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LOW LEVEL PRESENCE OF TRANSGENIC PLANTS IN SEED AND GRAIN COMMODITIES: ENVIRONMENTAL RISK/SAFETY ASSESSMENT, AND AVAILABILITY AND USE OF INFORMATION

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Series on Harmonisation of Regulatory Oversight in Biotechnology

No. 55

Low Level Presence of Transgenic Plants in Seed and Grain Commodities: Environmental Risk/Safety Assessment, and Availability and Use of Information

Environment Directorate

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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ABOUT THE OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 34 industrialised countries in North and South America, Europe and the Asia and Pacific region, as well as the European Commission, meet to co-ordinate and harmonise policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised committees and working groups composed of member country delegates. Observers from several countries with special status at the OECD, and from interested international organisations, attend many of the OECD's workshops and other meetings. Committees and working groups are served by the OECD Secretariat, located in Paris, France, which is organised into directorates and divisions.

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FOREWORD

The major output of the Working Group on the Harmonisation of Regulatory Oversight in Biotechnology over the years has been its Consensus Documents. They contain information for use during the regulatory assessment of a particular product. In the area of plant biosafety, these are being published on information on the biology of certain plant species, selected traits that may be introduced into plant species, and biosafety issues arising from certain general types of modifications made to plants.

The scope of this document is different from that of the Consensus Documents. It covers low level presence situations in which seed [or certain commodities] contain low levels of transgenic seed that have been reviewed for environmental risk/safety and received authorisation for commercial cultivation (unconfined release) in one or more exporting countries but not in the country of import.

The Bureau of the Working Group on the Harmonisation of Regulatory Oversight in Biotechnology took the lead in preparing the document, and the draft has been revised on a number of occasions based on the input from other member countries and stakeholders.

This document is published under the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology.

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PREAMBLE

1. The OECD's Working Group on the Harmonization of Regulatory Oversight in Biotechnology (hereafter referred to as the 'Working Group') has since its inception in 1995 developed technical documents that facilitate environmental risk/safety assessment of transgenic[1] organisms, especially plants. These tools for risk assessors and regulators include science-focused documents on the biology of the organism and introduced traits, 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, 2004) and recently, a document on molecular characterization of transgenic plants (OECD, 2010). In effect, a suite of documents has been developed concerning the environmental review of the products of modern biotechnology.

2. The environmental risk/safety assessment of transgenic organisms is based on information on the characteristics of the host organism, the introduced traits, the environment into which the organism is introduced, the interaction between these, and the intended application (OECD, 1986; OECD, 1993a). The OECD's Working Group decided at its first session to focus its work on identifying parts of this information, which could be commonly used by countries for environmental risk/safety assessment to encourage information sharing and prevent duplication of effort among countries. The trait and biology Biosafety Consensus Documents (BCDs) are one of the major outputs of its work. They are intended to be a "snapshot" of current information on a specific host organism or trait, for use during environmental risk/safety assessments. They address the key or core set of issues that member countries believe are relevant to environmental risk/safety assessment. They include documents which address the biology of crops, trees and micro-organisms as well as those which address specific traits which are used in transgenic crops. This information is said to be mutually acceptable among member countries. To date, 46 Biosafety Consensus Documents have been published (http://www.oecd.org/biotrack).

3. In addition, to the biology and trait BCDs, the Working Group also takes on important emerging issues related to environmental risk/safety assessment and regulatory harmonization. Each of these projects is different from the BCDs and from each other. Examples of such projects include the *Consensus Document on Molecular Characterisation of Plants Derived from Modern Biotechnology* (OECD, 2010), *OECD Guidance for Designation of a Unique Identifier for Transgenic Plants* (OECD, 2000 and 2006); and *Points to Consider for Consensus Documents on Biotechnology of Cultivated Plants* (2006). In 2007, the topic of information availability and sharing and possible guidance for environmental risk/safety assessment of low level presence of unauthorized transgenic plant material in seed in cases where such an assessment had been carried out in at least one country was proposed as a project for the Working Group. In 2008 a workshop to explore the topic was held in Paris and subsequently the Working Group agreed to develop a project proposal. This project was to align with the remit of the Working Group, whose terms of reference focus on scientific and technical aspects.

1 The OECD has described a transgenic plant as a plant with a gene or a genetic construct introduced by a molecular technique (OECD, 1993a [p.33]).

Finally, in 2009, the Working Group agreed to the project and at this time commodities were added to the scope. The final scope of the document is identified in paragraphs 8 and 9 of the Executive Summary as follows:

> **The scope of this document covers low level presence situations where […] seed contain low levels of transgenic seed that have been reviewed for environmental risk/safety and received authorisation for commercial cultivation (unconfined release) in one or more exporting countries but not in a country of import**. […] This document covers commercial seed used intentionally for planting as well as commodities (*e.g.* grains and oilseeds) that can germinate and grow into plants when unintentionally released into the environment during handling and transport or when intentionally used for planting."

4. A questionnaire was circulated late in 2009 to gather information on Working Group participant country experiences with LLP situations in seed and certain commodities to use as a basis for this document. Twenty participant countries (OECD members and non-members) and observers responded to a questionnaire on their experience in addressing low level presence (LLP) situations: Argentina, Australia, Austria, Belgium, Brazil, Canada, Chile, Czech Republic, Estonia, Japan, Korea, Mexico, Netherlands, New Zealand, Norway, Philippines, Spain, Turkey, the United States and the Business Industry Advisory Committee to the OECD (BIAC). In addition to responses to the questionnaire, the information contained in this document was obtained from extensive discussions within the Working Group and the dedicated workshop that took place in April 2008.

5. In developing this document, the Working Group discussed the possibility of taking the same approach as the Codex Alimentarius by linking the discussion of LLP to an existing text on environmental risk/safety assessment. 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 annex illustrates how to use the guideline as it would apply to an LLP situation in food based upon different predicted exposure scenarios. Similar to the Codex LLP annex, this document focuses on transgenic plants that have been reviewed for risk/safety in one or more countries and occasionally are present in importing countries in which the risk/safety of the relevant recombinant-DNA plants has not been determined. However, the LLP situations discussed are not in food or feed but in seed and grain commodities that can function biologically as seed and the concern is environmental risk/safety rather than food safety. LLP situations in seed and commodities are discussed in the context of the paradigm for environmental risk/safety assessment that has been articulated in the OECD Scale-up document (OECD, 1993a) and elsewhere.

EXECUTIVE SUMMARY

6. Modern trade and agriculture is characterised by the increasing exchange worldwide of agricultural commodities, including seed. Many countries import and export significant quantities of seed for sowing, as well as grain and oilseed commodities that can function biologically as seed if released into the environment. A feature of modern agriculture is the increased use of transgenic plants. From the mid-1990s onwards, the adoption of transgenic plants has increased in the numbers developed, the volumes grown and in the number of countries where such plants are grown. This increase in the development and use of transgenic plants occurs within the context of the continued use of the many crop plant varieties developed using conventional breeding techniques and the increasing exchange worldwide of seed and other propagules as well as viable grain and oilseed commodities.

7. Many countries have national legislation that addresses the need for regulation of the use of transgenic plants and most countries require prior domestic authorization involving an environmental risk/safety assessment before unconfined release into the environment (*i.e.* commercial cultivation) of such plants is allowed. Authorisations for commercial cultivation in each jurisdiction generally occur independently of other countries. At any given time, there may be transgenic plants authorized for commercial cultivation (unconfined release) in one country that have not been authorized in other countries with which the authorising country trades seeds and commodities. This is often referred to as "asynchronous" authorization. Such asynchrony can occur because the timing of the authorization process is different between countries or possibly because authorization is never sought from or granted by one or more of the countries involved in seed and/or grain importing activities.

8. Aggregation and mixing in crop production or trade along with biological factors such as cross pollination between crops can result in situations where traded seed or commodity lots contain unintended low levels of transgenic seed authorised in one or more exporting countries but not in an importing country due to asynchronous authorization. **The scope of this document covers low level presence situations where these seed contain low levels of transgenic seed that have been reviewed for environmental risk/safety and received authorisation for commercial cultivation (unconfined release) in one or more exporting countries but not in a country of import.** This is referred to as a low level presence (LLP) or an LLP situation.

9. This document covers commercial seed used intentionally for planting as well as commodities (*e.g.* grains and oilseeds) that can germinate and grow into plants when unintentionally released into the environment during handling and transport or when intentionally used for planting. In the document, "seed" refers to both seed and commodities. LLP situations in seed may potentially occur and be detected before planting, in plants in the field or in some cases along transport routes after a commodity grown from seed has been harvested. It is anticipated that the number of such LLP incidents is likely to increase globally (Stein and Rodriguez-Cerezo, 2009) because of increasing numbers of transgenic seeds entering the market and the increasing international movement of seeds and/or commodities.

10. The issue of LLP in seed raises questions regarding environmental risk/safety and compliance with mandated legislative requirements for the importing country as well as the seed and commodity trade industries in both importing and exporting countries. An environmental risk/safety assessment may be undertaken by the importing country to evaluate the environmental risk/safety of the

unauthorised transgenic plant in the LLP situation, not for the purpose of authorisation but rather, the assessment can provide a basis for, and may be used by, the importing country to inform decisions to mitigate and/or manage the LLP situation. This document presents approaches to information availability and sharing and risk/safety assessment in LLP situations where there is knowledge of the identity of the unauthorized transgenic plant.

11. Major considerations in responding to an LLP situation are likely to be managing any environmental risks and returning the situation to compliance with relevant legislation. The response by an importing country to an LLP situation can vary, depending upon the situation itself and the legal framework under which the country operates. Ultimately, legislative requirements will provide the underpinning for decisions by a national authority, including mitigation or other actions taken to address the potential environmental risk/safety of an LLP situation.

12. Many OECD countries have already had experience with LLP in seed and there is much value to be gained from sharing and understanding this experience. This document captures the experience of the participant countries of the OECD Working Group for the Harmonization of Regulatory Oversight in Biotechnology in addressing asynchronous authorization LLP situations in the environment, particularly with regard to information availability and sharing, and to the scientific basis and approach for undertaking an environmental risk/safety assessment in an LLP situation. This document does not prescribe how national authorities should manage incidents of LLP, make decisions, or define what LLP is, or what proportion of unauthorised transgenic seeds constitutes a LLP situation (*e.g*. threshold), under their own legislative framework.

13. One of the aims of this document is to serve as an aid to risk assessors and regulators; providing guidance on handling the aspects of an environmental risk/safety assessment and accessing and using information in an LLP situation where there is asynchronous authorization of the transgenic plant involved. Strategies to do an adequate risk/safety assessment in an LLP situation are discussed as well as how best to proceed in circumstances where a less than full information set may be available so that an importing country can still expeditiously determine appropriate mitigation measures for addressing the LLP situation in a manner commensurate with the risk presented. It is a compilation of current approaches to environmental risk/safety assessment, information access, and information use in addressing LLP situations in seed and includes examples of how such an assessment may be used to inform environmental risk management and returning an LLP situation to compliance with legislative mandates. It can be used as guidance in addressing an LLP situation in seed in combination with other OECD documents related to environmental risk/safety assessment such as the trait, biology and molecular characterization documents (see OECD BioTrack website).

Principles for Determining Environmental Risk/Safety for Transgenic Plants.

14. The general principles for determining risk/safety are the same for an LLP situation in the environment as they are for an authorization of a transgenic plant for unconfined release. These principles are articulated in the OECD *Safety Considerations for Biotechnology: Scale-up of Crop Plants* (OECD, 1993a). The "Scale-up of Crop Plants" document describes risk analysis[2] as being: "based on the characteristics of the organism, the introduced trait, the environment into which the organism is introduced, the interactions between these, and the intended application". The "[k]nowledge 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

2 This document discusses risk/safety analysis as being comprised of "hazard identification and, if a hazard has been identified; risk assessment" (OECD, 1993). 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.

having enough information to be able to judge the safety of the introduction or to indicate ways of handling the risks". These principles apply in the following ways to an LLP situation:

1) available knowledge and experience can guide the risk assessment;

2) an environmental risk/safety assessment can be used to evaluate potential risks to the environment in a particular LLP situation; and

3) use of information and understanding from previous assessments of the same or similar plant both domestically and in other countries may inform the assessment.

Availability of Data and Information to Perform a Risk/Safety Assessment in an LLP Situation.

15. In LLP situations, national authorities face numerous challenges including that relevant data for the environmental risk/safety assessment may be lacking because it is either not immediately available (*e.g.* in an application) or inadequate. Typically, the amount of data and information available in an LLP situation may not in the short term be equivalent to that which would be available from an application for full authorisation of the transgenic plant for cultivation. Information sharing between countries may be important in LLP situations where addressing the situation might be facilitated with expedited access to information. The importance of collaborative working relationships between national authorities in different countries cannot be over-emphasized. Data and information regarding relevant characteristics of the plant, the behaviour of the plant in the environment, including cultural practices, and the trait may be available from a variety of sources. Two obvious sources of information are 1) that developed for assessment in the country in which the transgenic plant was authorized prior to export and 2) that submitted to regulators for assessment in the importing country. However, even if information is available from either or both of these two sources, the risk assessor may still need to actively and rapidly access information from additional sources to obtain sufficient information to make an assessment of the environmental risk/safety.

16. Some of the information needed to adequately evaluate the environmental risk/safety of an LLP situation in seed can come from existing knowledge and experience with 1) the same non-modified plant species or similar closely-related plant species; 2) the known functions(s) of the same or similar gene and/or its expression products (*e.g.* protein); 3) the effect of the same or similar phenotype or trait in plants on the environment; and/or 4) the same or similar receiving environments. Much information may already be available from existing reviews of the same or similar plants within a country or in other countries.

17. Access to the required information can be facilitated by the use of internet databases listing authorizations. Because the usefulness of these sources is dependent on their content and currency, it is important for countries to keep their information updated in these databases to maximize their usefulness. To enhance information sharing between countries, the OECD BioTrack website (www.oecd.org/biotrack) provides information on biotechnology regulatory contacts for OECD and participating countries, including information on regulatory frameworks and access to OECD biology and trait documents. Knowledge of the OECD unique identifier of a transgenic plant can facilitate access to information in the OECD BioTrack and other databases (OECD 2006b).

Environmental Risk/Safety Assessment in an LLP Situation.

18. When approving a transgenic plant for potential cultivation, usually the environmental risk/safety assessment assumes 100% exposure over an extended period of time, *i.e.* the plant is cultivated on potentially very large areas of land. This is an assessment of a product for intentional use. However, when assessing an LLP situation the context may be different. The determination of

environmental risk that an unauthorized transgenic plant may pose is based not only on the hazards identified but on the potential exposure which will be related to the scale of an LLP situation. The amount and degree of information needed may be different for an LLP situation because of the reduced scale and the purpose of the assessment. By definition, generally, an LLP situation is at a scale reduced from that assumed present in a risk/safety assessment for authorization for large scale cultivation of the same plant. In an LLP situation, the environmental risk/safety assessment is not intended to lead to an authorization. However, the results of the assessment can be useful in supporting environmental risk management decisions through scientifically evaluating potential options for managing any risk identified.

19. Available knowledge and experience, data and information, about the scale (*i.e.* amount of seed distributed spatially and temporally) of the LLP situation, the trait and the plant and the receiving environment of the importing country can facilitate a rapid environmental risk/safety assessment of an LLP situation. While this guidance does not explain explicitly how to do such an assessment, it is noted that the types of information used are generally the same as for the review of an application for authorization where much of the information is supplied in the application itself. There is ample discussion of these types of information and their importance to environmental risk assessment in previous OECD publications (OECD, 1992, 1993a, 1993b). The basic safety issues that may potentially be of concern were also identified in these publications.

20. The majority of LLP situations to date have involved 'common' crop species and trait combinations that have been widely adopted and are under large scale cultivation where authorised. There is substantial knowledge and experience with these crop species as they are grown regularly within the countries in which LLP situations have occurred, as non-transgenic or transgenic crops. The available broad domestic or global experience and knowledge of how the major traits being used today, particularly the herbicide tolerant and insect resistant traits, affect different plant types in different environments may provide a range of possibilities of how the trait may affect the behaviour of the plant in the environment of a particular LLP situation.

21. Familiarity with the biology of the crop plant and its behaviour in the receiving environment in the context of the existing agricultural practices (cultivation and environmental management) of the country or region can be used to identify aspects of the environment that may potentially be affected in an LLP situation. Previous assessments of the same or a similar plant that have addressed what potential adverse effects might be predicted for the unauthorized transgenic plant can contribute to a rapid understanding of whether the LLP situation might result in any adverse effects. More or less information will be needed, depending upon the particular LLP situation, how quickly decisions are needed and the core information and comprehensiveness of that information needed to make those decisions. This can facilitate rapid assessment of potential environmental risk presented by an LLP situation in seed, along with the ramifications for mitigation or risk management of the situation. The importing country with the LLP situation may use this understanding to identify the unique or different aspects of its country/region compared to the exporting country (and other countries) where assessments for authorization of the transgenic plant have already been completed.

Risk Profile.

22. When an environmental risk/safety assessment of an LLP situation is undertaken, the goal is to determine any risk presented and to scientifically evaluate potential options for managing any risk presented. In a relatively short period of time, the identity of the unauthorized plant material may need to be confirmed, the potential for adverse effects be determined, and actions taken to minimize any identified environmental risk presented by the LLP situation. A risk profile characterizing the situation may be rapidly assembled based upon data and information from reviews of the same or similar

authorized plants and/or existing knowledge and familiarity with the plant, trait, environment and their interaction. The risk profile recognizes the scale of the LLP situation and may expeditiously inform decisions to manage or mitigate any risk presented as well as to return the situation to regulatory compliance.

23. The following process can be used to develop a risk profile to expeditiously address an LLP situation in the environment of the importing country subsequent to identification of the presence of an unauthorized transgenic plant:

- Determine where the LLP situation has been found in the environment and the potential distribution of the unauthorized transgenic plant;
- Identify relevant sources of information, including previous assessments of that unauthorized transgenic plant available either domestically, regionally, or from other countries;
- Determine if those assessments identified any potential hazards and whether/how these relate to the importing country's protection goals and could potentially affect the receiving environment harbouring the unauthorized transgenic plant;
- Determine/consider whether there are pathways for distribution of the unauthorized transgenic plant in the LLP situation through which the identified hazard can cause adverse effects in the receiving environment; and
- Assess the likelihood and consequence of those adverse effects being realised

24. A risk profile can characterize the risk that may occur or has occurred given the specifics of the LLP situation (case-by-case). The environmental risk/safety assessment may include evaluation of management options for any risk to the environment that might be presented such as an evaluation of existing or modified distribution systems and agricultural practices used with the particular plant species. The assessment can also provide the needed scientific basis to inform broader management objectives, such as those to return the situation to compliance with regulatory requirements. In the context of this discussion, such management options may include mitigation of any further release of unauthorized plant into the environment and/or remediation of any release that has already occurred.

Uses of an Environmental Risk/Safety Assessment in Management of LLP Situations in Seed.

25. The "Scale-up*"* document (OECD, 1993a) describes environmental risk management as "the way appropriate methods are applied in order to minimise scientifically identified risks…In principle, appropriate management is based on and should be in proportion to the results of the risk/safety" assessment. "Risk management encompasses all aspects of the management of the organism indirectly through management of the environment into which the organism is introduced, or directly, by management of the organism itself."

26. In general, management of an LLP situation may focus on the goals of protection of the environment (environmental risk management) and/or returning the situation to compliance with the requirements of a country's legislative framework.

27. An environmental risk/safety assessment may be useful in informing decisions for environmental risk management and returning the LLP situation to compliance with the regulatory requirements of the country or region, recognizing that the use of an environmental risk/safety

assessment for this purpose may depend on the provisions of the legislative framework of the country. The form that management of the LLP situation takes can be influenced by multiple factors. The complexity of the response may be influenced by, for example, socio-economic factors, legislative mandates, stakeholder preferences, or the availability of resources. In some cases an environmental risk/safety assessment may not be needed to address a particular LLP situation due to the adoption of processes to handle LLP. Or, alternatively, the legislative framework may stipulate that LLP situations must be returned to compliance regardless of whether or not an environmental risk/safety assessment is performed.

28. Depending on the country's legislative framework, an environmental risk/safety assessment can provide options for environmental risk management in a manner proportional to any risk presented to achieve protection goals (OECD, 1993a). The concept of risk management measures being proportional to the level of risk presented as determined by a risk assessment is consistent with internationally accepted risk management principles.

29. As part of an approach to managing an LLP situation overall, an environmental risk/safety assessment can be used to characterize the situation, including identifying any environmental risk associated with the situation, identifying the measures either in place or needed to manage any such risk presented and it may also suggest the most efficacious measures to return the situation to compliance with legislative mandates. The circumstance and timeframe of an LLP situation in seed is a major factor for determining the appropriate environmental risk management/mitigation measures, depending upon the risk presented – *e.g.* removal or destruction of the unauthorized transgenic plants prior to flowering may or may not be important in limiting potential spread or persistence. In addition, the same measures may contribute to returning the situation to compliance with legislative mandates; *e.g.* remediation and mitigation options that ultimately lead to limitation of the maintenance and/or spread and/or removal of the unauthorised plant from the environment and ultimately the seed supply. The situation and the assessment can indicate options for disposal of the plant material in a manner that is proportional to the risk identified, returns the situation to compliance and does so in a manner that is least disruptive to the agricultural system.

30. While it is for each country, considering its legislative framework, to decide on appropriate management strategies, options other than crop or seed destruction may be considered when attempting to manage the LLP situation in a manner that is proportional to the risk identified and the need to return the situation to compliance. For some countries, it may not be feasible to implement some of the options as their application may be governed by the legislative framework of the particular country. For many countries, an LLP situation is almost by definition, a situation of non-compliance with regulatory requirements and in many jurisdictions there are legal requirements for compliance that also set the context for any management for environmental risk.

Potential Ways to Proactively Address Environmental Risk for LLP Situations.

31. Given that the incidence of LLP situations resulting from asynchronous authorization is anticipated to increase globally (Stein and Rodriguez-Cerezo, 2009) and that such situations 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 (Annex II), countries and regions have taken several approaches to proactively address LLP situations. Some of these approaches focus on steps to limit the potential for uncertainty regarding environmental risk. Others attempt to work with industry to limit the potential for occurrence of LLP, and still others establish procedures to facilitate a rapid response to an LLP situation.

32. 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 unauthorized transgenic plants in the environment including those arising from LLP situations. These policies and plans serve to communicate to the public the government's approaches to dealing with potential environmental risk from LLP situations and to clarify responsibilities of various stakeholders including potential industries involved (*e.g.* seed production, breeding, trading, transport) in order to limit, as well as prepare for, a potential occurrence of LLP in the environment.

INTRODUCTION

33. Modern trade and agriculture is characterised by the increasing exchange worldwide of agricultural commodities, including seed. Many countries import and export significant quantities of seed for sowing, as well as grain and oilseed commodities that can function biologically as seed once released into the environment. A feature of modern agriculture is the increased use of transgenic plants. From the mid-1990s onwards, the adoption of transgenic plants has increased in the numbers of plants developed, the volumes grown and in the number of countries where such plants are grown. This increase in the development and use of transgenic plants occurs within the context of the continued use of the many crop plant varieties developed using conventional breeding techniques and the increasing exchange worldwide of seed and other propagules as well as viable grain and oilseed commodities.

34. Many countries have national legislation that addresses the need for regulation of the use of transgenic plants and most countries require prior domestic authorization involving an environmental risk/safety assessment before unconfined release into the environment (*i.e.* commercial cultivation) of such plants is allowed. Authorisations for commercial cultivation in each jurisdiction generally occur independently of other countries. At any given time, there may be transgenic plants authorized for commercial cultivation (unconfined release) in one country that have not been authorized in other countries with which the authorising country trades seeds and commodities. This is often referred to as "asynchronous" authorization. Such asynchrony can occur because the timing of the authorization process is different between countries or possibly because authorization is never sought from or granted by one or more of the countries in seed and/ or grain importing activities.

35. As a result of these trends and biological factors such as cross-pollination as well as aggregation and mixing of commodity lots in trade, imported seeds or certain commodities may inadvertently contain low levels of transgenic seed that have been reviewed for environmental risk/safety and received authorisation for commercial cultivation (unconfined release) in one or more exporting countries but not in the country of import. For the purposes of this document, "seed" refers to both seed and commodities (see paragraph 41) and such an occurrence is called a low level presence (LLP) situation.

36. The issue of LLP in seed concerns importing countries as well as the seed and commodity traders in both importing and exporting countries.

37. In an LLP situation in seed, a primary question may be that of the environmental risk/safety of the unauthorised transgenic plant in the country of import. Consequently, an environmental risk/safety assessment may be undertaken by the importing country to evaluate the environmental risk/safety of the transgenic plant in the LLP situation. It is important to note, however, that the intent of the assessment is not an authorisation of the transgenic plant that is present at a low level in seed or commodities. Rather the assessment can provide a basis for, and may be used by the importing country, to inform decisions to mitigate and/or manage the situation. A major consideration in managing an LLP situation is likely to be returning the situation to compliance with relevant legislation. Ultimately, legislative requirements will provide the underpinning for decisions by a national authority,

including mitigation or other actions taken to address any environmental risk presented by an LLP situation.

38. In an LLP situation in seed, an importing country may not have had the opportunity to complete an evaluation as to whether the unauthorized transgenic plant could negatively affect the importing country's environment and the country will need to comply with its relevant legislation. This means that an LLP situation in the environment can, in many cases, require the expeditious performance of an environmental risk/safety assessment. This document will discuss strategies to do an adequate risk/safety assessment in an LLP situation.

SECTION I – PURPOSE AND SCOPE

39. **The scope of this document covers a situation where seed contains low levels of transgenic seed that have been reviewed for environmental risk/safety and received authorisation for commercial cultivation (unconfined release) in one or more countries but not in the country of import.** This document is to serve as an aid to risk assessors and regulators conducting an environmental risk/safety assessment and accessing and using information in response to LLP situations in seed where there is asynchronous authorisation of the transgenic plant involved. It is anticipated that the number of such LLP incidents is likely to increase globally (Stein and Rodriguez-Cerezo, 2009) because of increasing numbers of transgenic seeds entering the market, the increasing international movement of seeds and/or commodities and biological factors (*e.g*. inadvertent cross-pollination between seed production fields). In such LLP situations there may be an actual or potential release of the unauthorized transgenic seed into the environment, necessitating an environmental risk/safety assessment. This document is intended to provide guidance on handling the aspects of an environmental risk/safety assessment in an LLP situation where there is asynchronous authorisation of the transgenic plant involved. It is a synthesis of current approaches to environmental risk/safety assessment, information access, and information use in addressing LLP situations in seed and includes examples of how such an assessment may be used to inform environmental risk management and returning an LLP situation to compliance with legislative mandates.

40. This document can be used in combination with other OECD documents related to environmental risk/ safety assessment such as the Consensus Documents which address the biology of specific plant species or traits used in transgenic plants. The OECD document on molecular characterisation may also be relevant (see OECD BioTrack website).

41. This document covers commercial seed used intentionally for planting as well as commodities (*e.g.* grains and oilseeds) that can germinate and grow into plants when unintentionally released into the environment during handling and transport or when intentionally used for planting. Except where indicated, in this document the term 'seed' refers to seed intended for planting as well as commodities that can function biologically as seed when released into the environment. LLP situations in seed may potentially occur and be discovered before planting, in plants in the field or in some cases along transport routes after a commodity grown from seed has been harvested.

42. This document presents approaches to risk/safety assessment in LLP situations where there is knowledge of the identity of the unauthorized transgenic plant. It **does not**, however, address the question of how to establish the identity of the unauthorized transgenic plant. In addition, this document **does not** address low level presence situations arising from field trials for product development or basic research, or situations in which no authorization has been granted in any country, although the approach described here may be fruitfully applied in such situations. It **does not** address issues related to food/feed safety.

43. Many OECD countries have already had experience with LLP in seed and there is much value to be gained from sharing and understanding this experience. While each LLP situation may manifest differently and is likely to be handled on a case-by-case basis by the importing country or region in which the situation occurs, there is benefit in identifying available sources of information and useful

environmental risk/safety assessment strategies that may assist in addressing these situations. This document describes approaches for appraising risk/safety expeditiously (*e.g.* the plant is already in the environment) in circumstances where a less than full information set may be available so that the national authority can rely on the assessment to determine appropriate mitigation measures for addressing the LLP situation in a manner commensurate with the risk presented. Typically, the amount of data and information available to the assessor in an LLP situation may not in the short term be equivalent to that available from an application for full authorisation of the plant for cultivation. However, much information may already be available from existing reviews of similar plants within a country. In addition, information sharing among authorities may be important in LLP situations where addressing the situation might be facilitated with expedited access to information.

44. This document captures the experience of the participant countries of the OECD Working Group in addressing LLP situations in the environment, particularly with regard to the scientific basis and approach for undertaking an environmental risk/safety assessment in an LLP situation in the environment (individual country experiences are captured in Annex II which includes references to national or regional guidance documents). As an aid to regulators and risk assessors, the following aspects are covered:

a) The occurrence of LLP situations in seed in OECD participant countries;

b) The types of information that can be used in an environmental risk/safety assessment and where these may be available;

c) How an environmental risk/safety assessment can be approached, particularly how existing knowledge and experience (familiarity) regarding the plant, trait, environment and their interactions may aid in performing an assessment; and

d) Whether and how an environmental risk/safety assessment may influence risk mitigation and management as well as the overall management of the situation.

45. The following points summarize and clarify how the document is intended to be appropriately used. This document:

- Encompasses seed that contains low levels of transgenic seed that have been reviewed for environmental risk/safety and received authorisation for commercial cultivation (unconfined release) in one or more countries but not in the country of import;

- Relates to LLP in seed including commodities that can function biologically as seed; and

- Highlights the importance of information sharing, experience, and environmental risk/safety assessment in an LLP situation.

46. On the other hand this document acknowledges national legislation and **does not**, amongst other things:

- Preclude a national or regional authority from undertaking or not undertaking an environmental risk/safety assessment for authorization of the transgenic plant present at low level within the context of its regulatory system;

- Prevent countries from abiding by existing international agreements on the topic of LLP (*i.e.* the Codex Alimentarius Commission, 2003);

- Prescribe how national authorities should manage incidents of LLP, make decisions, or define what LLP is under their own legislative framework;

- Prescribe what proportion of unauthorised transgenic seeds constitutes an LLP situation (*e.g*. threshold); or

- Address issues of food/feed safety, low level presence arising from field trials for product development or basic research, or situations in which no authorization has been granted in any country.

SECTION II – INFORMATION AVAILABILITY, INFORMATION USE AND ENVIRONMENTAL RISK/SAFETY ASSESSMENT IN LLP SITUATIONS

2.1 Occurrence of LLP in Seed

47. LLP of unauthorized transgenic seed may originate from a range of biological or non-biological causes during seed production of plant varieties, and the production of some commodities. It may occur during commercial cultivation, handling, harvest, transportation, shipment, etc. of seed, as well as of commodities. Commercial seed for intentional planting is produced to meet certain quality standards (viability, germination, purity, etc.) while commodities, grain harvested for food, feed or processing, are not intended to meet seed quality standards as they are not normally intended for planting.

48. In the development of new varieties, plant breeding may occasionally result in low-level mixing of genetic material from unintended plant sources. This is true for both conventionally bred plants as well as for transgenic plants. This mixing may also occur during seed production of any variety. The potential for such low-level mixing has been formally recognized through allowances for a set maximum level of "off types" in seed certified for purity (OECD, 2012b). However, with transgenic seed there is increased need to avoid cross-pollination and ensure adequate quality control as these can result in an LLP situation. LLP in seed can also occur via non-biological causes through commingling or mislabelling of transgenic seed. Commodities can have additional sources of unintended mixing that can lead to an LLP situation during handling, storage and transport after harvest. Given the complexity of the agricultural system, it may be very difficult to determine the actual initial cause of any particular LLP situation in either seed or commodities.

49. In 2011, 29 countries grew a total of 160 million hectares of crops that were transgenic and the majority of these contained herbicide tolerance and/or insect resistance traits (James, 2011). As a result, most of the LLP situations to date relating to the presence or release into the environment of unauthorized transgenic plants have occurred with common crop plant species and trait/gene combinations that have been reviewed by many countries. These LLP situations have included those with the commodity crops corn, cotton, rapeseed/canola and soybean containing herbicide tolerance (glyphosate or glufosinate ammonium) and/or insect resistance (*Bacillus thuringiensis* delta endotoxins effective against coleopteran or lepidopteran insect pests) traits.

50. Even though the plant and trait/gene combinations in these LLP situations may have been reviewed in one or more countries, the transgenic plants involved may not have been authorized for environmental release amongst all trading partners. In addition, there can be an asymmetry in the types of authorizations in the importing country compared to the exporting country; such asymmetry may occur because the national authorities either receive requests for, or grant authorization for, different uses. The following are examples of such situations[3] that can occur in an importing country:

3 There may be other factors outside the scope of this document that affect whether a plant is ultimately cultivated. For example, the importing country may have performed a risk/safety assessment on the plant for food and/or feed use and/or environmental release and concluded the material could be authorized. However, other legal constraints may exist (*e.g.* government seed variety certification/registration requirements) so that

- No application has been received requesting authorization either for importation for food and/or feed use or for environmental release (cultivation) of the transgenic plant; or

- No authorization has been granted though applications may have been received for food and/or feed use and/or possibly for environmental release; or

- Authorization has been granted for importation for food and/or feed use, but not for environmental release although an application for environmental release may have been received; or

- Authorization was granted for environmental release in the past, but that authorization has expired.

51. The seed industry has undertaken significant efforts to reduce the incidence of LLP in seed through adoption of best practice protocols for trait development, breeding, field trials and seed production and testing to affirm purity of seed (*e.g.* Excellence Through Stewardship, 2011)[4]. These protocols are more stringent for transgenic seed than those generally employed in conventional breeding and include isolation of plantings, cleaning of machinery and equipment, rogueing, management of pollination, and labelling, inventory, and disposal of material. If the seed industry could eliminate LLP entirely, it would do so in order to avoid the unproductive costs of LLP situations (SAA, 2009), including those that may occur in the food production system after harvest. However, even with the implementation of these quality control measures unintentional mixing of seed cannot always be prevented from occurring in agricultural production systems because of the complexity of modern agriculture. Testing at different points throughout the production system can give conflicting results (due to limits of quantification, sampling error, etc.), introducing uncertainty as to the effectiveness of best practice protocols and limiting the ability to determine whether there is LLP in any given seed lot or shipment.

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

52. Many countries have comprehensive regulatory systems for the assessment of the risk/safety of transgenic plants proposed for environmental release. In any given country, there may be several ministries involved in the evaluation of such plants. Typically agriculture- and environment-based ministries have the primary responsibility for evaluating the consequences of environmental release of transgenic plants.

53. Addressing an LLP situation nationally may involve more than one or two ministries and can be complex. Usually those ministries responsible for overseeing evaluation of applications for commercial cultivation (unconfined release) of transgenic plants take a lead role in any environmental risk/safety assessment and may also be involved in management of LLP situations. Which agencies are involved may depend upon the circumstances of the situation, such as the source of the LLP (commodity or seed) or the particular trait(s) involved. Additional ministries, agencies and government offices may also be involved in addressing a particular situation. These can include quarantine and inspection services, seed quality agencies, and plant variety protection agencies as well as agencies responsible for environmental management and public affairs.

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the plant would not be fully authorized for commercialization unless these other legal requirements are met. Seed certification or registration is not a component of environmental risk/safety assessment.

4 http://www.excellencethroughstewardship.org/ accessed January17, 2012

54. However, even when systems for environmental risk/safety assessment for authorization for cultivation are in place, some countries' legislative frameworks do not allow for such an assessment in an LLP situation.

55. While some countries have not experienced LLP situations, several have dealt with at least one incidence of LLP in the context of the environment, either in seed or from certain commodities. Some countries have more experience with LLP situations involving a commodity source than a seed source (see Annex II).

56. Most countries have not to date 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 unauthorized transgenic plants in the environment including that from LLP situations. These policies and plans serve to communicate to the public the government's approaches to dealing with the potential for environmental risk from LLP situations and to clarify responsibilities of various stakeholders including potential industries involved (*e.g.* seed production, breeding, trading, transport) in order to limit, as well as prepare for, a potential occurrence of LLP in the environment.

57. National authorities in the importing country may become aware of (or identify) 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 and grain handling industries, including producers, or importers or the owner of the imported plant material; or

4) Notification resulting from sampling and testing regimes of the government or others.

58. For national authorities in the importing country, an LLP situation in the environment from seed or commodities may represent a risk to the environment that may need environmental risk management. In addition, an LLP situation in the environment presents a situation of regulatory non-compliance with legislative requirements of the importing country where the plants are not authorized for cultivation (unconfined release). Regulatory agencies may be required to take action to address an LLP situation. In such cases, an environmental risk/safety assessment can support activities to 1) manage any risks to the environment in a manner commensurate with risk presented and 2) achieve compliance with national legislative frameworks. Generally, the primary purpose of an environmental risk/safety assessment in an LLP situation is to characterize the situation and the risk that may be present and to inform environmental risk management. However, the information developed for the environmental risk/safety assessment may also be useful in managing the situation for achieving compliance. The response by an importing country to an LLP situation can vary, depending upon the situation itself and the legal framework.

2.3 Principles for Determining Environmental Risk/Safety for Transgenic Plants

59. The goal of the environmental risk/safety assessment is the same for authorizations for commercial cultivation (unconfined release) as it is in LLP situations: to determine the environmental risk/safety. The general principles for determining environmental risk/safety are the same for an LLP situation in the environment as they are for an authorization of a transgenic plant for unconfined release. These are stated in the OECD *Safety Considerations for Biotechnology: Scale-up of Crop Plants*

(OECD, 1993a). The "Scale-up" document describes risk analysis [5] as being: "based on the characteristics of the organism, the introduced trait, the environment into which the organism is introduced, the interactions between these, and the intended application". The "[K]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 [field] trial or experiment. This increased familiarity can then form a basis for future risk/safety analysis" (OECD, 1993a, 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, 1993a, page 29).

60. In developing an approach to environmental risk/safety assessment of recombinant-DNA organisms, the OECD made recommendations in the document *Environmental Safety Considerations* (OECD, 1986) that were further elaborated in the "Scale-up of Crop Plants" document. These have been accepted as operational principles worldwide, that countries:

1) "use the existing considerable data on the environmental effects of living organisms to guide risk assessments";

2) "ensure that recombinant DNA organisms are evaluated for potential risk, prior to applications in agriculture and the environment by means of an independent review of potential risks on a case-by-case basis[6]"; and

3) "conduct the development of recombinant DNA organisms for agricultural or environmental applications in a stepwise fashion, moving, where appropriate, from the laboratory to the growth chamber and greenhouse, to limited field testing and finally, to large-scale field testing".

61. Normally, environmental risk/safety assessment is carried out prior to release into the environment. The above principles apply to evaluation of the stepwise development of an organism for its intended use and this development is based upon data and information gathered until an appropriate amount is consolidated in order to do an environmental risk/safety assessment for commercial cultivation (unconfined release). Usually assessments are done case-by-case and knowledge derived from one environmental risk/safety assessment can be applied to subsequent assessments. The stepwise development of a transgenic organism allows the identification of information and the accumulation of data that supports the environmental risk/safety assessment of the organism for uses at a broader scale. Even though, in an LLP situation it is likely that the unauthorized plant has already been found in the environment or environmental release may be imminent, the principles indicated above still apply because,

1) available knowledge and experience can guide the environmental risk assessment;

5 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.

6 Case-by-case means an individual review of a proposal against assessment criteria which are relevant to the particular proposal; this is not intended to imply that every case will require review by a national or other authority since various classes of proposals may be excluded.

2) an environmental risk/safety assessment can be used to evaluate the potential for risks to the environment in a particular LLP situation; and

3) stepwise development of the transgenic plant may or may not be underway in the importing country, but use of information and understanding from previous assessments of the same or similar plant domestically, regionally and from other countries may inform the assessment.

62. Based upon these principles, an environmental risk/safety assessment may be undertaken to identify and evaluate any risk presented by an LLP situation in seed or from certain commodities and the existing familiarity with the components of the situation can provide a basis for such an assessment. The resulting assessment can also inform what actions may be necessary to achieve adequate management of any scientifically identified environmental risk presented *e.g.* through standard agricultural practices; the need for additional measures; etc. In addition, such actions may also be useful in bringing the situation back into regulatory compliance. These topics are discussed in Section III.

63. Table 1 summarises similarities and differences of risk/safety assessment undertaken in response to applications for authorising unconfined environmental release of transgenic crop versus an LLP situation of an unauthorised transgenic plant.

Table 1. Environmental risk/safety assessment in LLP situations – key similarities and differences with applications for commercial release

Type of assessment	Application for authorization	LLP situation
Purpose/focus of assessment	Determine environmental risk/safety of proposed unconfined (commercial) environmental release of a transgenic plant	Characterise LLP situation (what, where, when, how) Determine environmental risk/safety of the unauthorized transgenic plant and the LLP situation
Release to the environment intended	Yes	No
Time-frame for assessment	Defined period for assessment	As soon as possible
Sources of Information	Detailed information provided directly to regulator by applicant	Information may be obtained by the regulator from various sources (*e.g.* application under evaluation, developer, other relevant regulatory assessments, published sources)
Information considered	Biology of the crop plant, transgenic trait, environment, and interactions, familiarity with cultivation of same or similar transgenic plants	Biology of the crop plant, transgenic trait, environment, and interactions, familiarity with cultivation of same or similar transgenic plants
Identity, amount and location of transgenic plants	Known Defined in application	Knowledge may be incomplete May be determined in environmental risk/ safety assessment
Regulatory action	Decision on authorization of release to the environment	Return situation to compliance Manage risks

2.4 Availability of Data and Information to Perform an Environmental Risk/Safety Assessment in an LLP Situation

64. LLP situations in the environment are dynamic, and a relatively rapid assessment of the risk of the situation is needed for appropriate action to occur in a timely manner. For example, a seed lot containing LLP of unauthorized transgenic seeds may have already been planted upon discovery of the LLP situation or unauthorized transgenic plants may have been found along a transport routes as a result of commodity spillage and subsequent germination. An environmental risk/safety assessment of the LLP situation is usually needed within weeks, days or even hours rather than within the measured pace a national authority might in general apply to an application submitted for authorization within the existing legal structure. In LLP situations, national authorities face numerous challenges including that relevant data for the environmental risk/safety assessment may be lacking because it is either unavailable or inadequate or it may not be possible to request additional needed data from an "applicant" through formal procedure as in an authorization process. Given the need for a relatively rapid environmental risk/safety assessment in an LLP situation, a profile of the environmental risk presented, the availability of relevant data and information can affect the speed at which a risk assessor can make an assessment of any potential for risk to the environment.

65. Data and information regarding relevant characteristics of the transgenic plant involved in the LLP situation in the environment, the behaviour of the plant in the environment, including agricultural practices, the LLP situation, and the trait may be available from a variety of sources most likely including the following:

1) Domestic authorizations of the particular transgenic plant imported for food and feed;
2) Application(s) submitted for the particular transgenic plant (review not completed by the importing country);
3) Authorization for commercial cultivation (unconfined release) for the particular transgenic plant from the authorizing/exporting country;
4) Food, feed and environmental authorizations of the transgenic plant by the exporting country;
5) Authorizations [7] completed for commercial cultivation (unconfined release) as well as completed environmental risk assessments of the same or similar transgenic plant in countries other than the exporting country;
6) Domestic authorizations for commercial cultivation (unconfined release) of similar transgenic plants (traits, genes, constructs) in the environment;
7) Data and information from the developer, producer, farmers and other involved industries;
8) OECD trait, plant biology and evaluation documents (OECD, 2006; OECD, 2010);
9) Publically available databases (domestic/international);
10) Peer reviewed published literature;
11) Direct communication with authorities in other countries, particularly the exporting country or authorizing country;

7 Assessments that did not lead to authorization, either domestic, regional or from other countries, may also provide useful information. However, there are a variety of reasons an application may not lead to authorization.

12) Detection procedures suitable for the LLP situation; and

13) Information and experience with similar LLP situations (see also Annex II).

66. Given the criticality of an efficient and effective environmental risk/safety assessment in response to an LLP situation, use of already existing domestic and/or internationally available knowledge and experience can give the risk assessor a "head start" in terms of performing the assessment, saving valuable time. As indicated above, in the case of asynchronous authorization, two obvious sources of information are 1) that developed for assessment in the country in which the transgenic plant was authorized and 2) that submitted to regulators for assessment in the importing country. However, the risk assessor may need to actively and rapidly access information from a wide range of sources to obtain sufficient information to make an assessment of the risk/safety.

67. Access to information can be facilitated by the use of websites containing databases that list authorizations from domestic, regional and sources from other countries. At a minimum, in the type of LLP situation that is being discussed here, the transgenic plant involved in the LLP situation would previously have been evaluated and authorized in another country or several other countries. Entries into these databases may include detailed environmental risk/safety assessments or provide valuable direction as to where this information may be found.

68. Such existing databases currently include the following:

1) BioTrack[8] hosted by the Organization for Economic Cooperation and Development

2) Biosafety Clearing-House[9] under the Cartagena Protocol on Biosafety

3) Crop Database hosted by the Center for Environmental Risk Assessment[10]

4) GM Approval Database [11] hosted by the International Service for the Acquisition of Agri-Biotech Applications

5) National and regional biosafety websites.[12] [13]

Knowledge of the unique identifier designed for individual transgenic plants based on transformation events and authorized by national authorities can serve as a key to facilitate access information from these databases (OECD 2006b).

69. To enhance information sharing between countries, the OECD BioTrack website provides information on biotechnology regulatory contacts for OECD and participating countries, including information on regulatory frameworks and access to OECD biology and trait documents. The Biosafety Clearing House (BCH) contains information on both the regulatory frameworks of the participating countries and on the available guidance for environmental risk/safety assessment as well as the results of environmental risk/safety assessments for specific transgenic plants conducted

8 http://www.oecd.org/biotrack

9 http://bch.cbd.int/

10 CERA. (2010). GM Crop Database. Center for Environmental Risk Assessment (CERA), ILSI Research Foundation, Washington D.C. http://cera-gmc.org/index.php?action=gm_crop_database

11 ISAAA's GM Approval Database. http://www.isaaa.org/gmapprovaldatabase/.

12 Biotechnology Regulatory Contacts in OECD Member Countries. http://www.oecd.org/chemicalsafety/biotrack/biotechnologyregulatorycontactsinoecdmembercountries.htm

13 Search for National Contact (at BCH website). http://bch.cbd.int/database/contacts/

according to a specific legislative framework. Direct communication with regulators in other countries as well as using information on the environmental risk/safety assessments done in those countries can facilitate risk/safety assessment in an LLP situation. It is important for countries to keep their information current in these databases to maximize their usefulness.

70. Information may be accessible directly from the authorities in the authorizing country (or countries) and from scientific literature. Collaborative working relationships between national authorities in different countries and/or with industry and public institutions have enhanced access to information, and establishing on-going communication may be beneficial to this process. The importance of working relationships between national authorities cannot be over-emphasized. For conducting environmental risk/safety assessment of an LLP situation, only limited information may be immediately available to the importing country. It is sometimes difficult for importing countries to obtain information needed from the developers and/or companies involved, particularly when the scale of production is not large. In such cases, the responsible government agency in the exporting countries may provide information that can be shared with the importing country. When the LLP situation results from asynchrony of authorization such that the transgenic plant involved is authorized in the exporting or other countries, a great amount of data will have accumulated.

71. Information may be available on the trait or phenotype within the crop plant in the particular environment and/or in a variety of environments along with the identification of any unintended effects in the environments of countries in which authorizations have been made. Such information may be adequate for the purpose of an environmental risk/safety assessment of the LLP situation, depending upon the specific regulatory requirements of the country or region.

72. Characterization of the introduced trait may come from an authorization or application received for food and feed, and/or environmental release of the same or a similar plant. Many times the information on molecular characterization of the introduced trait is very similar for these types of authorizations (OECD, 2010). Further, a feed or food safety assessment (*e.g.* done according to the Codex Alimentarius (2003)) contains information that may be useful in an environmental risk/safety assessment including a description of the transgenic plant, the unmodified plant, the donor organism of the introduced genetic material, and a characterization of the genetic modification. While information developed for food or feed safety assessments may be limited for the performance of an environmental risk/safety assessment (*e.g.* compositional analysis) it may set the context for an assessment of an LLP situation in the environment.

73. In cases where applications for a review necessary for an authorization for commercial cultivation (unconfined release) have not been received and more data or information is needed to address the LLP situation, the data and information available from the additional sources mentioned above may be assessed for adequacy for the purpose of an environmental risk/safety assessment in the importing country. In addition, communication between the importing and exporting countries can facilitate the exchange of as much data and information as possible within the boundaries of legal constraints. The importing country may also work with the developer of the unauthorized transgenic plant to obtain as much relevant data and information as possible to address the LLP situation efficiently.

2.5 Environmental Risk/Safety Assessment in an LLP Situation

74. When approving a transgenic plant for potential cultivation, usually the environmental risk/safety assessment assumes 100% exposure over an extended period of time, *i.e.* the plant is cultivated on potentially very large areas of land. This is an assessment of a product for intentional use. However, when assessing an LLP situation the context may be different. The determination of

environmental risk that an unauthorized plant may pose is based not only on the hazards identified but on the potential exposure, which will be related to the scale of an LLP situation. The amount and degree of information needed may be different for an LLP situation because of the reduced scale and the purpose of the assessment. By definition, generally, an LLP situation is at a scale reduced from that assumed present in a risk/safety assessment for authorization for large scale cultivation of the same plant. In an LLP situation, the environmental risk/safety assessment is not intended to lead to an authorization. However, the results of the assessment can be useful in supporting environmental risk management decisions through scientifically evaluating potential options for managing any risk presented.

75. The purpose of the following discussion of scale (Section 2.5.1), the trait (Section 2.5.2), and the plant and the receiving environment of the importing country (Section 2.5.3) is to indicate how the available knowledge and experience, data and information, can facilitate a rapid environmental risk/safety assessment of an LLP situation; the timeframe for the assessment and decisions is much shorter than for an authorization for cultivation. It does not explain explicitly how to do such an assessment. It is noted that the types of information used are generally the same as for the review of an application for authorization where much of the information is supplied in the application itself. There is ample discussion of these types of information and their importance to environmental risk assessment in previous OECD publications (OECD, 1992, 1993a, 1993b). The basic safety issues that may potentially be of concern were identified in these publications. They include gene transfer, weediness, trait effects, genetic and phenotypic variability, genetic material from pathogens, and worker safety.

2.5.1 Scale

76. Each country makes its own determination of what is considered to be LLP, most often on a case-by-case basis. In terms of the environmental risk/safety assessment, several approaches to determining the scale (*i.e*. amount of seed distributed spatially and temporally) of the presence of the unauthorized transgenic plant involved in the LLP situation may be useful. For commercial seed containing LLP that has been planted, the scale may be determined through information about the anticipated distribution and period of release especially information on seed distribution, and this is usually known by seed companies and farmers (*e.g.* where seed lots have been distributed or fields planted with that seed), although this may not always be the case. Results of *in situ* testing may also be available or useful, depending upon the situation. Availability of detection methodologies may provide information for this purpose. This testing may occur in unplanted seed, in plants in the field or in the harvested commodity and is a means of understanding the potential environmental distribution. Other potentially useful types of information may include an identification of the source of the unauthorized transgenic plant; information on seed lots (whether transgenic or not) that are not expected to contain unauthorized transgenic seed; and information on quality control of seed (whether transgenic or not) in seed producing countries. For both commodities and seed, knowledge of crop plant-specific international movement can provide information to allow examination of the amount and pathway(s) of distribution; such information could include known distribution routes, shipping manifests and trade statistics.

2.5.2 The Trait

77. Molecular characterization allows for the verification of the trait and genotype, which in turn supports the characterisation of the phenotype. Depending upon the situation, the verification needed may come from data and information about the protein, construct and/or the specific event. The nature of the genetic modification, particularly any protein(s) expressed by the transgenes (OECD, 2010), and biological functionality of the gene products allows for a determination of how similar they are to those found in transgenic plants authorized either domestically, regionally or in other countries. Useful data

and information for an assessment of an LLP situation can generally be extrapolated from that about the same or almost the same transgene; regulatory elements; transformation methods; introduction into the same genetic background as approved lines; similar expression levels; relevant field test data; lack of additional unintended genetic material; and effects of expression of a very similar protein.

78. When the LLP plant is known to be similar to an existing authorized transgenic plant, much of the information from previous domestic, regional, or other country determinations becomes relevant and directly applicable. Such knowledge facilitates the identification of potential adverse impacts such as known toxicity of the gene product or effects on non-target organisms (OECD, 1993a). The following questions point an assessor to the types of information that may prove useful in determining the degree of familiarity with the trait in the unauthorized plant in an LLP situation:

1) *Does the unauthorized plant belong to the same plant species as previously evaluated or authorized transgenic plants?*

2) *Does the unauthorized plant contain the same or similar trait, transgene, genetic components, and/or regulatory elements as previously evaluated or authorized plants?*

3) *Was the transformation method the same as used in a previously evaluated or authorized plant or, if not, does use of a different method present any additional issues?*

4) *Is the same or a very similar protein expressed in previously evaluated or authorized plant? Are protein expression levels and/or patterns similar to previously evaluated or authorized plants?*

5) *Are field test data available that support the conclusions of other assessments of similar transgenic plants?*

79. While data and information addressing all of the above questions may not be needed to understand the behaviour of the unauthorized plant, previous assessments of the same or a similar plant that have addressed what potential adverse effects might be predicted for the unauthorized plant can contribute to a rapid understanding of whether the LLP situation might result in any adverse effects. More or less information will be needed, depending upon the particular LLP situation; how quickly decisions are needed and the core information and comprehensiveness of that information needed to make those decisions.

80. Information on the unauthorized plant, when available, can further 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. In cases where the unauthorized plant contains combined traits, familiarity with the combination of traits may be useful. Domestic field trial data that may be available can support conclusions regarding the environmental effects of a particular trait in the LLP situation, particularly if an application for authorization has been received.

81. The available broad domestic or global experience and knowledge of how the major traits being used today, particularly the herbicide tolerant and insect resistant traits, affect different plant types in different environments may provide a range of possibilities of how the trait may affect the behaviour of the plant in the environment of a particular LLP situation. Such information can include that on the same trait introduced into different plant species and knowledge and experience with similar traits in the same crop plants developed through traditional plant breeding. Since a given trait may perform differently in different plant species, the existing combined global knowledge and experience of a particular trait in these different plant species gives a breadth of understanding that may be useful

in determining the potential range of responses of the plant-trait combination in the specific environment of an LLP situation.

82. There are several examples of genes and traits that have been evaluated by many countries. The phosphinocthricin acetyltransferase (PAT, conferring tolerance to glufosinate ammonium), and 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS, conferring tolerance to glyphosate) and *B. thuringiensis* crystal (Cry) proteins in the LLP situations to date have essentially been identical to those in similar authorized plants and have been produced from the same or similar gene constructs. Much information is available on these proteins and their associated expressed traits from the OECD (OECD, 1999a; OECD, 1999b; OECD, 2007). The herbicide tolerance and insect resistance traits resulting from most of these proteins as well as application of the complementary herbicides – in case of herbicide tolerance - have undergone multiple assessments and environmental reviews (CERA, 2011a; CERA, 2011b; CERA, 2011c; CERA, 2011d; Heard *et al*. 2005; Marvier *et al,* 2007; Wolfenbarger *et al.* 2008; Perez-Jones and Mallory-Smith (2010); Lang and Otto (2010); see also national and regional decision documents accessible thorough OECD BioTrack) with subsequent global commercialization over the past 20 years in a variety of crop plants. 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, the genes and proteins produced and the functioning in plants of associated genetic regulatory elements and markers (*i.e*. ampR, NOS, 35S CaMV), together with the respective risk assessments and risk managements, have been well documented in regulatory decision documents globally. This information may provide a solid knowledge base for the extrapolation of any environmental risk/safety assessment for an LLP situation containing these genes, expressed protein(s) and the resultant trait.

2.5.3 Plant and Receiving Environment of the Importing Country

83. The majority of LLP situations to date have involved 'common' crop plant species and trait combinations that have been widely adopted and are under large scale cultivation where authorized. There is substantial knowledge and experience with these plant species as they are grown regularly within the countries in which LLP situations can occur, as non-transgenic or transgenic crops. Familiarity with the biology of the crop plant and its behaviour in the receiving environment in the context of the existing agricultural practices (cultivation and environmental management) of the country or region can be used to identify aspects of the environment that may potentially be affected in an LLP situation. This can facilitate rapid assessment of the potential for any environmental risk to be presented by an LLP situation in seed. The importing country with the LLP situation may use this understanding to identify the unique or different aspects of its country/region compared to the exporting country (and other countries) where assessments for authorization of the transgenic plant have already been completed.

84. The use of existing information on cultivation of a plant species can facilitate rapid performance of an environmental risk/safety assessment and the development of environmental risk management plans in an LLP situation. Agricultural practices (*e.g*. crop rotation, tillage, planting dates, herbicide use, control of endemic pests and diseases) may vary within the same plant species and between countries or regions because of variations in climate, soil, and other factors. However, most crop plants, including transgenic ones, are normally restricted to (or dependent upon) the managed environment due to extensive domestication (this may vary according to the species of plant). Cultivation of authorized transgenic plants may include additional practices beyond standard ones, depending upon the trait(s) and/or any risk presented (*e.g*. insect resistance management). Practices such as herbicide usage for weed and volunteer control or use of pesticides/fungicides to manage pests and diseases may be important for determining the risk/safety of unauthorized seed containing traits for herbicide tolerance or insect resistance. Much information on different crop plant species and

associated agronomic practices in the environment is available in the OECD biology documents[14] as well as from various publications of national authorities. Over 25 OECD biology documents are currently available including documents for the major commodity crops (corn, cotton, rapeseed, and soybean) (OECD, 2003; OECD, 2008; OECD, 2012a; OECD, 2000). These OECD documents have proved useful in various national reviews, including those of LLP situations.

85. Important information for environmental risk/safety assessment in an LLP situation may also include that on any means of spread and persistence of the plant. Many crop plants, including most of the important seed and commodity crops, have lost the weed related traits of their wild progenitors through domestication and this history may be well understood. The OECD Biology Consensus Documents (see Preamble) may provide baseline information on the ability of a plant species to spread and persist in the environment.

86. However, some crop plants outcross prolifically within the crop or to sexually compatible species. When such plants are cultivated in areas geographically close to populations of sexually compatible wild or weedy relatives, the potential for exchange of genetic information may be a consideration in an environmental risk/ safety assessment. Where populations of wild or weedy relatives occur is information generally specific to a country or region: the OECD Biology Consensus Documents (see Preamble) may provide baseline information on several plant species' feral, wild and weedy relatives and the distribution of these relatives.

87. Some plant species only exchange genetic information at very low rates. In general, a reduced ability of a plant to cross with other plants of the same species or wild or weedy relatives would limit the possible extent of outcrossing, and thus reduce concern that the transgene may have moved, through the exchange of genetic information, from the original area of release.

88. Thus, the potential of the introduced transgenic trait to spread in the environment through the exchange of genetic information between the unauthorized transgenic plant and associated crop plantings or wild or weedy relatives may be of particular interest in an environmental risk/safety assessment. Once identified, these factors can be evaluated in the context of the existing agricultural practices for either the unmodified plant or a similar authorized versions of the transgenic plant and provide relevant information in evaluating an LLP situation.

89. Currently, many traits are introduced into crop plants to directly affect target pest species and disease organisms. In addition to the target species, a variety of organisms interact with crop plants in the field. The potential for direct or indirect effects on beneficial or endangered organisms depends upon this interaction and is directly dependent upon scale. The nature of the trait (*e.g.* virus resistance or insect resistance) may indicate whether a safety issue is of concern. Familiarity with the fauna of a region will indicate whether a trait in a particular crop plant is of concern. Information from previous authorizations may provide this knowledge efficiently, including whether standard agricultural practices provide sufficient management of the concern.

90. When commodities approved for food and feed use alone are the source of an LLP situation found in seed to be planted or in fields already planted, existing familiarity with the cultivated plant as indicated above can be used for the environmental risk/safety assessment. However, additional information, such as that on the maintenance of the transport route, including weed management, may be useful when such plants show up growing outside of cultivation *e.g.* in environmentally disturbed areas such as roadsides and railroad track beds. Knowledge of the conditions for plant growth and

14 http://www.oecd.org/env/ehs/biotrack/consensusdocumentsfortheworkonharmonisationofregulatoryoversightinbiotechnology.htm

survival in disturbed environmental settings, generally sub-optimal for many domesticated plant species as they require human maintenance, and whether the plant can just survive or can form self-sustaining populations and become weedy can inform an assessment of the potential for persistence or spread of the plant and/or trait. Knowledge of the presence of wild and weedy relatives in the local area or nearby compatible crop plantings can also be a factor in determining the potential for spread and/or persistence along with whether the plant species is listed as a weed in the region. Even if the plant species is not cultivated within the country, information is available from the OECD about the commonly traded crop plants.

2.5.4 Risk Profile

91. When an environmental risk/safety assessment of an LLP situation is undertaken, the goal is to determine any risk presented and to scientifically evaluate potential options for managing any risk presented. In a relatively short period of time, the identity of the unauthorized plant material may need to be confirmed, the potential for adverse effects be determined, and actions taken to minimize any identified risk presented by the LLP situation. A risk profile characterizing the situation may be rapidly assembled based upon data and information from reviews of the same or similar authorized plants and/or existing knowledge and familiarity with the plant, trait, environment and their interaction. The risk profile recognizes the scale of the LLP situation and may expeditiously inform decisions to manage or mitigate any risk presented as well as to return the situation to regulatory compliance.

92. The following process can be used to develop a risk profile to expeditiously address an LLP situation in the environment of the importing country subsequent to identification (See Section 2.2, paragraph 57) of the presence of an unauthorized transgenic plant:

- Determine where the LLP situation has been found in the environment and the potential distribution of the unauthorized transgenic plant;
- Identify relevant sources of information, including previous assessments of that unauthorized transgenic plant available either domestically, regionally, or from other countries;
- Determine if those assessments identified any potential hazards and whether/how these relate to the importing country's protection goals and could potentially affect the receiving environment harbouring the unauthorized transgenic plant;
- Determine/consider whether there are pathways for distribution of the unauthorized transgenic plant in the LLP situation through which the identified hazard can cause adverse effects in the receiving environment; and
- Assess the likelihood and consequence of those adverse effects being realised

93. The trait likely to be expressed and any similarity of such trait expressed in previously authorized plants provide an invaluable starting point. Further data and information may or may not be needed, depending upon how familiar the risk assessor is with the plant species and the trait in the environment in question. If the plant species is well understood, as in most LLP situations with seed, then the focus of the assessment is on the trait(s) in the unauthorized transgenic plants and any risk of harm it might present to the environment when present at low levels. The resulting environmental risk/safety assessment can characterize the risk that may occur or has occurred given the specifics of the LLP situation (case-by-case). The assessment may include evaluation of management options to address any risk to the environment that might be presented such as an evaluation of existing or

modified distribution systems and agricultural practices used with the particular plant species. The assessment can also provide the needed scientific basis to inform broader management objectives, such as those to return the situation to compliance with regulatory requirements. In the context of this discussion, such management options may include mitigation of any further release of unauthorized plant into the environment and/or remediation of any release that has already occurred.

94. If the unauthorized LLP plant is similar to existing transgenic plants authorized domestically, regionally or in other countries, much of the information from those previous assessments and conclusions of safety may be directly applicable. Table 2 provides several examples of the knowledge and information that may exist, depending upon the case. Any aspects of the receiving environment such as cultivation practices, biological aspects such as those for potential dissemination, persistence through natural means (*e.g.* pollination, dormancy, volunteers, etc.) or the potential for negative effects on beneficial or endangered species can be examined, as can human factors such as transport, handling, spillage, planting, and depending upon the trait, used to determine the applicability of the results of previous assessments in making a prediction of the risk presented by the LLP situation. In this context, knowledge of the source(s) and the scale of the LLP situation spatially (*e.g.* area and/or location) and temporally and of the amount of the unauthorized transgenic plants involved (*e.g.* a limited amount of seed might be distributed/spread over a wide geographic area) is relevant to the assessment. Should the trait influence the plant's ability to persist and spread, an assessment may evaluate whether the change in behaviour could lead to an adverse consequence. In addition, the assessment may evaluate whether such changes could present additional or novel pathways to harm within the environment of release. Finally, an assessment may evaluate whether such changes might directly impact the ability to control or manage the situation using existing practices. In performing such an evaluation, an assessor's knowledge of a particular managed agricultural environment, including information on the surrounding partially managed or natural environment, would inform the determination of risk/safety. 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 adverse consequence has been identified or whether there is a difference in the unauthorized plant's behaviour in the environment.

95. The environmental risk/safety assessment may identify areas of uncertainty that may need to be addressed by additional information. This may depend upon how familiar the risk assessor is with the plant and the trait in the environment in question. More data or information may be necessary, such as for molecular characterization or on the potential of the trait to increase weediness in a particular plant.

96. Ultimately, the environmental risk/safety assessment takes into account agricultural practices and the effectiveness of these practices to manage any risk presented either through limiting or removing the unauthorized plant from the environment. Familiarity with agricultural practice can indicate:

- where risk management can adequately be applied using standard agricultural practices; or
- when additional remedial or mitigating measures are needed.

Familiarity with agricultural practice may also potentially inform any actions to bring the LLP situation back into compliance with regulatory requirements.

97. To date, the LLP situations in the environment from seed and commodities that can function biologically as seed have allowed for relatively straight-forward case-by-case, comparative, scientific assessments of risk/safety based for the most part on existing information. As a result, when assessments have been done, it has been determined that the low level presence of these

unauthorized transgenic plants in seed or commodities in the environment posed a low level of risk, given the impacts and scale of the situations (Annex II). This conclusion was based on the review of available scientific data, the limited amount of the unauthorized plant in the environment, and comparison with either the unmodified plant or the close similarity of the unauthorized plant to authorized transgenic plants which had cleared regulatory review in the importing country.

98. In instances where an importing country has not carried out a previous assessment of the same or similar plant, globally available information may be used as the focus of assessments globally is on the biology of the plant, the trait, and the interaction of these in the receiving environment. Thus, there is much information about these factors that may be useful to expedite an environmental risk assessment in an LLP situation to inform the appropriate action needed to protect the specific environment in the importing country. International databases can function as a source of information to evaluate the adequacy of available risk/safety information for the requirements of a particular legislative framework (see Section 2.4). The aggregate of this broader set of information can give the assessor an indication of the range of potential interactions with the environment of the trait in the same plant species and in other species and this may be directly applicable to the environment of the importing country. This has been especially true with the LLP situations to date in which many countries have evaluated the crop plant with the herbicide tolerant and insect resistance traits grown and traded globally. However, when an application for authorization has already been received by the importing country, much of the needed information may already be available.

Table 2. Potential example scenarios indicating types of existing knowledge and information that may be used by an importing country to facilitate an environmental risk/safety assessment of an LLP situation

In these cases, the crop plant is grown in the importing country (unmodified or similar traits in authorized transgenic plants).

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 transgenic plants 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 in the importing country. 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 exporting or authorizing country; Agricultural areas where the crop is grown provided by seed company/industry; Experience with cultivating this crop in the importing country. Existing environmental risk/safety assessment data and experience with the unauthorized transgenic plant/event line within the importing country for the gene and expressed protein. The environmental risk/safety assessment of the same or similar authorized transgenic 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; Environmental risk/safety assessments available from other countries; Experience and information from similar plant/trait combinations deemed relevant by the importing country; and Relevant OECD consensus documents.	Characterization of the introduced trait completed in the exporting or authorizing country; Agricultural areas where the seed crop is grown provided by seed company/industry; Experience with cultivating the crop in the importing country, particularly regarding the tendency to persist or spread in the environment; Experience with the trait (or similar traits) in the other crops; Environmental 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.

SECTION III – USE OF INFORMATION AND AN ENVIRONMENTAL RISK/ SAFETY ASSESSMENT FOR MANAGEMENT OF LLP SITUATIONS IN SEED

3.1 Possible Approaches to Management of LLP Situations in Seed

99. The "Scale-up" document (OECD, 1993a) describes environmental risk management as "the way appropriate methods are applied in order to minimise scientifically identified risks…In principle, appropriate management is based on and should be in proportion to the results of the risk/safety" assessment. "Risk management encompasses all aspects of the management of the organism indirectly through management of the environment into which the organism is introduced, or directly, by management of the organism itself."

100. In general, management of an LLP situation may focus on the goals of protection of the environment (environmental risk management) and/or returning the situation to compliance with the requirements of a country's legislative framework. An environmental risk/safety assessment may be useful in informing decisions for environmental risk management and returning the LLP situation to compliance with the regulatory requirements of the country or region, recognizing that the use of an environmental risk/safety assessment for this purpose may depend on the provisions of the legislative framework of the country. An environmental risk/safety assessment may not be needed to address a particular LLP situation due to the adoption of processes to handle LLP (see Section 3.2) or, in contrast, the framework may not allow management measures for LLP situations in general to be based upon the results of an environmental risk/safety assessment. When performed, an environmental risk/safety assessment can be used to characterize the situation, including identifying any risk associated with the situation and identifying the measures either in place or needed to manage any risk presented. Overall, management measures undertaken by a country will likely address environmental risk management as well as measures to return the situation to compliance. The information provided by the risk assessment can identify whether risk management of the situation is inherent in the agricultural management practices already at hand; whether additional measures for mitigation are needed and, additionally, whether these same measures will be useful in returning the situation to compliance.

101. Familiarity with the biology of the crop plant and the associated agricultural practices can not only facilitate rapid assessment of any risk presented by an LLP situation in seed, but the ramifications for mitigation or risk management of the situation. In the LLP situations to date, major crop plants involved were corn, cotton, rapeseed/canola and soybean with commonly inserted genes for insect resistance and herbicide tolerance. Environmental risk/safety assessments have been useful in informing decisions for managing these situations, particularly in limiting or mitigating the spread and persistence of the unauthorized plant. Knowing the source of the LLP in seed may facilitate limiting further introduction of the LLP seed into the environment given the distribution of the plant, the ability of the plant to establish and spread, and the methods available for control or eradication. However, it may not always be possible to determine whether the source of the LLP of unauthorized plant found in the environment originated in seed or from some other source such as commodity spillage. In any case, an environmental risk/safety assessment can identify and evaluate any risks associated with an LLP situation and, depending on the country's legislative framework, provide options for environmental risk management in a manner proportional to any risk presented to achieve protection goals (OECD, 1993a; see also Section 2.3). The concept of risk management being proportional to the level of risk is standard

for all risk assessments. In addition, the same measures may contribute to returning the situation to compliance with legislative mandates; *e.g.* remediation and mitigation options that ultimately lead to limitation of the maintenance and/or spread and/or removal of the unauthorised plant from the environment and ultimately the seed supply.

102. The circumstances and timeframe of an LLP situation in seed are other major factors in environmental risk assessment and risk management (*e.g.* has the seed been planted; if the commodity has spilled is the season right for germination; if germination has occurred, what developmental stage are the plants at, especially with respect to sexual reproduction – flowering, seed set, harvest?). All these factors can be time critical for determining the appropriate environmental risk management/mitigation measures, depending upon the risk presented – *e.g.* removal or destruction of the unauthorized transgenic plants prior to flowering may or may not be important in limiting potential spread or persistence.

103. A significant factor for food and feed crop plants involved in an LLP situation is whether a food and feed safety evaluation has been undertaken or authorization given, either domestically or by another country. It may be relevant to consider information from safety assessments of food, feed, and processing of the implicated transgenic plant that may exist from different sources, including national sources, in setting the context for an assessment of an LLP situation in the environment. Food and feed safety evaluations can provide relevant information regarding the potential for adverse environmental consequences to wild animals that may inadvertently consume the plant.

104. If the environmental risk is determined to be insignificant in comparison with the unmodified counterpart or a similar authorized transgenic plant, and if the country's regulatory framework allows for it, one option might be "no action" to remediate or mitigate the particular situation from an environmental risk perspective. Depending upon the situation, seed and/or plants may be limited or removed from the agricultural production system including in the following manners:

1) recall of unplanted seed from distributers;

2) destruction of planted seed once germinated;

3) allowing planting and/or harvest, but controlling the distribution of any seed or harvested crop produced; or

4) permitting seed already planted to be utilised in a manner where processing procedures devitalize the plant so there is no further potential for plant growth (*e.g.* biogas utilization).

Each country will consider appropriate management strategies under its legislative framework, and therefore some of these options may not be feasible.

105. Although the conclusion of the environmental risk/safety assessment may suggest options that allow the management or mitigation of any risk of the unauthorized plant in a manner commensurate with the level of risk presented, other factors also play a role in determining appropriate management of an LLP situation. An LLP situation is, almost by definition, a situation of non-compliance with regulatory requirements and in many jurisdictions there are legal requirements for compliance that also set the context for management for risk. In addition, the complexity of the response may be influenced by, for example, socio-economic factors, legislative mandates, stakeholder preferences, or the availability of resources. In addition, the preferences of the grower, seed supplier or industry may also play a role and there are several examples of growers, developers and seed suppliers taking more rigorous action than mandated by the national authority. In many LLP situations, national authorities have demanded destruction, devitalisation or reshipment of seed lots to achieve compliance.

However, economic consequences to the farmer, importer and government may also play a role. The responsiveness and collaboration of the industries involved have been critical to addressing past LLP situations. Nonetheless, when performed, the environmental risk/safety assessment itself becomes an overriding consideration in the development of plans to mitigate and manage an LLP situation proportional to the risks presented.

106. In summary, important environmental risk assessment factors that are considered in developing management plans include:

- The present circumstance of the LLP situation in the seed or commodity, including where the unauthorized plant was discovered.

- Conclusions of an environmental risk/safety assessment.

3.2 Potential Ways to Proactively Address Environmental Risk for LLP Situations

107. In recognition of the fact that LLP situations are anticipated to increase 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 (Annex II), countries and regions have taken several steps to limit the potential for uncertainty regarding environmental risk. Some authorities undertake environmental assessment of transgenic plants authorized for use as food or feed and for processing in recognition of the potential of these commodities authorized for import to be found in the environment. Thus, when LLP situations in the environment have occurred with such plants, 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 transgenic plant is found in planted fields as well as along transport routes due to spillage during commodity transport. Other countries perform assessments for authorisation of commercial cultivation (unconfined release) of the plants that are destined to be imported for only food, feed and processing. When these plants have later been found in the environment, they have not been deemed illegal. In neither of these approaches does it mean that it is acceptable to allow commingling of seed material in an on-going manner. But, in some situations with identified low levels of an unauthorized plant, there may not be a general concern raised.

108. Some importing countries have set up comprehensive systems for working with potentially affected domestic government agencies and stakeholders, particularly affected industries, to prevent the import of seed or commodities containing unauthorized plants. Some countries work with the seed and plant breeding industries to ensure appropriate quality control systems are in place to prevent unauthorized plant material getting into breeding material. The industries themselves have also incorporated protocols to reduce the prospect of having seed or commodities rejected or destroyed upon arrival in the importing country due to the presence of a low level of an unauthorized plant. Preventive measures taken by industries are critical to reducing the occurrence of LLP situations.

109. Preparations for a possible LLP situation have occurred in some countries through the development of communication plans with other national government agencies and through educating stakeholders as to their roles and responsibilities in both preventing and managing an LLP situation. Such close relationships can enable importing countries to address LLP situations in an effective and efficient way.

110. Several countries, recognizing the potential for LLP to occur in seed, have set thresholds allowing for LLP if a food safety authorization has been done according to the CODEX plant guideline either regionally or in a country with a similar food safety review system as the importing country.

Since it may be impossible to entirely eliminate LLP in seed, in some cases thresholds have been set to assure an acceptable and predictable supply of seeds. This has been in response to several instances where the LLP was detected at such a low level that it was technically below the level of quantification using validated protocols for testing. In these situations, testing at different stages in the seed distribution system led to conflicting results regarding the presence of LLP in seed. Recognizing the inability to entirely eliminate LLP, thresholds have also been adopted by some importing countries to avoid the reduced availability of seeds in cases where it was known that the unauthorized plant had been authorized at least in one other country.

SECTION IV – REFERENCES

INTER-GOVERNMENTAL DOCUMENTS CITED:

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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[15]; 3) use of experience and familiarity in the assessment[16] 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?

15 How did access to this information occur?

16 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?[17] 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.

17 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 parentheses.

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 pertains 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 appropriate individuals 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, an 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[18]; Foreign Affairs and Trade; Education, Science and Training[19]; Industry, Tourism and Resources[20]; 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.

Since 2007, the OGTR has worked with the Australian Seed Federation to develop a review program of existing industry quality assurance measures. In 2009–10, the OGTR began quality assurance reviews of Australian and State government breeding programs. No issues of concern were identified for the companies that participated in the program.

The OGTR continues to liaise with the Australian Seed Federation to expand the quality assurance review program as needed.

18 Now the Department of Sustainability, Environment, Water, Population and Communities

19 Now the Department of Education, Employment and Workplace Relations

20 Now the Department of Department of Industry, Innovation, Climate Change, Science, Research and Tertiary Education

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 DAFF Biosecurity (formerly 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 Arts18, 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 industry best practice code of conduct refers to 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.
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 Assessment 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 March 2013, 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 DAFF Biosecurity (formerly the Australian Quarantine and Inspection Service) to permit access to data on imports. This information assists in identifying potential 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, lupin 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 Center for Environmental Risk Assessment GM database http://www.cera-gmc.org/?action=gm_crop_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, 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 a way as to protect the health and safety of people and the environment.

AUSTRIA

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

Introduction – Austrian national GMO regulatory requirements for seed:

The Austrian Ordinance on Genetically Modified Seed, BGBl. II Nr. 478/2001 as amended, regulates the adventitious presence of GMOs in seed as well as the labelling of GM varieties and seed from GM varieties.

In this Ordinance the authorized and unauthorized GMOs are commonly defined: organisms, whose genetic material has been modified in a way, which cannot be observed in natural crosses or by recombination or other conventional breeding techniques, see Act on Genetic Engineering 1994).

There is a zero tolerance policy in place for seed which is undergoing the certification procedure and for seed being marketed; in the enforcement process the Minimum Required Performance Limit of 0.1% for adventitious impurities of GM Seed in non GM seed is applied.

The requirements to the methods for GM-testing and statistical standards for the testing results are laid down in the Austrian Methods for Seed and Varieties. Examples of principal requirements are:

- The testing method shall be in accordance with the latest scientific and technical developments and with the standardized international methods for seed testing.
- The smallest reference quantity indicating the contamination of the seed with authorized and unauthorized GMOs is one seed; the size of the working sample for testing must be at least 3000 seed units.
- As a function of the detection level and the technical characteristics of the method utilized, a testing plan with sub-samples shall be designed, so that at least 1 genetically modified seed in 3000 seeds can be detected.

GMO-Monitoring program on seed - scope of annual activities and results:

The national seed program constitutes an integrated quality system and comprises a risk-based monitoring system performed by the Federal Office for Food Safety on one hand, and a systematically implemented self-monitoring system by the seed companies on the other hand. Due to the zero tolerance policy for seed certified and/or marketed in Austria, seed companies are requested to implement a comprehensive quality-control system during the whole seed production cycle. This encompasses the GM adventitious presence testing of the Basic or Pre-Basic seed utilized in field production, the strict removal of outcrosses (potential risk of GM-contamination) in the field, cleaning measures during seed processing and GM-testing of the final/certified seed.

Finally the governmental monitoring system of the Federal Office for Food Safety evaluates the effectiveness of the self-control system on the one hand by auditing the seed producers/suppliers to check the practice of implementation of QM standards (traceability from field to seed package) and on the other hand by testing for GM-material of seed lots which are marketed or used in seed production in Austria and further GM-testing of outcross plants found in seed production fields or in the national post control plots (details see table below).

Since 2001 this governmental monitoring program is ongoing.

GMO-Monitoring program	Type of sample	Season				
		2006	2007	2008	2009	2010
1. Seed lots certified in Austria	Seed/ kernel	82	83	80	75	76
thereof positive		4	1	1	1	2
2. Enforcement control: – marketing of seed certified in other EC- or Third countries	Seed/ kernel	51	38	35	41	42
thereof positive		1	2	1	5	1
3.a) Basic or Pre-Basic seed lots used in seed production in Austria	Seed/ kernel	21	23	34	34	39
thereof positive		0	0	2	1	1
3.b). Examinations and sampling in field production (field certification) and in post control plots Botanical examination of about 1,5 to 2,0 million plants	leaves (of approx. 1,5 to 2 million plants)	414	217	373	356	368
thereof positive		0	2	2	1	0
4. Seed material used in variety registration procedure in Austria	Seed/ kernel	26	25	27	29	27
thereof positive		0	0	2	2	0

In all cases of GM-positive results (≤ 0,1%) during control examination of the Federal Office of Food Safety (Institute for Seed), analytical reports confirming absence of GMOs according to the Methods for Seed and Varieties were submitted by the applicants for seed certification or alternatively by the seed marketing organisation. Thus, the affected seed lots met the requirements of the Ordinance on Genetically Modified 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?

The Seed Monitoring of the Federal Office of Food Safety came to the result that seed marketed in Austria had fulfilled the requirements of the Austrian Ordinance for GM Seed. There is a close cooperation between the Authority and the seed producers in Austria, in order to prevent contamination of seed with GM material.

As no GM crops are approved for cultivation in Austria, the seed industry must take steps to ensure that seed lots intended for our markets do not contain traces of GM Seed.

III. What lessons were learned?

According to our opinion one major issue for handling LLP cases is predictability of legal decisions. Therefore we strongly support the call for setting uniform thresholds for GM adventitious presence in conventional seed on EU level. Collaboration with the industry and information sharing are essential to minimize economic damages. The Austrian regulatory requirements provide a good basis for production of high quality seed and the acreage of seed production increased significantly in the last years.

The integrated approach of the Austrian quality system in seed production (systematic controls in all process steps including enforcement/post control) with a risk-based governmental monitoring program and the self-check system of the industry ensures that GM-free seed production is achieved.

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 large scale regional research project in Wallonia aimed at randomly sampling oilseed rape plants in the Walloon environment and checking for their GM status, a few 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[21]. Ms8, Rf3 and Ms8xRf3 oilseed rape are authorized for import and processing in the EU since 2007[22]. 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 these GM oilseed rape plants in the environment, the Federal Public Service Public Health, Food Chain Safety and Environment[23] 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.

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 specific policies are in place to address LLP in the environment, nor in Belgium nor in the EU. LLP situations are handled on a case by case basis.

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)[24]. In the risk assessments[25], the adventitious release of the GM events in the environment was also considered.

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21 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.

22 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.

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

24 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).

25 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

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 (compared to the total number of plants that were analysed), 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 these 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.

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 of 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 per cent 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?

In the Czech Republic, two cases of LLP have occurred so far – low contaminations of maize seed by GM admixtures.

The Ministry of the Environment of the Czech Republic, as the Czech Competent Authority for GMOs, was informed in April 2009 and in May 2010 by 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 transported to the Czech Republic. Trace amounts of GM maize not authorised for cultivation in EU had been detected by the German inspection and control services in conventional maize varieties. The detected amounts were below the limit of quantification (LOQ), thus being less than 0.1 % for each of the detected GMO events.

The Ministry of the Environment (MoE), 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). In each case, CISTA contacted the seed importer and required appropriate measures to be taken.
In 2009, the seed holder, 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 early start of the 2009 season.
In 2010, the situation was less complicated, because the affected seed lots were stored by the importer for the next season.

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 the events detected in conventional maize seed had been previously authorised in EU for import and processing and had been used in a number of field trials, so their environmental risk assessment had been conducted and its conclusions were widely available. Therefore, due to the very low level of contamination, the Czech authorities considered the risks for the environment of these two LLP cases as negligible.

Therefore in 2009, CEI issued the final decision ordering the farmers to destroy the plants of the contaminated variety 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 special supervision, for silage feed directly at the farm or for biogas at the nearest biogas facility. CEI inspected the fields after the harvest and checked the disposal of the GM plants. The affected fields were monitored for volunteers during the next season.

In 2010, the seed holder was ordered to export the seed to a country where the events are authorised for planting. The transport was supervised by CISTA.

III. What lessons were learned?

As a consequence of the first LLP case, the Competent Authorities in the Czech Republic set a technical threshold value 0.1 % for reliability of GMO analysis in seed, to provide for legal certainty of operators. According to this provision, an analysis is conclusive if the contamination is detected on or above this level.

The experience confirmed the importance of exchange of information among Authorities, both at national and international levels.

ESTONIA

Our response to this questionnaire is very short as Estonia has not yet experienced LLP situations.

We do not conduct any special risk assessment related to LLP of viable seeds in commodities, we conduct a normal risk assessment related to GMOs as required by EU legislation. We follow carefully the situation in other countries and we consider the cooperation between countries very important as well as information sharing. At this point of time we do not have any lessons learnt or anything else useful to share with other countries.

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 the 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), and the 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 totalling 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, and 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 (GMOs) based on the Biosafety Law of GMOs (LBOGMs*). Mexican legislation establishes different regulatory procedures according to the intended use (food or feed, or for processing or environmental release) and according to the GMO under evaluation (*i.e.* crop plants or forestry trees) (http://www.cibiogem.gob.mx/Norm_leyes/Paginas/default.aspx). Different authorities are involved in the decision making process under a separated approval system:

- The Secretary of Health is on charge of Authorizations for GMOs intended for direct use as food or feed, or for processing (FFPs).
  **Spanish acronym*

- Two Secretaries are involved in the regulation of GMOs intended for intentional unconfined release 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). In the case of GM crops SAGARPA is the national authority that decides on issuing a permit for environmental release, following a binding technical opinion from SEMARNAT.

Cases of Low Level Presence (LLP), according to the scope of this document includes to address the situation of LLP in commercial seed and/or commodities of transgenic plant material that have been reviewed for environmental risk/safety and received authorization for commercial cultivation (unconfined release) in one or more countries but not in the country of import. Mexican LBOGMs does not consider LLP cases, therefore situations are managed case by case.

Given the separated approval system in Mexico, situations of LLP under the context of this document could occur when:

- Authorization for commercialization (for FFP) has been granted for commodities but an authorization for environmental release has not been granted or
- Authorization for environmental release has not been granted for GM seeds.

Both of these situations represent cases of non-compliance with the LBOGMs and require the adoption of measures bound to enforce compliance of the regulation; some of these measures could include the application of administrative and federal legal sanctions.

The answers to the Questionnaire include two selected situations or cases that have been documented in Mexico.

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

Case 1 – Commodities
Mexico has faced a case of unintentional planting of GM maize grains authorized for FFP that entered the country as commodities. Since some of the traditional practices of small farmers include to

experiment with new seeds, around 2001, small farmers presumably planted grains from commodities that included GM material that was not intended for environmental release, it was assumed that although the presence of authorized GM maize in a shipment could be high, in these cases the proportion planted was low and represented a LLP situation.

Case 2 - Commercial seeds
This case has been documented in Mexico with the detection in 2009 of LLP of GM seed in conventional maize seed, this detection occurred after the seed was planted. In this **situation of LLP,** the product being commercialized was conventional seed, not requiring a permit, and the level of GM seed detected in these non GM seed was below a threshold that has been used previously for qualifying certified seed in the context of the Federal Law of Seed Production, Certification and Trade (LFPCCS*).
**Spanish acronym*

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?

Case 1 - Commodities
Response measures: Monitoring programs were established to determine levels of presence and to identify the GM events in a case by case approach. The frequencies detected in the region of the LLP situation where very low. Additionally, response measures included the design and application of surveys in the region 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 information was provided to prevent subsequent and similar situations in the region.

Case 2 - Commercial seeds
Response measures: In this situation the level of presence of GM seed in conventional seed was estimated. Since the percentage detected was below a threshold that was used previously for qualifying certified seed; for this case the LLP situation was analysed under the Federal Law of Seed Production, Certification and Trade (LFPCCS) instead of the legal framework of the LBOGMs. To prevent possible future cases of non-compliance of the LBOGMs, derived from a similar LLP situation, the authority will stipulate management measures, for example, monitoring to ensure compliance with the regulation of certified seeds, and also, take steps to ensure that the product of these crops is directed for the authorized use and that it will not be saved and re-planted.

III. What lessons were learned?

Several lessons have been learned from facing these situations of presence of GMOs in the environment without their corresponding authorization.

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 been identified as a situation that needs the attention of different authorities. To avoid situations described in Case 1, the importance of actions related to communication have been 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 unintentional 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 agro eco-systems contribute to the generation of varieties adapted to different local conditions. Communication with these small farmers needs to emphasize 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.

Following the situation of detecting LLP of GM seed in non-GM commercial seed, a way to confront it, has been identified based on the experience related to the application of the regulation pertaining 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 operators and other 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 proficiency to comply with varietal purity standards.

Therefore, it becomes relevant that the communication with all the operators involved emphasizes that all practices including seeds and grains that may contain non approved GM events in the country ought to be efficiently managed.

IV. Other comments

Since these situations 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[26]. 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.

26 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

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[27], 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.

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.

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

The Biosecurity Act 1993 provides the legal basis for excluding, eradicating and effectively managing pests and unwanted organisms (including 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 per cent) 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 voluntarily 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.

PHILIPPINES

Our national biosafety framework covers all types of LMOs. However, regulations currently exist only for the release into the environment of plants and plant products derived from modern biotechnology. The Department of Science and Technology supervises contained and confined field test of plants from modern biotechnology while the Department of Agriculture regulates field test, commercial propagation and direct use for food and feed or processing.

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

The following cases involving unapproved or unauthorized events occurred in the Philippines. These cases cannot be ascertained to be cases of LLP as the Philippines did not have any policy on LLP during the time of occurrence but the possibility exists that the case(s) may have been cases of low level unintended presence. The first case involving a commodity (commercial milled rice) does not represent a commodity that can function biologically as seed but is presented just the same as it forms part of the regulatory experience in LLP. The second case involves seed.

Liberty Link Rice (LL) 601:

In early 2006, Philippine regulatory agencies were confronted with allegations of the presence of LL601 by the Greenpeace, in imported commercial long grain rice from the US, being sold for consumption in named supermarkets. The Greenpeace cited a test.

The allegations of the Greenpeace and subsequent clamour led the National Food Authority to recall all commercial rice alleged to contain LL 601.

As the Philippines was to receive a shipment of rice under the US commodity grant program, the Government of the Philippines required that the shipment test negative for the presence of LL 601 and the shipment should come from the CY 2007 harvest. For this purpose, a Plant Quarantine Officer was sent to the US to check compliance with the request.

Corn TC 1507:

In 2008, Monsanto Philippines reported that a shipment of corn MON 810 for propagation which were due to arrive in the country were discovered to contain corn TC 1507 which was unapproved in the Philippines.

As the shipment was on its way to the Philippines and with Monsanto having declared the presence of an unapproved event, the Bureau of Plant Industry allowed the entry, subject to the agreement that the whole shipment be quarantined in a facility owned by the company while the manner of disposal was being addressed. Ultimately, the seeds were destroyed by using them as fuel in a commercial cement facility.

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 a policy and as per our regulations, DA AO No. 8s. 2002, "Rules and Regulations on the Importation and Release Into The Environment of Plant and Plant Products Derived from the Use of Modern Biotechnology," transformation events which have not obtained a biosafety permit are not allowed into the country and are subject to disposal.

Technology developers/importers are required to state clearly the identity of transformation events for propagation such as seeds in A Declaration of GM Content, which is attached to the Plant Quarantine Clearance, upon arrival of a shipment in the country.

All transformation events for direct use as food and feed or processing are likewise required to be "identified as may be contained in a shipment of commodities".

Under our current regulations, regulatory authorities are obliged to subject unapproved events to disposal in a manner provided by law.

III. What lessons were learned?

The particular circumstances described regarding unapproved and/or LLP-related cases prompted the Department to initiate work on the formulation on the rules on unintentional transboundary movement or low level presence.

For LLP of recombinant-DNA plant material in food, the Department of Agriculture adopted Annex 3 of the Codex Plant Guidelines in January 2009. The DA is currently consulting the proposed "Rules and Regulations on the Application of Codex Annex 3."

SPAIN

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

Yes, so far, we had detected two incidents with LLP in seed lots in our country, one with maize seeds and the other with cotton seeds. The introduction of seed lots with accidentally presence of non-authorised GM events is not permitted in Spain according with the EU and national legislation on genetically modified organisms (GMOs).

Commercial seeds:

1) Bt-10 maize: On 22 of March, 2005 a biotech seed company communicated to the Ministry of the Environment that they had found maize seeds used for some field trials carried out in Spain in 2003 and 2004 containing the Bt10 event instead of the Bt11. It seemed that the Bt11 seed bags contained an accidental mixture containing Bt10 seeds as well.

Immediately, the Spanish Competent Authority informed about this incident the European Commission and, on 29 of March of 2005, the Commission communicated this incident to the rest of Competent Authorities in accordance to the Directive 2001/18/EC and Regulation (EC) No. 1829/2003.

2) GM cotton seeds: In 2008 it was demonstrated the presence of traces of genetically modified events not approved in the EU, in 12 lots of cotton seeds of a Spanish seed company, by analysing a variety for exporting to an EU country.

Commodities: Some cases of LLP in commodities that can function biologically as seed have been detected in our country. Most of them have been communicated by other Member States or through the Rapid Alert System for Food and Feed (RASFF) of the European Commission. A few cases were detected in Spain, where bulk commodities of maize, soybean and rice were blocked in different harbours at the border. In one case, the shipment was blocked at the harbour for few months until the GM event was finally approved in the EU (at this stage, it was under the final procedure for its EU approval) and finally was release for food and feed purposes. All incidents in Spain were notified to the EU through the RASFF procedures.

Competent Authorities

The Competent Authorities in seed production and certification are the regional "Autonomous Communities (CCAA)". In the case of the imports of seeds, the Competent Authority for control and inspection is the Spanish Office for Plant Varieties (OEVV) of the Ministry of Agriculture, Food and the Environment. A Joint National Plan between the OEVV, responsible for the import of seeds and materials of multiplication and the Competent Services of the Regions in charge of the production, certification and commercialisation of seeds in the scope of their territory, is in place since several years ago. As far as possible accidentally presence of GMO, the species controlled in seeds of conventional varieties are maize, cotton and soybean (both for non-approved and approved events in conventional seeds which contain accidentally presence of GM events above the legal established threshold). The Unit of Plant Varietal Biotechnology of the OEVV is the one in charge to coordinate the analysis, sampling plan and control of seeds for the detection of the GMO presence in the mentioned species. In the CCAA there is an Inspection Unit for Seeds responsible for the official taking of samples, under the system of the International Seed Testing Association (ISTA). The producing and importing companies of maize, cotton, soybean and canola seeds must supply to the responsible authorities, before the official certification of these seeds or their introduction in the country, the results of the qualitative and quantitative analyses performed for the detection of GMOs, carried out by an credited laboratory, to all and each one of the different seed lots, as much for conventional varieties as for genetically modified varieties (i.e. MON810 maize). Later, an official supervision of a minimum of 10% of the indicated lots is made, that they are sampling by the official services of the Spanish regional authorities or by the authorities of other UE Member States before their transfer to Spain. These samples are analyzed in the Central Laboratory of Veterinary Medicine of the General Directorate of Public Health of the Ministry of Agriculture, Food and Environment located in Algete (Madrid).

Regarding LLP in commodities the Spanish Food Safety and Nutrition Agency (AESAN) of the Ministry of Health is responsible for the co-ordination regarding food safety, including GMO controls in food. Within the Ministry of Agriculture, Food and the Environment, the Sub-directorate General for Conservation and Animal Feed is responsible for GMO controls in feed other than imports. The Sub-directorate General for Health Agreements and Border Controls is responsible for controls of feed imports including GMO for feed. The multi-annual National Official Control Plan of the Food Chain (now in place the National Official Control Plan 2011-2015), provides the framework for official controls of food safety and includes programmes for control of GMO in food and feed.

The Spanish Commission on Biosafety (CNB) at the Ministry of Agriculture, Food and the Environment is the consultative scientific body which assesses the safety of all activities and issues relating to GMOs.

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?

1) Bt-10 maize:

This incident was immediately assessed by the Spanish Commission on Biosafety (CNB) during the meeting held also in March 2005, and assessed the information supplied by the company in relation with this specific genetically modified event. The Company informed that the Bt-10 event only differs from event Bt-11 in the insert location in the plant genome and that it contained an antibiotic resistance marker gene which was not expressed in the plant since it was regulated by a bacterial promoter. The proteins expressed in this maize are the same ones that those expressed in the Bt11 maize. The field experimental tests already done during years 2003 and 2004 took place under controlled isolation conditions, destroying the plant material, as well as the grain, so the CNB considered that they were properly managed and didn't supposed any risk for the human health and the environment.

Nevertheless, it was also conclude that a certification for the import of the Bt11 seeds for new experimental trials would be requested to the company, as well as, samples for identification and detection purposes and the validated detection method as soon as it was available. It was requested to the company to make available this method to the Joint Research Centre of the EU as well. The accomplishment of an experimental test with Bt-11 maize which had been already authorized for the field test in 2005 was permitted with the condition to supply a certificate of Bt-10 maize absence, emitted by a certified laboratory and following the method of identification validated by the Joint Research Centre (JRC).

However, in accordance with the Spanish regime of sanctioning of the Law 9/2003, of 25 of April, which settles down the legal requirements for the contained use, deliberate release and commercialization of genetically modified organisms, the Government opened an informative process to the company, but finally no sanctions were imposed.

For the import of product derived from maize the Spanish Government implemented the "Decision of the Commission, of 18 of April of 2005, on emergency measures related to the presence in maize products of no-authorized genetically modified Bt-10 maize. In this regards, it was confirmed by the food and feed authorities that no imports of grain of neither Bt-11 nor Bt10 maize for human or animal consumption in period 2001 to 2005 were reported. The control of these products is subject to the principles and requirements of the Regulation (EC) nº 178/2002 of the European Parliament and the Council, of 28 of January of 2002 on the Food and Feed Safety legislation, which created the European Food Safety Authority, and to the Regulation (EC) nº 1829/2003, of 22 of September of 2003 on genetically modified food and feed.

2) GM cotton seeds: The analysis was conducted under request of the mentioned organization who asked for the emission of a certificated analysis of no presence GM. It was demonstrated the presence of traces GM events (promotional CaMV 35S promoter and T-us terminator) in all of them, but, except for 2 samples, it could not be possible to identified these GM events. It was concluded that these GM events were not approved in the EU and all these lots were destroyed.

Commodities

As mentioned before, all possible incidents with LLP in commodities are managed through the RASFF. Internally, all bulks commodities with LLP are blocked at the borders, and the competent authorities search for additional safety information outside and inside Europe in order to know whether the GMO is already approved in a third country or/and is under assessment by the European Food Safety Authority (EFSA), or even if the product already have an positive EFSA Opinion. But, according with the EU legislation it is not permitted to introduce the product in the EU market until it was definitively

approved in the EU (zero tolerance). At this stage the exchange of information with other competent authorities or operators is very important.

On the other hand, since the "Commission Regulation (EU) No 619/2011 of 24 June 2011 laying down the methods of sampling and analysis for the official control of feed as regards presence of genetically modified material for which an authorisation procedure is pending or the authorisation of which has expired", has entered into force, Spain is making the necessary efforts to fully implement this legislation.

III. What lessons were learned?

The information sharing is one of the most important issues to tackle these LLP situations, both internationally and between domestic Competent Authorities. In this respect, the Units responsible at the Ministry of Agriculture, Food and the Environment work together with the Inspection Services at Customs.

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[28]. 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[29], described proposals and approaches directed at "further reducing in commercial seed lots, bulk commodities, and 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.[30] 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.

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28 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.

29 *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)

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

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=0900006
48026cbd2

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.

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[31] 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

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

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 (mislabelling 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 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.[32] 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

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

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.

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.