

International Standards for Phytosanitary Measures
Pest Risk Analysis for Living Modified Organisms
United States Comments
October, 2003

General:

The U.S. strongly supports the development of science-based, transparent risk assessment guidelines for LMOs under the IPPC and commends the working group for their efforts to produce the draft document.

We are, however, concerned that the current draft of the LMO standard does not provide clear guidance for the assessment of phytosanitary risks that may be associated with LMOs. This document will be used by national plant protection organization (NPPO) officials who may not be familiar with pest risk assessment criteria for LMOs that may differ from pest risk analysis (PRA) procedures for traditional pests. It is essential that the IPPC provide clear guidance on determining whether an LMO poses a plant pest risk (beyond any phytosanitary risk posed by the non-LMO counterpart), as well as how ISPM-11 should be applied to any LMOs determined to pose a pest risk based on a scientific risk assessment.

To this end, the U.S. recommends the following with respect to the format and text of the IPPC LMO standard:

1) Inclusion of clear guidance in Section 1 regarding use of ISPM-11 for the assessment of the pest risk potential of an LMO.

The guidance for how pest risk analysis under ISPM-11 relates to phytosanitary risks that may be posed by LMOs specifically is not clear in the current document. The focus of ISPM-11 has generally been on a risk analysis for pests that may accompany commodity shipments. Experience and practical knowledge has been the basis for determining if an organism may be considered a pest (i.e., a fungal pathogen, a weed, or an insect pest), and PRA under ISPM-11 is used to determine if that pest should be considered a quarantine pest in the country of import. LMOs are likely to be organisms, such as corn, not traditionally considered to be pests that may present a new risk as a result of the modification. Therefore, if ISPM-11 is to be the mechanism within the IPPC for pest risk analysis of LMOs, it is important that a determination is made early in the PRA process as to the potential pest risk of the LMO, based on a scientific risk assessment. Any LMO not determined to pose a phytosanitary risk, would not require further consideration under ISPM-11, beyond the phytosanitary risk analysis performed on the non-LMO counterpart of that organism.

To clarify how ISPM-11 could be used with respect to LMOs, we have proposed modifications to the first boxed text in Section 1 (see attached text). We also propose moving Section 1.1.4 to create a new section, 1.1.2.1, including some new language. These changes emphasize the need to determine the pest risk potential of an LMO early

in the PRA process and provide additional guidance on the types of organisms and potential phytosanitary risks that may be presented by LMOs resulting from the modification.

2) The U.S. also recommends that Section 1.1.5 be removed from the text of ISPM-11 and attached to ISPM-11 as Annex III.

The current document is confusing and unwieldy, and would be difficult to use, particularly for NPPO officials unfamiliar with any unique phytosanitary issues associated with LMOs.

Formatting issues were discussed at ICPM-4. At that session, the U.S. objected to the format of the document as a supplement. These concerns were reflected in the report from ICPM-4 with a note that the format would be reconsidered following development of the standard. We noted that it would be more practical to determine the appropriate format once we had actual text to review and consider. The current document is drafted with new language relating to LMOs as boxed text within the current text of ISPM-11. It is unclear what the final supplement will look like based on the current draft. It is also difficult to determine where language of the current version of ISPM-11 is meant to apply to LMOs, or how measures meant for conventional pests should be applied to LMO pests, as the potential new risks posed by an organism as a result of genetic modification are in many cases different from risks posed by conventional pests.

After reviewing the draft text, we recommend reformatting the document such that the lengthy discussion of determination of pest risk potential of an LMO (Section 1.1.5) be moved to become Annex III. Moving the language in Section 1.1.5 into an Annex, and including a referral to Annex III in Section 1, would streamline the document, and reinforce the conclusion of the Working Group that all LMOs will not present a phytosanitary risk.

Additionally, the format proposed in this recommendation would fulfill the ICPM's intent in recommending development of the LMO guidance as a "supplement" to the existing PRA standard while also meeting the specification that the LMO standard must be clear and easy to understand. This format would streamline the ISPM-11 document, and it would clarify the distinctions between a need for risk assessment to determine if an LMO may present a pest risk as compared to a determination of quarantine pest risk of an organism already considered to be a pest. In addition, the use of an Annex, as opposed to incorporation of this guidance into ISPM-11, would allow for easier revision and updating as the science advances.

3) Revision of the proposed text currently in Section 1.1.5 to ensure the information provided is clear and accurate.

The current text of Section 1.1.5 (Determining the Potential for an LMO to be a Pest) needs some modifications so that the guidance is clear, comprehensive, and scientifically and technically accurate. The purpose of this section is to provide guidance to phytosanitary officials on the determination of the potential plant pest risk that could be posed by LMOs. NPPO officials may be unfamiliar with risk assessment for LMOs and therefore we believe it is critical that this section provide clear and accurate information. To this end, we have attached specific recommendations and suggested text for revision of this section based on our experience in the area of LMO pest risk assessment.

4) Any changes within the text of the ISPM-11 LMO supplement itself should focus on new or altered criteria for performance of a quarantine risk assessment for LMO pests not covered by PRA for traditional pests under ISPM-11.

The current draft text is not clear as to how specific PRA criteria in ISPM-11 relate to additional risks that may be posed by LMO pests. Any supplement or modification to ISPM-11 with respect to LMOs should focus on specific considerations for LMO pests that may not be considered in a PRA for more traditional pests, since most of the time, the guidance in the standard will be used for the analysis of traditional pests. LMOs could present plant pest risks, as compared to the related non-LMO, as a result of the insertion of a new gene or genes, or from the expression of new RNA or protein. The risks could be presented by the modified organism itself (altered weediness or invasiveness), the inserted gene (genes from known plant pests such as viruses), or due to the phytosanitary consequences of the gene moving to another organism. The data generated for hazard identification and pest risk assessment of an LMO includes molecular genetic characterization, as well as data comparing the LMO to its conventional counterpart with regard to environmental and plant pest risks. These types of data and comparisons are not part of the traditional PRA for quarantine pests. However, once an LMO has been determined to represent a plant pest risk, the factors that should be considered prior to import are very similar to those for any pest under ISPM-11.

We have attached suggested modifications to the text that eliminate redundancies where the risk assessment criteria apply to both traditional pests and to LMO pests, as well as noting where specific criteria may apply uniquely to LMO pests.

Need for additional guidance: Finally, while the draft guidance in Section 1.1.5 (the proposed Annex III), provides a good basis for hazard identification for pest risk assessment of LMOs, IPPC member countries could benefit from additional detailed Guidance Documents, following adoption of the supplemental standard. As per the specification for the LMO standard agreed to at ICPM-4, Section 1.1.5 should provide comprehensive guidance on identification of hazards to be assessed and methods that can be used to assess the potential phytosanitary risks of LMOs. Due to the brevity of the current text, the document may not provide enough information for an actual assessment to be performed. We would point to the guidelines for safety assessment for foods

produced using biotechnology recently adopted under the Codex Alimentarius Commission as a model for the level of detailed guidance that would be useful and appropriate. We will recommend such work in the future work program, noting here that both the North American Plant Protection Organization (NAPPO) and COSAVE (the regional plant protection organization representing Argentina, Brazil, Chile, Paraguay, and Uruguay), are developing regional standards for analysis of the risks from the importation and release into the environment of transgenic plants. These guidelines could provide a framework for the development of more detailed Guidance Documents under the IPPC.

Summary of proposed changes to the draft text

The U.S. has extensive experience in the area of pest risk assessment for LMOs, and we have provided below a number of suggested changes to the text that we believe makes this a more comprehensive and useful document. We note that the final format of the supplement has not been clarified; it is unclear if the new text be inserted into ISPM-11 as was done for the Environmental Supplement, or if another format for the supplement is envisioned. This issue needs to be clarified before final adoption of the LMO supplement. It also made it difficult to provide specific comments on the text. Our detailed comments on the text are provided below. Our recommended revisions to the current draft text focus on several key areas:

- We propose reformatting the document in a way that outlines the requirements for PRA of LMOs in a more logical manner and that also makes the document clearer and easier to use. The most significant change would be to remove new Section 1.1.5 (*Determining the potential for an LMO to be a pest*) from the ISPM-11 text and to include this information as Annex III. We also propose moving new Section 1.1.4 (*Types of LMOs*) to become a sub-bullet under section 1.1.2 (*PRA initiated by identification of a pest*).
- We also propose a number of technical revisions, primarily to Sections 1.1.4 and 1.1.5, including some rearrangement of text, to make the document technically accurate and more comprehensive.
- Finally, we have recommended a number of additional revisions to the supplemental text that include editorial changes for clarity and accuracy. We tried to ensure that:
 - new criteria for risk analysis of LMOs are within the mandate of the IPPC to focus on risks to plant health;
 - revisions to the proposed text within ISPM-11 focus on new or altered criteria for performance of a quarantine risk analysis for LMO pests not covered by PRA for traditional pests under ISPM-11; and
 - the focus of the risk assessment process is evaluation of potential harm to plants, and not just any effects or interactions that may not be harmful to plant health (for example, gene flow can occur from both LMO and non-

LMO plants, and in and of itself is not a hazard; the assessment must consider the phytosanitary consequences of any potential gene flow.)

Where revisions are proposed to boxed text from the draft supplement, we have included the boxed text and indicated our changes as follows:

- Proposed deletions to the current text are noted by strikeouts.
- Proposed new text is noted in bold, underlined text.
- Explanatory text or the rationale for the recommended revisions are noted in italics.

Specific:

The United States recommends the following specific changes to the text of the draft LMO supplement to ISPM-11. We recognize that some of our recommended changes will depend on the final format of the proposed supplement, that is, whether the new language currently shown as boxed text is integrated into the text of ISPM-11, or whether the supplement is redrafted as a separate document.

- Page 1, first boxed text:

The purpose of this text is to provide more detailed guidance to National Plant Protection Organizations (NPPOs) on the assessment of living modified organisms (LMOs) regarding pest risk.

It is based on ISPM No. 11 (Pest Risk Analysis for quarantine pests), including the integrated supplement on environmental risks (as approved by the ICPM in 2003). The supplemental text on LMOs is shown in boxes in the relevant sections.

The supplemental text does not describe an independent PRA process for LMOs.

Comment – substance: This text should be deleted if the LMO text is integrated into ISPM-11. The boxed text under Scope is sufficient.

REFERENCES:

ADDITIONAL REFERENCES RELEVANT FOR LMOs

Convention on Biological Diversity, 1992. CBD, Montreal.

Cartagena Protocol on Biosafety to the Convention on Biological Diversity, 2000. CBD, Montreal.

Code of conduct for the import and release of biological control agents, 1996. ISPM No. 3, FAO, Rome.

Glossary of Biotechnology for Food and Agriculture, 2002. *Research and Technology Paper 9*, FAO, Rome.

Glossary of phytosanitary terms, 2003. ISPM No. 5, FAO, Rome.

Glossary supplement No. 1: Guidelines on the interpretation and application of the concept of official control for regulated pests, 2002. ISPM No. 5, FAO, Rome.

Glossary supplement No. 2: Guidelines on the understanding of potential economic importance and related terms including reference to environmental considerations, 2003. ISPM No. 5, FAO, Rome.

Guidelines for phytosanitary certificates, 2001. ISPM No. 12, FAO, Rome.

Comment – technical: The U.S. recommends adding the following OECD references:

OECD, 1992, Safety Considerations for Biotechnology. Paris: OECD Publications Service. Available electronically at: <http://www.oecd.org/publications>.

OECD, 1993, *Safety Considerations for Biotechnology: Scale-up of Crop Plants*. Paris: OECD Publications Service. Available electronically at: <http://www.oecd.org/publications>

Rationale: These OECD Documents were developed by international consensus between countries first involved in developing and regulating products of biotechnology as they were being field tested and released on a large scale. The concepts developed have been used as the basis for regulatory review.

- Boxed text under definition of “phytosanitary measure”:

Comment – Substance: The revised definition of “phytosanitary measure” was agreed to in the revision of the IPPC, and has been included in the IPPC glossary. It would thus be appropriate to replace the definition of this term in ISPM-11. However, replacement of the current definition with the agreed interpretation should not be dependent on integration of the supplemental text for LMOs into ISPM-11. This change should be made in the ISPM-11 text regardless of the status of the LMO supplemental language.

- Section 1: Initiation:

Comment – Substance and technical: Move the guidance currently in new section 1.1.5 to an Annex for clarity and ease of use of the document. Please see our detailed discussion of this point under Item (2), on page 2 of this document.

Some categories of LMOs may present a phytosanitary risk and therefore warrant a Pest Risk Analysis. However many categories of LMOs will not present phytosanitary risks **beyond those posed by related non-LMOs** and therefore will not warrant a Pest Risk Analysis. Thus, for LMOs, the aim of the Initiation stage is to identify those LMOs that have ~~the~~ characteristics of **that may cause them to present** a potential pest **risk** and need to be assessed further, and those which need no further assessment under ISPM No. 11. **Detailed guidance on determining if an LMOs has the potential to pose a plant pest risk can be found in Annex III.**

Comment – Technical: It is important to note early in the process that risk assessments for LMOs should be performed in comparison to the phytosanitary risks posed by the non-LMO counterpart of that organism.

Comment – Technical: Move the guidance currently in Section 1.1.5 of the draft standard to an Annex (Annex III) for clarity and ease of use of the document.

~~There are a number of references to “genetically altered plants” in the Initiation stage of the existing ISPM No. 11. These references should be understood to include plants altered by modern biotechnology.~~

Comment – Technical: For consistency with the agreed definitions, and particularly if the new language in the LMO standard will be integrated into the text of ISPM-11, change “genetically

altered” where it appears in the standard in 1.1.1 and 1.1.2 to “produced using modern biotechnology.” The term “genetically altered” is undefined.

- Section 1.1.1 of agreed text to ISPM-11, First bullet: **change “genetically altered plants” to “plants produced using modern biotechnology”**

Comment – Technical: See comment in the box above; change for consistency with agreed definitions.

- Section 1.1.2 of agreed text to ISPM-11, last bullet: Change as follows: an organism is ~~genetically altered~~ **modified using modern biotechnology (an LMO) such that the new gene or trait results in an increase in the plant pest potential of that organism (see Annex III.)** in a way which clearly identifies its potential as a plant pest.

Comment – Technical: Change is recommended for consistency with agreed definitions and for technical accuracy.

Comment – Technical: **Section 1.1.4: Move Section 1.1.4 Types of LMOs, into a new section 1.1.2.1 Types of LMOs that includes and expands on the information in 1.1.4.**

Suggested text for new section 1.1.2.1 follows:

[New section] ~~1.1.4~~ 1.1.2.1 Types of LMOs

LMOs are organisms that have been modified using techniques of modern biotechnology to express one or more new or altered traits. In most cases, the parent organism is not normally considered to be a plant pest and an assessment needs to be performed to determine if the new regulatory sequence, gene, or gene product results in a new trait or characteristic that may alter the potential of that organism to present a plant pest risk.

A plant pest risk may be presented by:

- **The organism(s) with the inserted gene(s);**
- **The gene itself (i.e., gene from plant pests such as viruses); or**
- **The consequences of the gene moving to another organism.**

Comment – Technical: Section 1.1.2 describes when the PRA process may be initiated by identification of a pest. It makes sense to include the text that elaborates on the types of LMOs that could pose a phytosanitary risk as a sub-bullet under Section 1.1.2. We proposed the new text above as explanatory language to provide context for the list of “types of LMOs” below. The proposed new text provides further clarification on the types of modifications and organisms that may require consideration as potential pests.

The types of LMOs that an NPPO may be asked to review for phytosanitary risk include, **but are not limited to:**

- ~~Genetically modified plants~~ **Plants produced using modern biotechnology** for use (a) as agricultural crops, ornamental plants **or trees in managed or unmanaged ecosystems forests**; (b) in bioremediation (as an organism that cleans up contamination); (c) for industrial purposes (e.g. **production of enzymes or bioplastics; pharmaceutical, nutraceutical production**); (d) as **in production of** therapeutic agents (**e.g., pharmaceuticals or nutraceuticals**);
- ~~Genetically modified invertebrates~~ **Invertebrates or vertebrates produced using modern biotechnology** that ~~may be intended as~~ **may be intended as** biological control agents **and that have been** modified to improve their performance in that role; or (b) **are** pests **with altered** ~~modified to alter their~~ pathogenic characteristics **for use in** and thereby make them useful for biological control **applications**. (See ISPM No. 3);
- ~~Genetically modified microorganisms~~ **Microorganisms produced using modern biotechnology that demonstrate improved** that may be genetically modified to improve characteristics for biofertilizer, biological control, bioremediation or industrial uses.

Comment – Technical: Changes above are editorial changes for clarification and consistency with agreed definitions.

Comment – Substance and Technical: (New Section) 1.1.5 Remove this section from the text of ISPM-11 and included as an Annex following Annex I and Annex II. This change would streamline the document, and reinforce the conclusion of the Working Group that all LMOs will not present a phytosanitary risk. We have recommended a number of specific changes to the text in this section based on our experience in risk assessment of LMOs. The focus of our suggested changes is on clarity and technical accuracy.

[New section] ~~1.1.5~~ Annex III: Determining the potential for an LMO to be a pest

In order to be categorized as a pest, the LMO has to be **determined to be** injurious or potentially injurious to plants or plant products under some conditions in the PRA area. This damage may be direct effects on plants or indirect effects that result in injury to plants or plant products (such as altering interactions in an ecosystem **in a way that is harmful to plants or plant biodiversity**, changing the susceptibility of a host to pathogens, altering the host range, etc.). **Potential risks of LMOs should be considered in the context of risks posed by the relevant non-modified organisms or parental organisms in the PRA area, with a focus on new risks that may result from the introduced gene or new protein, or from expression of the new trait.**

Comment – Technical: The first two changes in this paragraph are for clarification. The sentence added at the end of the paragraph reflects a key concept in risk assessment of LMOs, i.e., that it is important to compare phytosanitary risks that may be posed by an LMO with those of the non-LMO counterpart. This concept was stated below (in the fourth bullet under Item 5 in the draft supplemental text), but we believe is it important to note this early in the text of this section to help establish the framework for the risk assessment procedure.

This text is relevant for LMOs only where ~~there is~~ the potential for phytosanitary risks can be associated with some characteristic or property related to the genetic modification ~~the LMO~~ nature of the organism. Other phytosanitary risks associated with an organism should be assessed under other appropriate sections of ISPM No. 11 or under other appropriate ISPMs.

Comment – Technical: The term “LMO nature” is vague; change for clarity and specificity of the guidance.

The potential phytosanitary risks identified ~~above~~ below can also be associated with non-LMOs. The risk analysis procedures of the IPPC are generally concerned with phenotypic characteristics rather than genotypic characteristics. Genotypic characteristics may need to be considered when assessing the phytosanitary risks of LMOs.

Comment – Technical and Editorial: insert this paragraph here, and delete it from its location in the draft supplemental text (the first bullet following Item 5 below). This is a general statement regarding risk assessment of LMOs that helps set the context for the more specific recommendations below.

In order to evaluate the potential pest risk posed by an LMO, information may be required on the development and identity of the organism, including:

- the identity of the LMO to be imported;**
- taxonomic status of the donor and recipient organism, the common names, and any characteristic related to phytosanitary risk;**
- the genotype and phenotype of the donor and recipient organisms;**
- details of the transformation process;**
- characterization of the nucleic acid sequences inserted into the LMO, and of expression of the new RNA or protein;**
- the biology of the LMO with the inserted sequence(s) and any changes in the phenotype resulting from the modification;**
- the inheritance and stability of the new trait**

Comment – Technical and Substance: Collection of information about the development and identity of an LMO should be part of the risk assessment process for determination of the pest risk potential of the organism. We recommend elaboration of these requirements in this section of the Annex, rather than under section 1.3 of ISPM-11.

Other factors to be considered in the determination of the potential phytosanitary risks for LMOs may include, but may not be limited to:

1. Changes in adaptive characteristics ~~which~~ that may increase the potential for introduction or spread, including invasiveness. **Examples of such characteristics include** ~~for example:~~

- drought tolerance of plants;
- herbicide tolerance of plants;
- alterations in reproductive biology;
- **alterations in dispersal ability of pests;**
- **alterations in growth rate/vigor;**
- **alterations in host range or colonization ability;**
- **alterations in temperature or pH tolerance;**

- pest resistance; and
- pesticide resistance.

Comment – Technical and Substance: These changes are recommended to clarify the scope of the characteristics that could affect the ability of an LMO to establish and spread, possibly increasing the potential of that organism to pose a pest risk.

2. **Gene flow Potential negative phytosanitary consequences of gene transfer from the LMO to relatives or other species**, including for example:

- transfer of herbicide, **disease**, or pest resistance genes to compatible species **that could increase the ability of an organism to establish and spread, i.e., gene flow**; and
- **new pest risks that may result from gene transfer that the potential to overcome existing reproductive and recombination barriers resulting in pest risks**.

Comment – Technical: Gene flow in and of itself is not a phytosanitary risk. These changes emphasize that NPPO officials need to evaluate the consequences of gene transfer between relatives or between species with respect to the consequences for plant health when determining if an LMO is a potential plant pest. We also made a distinction between gene transfer and gene flow; gene flow is generally used with respect to movement of genes between sexually compatible relatives, while gene transfer is a broader term that can include horizontal gene transfer between species.

In case of phytosanitary risks related to gene transfer or flow, the LMO is acting more as a potential vector or pathway for introduction rather than a pest in and of itself. Therefore, once it is determined to be a potential pest, warranting consideration under the PRA, the term "pest" should be understood to include the potential of an LMO to act as a vector or pathway for introduction of a phytosanitary risk.

Comment – Technical and Editorial: Move this bullet, currently the fifth paragraph under Item 5, and include as a new sub-bullet under Item 2. This is a clarification or elaboration of the relationship between gene transfer and pest risk potential, and it makes more sense to include the text here.

3. Potential to adversely affect non-target organisms **or to have other unintended phytosanitary impacts**, including for example: *Comment – technical:* The changes in the introductory sentence distinguishes between effects of pesticidal substances on non-target organisms, i.e., organisms not meant to be affected by the pesticide, and other unintended phytosanitary effects from the LMO.

- ~~changes in host range of biological control agents or organisms claimed to be beneficial;~~
- ~~effects on other organisms, such as biological control agents, beneficial organisms or soil microflora, that result in a phytosanitary impact (indirect effects).~~

Comments – substance and technical:

Edit the two bullets from the draft supplemental text as indicated below for clarity and accuracy.

- We propose adding a bullet that specifically addresses non-target effects
- We also propose editing the second bullet to include any effects on other organisms that could have a phytosanitary impact. Direct effects would include changes in host range.

- negative direct or indirect effects of plant-produced pesticides on non-target organisms beneficial to plants;
- other direct or indirect effects on other organisms, such as biological control agents, organisms beneficial to plants, or soil microflora, such as nitrogen-fixing bacteria, that result in a phytosanitary impact

4. Possibility of phytopathogenic properties, including for example:

- phytosanitary direct risks to plants through disease or injury presented by new traits introduced using modern biotechnology into ~~in~~ organisms not normally considered a phytosanitary risk;
- enhanced or novel virus recombination, trans-encapsidation and synergy events related to the presence of virus sequences; ~~and~~
- ~~phytosanitary risks associated with nucleic acid sequences (markers, promoters, terminators, etc.) present in the insert.~~

Comment – technical and substance:

First bullet: clarification for technical accuracy

Second bullet: more inclusive

Third bullet: We recommend deletion of this bullet as it is not clear how the nucleic acid sequences in the insert relate to the possibility of new phytopathogenicity associated with an LMO. Characterization of the nucleic acid sequences inserted into the LMO, and the production of new proteins, including those that could affect the pathogenicity of the organism, should be performed as part of the collection of information about the organism (see above.)

~~5. Phenotypic and genotypic instability.~~

Comment – technical and substance: delete this bullet because determination of genotypic and phenotypic stability are included earlier in this guidance (in the bulleted list in Para. 4 of this section) as part of the initial characterization and gathering of information about the LMO. In addition, phenotypic and genotypic instability, that could result for example in the loss of a sterility trait introduced to prevent gene flow, should also be considered for LMO pests with respect to the potential for establishment and spread in the PRA area, as in Section 2.1.1.4.

5. Changes in agronomic practices or predicted planting area that could have phytosanitary consequences.

Comment – technical and substance: The intended use of the product, including anticipated changes in planting area that could occur as a result of the introduction of a new trait such as drought or salinity tolerance, could affect the pest potential of an LMO and should be considered as part of the pest risk assessment.

~~The potential phytosanitary risks identified above can also be associated with non-LMOs. The risk analysis procedures of the IPPC are generally concerned with phenotypic characteristics rather than genotypic characteristics. Genotypic characteristics may need to be considered when assessing the phytosanitary risks of LMOs.~~

Comment – editorial: move this bullet and include as the third paragraph in this section above, before the listing of assessment criteria. This is a general comment regarding considerations for

~~risk assessment of LMOs that is more appropriately placed above the detailed list of information requirements.~~

The potential for risk depends in part on the intended use. Certain intended uses may significantly manage risk and therefore PRA may not be needed (e.g. high security contained use).

~~There may be no evidence indicating that genetic modifications relating to physiological traits have significant quarantine risks and therefore these types of LMOs require no further consideration.~~

Comment – substance: *Delete this bullet. The term “physiological trait” is vague; most modifications to a plant could be considered a physiological change. In addition, we do not believe any one type of LMO or modification should be categorically excluded from the need for a determination of pest risk potential. All LMOs should be considered on a case-by-case basis.*

~~It may be useful to consider potential risks in the context of risks posed by the non modified recipients or parental organisms in the PRA area.~~

Comment – technical and substance: *This is a critical concept in pest risk assessment of LMOs and we recommend deleting this text and instead including text in the first paragraph of this section to reflect this idea (see above.).*

~~In case of phytosanitary risks related to gene flow, the LMO is acting more as a potential vector or pathway for introduction rather than a pest in and of itself. Therefore, once it is determined to be a potential pest, warranting consideration under the PRA, the term "pest" should be understood to include the potential of an LMO to act as a vector or pathway for introduction of a phytosanitary risk.~~

Comment – editorial: *Moved to Item 2 above. The text is a clarification as to the relationship between gene transfer and potential plant pest risk and makes more sense if included with Item 2 above that discusses the potential phytosanitary consequences of gene transfer or gene flow.*

Factors that may result in the need to subject a LMO to stage 2 of the PRA include:

- ~~- Technical and human capacities that the NPPO have in place to estimate the risk, design appropriate risk management, monitor for compliance and review the PRA as new evidence emerges;~~

Comment – technical and substance:

Delete this bullet because the resource capacities of the NPPOs should not be a factor in a determination of phytosanitary risk or the need for risk management. The decision should be based on a scientific risk assessment. The technical and human capacities of NPPOs are important considerations and need to be addressed by capacity building efforts supported by the IPPC, but should not be considered as part of the scientific risk assessment process.

- Lack of knowledge about a particular modification event;
- The ~~source and~~ credibility of information if it is an unfamiliar modification event;

Comment – substance: *It is unclear why the “source” of the information is included here; the credibility of the information is the important factor and should not be prejudiced with respect to the source.*

- ~~Where there is little~~ **Insufficient** data on the performance of the LMO in environments similar to the PRA area; *Comment - editorial change for clarity*
- Field experience **or laboratory data** indicating that the LMO is a potential pest; *Comment – technical: Consistency with bullet below*
- Where the LMO expresses characteristics such as invasiveness that are associated with pests under ISPM No. 11;
- Existing conditions in the country (or PRA area) that may result in the LMO being a pest;
- Where a PRA for similar organisms/LMOs or risk analyses has been carried out for other purposes that indicate a pest potential.

Factors that may lead to the conclusion that a LMO is not a potential pest and/or requires no further consideration under ISPM No. 11 include:

- Where the genetic modification is a familiar event that has previously been assessed by the NPPO (or other reliable experts) as having no phytosanitary risk;
- Where the LMO is to be confined in a reliable containment system and not be released;
- Evidence from laboratory trials or field trials that the LMO is unlikely to be a pest under the use proposed.

Section 1.3 Information

~~For LMOs, information gathering is an essential element of all stages of risk analysis. It is important at the initiation stage in order to clarify the identity of the LMO. Information required may include:~~

- ~~— Name and identity of the LMO and the risk management measures applied to the LMO in the state of export;~~
- ~~— Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety;~~
- ~~— Description of the nucleic acid or the modification introduced and the resulting characteristics of the LMO;~~
- ~~— Appropriate detection and identification methods and their specificity, sensitivity and reliability;~~
- ~~— Intended use.~~

Comment – technical and substance: The current text of Section 1.3 of ISPM-11 only includes general recommendations regarding the importance of information gathering and appropriate sources for this information. It does not include specific recommendations for types of information, as included here for LMOs. Collection of information about the development and identity of an LMO should be part of the risk assessment process for determination of the pest risk potential of the organism, and it is more appropriate to include these information requirements under Annex III (current Section 1.1.5). We recommend elaboration of these requirements in Annex III, rather than under section 1.3 of ISPM-11. The requirement for information about risk management measures in the country of export is more appropriately included in Section 2.1.1.3.

Information for risk analysis for LMOs may come from a variety of sources. The provision of official information regarding pest status is an obligation under the IPPC (Art. VIII.1c) facilitated

by official contact points (Art. VIII.2). A country may have obligations to provide information about LMOs under international agreements such as the **World Trade Organization's Agreement on the Application of Sanitary and Phytosanitary Measures (1994) and the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (2000; Cartagena Protocol)**. The Cartagena Protocol has a Biosafety Clearing-house that may contain relevant information. Information on LMOs is sometimes commercially sensitive and any applicable obligations with regard to release and handling of information should be observed.
Comment – substance and editorial: Obligations under the WTO are also important and should be mentioned here. Deletion of the word “any” is an editorial change; term is unnecessary.

Section 1.3.1 Previous PRA

For LMOs at the end of ~~this~~ **the initiation** stage a NPPO may decide that the LMO: *Comment - editorial change for clarity*

- is a potential pest and needs to be assessed further in stage 2 or;
- is not a potential pest and needs no further analysis under ISPM No. 11 (but see also the following paragraph).

For LMOs, PRA may constitute only a portion of the overall risk analysis for import and release. For example, countries may require the assessment of risks to human or animal health or to the environment beyond that covered by the IPPC. PRA under the IPPC only relates to the assessment and management of phytosanitary risks. As with other organisms or pathways reviewed by an NPPO, LMOs also may present other risks not falling within the scope covered by the IPPC. When an NPPO discovers potential for risks that are not phytosanitary it may be appropriate to notify the relevant authorities.

Section 2.1 Pest Risk Assessment

For LMOs, from this point forward in PRA, it is assumed that the LMO is being assessed as a pest and therefore "LMO" refers to an LMO that is a potential quarantine pest **due to new or altered characteristics or properties resulting from the genetic modification** ~~because of its LMO characteristic~~. LMOs that have pest characteristics unrelated to the genetic modification should be assessed using the normal procedures.

Comment – technical: Clarification

Section 2.1.1

For LMOs the potential for economic consequences (including environmental consequences) in the PRA area directly relates to the injurious nature of the pest on plants or plant products. **(See ISPM No. 5 Supplement 2)**. *Comment – substance: added for completeness.*

Section 2.1.1.1 I Identity of pest

In the case of LMOs, identification ~~requires~~ **may require** information regarding characteristics of the recipient or parent organism, the donor, the transgene vector and the modification.

Comment – technical: Information requirements are determined on a case by case basis.

Given the technology used to produce ~~a~~-LMOs, it is likely that the identity of the LMO is clear. However, in some cases it may be appropriate to carry out risk assessment on a particular **DNA** insert in various backgrounds or varieties/species. In these cases, detailed information on the various recipients may be needed. Information as provided under section 1.3 **and/or in Annex III** may be adequate. *Comment – technical and substance: Clarification.*

Section 2.1.1.3 Regulatory Status

In the case of LMOs, **LMO pests**, ~~this~~ **official controls** should relate to the ~~official control~~ (phytosanitary measures) applied because of the pest nature (**injurious to plants and plant products**) of the LMO. It may be appropriate to consider ~~the~~ **any official control measures in place for the** ~~regulatory status of~~ parent organism, **or** donor organism, **including regulatory status.** ~~or transgene vector.~~

Comment – editorial: Clarification. Official control measures would include regulatory status. Official control measures would apply to the organism but not to specific transgenes or vectors.

Section 2.1.1.4 Potential for establishment and spread in PRA area

For LMOs **pests**, consider the following:

- changes in adaptive characteristics **resulting from the genetic modification that** ~~which~~ may increase the potential for establishment and spread (invasiveness);
- gene flow that may result in the establishment and spread of pests;
- phenotypic and genotypic instability that could result in the establishment and spread of organisms with new pest characteristics, **e.g., loss of sterility genes designed to prevent outcrossing.**

For more detailed guidance on the assessment of these characteristics, see ~~section 1.1.5.~~ **Annex III.**

Comment – technical: First bullet - clarification.

Third bullet –the example is added to clarify how phenotypic or genotypic instability could result in increased probability for establishment of an LMO.

Section 2.1.1.5 Potential for economic consequences in PRA area

In the case of LMOs, the economic impact should relate to the pest nature (injurious to plants and plant products) of the LMO.

For LMOs, consider the following:

- potential economic consequences that could result from adverse effects on non-target organisms **that result in phytosanitary impact**; *Comment – technical: Clarification.*
- economic consequences that could result from pest properties.

For more detailed guidance on the assessment of these characteristics, see **section 1.1.5. Annex III.** *Comment – editorial.*

Section 2.1.2 Conclusion of pest categorization

~~In the case of LMOs, if it has been determined that the LMO has the potential to be a quarantine pest, the PRA process should continue. *Comment – editorial: This text is redundant with respect to the current text of 2.1.2. Once an LMO has been determined to pose a potential pest risk, the PRA requirements should relate to LMO and traditional pests.*~~

Section 2.2 Assessment of the probability of introduction and spread

~~Pest introduction is comprised of both entry and establishment. Assessing the probability of introduction of an LMO requires an analysis of each of the pathways (intentional or unintentional) with which a pest may be associated from its origin to its establishment in the PRA area.~~

~~*Comment – editorial: This text is redundant with respect to the current text of 2.2. Once an LMO has been determined to pose a potential pest risk, the PRA requirements should relate to LMO and traditional pests.*~~

Section 2.2.1.1 Identification of pathways for a PRA initiated by a pest

~~For LMOs, all relevant pathways should be considered (intentional and unintentional).~~

~~*Comment – substance: This concept is not just relevant for LMOs. Intentional and unintentional pathways should be considered for all pests. Insert the phrase “(intentional or unintentional)” at the end of the first sentence in the agreed text to this section, to read “All relevant pathways should be considered (intentional or unintentional)”.*~~

Section 2.2.1.2

~~For LMOs, the role of identity preservation systems should also be considered.~~

~~*Comment – substance: Delete this bullet, or adding a more general comment to the agreed text of Section 2.2.1.2 of ISPM-11. The use of handling systems to manage phytosanitary risks is already mentioned in this section, and should apply to all pests, including LMO pests. Any elaboration with respect to particular handling/documentation systems should apply to all pests.*~~

2.2.1.5. Probability of transfer to a suitable host

For LMOs, the probability of gene flow should also be considered, ~~such as where~~ **when** there is a trait of phytosanitary concern that may be transferred. *Comment: - editorial.*

2.2.2.3 Cultural practices and control measures

For LMOs **determined to pose a plant pest risk**, it may also be appropriate to consider specific ~~cultural or control~~ **agricultural management** practices related to LMOs (e.g. separation distances **between the LMO crop and other crops, including conventional or organic crops or non-pest LMOs**).

Comment – technical and substance: The phrase “cultural or control” practices is vague; changes are suggested for clarity.

Section 2.2.2.4 Other characteristics of the pest affecting the probability of establishment

~~For LMOs, genotypic and phenotypic instability may also need to be considered.~~

Comment – technical: This language is redundant with that in Section 2.1.1.4. There is already a recommendation to consider phenotypic and genotypic stability with respect to the potential for establishment and spread of a LMO pest in the PRA area.

Section 3.1 Level of risk

For LMOs, the acceptable level of risk ~~may also~~ **should** be expressed by comparison to the level of risk associated with similar or related organisms, **taking into account the associated agricultural practices**.

Comment – technical.

Section 3.4.1 Options for consignments

~~For LMOs, measures may also include procedures for the provision of information on the phytosanitary integrity of consignments (tracing systems, documentation systems, identity reservation systems).~~

Comment – substance: Measures that could be used to provide information on the phytosanitary integrity of consignments are not specific for LMO pests. This bullet should be deleted, or a new bullet added to the agreed text of Section 3.4.1. of ISPM-11 to reflect this point.

Section 3.4.2 Options for preventing or reducing infestation in the crop

For LMOs-~~pests~~, appropriate measures may also include, **but would not be limited to:**

- pest resistance management systems (e.g. buffer zones, refugia);
- management of trait expression;
- control of reproductive ability (e.g. male sterility);
- control of alternative hosts where feasible and desirable, **e.g., for LMO microbes or invertebrate plant pests.**

Comment – technical: Clarification

ANNEX III:

First bullet: Some categories of LMOs may present a phytosanitary risk and therefore warrant a Pest Risk Analysis. However many categories of LMOs will not present a phytosanitary risk and therefore will not warrant a Pest Risk Analysis. ~~For example, modifications to change the physiological characteristics of a plant (e.g. ripening time, storage life) may not present any phytosanitary risk.~~ **The pest risk that may be posed by an LMO is dependent on a number of factors, including the characteristics of the donor and recipient organisms, the genetic alteration, and the specific new trait or traits.** Therefore, ~~part of the supplemental text (see 1.1.5) Annex III of ISPM-11~~ provides guidance on how to determine if an LMO is a potential pest.

Comment – technical and substance: The term “physiological trait” is vague; most modifications to a plant could be considered a physiological change. In addition, we do not believe any one type of LMO or modification should be categorically excluded from the need for a determination of pest risk potential. All LMOs should be considered on a case-by-case basis. The proposed new text clarifies the factors that could affect the pest risk of an LMO.

Third bullet: Risks from LMOs may result from certain traits **introduced into** ~~of the~~ **organism**.....

Comment – editorial: Clarification