



Discussion Paper for Development of Module 4 of the NAPPO Standard for Importation of Transgenic Plants into NAPPO Member Countries

Importation for Non-Propagative Use Only

Prepared by the NAPPO Biotechnology Panel
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1. Summary

The Biotechnology Panel of the North American Plant Protection Organization is proposing options with respect to the development of a fourth module for the Standard for Importation of Transgenic Plants into NAPPO Member Countries (RSPM 14) that would address the assessment of plant pest risks for transgenic plant products imported for non-propagative purposes only. This paper outlines the options for regulatory approaches and policies in order to solicit input from NAPPO governments and stakeholders. Based on the input received, the Biotechnology Panel will present a recommendation to the NAPPO Executive Committee in October 2004 on whether, and if so, how, the Panel should proceed with development of Module 4.

2. Background

Standards for plant pest risk assessment of transgenic plants and plant products are being developed under NAPPO in the format of modules. Three modules have been finalized and adopted: Module 1: Importation for Contained Use; Module 2: Importation for Confined Environmental Release; and Module 3: Importation for Unconfined Release into the Environment. These modules were developed based on the current practices for pest risk assessment of transgenic plants in the United States and Canada, as outlined in the Canada and U.S. Bilateral Agreement on Agricultural Biotechnology (available at www.aphis.usda.gov/brs/canadian/usda01e.pdf); Mexico was also involved in the development of this bilateral agreement.

The NAPPO Biotechnology Panel has begun work on development of Module 4, which would provide guidance for use and importation of transgenic plant products in NAPPO member countries when there is no intention of releasing these products into the environment for cultivation or propagation. This will include products such as grains, fruits, and vegetables intended for direct use as food or feed only, or for processing into food or feed products. It could also include plants not intended for food use such as those engineered to produce chemicals with pharmaceutical or industrial applications, and other non-viable products such as cut flowers (that may have viable pollen). Note that Module 4 is intended to address commercial-scale imports, rather than research materials to be used in contained facilities (covered under Module 1 of this Standard.). Standards developed under NAPPO address the direct or indirect risk to plants or plant products that would be posed by the transgenic plant product, and, as defined under the International Plant Protection

Convention, include risks to both managed ecosystems and natural flora. Approval for importation may also be subject to appropriate review for food safety or other environmental safety considerations.

3. Rationale for Module 4

3.1. Domestic guidance

In most cases, a developer of a new biotech product will seek full regulatory approval, including use in food and feed, and for cultivation or propagation, in the country where they plan to commercialize that product. However, situations are likely to arise where the developer may wish to import a transgenic plant product for food, feed, or processing only, with no intent to grow that product in the importing country. This could be due to environmental considerations (the transgenic plant cannot be grown in the importing country, such as papaya in Canada) or the decision could be based solely on marketing considerations. However, unintended release may result, due to spillage, transportation accidents, theft, vandalism, undigested seed from food or feed use, or processing byproducts.

While all three NAPPO member countries have regulations in place, or in development, to address importation and use of transgenic plants intended for environmental release (see Section 4.1.1), none of the three countries have regulations in place or specific guidance to address the specific question of what type of pest risk assessment should be required for importation of transgenic plants intended solely for non-propagative use. Because the level of risk posed by crops imported for non-propagative use only is expected to differ significantly from the level of risk posed by crops intended for environmental release, treating the two categories of crops in the same manner (i.e., in terms of environmental review) is not logical or efficient.

3.2. International Obligations

NAPPO members also have obligations under international agreements that are relevant to the development of Module 4. The Cartagena Protocol on Biosafety (the Protocol) entered into force in September 2003. Mexico is a Party to the Protocol; Canada is a signatory and is considering ratification of the Protocol; and while the U.S. is not a party, U. S. and Canadian exporters will need to comply with domestic regulations implemented by importing Parties for compliance with the provisions of the Protocol.

The Protocol is a treaty under the United Nations Convention on Biological Diversity that provides a framework for the safe transboundary movement of living modified organisms (LMOs), including transgenic plants. Distinctions are made within the Protocol between importation of LMOs intended for environmental release (for field trials or commercial production) and LMOs imported only for food, feed or for processing (referred to as LMO-FFPs). LMOs intended for environmental release will be subject to the “advanced informed agreement” (AIA) procedure that includes a requirement for a risk assessment, prior to first importation. LMO-FFPs are exempt from the AIA procedure, and the Protocol describes a separate decision procedure governing importation of LMO-FFPs that allows for, but does not require, performance of a risk assessment prior to importation. The different procedures set out under the Protocol reflect the understanding that LMOs intended for food, feed,

or for processing would be expected to have a lower probability of environmental exposure than LMOs intended for planting or intentional release. The Biosafety Protocol provides general guidance for performance of a risk assessment for LMOs, but does not provide detailed guidance or distinguish between intended uses of the LMO in the country of import.

It is also relevant to this work that in April, 2004, a standard for pest risk analysis of LMOs was adopted at the 6th Meeting of the Interim Commission for Phytosanitary Measures (ICPM-6, the current governing body for the International Plant Protection Convention, IPPC). The standard was developed as a supplement to an existing standard, International Standard for Phytosanitary Measure No. 11 (ISPM-11; Pest Risk Analysis for Quarantine Pests). The standard acknowledges that all LMOs will not present a pest risk, and that a determination needs to be made early in the pest risk analysis (PRA) process as to whether the LMO poses a potential pest risk as a result of the genetic modification. Guidance on how to make this determination will be included in an Annex to the standard, and additional new language within the text notes where special consideration may need to be given within the PRA process for LMOs determined to be a potential pest. The standard covers importation of LMOs but does not provide specific guidance for LMOs destined only for non-propagative use as compared to LMOs intended for environmental release. However, the standard does provide for consideration of whether the LMO is to be confined and not released, and for consideration of the proposed use of the LMO in determination of pest risk potential of that LMO. For plants, including LMOs, determined to present a potential pest risk, ISPM-11 recommends consideration of whether an imported plant is intended for planting, as compared to use as feed or for processing, when assessing the probability of establishment and spread of a pest, and considers intended use when determining risk management measures in the PRA area.

The NAPPO Biotechnology Panel believes that NAPPO member countries, and Parties to the Biosafety Protocol or the IPPC wishing to import into NAPPO countries, would benefit from more detailed guidance for risk assessment and risk management of LMOs for specific uses, as developed in NAPPO Modules 1-3 of the Guidelines for Importation and Use of Transgenic Plants, and as proposed here for Module 4.

4. Options for regulating transgenic plants not intended for propagation:

This paper discusses the issues and provides options for regulatory strategies for plant pest risk analysis of transgenic plants intended only for non-propagative uses such as direct use in food, feed, or for processing, and is designed to solicit input from government officials and stakeholders in NAPPO member countries and elsewhere for development of Module 4. For consistency with Modules 1-3, the scope of the risk assessment would be a request for importation of a specific transgenic plant variety. Three general options are discussed below.

4.1. Option 1 - Status quo

Under this approach, each NAPPO country will continue to regulate transgenic plant products not intended for propagation under their current regulations and policies. The NAPPO Biotechnology Panel would not need to draft Module 4, and no change in domestic regulations or policies would be required for each country. The current domestic policies and regulations for each country are summarized below.

4.1.1. Current domestic policies and regulations

4.1.1.1. United States

Importation of transgenic plants and plant products into the United States is regulated by the Animal and Plant Health Inspection Service of the Department of Agriculture (APHIS/USDA) under the authority of the Plant Protection Act and the National Environmental Policy Act. Transgenic plants are reviewed to ensure that they will not present a plant pest risk in the United States. Currently, APHIS regulations do not provide separate guidance for transgenic plants imported exclusively for non-propagative use. However the regulations allow for consideration of the proposed conditions of use (confined field trials, unconfined release, research, etc.) in making case-by-case decisions for importation of genetically engineered products. In the past few years, (1997-2001) APHIS has addressed occasional requests for importation of transgenic plants or plant material for processing or other non-propagative use by issuing “opinion letters” that allow importation of a product based on consideration of the specific product and the proposed use (e.g., potatoes for processing, cut flowers, male sterile canola for processing.)

In January 2004, the USDA announced its intention to update its biotechnology regulations for importation, interstate movement, and environmental release of certain transgenic organisms, and consideration is being given to inclusion of specific guidance to address environmental risk assessment requirements for transgenic plants imported only for non-propagative uses. In addition to APHIS oversight, transgenic plants that produce a plant produced pesticide (PPs, e.g., Bt toxin produced in cotton or corn) are subject to the authority of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), with oversight by the Environmental Protection Agency (EPA). Importation of these transgenic plants or products for non-propagative use may require issuance of an import tolerance for pesticides not registered in the United States. In addition, any product intended for food or feed use would have to meet all appropriate food safety requirements of the Food and Drug Administration (FDA).

4.1.1.2. Canada

Importation of transgenic plants into Canada is regulated by the Canadian Food Inspection Agency (CFIA) under the authority of the Plant Protection Act and Regulations, as well as the Canadian Environmental Protection Act (CEPA. Importation of transgenic plants solely for non-propagative uses, such as direct use as food or feed, scientific research, educational, processing, industrial or exhibition purposes may be authorized under the Plant Protection Act and Regulations if the intended use of the transgenic plants poses minimum pest risk, determined on a case by case basis. A Permit to Import issued by the Canadian Food Inspection Agency is required with the appropriate import conditions to mitigate pest risk. Importation will be authorized if the proposed use of the transgenic plants also poses minimum environmental risk according to the CEPA. In addition, other federal acts and regulations may apply if the intended use is for food (Novel Foods Regulations), or feed (Feeds Regulations) use only.

4.1.1.3. Mexico

Living modified organisms, including transgenic plants, imported into Mexico for environmental release are regulated by Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria (SENASICA)) through the Dirección General de Salud Vegetal (Directorate for Plant Health). Currently, Mexico only has regulations to address national movement, importation and field trials

of transgenic plants; regulations for commercial planting are in development. Transgenic plants imported only for food use, or for processing, are regulated by the Secretaria de Salud (Ministry of Health) through the Comisión Federal para la Protección contra Riesgos Sanitarios (Federal Commission for the Protection from Sanitary Risks, COFEPRIS). Currently, transgenic products imported into Mexico for food or processing that are not intended for environmental release are subject only to assessment for safety for use in human food; no assessment is required for environmental or plant pest risk. LMOs imported only for feed use, or for processing into feed are subject to oversight through the Dirección General de Salud Animal (the Directorate for Animal Health), however there are currently no specific regulations to cover LMOs intended only for feed use. In Mexico, a new comprehensive Biosafety Law is currently under consideration by the Mexican Senate, and Mexico anticipates that it will be necessary to review and revise their current regulations for compliance with this law once it is finalized.

4.1.2. Pros and Cons of Option 1

4.1.2.1. Pros

- Applicants would already be familiar with the policies and the processes of review and approval.
- No new legislation or regulations needed.

4.1.2.2. Cons

- Lack of harmonization in the regulations and policies among the member countries could create confusion and potential liability for importers and exporters.
- Lack of clarity and predictability for applicants
- Possibility that regulatory oversight is inconsistent with potential risk

4.2. Option 2 - Full Evaluation of Phytosanitary Risk

Importation of any transgenic plant product not intended for propagation would only be allowed after a full pest risk assessment has been completed as per Module 3 of NAPPO RSPM No. 14 “Unconfined Release into the Environment”. All transgenic plant products to be imported would be treated the same in terms of evaluation of potential pest risk regardless of the species, its transgenic trait or the intended use, and a full data package would be required for all products. Any transgenic plant or product that has not undergone a full pest risk assessment would be considered a potential pest if imported for non-propagative use. Importation would only be allowed if conditions were placed on that action and the intended use, such as specific handling requirements, channeling, and risk mitigation protocols, intended to minimize or mitigate the effects of unintended environmental release.

4.2.1. Pros and Cons of Option 2

4.2.1.1. Pros

- This approach results in the highest level of protection from potential plant pest risk.
- The assessment process is well defined and predictable and would provide transparency to the applicants.

4.2.1.2. Cons

- May require regulatory or policy change in member countries.
- May pose unnecessary regulatory burden to applicants and governments.

4.3. Option 3 - Case-By-Case Determination of the Level of Risk for Identification of Appropriate Data Requirements

Under this approach, transgenic plant products imported into NAPPO member countries for non-propagative use would be evaluated on a case-by-case basis, according to a set of criteria designed to assess the potential plant pest risk posed by the importation of these organisms. The decision to import, and the conditions of importation, if any, would be based on a pest risk assessment with the criteria for the assessment determined at least in part by the specific intended use of the transgenic product under consideration. This option could provide the flexibility for the importing country to, on a case-by-case basis, determine if pest risk concerns warrant less scrutiny of the product, e.g., an abbreviated set of required data to support the regulatory decision, or a more complete data set to address products that present more concerns. The risk assessment should also indicate if any potential risks can be mediated by specific risk mitigation measures.

4.3.1. Pros and Cons of Option 3

4.3.1.1. Pros

- Potential for reduced regulatory burden for the applicants and regulatory agencies.
- Expedited regulatory review for importation of low risk transgenic plants.
- Adoption of a harmonized approach between NAPPO member countries would provide consistency and predictability.
- Provide flexibility for regulatory agencies in the importing country to determine how much data, if any, is necessary to make a pest risk for importation of a transgenic crop intended for non-propagative use

4.3.1.2. Cons

- May require development of new legislation or regulations, or modification of existing regulations.
- Lack of clarity, unless the criteria are very clear and consistently implemented between NAPPO member countries.
- Could result in lower level of protection from potential plant pest risk than Option 2

4.3.2. Elaboration of Option 3

The NAPPO Biotechnology Panel is requesting comments on all three options for Module 4, however Option 3 provides a promising approach with respect to flexibility as well as providing an adequate and appropriate level of regulatory oversight. The Panel recognizes that a number of issues must be resolved before Option 3 can be fully developed. These issues include the feasibility of any of the regulatory options presented in this paper, the likelihood that these options would be acceptable to each NAPPO member country, and whether there would be conflicts between the guidance that might be included in Option 3 and current standards in member countries.

To facilitate consideration of Option 3, a more thorough discussion of this option is provided below, including a description of the basic outline for the case-by-case approach. A number of issues and

options are presented in this discussion and the Biotechnology Panel is seeking feedback that addresses the feasibility and appropriateness of these options, as well as any other options that should be considered as part of Option 3.

Regulatory options under Option 3: The agency or agencies responsible for ensuring that transgenic plant products imported into NAPPO member countries do not pose any plant pest risks must first establish a regulatory framework for assessment of the potential risks associated with importation of these products. The first step of the review process would provide the regulatory agency in the importing country a range of options for the level of scrutiny to which the imported transgenic crop would be subjected.

4.3.3.1. Exemption from **pest risk assessment**

The most expeditious route for a transgenic plant imported for non-propagative use only under Option 3 could be an exemption from pest risk assessment. Exemption from pest risk assessment could be granted to transgenic plants that meet established criteria that indicate that these plants would not pose a significant environmental risk if imported for non-propagative use only. These criteria may be to the criteria listed in Section 4.3.3.3 that could be used to make a determination that indicates that importation would not pose a significant plant pest risk. The criteria could include the biology of the transgenic plant, availability of an existing pest risk assessment performed by the exporting country, and containment of that product during transportation and processing. Regulatory agencies would have two options for actions for products that meet these criteria:

- 1) Exemption of these transgenic plant products from regulatory oversight related to new traits resulting from the genetic modification; the products would still be subject to phytosanitary or food safety requirements imposed on the non-transgenic counterpart of this plant or plant product. Notification of the regulatory agency responsible for evaluation of transgenic organisms would not be required. For example, a country may want to fully exempt a transgenic plant that is incapable of survival in the importing country from the requirement for **pest risk assessment**.
- 2) Exemption of these transgenic plant products from the requirement for a **pest** risk assessment, but applicants would still be required to notify and receive concurrence from the regulatory agency about the proposed importation and intended use.

Before an exemption from **pest risk assessment** can be included in Option 3, several questions must be answered:

- 1) Do NAPPO member countries believe that exemption is a feasible option for their country? Or do current regulations prevent this from being an option?
- 2) If exemption is an option, can a set of criteria be developed from which the basis for exemption from **pest risk assessment** can be determined?
- 3) What criteria should be considered in the decision to exempt a transgenic plant product from pest risk assessment? (Discussed in more detail below.)

4.3.3.2. Case-by-case determination of potential risks and regulatory actions:

For all transgenic plant products that would not qualify for an exemption, or if it decided that exemption from pest risk assessment cannot be included in Option 3, some form of environmental review would be required. Option 3 would include development of criteria, possibly similar to the

criteria listed in Section 4.3.3.3, that would be considered as part of the determination of whether an imported transgenic product should be subject to an environmental safety analysis, and, on a case-by-case basis, these criteria could be used to determine a) if there is any significant potential risk posed by the imported transgenic product b) the level of risk; c) the amount and type of data required to make a regulatory decision regarding importation of this product and the extent of any mitigation measures that would be needed to mediate any risks and allow importation. The criteria used to determine the level of risk could be the same or similar to as those used to determine if a product could be exempted from review.

In such cases, the regulatory agency in the importing country would decide how much data would likely be necessary to complete an adequate assessment of the pest risk potential of the transgenic product. Issues considered when determining the level of data that would be necessary could include factors such as familiarity with the transgenic crop, regulatory history of transgenic crop, publicly available data and information, likelihood for significant environmental impact after accidental exposure, available containment and mitigation methods, etc. Essentially, it would be expected that for products for which there is a significant level of familiarity, the data requirements would be much less than the data requirements for crops which have not been the subject of extensive regulatory scrutiny. The regulatory agency in the importing country would then review this data to determine the risk potential posed by importation of this product.

4.3.3.3. Potential criteria for determination of plant pest risk posed by transgenic plants imported for non-propagative use:

If the decision is made to proceed with development of Module 4 as described here in Option 3, a decision will have to be reached regarding whether development of criteria is feasible, and if so, if the criteria suggested below are appropriate. The NAPPO Biotechnology Panel has compiled a list of criteria that could be used to determine if a transgenic plant product to be imported for non-propagative use should be subjected to an environmental risk assessment, and if so, the level of regulatory scrutiny, including the data requirements, the extent of the pest risk assessment, and any mitigating requirements that may be imposed as a condition of import. The Panel is requesting input on whether these are the appropriate criteria, and whether other criteria should be included in this determination.

1. Intended Use – This assessment would include a determination of the type and extent of environmental exposure that would be expected from the intended use of the product.
2. Mode of Transport/Handling/Containment – including identification of the point of entry and identification of specific environments to which the transgenic plant could possibly be exposed if released unintentionally into the environment.
3. Approval for Full Environmental Release of the Product in Country of Export/Originating Country – Consideration could be given to the availability of a pest risk assessment performed in the country of export and the regulatory status of the product in the exporting/originating country, particularly if there are similar environmental considerations in the importing and exporting country.
4. Pest Risk Assessments for Similar Crop/Trait Combinations in the Importing Country – Consideration could be given to whether there is a history of safe use of similar transgenic plant

products in the importing country, and if regulators are familiar with the potential plant pest risks or other environmental risks associated with these products.

5. History of Importation of Conventional Counterpart – Consideration could be given to whether there is a history of importation and use of the non-engineered counterpart of the transgenic product into the country of import. The likelihood exists that there would not be significant differences in the transportation/handling methods established for the non-engineered product.
6. Viability of the Product – Consideration could be given to the viability of the product and its potential to survive in the environment of the importing country. Included in this analysis will be whether the product has been processed, or treated otherwise and how the conditions of processing and/or treatment would affect viability.
7. Ability to Establish/Spread – Consideration could be given to the likelihood that the unintended release of the transgenic product could lead to establishment and spread of the transgenic plant variety in the importing country. If the likelihood exists for establishment and spread, consideration will be given to the potential for this transgenic plant to become a weed and/or a pest in the given environment, as compared to the conventional counterpart. Consideration should also be given to whether establishment and spread of the organism could have subsequent effects on land use, non-target organism, or wildlife as a result of the transgenic trait.
8. Availability of Field Trial Data in Country of Import – Consideration could be given to the availability of field trial data for the transgenic variety to be imported. Such data would be used to assess the likelihood that the transgenic variety could become a weed or pest in the importing country.
9. Crop Already Approved for Unconfined Release in Country of Import – Consideration could be given to whether this transgenic product was previously approved for unconfined release in the importing country. For example, the product may be a PIP where the pesticide registration has expired, but the applicant would like to import the product for a processing application.

4.3.4. Importation Decision

Once the level of risk is established, a decision regarding importation would be made based upon the identified potential risk. Here, the regulatory agency would decide whether the transgenic product could be safely imported, and if so, if there should be any restrictions placed on the handling and processing of this product. The potential outcomes could be: a) importation without restrictions; b) importation with restrictions; c) prohibition from importation. Under these three potential options, a transgenic plant product for which the risk is low to nonexistent may be allowed for importation without restrictions. If the risk assessment identifies some potential environmental safety concerns that could be mitigated by restrictions placed on the importation or use of the product, a conditional approval could be guaranteed that would allow importation for example, only under specific handling conditions or into a defined geographic region. For a transgenic product that would likely pose significant environmental risk, and for which containment could be difficult or impossible, importation of the transgenic variety may be prohibited.

5. Request for Input by NAPPO Parties and Stakeholders

The NAPPO Biotechnology Panel is requesting input from NAPPO Parties and any interested stakeholders on whether Module 4 of the NAPPO Standard for Importation of Transgenic Plants into NAPPO Member Countries would provide a benefit to NAPPO member countries and stakeholders and to Parties to the IPPC and the BSP. Based on the analysis performed in this discussion paper,

and on input received, the Panel will develop a specific proposal for whether, and if so, how to move forward on Module 4 for consideration by the NAPPO Executive Committee in November 2004.

Specific issues for consideration and comment include:

- 1) Do you believe that Module 4, which would provide guidelines on pest risk assessment criteria for importation of transgenic plants for non-propagative use only, would provide useful guidance for NAPPO countries and stakeholders, or for other Parties to the IPPC and the Biosafety Protocol?
- 2) If you agree that Module 4 would be useful, please provide comments on the proposed options for regulatory approaches. Do you support developing of NAPPO Module 4 according to Option 3, which provides for establishment of a set of criteria that would facilitate a case by case assessment of the need for, and extent of, pest risk assessment for transgenic plants not intended for environmental release, or do you prefer the regulatory framework outlined in Options 1 or 2 above? Is there another alternative or option not considered in this discussion paper?
- 3) What is the appropriate scope of Module 4? Should the standard address all transgenic plant products that could pose a plant pest risk, including material such as cut flowers (that may have viable pollen)? Or should the standard be limited to viable plant products such as grains, oilseeds, pulses, and fresh fruits and vegetables? Are there other examples of transgenic plant products that should be specifically considered in this standard?
- 4) Should the standard include guidelines for transgenic plant products not intended for direct use as food or feed, or processing into food or feed material, such as plants engineered to produce pharmaceuticals or industrial products? Or do the concerns and potential additional risks posed by these products warrant the development of a separate standard?
- 5) Is exemption of certain transgenic products from the need for an environmental risk assessment a viable regulatory alternative? Would complete exemption from regulatory review be acceptable for any transgenic products, or only with mandatory notification of the regulatory agency? What criteria would define transgenic plant products that could be exempted from environmental review?
- 6) Do you agree with the proposed criteria that could be used to determine whether a transgenic plant product should be subject to environmental review, and the extent of the assessment and data requirements necessary (in Section 4.3.3.3.) Are there additional criteria that should be included?

T. Dunahay/M. Watson
APHIS/BRS – 7/12/04