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Working Group on the Harmonisation of Regulatory Oversight in Biotechnology

ENVIRONMENTAL RISK/SAFETY ASSESSMENT AND USE OF INFORMATION IN SITUATIONS OF LOW LEVEL PRESENCE OF TRANSGENIC PLANT MATERIAL IN SEED AND COMMODITIES - Draft Document

25th Meeting of the Working Group, OECD Headquaters, 9-10 May 2011

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This is a first complete draft of the ”LLP project” of the OECD Working Group on the Harmonization of Regulatory Oversight in Biotechnology. The project deals with environmental risk/safety assessment and use of information in situations of low level presence (LLP) of transgenic plant material in seed and commodities.

The document takes into account the replies to the questionnaire circulated in October 2009, as well as extensive discussions and comments expressed within the Working Group since the launch of the project, including in a dedicated workshop.

The document is being made available to all delegates for discussion at the upcoming 25th meeting of the Working Group (9-10 May 2011), with the intent to agree on the subsequent process for its finalisation.

The Bureau suggests the following process for completion of the document:

- Receipt of written comments from delegations on the current document within a few-week period following the 25th meeting of the Working Group;
- Revision of the document by the Bureau, based upon comments received within the deadline;
- Circulation of the revision (REV1) to all delegates for comment within an 8-week period; and
- Preparation of REV2 by the Bureau based upon comments received, with the intent of reaching agreement for declassification at the 26th meeting of the Working Group in early 2012.

Action required: ***The Working Group is invited to discuss this document [ENV/JM/BIO(2011)6] at the upcoming 25th meeting, decide a deadline for providing written comments soon after the meeting, and agree on a process for finalisation.***

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FOREWARD / PREAMBLE[1]

INTRODUCTION

1. Many countries, including OECD member countries, are or will be importers or exporters of commercial seed, as well as commodities harvested as the result of planting such seed, that may inadvertently contain a low level presence (LLP) of biotechnology derived material that has not been approved by the importing country for use in the environment. It is anticipated that the number of incidents of LLP will continue to increase globally rather than decrease because of an increasing number of biotech derived seed products entering the market, the ever-increasing international movement of seeds and/or commodities and biological factors (*e.g.* inadvertent cross pollination between seed production fields). Often LLP situations exist because of the phenomena of "asynchronous" approvals where permission for commercial planting occurs in one country before it occurs in a second importing country.

2. Participants in the OECD's Working Group on the Harmonization of Regulatory Oversight in Biotechnology (hereafter referred to as the 'Working Group') recognise that the issue of LLP in seed and certain commodities that can function biologically as seed (hereafter referred to as 'LLP'), concerns all countries, including regulators, industry and trade. Many OECD countries have already had experience with LLP in seed and there is value to be gained from sharing and understanding this experience and, in particular, there is benefit in identifying useful environmental risk/safety assessment strategies and the availability of sources of information to address these situations. Information sharing among authorities can be important in LLP situations where an authority addressing an unauthorised incident might need more information.

3. The Working Group has developed technical documents that facilitate environmental risk/safety assessment of transgenic organisms, especially plants. These tools for risk assessors and regulators include science focused documents (on biology and trait), documents that supplement and expand upon the information in the biology and trait documents (*e.g.*, module II on herbicide tolerance; OECD, 2002), and guidance documents (*e.g.*, how to use information from detection technologies for bacteria; OECD,

[1] A foreword and preamble will be inserted at a later date.

2004) and most recently, a document on molecular characterization of transgenic plants (OECD, 2010). In effect, a suite of documents have been developed concerning the review of products of modern biotechnology for various kinds of approvals. Although the Working Group primarily works on the scientific and technical aspects of environmental risk/safety assessment, it is recognised that there are linkages for its work to risk management and trade, among other areas. It has therefore undertaken the task of capturing the experience of the participant countries of the Working Group in addressing these LLP situations in the environment, particularly in regard to the science basis for risk/safety assessment. As an aid to regulators and risk assessors, the experience presented covers the following aspects: a) types of LLP situations that have occurred in OECD participant countries; b) whether and how a determination of risk/safety was done, particularly how familiarity with the plant, trait, environment and their interactions aid in performing the assessment; c) what type of information was used and where was it available; and d) whether and how risk/safety assessment and information influenced risk mitigation, management and related policies. It is important to note that the risk/safety assessments referred to in this document do not lead to an authorisation of the transgenic plant material that is present at a low level. Rather the assessments aim to evaluate the risk/safety of the unauthorised plant material to the environment in the particular situation.

4. Sixteen participant countries (OECD members and non-members) and observers responded to the questionnaire on their experience in addressing LLP: Argentina, Australia, Belgium, Brazil, Canada, Chile, Czech Republic, Japan, Korea, Mexico, Netherlands, New Zealand, Norway, Turkey, United States and the OECD Business Industry Advisory Committee. The questionnaire itself and responses are contained in annexes I and II to this document, respectively. In addition to the questionnaire responses, the information contained in this document was obtained from extensive discussions within the Working Group, including a dedicated workshop that took place in April 2008.

5. Focused on food safety, the Codex Alimentarius has an annex addressing LLP as part of its Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (Codex Alimentarius, 2003). The Working Group discussed the possibility of taking the same approach as the Codex model and linking the discussion of LLP to an existing text on risk/safety assessment. The paradigm for environmental risk/safety assessment has been articulated in the OECD Scale-up document (OECD, 1993) and elsewhere. However, available texts do not address how to do environmental risk/safety assessment per se. Similar to the Codex approach, this document addresses the situation of low level presence of transgenic plant material that has received approval and been commercialised in at least one country but has not received approval (authorisation) in the country of import. Any reference to risk/safety assessment in this document refers solely to environmental risk/safety assessment in keeping with the mandate of the Working Group.

SECTION I – PURPOSE AND SCOPE

6. The purpose of this project is to provide an aid to risk assessors and regulators who may be faced with LLP situations where the plant material has received approval or all of the required reviews for planting and been commercialized in one country but has not received approval in the importing country. In many cases, an LLP situation will necessitate a requirement for expeditious access and retrieval of information to facilitate determination of environmental risk/safety. There are unique types of situations that may arise with LLP and countries either have or are preparing to deal with such situations. Although each LLP incident will likely be handled on a case-by-case basis by each respective country or region, an environmental risk/safety assessment of the LLP situation may support any actions taken to address the situation. Typically, the amount of available data and information in an LLP situation may not meet the standards that are set for environmental risk/safety assessments that are required for full authorisation of the plant material. The type of risk/safety assessment referred to in this document aims at an appraisal of the existing risk to allow commensurate mitigation measures to be taken to address the LLP situation. Such an environmental risk/safety assessment would be performed based upon the existing principles of risk/safety assessment.

7. This document contains a synthesis of current approaches to environmental risk/safety assessment, information access, and information use in addressing LLP situations in which LLP occurs in seed and commodities that can function biologically as seed. The scope covers commercial seed used intentionally for planting as well as commodities (*e.g.* grains and oilseeds) unintentionally released into the environment during handling and transport that can subsequently germinate and grow into plants or may be intentionally used for planting. The term "seed" used in this document refers to commercial seed produced to meet certain quality standards (viability, germination, etc.) for intentional planting while the term "commodities" refers to grain harvested for food, feed or processing. Commodities are not intended to meet seed quality standards, even if grown from such seed.

1.1 Criteria

8. To aid in defining the scope of this project further and to clarify the usefulness of the project, criteria were developed delineating what the project does or does not cover. This project:

- Aligns with the remit of the Working Group, whose terms of reference focus on scientific and technical aspects, specifically on environmental risk/safety assessment;
- Encompasses LLP plant material which has received approval or all of the required reviews for planting in one country but has not received approval in the country of import;
- Relates to LLP in seed including commodities that can function biologically as seed; and
- Facilitates information sharing and risk/safety assessment for an LLP situation.

9. On the other hand the project does not:

- Preclude a national or regional authority from undertaking or not undertaking a risk/safety assessment within the context of its regulatory system;
- Prevent countries from abiding by existing international agreements on the topic of LLP; and
- Address risk management or indicate how regulatory authorities should manage incidents of LLP, make decisions, or define what LLP is legally.

SECTION II – APPROACHES TO INFORMATION ACQUISITION, INFORMATION USE AND ENVIRONMENTAL RISK/SAFETY ASSESSMENT IN LLP SITUATIONS

2.1 National Systems for Risk/Safety Assessment and Dealing with LLP Situations

10. Countries participating in the OECD Working Group have comprehensive regulatory systems for the assessment of risk/safety of transgenic plants. Typically, there are several ministries involved in the evaluation of transgenic crops, with agriculture and environment-based ministries carrying the primary responsibility for evaluating the consequences of environmental release. While some countries have not experienced LLP situations, several have dealt with at least one incident of LLP in the context of the environment, either in seed or commodities. Some countries import both seed and commodities, some countries import commodities or seed primarily; and some countries grow, import, and export both seed and commodities. And, in each of these circumstances the seed or commodity may or may not contain unapproved transgenic plant material. For regulatory authorities in the importing country, an LLP situation in seed or from commodities presents a situation of potential risk to the environment as well as a situation of regulatory non-compliance. Regulatory agencies must take action to address any situation of non-compliance, and the potential risks that it may present. The risk/safety assessment supports the risk management activities commensurate with risk and domestic regulatory frameworks.

11. Usually the ministries that are responsible for overseeing evaluation of applications for unconfined (commercial) release of transgenic plants take a lead role in any risk/safety assessment and are also involved in management of the LLP situation. Since LLP situations vary, other agencies and government offices may be involved in addressing the particular situation. These can include quarantine and inspection services, seed quality, and plant variety protection agencies as well as agencies responsible for environmental management and public affairs. Usually, one ministry will take the lead role in coordination of the management of an LLP situation and which ministry may depend upon the circumstances of the situation, such as the source of the LLP (commodity or seed) or the particular trait involved.

12. Most countries have not developed explicit rules or policies to address LLP situations in the environment. However, a few have published policies and guidelines or elaborated more general strategies to limit the occurrence of unintended presence situations, including LLP situations. These policies and plans serve to communicate government approaches to dealing with potential risk from LLP situations to the public and to clarify responsibilities of various stakeholders including potential industries involved (*e.g*. seed, breeder, trader, transport) in order to limit, as well as prepare for, a potential occurrence of LLP in the environment. For governments generally, however, LLP situations in the environment are situations of non-compliance with statutory and regulatory requirements that must be addressed expeditiously as such. Environmental risk/safety and its assessment are the primary concern, and the focus of this document.

13. Government risk/safety assessment authorities may become aware of an LLP situation through a variety of mechanisms including the following: 1) notification by another country, such as the exporting country, or a regional authority; 2) notification by another government authority in the importing country (*e.g*. seed quality agency); 3) notification by the seed industry, producers, or importers or the owner of the plant material; or 4) as the result of sampling and testing regimes of the government or others (*e.g*., non-governmental organisations).

14. Plant breeding may occasionally result in low-level mixing of genes and gene products from unintended plant sources. This is true for both conventionally bred plants as well as biotechnology-derived plants. LLP may originate from a range of biological or non-biological causes in the seed-producing countries during seed production of transgenic plant varieties, including commercial cultivation of transgenic varieties and handling, harvest, transportation, shipment, etc. for use as seed, and commodities produced from that seed. Cross-pollination and inadequate quality control (*e.g.* mishandling of seed inventory) can result in an unintentional LLP situation in seed. Commodities can have additional sources of unintended mixture of grains in handling, storage and transport situations after harvest. However, it may be impossible to determine the actual initial cause of any particular LLP situation in either seed or commodities.

15. The seed industry has undertaken significant efforts to reduce the incidence of LLP through proactive use of best practice protocols for trait development, breeding, field trials and seed production and testing to affirm purity of products. These protocols include isolation of plantings, machinery and equipment cleaning, roguing, and management of pollination, labelling, inventory, and disposition of material. Even with these precautions, quality control measures undertaken by the seed producer and exporter do not always eliminate unauthorized plant material and testing protocols can give conflicting results at different points in the entire system.

16. LLP situations may be found in seed before planting or after planting in farmer's fields or in some cases after export of a commodity grown from that seed to a third country. Commodities can be a source of LLP in the environment through spillage, transportation accident, and illegal use, etc. Spillage can occur from trains and trucks along tracks and roadsides during transport and in areas around ports where shipments arrive from overseas. In some cases, a commodity may be intentionally (and, in some situations, illegally) planted or used for breeding purposes in the importing country. Other countries may have more experience with LLP situations in the environment that is from a commodity source than from seed.

17. Most of the LLP situations to date have occurred with common crop and trait/gene combinations that have been reviewed by many countries globally. These include corn, cotton, rapeseed/canola and soybean containing herbicide tolerance (glyphosate or glufosinate) and/or insect resistance (Bacillus thuringiensis delta endotoxins). However, the specific events or constructs may or may not be approved for environmental release in each country. Asynchrony of environmental approvals between exporting and importing countries occurs when transgenic plant material is approved in an exporting country for environmental release, but such approval does not exist in an importing country. The following are examples of such situations:

- The plant material is only approved for importation for food use, but is not approved for environmental release (cultivation);
- The plant material is not approved for importation though applications may have been received for food use and possibly for environmental release ;
- No application has been received for importation for food use or for cultivation; or
- The importing country has approved the plant material for environmental release but, where government seed variety certification/registration requirements exist, the material is not fully approved for commercialization or, the certification/registration has expired and the plant material is no longer fully approved.

2.2 Principles of Risk/Safety Assessment

18. While the response by a country to an LLP incident can vary, the general principles for a risk/safety assessment are the same for an LLP incident as they are for a product approved for unconfined release. These are stated in the OECD *Safety Considerations for Biotechnology: Scale-up of Crop Plants* (OECD, 1993). This document describes risk analysis[2] as being "based upon the characteristics of the organism, the introduced trait, the environment into which the organism is introduced, the interactions between these, and the intended application. Knowledge of and experience with any or all of these provides familiarity which plays an important role in risk/safety analysis […] Familiarity is not synonymous with safety; rather, it means having enough information to be able to judge the safety of the introduction or to indicate ways of handling the risks. A relatively low degree of familiarity may be compensated for by appropriate management practices. Familiarity can be increased as a result of a trial or experiment. This increased familiarity can then form a basis for future risk/safety analysis" (OECD, 1993, page 8). Further, "[f]amiliarity comes from the knowledge and experience available….Familiarity with the crop plant, environment, trait and interactions…facilitates a risk/safety analysis" (OECD, 1993, page 29).

19. Because countries may have experience with other similar products as that found in an LLP situation, and/or have access to available international knowledge and experience with such products, familiarity plays an important role in such an assessment. While familiarity cannot be considered as the conclusion of an assessment, it can serve as a useful starting point, allowing the risk assessor to take into consideration all available information (OECD, 1993).

20. The following indicates examples of the kinds of information that may be useful in determining the degree of familiarity with the unauthorized plant material based upon information from previously evaluated or authorized products*:*

1. *Does it contain the same or almost the same transgene and regulatory elements?*
2. *Was the transformation method the same or, if not, did it present any additional issues?*
3. *Was the transgenic material introduced into same genetic background as approved lines?*
4. *Is virtually the same protein expressed? Are protein expression levels and/or patterns similar?*
5. *Is field test data available that supports the conclusions of other assessments of similar authorized plant material?*
6. *Is the crop plant the same?*
7. *Others?*

21. While data and information on all of these factors may not be necessary, they can contribute to assurance that adverse affects of concern may not be an issue in an LLP situation. More or less information will be needed, depending upon the situation. The situation may also influence how quickly decisions will be needed and the core information needed to make those decisions.

[2] This document discusses risk/safety analysis as being comprised of "hazard identification and, if a hazard has been identified; risk assessment." Currently, the term "risk assessment" has replaced the term "risk analysis" as the term most commonly used to indicate both hazard identification and risk assessment.

2.3 Risk/Safety Assessment in an LLP Situation

22. When approving a transgenic crop for potential cultivation, usually the environmental risk/safety assessment assumes 100% exposure over an extended period of time, *i.e*. the crop is cultivated on potentially very large areas of land. This is an assessment of the product. However, when assessing an LLP situation the context may be different. The determination of the level of environmental risk that an unauthorised product may pose is based on the hazards identified and the potential scale (exposure). The amount and degree of information needed may be different for a LLP situation because of the different level of exposure. In an LLP situation, the risk/safety assessment is not intended to lead to an authorisation. However, the results of the assessment can be useful in supporting risk management decisions.

23. When a risk/safety assessment of an LLP situation is undertaken, the goal is to determine any potential risk and provide the scientific basis for evaluating potential options to return the situation to regulatory compliance; *e.g*., remediation and mitigation options that ultimately lead to limitation of the maintenance and/or spread and/or removal of unauthorised plant material from the environment and ultimately the market. The risk/safety assessment evaluates the risks associated with the non-compliant incident and can be used by governmental authorities as the basis for bringing the situation back into regulatory compliance in a manner proportional with the risk presented.

24. However, LLP situations in the environment are dynamic, and, as a result, a relatively rapid determination of the risk profile of the situation is needed for appropriate and proportional action to occur. For example, a seed lot containing LLP may have already been planted upon discovery or volunteer plants found along a transport thoroughfare. The assessment of the LLP situation is needed within days and weeks rather than as the result of the measured pace of product assessment. The degree of familiarity with the elements of the situation depends upon the amount of readily available existing data and information and this can determine the effectiveness and efficiency with which the risk assessor is able to make an assessment as to any potential risk to the environment. In some cases, some or all of the needed elements may exist in a comprehensive application received for food, feed, processing and/or environmental release but, in others, the risk assessor may need to actively access information from a wide range of sources to assure an adequate degree of familiarity. In the absence of sufficient information, there may be uncertainty regarding the safety of the product implicated in the LLP situation. How this information provides needed level of familiarity to support a risk/safety assessment of an LLP situation is described subsequently.

25. As emphasized previously, the risk/safety assessment principles and associated elements and considerations are the same for both product evaluation and LLP situations. The basis for this evaluation is the familiarity or knowledge and experience available to determine potential risk of introduction of the plant into the environment. This knowledge and experience focuses on the biology of the crop plant, the introduced trait(s), and their interaction in the environment.

2.3.1 The Trait

26. Molecular characterization of the unauthorized LLP plant material allows for verification of the identity of the unauthorized plant material. The nature of the genetic modification in terms of molecular characterization, particularly the protein(s) expressed by the transgenes (OECD, 2010), and biological functionality of the gene products facilitates the identification of potential hazards such as known toxicity of the gene product or effects on non-target organisms (OECD, 1993). This information forms the basis of the level of familiarity with the proteins and trait expressed and allows a determination of how similar they are to those found in either domestically, regionally or internationally authorized plant lines. Once the unauthorized LLP plant material is shown to be the same or similar to existing authorized plant products, much of the information from previous determinations becomes relevant and directly applicable.

The situations covered in this document assume that there is at least one authorization by a country outside the importing country indicating that this information has been developed for certain events, constructs and their resulting expressed proteins.

27. Phosphinocthricin acetyltransferase (PAT), and 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) and B. thuringiensis crystal (Cry1ac) proteins expressed by the unauthorized LLP events to date have essentially been identical to those expressed by similar authorized events and have come from the same or similar constructs. Much information is available on these proteins and their associated phenotypes from the OECD and elsewhere (Marvier *et al*, 2007; OECD, 1999a; OECD, 1999b; OECD, 2007). The herbicide tolerance and insect resistance traits resulting from these proteins have all undergone multiple environmental reviews with subsequent commercialization over the past 20 years by governments globally in a variety of crop plants (CERA, 2010a; CERA, 2010b). For example, Cry1ac has been authorized in three crops containing a variety of constructs in eleven countries, while glyphosate tolerance has been authorized by thirteen countries in eight different crop plants. Thus, the origin, history of development and safe use, the genes and proteins produced and the functioning in plants of the other genes, including regulatory elements and markers (*i.e*. ampR, NOS, 35S CaMV), have been well documented in decision documents by regulatory agencies globally. This information provides a solid knowledge base for the performance of any risk/safety assessment for an LLP situation containing these genes, expressed protein(s) and the resultant trait.

28. A specific characterization of the introduced trait may be available from an authorization for food, feed, or processing or an application received for import and/or environmental release. However, in some cases, more data or information is needed by authorities relating to molecular characterization, expression level in plants and experience with related authorized plants, including verification of the phenotype of the unauthorized plant material. The information characterizing the protein and, if needed, the specific construct and event may be available from the developer, seed owner or from the exporting country. Many times it has been made available when the LLP situation was discovered or soon after notification of the government was made.

29. Increased familiarity with the trait in a particular environment can come from available knowledge including: a) the genetic construct introduced, with regulatory sequences; b) experimental data on inheritance and genetics of the expressed trait in the crop plant; and c) experience with the genetics of the same trait expressed in other crop plants . Useful data and information for an assessment of an LLP situation can generally be extended to include familiarity with the same or almost the same transgene; regulatory elements; transformation methods; introduction into the same genetic background as approved lines; similar expression levels; available field test data; confirmed lack of additional unintended genetic material; and expression of virtually the same protein. Such information can confirm the applicability of existing general knowledge and/or experience of how the trait can affect the plant, including how it affects growth, survival and reproductive ability. The broader the experience and knowledge base of how the trait affects different plant types in different environments, the greater the familiarity of the range of possibilities the trait may have affecting the behaviour of the plant in the environment of the particular LLP situation.

30. Familiarity with the trait in the environment can also come from existing knowledge and experience with different combinations of crop plants and the trait. This can be particularly useful when information about the trait in a particular crop plant is insufficient. Since a given trait may perform differently in different crop species or possibly even in different varieties of the same crop, the existing combined global knowledge and experience of a particular trait in these different cases altogether gives a breadth of understanding that can be used to determine the potential range of responses of the crop-trait combination in the specific environment of the LLP situation. In addition, domestic field trial data may also be available that can support conclusions regarding the environmental effects of a particular trait in

the LLP situation. This familiarity can be extended to that with similar traits developed through traditional plant breeding.

2.3.2 Plant and Receiving Environment

31. Understanding the biology of the crop plant and its behaviour in the receiving environment with the existing agricultural practices of the country or region concerned can be important in assessing the risk presented in the LLP situation in commercial seed, along with the ramifications for mitigation or management of the situation. This includes familiarity with the means of spread and persistence of the plant and any agricultural practices associated with the trait. For example, maize overwinters poorly, if at all, in some countries. Practices such as herbicide usage for weed and volunteer control or to manage for pests and diseases could be important for the risk/safety assessment of unauthorized seed containing traits for herbicide tolerance or insect resistance. For commercial seed and many commodities, the experience to date has been with crop plants with which there is a high degree of familiarity, as these are grown regularly within the countries in which LLP situations have occurred, as non-transgenic or transgenic crops.

32. Familiarity is based upon already existing knowledge of the crop history in the particular managed agricultural environment, including the surrounding partially managed or natural environment, (*e.g.* the presence of wild and weedy relatives with which the crop plant can cross fertilize). Standard cultural practices (*e.g.* crop rotation, tillage, planting dates, herbicide use, control of endemic pests and diseases) may vary within the same crop species and between countries or regions because of variations in climate, soil, and other factors. However, cultural practices normally restrict crops, including transgenic ones, to the managed environment (this may vary according to the crop). Management of authorized transgenic plants may include additional practices to the standard ones, depending upon the trait(s) and/or any risk presented (*e.g.* insect resistance management). Much information on different crop plants and associated cultural practices in the environment is available in the OECD biology documents[3] as documents as well as national ones. There are over 25 OECD biology documents including for the major commodity crops (corn, cotton, and rapeseed) (OECD, 1997; OECD, 2003a; OECD, 2008) that have been utilized in LLP situations. Such documents provide a basis for rapid assessment and development of management plans in an LLP situation.

33. In general, the potential of the trait to facilitate the plant's spread and persistence as well as the ability of the plant to cross with associated crop plantings or wild or weedy relatives can be of particular interest in that it may present a hazard, or may directly impact the ability to control or manage the situation. Some commodity crops outcross prolifically within the crop or to sexually compatible relatives, while others do not. These factors are evaluated in the context of the existing cultural practices for either the unmodified crop or a similar authorized transgenic crop.

34. While the source of some LLP situations might be ascribed to commodities as the unauthorized material found in the environment is authorized for food, feed, and processing but not for cultivation, the source of the unauthorized material is not always easy to identify as to whether it came from the planted seed or from some other source. Many situations can, however, be evaluated as if they originated from the seed.

35. For commodities approved for import that are the source of an LLP situation found in seed to be planted or in fields already planted, familiarity can be based upon the knowledge and information indicated above for the trait, environment and their interaction. However, for commodity plants found in environmentally disturbed areas such as roadsides and railroad track beds, other information on

[3] http://www.oecd.org/document/60/0,3746,en_2649_34385_46720508_1_1_1_1,00.html

the maintenance of the thoroughfare, including weed management, may be useful. The less than optimal conditions for plant growth and survival in disturbed environmental settings and whether the plant can just volunteer or is weedy can affect any assessment of the potential for persistence or spread of the crop and/or trait. The presence of wild and weedy relatives in the local area or nearby compatible crops can also be a factor along with whether the plant is listed as a weed in the region. Even if the plant is not cultivated within the country, there is information about the commonly traded crop plants from the OECD.

36. As mentioned for traits, information on the behaviour of the unauthorized plant material in the environment exists and is available from countries in which the material has been authorized for environmental release. If an application for commercial release has been received by the importing country, such information will also be available. The information from the assessment of authorized plant lines domestically and that available in applications evaluated globally should be directly relevant. The comparators will be with unmodified plants but, as indicated above, the unauthorized material can also be compared with authorized transgenic material to see if any additional risks are identified.

37. If needed, familiarity with the plant and environmental interactions can also come from existing knowledge and experience with different crop-environment. Different plant genotypes can perform differently because of differences in climate, soil, pests etc. Familiarity with the unauthorized plant material can come from: 1) knowledge and experience with the same species or subspecies, grown in the same or different environments with traits introduced by traditional plant breeding or similar authorized transgenic plant lines; 2) information on the nature and behaviour of the actual genotype(s) of lines related to the unauthorized plant material and on the behaviour variations in different environments from unmodified crops or similar authorized transgenic crops; and 3) results of field trials of the unauthorized plant itself that may also be available. Information on the plant-trait-environment interaction for the particular variety of plant in which the LLP situation occurred can be supportive, although not always necessary. Field test data from regulated field trials comparing authorized transgenic and/or unmodified with unauthorized plant lines can help establish or confirm how the unauthorized plant material interacts with the environment. This can also sometimes be found in peer reviewed published literature. Such knowledge can provide insight into the potential of new trait to allow crop to succeed where unmodified plants might not.

2.3.3 Exposure

38. Each country makes its own determination of what is considered to be low level, most often on a case-by-case basis. For commercial seed that has been planted, the degree of exposure may usually be determined through information received on, for example, where seed lots have been distributed or fields planted and this is usually known by seed companies and farmers. In situ testing may also be available or useful, depending upon the situation. Other factors influencing a determination of exposure or potential exposure can include the identified source of the unauthorized plant material. For commodities and seed, familiarity with plant/crop-specific international movement can provide information to allow examination of the level and pathway of exposure elements, including known distribution routes and trade statistics.

2.4 Available Data and Information

39. Information needs may be different for an environmental risk/safety assessment in a LLP situation versus a risk/safety assessment for a “product submission for authorisation”, typically because there are differences in the environment, scale, and amount of the unauthorised plant material that may be present in a LLP situation compared to what may be expected in the authorisation or approval of a product. In the absence of important information or data there may be uncertainty regarding safety. Since it can be critical to complete a risk/safety assessment as efficiently and effectively as possible in response to an LLP incident, use of existing domestic and/or international experience, gives the risk assessor a “head start”

so to speak in terms of performing the assessment, saving valuable time. The familiarity needed to address LLP situations is based on existing knowledge and experience that can come with the same or similar plant species; the same or similar gene/protein; and/or the same or similar phenotype.

40. Useful existing knowledge and experience with particular traits may come from a variety of easily accessible sources including previous reviews and experience with cultivating similar or the same crop with the same or similar trait. Domestically, a country may have granted approvals for similar crop-trait, gene and/or construct combinations in the same or similar crops. An application for authorization may have been received and be under review. Additionally, there may be experience with the trait in a variety of other crops. Thus, extensive information may be available on the effects of the trait within the crop plant in the environment. Since the plant line was previously approved in another country, information on the expression of the trait in the particular plant line and the crop may be available from that country along with the identification of any unintended effects in the environment of the country in which the authorization was made. Knowledge can also come from additional countries that have granted approvals and that information may also be accessible either directly from the authorities in that country and/or through domestic and international databases (Biosafety Clearing-House[4], Center for Environmental Risk Assessment[5], OECD BioTrack[6]). This valuable knowledge and experience can support assessments of the behaviour of the unauthorized plant material and expression of the trait in the environment.

41. In summary, readily accessible existing data and information regarding relevant characteristics of the plant, the behaviour of the plant in the environment, including cultural practices, and the trait can be used for a risk/safety assessment of an LLP situation. This familiarity with the protein and trait, the crop plant and the environment can come from a variety of sources. The familiarity needed to make an assessment of risk/safety in an LLP situation will most likely be available from the following sources:

1) Domestic authorizations of similar transgenic plants in the environment;

2) Domestic authorizations of the particular transgenic plant for food and feed (import);

3) Application(s) submitted for the particular plant product (review not completed):

4) Food, feed and environmental authorizations of the plant by the exporting country;

5) Authorizations completed in other countries in addition to the exporting country;

6) Data and information from the developer, producer, farmers and other involved industries;

7) OECD trait, plant biology and evaluation documents (OECD, 2006; OECD, 2010);

8) Publically available databases (domestic/international);

9) Peer reviewed published literature; and

10) Direct communication with authorities in other countries, particularly the exporting country or authorizing country.

[4] http://bch.cbd.int/

[5] http://cera-gmc.org/

[6] http://www.oecd.org/department/0,3355,en_2649_34385_1_1_1_1_1,00.html

Table 1: Example scenarios indicating types of existing knowledge and information may be used by the importing country as a basis for familiarity to facilitate an environmental risk/safety assessment of an LLP situation

In these cases, the crop is grown in the importing country (unmodified or similar approved transgenic crops).

Scenario 1: ***Protein/construct/event authorized for import (food, feed and processing), but not for cultivation***	***Scenario 2:*** ***Protein/construct/event not authorized in the importing country but the inserted gene and protein produced are the same as or very similar to other events authorized in the importing country***	***Scenario 3:*** ***Protein/construct/ event that has no authorization in the importing country***
Characterization of the introduced trait completed in the importing country; Agricultural areas where the crop is grown provided by seed company/industry; Experience with cultivating this crop. Specifically the focus would be on the crop's inherent properties related to weediness (persistence and invasiveness) and pest management, depending upon the trait; Agricultural practices, with a special emphasis on those associated with the trait, such as the use of the target herbicide in the case of an herbicide tolerant trait; Environmental risk/safety assessments available from other countries; Experience and information from similar crop/trait combinations and deemed relevant by the importing country; and Relevant OECD consensus documents.	Characterization of the same or similar gene and protein in the importing country. Characterization of the introduced trait completed in the authorizing country; Agricultural areas where the crop is grown provided by seed company/industry; Existing environmental risk/safety assessment data and experience with the unauthorized event/plant line within the importing country for the gene and expressed protein. The environmental risk/safety assessment of the same or similar authorized plant line or event in the respective cropping system, focusing on the likelihood that the trait would alter the crop's weediness or effect on non-target organisms; Experience with cultivating this crop. Risk/safety assessments available from other countries; Experience and information from similar crop/trait combinations deemed relevant by the importing country; and Relevant OECD consensus documents.	Characterization of the introduced trait completed in the authorizing country; Agricultural areas where the seed crop is grown provided by seed company/industry; Experience with cultivating the crop particularly tendency to persist or spread in the environment; Experience with the trait (or similar traits) in the other crops; Risk/Safety assessments available from other countries; Information about the receiving environment and common agricultural practices in that receiving environment; Other considerations, such as the level of exposure to beneficial organisms, humans, and the environment; and Relevant OECD consensus documents.

2.5 Risk Profile

42. Since environmental risk/safety assessment is based upon the plant-trait-environmental interaction, the initial focus of the assessment is to verify the trait found in the particular seed or plants, based upon the protein expressed by the inserted genetic construct. Verification can come from data and information about the protein, construct and/or the specific event. The molecular characterization of the trait and its expression facilitates assessment of any hazard presented by the trait in the crop as available information regarding previous domestic and/or international authorizations of the trait become directly relevant. This includes attributes of the plant such as reproductive biology or weediness characteristics that provide the familiarity to determine the potential for spread and persistence. Environmental factors such as the presence of compatible wild and weedy relatives, non-target organisms *e.g*. beneficial insects or threatened and endangered species that may be vulnerable to exposure by the plant trait combination can be identified and assessed as to the likelihood of their occurrence given the low level of presence of the unauthorized plant material in the situation.

43. The risk/safety assessment process examines the information regarding the exposure or potential for exposure to the trait and any hazard associated with the trait in the crop plant. A determination as to whether there are any significant data gaps critical for a risk/safety assessment of the LLP situation then can be made. In cases where familiarity cannot be confirmed to the extent needed, more data or information may be necessary, such as for molecular characterization or expression levels of the protein in the plant, or on the potential of the trait to increase weediness in a particular plant, depending upon the crop plant and the situation. Ultimately, the risk/safety assessment of the LLP situation takes into account cultural management practices and the effectiveness of these practices to bring the LLP situation back into compliance either through limiting or removing the unauthorized plant material from the environment. Additional remedial or mitigating actions may be indicated. When appropriate, the results of the environmental risk/safety assessment can be combined with that of any food safety assessment of a particular protein to determine resultant mitigation and management actions in the environment.

44. The risk profile presented by the LLP situation can be determined by comparing the LLP plant to previously-authorised transgenic plant products, particularly comparing the constructs and evaluating the protein(s) likely to be expressed and the similarity of such expressed proteins to proteins expressed in previously authorized plant lines. For many LLP situations in seed to date, unauthorized plant lines were very similar to authorized products; generally the trait and the crop plant were the same, providing a substantial degree of familiarity, even if the authorization was given in another country. In addition, there was information on the influence of the trait in a variety of crop plants and environments, giving a broad indication of the potential interactions of the trait in plants in different environments.

45. The kinds of hazards presented in previous reviews can expedite the identification and evaluation of hazards that may be present in the specific LLP situation. Once the unauthorized LLP plant material is shown to be similar to existing authorized transgenic plant products, much of the information from previous determinations was available and the previous evaluations and conclusions of safety directly applicable. Any environmental factors such as cultivation practices, the potential for out-crossing to wild and weedy relatives at the low exposure levels or the potential for negative effects on beneficial or endangered species can be examined, depending upon the trait, to confirm the results of previous assessments. At the conclusion of the assessment any differences in risk profile compared to previously authorized and/or similar plants can be determined including whether a different hazard is presented or whether there is a difference in the unauthorized plant's behaviour in the environment.

46. To date, the LLP situations in commercial seed and commodities in the environment have allowed for relatively straight-forward case-by-case, comparative, scientific assessments of risk/safety to the environment from the LLP situation based for the most part on existing available information. As a result, when an assessment has been done governments have been able to determine that the low level presence of these unauthorized events in seed or commodities in the environment posed a low level of risk, given the combined hazard(s) and exposure in the situations that occurred. This conclusion was based on the review of available scientific data, the limited amount of the unauthorized plant material in the environment, and comparison with the baseline risks posed by either the unmodified plant or the close similarity of the unauthorized material to authorized transgenic plant material which had cleared regulatory review.

SECTION III – LESSONS LEARNED

3.1 Mitigation of LLP Situations

47. In the LLP situations to date, the crops involved were seed or commodity crops of major commodity crop plants–corn, cotton, rapeseed/canola and soybean with commonly inserted genes for insect resistance and herbicide tolerance. The risk/safety assessment informed decisions on limiting or mitigating exposure to the unauthorized plant material.

48. From the responses to the questionnaire, a major factor for determining the appropriate mitigation measures can be when the LLP situation is discovered – before planting, after planting, or after harvest. Another factor for food crops is whether a food safety evaluation has been done, usually domestically but food safety evaluations from by other authorizing countries have also been used. Thus, when the food safety evaluation has been done and the primary concern is to assure that environmental exposure is reduced or eliminated over time to bring the LLP situation into regulatory compliance, seed and/or plants may be limited or removed from the system in the following manner: 1) recall seed from distributers if it has not yet been planted; 2) remove product if only a small amount has been planted; 3) allow planting and/or harvest; and 4) permit food or feed processing or biogas utilization even if not allowed to be planted or go to harvest. Processing devitalizes the plant material so there is no further potential for plant growth. In some cases, the risk may be determined to be insignificant in comparison with the unmodified counterpart or a similar authorized transgenic plant material, no action may be taken to remediate or mitigate the situation and the crop may be allowed to go to harvest. In other cases, the crop may be removed and the resultant harvest may be used for biogas or feed. Other situations can result in harvest and subsequent processing. When food/feed safety is not an issue, several choices become available as to when and how to bring the situation back into compliance. Thus, the situation and the assessment can indicate options for disposition of the product proportional to the risk identified. Crop or seed destruct is not the only option for remediating or mitigating an LLP situation.

49. The evaluation that occurs in the environmental risk/safety assessment can allow the disposition of the unauthorized plant material to be done in a manner proportional to the risk presented. If the LLP situation in the environment has been determined to be low risk, other factors can influence the complexity of the response based upon the distribution of the organism, its ability to establish and spread, the methods available for control or eradication, the availability of resources, stakeholder preferences, and legislative mandates. Additional considerations can include the preference of the grower or seed supplier. There are several examples of growers, developers and seed suppliers taking more rigorous action than mandated by the regulators. Economic consequences to the farmer, importer and government may also play a role. The responsiveness and collaboration of the industries involved were critical to addressing LLP situations in a risk proportional fashion. However, the risk/safety assessment itself provides the cornerstone for regulators and industry to develop the plan to address the situation in proportion to the risk presented.

50. In summary, important factors that are considered in developing mitigation plans include:

- When discovered in the seed or commodity.
- Existence of food safety approval.
- Results of environmental risk/safety assessment.
- Government-seed/crop industry interaction.

3.2 Addressing Environmental Risk for LLP Situations Proactively

51. In recognition of the fact that LLP situations are inevitable and have the potential to be disruptive to trade and create economic hardship on seed producers, importers, shippers and farmers as attested in responses to the questionnaire, countries and regions have taken several steps to limit the potential for uncertainty regarding environmental risk. Some authorities undertake environmental assessment of products in recognition of the potential for "adventitious presence" in the environment of authorized imported commodities. Thus, when LLP situations in the environment have occurred with such products, countries have been able to rely on the determination that the risk presented is no greater than that presented in the unmodified plant. This applies to those situations in which the unauthorized plant material is found in planted fields of the crop as well as spillage during commodity transport. Other countries perform assessments for authorisation of unconfined commercial release of the products that are destined to be imported for only food, feed and processing. When these products have later been found in the environment, they have not been deemed illegal.

52. Some countries have set up comprehensive systems for working with potentially affected government agencies and stakeholders, particularly affected industries, to prevent the import of seed or commodities containing unauthorized plant material. The industries themselves have also incorporated protocols to reduce the prospect of having seed or commodity products rejected or destroyed upon arrival in the importing country due to the presence of even a low level of unauthorized plant material.

53. Preparations for the possibility of an LLP incident have occurred as part of a process for developing communication plans with other government agencies and for educating stakeholders as to their roles and responsibilities in both preventing and managing an LLP incident. Some countries work with the seed and developer industries to increase their quality control systems to aid in avoidance of unauthorized plant material getting into seed initially.

54. Several countries indicated in response to the questionnaire, that, in recognition of the potential for LLP, they have set thresholds for the allowance of LLP in seed if a food safety approval has been done either regionally or in a country with a similar food safety review system as the importing country. In some cases, where it may be impossible to know if LLP has been eliminated, and, to assure an acceptable supply of seeds, thresholds have been established to eliminate the prospect of very low levels, technically below the level of quantification, being detected in some cases and not others, making the seed distribution and supply system unpredictable. Thresholds have also been adopted to accommodate the inability to eliminate LLP in order to avoid the reduced availability of seeds when it was known that the unauthorized plant material has been authorized at least in one other country.

55. Collaborative working relationships between regulatory authorities and/or with industry have also facilitated access to information and problem resolution, and establishing ongoing communication was beneficial to this process.

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ANNEX I

ANNOTATED QUESTIONNAIRE FOR LLP IN SEED AND COMMODITIES IN THE CONTEXT OF ENVIRONMENTAL SAFETY

Introduction

This questionnaire is part of a project for the OECD Working Group on the Harmonisation of Regulatory Oversight in Biotechnology (Working Group) to address the situation of low level presence in commercial seed and/or commodities of transgenic plant material (LLP) that have received approval and been commercialised in at least one country but have not received approval (authorisation) in the country of import. Further information introducing the project, its organisation and its purpose, focusing on LLP in the environment can be found in the project proposal [ENV/JM/BIO(2009)2]. The questionnaire focuses on, but is not limited to, information acquisition and use and environmental risk assessment in LLP situations to conform within the remit of the Working Group. In addition, it should be noted that the Codex Alimentarius has an annex addressing LLP as part of its *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants*.

Working Group member countries and observers can provide information in response to this questionnaire about their experience with LLP in the environment as it relates to commercial seed used intentionally for planting and commodities (*e.g*. grains and oilseeds) unintentionally released into the environment during handling and transport that can subsequently germinate and grow into plants or may be intentionally used for planting. The term "seed" used in this document refers to commercial seed produced to meet certain quality standards (viability, germination, etc.) for intentional planting while the term "commodities" refers to grain harvested for food, feed or processing. Commodities are not intended to meet seed quality standards, even if grown from such seed. Commodities are generally not used for planting but, if they are planted, some may germinate and grow into plants, *i.e*. the commodity can function biologically as seed.

The situation specifically to be addressed in this questionnaire is the same as the scope above: situations in which the commercial seed product and/or commodity that can function biologically as seed has received approval for unconfined release and has been commercialised in one country but has not received such approval in an importing country. The questionnaire relates only to LLP situations in relation to the environment. If answers to the questionnaire are related to the unintentional release of commodities, please distinguish these situations from those LLP situations related to intentional release of seeds and/or commodities.

The purpose of this questionnaire is to: (1) obtain information on LLP situations in relation to the environment; (2) understand the availability of data and information needed to define and analyse an LLP situation, particularly that needed to assess any potential risk; (3) understand the approaches taken to identify and assess any potential risk and (4) obtain information on any mitigation of the LLP situation, as appropriate. In addition, information on how risk mitigation or management measures have been supported by an assessment of risk in an LLP situation may also be appropriate to submit. It is to be understood that, although the basic principles are the same, an assessment of risk/safety in an LLP situation is not a substitute for a risk/safety assessment for unconfined release of a product. Responses may be submitted in any form, *e.g*. in general terms, scenarios, case studies or a combination of all three.

The annotations or explanatory texts are only meant as indications on what aspects could be taken into account by countries formulating answers. They are not meant to be limiting or prescriptive.

Questions:

I. Has your country experienced LLP situations from commercial seed or commodities that can function biologically as seed?

The scope of this question is restricted to environmental issues associated with LLP in seed and commodities. Responses to this section can generally describe the circumstances or situations that a country has faced with regard to LLP in commercial seed used intentionally for planting or commodities released unintentionally into the environment or intentionally used for planting. Spillage of a commodity shipment of corn or oilseed rape that may function biologically as seed is an example of unintentional release.

Country responses to this question can include a general description of the situation, how it was discovered and how it occurred (type of situation). Specific information can include how it was determined that an LLP situation from commercial seed or commodities have occurred. Focus on the following questions if your country has experienced such LLP situations. What were the consequences or responses to the determination that an LLP situation had occurred? What agencies/ministries (and their function in addressing LLP) were involved? Were they the same as involved in the risk/safety assessment of commercial products for unconfined release? Were any applicable policies in place to address LLP before the situation(s) occurred? Are the same agencies/ministries involved in the case of an assessment of risk for an LLP situation? Responses may differ for LLP in commercial seeds for sowing as opposed to LLP in commodities but the focus is in relation to the environment. Responses to this question could also cover legislative requirements, regulations, proclamations and other arrangements, codes of practice, voluntary schemes, guidance documents, LLP strategies, contingency plans or any other relevant information.

II. How has your country addressed these LLP situations; if your country conducted risk assessments related to the environment, what scientific information formed the basis of the assessment of risk related to the environment?

Responses submitted for this question can elaborate the specifics of any LLP situation(s) indicated in question number one above--how, where, and when? In particular, responses can include whether and how a determination of risk was made (including, any evaluation of potential mitigation measures) and, if any assessment of risk/safety was done, information about the following would be useful including, but not limited to: 1) what factors were addressed regarding potential risk to the environment; 2) how available information was used to understand and address any potential risk to the environment[7]; 3) use of experience and familiarity in the assessment[8] and 4) the conclusion of the assessment. As a result, were any risks identified that were different from any risks assessed previously for similar evaluated and approved products, if relevant?

[7] How did access to this information occur?

[8] Was the plant involved in LLP similar to products and/or similar plants that have been previously approved under your country's jurisdictions? If so, the LLP situation may have been evaluated by looking at existing information on the biology of the crop plant, the trait (gene, molecular characterisation), familiarity with the plant, trait, and the environment and their interaction, experience with similar transgenic plants (*i.e*. same crop/trait/gene combination), and through identification of any additional data needs. See *Safety Considerations for Biotechnology: Scale-up of Crop Plants* (OECD, 1993).

III. What lessons were learned?

Responses to this question can show whether, in dealing with the LLP situation(s), it became apparent that the availability or lack of certain types of information facilitated or hindered the progress of dealing with the LLP situation, particularly in assessment of risk—the lessons learned in information sharing. What kinds of data and sources of information were available to identify and address the LLP situation, particularly in assessment of risk?[9] What role would industry organisations such as seed producers, gene technology providers, bulk handlers etc. have in providing data and information?

In addition, what mechanisms or procedures have been or can be developed to facilitate information sharing internationally by your country including fostering/developing formal contacts with regulatory bodies? What are valuable sources of needed information that could be used, what would have facilitated acquisition of information, and what mechanisms could be developed or used to access such information? This could come from actual LLP situations or from preparedness actions and contingency measures taken to prevent/contain such situations. Such responses could also indicate the possible need for further capacity building or collaboration in the case when the necessary scientific capacity is lacking to identify the LLP situation and conduct an assessment of risk appropriate for the situation.

IV. Other comments

Responses to this question can focus on areas of risk management and mitigation and any policies developed in regard to LLP in the environment as a result. There may be other contributions regarding LLP that a country would like to make that would be useful to regulators and this can be included in responses to this question. Thus, responses may indicate how the information gained from assessing an LLP situation was subsequently used to support risk management, including any mitigation measures, bringing a situation into compliance, and other management decisions as well as future dealings with LLP situations with commercial seed and commodities. In dealing with LLP, were any deficiencies identified and possible solutions found? Were policies developed or articulated with regard to LLP in the environment as a result?

For example, if an LLP situation occurred, the following questions might be considered. Were mitigation measures based upon identified risks? Did these measures include how the possible distribution and release into the environment was mitigated or prevented? Were any actions taken such as specific management measures (or other actions) to deal with the LLP situation? For example, were some sanctions applied? How was this based on regulations? What were the goals of the management measures or other actions taken? If management or other actions were taken and evaluated, did these turn out to be sufficient? Were any follow-up measures needed? If a similar LLP situation occurred in the future, would your country deal with LLP in the same way? Other approaches to risk management may also be indicated.

In addition, in cases where a country may not have experienced an LLP situation, it may be useful to indicate if LLP situations are being prepared for. For example, exporting countries may indicate the measures taken to prevent LLP situations from occurring and pro-actively sharing with importing partners the necessary information, including that to conduct an assessment of risk/safety.

[9] This can include information contained in previous domestic approvals, previous approvals in other countries, available public databases (domestic/foreign), assessments completed by other regulatory bodies, data available from the developer, the OECD plant biology and trait documents, and peer-reviewed published literature.

ANNEX II

COUNTRY RESPONSES TO QUESTIONNAIRE

ARGENTINA

Argentina wishes to commend the Bureau for the excellent document developed on LLP. The document covers appropriately the issues that can arise from LLP situations. Argentina only would like to advance a few comments.
Quotations of the annotated text are indicated as (modified annotation quoted) and the modifications are between parenthesis.

I. Has your country experienced LLP situations from commercial seed or commodities that can function biologically as seed?

The response below refers to "potential" LLP situations, as Argentina's regulatory framework is designed to avoid their occurrence. Argentina faces a particular challenge with regard to LLP situations. The main issues:

i) Commodity exports are an important component of country's trade. Therefore, LLP situations at the importing country may lead to rejection of shipments.
ii) Due to the above, authorisations of new GM crops are granted generally AFTER they were approved in the importing country. Therefore, these approvals delays will cause a transgenic crop, already favorable assessed with regards to environmental risks, to "wait" for regulatory decision at the importing country. This situation leads to the following:
    a. Agriculture development towards introduction of more advanced seeds (yields, quality, stress-resistant), is hampered,
    b. Developers (public sectors and private companies) will lack incentives for investments in the development of new seeds, because the uncertainty on the date the product can be placed on the market (companies) or on the eventual approval (public sector, in the case of orphan crops).
iii) Counter-season production of regulated seeds, only for export to Northern Hemisphere (U.S.) market. Already practiced in Argentina for maize, this activity brings employment and profits but requires great efforts (isolation, segregation, inspections) and strict regulatory oversight in order to avoid entrance into approved commodity channels. Counter-season production of regulated seeds is only allowed for maize but not for soybeans (although repeatedly requested for the industry), due its autogamous character.

II. How has your country addressed these LLP situations; if your country conducted risk assessments related to the environment, what scientific information formed the basis of the assessment of risk related to the environment?

On how the country addressed potential LLP situations: see above
Argentina has in place a science-based, on a case-by-case basis, regulatory framework. Risk assessment is a key consideration for approvals, which starts already at the field trials level. Commercialization approvals require the submission of a comprehensive dossier by the developer which is reviewed by an experts staff. In short, information required pertain to biology of the plant and of the trait, phenotypic expression, environmental risk assessment and molecular genetics characterization. Regulatory guidelines can be found in: http://www.minagri.gob.ar/, go to "Biotecnología Agropecuaria", English, Regulations
Scientific information submitted by applicants must have peer-reviewed quality.

III. What lessons were learned?

i) Argentina supports the view exposed in the *Codex Alimentarius* document "Guideline for the conduct of food safety assessment of foods Derived from recombinant-DNA plants", Annex 3 (*CAC/GL 45-2003).*

ii) Information sharing and ready availability of data would help risk managers in the importing country to assess environmental risks and to make informed decisions. Conditions for that are not only information sharing and ready access to the needed information, but also, and specially, building trust among regulatory bodies with regards to the regulatory procedures, including the basis of the pertinent regulatory decisions. Comprehensive databases, although a component in this approach, will work together with a trustful, permanent exchange which would allow to act proactively in LLP situations, by providing an advanced knowledge of eventual risks.

iii) Provision of the above could constitute a possible OECD initiative: to create a regulators "forum" which could start by exchanging each country's views and criteria on risk assessment. For example, different protecting goals mandated by competent authorities could then be known by risk managers, as this is an area which may lead to problems in LLP situations. Also, differences on the value and components of biological diversity, relevant geographic areas, climatic conditions, landscape and soil features, etc., could provide an anticipated knowledge allowing quicker decisions thereby avoiding trade disruption. Clearly, this is not an initiative of capacity building but one addressed at the community of regulators, to strengthen harmonization efforts.

IV. Other comments

i) Argentina agrees with the annotation of the text, taken as a positive approach. That is, we support the view that (modified annotation quoted) "the information gained from assessing an LLP situation (should be) subsequently used to support risk management, including any mitigation measures, bringing a situation into compliance, and (allowing) other management decisions as well as future dealings with LLP situations with commercial seed and commodities".

ii) We would add that mitigation measures should be commensurate with the risks and extension of the actual LLP, avoiding disproportionate reactions which would disrupt trade. This implies (modified annotation quoted) "mitigation measures (should be) based upon identified risks". Also, actions and sanctions should be based on regulations, clearly addressed at these risks. Perhaps, a initiative could be considered to include in future country's regulations, general guidelines for response pathways in LLP situations, in addition to and in agreement with, national policies.

For Argentina, preparedness for LLP situations currently means measures to avoid LLP in export shipments, as described in ***I***. above. Also, we fully endorse the proposal to (annotation quoted) "indicate the measures taken to prevent LLP situations from occurring and pro-actively sharing with importing partners the necessary information, including that to conduct an assessment of risk/safety". Some of these possible measures are indicated above.

AUSTRALIA

I. Has your country experienced LLP situations from commercial seed or commodities that can function biologically as seed?

In Australia, the Gene Technology Regulator (the Regulator) has primary responsibility for the regulation of GMOs and is responsible for protecting human health and safety and the environment by identifying and managing risks posed by, or as a result of, gene technology. The lead Australian agency in any GMO LLP situation would be the Office of the Gene Technology Regulator (OGTR).

Australia has no experience of unapproved LLP GMO situations from release of commercial seed or commodities into the environment.

Australia does however have in place a comprehensive GMO regulatory system and has developed a national unintended presence strategy (UP strategy) to minimize the occurrence of release into the environment of unapproved GMOs (outlined below). Three main overarching principles were used to guide development of this strategy:

- industry co-regulation;
- isolation of risks offshore, and;
- government monitoring to focus on imports posing the highest likelihood of unintended presence.

National Unintended Presence Strategy (UP Strategy)

The Office of the Gene Technology Regulator (OGTR) is responsible for implementing the strategy, although the strategy was developed by an interdepartmental working group that included the departments of Agriculture, Fisheries and Forestry; Environment and Heritage;[10] Foreign Affairs and Trade; Education, Science and Training;[11] Industry, Tourism and Resources;[12] Health and Ageing and Food Standards Australia New Zealand and the OGTR.

The UP strategy has six components (see Table 1) and employs a risk management approach, with resources dedicated to the areas posing the highest likelihood of unintended presence. The focus to date has been on seeds for sowing, which has been assessed as the highest priority; other areas will be targeted according to the risks they present. Over the last four years, the OGTR has worked with the Australian Seed Federation to develop a voluntary auditing and testing program of existing industry quality assurance measures and has assessed the effectiveness of the first stage of reviews completed in 2007. The OGTR continues to liaise with the Australian Seed Federation to expand the quality assurance review program as needed.

Table 1. Components of national strategy for unintended presence of unapproved GMOs

Component	Description
Risk profiling – identifying seed imports posing the highest likelihood of unintended presence	The OGTR has established a memorandum of understanding with the Australian Quarantine and Inspection Service (AQIS) to access data on imports. Data on imported seeds for sowing, together with information on overseas commercial production of GMOs and input from the Department of the Environment, Water, Heritage and the Arts, and other relevant agencies was used to identify eight priority crops. Four additional crops that may pose a higher likelihood of unintended presence were subsequently identified.
Quality assurance/identity preservation	Industry uses quality assurance and identity preservation systems for seed quality purposes. The OGTR has developed a program for auditing and testing industry quality assurance systems that industry has agreed and adopted.
Laboratory testing	The OGTR's voluntary code of conduct refers to industry testing programs. Industry needs to be able to assure itself that it is managing the risk of importing unapproved seeds. Discussions between the OGTR and the National Measurement Institute about appropriate testing methodologies are ongoing.
Approvals/advance risk assessments for Australia's regulatory agencies	The OGTR has prepared GMO incident response documents for 12 crops identified through risk profiling as having the highest likelihood of unintended presence in imports of seeds for sowing (canola, cotton, maize, potato, tomato, papaya, soybean, squash, alfalfa, grasses, rice and wheat). These documents will provide a basis for rapid risk assessment and management actions, should an unintended presence of an unapproved GMO be detected.

[10] Now the Department of the Environment, Water, Heritage and the Arts

[11] Now the Department of Education, Employment and Workplace Relations

[12] Now the Department of Innovation, Industry, Science and Research

Post market detection	The OGTR recognises the legislative limitations of preventing unintended imports of unapproved GMOs and has worked cooperatively with industry to develop a voluntary code. The code aims to isolate risks as early as possible in the commercial seed supply chain. This is supported by the standard OGTR practice of investigating information about potential and possible incidents.
Enforcement action	In the event of detection of unapproved GMOs, appropriate responses would be determined on a case-by-case risk management basis. The OGTR continues consultation with Australian Government agencies, relevant industry organisations and states and territories to develop an incident response plan.

Imported Commodities

If a bulk shipment contains GM grains not approved for unrestricted release into the environment in Australia, authorisation from the Regulator is required. Authorisation is by a licence from the Regulator for GMO Dealings Not involving Intentional Release (DNIR). DNIRs take place under specified physical containment conditions. The Regulator must prepare a Risk Analysis and Risk Management Plan for each DNIR application to identify any risks to human health and safety and the environment. The Regulator may impose conditions to manage any identified risks.

As at December 2009, the Regulator has issued five DNIR licences for import into Australia of GM soy (2), maize (2) and canola (1) grain destined for processing and subsequent stockfeed use. Licence conditions imposed to prevent accidental release of live and viable GMOs to the environment included: precautions against spillage; if any spills occur they must be cleaned up and the grain destroyed; grain must be transported in sealed vehicles from the port to an approved metropolitan processing plant and the grain must be processed to render it unviable.

II. How has your country addressed these LLP situations; if your country conducted risk assessments related to the environment, what scientific information formed the basis of the assessment of risk related to the environment?

Australia has not yet had to address a LLP incident in the Australian environment however it recognises the importance of maintaining a watching brief on LLP incidents in other countries that may have implications for Australia. To assist with determining risks to the Australian environment from international LLP incidents, the Regulator has an agreement with the Australian Quarantine and Inspection Service (AQIS) to permit access to data on imports. This information assists in identifying risks to the environment from LLP incidents overseas.

Appropriate responses to an LLP incident would be determined on a case by case basis but would be based on a risk assessment that would identify risks attributable to gene technology. Any identified risks posed by a particular LMO would be considered against the baseline risks posed by the unmodified parental organism, and in the context of the receiving environment. The OGTR has prepared biology documents for a number of species that provide an overview of baseline biology information to support comparative risk assessments. Such documents, in addition to informing the Risk Assessment and Risk Management Plans (RARMPs) that are prepared in response to applications for Dealings involving Intentional Release (DIRs) of a GMO also provide a basis for rapid risk assessment and management actions, should an unintended presence of an unapproved GMO be detected. Biology documents for canola, cotton, maize, papaya, pineapple, banana, white clover, Italian ryegrass, perennial ryegrass, tall fescue, rice, wheat, barley, sugarcane, carnation, torenia and rose are publicly available on the OGTR website at http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/riskassessments-1. These biology documents may be of use to other countries conducting risk assessments on relevant GM species.

Where a regulatory agency of another country has made an assessment of the same or similar GMO, their findings would be considered during the assessment of the LLP situation. Australia notes that the OECD BioTrack Product database and the Agbios GM database are good sources of information in regard to GMOs authorised for unconfined release in a country and emphasises the importance of such databases being kept up to date.

Copies of all RARMPs and licence conditions for GMOs released into the Australian environment (limited and controlled field trials and commercial releases) are publicly available through the Record of GMO and GM Product dealings (the GMO Record) on the OGTR website at http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ir-1.

III. What lessons were learned?

Australia recognizes that it is important to work cooperatively with stakeholders to isolate risks as early as possible. Within Australia this includes ongoing liaison with the seed industry in particular. This includes providing the industry with clear information on what should be done if they find an actual or suspected unintended presence event in their breeding program.
To facilitate industry cooperation, the Australia's *Gene Technology Act 2000* allows the Regulator to grant a temporary licence (for no longer than 12 months) to a person who finds they are inadvertently dealing with an unlicensed GMO. The licence may be issued to the person for the purposes of disposing of the GMO. There is no requirement to prepare a RARMP or consult in relation to inadvertent dealing applications but the Regulator must not issue a licence unless satisfied that the risks posed by the dealings can be managed in such as way as to protect the health and safety of people and the environment.

BELGIUM

I. Has your country experienced LLP situations from commercial seed or commodities that can function biologically as seed?

One case of LLP of genetically modified (GM) plants in the environment in Belgium could fall under the scope of this project and is reported hereunder.

General description of the situation
In the scope of a regional research project in Wallonia aimed at randomly sampling oilseed rape plants in the environment and checking for their GM status, several GM oilseed rape plants were discovered in 2007 and 2008. The GM oilseed rape plants were identified as being events GT73 and Ms8xRf3.

GT73 oilseed rape is authorized for import and processing in the European Union (EU) since 2005[13]. Ms8, Rf3 and Ms8xRf3 oilseed rape are authorized for import and processing in the EU since 2007[14]. These GM events are thus not authorized for cultivation in the EU.

Origin of the LLP situation
In order to try finding possible explanations for the occurrence of GM oilseed rape plants in the environment, the Federal Public Service Public Health, Food Chain Safety and Environment[15] organized a meeting with the researchers and the consent holders (Monsanto and Bayer CropScience in this case). No clear explanation for the occurrence of those plants could be given. The hypothesis for the origin of the GM oilseed rape plants could be commercial seed or commodities, or field trials conducted in the past.

[13] Commission Decision 2005/635 of 31 August 2005 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of an oilseed rape product (*Brassica napus* L., GT73 line) genetically modified for tolerance to the herbicide glyphosate.

14 Commission Decision 2007/232 of 26 March 2007 concerning the placing on the market, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of oilseed rape products (*Brassica napus* L., lines Ms8, Rf3 and Ms8xRf3) genetically modified for tolerance to the herbicide glufosinate-ammonium.

[15] In Belgium, the Federal State is competent for addressing LLP issues of GM plants.

II. How has your country addressed these LLP situations; if your country conducted risk assessments related to the environment, what scientific information formed the basis of the assessment of risk related to the environment?

Currently, no policies are in place to address LLP in the environment, nor in Belgium nor in the EU.

The risk assessment for the import and processing of the GM events GT73 and Ms8, Rf3 and Ms8xRf3 was realized by the European Food Safety Authority (EFSA)[16]. In the risk assessments[17], the adventitious release of the GM events was also considered.
The GMO Panel of the EFSA concluded that "*The GMO Panel agrees with the conclusions of the environmental risk assessment by the applicant that* ***the likelihood of unintended environmental effects due to the adventitious release and spread of GT73 oilseed rape will not be different from that of traditionally bred oilseed rape***" and that "*The GMO Panel agrees with the conclusions of the environmental risk assessment by the applicant that* ***the likelihood of unintended environmental effects due to the adventitious release and spread of Ms8, Rf3 and Ms8 x Rf3 oilseed rape will not be different from that of oilseed rape bred traditionally***".

As the number of GM oilseed rape plants discovered was very low, the presence of those plants was considered to be adventitious, and on **basis of the risk assessments of the EFSA, no specific management measures were applied.**
Nevertheless, the Federal Public Service Public Health, Food Chain Safety and Environment still works on finding possible explanations for the occurrence of the GM oilseed rape plants in the environment in order to identify the source of this LLP.

III. What lessons were learned?

It's sometimes very difficult to identify the source of an LLP, and therefore to correctly evaluate the amount/frequency of the LLP, which is key information for the risk management of an LLP. Therefore, by reference to this case, it would be interesting to know the transport routes of the commodities.

BRAZIL

Brazil is pleased to provide the following answers to the questionnaire for LLP in seed and commodities in the context of environment safety.
The answers have been prepared considering the instructions contained in document ENV/JM/BIO(2009)/14 and specifically focus situations of low level presence of GMO in commercial seeds and/or commodities with propagation potential. The situation of low level presence of GMO that this document deals with refers to an occurrence of transgenic plant material in low levels authorized in at least one country, but not authorized in Brazil.

[16] EFSA is the central organ for risk evaluation of GMOs in the EU (see Regulation (EC) No. 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety).

[17] Opinion of EFSA on GT73: http://www.efsa.europa.eu/en/scdocs/scdoc/29.htm - Opinion of EFSA on Ms8, Rf3 and Ms8xRf3 : http://www.efsa.europa.eu/en/scdocs/scdoc/281.htm

I. Has your country experienced LLP situations from commercial seed or commodities that can function biologically as seed?

The activities with genetically modified organisms (GMO) in Brazil are regulated by Law nº 11,105, published on 24th of March of 2005, which attributes to the National Biosafety Technical Commission (CTNBio) the competence to perform the analysis of the risk assessment relative to GMO on a case by case approach. This previous analysis of the CTNBio constitutes a requirement to register and commercial release of GMO. After approval of CTNBio the applicant must register the variety in the National Cultivars Register of the Ministry of Agriculture, Livestock and Food Supply (MAPA). Before Law nº 11,105/05 Law nº 8,974/05 also conferred this attribution to CTNBio.
Until now Brazil does not have any specific rule or policy related to Low Level presence in the context of this survey. It is always managed case by case.
Brazil has only one case that fits in the situation of low level presence indicated in this survey, which means an occurrence of low level presence of transgenic plant material in seeds authorized in another country but not yet authorized in Brazil.
During routine procedure of inspection of the cotton production in 2004, MAPA identified low level presence of non authorized GMOs in conventional seeds of cotton. Initially the detection was based on the element 35 S but later it was found that the seeds were contaminated with traces of GM cotton with the CP4EPSPS protein and, in lesser frequency, the Cry 1Ac protein. The analyses had been carried through by an accredited laboratory for official analyses. Considering that at that time no event of genetic modification in cotton had been authorized in Brazil all the seed lots with low level presence of GMO were confiscated and removed from the market place.

II. How has your country addressed these LLP situations; if your country conducted risk assessments related to the environment, what scientific information formed the basis of the assessment of risk related to the environment?

Due to the economic losses generated by the above situation the National Association of Seed Producers applied to the CTNBio for an analysis of that situation and the establishment of a tolerance limit for adventitious presence of non authorized GMOs in cotton seeds. For this purpose the applicant presented several elements for risk evaluation and some considerations regarding the convenience of that measure under the circumstances. The main elements of the risk evaluation presented by the applicant were:

- A comparative evaluation of a situation of low level presence of GMO in conventional seeds (less than 1%) under that circumstance in relation to a situation with standard of seeds with absolute purity (100%), taking into account the standards of cultivation and handling of the cotton crop;
- The consideration that the GMO present in low level in seeds was authorized in other countries which implement a rigid regulatory system like in Brazil;
- Considerations on the experience and historical use of those GMO in other countries with regard to any report of adverse effects;
- Adaptive ability, reproductive capacity and survival of the genetically modified individual seeds present in low levels in the conventional seeds of one harvest to another;
- Considerations of the level of exposure in a situation of low level presence and the possibility of pest selection of tolerance to “bts” under such conditions;
- Possible adverse effects related to the GMO taking into account that the scope of the evaluation was a GMO previously authorized in other countries.
- Possible changes to the system of crop cultivation.

For the definition of the threshold the national rule of labeling of foods was taken into consideration which requires labeling above the 1% limit. Some economic considerations related to the availability of seeds at that time and the compliance with the production rules has also been pointed out.

The CTNBio evaluated the application and set the tolerance limit of 1% for the adventitious presence of GMOs in conventional seeds of cotton as long as GMO were authorized in another country. However, in its technical opinion the CTNBio clarified that this limit did not characterize a favorable decision for cultivation of such GMO in Brazil. The CTNBio additionally restricted the use of these seeds containing traces of GMO in areas where wild species of cotton are found in Brazil.

Based on the CTNBio´s decision, MAPA released lots of seeds whether the percentage was lower than the limit and required tests for the detection of GMO in all cotton seeds produced from that moment on.

III. What lessons were learned?

The situation faced in Brazil evidences the need to revise the regulatory procedures related to GMO commercial release in Brazil, as well as the need to improve the industry´s quality controls to prevent situations like that. In the following year to that episode the new Biosafety Law was published, conferring more agility in the analysis of the applications for commercial release of OGM, as well as it improved the mechanisms of control and inspection.
In this specific case there was enough information on GMO related to the situation of low level presence facilitating the evaluation and decision taking by the competent authorities. At the time the company event holders of 1445 (CP4- EPSPS) and 531 (Cry 1ac) had already filed a biosafety dossier in CTNBio (applying) for the commercial approval f those GMO and the Commission had already some knowledge on those events, because of existing field trial and research taken place.

IV. Other comments

No other comments.

CANADA

I. Has your country experienced LLP situations from commercial seed or commodities that can function biologically as seed?

Canada has only experienced one LLP situation that falls within the scope of this survey. That is, an LLP situation that occurred either in seed or in commodities that can function biologically as seed, where the product has been commercially authorized in the country of export, but not in Canada. The transgenic plant material in this case was StarLink™ corn (OECD unique identifier ACS-ZM004-3).
StarLink™ corn is a variety of transgenic corn developed by Aventis CropScience that possesses insecticidal properties against certain lepidopteran insects, including the European corn borer (*Ostrinia nubilalis*).
Regulatory decisions in the United States (U.S) in 1998 allowed the cultivation of StarLink™ corn and its use as a livestock feed. At this time, a regulatory decision on the use of StarLink™ corn in food for human consumption had not been reached, therefore, the other uses of StarLink™ corn were conditional upon the segregation of the product to prevent its entry into food products for human consumption.
At this time in Canada, StarLink™ corn had been submitted to regulatory authorities for pre-market safety assessments. Full data packages on the food, livestock feed and environmental safety of the product had been submitted by Aventis CropScience and were under review by Canadian regulators. However, no regulatory decisions to authorize this product had been reached. Therefore, the presence of StarLink™ corn outside of confinement in the Canadian environment would constitute a regulatory non-compliance. The presence of StarLink™ corn in food or livestock feed would similarly represent regulatory non-compliance, but these areas are outside the scope of this survey.
In 2000, when it was discovered that StarLink™ corn was present at low levels in certain food products in the U.S, this indicated the product may not have been segregated and contained as intended in the U.S.

Canadian authorities saw that there was the potential for StarLink™ corn to be present in imported products, such as seed and grain, and to enter the Canadian environment. Actions to respond to this possibility were initiated.

II. How has your country addressed these LLP situations; if your country conducted risk assessments related to the environment, what scientific information formed the basis of the assessment of risk related to the environment?

Under Canadian legislation, the presence of an unauthorized product, including at low levels, in the marketplace or environment constitutes regulatory non-compliance. In such a case, the Canadian Food Inspection Agency (CFIA) and Health Canada (HC) evaluate the risks associated with the non-compliance. The CFIA then determines which risk management options and compliance actions are required.

The evaluation of risk in an LLP situation is distinct from the evaluation of a product prior to an authorization for commercial use, which in Canada is referred to as a "safety assessment." A safety assessment assumes that environmental exposure will be continuous (*i.e*. that the product may be grown by farmers for many years) and limited only by the context of Canadian agriculture (*i.e*. the acreage devoted to a particular crop kind in Canada), whereas a risk assessment considers exposure at the time of the assessment, which may be low or short-term.

Following an assessment of risk, the goal of the CFIA's response strategy is to manage the risk to the environment, while using the most appropriate level of intervention that would result in returning the situation to compliance. Compliance can be achieved either by having the products fully authorized for use in Canada, or by putting measures in place to remove the LLP from the marketplace or environment over time.

Risk assessments in LLP situations take into account two factors: hazard and exposure. Information to assess the potential hazard posed by StarLink™ corn in the environment was already available to Canadian regulatory authorities, as the product had been submitted for authorization for unconfined environmental release in Canada. This means that a complete data package was available to regulators. At the time of the LLP situation, a review of StarLink™ corn had been completed; however, there were unresolved scientific questions regarding the stability of the Cry9C protein and its potential for allergenicity.

Information to estimate the potential exposure (*i.e*. presence in Canada) of StarLink™ corn was also available to regulators, based on the amount of StarLink™ corn that had been planted in the U.S., the level of StarLink™ corn that had been detected in the U.S grain supply, and known corn distribution routes and trade statistics between Canada and the U.S.

Given the combined hazard and exposure for StarLink™ corn, it was determined that environmental risk was likely to be low. However, there was a degree of uncertainty related to the unresolved scientific questions regarding the stability of the Cry9C protein and its potential for allergenicity. It should be noted that responsive actions taken by Canada cannot be viewed as solely designed to manage environmental risk, but were also put in place to mitigate potential food and livestock feed risks.

In response to the potential for StarLink™ corn to enter Canada, CFIA and Canadian Grain Commission (CGC) programs officials developed approaches to establish regulatory surveillance and monitoring of imported feed, seed, and grain shipments from the U.S. These activities included:

- Gathering information from U.S authorities and Aventis CropScience, about the progress of remedial actions taking place in the U.S.
- Determining the availability and reliability of methods of detection for StarLink™ corn for potential use in regulatory surveillance and monitoring activities for seed products and grain in licensed elevators.
- Canadian authorities developed specific importation requirements and grain certification requirements for corn. Canada's monitoring and surveillance of imported U.S. food, feed, seed or grain focussed on the verification of documentation and testing results obtained by importers, in accordance with published guidelines. By 2001, Canadian authorities had verified documentation accompanying thousands of shipments of whole grain corn and corn products entering Canada from

the U.S., with an estimated 1 percent rate of refusal of entry for whole grain corn shipments (due to improper or absent documentation) occurring at U.S.-Canada points of entry.

- Canadian authorities also took samples of corn from a variety of grain handling facilities. Grain at two facilities where StarLink™ corn was determined to be present was redirected to prevent entry into food or feed streams.
- In addition to border surveillance activities for shipments of whole grain, new information that StarLink™ corn was present at low levels in seed corn not sold under the StarLink™ trademark, led the CFIA to issue a notice to seed importers. This notice reminded importers of their obligations to protect Canada's supply of seed destined for planting and to prevent the entry of unapproved products of biotechnology into Canada.

Ultimately, Canada's response to the StarLink™ situation considered:

- The effectiveness of the efforts made by US agricultural and agri-food stakeholders and regulatory agencies to quickly and effectively take action to identify the sources of StarLink™ corn in the US food, feed, and seed supply, and measures to ensure that it would be reduced over time
- Information shared between Canadian and US regulatory officials through routine administrative channels of communication, which occurs whenever there are potential trans-boundary matters of interest involving food safety or environmental safety of agricultural and agri-food products
- The developer of StarLink™ corn, Aventis CropScience, promptly cooperating with regulatory authorities and providing data, test protocols, and necessary reference materials in a timely manner.

III. What lessons were learned?

Issues arising from the LLP of StarLink™ corn stemmed in part from the split approval of the product: commercial cultivation and livestock feed use was allowed in the exporting country without having received authorization for use as a food. In order to help prevent entry of unapproved products into food and feed domestically, Canada developed a "no split approvals" policy. In this policy, the unconfined environmental release of a PNT in Canada intended for feed or food use will not be authorized until it receives both a positive determination of product safety as a novel livestock feed by the Animal Feed Division of the CFIA and a positive determination of product safety as a novel food by the Novel Foods Section of Health Canada.

In addition, the StarLink™ LLP incident highlighted the importance of aligning the timing of authorizations of new products between major trading partners. Canadian regulators encourage technology developers to make product submissions to regulatory agencies in Canada and other countries in a similar time frame. Canadian, Mexican, and U.S regulators increased their level of cooperation and coordination in the North American Biotechnology Initiative, a forum for policy dialogue and information exchange, in the years following the StarLink™ corn LLP situation.

As the first significant LLP occurrence to take place in Canada, StarLink™ tested the reactions and interactions between several departments within the Government of Canada. Given that the presence of StarLink™ corn in the commodity stream was known to be low, the realities of agricultural production, the nature of trade between Canada and the U.S and the bulk handling system for grain, the use of detection tests as an enforcement tool to mitigate environmental risk offered little value. In hindsight, the most important response to mitigating the potential environmental risks posed by StarLink™ corn were the efforts put in place to ensure its levels in the corn products would decrease over time.

IV. Other comments

In April 2009, the CFIA published its approach to dealing with the non-compliance of unapproved products of biotechnology, including those due to LLP. While this policy was not drafted in response to StarLink™, it does take into consideration the experience gained from addressing StarLink™ and other LLP events. The policy is available for viewing at the following URL:
http://www.inspection.gc.ca/english/plaveg/bio/nonapp/nonappe.shtml

This policy strives to maintain consistency between regulatory responses to LLP situations and other types of regulatory non-compliances that Canadian authorities encounter.

CHILE

Chile, under the framework of the resolution 1523/2001, sets standards for the introduction into the environment of living modified organisms (LMO).
Under this regulatory framework the only authorized activity is the multiplication of seed for export or testing, not being allowed the commercial production of a LMO in the country.

I. Has your country experienced LLP situations from commercial seed or commodities that can function biologically as seed?

Chile has not so far experienced in the detection of unauthorized events at low levels (LLP), either as seed or commodities with potential to be released into the environment.

The only experience with unauthorized events, but all of which corresponded to an unauthorized event arose in March 2005, when Syngenta informed us the export of an unauthorized event, BT10 declared as BT11 to various countries, not known whether this event could have come to Chile.
In April of that year, Syngenta, through a national seed company confirmed the import of BT10 seeds to Chile, which were declared as BT11 event. This consignment was destroyed.

Given that, so far there has been no experience with the detection of LLP and, to gather information base to address these situations, the Agricultural and Livestock Service decided, start a program of random sampling in conventional seed from 2010, for imported and domestic marketing, in order to make a diagnosis to determine the presence and occurrence of unauthorized event at low level presence in seed.

II. How has your country addressed these LLP situations; if your country conducted risk assessments related to the environment, what scientific information formed the basis of the assessment of risk related to the environment?

As noted above, Chile until now have no deal with situations related to LLP, however in the case of BT10 event, we proceeded to make territorial monitoring of each of the planted seedlings and the elimination of all corn within 300 meter radius and a monitoring plan after 6 months, in order to minimize the presence at low levels of BT10 event in conventional crops, this in addition to initiating an administrative fine.

III. What lessons were learned?

Whether the real case as possible detections in the short or long term, we estimated as a priority issue the need to establish ways of communication between regulatory agencies, in order to be notified promptly about the possible presence of LLP in a shipment of conventional seed or commodities capable of being released into the environment.
Not to ignore the vital role that should have the importers, whom must notify to the regulatory agencies LLP situations, in order to establish mechanisms of control and mitigation.

One of the main factors to consider is the asynchrony in approvals between exporting and importing countries, thus situations with LLP must be analyzed "case by case", based on a risk assessment that will determine whether a shipment or batch may be accepted or not.

Other issue is the needs that international databases, such as the Biosafety Clearing House of the Cartagena Protocol, are updated each time a country approve an event, in order to anticipate possible risk of an LLP.

CZECH REPUBLIC

I. Has your country experienced LLP situations from commercial seed or commodities that can function biologically as seed?

Only one case of LLP has occurred so far in the Czech Republic – low contamination of maize seed by GM admixtures.
The Ministry of the Environment of the Czech Republic was informed on 15 April 2009 by an e-mail from the German Competent Authority (BVL), in accordance with the requirements of EU Directive 2001/18/EC, about the low level presence of genetic modifications in maize seed lots intended for cultivation. Trace amounts of genetically modified maize not authorised for cultivation in EU, events 59122, 1507, and NK603 were detected by the German inspection and control services. The detected amount was below the limit of quantification (LOQ), thus being less than 0.1 % for each of the detected GMO events.
The analysed and affected variety was conventional maize, originating from USA. The holder of the seed lot was Pioneer Hi-Bred Northern Europe, Buxtehude, Germany. According to Pioneer Hi-Bred, 414 units of seeds of this variety had been exported to the Czech Republic prior to the analysis by BVL.
The Ministry of the Environment (MoE), as the Czech Competent Authority, immediately informed the Czech inspection and control Authorities: the Czech Environmental Inspectorate (CEI, in charge of supervision of GMOs) and the Central Institute for Supervising and Testing in Agriculture (CISTA, in charge of seeds and feedstuffs). CISTA contacted the Czech branch of Pioneer and required appropriate measures to be taken. Pioneer recalled all the seed from circulation except for 105 units that had already been sown on 96.9 ha by 4 farmers due to the unusual early start of the 2009 season. In following months MoE and CEI gathered information and necessary documents to substantiate the decision to terminate the release and to order the farmers to take remedial measures according to the EU legislation. During the negotiations, Pioneer presented its own analysis from October 2008 that was negative for the 35S and tNos promotor and terminator at the 0.1 % detection level. Based on this result, Pioneer placed the seed on the European market at the end of 2008. On request of CEI, two additional independent analyses of the withdrawn seed were conducted in May and June 2009 in Germany, also with negative results, which confirmed the very low level of contamination. The economical aspects of this case were discussed with the stakeholders and the Czech Ministry of Agriculture.

II. How has your country addressed these LLP situations; if your country conducted risk assessments related to the environment, what scientific information formed the basis of the assessment of risk related to the environment?

All three events detected in the conventional maize have been authorised in EU for import and processing and have been used in a number of field trials, so their environmental risk assessment have been previously conducted and the conclusions were widely available. Therefore, due to the very low level of contamination, the Czech authorities considered the risks for the environment of this LLP case as negligible.
Taking into account all the above mentioned facts, discussions and documents, CEI issued the final decision ordering the farmers to destroy the variety PR39H32 plants and any maize in the surrounding fields within the distance of 200 m, by cutting them into small pieces before ripening of kernels. The resulting biomass was allowed to be used, under the special supervision, for silage feed directly at the farm or for biogas at the nearest biogas facility. After the harvest CEI inspected the fields and checked the disposal of the GM plants. The contaminated fields will be monitored for volunteers during the next season.

III. What lessons were learned?

a) The information system in EU set under the Directive 2001/18/EC works well. However, alert information about the presence of unauthorised GMO should be further completed by providing relevant documents, because the withdrawal of seeds and/or termination of the unauthorised release, as well as any remedial measures, if needed, may lead to significant economic consequences for operators. The Authorities therefore have to substantiate their decisions comprehensively.
b) As a consequence of the described LLP case, the Competent Authorities in the Czech Republic laid down a technical threshold value 0.1 % for reliability of GMO analysis in seed on national level, to provide for legal certainty of operators. The analysis will be conclusive if the contamination is detected on or above this level.
c) On EU level the Czech Republic will support the call for setting of labelling threshold(s) for GM traces in conventional seeds.

JAPAN

I. Has your country experienced LLP situations from commercial seed or commodities that can function biologically as seed?

Japan imports a large quantity of agricultural products, particularly commodities. For maize, self sufficiency rate is about 1 %, and almost 100% of importation is for FFP (Food, Feed and Processing) uses and only 0.01% (1－2 thousand tons) is used as seeds for cultivation. Soybean is in the same situation, self sufficiency rate is about 5 % and only 0.2% (7,000 tons) of the importation is for the seeding. Imported oilseed rape and cotton are exclusively for FFP uses and negligibly small amount is used as seeds for ornamental purposes.

For the imported seeds for cultivation, checking on LLP situation is important for its implication on the environmental biosafety aspects. This has been governed by two Acts in Japan.

First, by "Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms" which was established in 2004 in accordance with Cartagena Protocol (hereinafter referred to as "the New Act"). Under the New Act, 77 events of GM crops have been approved for environmental release as of December 2009, but no commercial cultivation of GM plants has been practiced except GM roses. LLP aspects of this New Act have been administered by the Plant Products Safety Division (PPSD), Food Safety and Consumer Affairs Bureau (FSCAB), Ministry of Agriculture, Forestry and Fisheries (MAFF) and by the Wildlife Division (WD), Nature Conservation Bureau (NCB), Ministry of the Environment (MOE). The FSCAB has five Plant Protection Stations in Japan as inspection implementing organizations.

Secondly, by "Plant Variety Protection and Seed Act" administered by the Intellectual Property Division, Agricultural Production Bureau, MAFF. The purpose of this Act is self-explanatory from the name of the Act. This Bureau has the National Center for Seeds and Seedlings as the inspection organization which can also function as a checking system of unapproved GMOs included in commercialized seeds.

For the imported commodities, particular attention is needed for its huge quantity totaling more than 20 million tons and for its environmental aspects through unintentional release to the environment by spillage. The environmental issues have been governed also by the New Act and administered by PPSD－FSCAB of MAFF and by WD－NCB of MOE. The issues on feed safety have been governed by "Act on Safety Assurance and Quality Improvement of Feeds" administered by Animal Products Safety Division－FSCAB of MAFF. The issues on food safety have been governed by "Food Sanitation Act" administered by Ministry of Health, Labour and Welfare (MHLW).

Under these frameworks implemented by several jurisdictions, no real case of LLP situation as defined in this OECD・WG project has so far been confirmed in Japan. However, somewhat related cases are presented in the following section, Question II, for the information of participating parties.

II. How has your country addressed these LLP situations; if your country conducted risk assessments related to the environment, what scientific information formed the basis of the assessment of risk related to the environment?

Not real but somewhat related cases of LLP confirmed in Japan are presented below, for seeds and for commodities separately.

(1) Situations occurred from Seed

1) CBH351 maize (StarLink)(publicized in 2000)

In US, StarLink was approved for feed and environment but not for food. In Japan, it was approved only for importation and distribution under the former Guidelines in respect of biosafety (Guidelines for Application of Recombinant DNA Organisms in Agriculture, Forestry, Fisheries, the Food Industry and Other Related Industries) before 2000. But it was not approved for feed and food. In response to the announcement from US on the contamination in the processed food, upon-importation inspections were implemented in Japan by the inspection organizations of MHLW and MAFF. Contaminations of StarLink were confirmed and the contaminated cargoes were ship-backed to US. The detection methods include lateral flow strip assay, qualitative PCR assay and quantitative ELISA. Approvals for agricultural application of StarLink both in US and Japan supported that this case was not an LLP situation.

2) Bt 10 maize (publicized in 2005)

Environmentally unapproved Bt10 had accidentally been cultivated and distributed in US. Upon-importation inspections were implemented in Japan by respective organizations of MHLW and MAFF, and contaminations were confirmed. The contaminated cargoes were ship-backed to US. The detection method was qualitative PCR assay. Lack of environmental approval neither in US nor in Japan supported that this case was not an LLP situation.

3) DAS 59132 maize (publicized in 2008)

Environmentally unapproved DAS 59132 had accidentally been cultivated and distributed in US. Upon-importation inspections were implemented in Japan by respective organizations of MHLW and MAFF, and contamination was confirmed. The contaminated cargo was ship-backed to US. The detection method was qualitative PCR assay. This was not an LLP case with the same reason as Bt 10 maize.

(2) Unintentional release of Commodities

1) Oilseed rape (publicized in 2006 and 2007)

Volunteer GM plants from the spillage were surveyed at the nearby areas of oilseed rape-importing harbours of Japan by PPSD, FSCAB, MAFF. Volunteer GM plants were found in low frequencies. However, they had already been approved for their environmental safety in Canada, US and Japan, and hence these cases were not LLP situation. Detection methods include lateral flow-method and PCR method.

2) Oilseed rape (publicized through 2004 to 2008)

Volunteer GM plants from the spillage were surveyed at the unloading areas, roads and riverbanks of oilseed rape-importing harbours of Japan by MOE. Volunteer GM plants were continuously found in low frequencies. However, they were derived from spillage of commodities which had already been approved for their environmental safety in Canada, US and Japan, and hence these were not the case of LLP. Detection methods include immunochemical chromatography and PCR method.

All of the cases presented here were not really LLP cases as defined in this OECD・WG project. Measures instructed were simple disposition or ship-back. Some scientific methods of detection were employed, but

assessment and determination of risk were not conducted. We do not have relevant elements of information to be presented in this section of Question II.

III. What lessons were learned?

It is generally recognized that two materials, the New Act and OECD Scale-Up document, could be considered to compose elements of information required for assessing environmental safety of LLP. In addition, we learned from our experiences presented in the Question II that it would be important for the importing country to receive from exporting country some earlier information. This will include; i) expected time of environmental approval and commercial cultivation of GM crops which are in the course of exportation, ii) specific information, if any, on environmental biosafety aspects of the events scheduled for exportation, such as crossability to the wild species in the importing country, iii) event specific detection methods originally established at the developers, etc.
Also, we realized the importance of strengthening capacity―knowledge and facilities―of treating LLP situations. Further, upon-importation inspections on seeds for cultivation have been implemented regularly since 2005, based on the New-Act. More recently in 2009, detailed Guidance Document was developed by FSCAB of MAFF, for the use at each Plant Protection Station. This includes inspection methods for CBH351 (Starlink), Bt 10 and DAS 59132.

IV. Other comments

Under the current system, LLP situation in any case is illegal for use as seeds in Japan. Commodities receive similar attention and treatment for consideration on spillage. On the other hand, it will be extremely difficult to completely control the occurrence of LLP situation. LLP will even increase in the future. Also, the Japanese importation of a large quantity of seeds and commodities will not change in the foreseeable future. Current simple measures such as disposition or ship-back may not be the only choice to manage the future occurrence of LLP in Japan. Probably, science-based, stepwise and practical considerations will be needed on elements which compose life cycle of imported seeds and commodities that may pose issues of LLP. We expect that the Questionnaire will be able to facilitate common understandings on the scientific elements of risk assessment and determination towards promoting measures to LLP situations.

KOREA

I. Has your country experienced LLP situations from commercial seed or commodities that can function biologically as seed?

Environmental risk assessment of genetically modified organisms (GMOs) is mandatory under the "Laws on the Trans-boundary Movement and Living Modified Organisms" (LMOs) that took effect on 1 Jan 2008. The notification under the LMO Law indicates that the acceptable threshold level for LLP situation is 0.5% under the condition of submitted detection method and standard material. This threshold however, does not apply to those used as seeds but only to those used as feeds. Likewise, under the "Food Sanitation Law", safety assessment of foods derived from GM crops is also mandatory. There is 'zero tolerance' for LLP for unapproved GM foods. Korea has no experience yet on the LLP situation for unapproved GM seeds or commodities in the context of environmental safety. However, there have been some accidental releases of some GM commodities (maize, cotton) into the environment in areas near feed processing plants. The amount of spillage through accidental release was very small. All GM commodities that are unintentionally released were already approved for environmental risk assessment.

II. How has your country addressed these LLP situations; if your country conducted risk assessments related to the environment, what scientific information formed the basis of the assessment of risk related to the environment?

There is no case of LLP situation that is related to question I in Korea. But the accidental release of GM commodities could provide some insights for addressing LLP. Regulatory agency for risk assessment and management of GMO is classified according to its function in Korea. In relation to this question, the Ministry of Food, Agriculture, Forestry and Fishery (MIFAFF) is the lead institution in Korea that deals with GM seeds and agricultural commodities such as feeds. MIFAFF has however, devolved the risk assessment for agricultural GMOs to the Rural Development Administration (RDA). In the case of LMO-FFPs, RDA's review focuses on the effects of the unintentional release to agricultural environment. RDA's risk assessment is carried out according to the principles and approaches of the international organizations such as UNEP and OECD. They are science-based, comparative and case-by-case approaches. In order to address unintentional release, the regulatory authority requires preferably the information on reproductive biology, such as gene flow in the context of GMOs release to the environment, as well as the detection methods used. Similar information may be required for addressing the occurrence of an LLP situation.

III. What lessons were learned?

In terms of the unintentional release of GM commodities, Korea learned that the information on environmental risk assessment is very vital to addressing an LLP situation. Proper risk management of an LLP or unintentional release starts from the gathering of accurate information. Key information for identification of LLP situation is the molecular characteristics of GM crops, such as an event-specific detection method. Since the acceptable LLP threshold level is 0.5%, Korea needs to have a precise quantification method required to better assess and decide for any LLP situation. Korea also recognizes the important roles of the industry organizations such as seed producers, biotechnology providers, bulk handlers and others in providing the necessary data to conduct possible risk assessments of GM crops as well as their detection methods.

MEXICO

Introduction

Mexico regulates different activities with Genetically Modified Organisms (GMO's) according to the Biosafety Law of GMO's (LBOGMs). Mexican legislation establishes different regulatory procedures according to the intended use and according to the GMO under evaluation. Different competent authorities are involved in the decision making process under a separated approval system. The Secretary of Health regulates and grants Authorizations for GMO intended for direct use as food or feed, or for processing (FFPs). Additionally, two Secretaries are involved in the regulation of GMO's intended for intentional introduction into the environment; these are the Secretary of Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA) and the Secretary of Environment and Natural Resources (SEMARNAT). Depending on the use to be given to the GMO under evaluation, one of these Secretaries is in charge of the decision making process that could lead to issuing a permit. In relation to these different approval systems, there could be different cases of Low Level Presence (LLP), according to the scope of this document that includes "to address the situation of low level presence in commercial seed and/or commodities of transgenic plant material that have received approval and been commercialised in at least one country but have not received approval (authorisation) in the country of import." In our case it could be that Mexico has given an authorization for commercialization but has not granted a permit for environmental release.

The different situations of LLP that can occur are: 1) presence in the food chain of a GMO that is not authorized in Mexico for FFP; or 2) a GMO released to the environment without the corresponding permit, this could happen 2.1) with GMO's that are commodities that have been authorized for FFP, that function

biologically as seed, and are unintentionally released into the environment or intentionally used for planting and 2.2) at least there are two different situations (see below) with GMO's that correspond to commercial seed for intentional planting but that lack a permit.

The first situation corresponds to GMO's that are within the scope of the Codex Alimentarius, which focuses on food safety and not on environmental safety. The OECD Questionnaire relates to environmental safety, so the first case is not considered further in the present response.

Most of the situations referred to above represent cases of non compliance with the BLGMO and require the adoption of measures bound to enforce compliance of the regulation; some of these measures could include the application of administrative and penal sanctions. The case numbered 2.2 refers to commercial seeds for intentional planting without a permit under the LBOGMs and has two scenarios. One is when the commercial seed is GM and the corresponding permit was not requested giving rise to an illicit planting (since these cases represent high levels of presence they are not commonly recognized as LLP); and second situation occurs when the GMO is conventional seed that does not require a permit for its planting but that has LLP of GM seed.
The answers to the Questionnaire include four situations or cases that have been documented in Mexico, but not all these cases represent situations of LLP as defined in the OECD ENV/JM/BIO(2009)14 document. We included them in the response since they represent experiences in dealing with unapproved GMO's.

I. Has your country experienced LLP situations from commercial seed or commodities that can function biologically as seed?

Case 1 - Commodities
Mexico has faced three incidents of unintended release to the environment of commodities that functioned as seed; these resulted from train derailments resulting in cargo spills. Since the grains transported in these trains are viable, once in the ground and with adequate humidity they germinate and could grow and become established plants. Grains that enter the country as commodities should be authorised for FFP but do not need a permit for their release to the environment and therefore they cannot be legally planted. This situation may not represent a case of LLP, depending on the considered commodity; this situation may or may not fall under an established threshold. In the specific case of maize, commodity shipments could be assumed as above the threshold level for LLP in practically all cases, although some events could occur at low levels. Hence, spillage of a commodity, and its subsequent germination, **does not necessarily represents a case of LLP**; it is seen as an accidental release of a GMO that has been approved for use as food and for processing but not for environmental release.

Case 2 - Commodities
Mexico has faced a case of unintentional planting of maize grains authorised for FFP that are supposed to have entered the country as commodities. This case has been associated with the lack of knowledge of the kind of grain/seed (GM) and also to agricultural practices still predominant in traditional systems that include experimentation with new varieties, and selection of seed from each harvest for use in subsequent cultivation cycles. **Depending on the level of presence** of a GMO in the commodity shipped **and** also **on the ratio** planted (commodity/total planted) by a farmer; **this case could be classified as LLP**. Since farmers experiment with new seeds, we could assume that although the level of presence of GM in a shipment could be high (at least in the case of maize shipments), in many cases the ratio planted would be low and could reflect situations that qualify as LLP.

Case 3 - Commercial seeds
Mexico has also faced situations in which the presence of GM plants have been detected for parcels cultivating GM maize without the corresponding permit. For these cases the detected level was high and

hence was not treated **nor considered as a situation of LLP**. These situations have been treated as illegal releases of GMO into the environment and are associated with biosafety response measures as well as administrative procedures for the application of the corresponding sanctions.

Case 4 - Commercial seeds
This case has been documented in Mexico with the detection of LLP of GM seed in conventional maize seed, this detection could occur previously to the planting of the seed; however the documented case occurred after the seed was planted. This is a clear **situation of LLP** since the level of GM seed in non GM seed was below the threshold established.

II. How has your country addressed these LLP situations; specifically what scientific information formed the basis of the assessment of risk/safety related to the environment?

Case 1 - Commodities
Response measures: Following the notification of the incident, the competent authority corroborates the presence of GM grains and proceeds to establish control and mitigation measures directed to bringing the situation back to compliance. For example these measures have included isolating the area where the incident occurred, recovering the grains and setting up a monitoring program directed to eliminate voluntary plants; these measures are accompanied by inspections to corroborate compliance of biosafety measures. In these cases it has not been necessary to carry out a risk evaluation, since the response will always imply the application of control and mitigation measures that aim to the restoration of the initial condition, previous to the accident, and to bring the situation back to compliance.

Case 2 - Commodities
Response measures: On a case by case approach, monitoring programs were established to determine levels of presence. According to the detected frequencies and the events identified, an *ex post* risk assessment could be applied to determine mitigation measures associated with the presence of GM plants. Additionally, the response measures have included the design and application of surveys in the regions where this situation was detected. The aim of these surveys, applied to small farmers in the affected location and surrounding areas, was to gather information that would allow the identification of possible adverse effects to the environment and agricultural production. Moreover, key stakeholders were identified, management measures were agreed upon, and risk communication was done to enforce legal compliance.

Case 3 - Commercial seeds
Response measures: Once the presence of GM plants in the fields is detected and the competent authority corroborates the absence of the corresponding permit for the environmental release, necessary measures are taken aiming to enforce compliance. These measures have included confiscation of the product to ensure that it is not used for unauthorized activities (planting). In these situations, administrative sanctions apply to those who violated the law. Additionally a risk assessment is carried out to determine if any environmental damage has occurred following the illegal release of the GM plants; on a case by case basis, this could result in the establishment of mitigation and restoration measures as well as in penal sanctions to the guilty parties.

Case 4 - Commercial seeds
Response measures: In this situation the level of presence of GM seed in non GM seed is established. Once it is clear that the percentage is below the actual standard established for genetic quality (for the case of maize the qualification rule is 2%), then it is clear that this situation is under the Federal Law of Seed Production, Certification and Commercialization (LFPCCS) and no sanction proceeds from the LBOGMs. To prevent possible future cases of non compliance of the LBOGMs, derived from a LLP situation, the competent authority could identify and stipulate management measures, for example to ensure that the

product of these crops is directed for the authorized use and that it will not be saved and re-planted (which is the common practice in these agricultural systems where farmers buy certified seed each planting season). If the identified levels do not correspond to the standards, then the situation does not correspond to a LLP case and would be treated according to the LFPCCS with the corresponding issues related to the private contracts among seed seller and buyers and would have to be in accordance also to the LBOGMs.

III. What lessons were learned?

Several lessons have been learned from facing different situations of presence of GMO's in the environment without their corresponding permit.

In Case 1 situations, (accidental release) the prompt response from the stakeholders in notifying the competent authority following cases of accidental release, as well as the coordinated response of the authorities to facilitate, enforce and verify the application of control and mitigation measures, has resulted in reinforcing the importance of establishing the appropriate communication channels, and of maintaining this communication.

The common practice of small farmers associated with traditional agriculture, "to experiment" with different grains and seeds from which they sometimes, ignore their origin or regulatory status, has being identified as a situation that needs the attention of different authorities. To avoid situations described in Case 2, the importance of actions related to communication has being highlighted. To inform the involved communities has been a challenging task, particularly in the case of certain crops in Mexico like maize. This is because on the one hand, there is the need to ensure that small farmers avoid the use of grain or seeds that inadvertently present GM material; and on the other hand, there is the recognition of the importance of maintaining traditional farming systems, that include experimentation by farmers, given that these systems contribute to the generation of varieties adapted to different local conditions. Communication with these small farmers needs to emphasise the fact that their practices can be preserved as long as they experiment with local seeds from landraces and not from seeds or grains of unknown origin or nature.

In order to avoid situations like the one described in Case 3, communication also has been identified as a key issue, and accordingly implemented by the competent authority. In this case, emphasis has been placed on informing farmers of legislation that applies to planting GM crops. The main target groups for these workshops are big producers mainly in the North of the country willing to use the new technologies. The main message to these farmers is that the planting of GM crops is regulated by the LBOGMs, which establishes that obtaining a permit for the environmental release of these crops is required prior to their use as seeds and that this permit must be requested from the competent authority by the technology developers.

Following the situation of detecting LLP of GM seed in non-GM commercial seed, a way to confront it, has being identified based on the experience related to the application of the regulation related to seed certification. In this situation it is important to emphasize that the intention is the planting of conventional (non-GM) seed that is regulated by the LFPCCs and not by the LBOGMs. (The intentional planting of GM seeds is regulated by both legislative frameworks). Additionally, monitoring has an important role in providing an incentive for, and for verifying compliance with the regulation of certified seeds. Furthermore; communication with stakeholders is also a key issue, in this case among the seed production industry and certification bodies, in order to reach agreements related to the real capability to comply with varietal purity standards.

IV. Other comments

Since some of these situations are still ongoing or could re-occur, the learning process continues. Response actions in general are also related with incidence or reiteration of the non compliance situation. Capacity building of Government official has allowed the response actions.

THE NETHERLANDS

Replies from the Netherlands Ministry of Housing, Spatial Planning and the Environment (further refered to as 'Ministry of the Environment').

In the Netherlands, issues of LLP are handled by two authorities, dependent on the source of LLP.

- Environmental safety issues concerning LLP of live GMOs are handled by the Inspectorate of the Ministry of Housing, Spatial Planning and the Environment.
- Food and Feed safety issues concerning LLP of GMOs or derived products are handled by the Food and Consumer Product Safety Authority.

These replies refer only to handling of LLP by the Ministry of the Environment.

I. Has your country experienced LLP situations from commercial seed or commodities that can function biologically as seed?

Yes. All cases of LLP have been in 'commodities that can function biologically as seed'. We do not have experience with LLP in seed lots.
On most occasions the occurrence of LLP came to our attention through reports from other Members States, through the EU, or from third parties, including producers and importers.
Routine samples are taken randomly from imported lots of oilseed rape and maize, as commodities that have the highest chance of containing unapproved GM varieties[18]. No LLP was found. On one occasion, an EU approved GM variety was found that was above the threshold for labeling. Because this was a case of an approved variety, this was not a case of LLP.

II. How has your country addressed these LLP situations; if your country conducted risk assessments related to the environment, what scientific information formed the basis of the assessment of risk related to the environment?

The EU requires a common approach to deal with LLP. There is 'zero tolerance' for LLP of an unapproved GMO. In cases of LLP, like the LLRICE601[19], a Commission decision on emergency measures has been taken, that prohibits further import of lots containing the specific GMO.
After discovering an LLP situation, the immediate reaction depends on the case, and will be proportional with the situation. In principle measures will be taken to prevent dispersal of commodities (or seed lots) with LLP of unapproved GMOs. If dispersal has already occurred when the LLP situation is discovered, a decision will be taken on redress of the dispersal, proportional to the risks involved with the dispersal and the economic and social burden of recalling the dispersed GMOs.
Therefore, in the decision on proportional action, an assessment of the risks involved is required, that is fast. In this situation the availability and exchange of data is of the utmost importance.

[18] See also Potential environmental introduction of unapproved GM crop species in the Netherlands. T.W. Prins, C.C.M. van de Wiel, G.A. Kleter, O. Dolstra, E.J. Kok, RIKILT - Institue of Food Safety, PRI -Biodiversity and breeding; the Netherlands
http://bch.cbd.int/database/record-v4.shtml?documentid=100882

[19] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:244:0027:0029:EN:PDF

The nature of the genetic modification must be clear in terms of molecular characterization, expression of the transgenes and biological functionality of the gene products. It must be clear if and by which Competent Authority the GMO that causes the LLP has been approved for environmental release (in field trials) or for market release as food or feed or for cultivation. Risk assessments that have been used to underpin the approvals of environmental releases, should be available.

III. What lessons were learned?

The most important lesson is the importance of collaboration and of (international) information sharing.
Collaboration is essential in the tracing of cases of LLP. In that respect, the Inspectorate of the Ministry of the Environment is seeking collaboration with the Dutch Customs.
International information sharing is vital for conducting the type of quick scan (first approach) and more extensive risk assessment that is necessary for taking well informed decisions on proportional action in cases of LLP.

NEW ZEALAND

I. Has your country experienced LLP situations from commercial seed or commodities that can function biologically as seed?

Regulation of GMOs in New Zealand
The Hazardous Substances and New Organisms Act, 1996 (HSNO Act) has been in effect since July 1998. The purpose of the HSNO Act is to protect the environment, and the health and safety of people and communities, by preventing or managing the adverse effects of hazardous substance and new organisms.
The HSNO Act prohibits any new organism, including a GM organism, from being imported, developed or released in New Zealand unless the organism has been approved by the Environmental Risk Management Authority (ERMA). The Authority (the decision making body) of ERMA New Zealand makes decisions on applications to import, development, field test and release GMOs in New Zealand, after evaluating the risks, costs and benefits of the application.
The Biosecurity Act 1993 provides the legal basis for excluding, eradicating and effectively managing pests and unwanted organisms (inlcuding GM organisms) in New Zealand.
The Ministry of Agriculture and Forestry (MAF) implements and enforces the Biosecurity Act, and enforces the provisions on new organisms in the HSNO Act. MAF requires certain imported seed consignments to be tested for the presence of unapproved GM seeds under a specified seed testing protocol.
Food, medicines, and agricultural compounds that are, or contain GMOs are subject to dual regulation in New Zealand. In addition to the HSNO Act, The Food Act 1981, the Medicines act 1981 and the Agricultural compounds and veterinary medicines Act 1997 also govern the safety, quality and efficiency of these products.

New Zealand and Australia have a joint food standards system regulating the sale of food with regard to composition and labelling standards. Food Standards Australia New Zealand (FSANZ) is the bi-national agency that is responsible for developing standards under the joint system. Before any GM food or food ingredient can be sold in New Zealand, it must undergo a case-by-case pre-market safety assessment and be approved by Food Standards Australia New Zealand (FSANZ). The FSANZ approval must then be cleared by all Australian and New Zealand Ministers responsible for food.

Approvals for GMO crops in New Zealand
In New Zealand currently no GM crops are grown in New Zealand (none have been approved) and New Zealand has a zero tolerance policy for unapproved GMOs. Therefore, in New Zealand there are no examples of LLP occurring as a result of intentional planting.

Examples of LLP in New Zealand

New Zealand has experienced a number of LLP incursions with imported sweet corn and maize seed since 2000. The table below summarises these incursions and the response taken.

Date	Scenario and action taken
2006	Two consignments of maize seeds entered New Zealand during October and November 2006 with accompanying genetic modification (GM) testing certificates which indicated conflicting test results. The GM gene construct was confirmed as *Round Up Ready* corn, which is approved by Food Standards Australia, New Zealand (FSANZ) for use as a human food. MAF required that all crops were mechanically destroyed (by power harrowing) and some were treated with herbicide to ensure 100% crop destruction. The offshore seed supplier admitted an error in their seed inventory system had led to the non-contracted seed being sent to New Zealand growers. They reimbursed growers for the cost of the seed and some of the other costs incurred. MAF covered costs associated with the response and post-harvest field monitoring for volunteers. In the New Zealand climate maize and sweet corn seeds have poor persistence in the soil, and it is uncommon for them to survive in the soil through the winter period to germinate in spring the following year (though it occasionally occurs in Northland and Auckland in drier sites).
2005	Quality Assurance tests performed on imported maize suggested the presence of GM seed. MAF commissioned and paid for testing to determine the level of presence and the construct(s) involved, and discovered that the GM presence was due to the presence of GM soy flour which had previously been stored in the same holding area.
2004	An audit of a testing laboratory in the USA indicated some potential issues with reporting of test results. Upon re-testing, some maize seed was found to be positive for GM. The construct was already approved by FSANZ for human food. In this example MAF paid for all testing costs, and seed companies supplied seed where available from leftover, unplanted stock seed for testing. Seed lots testing positive were traced to the field. The crops were at full maturity and were removed from the field through normal harvesting methods, with additional procedures to clean down machinery on the field. Grain was dried, stored, and devitalised (by cracking) and eventually sold as animal feed. MAF made *ex gratia* payments to growers to cover costs of removing the crops from the fields. Field inspections were conducted to check for volunteers and herbicide was applied to some emerging volunteers in the harvest year.
2003	GM presence was discovered in sweet corn product exported from New Zealand to Japan. Upon detection, the product was traced back to where it was grown, and testing of crops in surrounding fields was conducted. No additional GM sweet corn was detected. In this case the testing costs were borne by MAF and post-harvest field inspections for volunteers were conducted and fields treated (through cultivation followed by herbicide application) as required.
2002	Quality assurance tests showed the presence of GM maize in crops harvested in Gisborne and Pukekohe earlier in the year. The grain producing companies paid for the testing of the crops. The grain was bound for animal feed, and the GM event detected was one that was approved for animal feed. As such the grain could have been devitalised (through cracking) and sold for animal feed, but the company decided to destroy the grain by incineration at their own cost.
2000	Quality assurance tests showed inconclusively a low level presence of GM sweet corn seed. Based on a preliminary assessment that the possible risks to human health were negligible and the possible environmental risks were very low, the Government took no further action with regard to this particular shipment. Testing costs were paid by MAF.

II. How has your country addressed these LLP situations; if your country conducted risk assessments related to the environment, what scientific information formed the basis of the assessment of risk related to the environment?

Testing for LLP

As no GM crops are approved to be grown in New Zealand and New Zealand has a zero tolerance policy for unapproved GMOs, it is illegal to knowingly import GM seeds in any quantities into New Zealand. Importers must therefore take steps using due diligence to ensure that their shipments do not contain unapproved GM seeds.

When the first cases of LLP were detected there were no specific procedures in place to test for the presence of GM material at the border. However, there are now procedures in place to allow sampling and testing for LLP of GM material for oil seed rape, soy bean, corn/maize and lucerne/alfalfa. MAF also monitor for new GM crops that might need to be tested for.

The MAF protocol for testing imported maize and sweet corn seed for GM presence is one of the strictest in the world. The protocol gives a high level of confidence (95 percent) that the inadvertent presence of one GM seed in 1000 seeds will be detected. MAF accredits offshore laboratories to test seed samples according to the method in the import protocol.

If the tests show that a consignment of seed contains GM material, the importer will be given the option to reship or destroy the consignment.

Dealing with LLP

The decision on how to deal with LLP situations is taken on a case-by-case basis. In New Zealand currently no GM crops are grown in New Zealand (none have been approved) and New Zealand has a zero tolerance policy for unapproved GMOs. Therefore, the usual response has been to remove from the environment the unapproved GMOs.

The way the LLP situations have been dealt with in New Zealand has depended on when the situation was discovered.

- Detection soon after planting has resulted in official crop destruction;
- Detection when crop is ready for harvest has led to crop harvest and devitalisation;
- Detection post-harvest - companies have vountarily destroyed in some cases.

  MAF implements and enforces the Biosecurity Act, and enforces the provisions on new organisms in the HSNO Act. If there is a LLP incursion MAF is therefore responsible for the risk analysis, developing and implementing a response and taking any enforcement action.

  The initial response is immediate risk management to limit the potential risk. Once the initial response has occurred then a risk analysis is undertaken.

The risk analysis is based on:

- The importance of the risk organism in terms of its potential impact on the environment, the economy, health and society and community.
- The complexity of the response, based on the distribution of the organism, the ability for it to establish and spread, the ability to detect the organism, the methods available for control or eradication, and the availability of resources.
- The barriers to success / opportunities to effectively managing the risks posed by the organism for example, the regulatory status of the organism, stakeholder and public concern and support, legislative barriers to taking action and whether the organism is associated with a controllable pathway.

Following the risk assessment a risk management plan is developed and implemented and then any enforcement action will be taken.

III. What lessons were learned?

The problem of managing low levels of unapproved genetically modified (GM) seeds unintentionally present in consignments of non-GM seed for sowing was addressed in depth by the New Zealand government's Local Government and Environment Select Committee.
In October 2002 the Committee began an inquiry into allegations that corn, containing adventitious unapproved GM seed, was planted in 2000. The terms of reference for the inquiry focused on establishing the facts of what occurred and the appropriateness of the responses by public authorities.
The Committee provided the following recommendations related specifically to low level presence (LLP) of GM material:

- The Committee proposed that a new process be developed for the management of future incidents where a very low level of GM content is detected following the importation of seeds that have passed the relevant border testing protocols for GM.
- The Committee considered it unfair that, having complied with the stringent testing regime, seed importers and growers remain at risk of being found in breach of the law if later, post-border tests find small levels of unapproved GM material in their crops.
- The Committee proposed that, if seeds have passed the border testing protocols, then the resulting crops should be allowed to be grown, harvested, and consumed, provided the GM variety detected has been approved for consumption by New Zealand or comparable overseas jurisdictions, and is not from a variety engineered to produce industrial chemicals or pharmaceuticals.

Government response to proposals for change
The government considered the Committee's recommendation had considerable merit but that they also raised a number of complex issues that required further consideration. Work in this area is ongoing, however, no regulatory changes have been made in response to the recommendation at this time.

IV. Other comments

In preparing for the situation where New Zealand does begin to grow GM crops MAF use the following publications containing best practice principles for segregation of GM and non-GM seeds which can be applied on a crop-by-crop basis:
http://www.misa.umn.edu/vd/GMOlegal-21_web.pdf
http://www.afaa.com.au/booklet/AFAA_Coexistence_Bklet_FINAL_Jan06.pdf
MAF also maintain a register containing the locations (and location controls) of conditionally released crops (and other organisms where practicable). However, MAF are currently working on replacing this register with Neighbour Notification/Agreement templates as this is likely to be a better means of communication between GM and non-GM neighbours.

NORWAY

I. Has your country experienced LLP situations from commercial seed or commodities that can function biologically as seed?

We have no experience from LLP situations from commercial seed. We have done some investigations in seed lots of maize and oilseed rape but no findings.

We have some experience from LLP situations from commodities that *may* function biologically as seed and could fall under the scope of this project and is reported hereunder.

In the scope of routine samples taken randomly during the years of 2004-2009 from imported lots of soy, maize and oilseed rape for use as food and/or feed, we found the following GMO events of LLP:

- RR soy, unique identifier MON-Ø4Ø32-6

- NK603 maize, unique identifier MON-ØØ6Ø3-6
- MON 810 maize, unique identifier MON-ØØ81Ø-6
- Bt11 maize, unique identifier SYN-BTØ11-1
- TC 1507 maize, unique identifier DAS-Ø15Ø7
- MON 863 maize, unique identifier MON-ØØ863-5

In addition, we have found CDC Triffid/FP967 linseed, unique identifier CDC-FLØØ1-2, in the food chain. The background for this finding was information from other countries in Europe through the Rapid Alert System for Food and Feed (RASFF).

II. How has your country addressed these LLP situations; if your country conducted risk assessments related to the environment, what scientific information formed the basis of the assessment of risk related to the environment?

The GM soy and GM maize:
As the amount of the GMO discovered was very low, and the risk for germinating, establishing and outcrossing in the Norwegian nature is from zero to very low, no specific environmental management measures were applied.

The GM linseed:
As the GM linseed was not approved in Norway, the relevant food products were withdrawn from the marked.

III. What lessons were learned?

In the case of the linseed, the Rapid Alert System for Food and Feed (RASFF) showed to be a useful tool for rapid exchange of information about findings of non approved GMO in the European Union and Norway.

TURKEY

I. Has your country experienced LLP situations from commercial seed or commodities that can function biologically as seed?

Not Yet. Regulatory Oversight in Biotechnology to the situation of low level presence (LLP) of commercial seed and/or commodities of transgenic plant material that have not received approval (authorization) in our country.

II. How has your country addressed these LLP situations; if your country conducted risk assessments related to the environment, what scientific information formed the basis of the assessment of risk related to the environment?

Not Yet.

III. What lessons were learned?

Capacity building and collaboration is needed on risk assessment and risk management.

IV. Other comments

Even though full risk assessment has not been done yet but, regarding the experience are gained until now, following can be useful for to support risk management further information multi country projects considering different environmental conditions.

The main objectives of this issue could be:

a) Detailed information on Environmental Biotechnology, bioremediation and Molecular Characterization.
b) To produce, advance, complete other existing projects.
c) Development of safe technology.

THE UNITED STATES

I. Has your country experienced LLP situations from commercial seed or commodities that can function biologically as seed?

Typically, the LLP situations within the United States to date have not been as described in the OECD Questionnaire (ENV/JM/BIO(2009)14); *i.e*., low level presence (LLP) in commercial seed and/or commodities of transgenic plant material that have received approval and been commercialized in at least one country (outside the United States) but have not received approval (authorization) in the country of import (within the United States). However, the United States has had experience with several LLP situations with transgenic plant material that had not been fully approved for commercial release and use in the United States but which nonetheless entered the commercial seed production system and was released into the environment. These situations involved corn and rice modified to express either the insecticidal protein from the bacterium *Bacillus thuringiensis* (Cry proteins) or the enzyme PAT (phosphinothricin acetyltransferase) for resistance to the herbicide phosphinothricin. The United States offers its experience from these situations in the hope that it will provide some useful parallels to other countries.

In most of the LLP situations in the United States, the owners of the unauthorized plant material notified the United States Government about the occurrences of low level presence of GE material in commercial seed production systems. The agencies responsible for regulatory oversight of the GE material scientifically evaluated the risk of each incident, recognizing that the exposure to the environment was low, and evaluated potential hazards given the low level of the unauthorized material in commerce[20]. In all cases of commercial seed and resulting commodity production, the United States government was satisfied that no safety concerns resulted from these LLP situations.

In the typical process of plant breeding, whether with conventional or GE plants, there is some potential for low levels of unauthorized genes and gene products to occasionally move into commercial seed and grain that enter commerce. Recognizing this fact, the United States Government, in a 2002 notice[21], described proposals and approaches directed at "further reducing in commercial seed lots, bulk commodities, and

[20] It should be noted that one other well-known situation, involving StarLink corn, was not in fact an LLP incident for the United States because the product was approved for growing under certain restricted circumstances only for use in feed within the United States. StarLink corn was grown on a large acreage and some of it entered the US human food supply. As the StarLink event could not be shown to be non-allergenic, measures were taken to remove it from the human food supply or divert it to safe approved uses.

[21] *Proposed Federal Actions to Update Field Test Requirements for Biotechnology Derived Plants and to Establish Early Food Safety Assessments for New Proteins Produced by Such Plants: Notice*. (Office of Science and Technology Policy, 2002)

processed food and feed the likelihood of the occurrence of intermittent, low levels of biotechnology-derived genes and gene products from crops under development for food or feed use until all appropriate safety standards have been met".

Subsequently, the Environmental Protection Agency (EPA) and the US Department of Agriculture's Animal and Plant Health Inspection Service (USDA-APHIS) published guidance and a policy, respectively, clarifying their existing approaches to addressing environmental safety in situations of LLP in commerce.[22] These documents transparently describe to researchers, developers, and the general public how the agencies with responsibility for environmental safety of genetically engineered organisms within the United States would approach evaluating risk in an LLP situation.

EPA Guidance on Small-Scale Field Testing and Low-Level Presence in Food of Plant Incorporated Protectants (PIPS) (2008)
http://www.regulations.gov/fdmspublic/component/main?main=DocumentDetail&o=090000648026cbd2

USDA-APHIS APHIS Policy on Responding to the Low-Level Presence of Regulated Genetically Engineered Plant Materials (2007)
http://www.aphis.usda.gov/brs/fedregister/BRS_20070330a.pdf

The EPA pesticide registration notice summarizes, explains, and provides guidance regarding compliance with existing rules under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA) in regard to Plant Incorporated Protectants (PIPs) and expectations of environmental use of PIPS that have not been reviewed with regard to food and/or environmental safety and whether there is a the potential for the PIP entering the food supply. Even if the LLP event is safe with no adverse human health or environmental adverse consequences, EPA may levy fines or other penalties for violations of the pesticide regulations.

USDA-APHIS' published policy on low-level presence of regulated genetically engineered (GE) plant material describes how the agency responds to such occurrences in commercial seeds and grain. The policy is to respond to these occurrences with actions appropriate to the level of risk and warranted by the facts in each case. The agency will always initiate an inquiry whenever regulated materials are detected in commercial seeds and grain to evaluate any risk, to determine the circumstances surrounding the release and to determine what remedial and/or enforcement actions may be required. If USDA-APHIS determines that an occurrence involving regulated GE plant material would result in the introduction of material that could pose a risk to plant health or the environment, it will take appropriate steps to mitigate that risk using its authority under the Plant Protection Act. In cases in which the occurrence of GE plant material poses no risk to plant health and the environment, USDA-APHIS may not take remedial action. This could include occurrences involving a plant that qualifies for USDA-APHIS' notification process, which is used for those plants that present minimal risk, as well as if the GE plant is similar to another GE plant that has already been deregulated, or shown to not pose a plant pest risk. USDA-APHIS will carefully assess the GE plant material, including the plant genotype, the introduced genes, and any proteins produced. Even if USDA-APHIS determines that no remedial action is necessary to mitigate the low-level presence of regulated GE material, the agency can still take legal action for violations of the agency's biotechnology regulations.

[22] Other procedures relating to food safety in LLP situations have also been described, but they are outside the scope of this questionnaire.

II. How has your country addressed these LLP situations; if your country conducted risk assessments related to the environment, what scientific information formed the basis of the assessment of risk related to the environment?

To date, the LLP situations in commercial seed in the United States have allowed for relatively straight-forward case-by-case scientific assessments of risk to the environment and human health Basic determination of safety was made in general by comparing the LLP plant to previously authorized transgenic plant products, particularly comparing the constructs and specifically evaluating the protein(s) likely expressed and the similarity of such expressed proteins to proteins expressed in previously authorized plant lines. Once the unauthorized LLP plant material was shown to be similar to existing authorized plant products, much of the information from previous determinations was available and the previous evaluations and conclusions of safety directly applicable. The US government also took into account the low exposure associated with each case.

Scientific information evaluated to determine how similar the LLP plant material was to existing authorized products has included the available knowledge and experience with the same or similar plant species, the same or similar gene/protein, and the same or similar phenotype. The assessments took into account the genes inserted, previous reviews of similar GE plants and constructs, including those for food safety. Familiarity with the crop, trait and environment were key factors for the assessment, based upon the protein(s) expressed and the several crops in which these particular proteins have been incorporated previously.

Molecular characterization of the unauthorized LLP plant material allowed for verification of the identity of the unauthorized plant material and whether proteins produced were similar to proteins found in authorized plant lines. The Cry and PAT proteins expressed by unauthorized events to date have essentially been identical to those expressed by similar authorized events. The EPA determined that the proteins produced by unauthorized PIP-containing events were identical to those produced by events authorized for use in the United States, making them "sister lines", from the same or similar constructs. This was not unexpected since the unauthorized and authorized plant lines had been developed at the same time to express the same phenotype.

When available, supporting information on the whole plant was also evaluated. Field test data from regulated field trials comparing the authorized and unauthorized plant lines helped establish how the plant line grew and interacted with the environment when compared to non-transgenic lines.

In some cases, more data from the responsible company was requested. Such information has included that related to molecular characterization, expression level in plants and experience with related or sister authorized plants, including verification of the phenotype of the unauthorized plant lines. The PAT and Cry proteins have all undergone extensive review with subsequent commercialization over the past 20 years by the US government in a variety of crop plants. The origin, history of development and safe use, the genes and proteins produced and the functioning in plants of the other genes, including regulatory elements and markers (ampR, ori, NOS, 35S CaMV), have been well documented in existing decision documents by the regulatory agencies.
Additional supporting information came from the scientific literature and other technical documents like the OECD documents.

In the United States, for the LLP situations in seed to date, the unauthorized plant lines and authorized products were very similar. Furthermore, the unauthorized plant lines met the criteria used for those GE

plants that present minimal plant pest risk[23] and the proteins were determined to have no adverse human health or environmental consequences. As a result, the United States government has been able to determine that the low level presence of the unauthorized events in seed in the environment had acceptable safety profiles. This conclusion was based on the review of available scientific data, the limited amount of the unauthorized event in the environment, and the close similarity of the unauthorized plant lines to the authorized plant lines which had cleared regulatory review. The documentation of past decision(s) by the US government is available on the United States Regulatory Agencies Unified Biotechnology Website (http://usbiotechreg.nbii.gov).

Additional support for the conclusions of safety of the PAT and Cry proteins in plants also came from authorizations from other countries in addition to those in the United States. Depending upon the case, there may have been food, feed, and environmental clearances in several other countries.

III. What lessons were learned?

To the US government, in general these cases suggested the importance of: (1) having sufficient information on hand to perform a rapid analysis of risk, (2) routine testing by the seed company of their parental lines even when no transgenic event is suspected to be present, and (3) maintaining and having access to appropriate records that enables tracking of LLP events through the production chain to ensure appropriate recall and in determining which lines might contain an unauthorized event, including those that might be below the level of detection.

Causes of the LLP situations were varied and included lack of quality control (mis-labeling of bags of seed) or pollen flow in seed production nurseries. However, in some cases, causes could not be determined. As a result of several LLP situations, USDA-APHIS published its policy regarding LLP in regulated plant materials, recognizing that rare occurrences may be unavoidable with the expansion of GE crop research, development, and use and may result in unauthorized introductions of regulated materials in commercial seeds and grain. This policy explicitly recognized that plant breeding may occasionally result in low-level mixing of genes and gene products from unintended plant sources and that these occurrences can result from natural processes such as the movement of seeds or plant pollen, or human mediated processes associated with field-testing, plant breeding, or seed production. As a consequence, determination of similarity to previously evaluated plant material was identified as a pragmatic way of evaluating safety efficiently in order to deal with the situation. Once safety was established, remediation focused upon restoring compliance with regulatory authorities.

IV. Other comments

In the LLP situations in the United States relevant to this questionnaire, risk assessments allowed the determination that no increased risk was present. As safety was no longer a consideration, subsequent actions were taken primarily to bring the LLP situation back into regulatory compliance. LLP situations differed particularly as to the plant and traits involved, and as to whether the discovery occurred before planting, after planting or after harvest. Depending upon the situation, unauthorized plant material may have been destroyed, seed stocks quarantined and subsequently disposed of and further distribution and planting of seed may have been stopped to address lack of compliance. In one case, all affected seed that had been shipped to dealers for the current planting season was recalled to prevent further planting in the year the unauthorized LLP plant material was discovered. In other cases, seed that had been planted may have been allowed to go to harvest. Compliance measures were determined case-by-case, depending upon

[23] The plant material would qualify for the USDA-APHIS field testing process used for plants that present minimal risk.

the details of each situation but measures to restore compliance with regulatory authorities were generally undertaken to limit the maintenance or spread of the LLP plant material in the environment.

The companies and industries involved may also have provided information, suggestions, and specific actions to the government that expedited the development and implementation of measures required by the regulatory agencies for removing seed and plant material from the marketplace or the environment. Decisions made by the companies that owned the unauthorized material, or that were affected by it, also influenced the course of action. For example, one LLP situation was discovered in summer, near the beginning of harvest. The government determined that the LLP plant material posed no food/feed safety concerns, so the movement or processing of unauthorized material harvested from the current and previous years was not prevented.[24] Subsequently, the company owning the unauthorized LLP plant material submitted and was granted a request authorizing use in the United States. In contrast, for a second similar unauthorized plant line, discovered in the late winter before planting, the affected company voluntarily retrieved all affected seed from the market and any material planted was destroyed. No request for authorization was submitted. In this example, the government agreed to and verified these measures for bringing the situation into compliance.

To advance compliance with regulatory requirements, in 2007, USDA-APHIS initiated the development of its Biotechnology Quality Management System (BQMS), a voluntary, audit-based compliance assistance program, to assist universities, small businesses, and large companies develop sound management practices to proactively enhance compliance with regulatory requirements. The goal of the voluntary program is to help developers establish policies and quality control practices that proactively address potential issues before they materialize.

Through the experience of several LLP incidents, the United States adopted an approach to response that was initiated when the government was notified of an LLP occurrence. The first priority was to determine the safety of the regulated GE plant material. Notification was followed by collection of information to support safety and regulatory assessment; performance of safety assessment and determination of regulatory status; communication to the public about safety and regulatory status; enactment of any measures necessary to protect public health and the environment; additional outreach to impacted stakeholders; and monitoring of compliance activities.

BIAC (The Business and Industry Advisory Committee to the OECD)

I. Has your country experienced LLP situations from commercial seed or commodities that can function biologically as seed?

In its response, BIAC will only address commercial seed used intentionally for planting. LLP situations in seed, or situations of regulatory non-compliance for seed, can be detected in seed shipments before seeds are planted or in farmers' fields after planting, such as in saved seed situations. BIAC believes it is important for the LLP project to take into consideration these different types of situations.

In determining how to provide the OECD Working Group with the most useful response to the questionnaire, BIAC has decided to base its response on possible scenarios of non-compliance. These scenarios differ in the level of familiarity associated with a specific product and are based on the assumption that at least one country has approved the product. The purpose of these scenarios is to illustrate how the concept of familiarity can guide a government's response in an LLP situation and to provide the range of LLP situations that could be faced by Competent Authorities.

[24] During processing, harvested plant material is devitalized, eliminating the possibility of any further planting or growth.

The three scenarios are:

Scenario 1: *An event that has been approved for import, but not cultivation, in the importing country.*
Scenario 2: *An event that has no approval in the importing country but the inserted gene and protein produced are the same as or very similar to other events approved in the importing country.*
Scenario 3: *An event that has no approval in the importing country and where there is familiarity with the crop but not the trait in the importing country.*

Scenario 1
This is a hypothetical case but based on experience. Event HYP001 is a biotechnology event that has been authorized for food, feed uses and cultivation in the country of origin. It has been authorized for import and for food and feed uses in the importing country. It has not been authorized for cultivation in the importing country.
Event HYP001 is in a plant species with a significant level of allogamy. Commercial plant varieties derived from HYP001 are already grown in the country of origin. A low level of HYP001 event was detected in commercial seed lots in the importing country.
The quality controls performed in the country of origin by the seed producer and exporter did not detect the HYP001 event but it was detected in the country of destination either by official inspection services or directly by the distributor that imports the seeds for sales in the importing country. In both cases the importer or the inspection services immediately notified the Competent Authority.
The Competent Authority immediately put the shipment in quarantine in order to prevent any sale, asked the importer for further information on the origin of the seeds, and started an inquiry on seed lots previously imported from the same origin.
In addition the Competent Authority asked the importer to provide additional information for conducting a risk assessment.

Scenario 2
While this scenario is hypothetical, as in Scenario 1, it is based on experience. In this hypothetical case, event HYP002 is an event that has been authorized for food, feed and cultivation in the country of origin, but it has not been reviewed by the importing country's Competent Authority and therefore does not have cultivation or import approval. A low level of HYP002 event was detected in commercial seed lots in the importing country. As in scenario 1, the quality control measures undertaken by the seed producer and exporter did not detect HYP002 in the seed lots. Event HYP002 was detected by a third party in seed that had been planted and had not yet begun to flower or shed pollen.
While environmental data for event HYP002 had not yet been reviewed in the importing country, a different event in the same crop, containing the same gene and expressing the same protein, had been reviewed by the importing country, was determined to be safe and had obtained import and cultivation approval. In this case, the Competent Authority had familiarity with the crop, trait and the environment where event HYP002 was detected.

Scenario 3
In this scenario, event HYP003 has been reviewed and approved for cultivation in the country of origin but not approved for cultivation or import in the country of import. This event, unlike HYP002, is not similar to any other events reviewed and approved for cultivation in the country of import. However, the country of import does have familiarity with the crop of event HYP003.
Unlike Scenarios 1 and 2, this scenario is not based upon experience. Given the predominance of familiar traits (herbicide tolerance, insect resistance) and the familiarity that breeders have with many of the traits being targeted for introduction in the near future, for example stress tolerance and modified oils, it is likely that a regulator would have access to at least "high level" information relevant for a risk assessment. While

the familiarity might be lower when compared to other traits, there should still be a base of experience and data that can be used when conducting a risk assessment in an LLP situation.

II. How has your country addressed these LLP situations; if your country conducted risk assessments related to the environment, what scientific information formed the basis of the assessment of risk related to the environment?

An environmental risk/safety analysis is based on the characteristics of the organism, the introduced trait, the receiving environment and the interactions among these elements. Familiarity, based on data, information and experience with any of these elements, plays a key role in the risk/safety analysis.

Scenario 1

The import authorization in the importing country covered the uses as food and feed of any commodity containing HYP001. The harvest of the crop grown from those seed lots containing low levels of HYP001 fell into this category and therefore was in regulatory compliance. The food/feed safety assessment has been completed and therefore did not have to be repeated. The new dimension, therefore, of the risk analysis was the potential hazard under the conditions of use; more specifically, the agricultural receiving environment where the seed would be cultivated.

The likelihood of adverse environment impact under the conditions of release of the LLP of event HYP001 in seed could be determined based on:

- Characterization of the introduced trait from the risk analysis for import completed in the importing country;
- Description of the agricultural areas where the crop will be grown;
- Description of the agricultural practices, with a special emphasis on those associated with the trait, such as the use of the target herbicide in the case of a herbicide tolerant trait. However, this aspect of the analysis would be limited by the fact that it is unlikely that agricultural practices aimed specifically at the HYP001 trait will be applied, since it is found at unintentional low levels in the seed lot.
- Safety assessments available from other countries;
- Experience and information from similar crop/trait combinations and deemed relevant by the importing country; and
- Relevant OECD consensus documents.

Scenario 2

The likelihood of adverse environment impact under the conditions of release of the LLP of event HYP002 in seed could be determined based on:

- The environmental risk assessment of the crop containing event HYP002 in the respective cropping system.
- Experience with cultivating this crop. Specifically the focus would be on the crop's inherent properties related to weediness (persistence and invasiveness) and pest management to gauge potential impacts to non-target organisms in a comparative manner.
- An environmental risk assessment of a different event with the same introduced gene in the context of the same crop focusing on the likelihood that the trait would alter the crop's weediness or effect on non-target organisms.
- Existing environmental risk assessment data and experience with HYP002 within the importing country for the gene and expressed protein.
- Safety assessments available from other countries.
- Experience and information from similar crop/trait combinations and deemed relevant by the importing country; and
- Relevant OECD consensus documents.

Scenario 3

Although the event, HYP003, is not similar to other events already approved for cultivation in the importing country, the concept of familiarity could still have been used to guide the risk assessment to determine the likelihood of adverse environmental impact under the conditions of release of the LLP of event HYP003 in seed. The assessment would be based on:

- Experience with cultivating the crop (inherent properties for weediness),
- Experience with the trait in other crops,
- Safety assessments available from other countries,
- Information about the receiving environment and normal agricultural practices in that receiving environment, and
- Other considerations, such as the level of exposure to beneficial organisms, humans, and the environment.

To the extent this information was not available, data may have needed to be generated to determine, under the conditions of release of LLP of HYP003, the likelihood of the trait/crop combination increasing weediness in the crop plant or in any existing sexually-compatible wild relatives, and the likelihood of adverse effects on non-target organisms.

III. What lessons were learned?

Applying the principle of familiarity would, in all of the scenarios above, allow risk assessors to make efficient determinations of risk and reasonable risk management decisions. Familiarity can be achieved through a country's previous risk assessments, other country's risk assessments, experience with cultivation of a crop, published data, and OECD consensus documents.

BIAC believes that the OECD project could provide valuable information useful for countries developing LLP policies. Importantly, the breadth of experiences shared in this project could help some parties make informed, risk-based, risk management decisions on a case-by-case basis in situations of regulatory noncompliance. Notably, the OECD Working Group could describe a science-based approach to environmental risk assessment and collecting relevant information that would support reasoned and risk-proportionate regulatory decisions.

In Scenario 1, the importing country had already conducted a risk analysis for import and the relevant aspects of that risk analysis could be used for the risk analysis for the LLP situation of the same event, particularly the product characterization and hazard identification aspects of the import risk analysis. While the seed was not immediately destroyed in this scenario, an efficient process for an analysis of risk would allow the possibility of a timely release of quarantined seed.

In the real-life situation on which Scenario 2 above is based, the Competent Authorities ordered a destruction of the fields planted with seed possibly containing HYP002 and a multi-year volunteer management / field monitoring scheme. The authorities recommended that growers who suffered financial loss seek recompense from the seed company. Remnant seed samples were collected from the seed provider in order to perform confirmatory test in government-certified laboratories. The destruction order was made without any risk assessment done by the Competent Authority.

For example, as in Scenario 1, the gene and expressed protein were familiar and if a risk assessment had been performed the Competent Authority could have confirmed whether crop destruction was in fact the only appropriate means for risk mitigation. Risk managers could have, based on this risk characterization, allowed the crop to grow to maturity and harvest, perhaps with some specific conditions, fully recognizing that the action does not constitute an environmental approval.

IV. Other comments

BIAC would like to reiterate the importance of the concept of familiarity and using existing data and information when conducting a risk assessment under LLP situations, and believes that both of these elements should be integral to the approach taken in the OECD LLP project. In addition, it is important to approach the LLP situation within the context of its occurrence. For example, the time of LLP detection, whether pre- or post-planting, will be relevant to deciding on how the situation is ultimately resolved. Similarly, regulatory authorities might decide to resolve the cause of the LLP situation or address the issue of best management practices depending on whether the LLP situation is a one-time occurrence or a chronic situation. For all of the scenarios presented in this response, exchange of information among Competent Authorities and between Competent Authorities and companies will be key to addressing the LLP situation.