ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND
THE WORKING PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY

Working Group on the Harmonisation of Regulatory Oversight in Biotechnology

PROJECT PROPOSAL FOR LLP IN SEED AND COMMODITIES IN THE CONTEXT OF ENVIRONMENTAL SAFETY
At the 21st meeting of the Working Group on the Harmonization of Regulatory Oversight in Biotechnology, it was agreed that work on the topic of LLP was feasible. In order to proceed in the evaluation of a possible project on this topic, it was agreed that the Bureau of the Working Group would develop a more specific project proposal on the topic of LLP for the 22nd meeting of the Working Group. This document was prepared by the Bureau to meet this charge.

Action required: The Working Group is invited to consider and provide comments on the proposal for a possible project on LLP.
1. This document proposes a project for the OECD Working Group for the Harmonization of Regulatory Oversight in Biotechnology (Working Group) to address the issue of the low level presence of unauthorized transgenic plant material (LLP) in seed and commodities. It is an outgrowth of the 21st meeting of the Working Group when it was decided that it was feasible for the Working Group to do work in this area. As a next step, the Bureau was requested to undertake development of a proposal for a possible project for the Working Group to consider at its 22nd meeting in February, 2009. This document is the result of the efforts of the Bureau and builds upon the discussions at past meetings of the Working Group as well as the special meeting on LLP held in April, 2008 [ENV/JM/BIO/M(2008)1] [ENV/JM/BIO/M(2008)1/ADD1].

2. This proposal outlines a project on information acquisition and use and environmental risk/safety assessment in situations of LLP in seed and commodities that can function biologically as seed and contains three main sections: 1) introduction (background and history), 2) purpose and scope, and 3) Working Group experience. The proposal provides a brief general description of what is covered in each section, the rationale for inclusion and a short outline of the section. Additional explanations for each section, developed from previous Working Group discussions may be found in the annexes.

PROJECT OUTLINE AND DESCRIPTION

I. Introduction (Background and History)

3. The introduction will provide an overview of the topic of LLP in seed and commodities produced from that seed including what aspects fit under the remit of the Working Group and the genesis of a project. Commercial seed will be the primary focus with an understanding that certain commodities that can function biologically as seeds, are also of interest. Commodities in this context are grains and oilseeds (e.g. corn, cotton, soybean and canola) that are intended for food, feed or processing. The products of seed production are intended for use in the environment (i.e. cultivation), while commodities are not intended for environmental release but may unintentionally be released into the environment and function biologically as seeds. As an aid to regulators and risk assessors, the project will capture and summarize OECD Working Group participant experience, particularly on information acquisition and use and environmental risk/safety assessment with regard to addressing situations in which LLP occurs in seed and commodities that can function biologically as seed. The relationship of this project to the Codex Plant Guideline which addresses food safety assessment in LLP situations will be described.

4. Rationale: Many countries, including OECD member states, are or will be importers or exporters of commercial seed, as well as commodities harvested as the result of planting such seed, that may be determined to contain a low level presence of biotechnology derived material that has not been approved for use in the environment. It is expected that the number of incidents of LLP will continue to increase rather than decrease in the near future because of biological factors and the ever-increasing international movement of seeds and commodities.
Outline for Section I:

A. The Working Group is taking up a project on LLP in commercial seed, and commodities that can function biologically as seed.
   i. Why the issue is important?
   ii. How the issue relates to the remit of the WG?

B. What is LLP and sources of LLP in seed, and commodities that can function biologically as seed?

C. Relationship to Codex Plant Guideline Document Annex related to food safety assessment and LLP situations.

Further explanation of this section may be found in Annex I.

II. Purpose and Scope of the Project

5. The purpose and scope section will describe what is included in the document and the criteria used to develop the purpose and focus the scope. The purpose of this project is to provide an aid to risk assessors and regulators regarding information acquisition and use and the environmental risk/safety assessment of LLP in seed commodities that can function biologically as seed in situations where the product has been approved in at least one country. This section will include discussion of the need for expeditious access and retrieval of information to facilitate risk/safety assessment based upon the principles of risk/safety assessment, and description of the unique types of situations that may arise with LLP, through capturing country experience in different LLP situations.

6. Rationale: The topic of LLP in seed is broad and can encompass many aspects from seed development, purity, and food and feed safety. Depending upon the specific LLP situation, certain commodities may also have potential environmental issues. The project will focus on the experience of Working Group members related to the information access and use and environmental assessment of LLP related to commercial seed and commodities that can function biologically as seed.

7. Even if multiple precautions are undertaken, it will be difficult to completely prevent the introduction of LLP in seed and commodity-receiving countries. The occurrence of an LLP incident can lead to a situation of regulatory non-compliance. This in turn leads to a problem for national authorities. To date, no transgenic plant may be commercialized within participating countries without prior authorization. Although each LLP incident will likely be handled on a case-by-case basis by each respective country, a risk/safety assessment of the non-compliant situation may inform any actions taken to address the situation.

Outline for Section II:

A. Topic is LLP in seed and commodities that can function biologically as seed

B. Scope is seed containing unapproved transgenic material

C. Purpose is to capture and summarize country experiences in information access and use and environmental risk assessment in regard to LLP in seed and commodities that can function biologically as seed

D. Criteria defining purpose and scope

E. Unique situations associated with LLP, including active acquisition of data/information
F. Principles of risk/safety assessment
   i. Risk/safety assessment paradigm developed by OECD
   ii. Risk/safety assessment for LLP (same as for other situations)
   iii. The use of knowledge, familiarity, and experience

Further explanation of this section may be found in Annex II.

III. Working Group Experience in Information Acquisition and Use and Environmental Risk/Safety Assessment in LLP situations

8. This section will summarize, based upon the case studies/scenarios submitted, the types of LLP situations that have occurred in OECD participant countries, the availability and use of sources of information that have supported risk/safety assessments and the commonalities found in addressing environmental risk/safety assessment, when such a risk/safety assessment was performed. It will include how environmental risk/safety assessment has been approached to date and the sources of information that have supported such risk/safety assessments. Information sharing among authorities can be important, in relation to LLP incidents, in situations where an authority addressing an unauthorized incident might not have sufficient information. This section will also give examples of how such risk/safety assessments were used to inform risk management. This summary will be based in part upon the specific case studies/scenarios submitted by countries and other Working Group participants that can be included in an annex of the final project. The format for submission of information for these case studies/scenarios is included in Annex III to this document.

9. Rationale: A summary of the types of LLP situations that have occurred to date and the practical approaches to completing risk/safety assessments based upon the use of available information will be an aid to risk assessors and regulators in the future for similar types of situations. The summary of information used by risk assessors will be based upon the risk/safety assessment paradigm indicated in the 1993 OECD document, Safety Considerations for Biotechnology: Scale-up of Crop Plants (Scale-up). The Scale-up document describes risk analysis as being “based upon the characteristics of the organism, the introduced trait, the environment into which the organism is introduced, the interactions between these, and the intended application. Knowledge of and experience with any or all of these provides familiarity which plays an important role in risk/safety analysis….Familiarity is not synonymous with safety; rather, it means having enough information to be able to judge the safety of the introduction or to indicate ways of handling the risks. Familiarity can be increased as a result of a trial or experiment. This increased familiarity can then form a basis for future risk/safety analysis (OECD, 1993, page 8).” Further, “[familiarity comes from the knowledge and experience available….Familiarity with the crop plant, environment, trait and interactions…facilitates a risk/safety analysis” (OECD, 1993, page 29; see http://www.oecd.org/findDocument/0,3354,en_2649_34385_1_1_1_1_1,00.html under ‘publications”).

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1 This document discusses risk/safety analysis as being comprised of “hazard identification and, if a hazard has been identified; risk assessment.” Currently, the term “risk assessment” has replaced the term “risk analysis” as the term most commonly used to indicate both hazard identification and risk assessment.
Outline for Section III:

A. **Country Experiences** (includes summaries + annex with case studies/scenarios)
   i. Entry into the Environment (summary)
      1. Description of types of LLP situations to date (that fall under the scope of the project)
         a. What LLP situations have occurred?
         b. How, where, when, how much?
      1. Use of Available Data/Sources of Information
         a. Previous domestic approvals
         b. Previous international approvals
         c. Publically available databases (domestic/international)
         d. Assessments completed by regulatory bodies in other countries
         e. Data available from developer
         f. OECD trait and plant biology documents.
         g. Published literature.
      2. The use of experience and familiarity
         a. Biology of Crop Plant
         b. Trait
            i. Gene
            ii. Molecular Characterization
         c. Familiarity with the plant, trait, and the environment and their interaction
         d. Experience with similar transgenic plants (i.e. same crop/trait/gene combination)
         e. Identification of any additional data needs
      3. Conclusion of Assessment
         a. Differences in risk profile compared to previously approved and/or similar plants:
            i. Different Hazard?
            ii. Difference in presence in the environment?
      iii. Practical approaches to resolving LLP situation (summary)
         1. How has risk management been informed by the risk/safety assessment?
         2. Actions taken to bring the situation into compliance.

B. **Information sharing** (mechanisms, what’s needed)
   i. Access
   ii. Information from risk/safety assessments as situation is happening
   iii. Identify sources of information from developers and other countries.

C. **Annex** (country case study/scenario submissions)

**IV. References**

ANNEX I

Further Explanation of the Background and History

Why the issue is important

Participants in the Working Group recognize that the issue of LLP in seed and certain commodities that can function biologically as seeds, concerns all countries, including regulators, industry and trade. They also recognize that many OECD countries have already had to deal with this issue and there is value to be gained from capturing and sharing the experience gained to date for LLP in seed regarding risk/safety assessment and sources of information with the potential for identifying further enhancements of information-sharing. In addition, although the work of the OECD Working Group primarily relates to the scientific and technical aspects of risk/safety assessment, it is recognized that there are consequences for its work products in the areas of risk management and trade, among others.

How the Issue Relates to the Remit of the Working Group

The Working Group normally focuses on the development of technical documents that facilitate environmental risk/safety assessment of transgenic organisms, especially plants, and has developed several kinds of documents for regulators including science focused documents (biology and trait documents), documents that supplement and expand upon the information in the biology and trait documents (module II on herbicide tolerance), and guidance documents (how to use information from detection technologies for bacteria). A suite of documents have been developed for review of products of modern biotechnology for various kinds of approvals. The Working Group recognizes that a science-based approach to the issue of risk/safety assessment of LLP in seed and certain commodities that can function biologically as seeds will be useful and has therefore undertaken the task of capturing the experience of the member countries of the Working Group in environmental risk/safety assessment of plant material found as LLP in seed and commodities and how countries have dealt with risk/safety assessment of LLP subsequent to this discovery.

Sources of LLP

LLP may originate from a range of biological or non-biological causes in the seed-producing countries during seed production of transgenic plant varieties, including commercial cultivation of transgenic varieties and handling, harvest, transportation, shipment, etc. for use as seed, and commodities produced from that seed.

Codex Plant Guideline

The Codex Alimentarius has developed an annex the plant guideline for addressing safety assessment of food in LLP situations. The Working Group discussed the potential to follow the same approach as in Codex, that is, to link a discussion of LLP to an existing text on risk/safety assessment. The environmental risk/safety assessment paradigm has been articulated in the OECD Scale-up document (OECD, 1993) and elsewhere. However, neither this document nor the environmental considerations project currently under development addresses how to do risk/safety assessment per se. Thus, it was concluded that a project on LLP in seed done by the OECD could not parallel the Codex annex on food safety in LLP situations but could be complementary, focusing on environmental risk/safety assessment issues.
ANNEX II

Further Explanation of the Purpose and Scope

Criteria

To clarify the usefulness of the project as well as to define the scope it is to be understood that the project will:

- Fit into the remit of the Working Group, whose terms of reference focus on scientific and technical aspects of environmental risk/safety assessment;
- Assume a product approval of the transgenic material present as LLP in one or more countries;
- Assume that countries themselves determine what low level presence is, and how to respond to it;
- Relate to LLP in seed including commodities that can function biologically as seed; and
- Facilitate risk/safety assessment

On the other hand the project would not:

- Address risk management or indicate how regulatory authorities should manage incidents of LLP, make decisions, or define what LLP is legally;
- Conflict with existing international agreements on the topic of LLP;
- Conflict with case-by-case approaches;
- Preclude a national authority from undertaking a risk/safety assessment within the context of its regulatory system.
- A project should not interfere with legal frameworks of participant countries or imply a short cut for commercial approval.

Situations of LLP and Information Acquisition

When approving a transgenic crop for potential cultivation, most of the time the risk/safety assessment assumes 100% exposure over an extended period of time, i.e. assumes a situation where the crop is cultivated on thousands of acres/hectares of land. This is an assessment of the product. However, when assessing an LLP situation the context is different. The determination of the level of risk that an unauthorized product may pose is based on potential exposure and hazards identified. This is an assessment of an LLP situation. In this case, the risk/safety assessment typically does not lead to an authorization. However, the results of the assessment can inform risk management decisions.

Information needs may be different for a risk/safety assessment in a situation of “non-compliance” versus a risk/safety assessment for a “product submission for authorization”, typically because there are
differences in the amount of the unauthorized plant material that may be present in a “non-compliant” situation compared to what may be expected in following the authorization or approval of a product. The “non-compliant” risk/safety assessment informs decisions on whether there is any environmental risk due to the presence of the unauthorized plant material. In the absence of information or data there will be uncertainty regarding safety. Since it can be critical to complete a risk/safety assessment as efficiently and effectively as possible in response to an LLP incident, use of existing domestic and/or international experience, gives the risk assessor a “head start” so to speak in terms of completing the assessment, saving valuable time.

**Principles of Risk/Safety Assessment**

While the response by a country to an LLP incident can vary, the general principles for a risk/safety assessment are the same for an LLP incident as they are for a product approved for unconfined release. These are stated in the 1993 OECD document, *Safety Considerations for Biotechnology: Scale-up of Crop Plants.*

Because countries may have experience with other similar products as that found in an LLP situation, and/or international experience with such, familiarity can play an important role in such an assessment. While familiarity cannot be considered as the conclusion of an assessment, it can serve as a useful starting point, allowing the risk assessor to take into consideration all available information (OECD, 1993). However, the data and information necessary to complete that risk/safety assessment in an LLP situation may vary depending upon the modalities that include experience, familiarity and available information.

The risk/safety assessment informs the risk management activities commensurate with risk and domestic frameworks.
ANNEX III

FORMATT FOR OECD WORKING GROUP PARTICIPANT SUBMISSIONS

A number of countries have deliberated on situations of LLP associated with the environment. This format is intended to aid the collection of this information in submissions to the Working Group for development of the project.

I. Country
II. Agency or Agencies that were involved
III. Situation
   a. What was the general situation and how did it occur (type of situation)?
      i. What determined that a LLP situation had occurred?
      ii. What were the parameters of the situation - How, where, when, how much?
IV. How was the potential risk to the environment assessed?
   a. Was a risk/safety assessment done?
   b. What factors were addressed?
      1. What kinds of data/sources of information were available and how were they used?
         a. Previous domestic approvals?
         b. Previous international approvals?
         c. Publically available databases (domestic/international)?
         d. Assessments completed by other regulatory bodies?
         e. Data available from developer?
         f. OECD trait and plant biology documents?
         g. Published literature?
         h. Other?
      2. How did experience and familiarity aid in the assessment
         a. Was the plant similar to previously approved products and/or similar plants?
         b. Biology of Crop Plant
         c. Trait
            i. Gene
            ii. Molecular Characterization
         d. Familiarity with the plant, trait, and the environment and their interaction
         e. Experience with similar transgenic plants (i.e. same crop/trait/gene combination)
         f. Identification of any additional data needs
      3. What was the conclusion of the assessment? Did the plant present a different risk profile than previously approved and/or similar plants?
         a. Different Hazard?
         b. Difference in presence in the environment?
V. Did the assessment inform risk management?
   a. Did it inform mitigation measures?
   b. Did it inform other management decisions?
   c. What actions were taken to bring the situation into compliance?
VI. What types of information sharing or availability would have facilitated the risk/safety assessment?
   a. What information was used?
   b. How was the information obtained?
   c. Was the needed information available?
   d. Was information regarding the risk/safety assessment done in another country available?
   e. What are valuable sources of needed information that could be used?
   f. What would have facilitated acquisition of information?
   g. What mechanisms could be developed or used to access such information?