (Article 16.1)												
a)	yes	32	76	15	100	2	50	4	57	9	75	2	50
	dz (as part of NBF), at, be, cm, cu, eg, ee, eur, fi, fr, de, hu, id, ie, it, jp, lv, lt, mx, nl, no, pl, pt, md, ro, sk, si, za, es, se, ch, gb,												
b)	no	10	24	0	0	2	50	3	43	3	25	2	50
	al, bz, bg, kh, et, ir, ml, kn, tg, ua,												
20.	Has your country adopted appropriate measures to prevent unintentional transboundary movements of living modified organisms? (Article 16.3)												
a)	yes	32	76	15	100	2	50	4	57	10	83	1	25
	dz (as part of NBF), at, be, cm, cu, eg, ee, eur, fi, fr, de, hu, id, ie, it, jp, lv, lt, mx, nl, no, pl, pt, md, ro, sk, si, za, es, se, ch, gb,												
b)	no	10	24	0	0	2	50	3	43	2	17	3	75
	al, bz, bg, kh, et, ir, ml, kn, tg, ua,												
21.	Does your country endeavour to ensure that any living modified organism, whether imported or locally developed, undergoes an appropriate period of observation commensurate with its life-cycle or generation time before it is put to its intended use? (Article 16.4)												
a)	yes - in all cases	31	75	15	100	2	50	3	43	10	91	1	25
	dz, at, be, bg, eg, ee, eur, fi, fr, de, hu, id, ie, it, jp, lt, mx, nl, no, pl, pt, md, ro, sk, si, za, es, se, ch, ua, gb,												
b)	yes - in some cases (please give further details below)	4	10	0	0	2	50	1	14	0	0	1	25
	Kh (yes, in some cases. For the first time when LMOs are allowed to develop or conduct a field trial and has gone through a full RA (the notifier has a licence). Thus domestic reproduction does not require a full scale RA unless adverse affect exposes into the environment), cm, cu (locally developed LMOs), ir,												
c)	no (please give further details below)	0	0	0	0	0	0	0	0	0	0	0	0
	-												
d)	not applicable (please give further details below)	6	15	0	0	0	0	3	43	1	9	2	50
	al, bz, et (The mechanism has not been yet in place), ml, kn, tg,												
22.	Has your country cooperated with others for the purposes specified in Article 16.5?												
a)	yes (please give further details below)	24	60	13	93	0	0	1	14	9	75	1	34
	al, at, be, cu, ee, eur, fr, de, hu, ie, it, lv, lt, ml, nl, no, pl, pt, sk, si, es, se, ua, gb,												
b)	no (please give further details below)	16	40	1	7	4	100	6	86	3	25	2	66
	dz, bz, bg, kh, cm, eg, et (There was no such circumstance that required for cooperation), id, ir, jp, mx, md, ro, za, ch, tg,												

Country codes: al (Albania); dz (Algeria); at (Austria); be (Belgium); bz (Belize); bg (Bulgaria); kh (Cambodia); cm (Cameroon); cu (Cuba); dk (Denmark); eg (Egypt); ee (Estonia); et (Ethiopia); eur (European Community); fi (Finland); fr (France); de (Germany); hu (Hungary); id (Indonesia); ir (Iran); ie (Ireland); it (Italy); jp (Japan); lv (Latvia); lt (Lithuania); ml (Mali); mx (Mexico); nl (Netherlands); no (Norway); pe (Peru); pl (Poland); pt (Portugal); md (Moldova); ro (Romania); kn (St Kitts and Nevis); sk (Slovakia); si (slovenia); za (South Africa); es (Spain); se (Sweden); ch (Switzerland); tg (Togo); ua (Ukraine); gb (United Kingdom);

Annex –

RESPONSES TO QUESTION 23 OF THE INTERIM NATIONAL REPORT ON IMPLEMENTATION OF THE CARTAGENA PROTOCOL ON BIOSAFETY

Africa

Cameroon (cm)
For question # 21 (b):“case by case” provision in the law For question # 22 (b): Cameroon was not involved in the activity of article 16 (5) during the reporting period.
Egypt (eg)
Courtesy Translation: Questions 16, 17, 19, 20, 21 The draft national law for regulation of the handling of genetically engineered products includes instruments regulating: 1. The method of risk assessment in cases which the Higher National Committee for Biosafety of the competent national authority decides must be carried out after preliminary examination of the submitted application for handling - the method of cost accounting - the method and authority for carrying out these studies - the charging of the applicant with depositing the cost of this with the competent national authority - the reference laboratories authorized to participate therein - the scope(s) of these studies, the method of their presentation and their role in the taking of a decision about the handling - the method of appealing the decision. 2. The method of managing the probable risks that are consistent with the application and of restoring matters to the condition they were in prior to handling. 3. The methods of monitoring the handling and determining the competent authority or authorities to do this during the period of validity of the handling license, in accordance with the nature of the product and the location or locations of its release. 4. The possibility of amending or withdrawing the license should new information emerge that alters the probable influence of the licensed product on biological diversity and the environment, notifying the licensee of the details of and reasons for the decision and the method of appeal. 5. The regulation of the transit of genetically engineered products through Egyptian territory. 6. The procedures for dealing with the unintended movement of genetically engineered products. The instruments referred to have not yet been put into operation in view of the fact that the law has not been promulgated to date and the fact that no licensing applications have been submitted to the competent national authority. However, these procedures shall be applied in their capacity as elements in the Protocol (which Egypt has ratified and has thereby become national law), should the competent national authority receive relevant applications.
Ethiopia (et)
The National Biosafety regulatory framework has not yet approved and no application received and decisions has been made that relates to risk assessment and management.

Mali (ml)
Courtesy Translation: The National Biosafety Framework has been established but has still not been implemented. A draft decree on genetically modified plants is currently being reviewed by the Government. There is the initiative of the ECOWAS Ministerial Conference on Biosafety and Biotechnology.
South Africa (za)
All applicants (notifiers) are required to conduct risk assessments at their own cost and submit this with any application for contained use, release into the environment or food, feed and processing. This information is reviewed through an extensive process before authorization is approved.
Togo (tg)
Courtesy Translation: The Protocol has not yet been implemented. Nevertheless, the draft bill and the decrees concerning biosafety mandate the Competent National Authority to develop risk assessment mechanisms which promote collaboration among competent government bodies on the national level, collaboration among neighbouring countries as well as support of exterior partners. Specific or combined measures are to be adopted in the process of developing GMOs or their products in regard to their different risk levels and life-cycle phases. The notifier/applicant should proceed with, or have proceed with, the biotechnological risk assessment. The risks targeted concern human and animal health, biological diversity, the socio-economic fibre and cultural values.

Asia and the Pacific

Indonesia (id)
Based on the existing regulation, the proponent applying for the introduction of a GEP has to submit a written application for the biosafety and/or food safety assessment to the NCA. After receiving the application, the abovementioned official requests the considerations on the technical aspects of biosafety and/or food safety from the Biosafety Committee (BC). The BC examines the application for its completion, and if necessary corresponds with the proponent to complete the applications. After getting all of the complete information needed, the BC asks the Biosafety Technical Team (BTT) to carry out an appropriate technical study (risk assessment and risk management). The BTT is obligated to submit a report on the result of the risk assessment and risk management study to the BC. On the basis of the report on the risk assessment and risk management results, the BC submits its suggestions, considerations or recommendations to the responsible minister who will issue the permit. In the case that the GEP has once been utilized in Indonesia, the BC will provide the responsible Minister its suggestions, consideration or recommendation about the case The obstacles : It has not been decided yet which institution will be responsible for budgeting the mechanism.

there was no indication about timeframe and public notice for participation

Iran (Islamic Republic of) (ir)

No cooperation was requested under article 16.5 to Iran.

Japan (jp)

Under the domestic law for the implementation of the Protocol, persons who wish to use new LMOs in the environment (developers and importers, etc.) must carry out a prior risk assessment of adverse effect on biological diversity in accordance with the Guidance of Implementation of Assessment of Adverse effect on Biological Diversity. The competent ministers may grant approval when recognizing, taking account of the content of consultation with experts, that no adverse effect on biological diversity could arise. Persons who wish to export LMOs to Japan from a foreign country and to make them used in Japanese environment, may appoint a Domestic Manager who has an address in Japan and obtain such approval.

Latin America and the Caribbean (GRULAC)

Belize (bz)

The Government of Belize has a temporary moratorium on any imports of LMOs/GMOs until the National Biosafety Framework is fully established. This includes the establishment of legal, administrative and risk assessment that will be needed.

Cuba (cu)

Courtesy Translation:
In 2000, the National Authority established the procedures for granting biosafety authorizations linked to the development, use, handling and transboundary movement of LMOs, through Resolution 76/00 of CITMA: Regulation respecting biosafety authorizations. The Resolution stipulates that the applicant must present to the National Authority a technical file including the elements required to carry out the risk assessment and the proposed measures to manage the risks involved in the activity to be carried out, as part of the risk analysis process, and for the purpose of preventing adverse effects. These measures are analysed by the National Authority's experts and, if necessary, new measures are imposed according to the conditions in effect under the Biosafety authorizations. Risk management measures are monitored through inspections carried out by the Regulating Body and the territorial Biosafety specialists before, during and after the activity is carried out.
In order to deal with the particular case of LMOs within the system of authorizations, a methodology was developed to assess and manage risks for their confined use and release. The methodology contains specific guidelines to be used as a basis for risk assessment of the various types of LMOs: plants, aquatic and non-aquatic animals and microorganisms. The methodology contains guidance regarding internationally recognized techniques that can be used to identify the dangers represented by LMOs, and develops the necessary checklists.
With respect to risk management, the methodology sets out in detail the measures that can be used to prevent adverse effects for the different types of LMOs and according to the type of activity carried out. As part of the risk management aspect, the National Authority is currently developing a methodology for tracking and monitoring the adverse effects of LMOs.
The case of involuntary transboundary movements of LMOs is difficult, since our country is an island. Nevertheless, the risk assessment process contemplates the necessary measures to prevent this type of movement, based on which, the National Authority is setting up appropriate contention measures, fundamentally for aquatic organisms, as well as

measures for emergencies, which must be established to deal with potential leaks that would imply transboundary movement.

Mexico (mx)

One of the more decisive obstacles is the lack of information to conduct the best possible risk assessments and analyses; since the interested parties are not always willing to provide all of the information.

In answer to Question 16:

Risk assessments prior to the Biosafety Law (BL) were conducted according to the provisions of NOM 056-FITO 1995. The published text of the Biosafety Law (DOF 18 March 2005) stipulates that imports of GMOs are subject to the phytosanitary or aquatic regime established in the corresponding legislation. However, the BL (Federal Law that deals specifically with biosafety) determines that, for imports, the importer must provide the following annexes to his application:

- A characterization of the GMO, taking into consideration the stipulations of the Official Mexican Standards derived from the Law in each case.
- An identification of the area where the GMO is intended to be released experimentally, including the specific surface area over which the release will take place;
- A study of the possible risks that the release of the GMOs could represent for the environment and biological diversity.

For cases that fall under the jurisdiction of SEMARNAT (Ministry of the Environment and Natural Resources), it has the following powers with respect to activities involving all GMOs, except for those that fall under the authority of SAGARPA (Ministry of Agriculture, Livestock Raising, Rural Development, Fisheries and Food):

I- To participate in the drafting and implementation of the general biosafety policy;

II - To analyse and evaluate, on a case-by-case basis, the possible risks that activities involving GMOs could create for the environment and biological diversity, based on the risk analyses and reports on findings drafted and submitted by the interested parties, as set out in the present Law;

III - To decide on and issue permits for activities to release GMOs into the environment, and to establish and follow up on the conditions and measures to which such activities should be subject, in accordance with the provisions of the present order, including the release of GMOs for bioremediation.

IV - To monitor the potential effects of the permitted or accidental release of GMOs on the environment and biological diversity, according to the provisions of the present Law and the Official Mexican Standards arising therefrom.

V - To participate in the drafting and issuing of the lists referred to in this Law.

VI - To suspend the effects of permits, based on scientific and technical information from which it can be deduced that the permitted activity implies greater risks than foreseen, and could have a potentially negative effect on the environment, biological diversity, human health, or animal, plant or aquatic health. In the last two cases, suspension is at the request of SAGARPA or SSA, according to their authority under the present Law, based on technical and scientific elements.

VII - Order and apply the relevant safety or emergency measures, based on scientific and technical information and the precautionary approach, according to the terms of the present Law.

VIII - To inspect and watch over compliance with the present Law, its regulations and the Official Mexican Standards arising therefrom.

IX - To impose administrative sanctions on those who violate the precepts of the present Law, its regulations and derived Official Mexican Standards, without prejudice, as the case may be, to the corresponding sentences in the event that their acts or omissions constituting infractions of the present order also constitute crimes, nor to the civil and environmental liability that could result, and

X - To exercise all other powers attributed by the present Law (Article 11, LBGMOs)

SAGARPA has the authority to exercise the powers attributed by the present Law in the following cases of activities involving GMOs:

I - Plants that are considered to be agricultural species, including seeds, and any other organism or product considered within the scope of application of the Federal Phytosanitary Law, except for the wild and forest species regulated by the Wildlife Law and the Sustainable Forest Development Law, respectively, and those covered by a protection regime under Official Mexican Standards arising from those laws;

II - Animals that are considered to be livestock species, and any other type of animal included within the scope of application of the Federal Law on Animal Health, except for wild species regulated by the Wildlife Law and those covered by a protection regime under Official Mexican Standards arising from those laws;

Phytozoosanitary and animal and plant feed inputs;

III - Fish and aquatic species, except for those covered by a protection regime under Official Mexican Standards;
IV - GMOs used for immunization purposes to protect and avoid the dissemination of animal diseases;
GMOs that are fungus, bacteria, protozoa, viruses, viroids, espiroplasm, phytoplasm and other microorganisms that are used for agricultural, fishing, aquatic or phytosanitary production purposes, and;
V - The other organisms and products determined by the regulation of the present Law (Article 12, LBGMOs)
In the cases set out in the article above, it falls to SAGARPA to exercise the following powers:
I - To participate in the drafting and implementation of the general biosafety policy;
II - To analyse and evaluate, on a case-by-case basis, the possible risks that activities involving GMOs could create for animal, plant and aquatic health, as well as for the environment and biological diversity, based on the risk analyses and reports on findings drafted and submitted by the interested parties, as set out in the present Law;
III - To decide on and issue permits to carry out activities involving GMOs, and to establish and follow up on the conditions and measures to which such activities should be subject, in accordance with the provisions of the present order;
IV - To monitor the potential effects of the permitted or accidental release of GMOs on animal, plant and aquatic health, and on the environment and biological diversity, according to the provisions of the present Law and the Official Mexican Standards arising therefrom.
V - To participate in the drafting and issuing of the lists referred to in this Law.
VI - To suspend the effects of permits, based on newly arising scientific and technical information from which it can be deduced that the permitted activity implies greater risks than foreseen, which could have a potentially negative effect on animal, plant or aquatic health, biological diversity, or human health. In the last two cases, suspension is at the request of SEMARNAT or SSA, according to their authority under the present Law, based on technical and scientific elements.
VII - Order and apply the relevant safety or emergency measures, based on scientific and technical information and the precautionary approach, according to the terms of the present Law.
VIII - To inspect and watch over compliance with the present Law, its regulations and the Official Mexican Standards arising therefrom.
IX - To impose administrative sanctions on those who violate the precepts of the present Law, its regulations and derived Official Mexican Standards, without prejudice, as the case may be, to the corresponding sentences in the event that their acts or omissions constituting infractions of the present order also constitute crimes, nor to the civil and environmental liability that could result, and
X - To exercise all other powers attributed by the present Law (Article 13, LBGMOs)
In cases where SEMARNAT is informed of and asked to process and decide upon a permit application involving wild and forest species, it must send the file in question to SAGARPA so that it may issue the appropriate decision (Article 14, LBGMOs).
In cases that are under SAGARPA's authority, SEMARNAT shall do the following:
I - Issue the appropriate biosafety ruling, before SAGARPA makes its decision, as a result of its analysis and risk assessment based on the study drafted and presented by the interested parties, on the possible risks that the activity involving GMOs could cause for the environment and biological diversity, in cases where the permit applications are for the release of said organisms, or based on the reports of findings and the information that the interested parties annex to their permit applications for release as part of a pilot program, and for commercial release;
II - Require SAGARPA to suspend the effects of permits issued by that Ministry, based on scientific and technical information from which it can be deduced that the permitted activity implies greater risks than foreseen, which could have a potentially negative effect on the environment and biological diversity, and
III - Exercise the powers established in subparagraphs I, II, III, V, VII and VIII of article 11 of this Law.
The biosafety ruling referred to in subparagraph I of the present article shall be binding, prior to the granting of the permits to be issued by SAGARPA, and shall be handed down according to the terms of article 66 of the present Law (Article 15, LBGMOs).

In answer to Q17

They are asked to carry out a risk analysis. According to Article 60 of the Biosafety Law, the risk assessment is an act of authority.

In answer to Q18

In national cases, our legislation indicates that the risk assessment is the process of case-by-case analysis based on the scientific and technical studies performed by the interested parties, of the potential risks or effects that the experimental release of GMOs into the environment could cause for the environment and biological diversity, as well as animal, plant and aquatic health.

According to the Biosafety Law, the potential risks for human health must be included in the risk analysis performed to obtain authorization for the GMO in question.

The Law indicates that the following guidelines must be followed when conducting the risk analysis and risk assessment:

- They must be conducted on a case-by-case basis in a transparent manner, and be based on scientific principles and the precautionary approach, according to the terms of the present Law, taking into account expert advice;
- They shall be conducted in the relevant areas of specialization;
- The lack of scientific knowledge or consensus shall not necessarily be interpreted as denoting a given degree of risk, of absence of risk, or of the existence of acceptable risk;
- The baseline should be the potential risks created by non-genetically-modified host or parent organisms if they were to be released into that environment;
- The recipient organism, the genetic modification, including genetic makeup and method of insertion, and the environment into which the GMO is intended to be released must all be taken into account, and
- The nature and degree of detail of the information contained therein may vary from one case to the other, depending on the GMO in question, its previous use and probable recipient environment. The Law also sets out the following basic steps for performing the risk analysis and risk assessment, which include: the identification of new characteristics associated with the GMO that could create potential risks to biological diversity; an assessment of whether these potential risks will actually occur, taking into account the degree and type of exposure to the GMO; an assessment of the consequences if the potential risks were to actually occur; an estimate of the potential overall risk represented by the GMO, based on an assessment of the probability that the potential risks and identified consequences will actually occur, and a recommendation as to whether or not the potential risks are acceptable or can be handled, including the definition of strategies to handle those potential risks.
- In the event of uncertainty with regard to the degree of potential risk that the GMO could create for biological diversity, the Federal Regulatory Departments (SAGARPA and SEMARNAT) shall request additional information on concrete points of the analysis, or shall adopt appropriate strategies to handle the risk and/or monitor the GMO in the recipient environment.
- In the event of danger of severe or irreversible damage, uncertainty as to the degree of the potential risks caused by the GMOs to biological diversity or human health shall not be used as a reason for the corresponding Ministry to postpone the adoption of effective measures to prevent a negative impact on biological diversity or human health. In adopting such measures, the corresponding Ministry shall take into account: existing scientific evidence that can be used as an argument or criterion for establishing the measure; the administrative procedures established in the present Law; and trade regulations contained in the international treaties and agreements to which Mexico is a party.

Furthermore, the interested party may present, as a complement to the potential risk analysis, other analyses or considerations that examine: the GMO's contribution to solving environmental, social, production or other problems; the socioeconomic considerations linked to releasing GMOs into the environment; and an assessment of the risks of alternative technological options to deal with the specific matter for which the GMO was designed. These analyses must be supported by scientific and technical evidence, and on precedents of use, production and consumption, and may be considered by the competent authorities as additional elements for making a decision regarding experimental release into the environment, and subsequent release into the environment in the context of pilot programs and commercial release, respectively, of the GMO in question.

Finally, the Biosafety Law stipulates that the characteristics and requirements of analyses for the assessment of potential risks shall be set out in the Official Mexican Standards arising from the present Law, which are legal instruments that regulate the activities of citizens and are subject to amendment every five years, or whenever the enabling authority deems its improvement to be necessary.

Q19

The Biosafety Law indicates, in several of its provisions, that the Ministries (SAGARPA, SEMARNAT, HEALTH), within the scope of their authority under that Law, shall order one or more of the measures contained therein, should the following occur in the course of activities involving GMOs:

I. Originally unforeseen risks arise, which could cause damages or significant adverse effects for human health or biological diversity or animal, plant or aquatic health;

II. There are damages or significant adverse effects for human health or biological diversity, or animal, plant or aquatic health, or

III. GMOs for which there is no permit and/or which are unauthorized are accidentally released into the environment.

In those cases, measures may include the following:

A. Temporary, partial or total closure of the locations and/or facilities where the GMOs are handled or stored, or where the activities generating the circumstances that give rise to the measure take place;

B. Insuring, on a precautionary basis, the GMOs, as well as the goods, vehicles, tools and equipment directly linked to the act or omission giving rise to measure;

C. The temporary, partial or total suspension of the activity motivating the measure;

D. Repatriating GMOs to their country of origin;

E. Taking the necessary actions and measures to stop the circumstances motivating the measure, and

F. Destroying the GMOs in question, at the interested party's expense, for which the following shall apply:

- This shall only take place if the risks or damages are severe or irreparable, and only if imposing this measure is the only possible means of preventing, lessening or mitigating the risks or damages that gave rise to the measure;
- In order to decree the measure, the competent authority must hand down a ruling, with scientific and technical proof, that justifies the destruction of the GMO in question. It must bring the ruling to the attention of the interested party so that said party may, within five days, avail itself of its rights and, if applicable, present any proof which it may hold, and
- While the competent authority is handing down the appropriate resolution, it may order, prior to the resolution, precautionary insurance of the GMOs, which may be carried out by the Ministry itself, or through the interested party.

Furthermore, the competent Ministry imposing the measures mentioned in the Law may apply to the other competent Ministries to enforce one or more of the measures established in other existing orders within the National Legal Framework.

When the competent Ministries order one of the above-mentioned measures, they shall indicate to the interested party the actions that must be carried out to rectify the irregularities that motivated said measures, as well as the timeframe for performing those actions, so that, upon fulfillment, an order can be issued to withdraw the imposed measures.

Should the interested party refuse to carry out the actions to rectify the irregularities that motivated the imposition of the measure or measures in question, the Ministry that has imposed the measures shall carry them out immediately, entirely at the expense of the unwilling interested party.

In the event that the interested party carries out the safety or emergency measures, or rectifies the irregularities caused, before the competent Ministry imposes one or more of the sanctions contemplated by the present Law, said Ministry must consider this to be an extenuating circumstance of the infraction committed.

In answer to Q20

Not practically speaking, but, in the Law: with regard to this point, the biosafety legislation stipulates, in article 115, subparagraph III, that when non-permitted and/or unauthorized GMOs are accidentally released into the atmosphere, measures like the following may be applied:

A. Temporary, partial or total closure of the locations and/or facilities where the GMOs are handled or stored, or where the activities generating the circumstances that give rise to the measure take place;

B. Insuring, on a precautionary basis, the GMOs, as well as the goods, vehicles, tools and equipment directly linked to the act or omission giving rise to measure;

C. The temporary, partial or total suspension of the activity motivating the measure;

D. Repatriating GMOs to their country of origin;

E. Taking the necessary actions and measures to stop the circumstances motivating the measure, and

F. Destroying the GMOs in question, at the interested party's expense, for which the following shall apply:

- This shall only take place if the risks or damages are severe or irreparable, and only if enforcing this measure is the only possible means of preventing, lessening or mitigating the risks or damages that gave rise to the measure. In order to decree the measure, the competent authority must hand down a ruling, with scientific and technical proof, that justifies the destruction of the GMO in question. It must bring the ruling to the attention of the interested party so that said party may, within five days, avail itself of its rights and, if applicable, present any proof which it may hold. While the competent authority is handing down the appropriate resolution, it may order, prior to the resolution, precautionary insurance of the GMOs, which may be carried out by the Ministry itself, or through the interested party.

Peru (pe)

Not applicable yet.

Saint Kitts and Nevis (kn)

St. Kitts and Nevis have not yet completed its Biosafety Framework Project and as a result have not done any work on risk assessment in relation to Biosafety.

Central and Eastern Europe

Albania (al)

During the reporting period Albania has not imported or produced LMO. Albania has been cooperated with UNEP/GEF on the project of Development of National Biosafety Framework.

Bulgaria (bg)

At the moment no special mechanisms for regulation, management and control of the risks, identified in the risk assessment exist, besides those, provided by the Bulgarian GMO Act. According to those provisions each exporter must enclose to the risk assessment the proposed methods for safe handling, storage, transport and use, including packaging, labeling, record keeping, destruction and emergency procedures. Also if a risk for the human health or the environment is identified, there are procedures for temporary limitation or prohibition of the use or marketing of the GMO, object to the risk assessment.
The observation of the described measures prevents the unintentional transboundary movements. Anyway, if such occur and are identified the advanced informed agreement procedure of the Protocol applies, as stipulated by the Bulgarian GMO Act.

Estonia (ee)

Estonia has a system of risk assessment dealing with releases into the environment or placing on the market of GMOs, whether imported into or developed within the EC, according to the existing EC legislation. The risk assessment is performed on a case by case basis, aiming to identify and evaluate potential adverse effects of the GMO on human health and the environment.
Estonia established a Committee on Gene Technology, which is a scientific advisory body that evaluates the potential risk of an LMO in order to work out a scientifically acceptable

and socially balanced decision for the authorisation of genetically modified organisms.
EU Member States cooperate for the purposes laid down in Articles 15 and 16 of the Cartagena Protocol on Biosafety.

Hungary (hu)

Hungary has put in place a comprehensive system of risk assessment and risk management dealing with releases into the environment or placing on the market of GMOs, whether imported into or developed within the EC, according to the existing EC legislation. The aim of the environmental risk assessment is, on a case by case basis, to identify and evaluate potential adverse effects of the GMO, either direct or indirect, immediate or delayed, on human health and the environment (See Report of the Commission on Implementation of the Cartagena Protocol on Biosafety by the European Community).
Hungary established a Scientific Advisory Body which evaluates the risk may be posed by an LMO in order to promote the scientific based decision of the authorities on the authorization of genetically modified organisms.
EC Member States cooperate for the purposes laid down in Articles 15 and 16 of the Cartagena Protocol on Biosafety.

Latvia (lv)

Procedure for risk assessment is set in accordance with EU provisions. The main responsibility for risk assessment relies to the experts of Monitoring Council of GMOs and Novel Foods. Having regard that no one application with respect to deliberate release or placing on the market of GMO as well as import of LMOs has been submitted to Council, the experts activities are limited to assessment of report made by other Competent Authorities or EFSA within the provisions set by EU regulatory framework.

Lithuania (lt)

Lithuania has put in place a comprehensive system of risk assessment and risk management dealing with releases into the environment or placing on the market of GMOs.
A specific risk assessment is carried out under the Order on Regulation of Risk Assessment on GMOs (adopted by agreement: the Minister of Environment, the Minister of Health, the Minister of Agriculture and the Director of State Food and Veterinary Service; came into force on 31/12/2002) which has transposed the requirements laid down in the European Union Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, and supporting documents (Commission Decision 2002/623/EC; Council Decision 2002/811/EC; Council Decision 2002/812/EC) and approximated according to the requirements of the Cartagena Protocol on Biosafety.
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, environment and agriculture. Environmental risk assessment in Lithuania is to be carried out in accordance with the precautionary principle. The order applies to all natural and legal persons, releasing into the environment or placing on the market GMOs or GMPs in the territory of the Republic of Lithuania.
The Ministry of Environment, upon receipt of the application and request for the deliberate release into the environment or placing on the market GMOs or GMPs, without delay, but no later than 10 days forwards it to the GMOs Steering Committee and the GMOs Experts Committee requesting them to submit possible risk assessment posed by GMOs and GMPs to human health, environment and agriculture, and preliminary findings. The GMOs Experts Committee is a consultative advisory body with a clear task to act as an advisor to the competent authority in carrying out risk assessment, thus advising the GMOs Steering Committee in relation to risk assessment and risk management posed to the environment, agriculture and human health by GMOs and GMPs.
The Order on Regulation for Preparation of Monitoring Plan of GMOs after the Placing on the Market adopted by the order of the Minister of Environment in December 2003. The order was drafted according the requirements of the European Union Directive 2001/18/EC on the deliberate release into the environment, and the provisions of the European Union Decision 2002/811/EC. The general aim of the order is to lay down and regulate the process for preparation of general monitoring strategy, program, data analysis, and subsequent reporting. Notifier before preparation of the monitoring plan has to develop general surveillance strategy. During the preparatory process, notifier has to evaluate several factors,

among others: probability of direct, indirect, immediate or delayed impact by GMOs, possible unintended effects, GMPs characteristics according to the intended usage and receiving environment. The main goal of the monitoring is to protect biological diversity, soil functionality, surface and ground waters, sustainable/organic farming, the quality of agriculture products, plant and animals, human health from possible negative influence. The specific aim is focused on defining whether assumptions and findings during the conduction of risk assessment for human health and environment have proven; to determine unintended negative impacts for environment and human health, not evaluated during the environmental risk assessment.
Lithuania plans to establish the national mechanisms for monitoring of environmental effects and enforcement control and inspection (by 2007). The Ministry of Environment has prepared draft of National Environmental Monitoring Program (NEMP) of plant, animals, soil and water GMOs monitoring since 2007. In new NEMP the 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.
Lithuania, as the European Union Member State, considers common European Union criteria concerning GMOs and GMPs risk assessment and risk management. (See Report of the Commission on Implementation of the Cartagena Protocol on Biosafety by the European Community).
No obstacles and impediments have been encountered.

Poland (pl)

Poland has built complex system involving risk assessment for human health and environment, taking into consideration the contained use of GMO, the deliberate release into the environment of GMO and the placing on the market of GMOs as well as products containing or consisting of GMOs. Such necessary results from regulations in section 6 and 7 of the Act of 22 June 2001 on Genetically Modified Organisms (Official Journal No. 76, Item 811; 2002, No. 25, Item 253, and No. 41, Item 365) and the regulation of the Ministry of the Environment of 8 July 2002 laying down the detailed manner of carrying out the assessment of risks to human health and the environment related to the undertaking of activities involving the contained use of GMOs, the deliberate release of GMOs into the environment, including the placing of GMO products on the market, and the requirements which should be satisfied by the documentation containing the results of such an assessment (Official Journal of 16 July 2002), pursuant to Article 6(4) of the Act on Genetically Modified Organisms of 22 June 2001.
Risk assessment shall be based on:
- potential adverse effects (direct effects of GMOs, the indirect effects of GMOs, the immediate effects, the delayed effects of exposure),
- possible harmful effects related to the recipient organism,
- possible harmful effects related to the donor organism,
- possible harmful effects related to GMO,
- possible harmful effects (human contagious diseases as well as allergic symptoms and toxic effects, diseases caused in animals and plants, including their toxicity and - where they may arise - allergic symptoms, the effects on the population of organisms present in a given environment and their genetic diversity, change in vulnerability to pathogens which facilitate the dissemination of contagious diseases or the establishment of new foci of diseases or vectors,
a reduction in the effectiveness of prophylactic or therapeutic measures applied in the medical and veterinary fields as well as in plant breeding and protection, caused, inter alia, by transfer of genes conferring resistance to antibiotics used in the therapy of humans and animals, the potential for uncontrolled spread of GMOs to the areas of crops cultivated by organic methods , the spread of GMOs in the environment, the transfer of the genetic material introduced to other organisms or specimens of the same species),
- the waste related issues.
The contained use of GMOs shall require consent from the Minister of the Environment. All requirements are included in the regulation of the Ministry of the Environment of 6 June 2002 laying down the formats of application forms for consent and authorization of activities involving genetically modified organisms(Official Journal of 27 June 2002) pursuant to Article 22 of the Act on Genetically Modified Organisms of 22 June 2001 (Official Journal No. 76, Item 811; 2002, No. 25, Item 253, and No. 41, Item 365).

The contained use of GMO must be conducted taking into consideration the regulation of the Ministry of the Environment on 29 November 2002 laying down the list of pathogenic organisms and their classification, as well as the measures required for particular containment levels (Official Journal 02.212.1798 on 16 December 2002, pursuant to Article 13 of the Act on Genetically Modified Organisms of June 22 2001).
The polish regulations have been laid down on the basis of the legally binding EC regulations, such as:
- Directive 2001/18/EC of 12 March 2001 on the deliberate release into the environment of genetically modified organisms, covering the field testing of GMOs (mainly Part B) and the placing on the market of GMOs as well as products containing or consisting of GMOs, e.g. for cultivation, import or processing into industrial products (mainly Part C),
- 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,
- 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,
- Council Decision (2002/812/EC) of 3 October 2002 establishing pursuant to Directive 2001/18/EC the summary information format relating to the placing on the market of genetically modified organisms as or in products.
Users conducting the deliberate release into the environment of genetically modified organisms are obliged to prepare the monitoring plan. In a such plan must be taken into consideration characteristics and use of GMO, environment conditions and long enough period, that will enable detection of all potential adverse effects of the GMO identified in the risk assessment for human health and environment. The objective of such plan is to confirm that any assumption regarding the occurrence and impact of or its use are correct, and to identify the occurrence of adverse effects of the GMO.
The release of the GMO must be still under surveillance and all observations should be regular recorded during entire period of the release. Every year at least for two years after the end of deliberate release the GMO user is obliged to keep monitoring of his experimental fields to prove a lack of presence of transgenic plants in the environment. Moreover the GMO user is obliged to make such records accessible immediately upon request of the Minister of the Environment and other competent authorities.
There no obstacles or impediments have been encountered.

Republic of Moldova (md)

Courtesy Translation:
According to the Act on Biological Safety, the risk assessment must be carried out according to scientific principles and transparency and using the appropriate risk assessment methods. The goal of the assessment is to find and determine any negative effects of the genetically modified organisms and/or the products derived therefrom on people’s health or on the environment.
The National Commission decides which qualified public bodies or scientific institutions will carry out the risk assessment.
The National Commission must ascertain that a risk assessment has been made on the basis of which a decision may be made.
The National Commission is responsible to see that the risk assessment relating to micro-organisms and, in some cases, to other genetically modified organisms, is carried out in contained facilities.
The financial burden of the risk assessment is borne by the applicant.
Regulations concerning the issuance of a license for any type of activity related to the testing, manufacture, utilization and creation of genetically modified organisms provides for the submission of detailed information.
The risk assessment report regarding the import of genetically modified organisms and/or products derived therefrom (the purpose and the function of the report, basic principles, risk assessment methodology, questions to be considered).
Principles guiding the implementation of testing the risk assessment on the environment (purpose, main guidelines, methodology, and conclusions of the risk assessment).

Romania (ro)
A specific risk assessment is mandatory as a part of the notification dossier and is carried out according to the requirements of the Law 214/2002 which is transposing the provisions of the European Union Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. Its aim is, on a case by case basis, to identify and evaluate potential adverse effects of the GMO, either direct or indirect, immediate or delayed, on human health and the environment. The risk assessment report is presented by the notifier, in concordance with Annexes 12 and 121 of the Law 214/2002, which are complying with provisions of Annex III of the Protocol. In the decision- making process, MEWM consults the Biosafety Commission, as scientific body in risk evaluation.
Slovenia (si)
All activities within the biosafety framework of the Protocol and intended for deliberate release into the environment in Slovenia are subject to prior risk assessment and management. This assessment conducted on the “case by case” basis of scientific aspects in accordance with the procedures established in Community and domestic legislation, is carried out in the first place by the notifier and then evaluated according to the scientific subject by the Scientific Committee for contained use or Scientific Committee for deliberate release of GMO’s into environment and placing on the market, which are two national scientific advisory technical bodies in order to provide professional assistance to ministries responsible for deciding on GMO’s management. Since Slovenia become a member of European Union it cooperates with other EU countries for the purposes specified in Articles 15 and 16 of the Protocol.
Ukraine (ua)
Courtesy Translation: At the present time, we are only defining the means of developing the appropriate mechanisms, measures and strategies for regulating, reducing and controlling the risks when LMOs are used. Work has started on creating a centre for tracing LMOs. Meeting these requirements is being held up by the absence of a special law on the biosafety of LMOs.

Western European and Others (WEOG)

Austria (at)
Austria has objected to nearly all applications of marketing or cultivating genetically modified plants as the undertaken environmental and health risk assessments seem incomplete so far. For those reasons Austria has also maintained national safeguard measures for the time being. The basis for risk assessment and risk management lies within our national legislation (see above). We have established an Advisory Board and a scientific subcommittee for deliberate release and placing on the market. We have ongoing co-operation within the EU on the questions raised above.

European Community (eur)
The EC has put in place a comprehensive system of risk assessment and risk management dealing with releases into the environment or placing on the market of GMOs, whether imported into or developed within the EC. The aim of the environmental risk assessment is, on a case by case basis, to identify and evaluate potential adverse effects of the GMO, either direct and indirect, immediate or delayed, on human health and the environment. Risk assessment is conducted with a view to identifying if there is a need for risk management. Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms establishes in Annex II principles for the environmental risk assessment, in Annex VI guidelines for the assessment reports and in Annex VII guidelines for the monitoring plan to be applied in cases where consent has been given to the placing on the market of GMOs. Several supporting documents specify provisions contained in the Directive: Commission Decision 2002/623/EC of 24 July 2002 establishes guidance notes on the objective, elements, general principles and methodology of the environmental risk assessment referred to in Annex II to Directive 2001/18/EC. Council Decision 2002/811/EC of 3 October 2002 establishes guidance notes supplementing Annex VII to the Directive, describing the objectives and general principles to be followed to design the monitoring plan. Council Decision 2002/812/EC of 3 October 2002 establishes the summary information format. The EU Scientific Steering Committee published in March 2003 the 'Guidance Document for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed', which was replaced by the updated 'Guidance Document of the Scientific Panel on Genetically Modified Organisms for the Risk Assessment of Genetically Modified Plants and Derived Food and Feed', published by the European Food Safety Authority in November 2004. Environmental risk assessment in the EC is to be carried out in accordance with the precautionary principle and is based on the following principles: GMO characteristics and GMO use that have the potential to cause adverse effects are to be compared to characteristics and use of the non-modified organism from which the GMO is derived; Risk assessment should be carried out in a scientifically sound and transparent manner based on available scientific and technical data; Risk assessment should be carried out on a case by case basis; New information on the GMO and its effects may need to be readdressed in order to determine whether the risk has changed and whether there is a need for amending the risk management accordingly. Article 4 of Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms demands that any person submitting a notification under the authorisation procedures for GMO releases into the environment or placing on the market of GMOs as or in products needs to carry out an environmental risk assessment. Annex III of the Directive specifies the information that may be necessary to carry out the risk assessment. The environmental risk assessment comprises several steps that need to be addressed: Identification of characteristics which may cause adverse effects. These characteristics will vary from case to case and may include direct effects on human health or the environment as well as indirect effects occurring through a causal chain of events, through interactions with other organisms, transfer of genetic material or changes in use or management. As observations of indirect effects are likely to be delayed, immediate effects during the period of the release of the GMO as well as delayed effects that become apparent at a later stage or after termination of the release need to be considered. Evaluation of the potential consequences of each adverse effect, if it occurs. Evaluation of the likelihood of the occurrence of each identified potential adverse effect. Estimation of the risk posed by each identified characteristic of the GMO. Application of management strategies for risks from the deliberate release or marketing of GMOs. Determination of the overall risk of the GMO.

Annex VII of the above Directive provides guidance on the monitoring plan as part of the risk management strategy. More specific guidance notes are provided in Council Decision 2002/811/EC of 3 October 2002. The objective of the monitoring plan is to confirm that any assumption regarding the occurrence and impact of potential adverse effects of the GMO or its use in the risk assessment are correct, and to identify the occurrence of adverse effects of the GMO or its use which were not identified in the risk assessment.
The design of the monitoring plan should, among others:
Be detailed on a case by case basis;
Take into account the characteristics of the GMO, its use and scale of use, and the range of relevant environmental conditions;
Incorporate general surveillance for unanticipated adverse effects;
Provide for case-specific monitoring for a sufficient time period to detect immediate and direct as well as, where appropriate, delayed and indirect effects which have been identified in risk assessment.;
Provide for the use of already established routine surveillance practices where appropriate.
At last, it may be interesting to know that the EC has cooperated with members of the European Economic Area (Norway, Iceland and Liechtenstein) on the issue of antibiotic resistance markers in risk assessment.

Finland (fi)

All activities within the framework of the Protocol and intended for release into the environment or placing on the market of GMOs in Finland are subject to the prior risk assessment and management. Comprehensive risk assessment is conducted in accordance with the procedures established in the Community and domestic legislation with a view to identify if there is a need for risk management. The risk assessment is carried out by the notifier and evaluated by the competent authority in Finland, which can consult relevant scientific expert institutions on a case-by-case basis.
Finland has cooperated with the EU member states for the purposes specified in Articles 15 and 16.

France (fr)

Cf. rapport de la CE.
Les évaluations de risque sont d'abord conduites par les entreprises notifiantes. En France, elles sont alors étudiées et évaluées par la Commission du génie biomoléculaire.
(Please see EC report
- Risk assessments are first carried out by notifiers. In France, they are then studied and evaluated by the Commission du Génie Biomoléculaire)

Germany (de)

The competent German authorities conduct necessary risk assessements on the basis of the relevant EU legislation. For an outline of the EU procedure please see the reply of the EU.

Ireland (ie)

Ireland cooperates with our EU partners within the framework of Community legislation in relation to the matters specified in Articles 15 and 16 of the Protocol.

Italy (it)

A general overview of the mechanisms for the risk assessment and risk management in the EU is provided by the interim Report of the EC. As EU Member State, Italy participates

to the LMOs risk assessment and risk management procedures established in the Community for the placing in the market of such products.
For the experimental release of LMOs, Italy has a national procedure according to Dir. 2001/18/EC. The procedure includes a risk assessment by the National Interministerial Advisory Committee (Commissione Interministeriale di Valutazione). The Committee must take in consideration the opinion of the public, which is informed though the Italian node of the Biosafety Clearing House. A decision on the request for experimental release of LMOs is taken by the National Competent Authority, based on the opinion of the Advisory Committee.

Netherlands (nl)

From the earliest discussions on LMO (GMO) risk assessment strategies till the present, the Netherlands has very actively contributed to the work undertaken by the OECD on risk assessment and risk management.
Although the Netherlands has not yet had to perform LMO risk assessments under the requirements of the Protocol, it has ample experience with the risk assessment procedures required, as these are very similar to the risk assessment performed for deliberate release and placing on the market under EU legislation.

Norway (no)

Further details q.18: Norway did not take a decision regarding article 10 during the reporting period.
Further details q. 20: The Norwegian Food Safety Authority collects samples from imported food, feed and seed which are analysed for content of GMO. The analyses of the samples are carried out by The Norwegian Veterinary Institute which has an extensive cooperation with other European GMO-detection laboratories to develop and validate GMO-detection protocols.
Further details q. 21: The Norwegian Gene technology Act requires that releases of GMO to the environment should take place stepwise in order to be able to detect unforeseen adverse effects on the environment or human health before a full scale release is granted.
Further details q. 22: Norway cooperates with the European Union in a working group under Directive 2001/18/ EC, with the aim of phasing out GMO with antibiotic resistance marker genes that may have adverse effects on human health or the environment.
Directive 2001/18/EC on the deliberate release of GMO calls for a phasing out of antibiotic resistance marker genes which may have adverse effects on human health and the environment. The Scientific Panel on Genetically Modified Organisms under the European Food Safety authority adopted an opinion in April 2004 that one category (category II) of ARMG that are being used in GMO should be restricted to field trial purposes, and that one other category of ARMG should be restricted to contained use only (category III). The opinion is available on
http://www.efsa.eu.int/science/gmo/gmo_opinions/384_en.html
The Norwegian Scientific Committee for Food Safety will deliver “An assessment of potential long-term health effects caused by antibiotic resistance marker genes in GMO based on antibiotic usage and resistance patterns in Norway” ultimo September 2005. According to the preliminary summary the Committee is of the same opinion as EFSA regarding the risk of ARMG in Groups II and III, but expresses somewhat more concern regarding the nptII-gene in Group I. The preliminary summary of the report is enclosed in Annex II. The final report will be made available through the Biosafety Information Resource Center on the Biosafety Clearing House, where further information on horizontal gene transfer can be found.
Further details q. 23: A risk assessment must be carried out by the notifier both for notifications of GMO intended for intentional introduction into the environment and for notifications of GMO intended for direct use as food or feed, or processing, The requirements for the risk assessment are in line with the requirements specified in annex III to the Cartagena Protocol. It should be carried out on a case by case basis, and must be based on the precautionary principle. The Norwegian authorities assesses whether the information in the risk assessment is in line with the national requirements, and ask for further documentation if the information is not sufficient as basis for a decision.
A consent under the Norwegian Gene Technology Act may be granted on condition that the notifier carries out risk management measures such as post market monitoring, isolation

distances and provisions ensuring traceability of the GMO.
Norway is of the opinion that further guidelines supplementing Articles 15, 16 and Annex III on Risk Assessment to the Protocol is necessary for a common approach, which again is important to fulfil the objectives of the Protocol. The work to be carried out by the Ad Hoc Technical Expert Group established by MOP BS-II/9 on identifying the relevance of, and gaps in existing approaches to and guidance material on risk assessment and the need for capacity building activities, will be an important contribution towards the development of necessary further guidelines.
Norway is furthermore of the opinion that the reports on antibiotic resistance marker genes (ARMG) mentioned above clearly indicate that such genes are examples of specific traits covered by Article 16(5). The Parties to the Protocol are obliged to identify such traits and take appropriate measures regarding their treatment.
Norway is therefore in favour of a scientific committee being appointed with the task of providing scientific and technical guidance on risk assessment guidelines, ARMG in GMO and other tasks that might be considered important for the fulfilment of the objectives of the Protocol, such as tasks pursuant to Article 18(3) identified by Norway in the answer to Question 30 of this Report.

Portugal (pt)

Portugal has not been a party of import during the reporting period. But several notifications for placement on the market have been made via the EU application system. EU legislation stipulates that all notification must contain a risk assessment as outlined in EU Dir. 2001/18. This implies an assessment of the LMO on a lifetime basis. Risk assessments are to be evaluated by all member-states.
This assessments conducted on a “case by case” basis in accordance with the procedures laid down in EU and national legislation, are carried out firstly by the notifier and then evaluated by the national scientific advisory technical bodies that support decisions taken by ministries responsible for GMO’s management.
As a EU Member State, Portugal performs risk assessment and risk management following the procedures laid down in the European legal framework concerning placing on the market of LMO.

Spain (es)

All activities within the framework of the Protocol and intended for deliberate release into the environment in Spain are subject to prior risk assessment and management. This assessment, conducted on the basis of scientific aspects in accordance with the procedures established in Community and domestic legislation, is carried out in the first instance by the notifier and then studied and evaluated by the Spanish Biosafety Commission, which is the national scientific-technical advisory body.
Spain has cooperated with other European Union countries for the purposes specified in Articles 15 and 16 of the Protocol.

Sweden (se)

Items 16 ,17, 21 and 22. Sweden has not been a party of import. But several notifications of imports placement on the market have been made via the EU application system. EU legislation stipulates that all notification must contain a risk assessment as outlined in EU Dir. 2001/18. This implies an assessment of the LMO on a lifetime basis. Risk assessments are to be evaluated by all member-states. Risk assessments contained in notifications made under EU Reg. 1829/2003 are evaluated by the European Food Safety Authority and the competent authorities of the member-states
Item 18 The notifier bears the costs of the risk assessment in the notification. In Sweden, the notifier is also responsible for the costs of evaluating the notification and for its processing in the EU legal system, but this is not the case with all member-states. Notifications originating with other member-states will be evaluated by Swedish authorities at no cost.
Item 19. Monitoring is required by EU Dir. 2001/18 and the Swedish Ordinance (SFS 2002:1086) on the Deliberate Release of Genetically Modified Organisms in the

Environment.
Item 20 The Swedish Seed Testing and Certification Institute conducts tests of seed consignments that may possibly contain GMOs. The National Food Administration conducts a programme for investigating the presence of GMOs in foodstuffs.

United Kingdom of Great Britain and Northern Ireland (gb)

The UK implements articles 15 and 16 fully, through the provisions of EC legislation, in particular Directive 2001/18/EC. For details of this legislation, please see EC interim national report.

Other information (Q56)

Western European and Others (WEOG)

Risk assessment

Belgium (be)

Around 2004-2005, the Federal Ministry of Environment has financed a research project ordered by the DG Environment (National Focal Point for the Protocol) to a research team of the Faculty of Agronomy of Gembloux and aimed at establishing a methodology of study on the spacialized potential of hybridization of GMOs cultures with indigeneous flora, with Colza as a case study. Results of that study (that mainly shows lack of available data to make accurate evaluations of such potential of hybridization) should soon be available on the FPS portal.

Risk assessment / subsidiary bodies

Norway (no)

As stated in the answers to questions 23 and 30 above, Norway is in favour of a scientific committee being appointed with the task of providing scientific and technical guidance on risk assessment guidelines, ARMG in GMO and other tasks that might be considered important for the fulfilment of the objectives of the Protocol, such as tasks pursuant to Article 18(3).
The scientific committee should be appointed to fulfil specific tasks, not on a permanent basis. It should receive funding from the core budget and each Party should be entitled to appoint one expert to participate in its meetings. We call upon the Secretariat to make a budget proposal for the establishement of such a committe that could meet annually or biannually as the need may be.
