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Report No. 142

Biosafety in Egypt: Combined Guidelines for Food and Feed and Environmental Safety Assessment

Prepared Upon The Request Of:

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of the National Biosafety Committee
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By

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Part 1. Introduction and Organization of the Summary Report

Steps to Update Egypt's Biosafety Regulations and Guidelines

Scientists in both the public and private sectors in Egypt are currently using the techniques of genetic engineering to develop new, improved varieties of crops for eventual use by Egyptian farmers. Up until now, this work has been restricted to research and contained testing, but soon some new varieties will become ready for commercial release for planting. Such release will need to be regulated to ensure safety.

Egypt's National Bio-Safety Committee (NBC) uses the Biosafety Regulations and Guidelines to guide its work in regulating the use of genetically engineered plants in Egypt. These Guidelines focus mainly on issues of controlled testing. The Guidelines are underdeveloped when it comes to specifying requirements for approving the release of such plants for commercial purposes. This report proposes a draft amendment to the Guidelines (see Part 2) to remedy this deficiency, with particular emphasis on the necessity of : (a) food and feed safety assessments, and (b) environmental safety assessments, as conditions for approval. The draft amendment would become Section III of the Biosafety Regulations and Guidelines: Procedure for the Commercial Approval of Genetically Modified Plants in Egypt

Part 3 of this report proceeds to propose draft Guidelines for the Assessment of Food and Feed Safety and Environmental Safety of Genetically Engineered Plants. These guidelines would become Appendix VIII of the Biosafety Regulations and Guidelines.

Information responsive to the proposed safety assessment guidelines may be obtained from the existing literature, observational data gathered from cultivated or natural populations, or specific tests. It the responsibility of the applicant to arrange for and supply appropriate data to the National Biosafety Committee, and it is the responsibility of the NBC to review and assess the data, and, if necessary, request or arrange for additional testing.

A preliminary appraisal of the human and physical resources of Egyptian laboratories suggests that the capacity already exists in Egypt to conduct the testing required for most safety assessments.

Methodology in Developing the Proposed Safety Assessment Guidelines

In April 2001, the Executive Secretariat of the National Biosafety Committee requested the assistance of the Agricultural Policy Reform Project to provide an expert consultant in the field of biosafety regulations. The Project provided the services of Dr. Hector Quemada, Prof. Dr. Amin El-Nawawy, and Lawrence Kent to consult with key members of the National Biosafety Committee, review international biosafety regulations, and propose an updating of Egypt's regulations.

Dr. Quemada made two trips to Egypt. During the first, he focussed on developing food and feed safety assessment regulations. He drafted regulations based on the generally accepted principle, expressed by the Codex Alimentarus Commission, that "the safety of foods derived from new plant varieties, including recombinant DNA plants, is assessed relative to a similar product having a history of safe use, taking into account both intended and unintended effects. Rather than trying to identify every hazard

associated with a particular food, the intention is to identify new or altered hazards relative to a conventional counterpart." (Codex Ad Hoc Intergovernmental Task Force on Foods Derived From Biotechnology, 2000)

This approach employs the concept of "substantial equivalence." The assessment judges whether a new food is substantially equivalent to a comparable food presently being consumed, and is therefore at least as safe as the food to which it is being compared. The areas where substantial equivalence does not exist are then the foci of further safety assessment. The safety assessment of foods derived from a genetically engineered plant focus on the plant itself. However, the ways in which the plant will be prepared for food must also be taken into account

These food and feed safety assessment guidelines are compatible with internationally accepted data requirements, as expressed by the Codex Alimentarus Commission (Codex Ad Hoc Intergovernmental Task Force on Foods Derived From Biotechnology, 2000), the WHO (2000), ANZFA (1998), FAO (1996), UNEP (1996), USFDA (1992), and Health Canada (1994).

The findings and recommendations of Dr. Quemada et. al. were published in Report 134: Regulating the Commercialization of Transgenic Plants for Food and Feed in Egypt: Food Safety Assessment. This 110 page report, complete with annexes showing how such assessments are carried out in other countries and how, for example, they could be applied to a genetically-modified potato in Egypt, is available through the Secretariat of the National Biosafety Committee.

In June 2001, at the request of the NBC Secretariat, Dr. Quemada made a second visit to Egypt to develop draft environmental safety assessment guidelines. Working in collaboration with Prof. Dr. El-Naway and others, Dr. Quemada developed guidelines by combining the must useful and practical elements of a number of guidelines used in other countries as well as those of the Cartagena Protocol on Biosafety.

As a party to the Convention on Biological Diversity (CBD), Egypt has also signed the Convention's Cartagena Protocol on Biosafety. These environmental safety assessment guidelines are based on a review of the Cartegena Protocol and existing risk assessment guidelines from the European Union and other countries. The proposed guidelines are consistent with the Cartagena Protocol, and they incorporate the most important and specific data requirements used in other countries' risk assessment regulations.

The findings and recommendations of Dr. Quemada's second trip were published in Report 139: Regulating the Commercialization of Transgenic Plants for Food and Feed in Egypt: Envrionmental Safety Assessment. This 137 page report, complete with annexes showing how environmental safety assessments are carried out in other countries and how, for example, they could be applied to a genetically-modified potato in Egypt, is available throug the Secretariat of the National Biosafety Committee.

Objective of this Summary Report

Given the length and depth of Dr. Quemada's two reports, the Executive Secretariat of the NBC requested that a "combined, summary" report be assembled to facilitate the work of the NBC in considering the proposed amendments to its Biosafety Regulations and Guidelines. The Executive Secretariat also requested that the two sets of proposed guidelines (one for food and feed and one for environment) be combined into a single

set of guidelines for the assessment of both food and feed safety and environmental safety. The result is Part 3 of this report: Guidelines for the Assesment of Food and Feed Safety and Environmental Safety of Genetically Engineered Plants.

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United Nations Environment Programme, 1996. International Technical Guidelines for Safety in Biotechnology.

Selected Annexes

(note: additional annexes available in Reports 134 and 139 with the Secretariat)

Annex 1: Biosafety Regulations and Guidelines
Annex 2: Decree No. 1688/1998: Procedure for Commercial Registration of Genetically Engineered Plant Varieties
Annex 3: Current Decrees and Laws Impacting on the Commercial Release of Transgenic Plants (including a diagram outlining steps for release)
Annex 4: Risk Assessment Principles Provided by the Cartagena Biosafety Protocol of the Convention on Biodiversity
Annex 5: Consistency Of the Information Requirements of Selected Regions or Countries with the Risk Assessment Points to Consider Provided the Cartagena Biosafety Protocol of The Convention On Biodiversity.

Part 2

Proposed Section III of Biosafety Regulations and Guidelines:

Procedure for the Commercial Approval of Genetically Modified Plants in Egypt

The applicant is required to make available to the National Biosafety Committee the information and data described below. The NBC will review and assess this information to inform its decision on the application.

1. Prior to submission of an application for registration of a genetically engineered variety to the Variety Registration Committee, the applicant must:

    a. Consult with the National Biosafety Committee Regarding the food and feed and environmental safety assessment that must be conducted. The National Biosafety Committee will make recommendations with the advice and consent of the Supreme Committee for Food Safety. For foreign applicants, the NBC can decide whether to accept results of tests accepted and approved by regulatory agencies of other countries.
    b. Arrange for the testing and collection of data required by the National Biosafety Committee.
    c. Obtain the approval of the National Biosafety Committee, which will be forwarded to the Variety Registration Committee.

2. The information submitted for assessment of food and feed safety and environmental safety should be consistent with the guidelines set forth in Appendix VIII.

3. The National Biosafety Committee and the Supreme Committee on Food Safety, will review the information submitted, and decide:

    a. To approve the application,
    b. To approve the application with additional conditions imposed, or
    c. Require further tests and consultations where additional requested data are reviewed. Additional tests may be requested especially when the results of the first assessment reveal a safety concern that needs to be resolved.

4. Further consultations shall take place until the following endpoints are reached:

    a. The National Biosafety Committee approves the application, with concurrence by the Supreme Committee for Food Safety;
    b. The National Biosafety Committee approves the application, with concurrence by the Supreme Committee for Food Safety, with additional conditions imposed;
    c. The National Biosafety Committee rejects the application because the plant is judged to be unsafe;
    d. The National Biosafety Committee and/or the applicant conclude that remaining safety issues cannot be resolved scientifically; or

e. The applicant withdraws the application.

5. The applicant may resume the application for approval, at which time the process for approval begins at the point at which it was terminated.

6. Upon approval, the National Biosafety Committee forwards its decision and recommendation to the Variety Release Committee in accordance with MALR Decree 1648/1998.

7. The National Biosafety Committee may call on experts in relevant scientific fields to assist in the review of the data presented, or to serve in a general advisory capacity during the assessment of specific applications.

8. The decisions of the National Biosafety Committee stating the basis for their decision shall be published in printed form, and made accessible via the internet or other publicly available media that the Minister of Agriculture deems appropriate.

9. After approval, the National Biosafety Committee will forward a copy of the applicant's information package to laboratories that require it to develop the necessary testing to detect transgenic material if mandated by any future labeling or quality standards regulations.

Part 3:

Proposed Appendix VIII to the Biosafety Regulations and Guidelines

Guidelines for the Assessment of Food and Feed Safety and Environmental Safety of Genetically Engineered Plants

I. Introduction:

These guidelines govern the assessment of the safety of genetically engineered plant varieties proposed for commercial planting in Egypt. The guidelines cover both:

a) food and feed safety, and
b) environmental safety

To assess food and feed safety, these guidelines follow the generally accepted principle, expressed by various regulatory agencies and international bodies, such as the Codex Alimentarus Commission, that states that

> the safety of foods derived from new plant varieties, including recombinant DNA plants, is assessed relative to a similar product having a history of safe use, taking into account both intended and unintended effects. Rather than trying to identify every hazard associated with a particular food, the intention is to identify new or altered hazards relative to a conventional counterpart. (Codex Ad Hoc Intergovernmental Task Force on Foods Derived From Biotechnology, 2000)

This approach employs the concept of "substantial equivalence." The assessment judges whether a new food is substantially equivalent to a comparable food presently being consumed, and is therefore at least as safe as the food to which it is being compared. The areas where substantial equivalence does not exist are then the foci of further safety assessment. The safety assessment of foods derived from a genetically engineered plant focus on the plant itself. However, the ways in which the plant will be prepared for food must also be taken into account

These food and feed safety assessment guidelines are compatible with internationally accepted data requirements, as expressed by the Codex Alimentarus Commission (Codex Ad Hoc Intergovernmental Task Force on Foods Derived From Biotechnology, 2000), the WHO (2000), ANZFA (1998), FAO (1996), UNEP (1996), USFDA (1992), and Health Canada (1994).

As a party to the Convention on Biological Diversity (CBD), Egypt has also signed the Convention's Cartagena Protocol on Biosafety. These environmental safety assessment guidelines are based on a review of the Cartegena Protocol and existing risk assessment guidelines from the European Union and other countries. The proposed guidelines are consistent with the Cartagena Protocol, and they incorporate the most important and specific data requirements used in other countries' risk assessment regulations.

Information responsive to these guidelines may be obtained from the existing literature, observational data gathered from cultivated or natural populations, or specific tests. On a case by case basis, the National Biosafety Committee can specify the applicable data requirements and types of data adequate to answer each data requirement. It the responsibility of the applicant to arrange for and supply appropriate data, and it is the responsibility of the National Biosafety Committee to review and assess the data. Finally, the guidelines should not be viewed as rigid requirements. The NBC may decide to waive requirements, or to impose additional requirements, if scientific evidence exists to support the decision.

II. Information on the recipient plant (or parental plants)

A. Taxonomy:
   1. family name;
   2. genus;
   3. species;
   4. subspecies;
   5. cultivar/breeding line; (designation of the engineered line or lines should be provided)
   6. common name.

B. Other plant species or varieties that have contributed to the recipient plant's genetic background. For example, if the original plant genotype (before transformation) were the result of traditional hybridization of two compatible species, this information should be provided. Information in this category would be typically that which a breeder would know.

C. Reproductive characteristics of the recipient plant
   1. Information concerning reproduction:
      a. mode(s) of reproduction;
      b. specific factors affecting reproduction, if any;
      c. generation time.
   2. Sexual compatibility with other cultivated or wild plant species, including the distribution in Egypt of compatible species.

D. Survivability:
   1. ability to form structures for survival or dormancy;
   2. specific factors affecting survivability, if any.

E. Allelopathy

F. Dormancy

G. Dissemination (pollen, seed, vegetative means):
   1. ways and extent (e.g. an estimation of how viable pollen and/or seeds declines with distance) of dissemination;
   2. specific factors affecting dissemination, if any.

H. Geographical distribution of the plant, including the centers of origin and genetic diversity, if known.

I. In the case of plant species not normally grown in Egypt, description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.

J. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centers of origin of the likely potential receiving environment

K. Other potential interactions of the plant with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.

III. Characteristics of the genetically engineered plant and the effects of the transformation on known toxicants, antinutrients, or nutrients

A. Relevant information on the recipient plant's background genotype and phenotype, including any known toxicity or allergenicity. Such information should be provided not only for the recipient plant, but also for the related species and for plants that have made or may make a significant contribution to the genetic background of the recipient plant. For example, in the case where a breeding line known to produce a high level of alkaloids was part of the pedigree of the line that was transformed, this information should be provided. As another example, in the case of genetically engineered peanuts, information regarding allergies normally caused by non-engineered peanuts should be discussed.

B. History of safe use for consumption as food. The history of use may include information on how the plant is typically cultivated, transported and stored, whether special processing is required to make the plant safe to eat, and the plant's normal role in the diet (e.g. which part of the plant is used as a food source, whether its consumption is important in particular subgroups of the population, what important macro- or micro-nutrients it contributes to the diet).

C. A safety assessment carried out by the NBC based on this information might proceed by a series of questions and answers, as follows:

a. Does the non-engineered species or plant variety have a history of safe use? **If yes, go to 2. If no, go to 3.**

b. Does the information on the non-engineered species or related species indicate the need for analytical or toxicological tests of the genetically engineered plant? **If yes, go to 3.** (The tests, would be determined by the NBC with input from the Supreme Committee for Food Safety, and would be focused on the levels of the toxicants or antinutrients that are known to exist in the non-engineered plant species or variety.). **If no, go to 4.**

c. Do test results provide evidence that toxicant levels in the genetically engineered plant do not present a safety concern? **If yes, then go to 4. If no, then reject the application.**

d. Is the concentration and bioavailability of important nutrients in the genetically engineered plant within the range normally seen in the non-engineered species or variety? **If yes, then conclude no unintended and unpredicted effects on known toxicants, antinutrients, or nutrients. If no, then consult with the NBC for any additional tests to be done to satisfy concerns about safety.**

IV. Sources of new genetic materials (donor organisms & vectors) and their characterization in the genetically engineered plant

A. Information on the donor organism(s) and, when appropriate, on other members closely related to the donor organism(s), including:

1. Its scientific name, taxonomic classification, and usual or common name.

2. Information on pathogenicity or other potential toxic concerns, particularly the relationship to known pathogens or known producers of toxins, allergens or anti-nutrients within the same family.
3. Information on the past and present uses, if any, in the food supply and exposure route(s) other than intended food uses (e.g. possible presence as contaminants). The information should include typical methods of processing and the impact of this processing on the reduction or enhancement of effects from potentially harmful constituents.

B. Information on all genetic material potentially delivered to the engineered plant:
1. The specific method used for transformation.
2. The vector DNA, including the source (e.g. plant, microbial, viral , synthetic), identity and expected function in the plant.
3. Intermediate host organisms including the organisms (e.g. bacteria) used to produce or process DNA for transformation of the host organism
4. The DNA to be introduced (other than the vector), including:
   a. the characterization of all the genetic components including marker genes, regulatory and other elements affecting the function of the DNA
   b. the size and identity;
   c. the location and orientation of the sequence in the final vector/construct
   d. the function

C. Molecular and biochemical characterization of the DNA actually inserted into the plant genome, including[1]:
1. The number of insertion sites and locations (e.g. chromosomal, chloroplast, mitochondrial).
2. The organisation of the inserted genetic material at each insertion site, including sequence data of the inserted material and of the surrounding region if deemed necessary. Information should be presented regarding the arrangement of the genetic material used for transformation has been conserved or whether significant rearrangements have occurred upon integration.
3. The level and site of expression in the plant of the introduced gene product[2].
4. Data to demonstrate that all introduced traits are expressed and inherited in a stable manner.
5. Information on all known open reading frames, including those that could result in fusion proteins
6. Any new substances in the genetically engineered plant as a consequence of the introduced DNA, including:

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[1] Additional guidance for molecular characterization is provided by a joint USDA/CFIA document (Summary Report, Canada – U.S. Bilateral Discussions on Agricultural Biotechnology, July 15-16, 1998 Ottawa, Ontario, CANADA Appendices I and Reviewers Checklists). These documents are available through the Secretariat of the National Biosafety Committee, and can be used as guidance for the information required for food and feed safety assessment as well.

[2] This information is necessary not only for food and feed safety assessment, but also for the assessment of environmental questions such as the expected amount or residues of certain novel proteins. If the properties of those proteins present an environmental concern, then it would be appropriate to calculate the potential environmental exposure to them.

a. The gene product (e.g. a protein or an untranslated RNA)
b. The gene product's function and any resulting new substances expected from that function
c. The phenotypic description of the new trait(s)
d. The level and site of expression in the plant of the introduced gene product(s), and the levels of its metabolites in the plant, particularly in the edible portions. This information should indicate if the newly introduced trait(s) are expressed as expected, in the appropriate tissues, in a manner and at levels that are consistent with the associated regulatory sequences driving the expression of the corresponding gene
e. If the function of the introduced sequence(s)/gene(s) is to regulate the expression of a specific endogenous mRNA or protein, the level and expression pattern of this alteration relative to the original
f. Data to demonstrate whether modifications made to the amino acid sequence of the expressed protein result in changes in its post-translational modification or affect sites critical for its structure or function
g. Data to demonstrate that all introduced traits expressed and inherited in a stable manner.
h. If there exists evidence to suggest that a gene in the host plant has been affected by the insertion event, that evidence should be provided. If any new proteins are produced as a result, those new proteins should be characterized.

V. Information on the genetically engineered plant and its effect on the receiving environment

A. Information relating to known and potential differences between the genetically modified plant and the recipient plant in:
1. Plant pest risk characteristics
2. Disease and pest susceptibilities
3. Expression of the gene product
4. New enzymes
5. Changes to plant metabolism
6. Weediness of the genetically engineered plant, including:
   a. information concerning reproduction
      i. mode(s) or reproduction
      ii. specific factors affecting reproduction, if any
      iii. generation time
   b. dissemination (pollen, seed, vegetative means)
      i. ways and extent (e.g. an estimation of how viable pollen seeds declines with distance) of dissemination
      ii. specific factor affecting dissemination, if any
   c. survivability
      i. ability to form structures for survival or dormancy
      ii. specific factors affecting survivability, if any
   d. allelopathy
   e. dormancy
7. Impact on the weediness of any other plant with which it can interbreed

8. Intended use and agricultural or cultivation practices, including where applicable:
   a. altered geographic range of cultivation
   b. altered habitat adaptation
   c. altered cultivation practices, including
      i. information showing the effect of these changes on sustainability, especially with respect to pesticide use, frequency of tillage, soil erosion and consequential changes in energy and soil conservation
      ii. information on any effect of volunteer plants on crop rotation practices
      iii. specific containment or postharvest procedures, including procedures for disposal of remaining plant matter.
         - any specified conditions for isolation as standard operating procedure for production
         - any specified conditions for handling crop rotations as standard operating procedure for production
         - any specified conditions for dealing with volunteers as standard operating procedure for production
      iv. planting practices and policies (e.g. planting of mixtures to delay the evolution of resistance).
9. Effects of the genetically engineered plant on non-target organisms. If the introduced gene product is known to act by a toxic mechanism, the effects on potential non-target organisms that might be affected by such a mechanism should be evaluated, including soil micro flora and fauna.
10. Indirect plant pest effects on other agricultural products
11. Transfer of genetic information to organisms with which it cannot interbreed
12. Potential interaction with the abiotic environment.

B. Description of detection and identification techniques for the genetically modified plant.

C. Information about previous releases of the genetically modified plant, if applicable, including past reports provided to other regulatory agencies.

VI. Food and feed safety assessment of the gene products in the genetically engineered plant.

A. Information relating to the safety of the new gene products:
   1. The concentration of the substance in the parts of the genetically engineered plant used as food. This information will be already determined in IV.C.6.d. above.
   2. In the case of proteins, information on amino acid sequence similarity between the protein and known protein toxins and anti-nutrients (e.g. protease inhibitors, lectins) as well as stability to heat or processing and to degradation in appropriate representative gastric and intestinal model systems.
   3. Information to demonstrate that genes coding for known toxins or anti-nutrients present in the donor organisms are not transferred to the

engineered plants, if those plants do not normally express those compounds.

4. Toxicology studies if needed. Conventional toxicology studies would not be required in all cases. For example, they would not be necessary when the substance or a closely related substance that has been consumed safely in food made from the non-engineerd plant is found in similar amounts in the engineered plant. A specific example of such as case would be the engineering of plants to express viral coat proteins. Such proteins are known to be a normal part of the human diet, occurring at much higher concentrations in the normal human food supply. Appropriate oral toxicity studies may be carried out in cases where the protein has biological activity in humans or animals, but is not similar to proteins that have been safely consumed in food, and has not previously been consumed safely in food. Careful consideration should be paid to the design of such studies, since toxicology studies designed to assess the safety of specific compounds such as food additives or pesticides might not be appropriate for whole foods.
5. Information relating to the allergenicity of the new products (particularly proteins) produced in the genetically engineered plant. Guidance on the process for assessing the allergenicity of the new product has been provided by the FAO and WHO (FAO, 2001; WHO, 2000), in the form of a decision tree.

B. Information relating to the nutritional value of the engineered plant relative to the original, non-engineered plant. An analysis should be done of the nutrients which are typically expected to be found in the plant when used as food. Guidance for the types of nutrients to measure in various foods can be found in reference texts, as well as in specifications ·' at have either been or can be set by the Egyptian Office of Standards.

C. Any other information that might indicate a scientific reason for a safety concern. As these requirements illustrate, a proper safety assessment need not rely solely upon the results of testing. Information from existing scientific literature, databases, and other relevant and reliable sources of scientific information cannot be ignored and should be used to assess the safety of a genetically engineered plant. The existing body of information can be judged sufficient to the conclude that specific toxicology or allergenicity tests would not be required.

D. A series of questions and answers that could be used by the NBC to assess the food and feed safety of the donor(s) are as follows:
   1. Is food from the donor(s) commonly allergenic? **If yes, go to 2. If no, go to 3.**
   2. Can it be demonstrated that the allergenic determinant has not been transferred to the genetically engineered plant? **If yes, go to 3. If no, go to 4.**
   3. Do characteristics of the donor species, related species, or progenitor lines indicate a need for analytical or toxicological tests? **If yes, go to 5. If no, conclude that there is no concern for toxicity.**
   4. Require allergenicity tests, using protocols such as the FAO/WHO decision tree and other subsequent refinements as guidance. **If tests**

show no evidence of allergenicity, proceed with toxicology considerations beginning at 3. If allergenicity tests show the potential for allergenicity, then reject the application or decide to approve under special restrictions such as labelling, and proceed with toxicology assessments at 3.

5. Do test results provide evidence that toxicant levels in the genetically engineered plant do not present a safety concern? **If yes, conclude that there is no concern for toxicity. If no, then reject application.**

E. The following is a series of questions and answers that could be used by the NBC to assess the food and feed safety of new proteins produced in the genetically engineered plant:

1. Will the new protein be present in food made from the genetically engineered plant? **If yes, go to 2. If no, conclude that there are no safety concerns.**
2. Is the new protein derived from a food source, or substantially similar to an edible protein? **If yes, go to 3. If no, go to 4.**
3. Is food from the donor commonly allergenic? **If yes, go to 5. If no, go to 6.**
4. Does the biological function of the introduced protein raise any safety concern, or is the introduced protein reported to be toxic? **If yes, reject application or consider restricted approval for specific purposes. If no, go to 8.**
5. Can it be demonstrated that the allergenic determinant has not been transferred to the genetically engineered plant? **If yes, go to 6. If no, go to 9.**
6. Is the introduced protein reported to be toxic? **If yes, reject application, or consider restricted approval for specific purposes. If no, go to 7.**
7. Will the intake of the donor protein in the new variety be generally comparable to the intake of the same or similar protein in donor or other food? **If yes go to 8. If no, go to 4.**
8. Is the introduced protein likely to be a major constituent in the human or animal diet? **If yes, consider the potential impact on nutrition, and approve application if nutritional impact is neutral or positive. If negative, consider reasons for or against approval before final decision. If no, conclude that there are no safety concerns.**
9. Conduct allergenicity tests as required by the NBC, using the FAO/WHO decision tree and other subsequent refinements as guidance. **If tests show no evidence of allergenicity, proceed with toxicology considerations beginning at 6. If allergenicity tests show the potential for allergenicity, then reject the application or decide to approve under special restrictions such as labelling, and proceed with toxicology assessments at 6.**

F. The following is a series of questions and answers that could be used by the NBC to assess the safety of new or modified fats or oils produced in the genetically engineered plant:

1. Has there been an intentional alteration in the identity, structure, or composition of fats or oils in the genetically engineered plant? **If yes, go to 2. If no, conclude that there are no safety concerns.**

2. Have intentional alterations been in a fat or oil that will be a major constituent in the human or animal diet? **If yes, consider the potential impact on nutrition, and go to 3 if nutritional impact is neutral or positive. If negative, reject or decide to proceed to 3. If no, go to 3.**
3. Are any unusual or toxic fatty acids produced in the new variety? **If yes, reject application, or consider restricted approval for specific purposes. If no, conclude that there are no safety concerns.**

G. The following is a series of questions and answers that could be used by the NBC to assess the safety of new or modified carbohydrates produced in the genetically engineered plant:

1. Has there been an intentional alteration in the structure, composition, or level of carbohydrates in the genetically engineered plant? **If yes, go to 2. If no, conclude that there are no safety concerns.**
2. Have any structural features or functional groups been introduced into the carbohydrate that do not normally occur in food carbohydrates? **If yes, reject application, or consider restricted approval for specific purposes and proceed to 3. If no, go to 3.**
3. Has there been any alterations that could affect digestibility or nutritional qualities in a carbohydrate that is likely to be a major constituent of the human or animal diet? **If yes, reject application, or consider restricted approval for specific purposes. If no, conclude that there are no safety concerns.**

Annex 1

MINISTRY OF AGRICULTURE
AND LAND RECLAMATION
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BIOSAFETY
Regulations and Guidelines
EGYPT

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INSERT HERE SECTION 3 PROCEDURE FOR [illegible] APPROVAL →

Appendix I NIH Guidelines

Appendix II The Code of Conduct

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Appendix IV Permits & Time Line, Sample Applications

Appendix V Examples of Research Evaluated Under the Guidelines

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Appendix VII Facility Inspection Checklists for Regulated Articles

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Applications of biotechnology are on the verge of great expansion in this decade. The production and release of the resulting Genetically Engineered organisms (GEOs) have raised concern about possible risks to human and to the environment. Accordingly, all biotechnology research has to be carried within a Regulatory Biosafety Framework.

This document recommends the establishment of a National Biosafety System in Egypt. The purpose is to provide a guide for policy makers to assist the establishment of an appropriate national biosafety framework, as no adequate structure currently exists. A national regulatory structure is proposed and biosafety guidelines developed by international organizations are attached.

The establishment of such a system will ensure that Biotechnology continues to be safe and does not expose employees, the community and the environment to any possible hazards.

Introduction

Biotechnology refers to any technique that uses living organisms or substances from these organisms to modify or improve quality and product of crops and food, drugs and health care products, vaccines, industrial chemicals and its products. It consists of gradient of technologies ranging from the widely used techniques of traditional biotechnology through modem biotechnology which is based on the use of new techniques of Recombinant DNA (r-DNA) technology, known as Genetic Engineering.

Proposed uses of the resulting genetically altered microorganisms include controlling pests and weeds in agriculture, producing vaccines, cleaning up toxic chemicals at waste sites, microbial leaching of mineral ores, and enhancing oil recovery. Plants are being genetically engineered to enhance many traits: increasing pest and herbicide resistance, tolerating draught or other environmental stresses, decreasing loss of food during storage and transport and increasing nutritional value of food products.

Biosafety is one term that is used to describe the policies and procedures adopted to ensure the environmentally safe application of modem biotechnology. It is a term that is gaining wider currency as more countries seek to benefit from the application of modern science in agriculture, medicine, and the environment, without endangering public health or environmental safety.

Many industrialized countries have instituted mechanisms for the regulation of biotechnology. The R-DNA Advisory Committee of the National Institute of Health (NIH) has developed procedures for examining and assessing the safety of proposed experiments and has published extensive guidelines on the conditions under which various types of experiments should be done. The NIH guidelines were originally formulated exclusively for the laboratory use of R-DNA and do not extend to the introduction of rDNA engineered organisms into the environment. The NIH Guidelines are attached as Appendix I.

Since recombinant-DNA engineered organisms must be tested outside the laboratory, a procedure known as the "Deliberate Release" or "Planned Introduction" of these genetically engineered organisms (GEOs) into the environment, there may be risks associated with the release of these GEOs.

Questions and concerns related to identifying hazards posed by microorganisms when released into the environment, [1]include:-

1. ——————————

[1] Introduction of Recombinant DNA-engineered Organisms into the Environment. Key Issues: National

- Will the use of R-DNA techniques accidentally create new plant pests?
- Can R-DNA accidentally convert a nonpathogen to a pathogen?
- Can introduced gene spread in microbial population?
- Will r-DNA- engineered microorganisms alter soil microbial communities?

The US National Academy of Science (NAS) made the following general conclusions regarding risks to the release of GMOs[2]:

- There is no evidence that unique hazards exist either from the use of r-DNA techniques or from the transfer of genes between unrelated organisms.

- The risk associated with the introduction of GEOs are the same in kind as those associated with the introduction of unmodified organisms and organisms modified by other methods.

As a step further the United Nation Industrial Development Organization (UNIDO) has organized an expert group meeting in Vienna on March 1991 consisting of 20 experts representing academia, industry and governments from developing and developed countries and international organizations to prepare a draft code of conduct on the safe handling, use and the release of Genetically Modified Organisms (GMOs) into the environment. This code attempts to harmonize existing guidelines, capturing the minimum commonly accepted principles into an international frame-work in the form of a code of conduct for the release of GMOs. It aims to-set forth minimum acceptable components necessary for international cooperation. These guidelines expressed in the code are meant to be user friendly and aimed at promoting the process of biotechnology progress, which can be modified or extended to suit specific situations according to the desire of each country[3]. The code of conduct is attached as Appendix II.

Developing countries are also being increasingly faced with requests to conduct r- DNA research. Hence, there is an urgent need for the scientific community to provide guidance for both investigators and regulators in evaluating risks associated with

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Academy Press. D.C. 1987

[2] Risk Assessment in Genetic Engineering; M. Levin & H. Strauss

[3] The code of conduct is available in the Genetic Engineering and Biotechnology Monitor Journal Issue No.39 Sept. 1992

biotechnology. A National Biosafety System should be established within the existing regulatory framework, drawn on existing institutions, personnel, and current legislation to the greatest extent possible. This system should provide appropriate regulatory mechanisms for both contained and uncontained applications, to ensure that products produced by the use of new techniques are as safe as those produced by traditional biotechnology.

In order to prepare a national policy for the regulation of r-DNA research in a developing country, the following must be available:

1. National regulatory structure and finance to support it, The regulatory structure would consist of:

i. Biosafety Committees that form the regulatory authorities,

ii. A set of Biosafety legislation, regulations and guidelines to be followed.

1.

2. Availability of funds and appropriate scientific & technical expertise for risk assessment analysis and modeling.

3. Coordination with international organizations,

4. Mechanism to gather information on local agronomic and environmental conditions

5. Systems to monitor developments in biotechnology that could affect worker health and safety,

6. Confidence in decision-making expertise.

7. Systems for the provision of information to, and education of the public.

This document provides specific suggestions for policies and procedures that national authorities may wish to consider in establishing a biosafety system. A national regulatory structure is suggested and examples of methods of risk assessment and biosafety guidelines tailored to the Egyptian environment are introduced. Internationally accepted standards (NIH Guides, UNIDO Code of Conduct) are attached and examples of research evaluated under the guidelines is presented.

It is important to remember that all these items will be presented and discussed as examples of a coordinated plan for biosafety regulations. It is furthermore important to remember that these

presentations are only a small selection out of a large number of world wide used mechanisms for safety.

Finally, it is important to note that concern about risks to human health and to the environment is not peculiar to biotechnology. Rather, these questions have emerged as an important component in the development, regulation and promotion of the products of many new and older technologies such as chemicals and pharmaceuticals.

Definitions .

Accessible environment : refers to the environment that can be reached by the organism and its progeny if introduced at the research site.

Biosafety : refers to the polices and procedures adapted to ensure the environmentally safe application of biotechnology.

Confinement : refers to that which restrains or limits the spread or survival of the organisms and their products in research involving planned introduction of organisms into the environment.

Contained facility : refers to a structure, (e.g., a laboratory or greenhouse) which surrounds and encloses the organism to effectively restrict its movement outside the structure.

Genetically Modified Organism : is operationally defined as an organism whose hereditary traits have been modified by human intervention using any method that results in the introduction, rearrangement or removal of genetic material from the genome of an organism.

Managed or natural ecosystem : refers to all plants, animals microorganisms, and their interactions, in domesticated and wild environment.

Organism : refers to any biological entity, cellular or noncellular with the capacity for self-perpetuation and response to evolutionary forces.

Parental organism : refers to the initial organism which is to be the recipient of introduced genetic material or whose genome is to be altered by removal or rearrangement of genetic material.

Research involving planned introduction into the environment : refers to research outside a contained facility at a designated site(s) with appropriate confinement.

Risk Assessment : refers to assessment of the risks of introducing R-DNA engineered organism into the environment, to human and natural or managed ecosystem.

Acronyms

ABRAC	:	Agricultural Biotechnology Research Advisory Committee
APHIS	:	Animal and Plant Health Inspection Service
BSO	:	Biological Safety Officer
EA	:	Environmental Assessment
FONSI	:	Finding Of No Significant Impact
GEOS	:	Genetically Engineered Organisms
GMOS	:	Genetically Modified Organisms
IBC	:	Institutional Biosafety Committee
LSC	:	Level of Safety Concern
NAS	:	National Academy of Science
NBC	:	National Biosafety Committee
NEIAP	:	National Biological Impact Assessment Program
NIH	:	National Institutes of Health
PI	:	Principal Investigator
UNIDO	:	United Nations Industrial Development Organization
USDA	:	United States Department of Agriculture

The establishment of a National Biosafety System has become a necessity due to the introduction and the rapid increase of biotechnology applications in Egypt.

Establishing a National Biosafety System and assuring compliance with biosafety regulations would :

1. Ensure that Biotechnology continues to be safe and does not expose employees, the community and the environment to any avoidable ill effects.

2. Facilitate access to modern biotechnology generated abroad, as many international institutions and companies will not test genetically engineered organisms unless the tests have been approved by a responsible governmental body.

3. Result in faster public acceptance and further development of modem biotechnology.

The key principles relevant to the preparation of national policy for the regulation of biotechnology are:

1. Regulatory review should focus on the characteristics and identified risks of the biotechnology products, not mainly on the process by which it was created.

2. For those biotechnology products that require review, the review process should be designed for efficiency and I effectiveness while assuring the protection of public health and environmental safety

3. Regulatory requirements for modern biotechnology should be integrated into the overall regulatory system which governs the release of new products in the agricultural sector.

4. The degree of familiarity with the behavior of similar organisms when released into the environment should determine the level of regulatory required, ranging from minimal to extensive depending on the degree of hazard identified.

5. Regulatory programs should be flexible and capable of adapting quickly to the new knowledge and rapid advances in biotechnology.

SECTION 1: BIOSAFETY COMMITTEES

The first step in developing appropriate policies and procedures for the regulation of biotechnology is to establish a national biosafety advisory committee. The national committee should then move quickly to establish policies and procedures to govern the use of modern biotechnology in the country.

1. National Biosafety Committee (NBC):

An Egyptian National Biosafety Committee is being established, comprising policy makers and designers, scientific experts in Agriculture, Health, Industry and Environment from government and academic research institutes.

1.1 Roles and Responsibilities of NBC:

The purpose of the national committee is to establish policies and procedures to govern the use of modem biotechnology in the country. This includes publishing the National Biosafety Committee guidelines (NBC Guidelines) to be followed at the national level. The committee would also provide technical advice to the regulatory authorities and the institutions responsible for the development of biotechnology in the country.

1.2. National Biosafety Committee Members

In order to ensure the competence necessary to set biosafety policies at the national level it is recommended that the NBC include:

- Representative/s from the Ministry of Agriculture
- Representative/s from the Ministry of Education
- Representative/s from the Ministry of Industry
- Representative/s from the Ministry of Health
- Representative/s from the sector of Environmental Affairs
- Representative/s from the private sector
- Policy makers and consultants knowledgeable in policies and applicable laws
- Non-technical members who represent the interest of the surrounding community with respect to health and protection of the environment

1.3 Activities of NBC

a) Formulate, implement and update safety codes
In order to establish safety research policies, NBC shall formulate guidelines for both contained and uncontained applications to cover laboratory practices, greenhouse facilities, small scale field trials, and finally commercial release. This will include guidelines for research with natural organisms that are exotic to the host country.

b) Risk assessment and license issuance
NBC shall review new initiatives to evaluate the benefits and potential risk of conducting research with modified organisms to the environment and to human community. If a license is issued after performing risk assessment analysis, NBC should periodically review containment measures and facilities to ensure that adequate safety guidelines are being followed.

c) Coordination with international and national organizations
NBC would establish contact and maintain communication with international and national organizations, taking into account new scientific and technical knowledge as they evolve. It would also monitor changes in intellectual property rights issues at the national and international level.

d) Provide training and technical advice
NBC is responsible that all personnel involved in biosafety issues receive adequate training on the most recent developments in safety procedures. It would also provide technical advice to the Institutional Biosafety Committees.

e) Report at least annually to governmental authorities
An annual progress report would be submitted to governmental authorities covering NBC activities throughout the year.

1.4 Principal Investigator (PI):

The National Biosafety Committee would designate one or more Principal Investigators whose duties include:

a) Inspect to determine whether institute facilities adhere to the local regulations and guidelines of the NBC.

b) Upon receiving a permit request, the PI will visit the location to evaluate its facilities. Next, he will submit a report to the NBC upon which the permit will be issued or denied.

c) Instruct and advise staff in practices and techniques to assure levels of safety concern.

2. The Institutional Biosafety Committee (IBC):

The National Biosafety Committee should request that all institutions conducting R-DNA research assemble an Institutional Biosafety Committee.

2.1 Roles and Responsibilities of IBC:

The IBC is responsible for ensuring that the r-DNA research is carried Out in full conformity with the Provisions of the NBC Guidelines. As part of its general responsibilities for implementing the NBC Guidelines, the IBC may establish additional Procedures as deemed necessary to govern the institution activities.

2.2 Institutional Biosafetv Committee Members:

In order to ensure the competence necessary to review R-DNA research activities, it is recommended that:

i. the IBC include persons with expertise in R-DNA technology that cover the research directions in the institute

ii. the IBC include persons with expertise in biological safety and physical containment

iii. the IBC have available as consultants persons knowledgeable in institutional commitments, Policies and applicable law

iv. IBC designate a Biologic I Safety Officer (BSO) that meets the a requirements set in section 1.4

2. 3 Activities of IBC

a) Assemble a comprehensive set of research- and containment oriented guidelines that are tailored to the research activities of the institute and that comply with the NBC Guidelines.

b) Establish a program for inspection to ensure that the physical containment facility continues to meet with the requirements.

c) Assessment of the facilities procedures . and practices. and of the training and expertise of R-DNA personnel.

d) Review periodically R-DNA research being conducted at the institute to insure that the requirements of the NBC Guidelines are being fulfilled.

e) Adopt emergency plans covering accidental spills and personnel contamination resulting from such research.

f) Periodically review containment measures and facilities taking into account new scientific and technical knowledge relevant to treatments for disposals and spills of biohazardous wastes.

g) Monitoring changes in intellectual property rights issued at the national and international levels.

h) Reports annually to the National Biosafety Committee.

2.4 Biological Safety Officer (BSO):

The institute should appoint a Biological Safety Officer who should be familiar with the biosafety requirements for the R-DNA work and the facilities. His duties include the following:

a) Enforces policies and regulations approved ensuring that these regulations are not compromised by other considerations.

b) Ensure through periodic inspections that laboratory standards are rigorously followed.

c) Ensure safety of laboratory work and prevent the accidental escape of R-DNA modified organisms.

d) Maintain a data base on all aspects of biosafety related to mandate crops.

e) Checks and gives advice on biosafety issues on a day to-day basis.

f) Monitor worldwide biosafety requirements for R-DNA, also act as a member of the biosafety committee, reporting all related issues.

SECTION II: BIOSAFETY GUIDELINES

1. Risk Assessment

Risk to the health of workers and others in the immediate vicinity of the work-place is one of the main concern in assessing the hazards associated with the contained use of GMOs. These risks are considered proportional to the scale of the operation and all regulatory systems distinguish small-scale use for research and development. As for large-scale use, the risk to health and possible risks to environment in the event of escape of organism from the production area must be evaluated and an appropriate level of containment applied. Containment may be physical, e.g. barriers limiting the escape of the organisms, or biological, e.g. physiological limitations to the survival and replication of the organism outside the process environment[1].

NAS posed the following three questions, used in making judgments of risk (1989):

- Are we familiar with the properties of the organism and the environment into which it may be introduced ?

- Can we confine or control the organism effectively ?

- What are the probable effects on the environment, should the introduced organism or a genetic trait persist longer than intended or spread to nontarget environment?

The development of new technology opens up a series of questions on risk for which there are few or no data to help in its evaluations[2]. A definition that was suggested is :-

Risk = Probability of hazard X Magnitude of hazard

As it was mentioned earlier biotechnology aims to produce crops with new properties presumably for the benefit of mankind. This means that if there is any increased in risk it has to be balanced against the benefits which would accure from using that transgene and we should consider redefining risk as "acceptable risk".

$$\text{Acceptable risk} = \frac{\text{Probability of hazard X Magnitude of hazard}}{\text{Benefits from product}}$$

1. _____

1 Curtiss 1988

2 The second International Symposium on the Biosafety Results of Field Tests of Genetically Modified Plnats and Microorganisms. May 11. 1992. Germany

In order to understand the circumstances under which a genetically engineered crop plant might become a persistent agricultural weed or become invasive of natural habitats, it is essential to know the value of the parameters in the following model:

The rate of increase
of the transgenic plant = Plant development rate
in a given habitat.
+ Its seed production (timing and duration)
+ Survival of vegetative parts (discounted by their mortality rate)
- The effects of competition with other plants of the same kind
- The effects of competition with other plant species.
- The effects of herbivores (insect and vertebrate)
- The effect of fungi and other plant diseases.
+ Immigration of transgenic seed from other sites.
+ Establishment of transgenic plants from dormant seed in the soil (seed bank).

The conditions under which research with a genetically modified organism can be conducted safely should be assessed relative to the conditions that are normally accepted for conducting research with the parental organism. Therefore, the safety evaluation determining the level of safety concern is essential.

2. Determination of the Level of Safety Concern (LSC):

The Agricultural Biotechnology Research Advisory Committee (ABRAC) has recommended a step-wise process to the Assistant Secretary for Science and Education for the evaluation of level of safety concern of the Genetically Modified Organism into three levels[3].

Determining the level of safety concern is of great importance for analyzing the risks to human health and natural ecosystem for GMOs.

Step1 : Determine the level of safety concern of parental organism

Depending on two criteria:-

1. _____

[3] Available in the Federal Register of February1, 1991 (56 FR 4134)

Appendix IV

Permit & Time Line, APHIS FORM 2000 Sample Applications

These are sample applications for permit release for a genetically modified organism movement or release into the environment. Several examples are provided to give an indication of the kind of information to include.

A suggested application form that can be submitted to the Egyptian regulatory authorities is included at the end.

Not attached

Appendix V

Examples of Research Evaluated Under the Guidelines

To assist users of the guidelines to analyze level of safety concern for their research organisms, four examples have been evaluated in a step-wise process. Theses examples are presented in the following order:

1. *Bos taurus* (domestic cattle)
2. *Brassica napus* (oil rapeseed)
3. *Drosophila melanogaster* (fruit fly)
4. *Clavibacter xyli subsp. cynodontis*

Not attached

Appendix VII

Facility Inspection Checklist For Regulated Articles

This is an example of a checklist that would be completed by the Principal Investigator during a facility inspection visit.
According to this checklist the NBC will decide if a permit will be issued,

Not attached

Annex 2

Procedure for Commercial Registration of Genetically Engineered Plant Varieties as Outlined in MALR Ministerial Decree No. 1648/1998*

This protocol provides framework for the steps and procedures that must be observed by private or public companies and institutions concerned with the production of the genetically modified plant varieties, whether those companies are Egyptian or foreign. The protocol outlines steps required before permitting the handling of those varieties on a commercial scale.

Step 1.

The company or the cooperating organization willing to commercialize a genetically modified plant variety must apply to the Secretariat of the National Biosafety Committee for a permit application, a special form for handling genetically modified plant material. The address of the NBC Secretariat follows:

Agricultural Genetic Engineering Research Institute
Agricultural Research Center
9, Gamaat El –Qahera St., Giza 12619

Step 2.

The applicant must fill in the form to provide necessary information on the genetically engineered plant material which in this case are the plant variety, the genetic modification technique used, and other related data as itemized in the permit application. The applicant should submit all the pertinent studies that indicate the bio-safety level of the GM variety: environmental safety and food safety (with an assertion that no risk of any kind is evident on humans, animals, plants and all the other components of the environment). The applicant shall also submit a document that confirms the use of the GM plant variety in the country of origin.

Step 3.

The NBC Secretariat shall submit the completed form at the first consecutive meeting of the Committee for consideration and a decision on whether or not to approve the handling of the variety applied for and the level of its handling (i.e., open field testing, limited field testing or testing inside greenhouses).

Step 4.

If and when the NBC approves the handling of the GM plant variety and specifies the level of that handling, the following procedures shall be applied:

***(Unofficial translation with minor modifications for ease of reading in English)**

1. If the GM plant variety has been produced in Egypt, the applicant will be allowed to initiate testing only at the set level of handling. The NBC may inspect the testing sites by itself or by whomever it designates for this task (e.g., AGERI/ARC). Inspection shall be undertaken at any time NBC deems appropriate to ascertain conformity with the prerequisite technical standards. The committee has the right to draw samples from the genetic material for molecular analysis to confirm the nature of genes introduced and the degree of gene expression in the GM plant variety.

2. If the GM plant variety has been produced outside Egypt and the original producer thereof (or his representative in Egypt) is willing to initiate testing within the approved level of handling, the applicant must obtain a permit for importation of a limited quantity of the planting material (normally seeds) as a preliminary step for testing (i.e., field experimentation) within the approved level of handling.

   The following procedures are to be observed:

   1. The foreign company, or its Egyptian agent, shall apply to the "Supreme Committee on Food Safety," a standing committee within MOH, for an import permit, having authenticated its application by the NBC. The application may take the form of a Material Transfer Agreement (MTA) or any other form, provided that transparency and clarity are fulfilled.

   2. If the import permit has been issued by the Supreme Committee for Food Safety and the foreign company (or its agent in Egypt) has initiated the testing operation at the set level of handling, the NBC shall, either by itself or by whomever it officially designates (e.g., AGERI/ARC), inspect the testing experimentation sites at anytime it deems appropriate to ensure compliance with the needed technical standards. The Committee shall have the right to draw samples from the genetic materials for analysis at the molecular level in order to elicit the nature of genes introduced into (the genetic structure of) the plant variety and to detect the degree of gene expression in that variety.

Step 5:

Having completed field testing (i.e., open or limited) of the GM plant variety in Egypt, and having confirmed that the variety meets all biosafety and environmental considerations, the applicant willing to commercialize the GM plant variety can file an application for registration of the GM plant variety with the Secretariat of the VRC (Variety Registration Committee) of MALR. Special forms are accessible from the Secretariat's headquarters at the following address:

The Central Administrations for Seed Certification
Agricultural Research Center 9, Cairo University St.
Giza, 12619

Annex 3

Current Decrees and Laws with Impact upon the Commercial Release of Transgenic Plants

Prof. Dr. Amin Sayed El-Nawawy

During the period 1994-99, a number of Ministerial Decrees were issued to accommodate plant breeders and/or private sector rights and obligations for releasing GM plants.

(1) Decree No. 242/1997, Ministry of Health: This decree prohibits importing any foodstuff produced through GMOs, unless its safety is confirmed. The act also necessitates that a certificate should accompany any imported seeds from the country of origin, confirming that these seeds were not produced from untested genetically modified (GM) plants, GM plants or seeds can be imported if previously approved for use in the country of origin and deemed safe.

(2) Decree No. 821/1998, Ministry of Agriculture: This decree establishes policy and provides guidance on procedures for the release of crop varieties developed by the ARC. It makes no distinction between varieties developed through conventional breeding and those derived by genetic engineering. Variety identification or Distinctness, Uniformity and Stability (DUS) tests are conducted in one location during seed multiplication. Model descriptors issued by the International Union for the Protection of New Varieties of Plants (UPOV) are used for a comparative evaluation against standard varieties as defined by the relevant Crop Seed technical committee, which are grown in parallel with the new variety. Variety performance or Value of Cultivation and Use (VUC) tests examine the new variety's agricultural, industrial, and economic value as compared with other superior varieties in use. Such tests are conducted in more than one location to ensure that the variety tolerates a diversity of local environment conditions. The candidate variety is recommended to be registered only when all required tests have been satisfactorily completed.

(3) Decree No. 1648/1998, Ministry of Agriculture: This decree confirms the authority and responsibility of CASC for releasing GM as well as conventional seeds. It describes procedures for obtaining a small-scale release permit for a new genetically engineered crop variety, registering it, and releasing it for commercial use. It outlines important steps to be followed by government or private sector applicants, as well as other local or foreign organizations seeking to commercialize their products. The decree specifies the roles and responsibilities of the NBC, the Seed Registration Committee, and the Committee for Food Safety. A draft paper outlining the protocol for commercial release of GMO crop varieties

was developed by a panel of experts from MALR and the USAID. The final document was approved by deputy Prime Minister and Minister of Agriculture in July 1999.

(4) Decree No. 702/1999, Ministry of Agriculture: This decree adds DNA fingerprinting to the required protocol for registration of all new agriculture crop varieties in order to confirm identity during the registration process and for subsequent use as a reference, if required. The decree stipulates that:

- DNA fingerprints of the new hybrid variety and its parents are a prerequisite for registration. One copy of the fingerprint is to be kept in the secretariat of the Seed Registration Committee and another copy is to be kept in the management office of the applicant's institution
- The relevant crop technical committee should verify the fingerprint and its specifics through a laboratory certified to have the required scientific and technical capabilities.
- The applicant is to pay all costs required for the finger printing process, as determined by the registration committee for agricultural varieties. Sample material is to be submitted to the SRC secretariat, which will pass it to the relevant certified lab.

(5) Law 4 of 1994 is by far the most comprehensive environmental legislation to date. It defines (in article 2-13) the scope and responsibilities of the Egyptian Environmental Affairs Agency (EEAA), establishes (in article 14-16) the Environmental Protection Fund (EPF), provides for the setting up of a system of environmental incentives (articles 17-18), spells out the necessity of environmental impact assessments as a pre-requisite of development projects (article 19-23), establishes environmental monitoring networks with their stations and working units (article 24), authorizes the EEAA to prepare an Environmental Contingency Plan (article 25), and forbids the hunting of specified types of wild birds and animals (article 28) as well as the destruction of their natural habitats. Articles 29-83 cover the protection of air, water and land from all sources of pollution. Articles 84-101 deal with the penal code for violation of articles 1-83. In August 1997 the EEAA became part of the newly established Ministry of State for Environmental Affairs. This law does not mention any direct statement on GMOs. However, the NBC is in contact with the Ministry of Environment for the preparation of appropriate regulations under a law and not only as a ministerial decree.

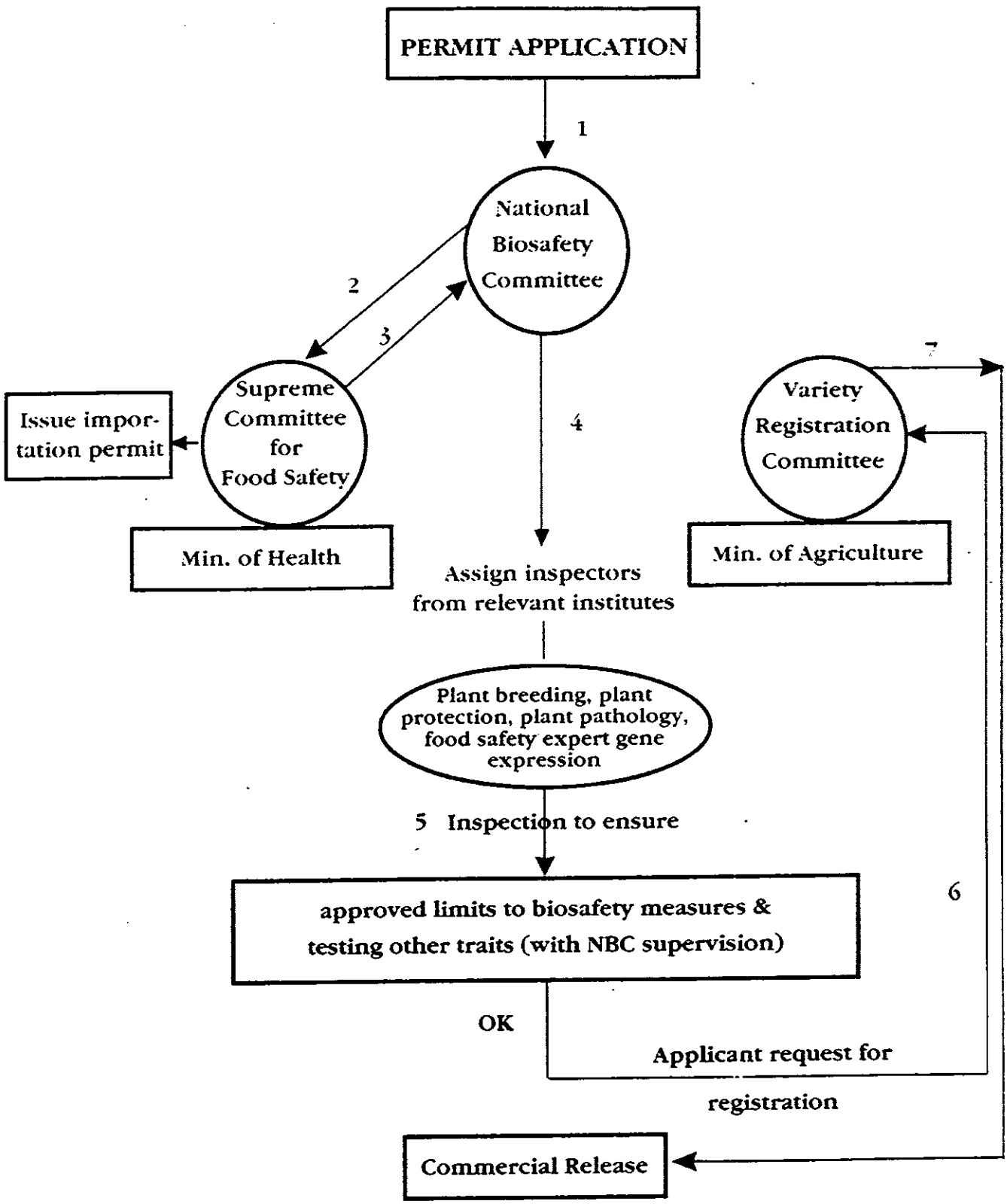

Chart I: Steps for Commercial Release of Genetically Engineered Plants in Egypt

Annex 4

Risk Assessment Principles Provided by the Cartagena Biosafety Protocol of the Convention on Biodiversity

Objective

1. The objective of risk assessment, under this Protocol, is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.

Use of risk assessment

2. Risk assessment is, inter alia, used by competent authorities to make informed decisions regarding living modified organisms.

General principles

3. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations.

4. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

5. Risks associated with living modified organisms or products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

6. Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment.

Methodology

7. The process of risk assessment may on the one hand give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process, while on the other hand information on other subjects may not be relevant in some instances.

8. To fulfil its objective, risk assessment entails, as appropriate, the following steps:

(a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse

effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health.

(b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;

(c) An evaluation of the consequences should these adverse effects be realized;

(d) An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;

(e) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and

(f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

Points to consider

9. Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:

(a) Recipient organism or parental organisms. The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, centres of origin and centres of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;

(b) Donor organism or organisms. Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;

(c) Vector. Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;

(d) Insert or inserts and/or characteristics of modification. Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;

(e) Living modified organism. Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms;

(f) Detection and identification of the living modified organism Suggested detection and identification methods and their specificity, sensitivity and reliability;

(g) Information relating to the intended use. Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms; and

(h) Receiving environment. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment.

41

Annex 5

Consistency of the Information Requirements of Selected Regions or Countries with the Risk Assessment Points to Consider Provided in Annex III of the Cartagena Biosafety Protocol of the Convention on Biodiversity.

(a) **Recipient organism or parental organisms. The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, centres of origin and centres of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;**

European Directive

B. Information relating to (A) the recipient or (B) (where appropriate) parental plants

1. Complete name:
   (a) family name;
   (b) genus;
   (c) species;
   (d) subspecies;
   (e) cultivar/breeding line;
   (f) common name.
2. (a) Information concerning reproduction:
   i. mode(s) of reproduction;
   ii. specific factors affecting reproduction, if any;
   iii. generation time
   (b) Sexual compatibility with other cultivated or wild plant species, including the distribution in Europe of the compatible species.
3. Survivability:
   (a) ability to form structures for survival or dormancy;
   (b) specific factors affecting survivability, if any.
4. Dissemination:
   (a) ways and extent (e.g. an estimation of how viable pollen and/or seeds declines with distance) of dissemination;
   (b) specific factors affecting dissemination, if any.
5. Geographical distribution of the plant.
6. In the case of plant species not normally grown in the Member State(s), description of the natural habitat of the plant, including information on natural predators, parasites, competitors and symbionts.
7. Other potential interactions,relevant to the GMO, of the plant with organisms in the ecosystem where it is usually grown, or elsewhere, including information on toxic effects on humans, animals and other organisms.

United States (USDA)

Description of the biology of the nonmodified recipient plant and information necessary to identify the recipient plant in the narrowest taxonomic grouping applicable.

Canada (CFIA)

Not specifically required; this information will be inherent in the descriptions of the plant with novel traits.

(b) <u>Donor organism or organisms</u>. Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;

European Directive

C. Information relating to the genetic modification
   3. Size, source (name) of donor organism(s) and intended function of each constituent fragment of the region intended for insertion.

United States (USDA)

A detailed description of the differences in genotype between the regulated article and the nonmodified recipient organism. Include all scientific, common, or trade names, and all designations necessary to identify: the donor organism(s), the nature of the transformation system (vector or vector agent(s)), the inserted genetic material and its product(s), and the regulated article. Include country and locality where the donor, the recipient, and the vector organisms and the regulated articles are collected, developed, and produced.

Canada (CFIA)

C2.2 Describe the following about the modification:

1. Novel gene products conferring the novel traits

2. Methods used to introduce the novel traits (briefly describe the techniques, if not through recombinant DNA)

3. If the modification was achieved through recombinant DNA techniques:

   (a) supply a map of each genetic construct.

   (b) for each genetic construct, list, identify source and describe in detail:

      i. genes, including antibiotic resistance, other marker genes or regulatory genes;

      ii. the products of the introduced genes;

      iii. regulatory sequences, i.e., promoters, modifiers, enhancers, signal peptides, and terminators;

      iv. any other DNA sequences.

   (c) was the transformation vectorless? If yes, describe in detail.

   (d) if a vector was employed, answer:

      i. what is the vector name and cloning method?

ii. is the vector naturally pathogenic?

iii. was the vector disarmed?

iv. how was the vector disarmed?

v. is there expression of the gene in the vector?

(c) <u>Vector</u>. Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;

European Directive

C. Information relating to the genetic modification
   1. Description of the methods used for the genetic modification
   2. Nature and source of the vector used.
   3. Size, source (name) of donor organism(s) and intended function of each constituent fragment of the region intended for insertion.

United States (USDA)

A detailed description of the differences in genotype between the regulated article and the nonmodified recipient organism. Include all scientific, common, or trade names, and all designations necessary to identify: the donor organism(s), the nature of the transformation system (vector or vector agent(s)), the inserted genetic material and its product(s), and the regulated article. Include country and locality where the donor, the recipient, and the vector organisms and the regulated articles are collected, developed, and produced.

Canada (CFIA)

C2.2 Describe the following about the modification:

3. If the modification was achieved through recombinant DNA techniques:

   (a) supply a map of each genetic construct.

   (b) for each genetic construct, list, identify source and describe in detail:

      i. genes, including antibiotic resistance, other marker genes or regulatory genes;

      ii. the products of the introduced genes;

      iii. regulatory sequences, i.e., promoters, modifiers, enhancers, signal peptides, and terminators;

      iv. any other DNA sequences.

   (c) was the transformation vectorless? If yes, describe in detail.

   (d) if a vector was employed, answer:

      i. what is the vector name and cloning method?

ii. is the vector naturally pathogenic?

iii. was the vector disarmed?

iv. how was the vector disarmed?

v. is there expression of the gene in the vector?

(d) <u>Insert or inserts and/or characteristics of modification</u>. Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;

European Directive

D. Information relating to the genetically modified plant
   1. Description of the trait(s) and characteristics which have been introduced or modified.
   2. Information on the sequences actually inserted/deleted:
      (a) size and structure of the insert and methods used for its characterization, including information on any parts of the vector introduced in the GMHP or any carrier or foreign DNA remaining in the GMHP;
      (b) in case of deletion, size and function of the deleted region(s);
      (c) copy number of the insert;
      (d) location(s) of the insert(s) in the plant cells (integrated in the chromosome, chloroplasts, mitochondria, or maintained in a non-integrated form), and methods for its determination;
   3. Information on expression of the insert:
      (a) information on the developmental expression of the insert during the lifecycle of the plant and methods used for its characterization;
      (b) parts of the plant where the insert is expressed (e.g. roots, stem, pollen, etc.).

United States (USDA)

A detailed description of the differences in genotype between the regulated article and the nonmodified recipient organism. Include all scientific, common, or trade names, and all designations necessary to identify: the donor organism(s), the nature of the transformation system (vector or vector agent(s)), the inserted genetic material and its product(s), and the regulated article. Include country and locality where the donor, the recipient, and the vector organisms and the regulated articles are collected, developed, and produced.

Canada (CFIA)

C2.5 Once inserted into the plant, has each genetic modification and its expression been shown to be stable? Provide data demonstrating stability.

(e) <u>Living modified organism</u>. Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms;

European Directive

D. Information relating to the genetically modified plant

4. Information on how the genetically modified plant differs from the recipient plant in:
   (a) mode(s) and/or rate of reproduction;
   (b) dissemination;
   (c) survivability.
5. Genetic stability of the insert and phenotypic stability of the GMHP.
6. Any change to the ability of the GMHP to transfer genetic material to other organisms.
7. Information on any toxic, allergenic or other harmful effects on human health arising from the genetic modification.
8. Information on the safety of the GMHP to animal health, particularly regarding any toxic, allergenic or other harmful effects arising from the genetic modification, where the GMHP is intended to be used in animal feedstuffs.
9. Mechanism of interaction between the genetically modified plant and target organisms (if applicable).
10. Potential changes in the interaction of the GMHP with nontarget organisms resulting from the genetic modification.
11. Potential interaction with the abiotic environment.
12. Description of detection and identification techniques for the genetically modified plant.
13. Information about previous releases of the genetically modified plant, if applicable.

United States (USDA)

A detailed description of the differences in genotype between the regulated article and the nonmodified recipient organism. Include all scientific, common, or trade names, and all designations necessary to identify: the donor organism(s), the nature of the transformation system (vector or vector agent(s)), the inserted genetic material and its product(s), and the regulated article. Include country and locality where the donor, the recipient, and the vector organisms and the regulated articles are collected, developed, and produced.

A detailed description of the phenotype of the regulated article. Describe known and potential differences from the unmodified recipient organism that would substantiate that the regulated article is unlikely to pose a greater plant pest risk than the unmodified organism from which it was derived, including but not limited to: Plant pest risk characteristics, disease and pest susceptibilities, expression of the gene product, new enzymes, or changes to plant metabolism, weediness of the regulated article, impact on the weediness of any other plant with which it can interbreed, agricultural or cultivation practices, effects of the regulated article on nontarget organisms, indirect plant pest effects on other agricultural products, transfer of genetic information to organisms with which it cannot interbreed, and any other information which the Administrator believes to be relevant to a determination. Any information known to the petitioner that indicates that a regulated article may pose a greater plant pest risk than the unmodified recipient organism shall also be included.

Canada (CFIA)

C.2.0 Description of the PNT and its Modification

C2.1 Describe the following about the PNT:

1. Confirmation of taxonomy;
2. Designation given to the PNT, including all synonyms;
3. Pedigree information of the PNT (including any relationship to a previously assessed PNT);
4. Give details of the use of the PNT (e.g., to be grown as a field crop for grain production; to be grown as field crop for grain production on lands contaminated with persistent herbicide; to reclaim lands contaminated with heavy metals).

C2.2 Describe the following about the modification:

1. Novel gene products conferring the novel traits
2. Methods used to introduce the novel traits (briefly describe the techniques, if not through recombinant DNA)
3. If the modification was achieved through recombinant DNA techniques:
   (a) supply a map of each genetic construct.
   (b) for each genetic construct, list, identify source and describe in detail:
      i. genes, including antibiotic resistance, other marker genes or regulatory genes;
      ii. the products of the introduced genes;
      iii. regulatory sequences, i.e., promoters, modifiers, enhancers, signal peptides, and terminators;
      iv. any other DNA sequences.
   (c) was the transformation vectorless? If yes, describe in detail.
   (d) if a vector was employed, answer:
      i. what is the vector name and cloning method?
      ii. is the vector naturally pathogenic?
      iii. was the vector disarmed?
      iv. how was the vector disarmed?
      v. is there expression of the gene in the vector?

C2.3 In the case of an allopolyploid PNT, in which parental genome is the genetic modification?

C2.4 Number of generations removed from the original modification.

C2.5 Once inserted into the plant, has each genetic modification and its expression been shown to be stable? Provide data demonstrating stability.

C.3.0 Description of the Novel Traits

C3.1 Characterize in detail the gene products, breakdown products, by-products and their metabolic pathways.

C3.2 Are the gene products tissue-specific?

C3.3 Are the genes expressed during a specific developmental stage?

C3.4 Is gene expression induced? If yes, what are the inducing agents?

C3.5 Describe the activity of the gene products, breakdown products and by-products in the host plant. Describe any changes to existing metabolic pathways (including altered accumulation and storage patterns), including those that might not be intended.

C3.6 The toxicity of the novel gene products, breakdown products and by-products in the environment must be established. Describe:

1. potential toxigenicity to known or potential predators, grazers, parasites, pathogens, competitors and symbiont;
2. potential for adverse human health effects, e.g., exposure to toxins, irritants and antigens. Include estimated level and most likely route of human exposure to the gene products, breakdown products and by-products.

D1.0 Interactions of the PNT

D1.1 Relative phenotype expression of the PNT (species replacement or competition studies may be appropriate when there is reason to believe that the biology of the plant has been altered in unpredictable ways).

1. Reproductive and survival biology;
2. Adaptations to stress factors (for biotic stress factors, identify those life forms with which the PNT interacts differently);
3. Biochemistry: For novel gene products identified in Part C3.6 that are known to be toxic, describe:
   (a) likelihood and change of level of exposure of consumers and symbiont;
   (b) the effect on soil micro flora and fauna. Residual studies may be conducted to determine macro changes. Observed changes at this level may warrant further in-depth studies (See Appendix IV)

(f) Detection and identification of the living modified organism. Suggested detection and identification methods and their specificity, sensitivity and reliability;

European Directive

D. Information relating to the genetically modified plant
   1. Description of detection and identification techniques for the genetically modified plant.

United States (USDA)

A detailed description of the differences in genotype between the regulated article and the nonmodified recipient organism. Include all scientific, common, or trade names, and all designations necessary to identify: the donor organism(s), the nature of the transformation system (vector or vector agent(s)), the inserted genetic material and its product(s), and the regulated article. Include country and locality where the donor, the recipient, and the vector organisms and the regulated articles are collected, developed, and produced.

Canada (CFIA)

Not specifically required

(g) <u>Information relating to the intended use</u>. Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms

European Directive

Not specifically required; this information will be inherent in the descriptions of the genetic modification.

United States (USDA)

A detailed description of the phenotype of the regulated article. Describe known and potential differences from the unmodified recipient organism that would substantiate that the regulated article is unlikely to pose a greater plant pest risk than the unmodified organism from which it was derived, including but not limited to: Plant pest risk characteristics, disease and pest susceptibilities, expression of the gene product, new enzymes, or changes to plant metabolism, weediness of the regulated article, impact on the weediness of any other plant with which it can interbreed, agricultural or cultivation practices, effects of the regulated article on nontarget organisms, indirect plant pest effects on other agricultural products, transfer of genetic information to organisms with which it cannot interbreed, and any other information which the Administrator believes to be relevant to a determination. Any information known to the petitioner that indicates that a regulated article may pose a greater plant pest risk than the unmodified recipient organism shall also be included.

Canada (CFIA)

D1.2 Agricultural-Silvicultural Practices:

1. What are the proposed release sites for the PNT?
   (a) all of Canada?
   (b) specific regions?
   (c) what is the projected area (ha) of release?
2. Will the modification result in the PNT being grown outside of the normal geographic production area for the species?
3. Will the modification result in the PNT being grown outside of the usual habitat (e.g., cultivated agricultural lands) for the species?
4. Will the cultivation practices (land preparation, weed and pest control, harvest, and post-harvest protocols) involved in growing the PNT vary from those traditionally used?
   (a) if no: no further information required
   (b) if yes:
      i. describe the change in cultivation practices;
      ii. provide information showing the effect of these changes on sustainability, especially with respect to pesticide use, frequency of tillage, soil erosion and consequential changes in energy and soil conservation;
   (c) will volunteer plants of the PNT result in altered cultivation practices for succeeding crops?

5. If it is anticipated that the PNT will be cultivated only under contract controlled conditions, describe:
   (a) any control and mitigation procedures;
   (b) post-harvest procedures, including procedures for disposal of remaining plant matter.
6. What deployment strategies are to be used? (for example, in forestry, the avoidance of monocultures).

D1.3 Potential environmental effects resulting from introgression.

Where there is potential for gene flow from the PNT into related species, detail the consequences of novel gene introgression into those species and resulting expression. Interactions identified for the original PNT should be considered, as appropriate, for these species.

(h) Receiving environment. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment.

European Directive

Information relating to the genetically modified plant

9. Mechanism of interaction between the genetically modified plant and target organisms (if applicable).
10. Potential changes in the interaction of the GMHP with nontarget organisms resulting from the genetic modification.
11. Potential interaction with the abiotic environment.

United States (USDA)

(Required by U.S. law (National Environmental Protection Act) to be included in the Environmental Assessment conducted by USDA/APHIS. USDA/APHIS relies on information it has, and can request it from the applicant):

A detailed description of the phenotype of the regulated article. Describe known and potential differences from the unmodified recipient organism that would substantiate that the regulated article is unlikely to pose a greater plant pest risk than the unmodified organism from which it was derived, including but not limited to: Plant pest risk characteristics, disease and pest susceptibilities, expression of the gene product, new enzymes, or changes to plant metabolism, weediness of the regulated article, impact on the weediness of any other plant with which it can interbreed, agricultural or cultivation practices, effects of the regulated article on nontarget organisms, indirect plant pest effects on other agricultural products, transfer of genetic information to organisms with which it cannot interbreed, and any other information which the Administrator believes to be relevant to a determination. Any information known to the petitioner that indicates that a regulated article may pose a greater plant pest risk than the unmodified recipient organism shall also be included.

Canada (CFIA)

D1.3 Potential environmental effects resulting from introgression.

Where there is potential for gene flow from the PNT into related species, detail the consequences of novel gene introgression into those species and resulting expression. Interactions identified for the original PNT should be considered, as appropriate, for these species.