

Chapter 1.

Low-level presence of transgenic plants in seed and grain commodities: Environmental risk/safety assessment and availability and use of information

This chapter provides guidance and information on the environmental risk/safety assessment of low-level presence (LLP) situations. LLP relates to seed containing small amounts of transgenic material that have been authorised for cultivation in an exporting country, but not in the country of import. It covers agricultural seed used for planting, and commodities (e.g. grains and oilseeds) that can grow into plants when unintentionally released in the environment or used for cropping. This chapter discusses the availability and the use of information when facing LLP situations: LLP occurrences in seed, national systems dealing with them, principles for determining environmental risk/safety for transgenic plants, data and information available to perform such an assessment, with examples of scenarios. Approaches to the management of LLP situations and possible ways to proactively address their environmental safety are considered.

This chapter was prepared by the OECD Working Group on the Harmonisation of Regulatory Oversight in Biotechnology, with the Bureau of the Working Group having served as lead. It was initially issued in September 2013, together with replies from 20 countries and observers to a questionnaire on experiences with LLP situations (OECD, 2013).

Foreword

The major output of the Working Group on the Harmonisation of Regulatory Oversight in Biotechnology over the years has been its consensus documents. These documents contain information for use during the regulatory assessment of a particular product. In the area of plant biosafety, consensus documents are 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 chapter 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 this chapter, and the draft has been revised on a number of occasions based on the input from other member countries and stakeholders.

Preamble

The OECD's Working Group on the Harmonisation 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 transgenic¹ 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 a document on molecular characterisation of transgenic plants (OECD, 2010). In effect, a suite of documents has been developed concerning the environmental review of the products of modern biotechnology.

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, 1993a; 1986). 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 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, 53 biosafety consensus documents have been published.²

In addition to the biology and trait biosafety consensus documents, the Working Group also takes on important emerging issues related to environmental risk/safety

assessment and regulatory harmonisation. Each of these projects is different from the biosafety consensus documents 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; 2006b); and “Points to consider for consensus documents on biotechnology of cultivated plants” (2006a). In 2007, the topic of information availability and sharing and possible guidance for environmental risk/safety assessment of low-level presence of unauthorised 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. 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 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 (OECD, 2013).

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

In developing this chapter, 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 Commission, 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 Alimentarius LLP annex, this chapter 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

Modern trade and agriculture are 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. Since the mid-1990s, the adoption of transgenic plants has increased in the numbers developed, the volumes grown and 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.

Many countries have national legislation that addresses the need for regulation of the use of transgenic plants and most countries require prior domestic authorisation 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 authorised for commercial cultivation (unconfined release) in one country that have not been authorised in other countries with which the authorising country trades seeds and commodities. This is often referred to as “asynchronous” authorisation. Such asynchrony can occur because the timing of the authorisation process is different between countries or possibly because authorisation is never sought from or granted by one or more of the countries involved in seed and/or grain importing activities.

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 authorisation. The scope of this chapter covers low-level presence (LLP) 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 chapter 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 this chapter “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.

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 chapter presents approaches to information availability and sharing and risk/safety assessment in LLP situations where there is knowledge of the identity of the unauthorised transgenic plant.

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.

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 chapter captures the experience of the participant countries of the OECD Working Group for the Harmonisation of Regulatory Oversight in Biotechnology in addressing asynchronous authorisation 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 chapter does not prescribe how national authorities should manage incidents of LLP, take 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.

One of the aims of this chapter 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 authorisation 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. This chapter 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. This chapter 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 characterisation documents (see OECD BioTrack website)².

Principles for determining environmental risk/safety for transgenic plants

The general principles for determining risk/safety are the same for an LLP situation in the environment as they are for an authorisation 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), which describes risk analysis³ 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 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
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

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-emphasised. 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 authorised 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.

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.

Access to the required information can be facilitated by the use of Internet databases listing authorisations. 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 maximise 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

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 unauthorised 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 authorisation for large-scale cultivation of the same plant. In an LLP situation, the environmental risk/safety assessment is not intended to lead to an authorisation. 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.

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 authorisation 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, 1993a; 1993b; 1992). The basic safety issues that may potentially be of concern were also identified in these publications.

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.

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 unauthorised 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 take 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 authorisation of the transgenic plant have already been completed.

Risk profile

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 such risks. In a relatively short period of time, the identity of the unauthorised plant material may need to be confirmed, the potential for adverse effects be determined and actions taken to minimise any identified environmental risk presented by the LLP situation. A risk profile characterising the situation may be rapidly assembled based upon data and information from reviews of the same or similar authorised plants and/or existing knowledge and familiarity with the plant, trait, environment and their interaction. The risk profile recognises 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.

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 unauthorised transgenic plant:

- determine where the LLP situation has been found in the environment and the potential distribution of the unauthorised transgenic plant
- identify relevant sources of information, including previous assessments of that unauthorised 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 unauthorised transgenic plant
- determine/consider whether there are pathways for distribution of the unauthorised transgenic plant in the LLP situation through which the identified hazard can cause adverse effects in the receiving environment
- assess the likelihood and consequence of those adverse effects being realised.

A risk profile can characterise 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 an 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 unauthorised plants into the environment and/or remediation of any release that has already occurred.

Uses of an environmental risk/safety assessment in the management of LLP situations in seed

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.”

In general, management of an LLP situation may focus on the goals of protecting 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, recognising 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 an 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.

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.

As part of an approach to managing an LLP situation overall, an environmental risk/safety assessment can be used to characterise the situation, including identifying any environmental risk associated with the situation and the measures either in place or needed to manage any such risk presented; it may also suggest the most efficacious measures to return the situation to compliance with legislative mandates. The circumstances 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 unauthorised 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.

While it is up to 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

Given that the incidence of LLP situations resulting from asynchronous authorisation 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 OECD questionnaire (Annex 1.A1), 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 the occurrence of an LLP, and still others establish procedures to facilitate a rapid response to an LLP situation.

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 unauthorised 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 the 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 an LLP in the environment.

Introduction

Modern trade and agriculture are 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. Since the mid-1990s, 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.

Many countries have national legislation that addresses the need for regulation of the use of transgenic plants and most countries require prior domestic authorisation 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 authorised for commercial cultivation (unconfined release) in one country that have not been authorised in other countries with which the authorising country trades seeds and commodities. This is often referred to as "asynchronous" authorisation. Such asynchrony can occur because the timing of the authorisation process is different between countries or possibly because authorisation is never sought from or granted by one or more of the countries in seed- and/or grain-importing activities.

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 chapter, “seed” refers to both seed and commodities and such an occurrence as referred to above is called a low-level presence (LLP) situation.

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

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.

In an LLP situation in seed, an importing country may not have had the opportunity to complete an evaluation as to whether the unauthorised 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 chapter will discuss strategies to do an adequate risk/safety assessment in an LLP situation.

Purpose and scope

The scope of this chapter 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 chapter 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 unauthorised transgenic seed into the environment, necessitating an environmental risk/safety assessment. This chapter 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.

This chapter 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, 2010).

This chapter 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 chapter 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.

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

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 chapter 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.

This chapter 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 1.A1 of the original issue, which includes references to national or regional guidance documents; see OECD, 2013). As an aid to regulators and risk assessors, the following aspects are covered:

- the occurrence of LLP situations in seed in OECD participant countries

- the types of information that can be used in an environmental risk/safety assessment and where these may be available
- 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
- whether and how an environmental risk/safety assessment may influence risk mitigation and management as well as the overall management of the situation.

The following points summarise and clarify how this chapter is intended to be appropriately used. This chapter:

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

On the other hand, this chapter 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 authorisation of the transgenic plant present at low levels 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, take decisions or define what an LLP is under their own legislative framework
- prescribe what proportion of unauthorised transgenic seeds constitutes an LLP situation (e.g. threshold)
- address issues of food/feed safety, low-level presence arising from field trials for product development or basic research, or situations in which no authorisation has been granted in any country.

Information availability, information use and environmental risk/safety assessment in low-level presence situations

Occurrence of low-level presence in seed

The LLP of unauthorised 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, transport, 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.

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 recognised through allowances for a set maximum level of “off types” in seed certified for purity (OECD, 2016). However, with transgenic seed there is an 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.

In 2014, 28 countries grew a total of 181.5 million hectares of crops that were transgenic and the majority of these contained herbicide tolerance and/or insect resistance traits (James, 2015). As a result, most of the LLP situations to date relating to the presence or release into the environment of unauthorised 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.

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 authorised for environmental release amongst all trading partners. In addition, there can be an asymmetry in the types of authorisations in the importing country compared to the exporting country; such asymmetry may occur because the national authorities either receive requests for, or grant authorisation for, different uses. The following are examples of such situations⁴ that can occur in an importing country:

- no application has been received requesting authorisation either for importation for food and/or feed use or for environmental release (cultivation) of the transgenic plant or
- no authorisation has been granted though applications may have been received for food and/or feed use and/or possibly for environmental release or
- authorisation 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
- authorisation was granted for environmental release in the past, but that authorisation has expired.

The seed industry has undertaken significant efforts to reduce the incidence of LLPs 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, n.d.). 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 LLPs 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 errors, etc.), introducing uncertainty as to the effectiveness of best practice protocols and limiting the ability to determine whether there is an LLP in any given seed lot or shipment.

National systems for environmental risk/safety assessment and dealing with LLP situations

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.

Addressing an LLP situation nationally may involve more than one or two ministries and can be complex. Usually those ministries responsible for overseeing the 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 the 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.

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

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 1.A1 available at OECD, 2013).

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 unauthorised 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 the responsibilities of various stakeholders, including the 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.

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.

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 require 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 authorised 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 the 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 characterise 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.

Principles for determining environmental risk/safety for transgenic plants

The goal of the environmental risk/safety assessment is the same for authorisations 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 authorisation 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 analysis⁵ 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:

... 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: 8).

Further, “familiarity comes from the knowledge and experience available. Familiarity with the crop plant, environment, trait and interactions facilitates a risk/safety analysis” (OECD, 1993a: 29).

In developing an approach to environmental risk/safety assessment of recombinant DNA organisms, the OECD made recommendations in *Environmental Safety Considerations* that were further elaborated in the “Scale-up of crop plants” document. These have been accepted as operational principles worldwide, that countries:

- “use the existing considerable data on the environmental and human health effects of living organisms to guide risk assessments
- 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 basis⁶
- 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”.

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 unauthorised 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
2. an environmental risk/safety assessment can be used to evaluate the potential for risks to the environment in a particular LLP situation
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. (OECD, 1986)

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 below in the section on the “Use of information”.

Table 1.1 summarises similarities and differences of a risk/safety assessment undertaken in response to applications for authorising unconfined environmental release of a transgenic crop versus an LLP situation of an unauthorised transgenic plant.

**Table 1.1. Environmental risk/safety assessment in low-level presence situations:
Key similarities and differences with applications for commercial release**

Type of assessment	Application for authorisation	Low-level presence situation
Purpose/focus of assessment	Determine environmental risk/safety of proposed unconfined (commercial) environmental release of a transgenic plant	<ul style="list-style-type: none"> – Characterise LLP situation (what, where, when, how) – Determine environmental risk/safety of the unauthorised transgenic plant and the LLP situation
Release to the environment intended	Yes	No
Timeframe 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	<ul style="list-style-type: none"> – Known – Defined in application 	<ul style="list-style-type: none"> – Knowledge may be incomplete – May be determined in environmental risk/safety assessment
Regulatory action	Decision on authorisation of release to the environment	<ul style="list-style-type: none"> – Return situation to compliance – Manage risks

Availability of data and information to perform an environmental risk/safety assessment in an low-level presence situation

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 an LLP of unauthorised transgenic seeds may have already been planted upon discovery of the LLP situation or unauthorised transgenic plants may have been found along a transport route 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 authorisation 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 authorisation 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.

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 authorisations 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. authorisation for commercial cultivation (unconfined release) for the particular transgenic plant from the authorising/exporting country
4. food, feed and environmental authorisations of the transgenic plant by the exporting country
5. authorisations⁷ 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 authorisations 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 (see OECD BioTrack Website)²
9. publically available databases (domestic/international)
10. peer reviewed published literature
11. direct communication with authorities in other countries, particularly the exporting country or authorising country
12. detection procedures suitable for the LLP situation
13. information and experience with similar LLP situations (see also Annex 1.A1 in OECD, 2013).

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 authorisation, two obvious sources of information are: 1) that developed for assessment in the country in which the transgenic plant was authorised; 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.

Access to information can be facilitated by the use of websites containing databases that list authorisations 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 authorised 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.

Such existing databases currently include:

- BioTrack Product Database⁸ hosted by the OECD
- Biosafety Clearing-House⁹ under the Cartagena Protocol on Biosafety
- Crop Database hosted by the Center for Environmental Risk Assessment (CERA, 2012)

- GM Approval Database¹⁰ hosted by the International Service for the Acquisition of Agri-Biotech Applications
- national and regional biosafety websites.^{11,12}

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

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 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 maximise their usefulness.

Information may be accessible directly from the authorities in the authorising 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 ongoing communication may be beneficial to this process. The importance of working relationships between national authorities cannot be over-emphasised. 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 the 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 country may provide information that can be shared with the importing country. When the LLP situation results from asynchrony of authorisation such that the transgenic plant involved is authorised in the exporting or other countries, a great amount of data will have accumulated.

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 authorisations 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.

Characterisation of the introduced trait may come from an authorisation or application received for food and feed, and/or environmental release of the same or a similar plant. Many times the information on molecular characterisation of the introduced trait is very similar for these types of authorisations (OECD, 2010). Further, a feed or food safety assessment (e.g. done according to the Codex Alimentarius Commission [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 characterisation 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.

In cases where applications for a review necessary for an authorisation for commercial cultivation (unconfined release) have not been received and more data or information are 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 unauthorised transgenic plant to obtain as much relevant data and information as possible to address the LLP situation efficiently.

Environmental risk/safety assessment in an LLP situation

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 unauthorised 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 authorisation for large-scale cultivation of the same plant. In an LLP situation, the environmental risk/safety assessment is not intended to lead to an authorisation. However, the results of the assessment can be useful in supporting environmental risk management decisions by scientifically evaluating potential options for managing any risk presented.

The purpose of the following discussion of scale, the trait, and the plant and the receiving environment of the importing country 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 authorisation 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 authorisation 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.

Scale

Each country makes its own determination of what is considered to be an 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 unauthorised transgenic plant involved in the LLP situation may be useful. For commercial seed containing an 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 unauthorised transgenic plant, information on seed lots (whether transgenic or not) that are not expected to contain unauthorised 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.

The trait

Molecular characterisation 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 authorised either domestically, regionally or in other countries. Useful data and information for an assessment of an LLP situation can generally be extrapolated from that of 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.

When the LLP plant is known to be similar to an existing authorised 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 unauthorised plant in an LLP situation:

- Does the unauthorised plant belong to the same plant species as previously evaluated or authorised transgenic plants?
- Does the unauthorised plant contain the same or similar trait, transgene, genetic components and/or regulatory elements as previously evaluated or authorised plants?
- Was the transformation method the same as that used in a previously evaluated or authorised plant or, if not, does use of a different method present any additional issues?
- Is the same or a very similar protein expressed in a previously evaluated or authorised plant? Are protein expression levels and/or patterns similar to previously evaluated or authorised plants?

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

While data and information addressing all of the above questions may not be needed to understand the behaviour of the unauthorised plant, previous assessments of the same or a similar plant that have addressed what potential adverse effects might be predicted for the unauthorised 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 take those decisions.

Information on the unauthorised 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 unauthorised 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 authorisation has been received.

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.

There are several examples of genes and traits that have been evaluated by many countries. The phosphinothricin 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 authorised 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; 1999b; 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, 2011b, 2011c, 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 the OECD BioTrack database) with subsequent global commercialisation over the past 20 years in a variety of crop plants. For example, *cryIac* has been authorised in three crops containing a variety of constructs in 11 countries, while glyphosate tolerance has been authorised by 13 countries in 8 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.

Plant and receiving environment of the importing country

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 authorised. 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 authorisation of the transgenic plant have already been completed.

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 authorised 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 unauthorised 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 documents² as well as from various publications of national authorities. Over 30 OECD biology documents are currently available, including documents for the major commodity crops (corn, cotton, rapeseed and soybean) (OECD, 2003; 2008; 2012; 2000). These OECD documents have proven useful in various national reviews, including those of LLP situations.

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 above) may provide baseline information on the ability of a plant species to spread and persist in the environment.

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, information is generally specific to a country or region: the OECD biology consensus documents may provide baseline information on several plant species' feral, wild and weedy relatives and the distribution of these relatives.

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.

Thus, the potential of the introduced transgenic trait to spread in the environment through the exchange of genetic information between the unauthorised 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 similar authorised versions of the transgenic plant and provide relevant information in evaluating an LLP situation.

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 authorisations may provide this knowledge efficiently, including whether standard agricultural practices provide sufficient management of the concern.

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 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.

Risk profile

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 unauthorised plant material may need to be confirmed, the potential for adverse effects be

determined and actions taken to minimise any identified risk presented by the LLP situation. A risk profile characterising the situation may be rapidly assembled based upon data and information from reviews of the same or similar authorised plants and/or existing knowledge and familiarity with the plant, trait, environment and their interaction. The risk profile recognises 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.

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 unauthorised transgenic plant:

- determine where the LLP situation has been found in the environment and the potential distribution of the unauthorised transgenic plant
- identify relevant sources of information, including previous assessments of that unauthorised 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 unauthorised transgenic plant
- determine/consider whether there are pathways for distribution of the unauthorised transgenic plant in the LLP situation through which the identified hazard can cause adverse effects in the receiving environment
- assess the likelihood and consequence of those adverse effects being realised.

The trait likely to be expressed and any similarity of such trait expressed in previously authorised plants provide an invaluable starting point. Further data and information may or may not be needed depending on 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 unauthorised 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 characterise the risk that may occur or has occurred given the specifics of the LLP situation (case-by-case). The assessment may include an evaluation of the 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 unauthorised plants into the environment and/or remediation of any release that has already occurred.

If the unauthorised LLP plant is similar to existing transgenic plants authorised domestically, regionally or in other countries, much of the information from those previous assessments and conclusions of safety may be directly applicable. Table 1.2 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. Depending upon the trait, these elements can be 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 unauthorised transgenic plant 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 authorised and/or similar plants can be determined including whether a different adverse consequence has been identified or whether there is a difference in the unauthorised plant's behaviour in the environment.

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 characterisation or on the potential of the trait to increase weediness in a particular plant.

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 unauthorised 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.

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 carried out, it has been determined that the low-level presence of these unauthorised transgenic plants in seed or commodities in the environment posed a low level of risk, given the impacts and scale of the situations.

This conclusion was based on the review of available scientific data, the limited amount of the unauthorised plant in the environment, and comparison with either the unmodified plant or the close similarity of the unauthorised plant to authorised transgenic plants which had cleared regulatory review in the importing country.

Table 1.2. 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

Scenario 1: Protein/construct/event authorised for import (food, feed and processing), but not for cultivation	Scenario 2: Protein/construct/event not authorised in the importing country but the inserted gene and protein produced are the same as or very similar to other transgenic plants authorised in the importing country	Scenario 3: Protein/construct/event that has no authorisation in the importing country
Characterisation of the introduced trait completed in the importing country	Characterisation of the same or similar gene and protein in the importing country Characterisation of the introduced trait completed in the exporting or authorising country	Characterisation of the introduced trait completed in the exporting or authorising country
Agricultural areas where the crop is grown provided by seed company/industry	Agricultural areas where the crop is grown provided by seed company/industry	Agricultural areas where the seed 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	Experience with cultivating this crop in the importing country	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
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	Existing environmental risk/safety assessment data and experience with the unauthorised transgenic plant/event line within the importing country for the gene and expressed protein. The environmental risk/safety assessment of the same or similar authorised transgenic plant line or event in the respective cropping system, focusing on the likelihood that the trait would alter the crop's weediness or have an effect on non-target organisms	Environmental risk/safety assessments available from other countries
Environmental risk/safety assessments available from other countries	Environmental risk/safety assessments available from other countries	Information about the receiving environment and common agricultural practices in that receiving environment
Experience and information from similar crop/trait combinations and deemed relevant by the importing country	Experience and information from similar plant/trait combinations deemed relevant by the importing country	Other considerations, such as the level of exposure to beneficial organisms, humans and the environment
Relevant OECD consensus documents	Relevant OECD consensus documents	Relevant OECD consensus documents

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

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: 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 above). 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 authorisation has already been received by the importing country, much of the needed information may already be available.

Use of information and an environmental risk/safety assessment for management of low-level presence situations in seed

Possible approaches to the management of low-level presence situations in seed

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.”

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, recognising 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 LLPs 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 characterise 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.

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 unauthorised 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 unauthorised 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 above). 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.

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 of 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 unauthorised transgenic plants prior to flowering may or may not be important in limiting potential spread or persistence.

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 authorisation 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.

If the environmental risk is determined to be insignificant in comparison with the unmodified counterpart or a similar authorised 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:

- recall of unplanted seed from distributors
- destruction of planted seed once germinated
- allowing planting and/or harvest, but controlling the distribution of any seed or harvested crop produced
- 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 utilisation).

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

Although the conclusion of the environmental risk/safety assessment may suggest options that allow the management or mitigation of any risk of the unauthorised 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.

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 unauthorised plant was discovered
- conclusions of an environmental risk/safety assessment.

Potential ways to proactively address environmental risk for low-level presence situations

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 OECD questionnaire (Annex 1.A1 available at OECD, 2013), countries and regions have taken several steps to limit the potential for uncertainty regarding environmental risk. Some authorities undertake environmental assessment of transgenic plants authorised for use as food or feed and for processing in recognition of the potential of these commodities authorised 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 unauthorised 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 ongoing manner. But, in some situations with identified low levels of an unauthorised plant, there may not be a general concern raised.

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 unauthorised plants. Some countries work with the seed and plant-breeding industries to ensure appropriate quality control systems are in place to prevent unauthorised plant material from 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 unauthorised plant.

Preventive measures taken by industries are critical to reducing the occurrence of LLP situations.

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.

Several countries, recognising the potential for LLP to occur in seed, have set thresholds allowing for LLP if a food safety authorisation has been done according to the Codex Alimentarius 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. Recognising 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 unauthorised plant had been authorised at least in one other country.

Notes

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: 33).
2. See: www.oecd.org/biotrack.
3. This chapter discusses risk/safety analysis as being comprised of “hazard identification and, if a hazard has been identified; risk assessment” (OECD, 1993a). 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.
4. There may be other factors outside the scope of this chapter 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 authorised. However, other legal constraints may exist (e.g. government seed variety certification/registration requirements) so that the plant would not be fully authorised for commercialisation unless these other legal requirements are met. Seed certification or registration is not a component of environmental risk/safety assessment.
5. This chapter 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.
7. Assessments that did not lead to authorisation, 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 authorisation.
8. OECD BioTrack Product Database available at <http://www2.oecd.org/biotech/>.
9. Biosafety Clearing House of the CBD available at <http://bch.cbd.int>.
10. ISAAA’s GM Approval Database, available at: www.isaaa.org/gmapprovaldatabase.
11. Biotechnology Regulatory Contacts in OECD Member Countries, available at: www.oecd.org/chemicalsafety/biotrack/biotechnologyregulatorycontactsinoecdmemberecountries.htm.
12. Search for National Contact (at BCH website), <http://bch.cbd.int/database/contacts>.

Annex 1.A1:
Questionnaire on LLP situations and country responses

A questionnaire was circulated in 2009 to gather information on participating countries and observers' experience with low-level presence situations in seed and certain commodities. The comprehensive text of the questionnaire was issued in the original document, in Annex 1 – Annotated Questionnaire for LLP in Seed and Commodities in the Context of Environmental Safety (OECD, 2013).

Responses were collated in Annex 2 of the original document (OECD, 2013). Annex 2 comprised inputs from 19 countries and one observer, namely Argentina, Australia, Belgium, Brazil, Canada, Chile, Czech Republic, Estonia, Japan, Korea, Mexico, the Netherlands, New Zealand, Norway, Philippines, Spain, Turkey, the United States, and the Business and Industry Advisory Committee to the OECD (BIAC).

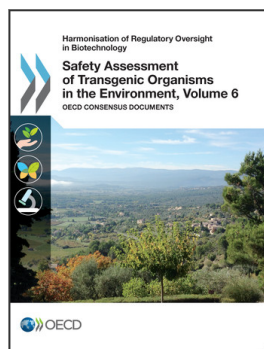
Most of the information was provided by national authorities during the year 2010, or shortly after. Because more experience is gained to date, and elements of the responses would have probably evolved significantly since the original issue of the document, Annex 2 is not reproduced here to avoid mis-interpretation. However, the original document is available on the OECD BioTrack Website and Annex 2 should be understood as an incomplete source of information that was valid at the time of the circulation of the questionnaire.

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