

**PROCESS MANAGEMENT
MANUAL
FOR RELEASE INTO THE
ENVIRONMENT OF
GENETICALLY MODIFIED
AGRICULTURAL ORGANISMS**



**By
Adelaida Harries
Seed Science Center/Biosafety Institute for Genetically
Modified Agricultural Products BIGMAP
Iowa State University
Ames, Iowa**

Copyright© 2005 Biosafety Institute for Genetically Modified Agricultural Products
Iowa State University. All rights reserved.

TABLE OF CONTENTS

- 1. INTRODUCTION**
- 2. ACKNOWLEDGMENTS**
- 3. PROCEDURE FOR APPLICATION OF ENVIRONMENTAL
RELEASE OF GMO**
- 4. PROCEDURE FOR CONFIDENTIAL BUSINESS
INFORMATION HANDLING**
- 5. PROCEDURE FOR ENVIRONMENTAL RELEASE
INSPECTION**
- 6. PROCEDURE FOR FIELD RELEASE MONITORING**
- 7. PROCEDURE FOR TECHNICAL EVALUATION**
- 8. PROCEDURE FOR APPEAL**
- 9. PROCEDURE FOR DOCUMENT CONTROL**
- 10. PROCEDURE FOR RECORD CONTROL**
- 11. REFERENCES**
- 12. GLOSSARY OF TERMS**

1- INTRODUCTION

Regulatory oversight of biotechnology had its origins in the seventies when guidelines were developed for laboratory experiments using recombinant DNA techniques. In the mid-eighties when the environmental releases or field tests of genetically modified crop plants started, countries began to develop systems for regulatory oversight of biotechnology to ensure adequate risk assessments.

Worldwide regulations were developed in the late 1980s and early 1990s. The introduction of genetically modified organism products in agriculture forced the countries to create or adapt regulatory frameworks specifically targeted to modern technology, biotechnology. Nevertheless, most of the countries are using their existing regulations of Plant Protection for the introduction of genetically modified organisms, improving the regulatory systems to ensure the safety and effective evaluation of their impacts.

Nowadays, almost a hundred countries have developed or adapted the regulatory framework related with biosafety of genetically modified organism for the agriculture. The global area of these products is approximately 60 million of hectares, where the principal producer's countries are USA, Argentina, Canada, and China. There is a high rate of adoption of the new technology in both industrial and developing countries and it is reflected in the number of countries growing transgenic crops (16 in 2003).

In September 2003, the Cartagena Protocol on Biosafety, a supplementary agreement of the Convention on Biological Diversity, came into force. This international agreement seeks to protect biological diversity from the potential risks in the transfer, handling, and use of the living modified organisms resulting from modern biotechnology. There is no doubt that the protocol will have implications for international trade of LMO and it will be necessary to develop and implement the risk assessment in both parties and non-parties of the agreement. It is clearly established under the Cartagena Protocol the implementation of the risk assessment based on scientific manner to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity.

Risk assessment is a scientific process used to identify hazards, the likelihood of occurrence, and the impacts on human and animal health and on the environment. So the potential for adverse environmental and human health consequences resulting from the introduction of the genetically modified plants into the agriculture has aimed to develop the regulatory framework that are applied to assessing the risk assessment and management of these genetically modified products.

The risk assessment is based not only on the genetic characteristics of the organism, its phenotype, and the environment where it will be released, but also the equivalence to the similar non-transgenic counterpart. The risk assessment in regulatory and associated procedures requires familiarity with the biology of the crop plant itself and the agricultural practices utilized.

This concept of familiarity is based on the fact that most genetically modified organisms are developed from organisms such as crop plants whose biology is well understood (OECD, 2000). This concept facilitates risk assessments because to be familiar means having enough information to make a judgment of safety (US NAS, 1989). Familiarity can also be used to indicate appropriate management practices and depends on the knowledge about the environment and its interaction with the introduced organism. The risk assessment in one country may not be applicable to another country but allows gathering data about the interactions with the environments. This concept is applied in the majority of the regulations.

Another concept that is also used as a guide by some countries, such as those of the EU, is the “precautionary principle” that was introduced in the Convention of Biological Diversity and recently adopted by the Cartagena Protocol on Biosafety. The “precautionary principle”, states that it is justifiable to take preventive action in the absence of scientific certainty of the adverse effects of a product or process, if the benefits of the product or process are relatively low and the risks high. It is a difficult concept and there is considerable controversy on the meaning, scope, and application of this principle. According to some authors, the precautionary principle has often been used to justify the ban on genetically modified crops.

Despite the differences in philosophy and implementation of the regulations among the countries, the risk assessment requirements are generally alike. Regulatory bodies among the world require similar information for the application to release into the environment of GMO crops. In general, the national requirements are based on international guidelines like UNEP (1995), IPPC (2002), and Biosafety Protocol (2000).

The requirements include general information of the institution/company who apply for the release and a detailed description of the biological characteristics of the recipient organism or parental organisms, including information about taxonomic status, common name, origin, centers of origin and centers of genetic diversity, and description of the habitat where the organisms may persist or proliferate. As well as the taxonomic status and common name source and the relevant biological characteristics of the donor organisms, the characteristics of the vector, including its identity, and its source or origin and its host range; the genetic characteristics of the inserted nucleic acid and the function it specifies, and/or the characteristics of the modified introduced; the identity of the genetically modified organism and the differences between its biological characteristics and those of the recipient organism or parental; information related with the methods for detection and identification; information about the intended use of the GMO including new or changed use compared to the recipient or parental organisms and information relating to the location, geographical, climatic and ecological characteristics of the environment.

In summary, the requirements include description of the genetic material, of the molecular biology of the system (donor, recipient, vector), of the trait(s) and characteristics of the GMO plant, as well as, the information relating to the site of the release, to the purpose of the release, control, monitoring and post release plans, measures of contingency, and information on potential environmental impact of the release of the GMO plants. Besides,

some country regulations require information about the potential harm to human and animal health with the environmental release application. In all the regulations the environmental risk assessment is on a case-by-case basis, to identify and evaluate the potential adverse effects of the GMO on the environment and on human health.

There are different experiences in different countries where the biosafety frameworks are based on non-statutory guidelines, or based on existing or new legislation, or some combination of these approaches. These non-statutory guidelines may include standards for facilities and practices designed to prevent the unintended release of a GMO, conditions of isolation, monitoring field trials and standards for risk assessment for conducting the environmental release. That is the case of Argentina, the second largest producer of transgenic crops, where using these non-statutory guidelines in the last ten years has not compromised the environmental safety.

The evaluation body also varies according to the country and its' regulations. It may be made up by a panel of experts or an advisory committee that reviews the applications and gives advice to the regulatory body in making the final decision, such as Argentina, Brazil, Kenya, and India. The bodies normally include experts from the government, private sector, professional societies, and academic institutions with clearly established responsibilities of the members. In other countries, the expert staff from the government agency has the responsibility to evaluate and approve the environmental release applications, such as in the USA.

Also, in some countries the applications are usually communicated to the public, giving the opportunity for public comments during the approval process. Public communication is a key approach used in giving transparency to the process of approval of a genetically modified organism. Involving the public in the process of the risk assessment gives confidence to the general public in the government authority, scientists, and biotech companies and builds public trust in biotechnology.

A number of countries around the world have established and implemented a biosafety system and others are now improving the regulatory systems to ensure the safe and effective evaluation of the impact of GMO crops. Information and data included in this manual will be very useful for those countries without experience which at the beginning government agency and applicants may want to know and learn about the process.

Process management is a tool widely utilized in the public and private sector to control the processes, procedures, and activities of a government agency to streamline operations or in private business to minimize faulty products. In the seed area, private seed companies seeking ISO registration utilize the process management tool. Process management is also an appropriate tool for developing a quality system for biosafety risk assessment.

The Seed Science Center has developed a Process Management Manual for the risk analysis of the environmental release of a genetically modified agricultural organism. This manual is a blueprint for the establishment of an ISO-like management biosafety system with specific procedures, timelines, responsibilities, and requirements.

This manual would be an appropriate tool for government agencies to be efficient and effective and give to the users more confidence. Adopting and adapting the manual in different countries, regions, or sub-regions would also allow the harmonization of the process, procedures, and activities of the genetically modified approval.

The first step is to define the core processes and in each of them, the appropriate procedures. The content of each procedure includes the purpose, scope, references, definitions, responsibility, activities, records, and flowcharts. In each procedure it is important to indicate why the procedure is important, which should be described in the purpose, and the scope defines the beginning and ending of each procedure. It is also necessary to clearly describe the activities defining the “what”, “when”, and “where” and describing the sequence that must be followed. These activities are directly linked with the flowchart that reflects a visual representation of each procedure. Reports and records proposed through process management will assure effective biosafety checks at every necessary step.

This manual contains the risk analysis of the genetically modified organism for the environmental release, including the risk assessment, the risk management, and the risk communication.

This manual includes eight proposed government procedures for authorizing, inspecting, evaluating, and monitoring a release into the environment of a genetically modified agricultural organism. The six operational procedures are:

1. Application for environmental release of a GMO procedure
2. Confidential business information handling procedure
3. Environmental release inspection procedure
4. Field release monitoring procedure
5. Technical evaluation procedure
6. Appeals procedure

The two support procedures are:

1. Document Control
2. Record Control

This proposed manual is based on the review of different countries regulations including Argentina, Brazil, European Union, India, Kenya, South Africa, and USA. The international guidelines and agreements of the United Nations Environment Program (UNEP), the Organization for Economic Co-operation and Development (OECD), the Convention on Biological Diversity (CBD), International Plant Protection Convention (IPPC), the Cartagena Biosafety Protocol and the Biotechnology Guidelines of Crop Life International were also included.

2. ACKNOWLEDGMENTS

We would like to thank the individuals listed below for contributing to the revision of this manual:

Jeff Wolt

Risk Assessment
Biosafety Institute for Genetically Modified Agricultural Products
BIGMAP, Iowa State University

Quentin Kubicek

Food Safety and Ag Health Specialist
Inter-American Institute for Cooperation on Agriculture
IICA, Miami, Florida

Joseph Cortes

Coordinator International Programs
Seed Science Center
Iowa State University

Cynthia Stauffer

Regulatory Affairs Manager
Pioneer Hi-Bred International, INC.

John M. Cordts

Biotechnologist
Biotechnology Regulatory Services
USDA/APHIS

The editing of this manual by Suzanne Schuknecht, Program Assistant Department of Economics, ISU is much appreciated.

3- PROCEDURE FOR APPLICATION OF ENVIRONMENTAL RELEASE OF GMO

In this procedure for an application to conduct environmental release of a genetically modified organism (GMO), the designated government authority has the responsibility of receiving the submissions and the application and coordinating the different activities during the review process of the application until the final decision.

The key issue in this procedure is the government's application form in which the content and the completeness of the application form are indispensable. The application requires information to assess the environmental release of a GMO. The information varies on a case-by-case basis and for each release. We have considered release in greenhouses or fields because in some countries the approval system is for both; and in others there is a specific guideline for greenhouses because it is considered a confinement release. The application could contain information considered as Confidential Business Information (CBI) by the applicant and in that case it is necessary to follow the CBI procedure. The CBI includes trade secrets, commercial information, or financial information that must be protected.

The application form also requires information on the source(s) of the gene(s) introduced, how the gene(s) is (are) expressed in the genetically modified organism, and the nature of the gene product. The characteristics of the organism are taken into account, as well as its expected performance and potential impact to the environment where it will be released. The exposure and toxicity data are used to examine potential ecological effects to resident wildlife and biodiversity. (For example, plants with pesticide genes may impact non-target insect species.) Therefore, some key information is required for the risk assessment, such as: potential for gene transfer, weediness potential, trait, genetic or phenotypic variability, and the use of vectors and genes from pathogens.

One issue for the risk assessment is the possibility that genes may be transferred by pollen to populations of the same crop species or to sexually compatible wild relatives that grow in the surrounding area. However, for gene transfer to happen many factors must take place during the environmental release such as the occurrence of sexually compatible plants, flowers receptivity at the same time of pollination, seed viability, germination and the fertility and progeny of the resulting hybrid plant. Hence, the necessity to consider the species that can be in contact with the transgenic crop, the potential dispersal of the pollen, the expression of the gene in the plant, and the prevalence or survival of the hybrid plant and its potential effects.

Another technical issue is the release test site requirements addressing inadvertent seed mixing, persistence of volunteer plants because these deal with the biology of the plant, and the field site location. One of the critical performance elements is to minimize cross - pollination between GMO and sexually compatible plants, including other cultivated plants, free living plants of the same crop species, or any compatible wild plants related to the GMO. A description of the site, physical and biological measures that will be taken to

avoid the dissemination of plant parts capable of propagating, methods for preparing and managing the release site, prior to, during and after the release is necessary information for the evaluation process.

Some countries use isolation standards established for foundation seed to set minimum separation distances between field sites and neighboring field. Others countries have regulated specific distances for some GMO crops. In addition, some countries, such as the USA, have established a list of most of the crops growing in the USA which have free-living populations of the same species or compatible species. OECD has published monographs (Consensus Documents) discussing the biology of important host crops with emphasis on key information relating to the environmental releases.

Other important information is related to the control and monitoring of GMO during the post release period. The post release period is considered to be the time after which a field test has been completed and the test plants discarded. Typically, during the post release period the field site is monitored for emergence of volunteer plants. The crop and the location will strongly influence the duration of the monitor period. After the release is completed the method proposed for final disposition and devitalization will depend on the crop and the type of release. Some of the acceptable methods of disposition and devitalization are cultivation into soil at the site, incineration, burial, fermentation, composting, autoclaving, and storage in a secure facility.

The risk assessment of the genetically modified plant is based on the characteristics of the organism, the introduced trait(s), the environment into which the organism will be introduced, and the interaction between these and the intended application. This information is noted in the application form in Annex A and must be completed by the applicant. Occasionally, and depending on the crop and the type of release, additional information may be requested by the designated government authority for the evaluation.

An important activity of this procedure is the technical evaluation of the application. It should be conducted by experts from the government authority or by the National Biosafety Commission. The content of the technical evaluation will be based on the properties the engineered trait (i.e. pest resistance) confers to the crop; its ability to establish, persist, and disperse in the environment; the history/ experience of other release; the potential out-crossing with other species; the effects on the flora, fauna, and non-target organisms; the potential risks in relation to hazard and exposure; and risk management actions to mitigate these potential risks.

Regarding the potential environmental impacts of GMO, it is necessary to understand the biology of the GMO as well as its relationship with the environment where it will be released. The information on the basic biology of the plant and their interactions with the environment including genetic characteristics, reproductive biology, the center of origin and biodiversity, pests, diseases, and ecological characteristics are important issues in evaluating environment safety. All these issues must be taken into account in the evaluation of the GMO in relation with the potential risks to the environment.

After the approval of the application, the GA notifies the applicant and the public of its decision. The notification shall specify that comments will be accepted from the public within a maximum of 60 days after the publication. When the decision is the non-approval of the application, the applicant may appeal the decision following the appeal procedure. For the case that the GMO has been approved in the origin country where the agro-ecosystem conditions are similar, the application form that included the field release results would be passed to the procedure for Technical Evaluation.

The establishment of an appropriate public involvement system to ensure the transparency of the evaluation and risk assessment processes and to enhance public confidence in the decision-making process is highly recommended. The public must be heard in the process of decision-making but, ultimately, the decision has to be the government's based on the safety evaluation.

The national authority should use an effective way to inform the public, such as: the official gazette, a national, regional, or local newspaper, and/or an internet-site. Furthermore, it is recommended that national authorities set general criteria for publishing notices of requests for applications to conduct field releases and an effective mechanism to receive comments from the public. These general criteria may contain information such as the type of GMO, the characterization of the GMO, the intended use, the scale of the release, the location of the release, the risk management measures, the potential effects into the environment, a summary of previous releases, and the potential effects on human and animal health.

**APPLICATION FOR ENVIRONMENTAL RELEASE
OF GMO PROCEDURE**

GOVERNMENT AGENCY

Authorization Date

Effective Date

Created by

Approved by

1. **Purpose:**
 - 1.1 The objective of this procedure is to define the sequence of events, interfaces, and responsibilities involved in the process of applying for an environmental release of a genetically modified organism of an agricultural crop.

2. **Scope:**
 - 2.1 From submission of the application for an environmental release of a GMO to the approval / disapproval of the application.

3. **References:**
 - 3.1 GMO introduction regulations.
 - 3.2 National Biosafety regulations.
 - 3.3 Application details.
 - 3.4 Data/reports, other statistics.
 - 3.5 Crop guidelines.
 - 3.6 OECD Consensus documents.
 - 3.7 Crops Isolation Standards.
 - 3.8 List of crops with free-living populations of the same species or sexually compatible free -living relatives.
 - 3.9 Applicant's protocols.

4. **Definitions:**
 - 4.1 GMO: Genetically modified organism.
 - 4.2 GA: Government Authority.
 - 4.3 NBC: National Biosafety Committee.
 - 4.4 OECD: Organization for Economic Cooperation and Development.
 - 4.5 CBI: Confidential Business Information.
 - 4.6 PIS: Public Information System.

5. **Responsibility and Authority:**
 - 5.1 The GA is responsible for receiving and registering the applications.
 - 5.2 The GA is responsible for reviewing the applications administratively.
 - 5.3 The GA is responsible for distributing the applications and summaries to the members of the NBC.
 - 5.4 The NBC is responsible for evaluating the technical merits of the application.
 - 5.5 The NBC is responsible for making a technical report of the application to the GA.
 - 5.6 The GA is responsible for notifying the approval, approval with conditions, or non-approval to the applicant and the reasons for this decision.
 - 5.7 The GA is responsible of communicating its decision and the reasons thereof to the public through PIS.

- 6. Activities:**
- 6.1 Receive application.
 - 6.1.1 The GA will receive the application (Annex A) and summary of the application. (Annex B)
 - 6.1.2 The GA will record applications received. (Annex C)
 - 6.1.3 If the application contains Confidential Business Information (CBI) continue with the procedure of handling the CBI.
 - 6.2 Review application completeness.
 - 6.2.1 The GA will analyze and verify the completeness of the application checking that all sections have been submitted of Annex A.
 - 6.2.2 The GA will verify the completeness in a period of _____ working days, filling the application checklist. (Annex D)
 - 6.2.3 If the application is complete continue with 6.4.
 - 6.2.4 If the application is not complete continue with 6.3.
 - 6.2.5 If the application is complete and field release as been approved in the origin country continue with the Technical Evaluation Procedure.
 - 6.3 Notify applicant of missing/deficient information.
 - 6.3.1 The GA will notify the applicants for more information through a memorandum (Annex E) in a maximum of _____ working days.
 - 6.4 Distribute application.
 - 6.4.1 The GA will provide the application to the members of the NBC with a memo (Annex F) to evaluate the technical aspects in _____ working days.
 - 6.4.2 The NBC will evaluate the technical aspects taking into account the crop isolation standards, OECD consensus documents; and other relevant information and develop a technical report for the GA.
 - 6.5 Receive technical report.
 - 6.5.1 The GA will receive a technical report (Annex G), record the reports received from each member of the NBC by the date stated in the memo (Annex F).
 - 6.5.1.1 If the GA does not receive the technical report it must then follow procedures established in the Code of Conduct.
 - 6.5.2 The GA will convene a meeting of the NBC sending a memo to the members and record. (Annex H)
 - 6.6 Evaluate application.
 - 6.6.1 The NBC will evaluate the application and make a report following the technical aspects. (Annex I)
 - 6.6.2 If the result of the evaluation is favorable go to 6.9.
 - 6.6.3 If the result of the evaluation is unfavorable continue with 6.8.
 - 6.7 Notify non-approval.
 - 6.7.1 The GA will notify the applicant of its decision of non-approval of the application of the GMO to release into the environment _____ days after the evaluation meeting, utilizing the memo. (Annex J)
 - 6.7.2 The applicant may appeal through the appeals process.

- 6.8 Notify approval.
 - 6.8.1 The GA will notify the applicant of its decision of approval of the environmental release _____ days after the evaluation meeting. (Annex K)
 - 6.9.1.1 If the decision of approval includes special conditions, they must be clearly described in the approval notification.
- 6.9 Communicate to public.
 - 6.9.1 The GA will make public the approval record through an information system (official government gazette, national, regional or local newspaper, internet site, etc.) after notifying the applicant and providing a copy of the record of decision. (Annex L)

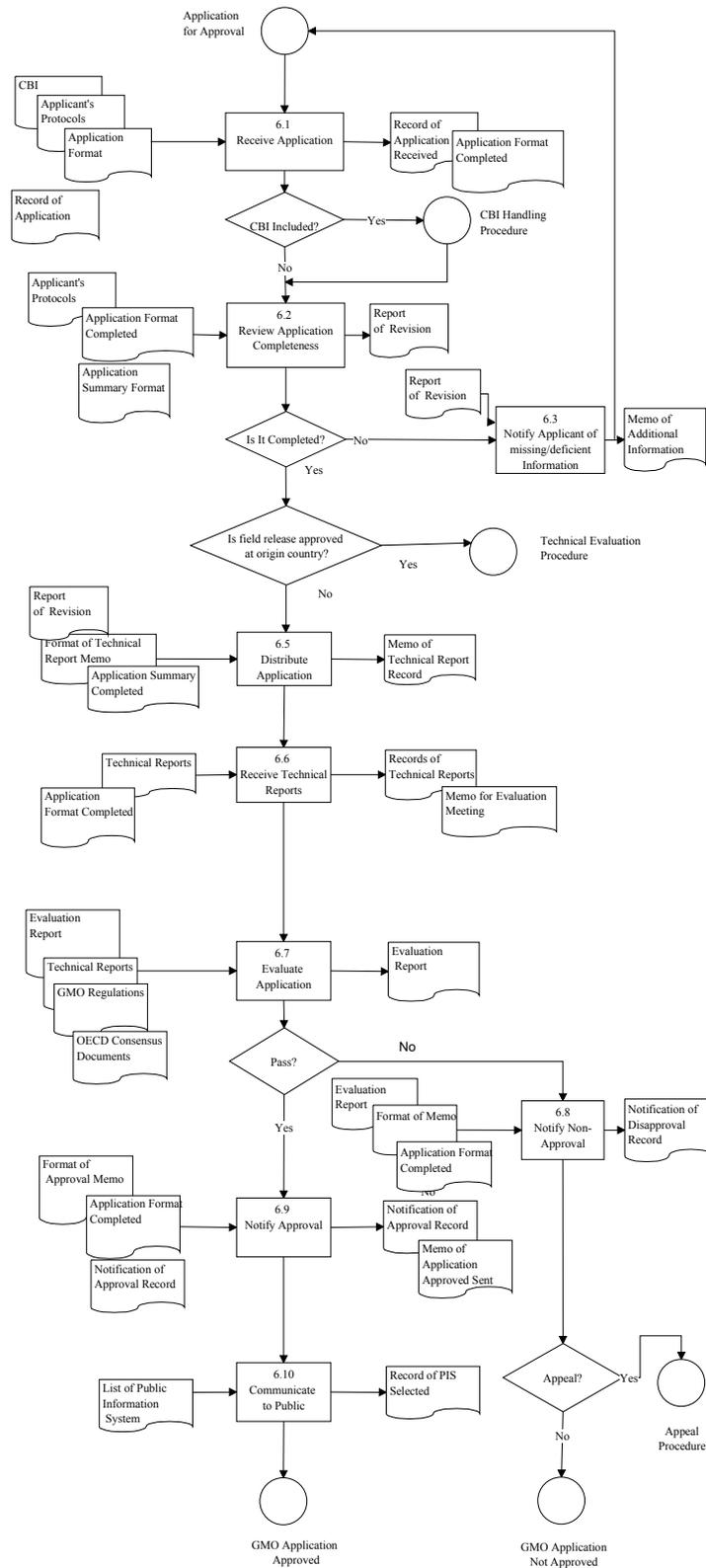
7. Records:

- 7.1 Record of application received.
- 7.2 Record of technical reports.
- 7.3 Record of evaluation report.
- 7.4 Record of application approved.
- 7.5 Record of application not approved.
- 7.6 Record of PIS selected.

8. Flowchart and Annexes:

- 8.1 Flowchart
- 8.2 Annex A: Application Format.
- 8.3 Annex B: Application Summary Format
- 8.4 Annex C: Format of an Application Received
- 8.5 Annex D: Application Checklist
- 8.6 Annex E: Format for Memo Requesting Additional Information
- 8.7 Annex F: Format of Technical Report Memo
- 8.8 Annex G: Technical Report Format.
- 8.9 Annex H: Format of Evaluation Report Meeting
- 8.10 Annex I: Technical Report Evaluation Format
- 8.11 Annex J: Format of Notification of Non- Approval Memo
- 8.12 Annex K: Format of Notification of Approval Memo
- 8.13 Annex L: Format of Record of PIS Selected

APPLICATION FOR ENVIRONMENTAL RELEASE OF GMO FLOWCHART



ANNEX A

APPLICATION FORMAT

1. APPLICANT'S INFORMATION

Name:

Address:

Telephone/Fax/E-mail:

2. CONTACT PERSON (HANDLING THE APPLICATION)

Name:

Address:

Telephone/Fax/E-mail:

3. CONFIDENTIAL BUSINESS INFORMATION

- Clearly identify the information claimed as CBI ("CBI Copy") and provide a copy of the application with the omitted CBI information ("Non-CBI Copy"). Provide a justification for each information claimed CBI.

4. DESCRIPTION OF THE GMO

- Scientific name of the recipient organism.
- Description of the method used for genetic transformation.
- Description of the inserted gene(s) and nucleotide sequence(s).
- Description of the regulatory sequences and their function in the construct.

5. COUNTRY AND LOCALITY WHERE THE DONOR ORGANISM(S), RECIPIENT ORGANISM, AND VECTOR WERE COLLECTED, DEVELOPED, AND PRODUCED

6. CHARACTERIZATION OF THE GMO

6.1 THE RECIPIENT ORGANISM

- Name, family, genus, species, subspecies, cultivars (Taxonomic status).
- Phenotype.
- Geographic distribution and natural habitat.
- Genetic stability.
- Out-crossing with other cultivated or wild plant species.
- Reproductive features.
- Survival in the environment.
- Dispersal/Dissemination features.
- Interactions with other organisms in the environment.
- Pathogenic, toxic or other characteristics that may be harmful to human or animal health.
- History of previous genetic modifications of the recipient organism.

6.2 THE GENETIC MODIFICATION

- Description of the technique used in the transformation.
- Characterization (nature and source) of the vector.
- Description of the construct.
- Nucleotide and/or Amino-acid sequences of the products from the expression of the newly introduced genes.
- Gene transfer properties.
- Regions of the vector which are inserted into the recipient organism.
- Techniques for detection and identification of the GMO (molecular or biological methods) specificity, sensitivity and reliability.
- Differences between the biological characteristics of the GMO and those of parental organism.

6.3 THE DONOR ORGANISM

- Taxonomic status.
- Common name.
- Relevant biological characteristics.
- Pathogenic characteristics.
- Other harmful characteristics.
- Size, function and donor organism (s) of each inserted nucleotide sequence.
- Potential of natural transfer of the genetic elements within the construct, from the donors to other organisms.

7. POTENTIAL ENVIRONMENTAL CONSEQUENCES OF INTRODUCTION

- General description of the site of environmental release.
- General description of the local agro-ecosystem.
- Existence of Threatened or Endangered Species.
- Potential effects on non-target organisms.
- Applicants Protocols to conclude experiment.

8. APPLICATION REQUEST

- New.
- Renewal (Record number) of a previous application request.
- Supplemental Information to support a pending application (Record Number).

9. INFORMATION ON GMO FOR IMPORTATION

- Country of destination origin.
- Government Authority who approved.
- Type and requirements of permit.
- Provide a copy of permit, conditions, data and results of the environmental release.

10. TRANSPORT / MEANS OF MOVEMENTS

10.1 Domestically Developed

- Mail.
- Common Carrier.
- Hand Carrier.

10.2 Introduction

- Mail.
- Common Carrier.
- Hand Carrier.

10.3 Importation (process of import permit)

- Courier.
- Hand Carrier.
- List of Point of Entry Approved.

11. CHARACTERISTICS OF THE GMO DEOMESTICALLY DEVELOPED

- Quantity.
 - Type of material.
 - Place and institution of origin (name, address, Te/fax).
 - Recipient institution (name, address, Te/fax).
 - Dates estimated* of movements.
 - Dates estimated* of greenhouse/field release.
- *Any significant delay should be reported.

12. CHARACTERISTICS OF THE IMPORTED GMO

- Quantity.
- Type of material.
- Country of origin.
- Date of importation.
- Port of arrival.
- Dates of movements.
- Recipient Institutions (name, address, Te/fax).
- Destination of movement.
- Location(s) of release.
- Date(s) of release(s) (greenhouse/field).

13. INTERACTION OF THE GMO WITH THE ENVIRONMENT OF ORIGIN COUNTRY

- Survival in the environment (germination, dormancy, vigor).
- Susceptibility to disease, pests and insects.
- Survival capacity.
- Yield.
- Effects on non-target organisms.
- Effects on the flora and fauna.
- Crop management.
- Specific procedures for the management of the environmental effects of the GMO.

14. TYPE OF RELEASE

- Greenhouse
- Field

15. GREENHOUSE RELEASE

- Description of the site and localization.
- Quantity of the material.
- Purpose of the release.
- Dates and duration of the release.
- Biosafety and isolation measures.
- Techniques to detect the potential gene flow.
- Destination of products.

16. FIELD RELEASE

- Description of the field site and neighboring locations.
- Localization.
- Size of the plots.
- Quantity of material to be sown and grown (GMO and border/trap plants).
- Field plot design.
- Purpose of the release.
- Date(s) and duration of the release(s).
- Description of each release site ecosystem, climate, flora and fauna.
- Details of any sexually compatible wild relatives or cultivated plants present at each release site.
- Description of the process, procedures and safeguards which will be used to prevent contamination and dissemination in the production of the donor organism, recipient organism, vector or vector agents.
- Description of the final disposition and devitalization of GMO including border/trap plants.
- Description of the agricultural practices.
- Description of the post harvest monitoring practices/protocols of the release site.

17. POTENTIAL EFFECTS ON HUMAN HEALTH

- Toxicity or allergenic effects of the GMO, including the products and byproducts derived thereof and its metabolic products.
- Characteristics of the GMO known to be hazardous or pose a health risk.
- Level of expression of the new protein(s).

ANNEX B

APPLICATION SUMMARY FORMAT

I. APPLICANT'S INFORMATION

Name: _____
Address: _____
Tel/ Fax/E-mail: _____
Record No: _____
Name of Contact Person: _____
Address: _____
Tel/Fax/E-mail: _____

II. CHARACTERIZATION OF GMO

- Recipient organism
- Genetic modification
- Donor Organism

III. DENOMINATION OF THE EVENT

IV. CONFIDENTIAL BUSINESS INFORMATION (CBI)

V. DESCRIPTION OF GMO

Scientific resume of the recipient organism: _____
Description of the inserted genes or nucleotides sequences
Name: _____
Function: _____
Name of the donor organism(s): _____
Description of the regulatory sequences and their function in the inserted construct:
Name: _____
Function: _____
Name of the donor: _____

VI. USES OF GMO

Description: _____

VII. DETAIL DESCRIPTION OF PREVIOUS TESTS AND RELEASES INTO THE ENVIRONMENT IN THE COUNTRY OR IN OTHER COUNTRIES

VIII. PROTOCOLS FOR GROWING THE CROP, FOR HANDLING OF PRODUCTS DERIVED THEREOF, AND FOR THE STORAGE PRACTICES

- IX. PROTOCOLS OF PACKAGING, LABELING, AND PROCESSING TECHNOLOGY**
- X. PROTOCOLS OF ACTIONS REQUIRED IN THE CASE OF AN ACCIDENTAL RELEASE**
- XI. OTHER RELEVANT INFORMATION**

ANNEX C

FORMAT OF AN APPLICATION RECEIVED

APPLICATION NUMBER/CODE	APPLICANT/ INSTITUTION	PLANT SPECIES	TRANSGENIC PHENOTYPE	TRANSFORMATION EVENT

ANNEX D

APPLICATION CHECKLIST

	ENCLOSED (YES/NO)	RENEWAL REFERENCE
I. APPLICANT'S INFORMATION		
II. CONFIDENTIAL BUSINESS INFORMATION		
III. TYPE OF APPLICATION (N: New; R: Renewal; S: Supplemental)		
IV. TYPE OF ENVIRONMENTAL RELEASE		
V. INFORMATION OF RECIPIENT ORGANISM		
VI. INFORMATION OF DONOR ORGANISM AND VECTOR		
VII. INFORMATION OF THE GENETIC TRANSFORMATION ORGANISM		
VII. INFORMATION OF THE RELEASE (PURPOSE, DATE, DURATION, QUANTITY, ENVIRONMENT)		
VIII. DESCRIPTION OF GROWING THE CROP		
IX. PROTOCOLS OF PACKAGING, LABELLING AND PROCESSING TECHNOLOGIES		
X. PROTOCOLS OF THE AGRICULTURAL PRACTICES, MANAGING, CONTROL, MONITORING, POST RELEASE AND CONTINGENCY MEASURES		

ANNEX E

**FORMAT FOR MEMO REQUESTING ADDITIONAL
INFORMATION**

TO: APPLICANT/ INSTITUTION

FROM: GOVERNMENT AUTHORITY

DATE:

APPLICATION NUMBER:

After the revision of your application number _____ requesting a permit to release into the environment the GMO (crop/phenotype), we hereby notify you that the following information has been deemed to be necessary _____

Upon receipt of all the above requested information we will proceed with our evaluation of your application. That information must be submitted in the next _____ working days; otherwise we would not be able to continue with the application evaluation.

AUTHORITY SIGNATURE

ANNEX F

FORMAT OF TECHNICAL REPORT MEMO

TO: GOVERNMENT EXPERTS /NBC MEMBERS

FROM: GOVERNMENT AUTHORITY

DATE:

APPLICATION NUMBER:

I would be grateful if you could send a technical report about the attached application for the environmental release of a genetically modified organism. You must submit the report by _____ (date).

AUTHORITY SIGNATURE

ANNEX G

TECHNICAL REPORT FORMAT

The Technical Report must include:

1. The construction of the gene(s)/the genetic modification.
2. The species of the GMO.
3. The origin of the inserted nucleic acid sequences.
4. The expressed proteins and/or DNA and the resulting phenotype.
5. The advantages of the introduction of the foreign inserted gene(s).
6. The equivalence of the GMO with its non-GMO counterpart, referring to:
 - Compositional analysis, processing technology, derived products.
 - Agricultural practices, geographic area, environmental conditions.
 - Equivalence from the standpoint of the end users of the product.
7. Location(s) for the release.
8. Isolation, potential out-crossing, measures proposed, and survival capacity.
9. Interaction with other organisms in the environment (flora, fauna).
10. The potential hazardous effects: susceptibility to disease, pests, and insects.
11. The measures proposed to prevent any escape.
12. Final disposition and devitalization.
13. Pathogenic, toxic, or other characteristics that may be harmful to human or animal health.

ANNEX H

FORMAT OF EVALUATION REPORT MEETING

TO: GOVERNMENT STAFF/NBC MEMBERS

FROM: GOVERNMENT AUTHORITY

DATE:

APPLICATION NUMBER:

I would like to convene a meeting of NBC members to carry out the technical evaluation for the application of environmental release of a genetically modified organism (crop/phenotype).

The meeting will be held _____ (date, time, and place). I want to remind you about the quorum established in the code of conduct.

AUTHORITY SIGNATURE

ANNEX I

TECHNICAL REPORT EVALUATION FORMAT

- APPLICATION NUMBER
- APPLICANT'S INFORMATION
- CHARACTERISTICS OF THE GMO
- PURPOSE OF THE RELEASE
- TYPE OF RELEASE
- CHARACTERIZATION OF THE GMO
- EQUIVALENCE STATEMENT
- HISTORY/RECORD OF THE RELEASE
- INTERACTIONS WITH OTHER ORGANISMS IN THE ENVIRONMENT
- OUT-CROSSING POTENTIAL WITH RELATED CULTIVATED/WILD SPECIES
- SURVIVAL IN THE ENVIRONMENT
- EFFECTS ON NON-TARGET ORGANISMS
- SUSCEPTIBILITY TO DISEASE, PESTS AND INSECTS
- EFFECTS OF THE GMO ON THE FLORA AND FAUNA
- CROP MANAGEMENT TECHNOLOGIES
- MANAGEMENT OF POTENTIAL UNDESIRABLE EFFECTS
- PROPOSAL OF MONITORING POSSIBLE LONG TERM EFFECTS
- TOXICITY ASSESSMENT

ANNEX J

FORMAT OF NOTIFICATION OF NON-APPROVAL MEMO

TO: APPLICANT/INSTITUTION

FROM: GOVERNMENT AUTHORITY

DATE:

APPLICATION NUMBER:

Your application # _____ requesting a permit to release into the environment a genetically modified organism (crop/phenotype) has not been approved. Attached is the respective technical report which provides the reasons for not approving. You may appeal this decision in accordance with the regulations.

AUTHORITY SIGNATURE

ANNEX K

FORMAT OF NOTIFICATION OF APPROVAL MEMO

TO: APPLICANT/INSTITUTION

FROM: GOVERNMENT AUTHORITY

DATE:

APPLICATION NUMBER:

I want to inform you that the application # _____ requesting a permit for release into the environment a genetically modified organism (crop/phenotype) has been approved. Attached is the respective technical report which includes the conditions of approval.

AUTHORITY SIGNATURE

ANNEX L

FORMAT OF RECORD OF PIS SELECTED

GMO APPLICATION NUMBER	PUBLICATION SITES	DATE OF PUBLICATION	COPY OF THE PUBLICATION

4- PROCEDURE FOR CONFIDENTIAL BUSINESS INFORMATION HANDLING

The Confidential Business Information (CBI) includes trade secrets, and/or commercial or financial information that must be protected. CBI is information relating to the production process such as production data, formulas, processes, quality control tests, research methodology, and data. This information is commercially valuable, used in the business and maintained in secrecy, and should be considered confidential if substantial competitive harm would result from disclosure.

Applicants may determine that some information required in the application is business sensitive and should be kept confidential. Applicants that claim CBI must provide written justification. The GA will determine the validity of the justification and inform the applicant in the event the GA disagrees. Therefore it is necessary to establish procedures for handling the CBI to secure its identification, physical security, handling of the documents, and the access to these documents. Applicants must provide the GA with a non-CBI copy. A non-CBI copy is a reproduction of the CBI copy with the CBI having been blanked out from the text and each page clearly marked with “CBI deleted” in bold and enlarged text.

Upon receipt of the CBI documents the GA will mark these documents with unique identification, assign the application a number, and maintain a CBI and non-CBI copy.

In addition, the GA will designate an official staff that will have the responsibility of handling and controlling the CBI documents. The GA must also implement a mechanism to assure the storage of the documents, such as: locked areas, alarm activated, file systems, or other appropriate means.

Sometimes during the evaluation of the application, the experts will require to review CBI information. As a result, the GA must establish a list of experts designated to have access to CBI. These experts should receive training on safeguarding CBI before obtaining the authorization to be incorporated in the list. Each expert is responsible for securing the CBI documents while in their possession during the revision process. They cannot reveal or allude to any data deemed CBI in the biosafety reports. The GA will provide secure/private areas for the experts where they can review the CBI. The GA will establish the safeguards during the individual use of the CBI documents.

**CONFIDENTIAL BUSINESS INFORMATION
HANDLING PROCEDURE**

GOVERNMENT AGENCY

Authorization Date	<input type="text"/>
Effective Date	<input type="text"/>
Created by	<input type="text"/>
Approved by	<input type="text"/>

1. **Purpose:**
 - 1.1 The objective of this procedure is to define the sequences of events, interfaces, and responsibilities involved in the procedure of handling CBI with an application to conduct a field release of a GMO.
2. **Scope:**
 - 2.1 From receipt of an application containing CBI to file maintenance of application.
3. **References:**
 - 3.1 National Regulations on the Protection of CBI.
 - 3.2 List of authorized experts to receive CBI.
4. **Definitions:**
 - 4.1 GA: Government agency.
 - 4.2 NBC: National Biosafety Committee.
 - 4.3 CBI: Confidential Business Information.
5. **Responsibility and Authority:**
 - 5.1 The GA is responsible for receiving the CBI and implementing a secure a document tracking system and storage system.
 - 5.2 The GA is responsible for designating the experts who will be given access to CBI.
 - 5.3 The designated technical experts are individually responsible for maintaining the confidentiality of the information throughout the revision of the application.
6. **Activities:**
 - 6.1 Receive and evaluate CBI.
 - 6.1.1 The GA will receive an application containing information the applicant claims to be CBI.
 - 6.1.2 The GA will assess applicant's justification for claiming CBI.
 - 6.1.2.1 If the GA does not uphold the applicant's justification continue with 6.2.
 - 6.1.2.2 If the GA has justified the CBI documents continue with 6.3.
 - 6.1.3 The GA will record date of receipt and give each CBI document a record identity. (Annex A)
 - 6.1.4 The GA will authorize and train personnel from the GA who will be responsible for handling CBI documents.
 - 6.2 Notify denied CBI.
 - 6.2.1 The GA will notify applicant the justification for not claiming CBI. (Annex B)
 - 6.2.2 The applicant may appeal the decision following the appeal procedure.

- 6.3 Store CBI.
 - 6.3.1 The authorized personnel of the GA will store the CBI in a secure area when it is not in used.
- 6.4 Authorize access to CBI.
 - 6.4.1 The GA will designate and list the technical experts who will be allowed to review the CBI.
 - 6.4.1.1 Authorized personnel of the G.A. will only provide CBI documents to technical experts whom the G.A. has designated and are listed. (Annex C)
 - 6.4.2 The authorized personnel will record date when technical experts receive and return CBI documents. (Annex D)
 - 6.4.2.1 The GA will take precautions so that unauthorized persons are not present at meetings where CBI documents and CBI are discussed.
 - 6.4.2.2 The authorized experts are individually responsible for maintaining confidentiality of the CBI.
 - 6.4.3 The authorized experts will prepare their reports without revealing any data deemed CBI.
 - 6.4.3.1 The GA will train the authorized experts on safeguarding CBI before giving authorized status.
 - 6.4.3.2 The GA will provide private working areas for receiving the CBI documents.

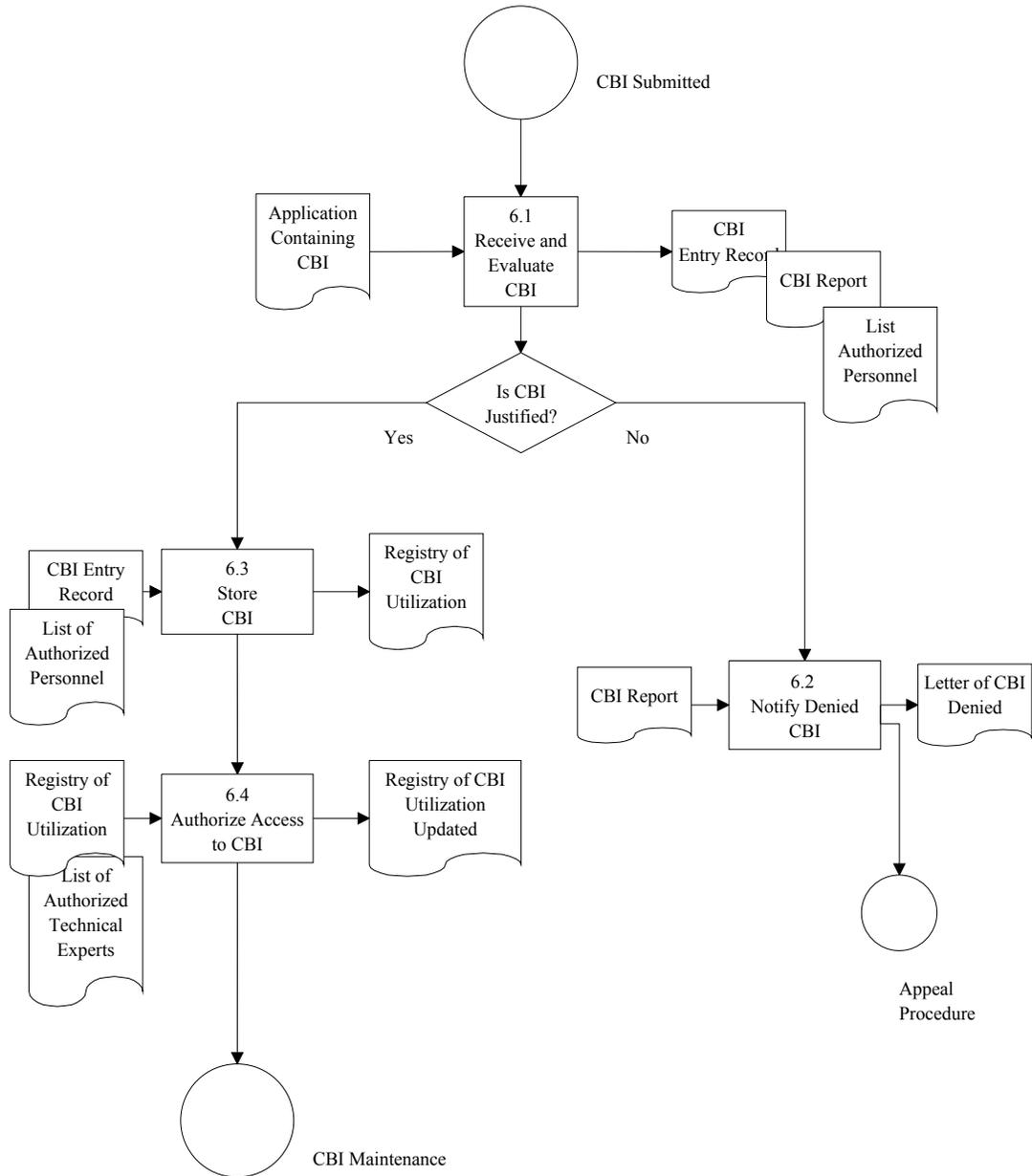
7. Records:

- 7.1 Date of receipt of application containing CBI.
- 7.2 List authorized technical experts.
- 7.3 Registry of CBI utilization.
- 7.4 List of authorized personnel.

8. Flowchart and Annexes:

- 8.1 Flowchart.
- 8.2 Annex A: CBI Entry Record Format.
- 8.3 Annex B: Letter of denying CBI justification format.
- 8.4 Annex C: CBI Utilization Registry Format.
- 8.5 Annex D: List of Designated Experts Format.

CONFIDENTIAL BUSINESS INFORMATION HANDLING FLOWCHART



ANNEX A

CBI ENTRY RECORD FORMAT

APPLICATION # CBI	DATE OF RECEIPT	STAFF NAME	SIGNATURE

ANNEX B

LETTER OF DENYING CBI JUSTIFICATION FORMAT

TO: APPLICANT

FROM: GA

APPLICATION # CBI

DATE:

I am informing you that the application # _____ requesting a permit for release into the environment which contains CBI documents claimed by you has not been justified as a CBI. You may appeal the decision following the appeal procedure.

GOVERNMENT AUTHORITY

5- PROCEDURE FOR ENVIRONMENTAL RELEASE INSPECTION

The release into the environment of a genetically modified plant refers to planned open field plot experiments and experiments in containment facilities like greenhouses. The inspections will be conducted by official inspectors according to the type of the release the government agency plans. The inspections occur during the conduct of the field trial and the greenhouse. The designated inspector should have general knowledge in the biology of plants, sufficient knowledge of the GM plant species, and their interactions with the environment. Prior to carrying out release inspections, inspectors must be knowledgeable with details of the application to ensure familiarity with the conditions of the GMO release. This may be an area of training necessary for the government agency to implement.

During inspections the first aspect that should be checked is the identification of the material that will be planted and the applicant's protocols to prevent accidental mixing. On the first visit, the inspector must verify the approved GA isolation and containment conditions. As early in the season as possible, the inspector will check if there are any other cultivated or free-living plants of the same species and any compatible wild plants located within pollination distance. The inspector must check the method(s) described in the applicants' protocols to minimize the pollination of GM plants receptive plants outside the field release site. The field site must be clearly identified for the following growing season when volunteer transgenic plants may arise.

Another important aspect to ensure is machinery cleanliness. The inspector should check that all the equipment has been cleaned prior to and after planting and harvesting the GMO material.

During harvest, the procedure for final disposition and devitalization of any harvested material must be inspected. These procedures will depend on the crop, the amount of harvested material, the local conditions and the method selected by the applicant to devitalize any harvested material (i.e. autoclave, steamer, burial, incineration etc). _____ days after each inspection, the inspectors must submit a report with their observations of the release and the degree of compliance with the biosafety requirements. The report includes phenotypic characteristics observed, vegetative growth, efficacy of the new trait, susceptibility to diseases and pests, consistency with the applicant protocols, efficacy of the biosafety measures, and others observations considered important by the inspector.

ENVIRONMENTAL RELEASE INSPECTION PROCEDURE

GOVERNMENT AGENCY

Authorization Date

Effective Date

Created by

Approved by

1. **Purpose:**
 - 1.1. The objective of this procedure is to define the sequence of events, actions, interfaces, and responsibilities involved in the process of conducting the environmental release inspection required of biosafety risk assessment.

2. **Scope:**
 - 2.1. From approval of the GMO application to the summary report of the release inspections.

3. **References:**
 - 3.1. National biosafety regulations.
 - 3.2. Applicants' protocols.
 - 3.3. Application Approved
 - 3.4. Environmental Release Inspection Guidelines.
 - 3.5. Crop isolation standards.
 - 3.6. OECD consensus documents.
 - 3.7. List of crops with free-living populations of the same species or sexually compatible free-living relatives.

4. **Definitions:**
 - 4.1. GA: Government agency.
 - 4.2. Inspector: Technician responsible of carrying out the field inspections.
 - 4.3. Company: Applicant / Petitioning Institution.
 - 4.4. NBC: National Biosafety Committee.
 - 4.5. GMO: Genetically modified organism.
 - 4.6. OECD: Organization for Economic Cooperation and Development.

5. **Responsibility and Authority:**
 - 5.1. The GA is responsible for the entire procedure.
 - 5.2. The Inspector is responsible for conducting the inspections and preparing the reports on behalf of GA.
 - 5.3. The Company Contact Person is the designated technical expert of the applicant and is responsible for handling the application of the environmental release.

6. **Activities:**
 - 6.1. Plan release inspection.
 - 6.1.1. The GA shall prepare the schedule of inspections, taking into account the type of release, the crop and the location of release(s). Annex A), (Annex A.1)
 - 6.2. Conduct environmental release inspection.
 - 6.2.1. The applicant will in _____ working days give notice to the GA of estimated dates of planting, flowering and harvesting. (Annex B)

- 6.2.2. The inspector shall coordinate the date of inspection(s) with the company contact person for each of the different stages of the crop (planting, flowering, harvesting, post harvest monitoring).
- 6.2.3. The inspector shall conduct each inspection in accordance to the Environmental Release Inspection Guidelines. (Annex C)
- 6.2.4. In the case of containment facility the inspector will conduct the inspection using the Inspection Guidelines for Greenhouses (Annex D).
- 6.2.5. The inspector shall present a report of each inspection after _____ working days from the date of finishing the inspection. (Annex E)
- 6.2.6. If it is not a harvest inspection, continue the inspection schedule and conduct next inspection in 6.2.
- 6.2.7. If it is a harvest inspection continue with 6.3.
- 6.3. Check the final disposition and devitalization.
 - 6.3.1. The inspector must check the efficacy of the final disposition and devitalization of any plant material harvested or remaining in the field conducted in accordance to the applicant's protocols.
 - 6.3.2. The inspector shall present a report to the GA in the next _____ working days. (Annex F)
- 6.4. Summarize inspection reports.
 - 6.4.1. The GA shall in _____ working days summarize the inspection reports. (Annex G)

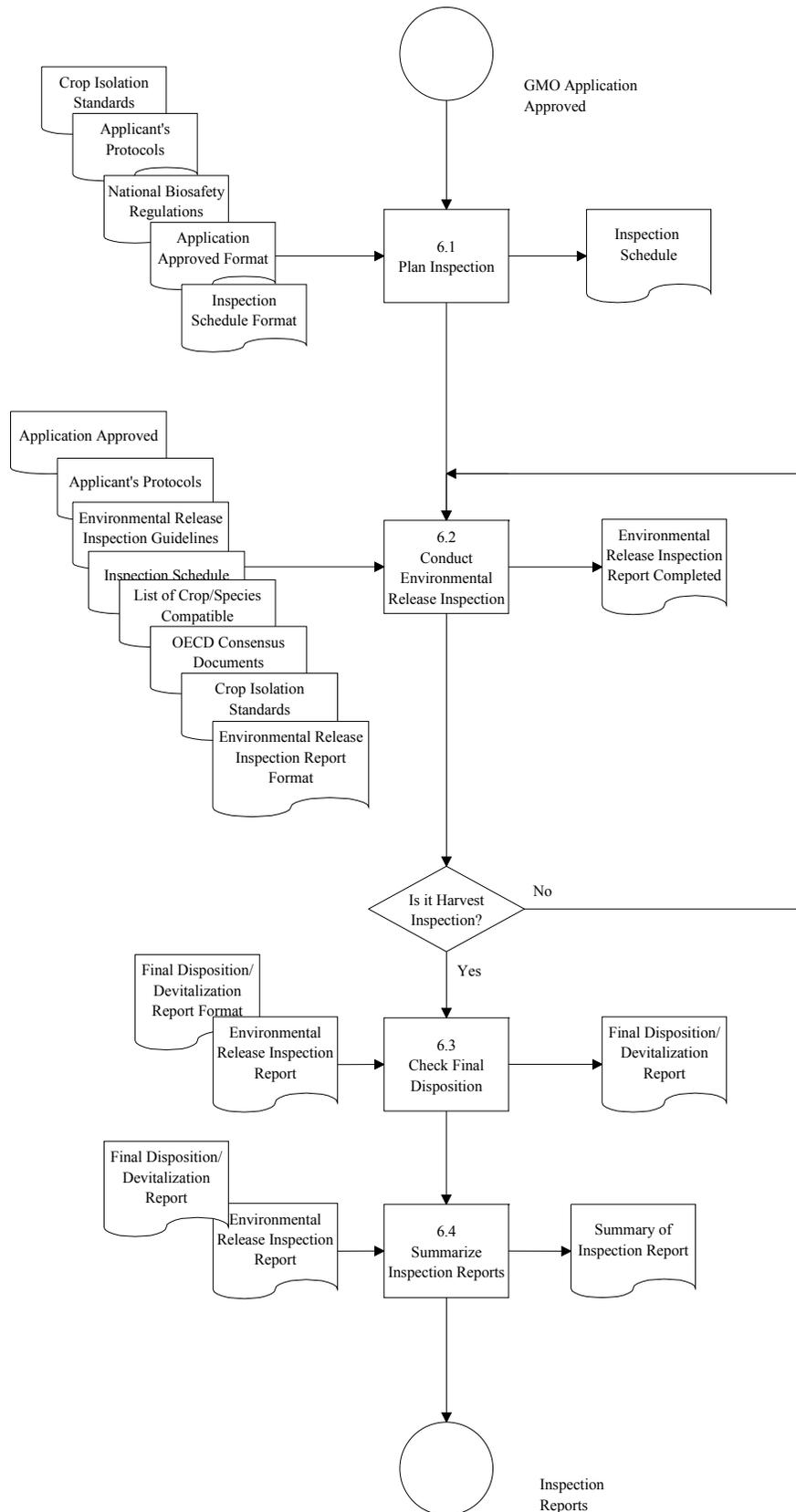
7. Records:

- 7.1. Inspection Schedule.
- 7.2. Inspection Reports.
- 7.3. Final Disposition and Devitalization report.
- 7.4. Summary Report.

8. Flowchart and Annexes:

- 8.1. Flowchart.
- 8.2. Annex A: Inspection Schedule Format.
- 8.3. Annex A.1: Inspections Plans.
- 8.4. Annex B: Applicant Notification Format.
- 8.5. Annex C: Environmental Release Inspection Guidelines for Field Plots.
- 8.6. Annex D: Inspection Guidelines for Containment Facilities.
- 8.7. Annex E: Environmental Release Inspection Report Format.
- 8.8. Annex F: Final Disposition and Devitalization Report.
- 8.9. Annex G: Summary Report of Environmental Release.

ENVIRONMENTAL RELEASE INSPECTION FLOWCHART



ANNEX A

INSPECTION SCHEDULE FORMAT

- APPLICATION NUMBER
- APPLICANT
- PLANT SPECIES
- TRAIT/GENE
- PHENOTYPE
- PURPOSE OF RELEASE
- TYPE OF RELEASE
 - FIELD
 - GREENHOUSE
- LOCATION OF RELEASE (If more than one location list each separately)
- SIZE OF EACH RELEASE (Size of each release at each location)
- PLANTING INSPECTION DATE * (If more than one location note planting date for each release and location)
- FLOWERING INSPECTION DATE * (For each release and location)
- HARVEST INSPECTION DATE * (For each release and location)
- FINAL DISPOSITION INSPECTION DATE * (For each release and location)

*May be subject to change depending on environmental conditions

ANNEX A.1

INSPECTIONS PLANS

APPLICATION NUMBER	PLANT SPECIES	TRAIT/ GENE	LOCATION	PLANTING DATE	FLOWERING DATE	HARVEST DATE	FINAL DISPOSITION DATE

ANNEX B

NOTIFICATION OF INSPECTIONS FORMAT

To: Government Authority

From: Applicant (Company Contact Person)

Date:

Application Number:

GM Plant Species (Common and Scientific Names):

Trait/Gene:

I hereby inform you that the established dates for planting, flowering, harvesting, processing, transporting and final disposition of the GMO (for each field release) are:

Location A:

Planting: _____ (DD/MM/YY)
Flowering: _____ (DD/MM/YY)
Processing: _____ (DD/MM/YY)
Transporting: _____ (DD/MM/YY)
Final Disposition: _____ (DD/MM/YY)

I will meet your inspector in the site of release.

COMPANY CONTACT PERSON
SIGNATURE/ADDRESS

ANNEX C

ENVIRONMENTAL RELEASE INSPECTION GUIDELINES **FOR FIELD PLOTS**

- Application Number
- Applicant's Name
- Responsible Applicant (name, Te/Fax)
- Contact Person (name, Te/Fax)
- Plant Species
- Trait/Gene
- Location of Site(s) (listed each location separately) (state, province, county, street address, GPS)
- History of prior use of the plot (last 2 years)
- Date of inspection
- Type of inspection (planting, flowering, harvesting, processing, final disposition)
- Conditions of the plot according to the application
- Identity of the field trial (seed storage, planting-harvest site, borders)
- Seeds for planting (quantity, conditions)
- Conditions of equipment (planting and cleanliness machinery)
- Applicant's protocols for preparing and managing the release site
- Distance from nearest cultivated plantings
- Distance from nearest sexually compatible free-living plants
- Description of vicinity fields
- Presence of volunteer plants from previous field release

- Containment:
 - Removing flowers
 - Bagging flowers/tassels
 - Physical isolation
 - Temporal isolation
- Detailed method of disposal of any extra seeds or plants
- Flowering inspection: describe pollen management procedures (bagging, de-tassel)
- Increased susceptibility for disease, pests and weeds
- Harvest inspection: methods of disposal, cleanliness of equipment, unload control
- Post harvesting: cleanliness of equipment, disposal of control plants
- Detailed method of movement and transport of harvested material: identification and cleanliness
- Description of seed: processing plant, identification, weight, storage and final destiny of the material
- Method of transportation/movement of the harvested material out of the plot (conditions of movement)
- Description of final disposition and devitalization (methods)

ANNEX D

INSPECTION GUIDELINES FOR GREENHOUSES

- Application number
- Applicant's name
- Responsible applicant
- Contact person
- Plant species
- Trait/gene
- Location of facility (state, province, county, street address GPS)
- Building identification (name/number)
- Description of used guidelines for recombinant DNA research
- Facility physical design and security
- Description of the facility
- System of handling material
- Personnel authorized to handle GM material
- Method of handling test material
- Identification of test material
- Final disposal of test material

ANNEX E

ENVIRONMENTAL RELEASE INSPECTION REPORT FORMAT

- I. APPLICATION INFORMATION
 - Application Number
 - Applicant's Name Te/Fax
 - Contact Person Te/Fax
 - Plant species
 - Trait/gene
 - Location of site
 - Type of release
 - Date/Type of inspection
- II. FINAL EXPERIMENTAL DESIGN OF THE RELEASE
- III. OBSERVED SEXUALLY COMPATIBLE FREE LIVING PLANTS
- IV. CONTAINMENT CONDITIONS: REMOVAL OF FLOWERS, BAGGING OF FLOWERS, PHYSICAL ISOLATION, AND/OR TEMPORAL ISOLATION FROM COMPATIBLE PLANTS
- V. INCREASED SUSCEPTIBILITY TO DISEASES AND PESTS
- VI. CONSISTENCY WITH THE APPLICANT'S PROTOCOLS
- VII. USE AND DISPOSAL OF PRODUCTS OR RESIDUES
- VIII. FURTHER USE OF THE PLOT/LAND
- IX. EFFICACY OF THE BIOSAFETY MEASURES/RISK ASSESSMENT
- X. AGRICULTURAL PRACTICES
- XI. ADDITIONAL OBSERVATIONS

ANNEX F

FINAL DISPOSITION AND DEVITALIZATION REPORT

- I. APPLICATION INFORMATION
 - Application Number
 - Applicant's Name Tel/Fax
 - Contact Person Tel/Fax
 - Plant species
 - Trait/gene
 - Location of site
 - Type of release
 - Date of harvest notification
 - Date of harvest inspection.
- II. DESCRIBE THE METHOD OF DISPOSAL OF THE PLANT MATERIAL
- III. DESCRIBE THE EQUIPMENT CONDITIONS
- IV. DESCRIBE THE FINAL DESTINATION OF DISPOSED/DEVITALIZED PRODUCT
- V. COMPLIANCE WITH THE APPLICANT'S PROTOCOLS
- VI. OTHER OBSERVATIONS/CONSIDERATIONS

ANNEX G

SUMMARY REPORT OF ENVIRONMENTAL RELEASE INSPECTION

- APPLICATION INFORMATION
 - Application Number
 - Date
 - Applicant's Name
 - Plant species
 - Trait/gene
 - Location of site
 - Type of release
 - Date/type of inspection

- FINAL DESIGN OF THE RELEASE

- CONSISTENCY WITH THE APPLICANTS PROTOCOLS

- INCREASED SUSCEPTIBILITY TO DISEASES AND PESTS

- EFFICACY OF THE BIOSAFETY MEASURES

6- PROCEDURE FOR FIELD RELEASE MONITORING

The monitoring procedure will begin soon after completion of the field trial. Monitoring can contribute significantly to gaining knowledge and experience with the use of GMO. Monitoring can be carried out by the government agency or authorized representatives and is used to verify the assumptions made in a risk assessment, compliance with the permit conditions, and to evaluate whether the risk management measures used were appropriate and effective.

Monitoring of a field release refers to the inspection of each location where a GMO field release was conducted and may begin immediately after completion of the field release. Depending on the crop and location, additional visit(s) may be made in subsequent growing seasons to confirm that the same crop is not planted in the field release site; to determine the presence of volunteer plants and to check for any adverse effects that could have occurred as a result of the field release. Monitoring is very important to collect environmental data that can complement the technical and scientific information gathered during the environmental release.

Monitoring of the release sites is carried out to check the survival capacity of the GM plants. If any volunteer GM plants appear in the field they should be destroyed using the treatment proposed in the applicants' protocols and approved by the GA. It is also necessary to check any other effects on the flora and fauna at the site and in the neighboring fields and ecosystems, as well as, any diseases, pests or insects that could be invasive.

The inspector must report the result of each monitoring inspection to the GA. Each inspection report should include all observations related with the environment and the potential susceptibility to diseases and pests. Each release site must remain identifiable during the next growing season in order for the inspectors to conduct subsequent monitoring inspections. The applicant is responsible for maintaining these sites separate from other plantings or uses and to restrict access if necessary. Key to monitoring is having inspectors with a broad knowledge and understanding of plant biology, cultivation, and the local environment.

FIELD RELEASE MONITORING PROCEDURE

GOVERNMENT AGENCY

Authorization Date	<input type="text"/>
Effective Date	<input type="text"/>
Created by	<input type="text"/>
Approved by	<input type="text"/>

1. **Purpose:**
 - 1.1. The objective of this procedure is to define the sequence of events, actions, interfaces, and responsibilities involved in monitoring the field plots where an environmental release has been conducted.

2. **Scope:**
 - 2.1. From each field site approved by the GA for a field release plot to the plot monitored.

3. **References:**
 - 3.1. National biosafety regulations.
 - 3.2. Report of field release inspections.
 - 3.3. Applicant's protocols.
 - 3.4. Application approved.
 - 3.5. Crop requirements.
 - 3.6. OECD Consensus Documents.

4. **Definitions:**
 - 4.1. GA: Government Agency.
 - 4.2. NBC: National Biosafety Committee.
 - 4.3. GAI: Government Agency Inspectors.

5. **Responsibility and Authority:**
 - 5.1. The GA is responsible for planning the schedule of the plots to be monitored.
 - 5.2. The GAI are responsible for conducting the monitoring of the plots and reporting their findings to the GA.
 - 5.3. The GA is responsible for preparing an annual monitoring report and summarizing the annual monitoring reports.

6. **Activities:**
 - 6.1. Plan schedule of monitoring.
 - 6.1.1.1. The GA, in coordination with the applicant, will plan a schedule for conducting the monitoring inspection dates and visits of each field release site based on the list of plots recorded and the application completed. (Annex A)
 - 6.2. Conduct monitoring.
 - 6.2.1.1. The GAI shall conduct the monitoring inspection according to the GA's Annex A and present the GA with a report _____ days after finishing each monitoring inspection. (Annex B)
 - 6.3. Prepare Annual Report
 - 6.3.1.1. The GA will prepare the annual monitoring report from the monitoring inspection reports of each environmental release. (Annex C)
 - 6.4. Summarize annual monitoring reports.
 - 6.4.1. The G.A. will summarize the annual monitoring reports. (Annex D)

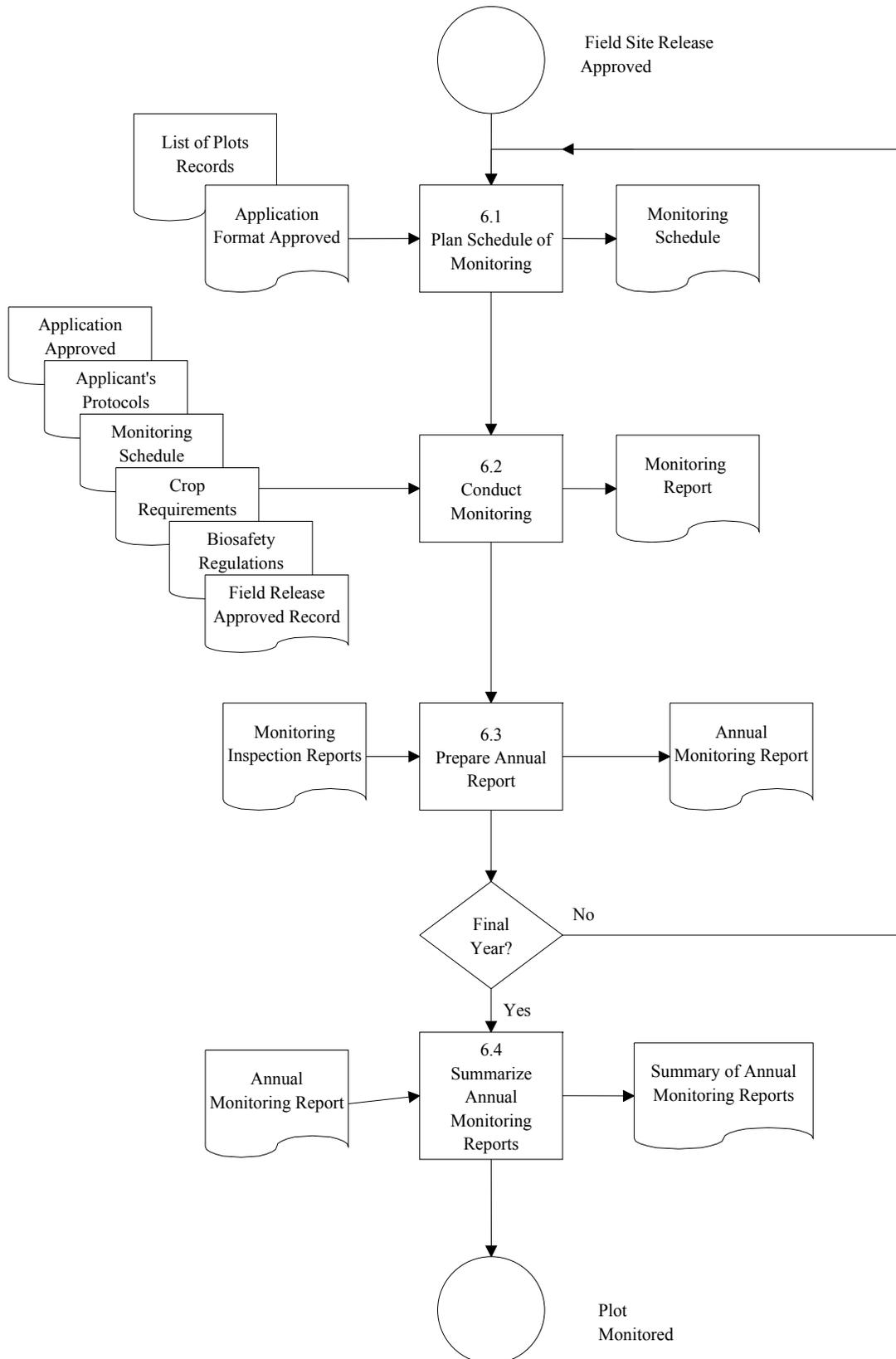
7. Records:

- 7.1. Monitoring Inspection Report.
- 7.2. Monitoring Schedule.
- 7.3. Annual Monitoring Report.
- 7.4. Summary of Annual Monitoring Reports.

8. Flowchart and Annexes:

- 8.1. Flowchart.
- 8.2. Annex A: Monitoring Schedule Format.
- 8.3. Annex B: Monitoring Inspection Report Format.
- 8.4. Annex C: Annual Monitoring Report Format.
- 8.5. Annex D: Summary of Annual Monitoring Reports Format.

FIELD RELEASE MONITORING FLOWCHART



ANNEX A

MONITORING SCHEDULE FORMAT

- APPLICATION NUMBER:
- APPLICANT:
- PLANT SPECIES:
- TRAIT/GENE:
- PURPOSE OF RELEASE:
- TYPE OF RELEASE:

LOCATION OF THE RELEASE	MONITORING DATE (DD/MM/YY)
1.	
2.	
3.	
4.	
5.	
6.	
7.	
8.	
9.	
10.	

ANNEX B

MONITORING INSPECTION REPORT FORMAT

APPLICATION INFORMATION

- Application Number
- Applicant's Name Tel/Fax/Address
- Contact Person Tel/Fax/Address
- Plant Species
- Trait/gene
- Location of Site (if more than one list separately)
- Purpose of the release
- Date of monitoring (if more than one list separately)

OBSERVATIONS OF MONITORING INSPECTION

- PRESENCE OF VOLUNTEER PLANTS AND THEIR SURVIVAL CAPACITY
- OBSERVATION OF RESIDUES
- FIELD PRACTICES
- OBSERVATION OF ANY ADDVERSE EFFECTS
- PLANNED/ANTICIPATED USES OF LAND/PLOT
- EFFICACY OF THE BIOSAFETY MEASURES
- CONSISTENCY WITH THE APPLICANT'S PROTOCOLS
- OTHER OBSERVATIONS

ANNEX C

ANNUAL MONITORING REPORT FORMAT

- APPLICATION NUMBER
- YEAR
- APPLICANT'S NAME/TEL/FAX/ADDRESS
- CONTACT PERSON TEL/FAX/ADDRESS
- PLANT SPECIES
- TRAIT/GENE
- LOCATION OF SITE (if more than one list separately)
- PURPOSE OF RELEASE
- DATE OF MONITORING
- SURVIVAL CAPACITY /VOLUNTEER PLANTS
- OBSERVATION OF RESIDUES
- FIELD PRACTICES
- OBSERVATION OF ANY ADVERSE EFFECTS/DIFFERENCES/ABNORMALITY
- FURTHER USE OF THE LAND/PLOT
- EFFICACY OF THE BOSAFETY MEASURES
- CONSISTENCY TO APPLICANT'S PROTOCOLS
- OTHER OBSERVATIONS

ANNEX D

SUMMARY OF ANNUAL MONITORING REPORTS FORMAT

APPLICATION#	PLANT/SPECIES	RELEASE SITE	DATE OF MONITORING	OBSERVATIONS

7- PROCEDURE FOR TECHNICAL EVALUATION

After each environmental release of GMO it may be necessary to evaluate the results of the inspections and if applicable the results of the monitoring inspections. The objective of the evaluation is on case- by -case basis, to identify and evaluate potential adverse effects of the GMO on the environment and human health. This procedure is a feedback which allows an assessment of previous procedures and evaluates if the steps and tasks met their goals. The technical evaluation is required to decide whether to proceed, cancel, or to modify the risk analysis and the risk management which led to approving a request for an environmental release.

The evaluation is normally carried out by a staff of experts from the GA or by the members of NBC and the number and kind of experts will depend on the characteristics of the environmental release. The experts and the members of the NBC must have, collectively, the expertise in the professional fields necessary to perform an environmental risk assessment. It is recommended that as a group, the members have formal academic qualifications in agronomy, molecular biology, ecology, plant pathology, biology, biochemistry, and biosafety. The NBC should include experts from the government agencies, private sector, professional societies, academic institutions, consumers, and environmental advocacy groups. The establishment of a NBC provides greater transparency to the decision making process as well as serving in an expert capacity to evaluate the potential risks of the GMO to the environment and human health. Furthermore, we can assert that taking only technical considerations into account ensures transparency, as both biosafety reviews and decisions must be consistent with available scientific information.

The relevant technical and scientific details regarding the characteristics of the parental organism(s), the genetic construct, the modified organism and the environment where the GMO is to be released must be taken into account for the purpose of evaluation. In addition, the determination of the appropriate level of risk is based on a comparison of the GMO to its corresponding non-transformed parent is known as the concept of familiarity. In itself familiarity is not a safety assessment. The experts in the evaluation process take the concept of familiarity into account.

Other environmental impacts, which must be evaluated, are those related with weediness, gene flow, pests or pathogen effects, and toxicity to other organisms. With the information gathered in the release inspection and monitoring reports, the experts can evaluate the likelihood of any adverse impacts of the GMO and the effectiveness of the risks management strategies used in the release. The final report of the evaluation will be a feedback for the risk assessment.

During the evaluation it may be necessary for members to again review the Confidential Business Information (CBI). CBI must be handled according to the procedures developed for handling CBI.

Transparency and public participation are essential components to building trust in public institutions and in the risk assessment and risk management of new technologies. Therefore, it is necessary to choose a public information system that provides timely and pertinent information and encourages public comment and participation. The process of soliciting public comment provides a background to the application during the risk assessment process and confidence that the biosafety system is credible

TECHNICAL EVALUATION PROCEDURE

GOVERNMENT AGENCY

Authorization Date

Effective Date

Created by

Approved by

1. **Purpose:**
 - 1.1. The objective of this procedure is to define the sequence of events, actions, interfaces, and responsibilities involved in the process of evaluating of a GMO plant.

2. **Scope:**
 - 2.1. From the reports of the field release inspections, monitoring, and technical data of an environmental release of a GMO to favorable/unfavorable report.

3. **References:**
 - 3.1. Application approved.
 - 3.2. National Biosafety Regulations.
 - 3.3. Report of field inspection.
 - 3.4. Report of monitoring Inspections.
 - 3.5. Specific crop regulations.
 - 3.6. Confidential business information data.
 - 3.7. Public comment records.

4. **Definitions:**
 - 4.1. GMO: Genetically modified organism.
 - 4.2. NBC: National Biosafety Committee.
 - 4.3. CBI: Confidential Business Information.
 - 4.4. GA: Government agency.
 - 4.5. PIS: Public Information System.

5. **Responsibility and Authority:**
 - 5.1. The NBC is the advisory body responsible for evaluating the scientific and technical issues associated with the potential environmental impacts of GMO's.
 - 5.2. The GA is the agency responsible for distributing the final report from applicant, inspection reports, and the public comments to the members of the NBC.
 - 5.3. The GA is responsible to ensure the evaluation meeting with the experts.
 - 5.4. The GA is responsible to notify the favorable/unfavorable evaluation report of the environmental release to the applicant and to the public.

6. **Activities:**
 - 6.1. Receive applicant final report.
 - 6.1.1 The GA will receive the final report from the applicant and record them. (Annex A)
 - 6.2. Distribute reports.
 - 6.2.1. The GA will distribute the summary reports of the environmental release inspections and the monitoring reports to the members of the NBC through a Memo. (Annex B)
 - 6.2.2. The GA will inform the public of the availability of the summary reports of the inspections and monitoring (Annex C) conducted for

- an environmental release. The GA will promote public comments on these summary reports and set a period of time for public comments.
- 6.2.2.1. The GA will select a system to communicate to the public the summary reports of the environmental inspections and monitoring.
 - 6.2.2.2. The GA will maintain records of media contracted and copies of media product.
- 6.3. Receive public comments.
 - 6.3.1. The GA will receive and record comments from the public to the aspects of the data established in Annex B within the established limit of time for public comments.
 - 6.4. Receive technical reports.
 - 6.4.1. The GA will record the technical reports from the members/experts of the NBC by the date established in Annex B.
 - 6.4.2. The GA will convene a meeting of members/experts of NBC through a Memo to evaluate the results of the environmental inspections and if applicable, the monitoring reports. (Annex D)
 - 6.5. Evaluate inspection and monitoring reports.
 - 6.5.1. The members/experts of the NBC will evaluate inspections and monitoring reports and public comments and prepare a report of their evaluation for GA. (Annex E)
 - 6.5.1.1. If GMO release report is favorable continue with 6.5.
 - 6.5.1.2. If GMO release is unfavorable continue with 6.7.
 - 6.6. Notify favorable report.
 - 6.6.1. The GA will notify the applicant that the environmental release has been approved and send a memo. (Annex F)
 - 6.6.2. The GA will record in database details of the GMO release approved.
 - 6.7. Communicate to public.
 - 6.7.1. The GA will communicate to the public that the environment release has been approved (Annex G) through the selected PIS, maintaining records of media contract and copies of media product.
 - 6.8. Notify for more information.
 - 6.8.1. The GA will notify the applicants if additional information is required to complete the evaluation (Annex H) within a maximum of _____ working days.
 - 6.9. Notify unfavorable report.
 - 6.9.1. The GA will notify the applicant, through a memo, the non-approval of the GMO environmental release. (Annex I)
 - 6.9.2. The applicant may appeal the GA decision within _____ days after GA's notification following the appeals procedure.
 - 6.9.2.1. If the appeal is received within the time limit continue with the appeal procedure.
 - 6.9.2.2. If no appeal is received within the time limit, continue with 6.8.

- 6.10. Communicate to public.
 - 6.10.1. The GA will communicate to the public the non-approval of the GMO environmental release through the PIS selected, maintaining a record of media contracted and copies of media product.

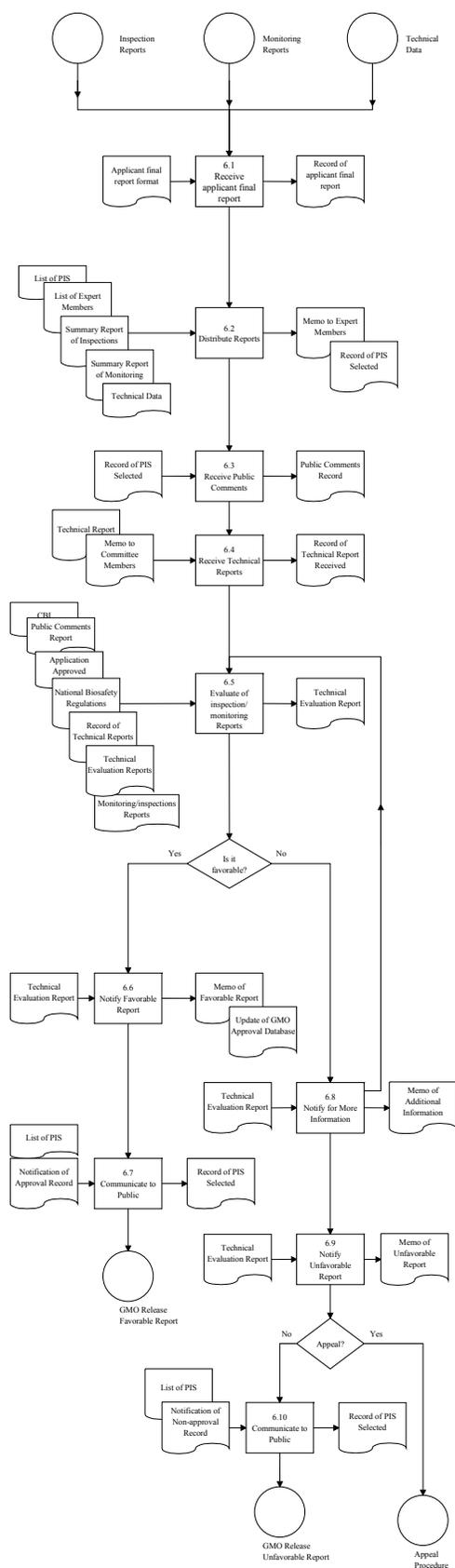
7. Records:

- 7.1. Record of final report from applicant.
- 7.2. Memo for report distribution to NBC members.
- 7.3. Inspections and monitoring information for public.
- 7.4. Memo for GMO release evaluation meeting.
- 7.5. Environmental release evaluation report.
- 7.6. Public comments.
- 7.7. PIS contracted and copy of media report.
- 7.8. Note of the GMO release approved.
- 7.9. Note of the GMO release not approved.
- 7.10. Public communication on GMO environmental release.

8. Flowchart and Annexes:

- 8.1. Flowchart.
- 8.2. Annex A: Applicant Final report Format.
- 8.3. Annex B: Format Memo for Report Distribution to NBC Members.
- 8.4. Annex C: Format of Inspections and Monitoring Information for Public Dissemination.
- 8.5. Annex D: Format Memo for GMO Release Evaluation Meeting.
- 8.6. Annex E: Technical Evaluation Report Format.
- 8.7. Annex F: Format Memo of Favorable Evaluation Report.
- 8.8. Annex G: Format for Public Communication on GMO Environmental Release with Favorable Report.
- 8.9. Annex H: Format Memo to Applicant Requesting Additional Information.
- 8.10. Annex I: Format Memo of Unfavorable Evaluation Report.

TECHNICAL EVALUATION FLOWCHART



ANNEX A

APPLICANT FINAL REPORT FORMAT

- ✓ Application Number
- ✓ Characteristics of the GMO
- ✓ Purpose of the Application
- ✓ Application Request
- ✓ Final Release
- ✓ Description of the site (localization, size, design)
- ✓ Quantity of material sown
- ✓ Quantity of material grown/harvest
- ✓ Effects on the flora, fauna and/or non-target organisms
- ✓ Advantages and competitiveness of the GMO versus the non-transgenic counterpart in natural habitats and in agro-ecosystems
- ✓ Observed phenotypic characteristics, germination, vegetative growth, macroscopic characteristics and yield
- ✓ Agricultural practices
- ✓ Harvest information (quantity, method, date)
- ✓ Consistency with the application protocol
- ✓ Efficacy of the biosafety measures if it is the case
- ✓ Final disposition (describe the final destination of products, method, date, quantity)
- ✓ Any difference or discrepancy with the original protocol
- ✓ Other observations

ANNEX B

**FORMAT MEMO FOR REPORT DISTRIBUTION TO NBC
MEMBERS**

TO: EXPERT (STAFF/NATIONAL BIOSAFETY COMMITTEE)

FROM: GOVERNMENT AUTHORITY

DATE:

APPLICATION NUMBER:

This is in reference to Application # _____ requesting permission to release into the environment of GMO crop, attached are the summary reports of the inspections and monitoring conducted by GA officials. I would be grateful if you would send me your technical report in the next _____ working days. If you require any further information, please do not hesitate to contact me.

AUTHORITY SIGNATURE

ANNEX C

FORMAT OF INSPECTIONS AND MONITORING INFORMATION FOR PUBLIC DISSEMINATION

- APPLICATION NUMBER
- INSTITUTION/APPLICANT
- PLANTS SPECIES AND COMMON NAME
- TRANSGENIC PHENOTYPE
- TRANSFORMATION EVENT OR LINE
- TYPE OF RELEASE
 - Greenhouse
 - Field
- LOCATION (s) OF THE RELEASE (if more than one list separately)
- DATE(s) OF INSPECTION/MONITORING (if more than one list separately)
- RESULT OF THE INSPECTION/MONITORING

ANNEX D

FORMAT MEMO FOR GMO RELEASE EVALUATION MEETING

TO: EXPERT STAFF/NBC MEMBERS

FROM: GOVERNMENT AUTHORITY

DATE:

APPLICATION NUMBER:

You are hereby convened to participate on _____ (date & time) to evaluate the final inspection and monitoring reports for Application # _____. This meeting will take place at _____ (address). The evaluation of these reports will be made in the form of a final report to the G.A. If you are unable to participate, please send your written comments by _____ (date).

AUTHORITY SIGNATURE

ANNEX E
TECHNICAL EVALUATION REPORT FORMAT

- APPLICATION NUMBER:
- DATE:
- APPLICANT NAME:
- PLANT SPECIES AND COMMON NAME:
- PHENOTYPE:
- TRAIT/GENE:
- DESCRIPTION OF INSERTED GENES:
- DESCRIPTION OF DNA SEQUENCES:
- TYPE OF RELEASE:
 - Greenhouse
 - Field
- LOCATION(s): (if more than one list separately)
- DATE OF INSPECTION:
- SURVIVAL CAPACITY:
- POTENTIAL OUTCROSSING:
- SUSCEPTIBILITY TO DISEASE AND PESTS:
- INTERACTIONS WITH SEXUALLY COMPATIBLE SPECIES:
- EFFECTS ON NON-TARGET ORGANISMS:
- EFFECTS ON FLORA AND FAUNA:
- ADVANTAGES AND COMPETITIVENESS OF THE GMO:
- EFICACY OF THE BIOSAFETY MEASURES:
- FINAL DISPOSITION/ DEVITALIZATION:

ANNEX F

FORMAT MEMO OF FAVORABLE EVALUATION REPORT

TO: APPLICANT INSTITUTION

FROM: GOVERNMENT AUTHORITY

DATE:

APPLICATION NUMBER:

I hereby inform you that your Application # _____ requesting permission to release into the environment the GMO (crop/phenotype) has been evaluated with a favorable report. Attached is the technical report for your information.

AUTHORITY SIGNATURE

ANNEX G

FORMAT FOR PUBLIC COMMUNICATION OF A GMO ENVIRONMENTAL RELEASE WITH A FAVORABLE REPORT

- APPLICATION NUMBER
- INSTITUTION/APPLICANT
- CROP PLANT SPECIES AND COMMON NAME
- TRANSFORMATION EVENT OR LINE
- TRANSGENIC PHENOTYPE
- LOCATION (S)
- TYPE OF RELEASE
 - Greenhouse
 - Field
- PERFORMANCE STANDARDS

ANNEX H

**FORMAT MEMO TO APPLICANT REQUESTING ADDITIONAL
INFORMATION**

TO: APPLICANT/INSTITUTION

FROM: GOVERNMENT AUTHORITY

DATE:

APPLICATION NUMBER:

After the revision of your application # _____ to release into the environment the GMO (crop/phenotype) including the results of the inspections and monitoring, I request that you would send more information about _____.
That information must be submitted in the next _____ working days; otherwise we will not be able to continue with the evaluation.

AUTHORITY SIGNATURE

ANNEX I

FORMAT MEMO OF UNFAVORABLE EVALUATION REPORT

TO: APPLICANT INSTITUTION

FROM: GOVERNMENT AUTHORITY

DATE:

APPLICATION NUMBER:

Upon review of the information contained in your application # _____ your request for permission to conduct an environmental release has been denied. Enclosed is the technical report on which the decision to deny your request is based. If you disagree with the findings of the technical report, you may opt to appeal. In accordance to the regulations, you have _____ working days from the date of this communication to lodge your appeal.

AUTHORITY SIGNATURE

8- PROCEDURE FOR APPEAL

When an application for permission to conduct an environmental release of a GMO is denied, or approved under specific conditions, the applicant may appeal the GA's decision through an appeals procedure within an allowable time limit.

The GA is responsible for receiving the appeal and reviewing the observations presented by the appellant. The GA will prepare a preliminary report taking into account the considerations of the appellant and arrange a meeting between the National Biosafety Committee/experts and the appellant.

The purpose of the meeting is to give the appellant an opportunity to present and debate the merits of the appeal with the NBC/experts. Based on the evaluation and discussion the NBC/experts will review the appeal and prepare a report to the GA.

If the decision taken by the GA is favorable, the GA will notify the appellant that their appeal has been accepted therefore the permission for conducting an environmental release of a GMO is approved.

If the decision is unfavorable the legal department must review the decision report based on legal aspects to ensure the compliance of all legal processes and then the government agency will notify the appellant the disapproval of the release into the environment of agricultural GMO.

APPEALS PROCEDURE

GOVERNMENT AGENCY

Authorization Date

Effective Date

Created by

Approved by

1. **Purpose:**
 - 1.1. The objective of this procedure is to define the procedures to be followed to appeal a decision taken by the G.A.

2. **Scope:**
 - 2.1. From the reception of the appeal to the report of the final decision.

3. **References:**
 - 3.1. Biosafety regulations, standards.
 - 3.2. Legal procedures.

4. **Definitions:**
 - 4.1. GA: Government agency.
 - 4.2. NBC: National Biosafety Committee.

5. **Responsibility and Authority:**
 - 5.1. The GA is responsible of receiving the appeal, establishing the date to meet with the NBC, and obtaining reports and previous documents.
 - 5.2. The NBC is responsible of publishing a report of the meeting's discussion and findings.
 - 5.3. The GA is responsible for making a decision, which will be considered definitive.
 - 5.4. The legal department is responsible for analyzing the final decision and publishing a report.

6. **Activities:**
 - 6.1. Receive appeal.
 - 6.1.1. The GA will receive and record the appeal request with the allowable time limit. (Within 60 days after the notification) (Annex A)
 - 6.2. Review appeal.
 - 6.2.1. The GA will review the appeal request and make a preliminary report in a period of time of _____ working days.
 - 6.2.2. The GA will schedule a date to have a meeting with the members of the NBC and the appealing company.
 - 6.3. Meeting with the appellant.
 - 6.3.1. The GA will convene the meeting with the NBC and the appellant. (Annex B)
 - 6.4. Review Decision.
 - 6.4.1. After the meeting, the GA will make a decision within the legal period established by the country.
 - 6.4.1.1 If the decision is favorable the GMO will be approved.
 - 6.4.1.2 If the decision is to uphold the GA decision, continue with
 - 6.5.

- 6.5. Review by the legal department.
 - 6.5.1. The legal department will review the appeal, the preliminary report, and the decision report and will report its conclusions.
- 6.6. Notify the appellant.
 - 6.6.1. The GA with the legal report and the decision report will notify the definitive decision to the appellant.

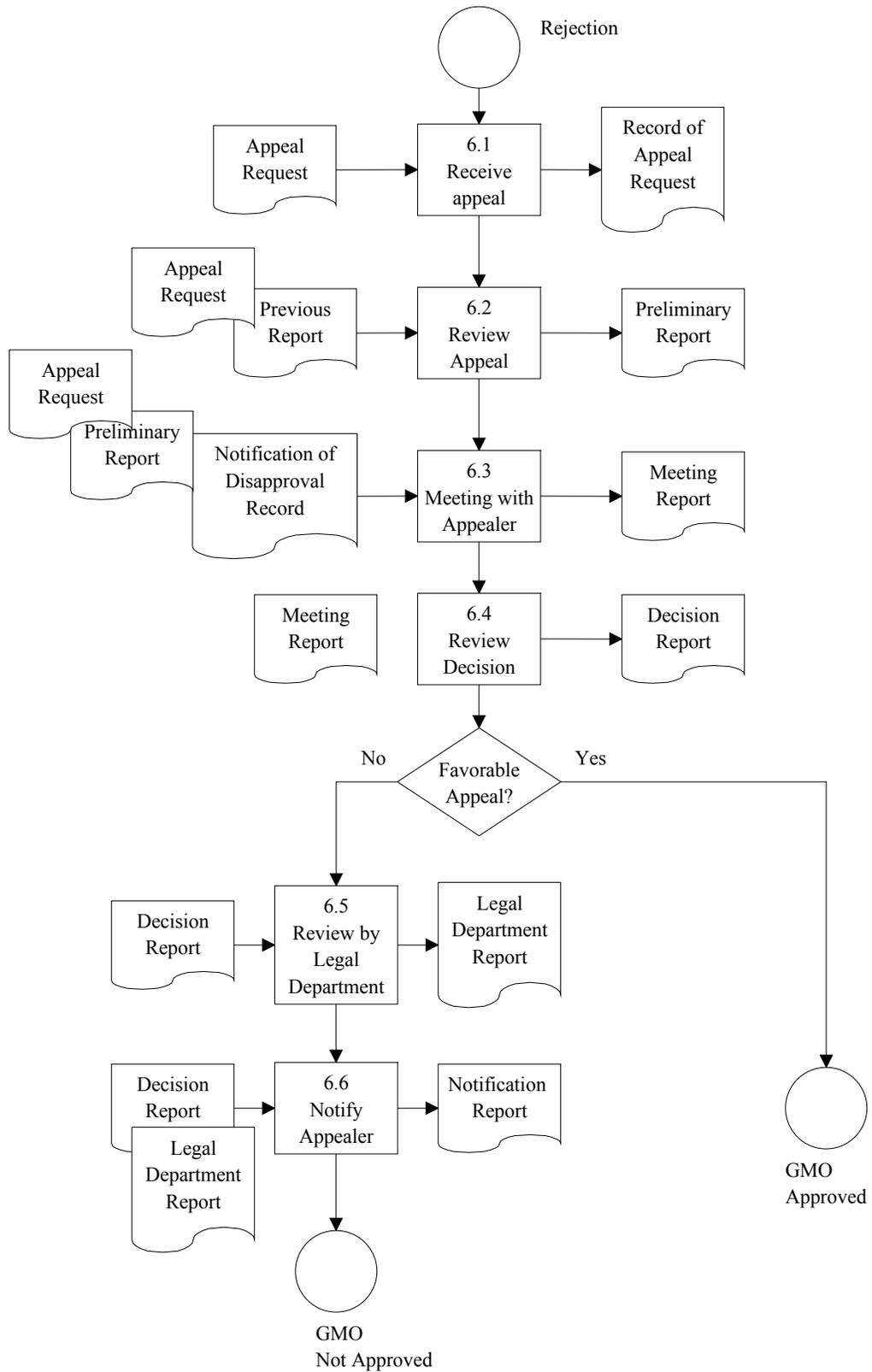
7. Records:

- 7.1. Record of appeal request.
- 7.2. Preliminary report.
- 7.3. NBC meeting report.
- 7.4. Decision report.
- 7.5. Report of the legal department.
- 7.6. Notification report.

8. Flowchart and Annexes:

- 8.1. Flowchart.
- 8.2. Annex A: Format Memo for Appeal request.
- 8.3. Annex B: Format Memo for Appeal Meeting.

FLOWCHART: APPEALS PROCEDURE



ANNEX A

FORMAT MEMO FOR APPEAL REQUEST

TO: GOVERNMENT AUTHORITY

FROM: APPLICANT

APPLICATION NUMBER:

DATE:

I have been notified of the denial of my permission to conduct a field release of my application # _____. I wish to exercise my right to appeal the decision. In accordance with your procedures, I am filing this appeal within the established time limits and annexing pertinent additional information.

APPLICANT SIGNATURE

ANNEX B

FORMAT MEMO FOR APPEAL MEETING

TO: APPLICANT AND NBC/EXPERTS

FROM: GOVERNMENT AUTHORITY

APPLICATION NUMBER:

DATE:

I hereby notify you that your participation is need for an appeal meeting. The meeting will be held on _____ (date) in _____ (address) at _____ (time). During the meeting we will discuss the technical aspects presented in the applicant's appeal.

AUTHORITY SIGNATURE

9- DOCUMENT CONTROL PROCEDURE

GOVERNMENT AGENCY

Authorization Date

Effective Date

Created by

Approved by

1. **Purpose:**
 - 1.1 Identify events, actions, activities and responsibilities involved in the creation, identification, approval, distribution, and storage of controlled documents.

2. **Scope:**
 - 2.1 From the document and data identification to the implementation of their control. This will be applied to documents and data related to release into the environment of GMO's.

3. **References:**
 - 3.1 Model for Document Generation

4. **Definitions:**
 - 4.1 Document: Procedures, work instructions, references, specifications or regulatory material for the administration of the system.
 - 4.2 Data: Quantified information in documents.
 - 4.3 Controlled document: Documents formally identified. These documents are registered, maintained and their change, as well as, their implementation is regulated.
 - 4.4 Procedure: Document that describes, "Who does the job", "when", "where", and "why".
 - 4.5 Work instructions: Document that identifies the procedures to perform a task or activity.
 - 4.6 Internal document: Document generated outside the limits of the administrative system for example: a regulatory document that is referred to a procedure or work instruction.
 - 4.7 Master List: List that contains information related to documents and includes information such as documents titles, revision number and document codes.

5. **Responsibility and Authority:**
 - 5.1 The GA will assure that the control of documents is conducted following this procedure.

6. **Activities:**
 - 6.1 Identify Documents:
 - 6.1.1 Any representative of the GA that needs a new controlled document will inform the GA, which will determine whether or not to proceed with the request and create the Master List of Controlled Documents.
 - 6.2 Create Documents:
 - 6.2.1 If the Document does not exist, the GA will assure that this Document is created. The procedures and work instruction will be prepared following the model approved by GA.

- 6.3 Review Document:
 - 6.3.1 If the document already exists, the GA will review it to assure that the information is current and achieves the needs of the system, and that it is on the Document Master List. If the document is not adequate, the GA will modify the internal document according to the activity 6.5
 - 6.3.2 The GA before their approval will review the new documents.
- 6.4 Approve Document:
 - 6.4.1 Changes in the procedures won't be allowed, except for those related to work instructions and identification of responsibilities.
 - 6.4.2 The GA will review and approve the new document to verify its precision.
- 6.5 Request Document Change:
 - 6.5.1 Any representative of the GA can request any change to the documents through the Document Change Application. The GA will evaluate the application as well as its consequences and will either authorize it or not.
 - 6.5.2 The modified document will be controlled through the activity 6.6
- 6.6 Control Documents:
 - 6.6.1 The _____ of GA will assure that:
 - 6.6.1.1 The Master List of Controlled Documents is kept in both hardcopy and electronically.
 - 6.6.1.2 The controlled documents are available and identified in the Master List.
 - 6.6.1.3 These documents are stamped as "controlled document".
 - 6.6.1.4 In the case that the elements of the system are kept electronically (in red), the obsolete documents will be identified and removed to prevent use.
 - 6.6.1.5 Confidential documents will be identified with the stamp and will handle by authorized personnel who will be identified in the work instructions.
 - 6.6.2 Obsolete Documents:
 - 6.6.2.1 The GA will discard either the obsolete documents or file them. The word "OBSOLETE" will be stamped on the cover page or diskette, and they will be filed in the section of obsolete documents.
 - 6.6.3 Photocopies:
 - 6.6.3.1 Photocopies and printouts of controlled documents will be made just for internal training and revisions. Photocopies of confidential documents are not allowed under any circumstance.
- 6.7 Distribute Documents.
 - 6.7.1 The GA will determine a date for the document to become valid.
 - 6.7.2 The GA will distribute the new document.

- 6.8 Inform the concerned personnel and institutions.
 - 6.8.1 The GA will assure that the concerned personnel understand the content of the new document or any change made to the original documents.
 - 6.8.2 The GA will provide the training to the personnel when necessary to achieve the new requirements.
- 6.9 Ensure the access.
 - 6.9.1 The GA will ensure that documents of reference are available.

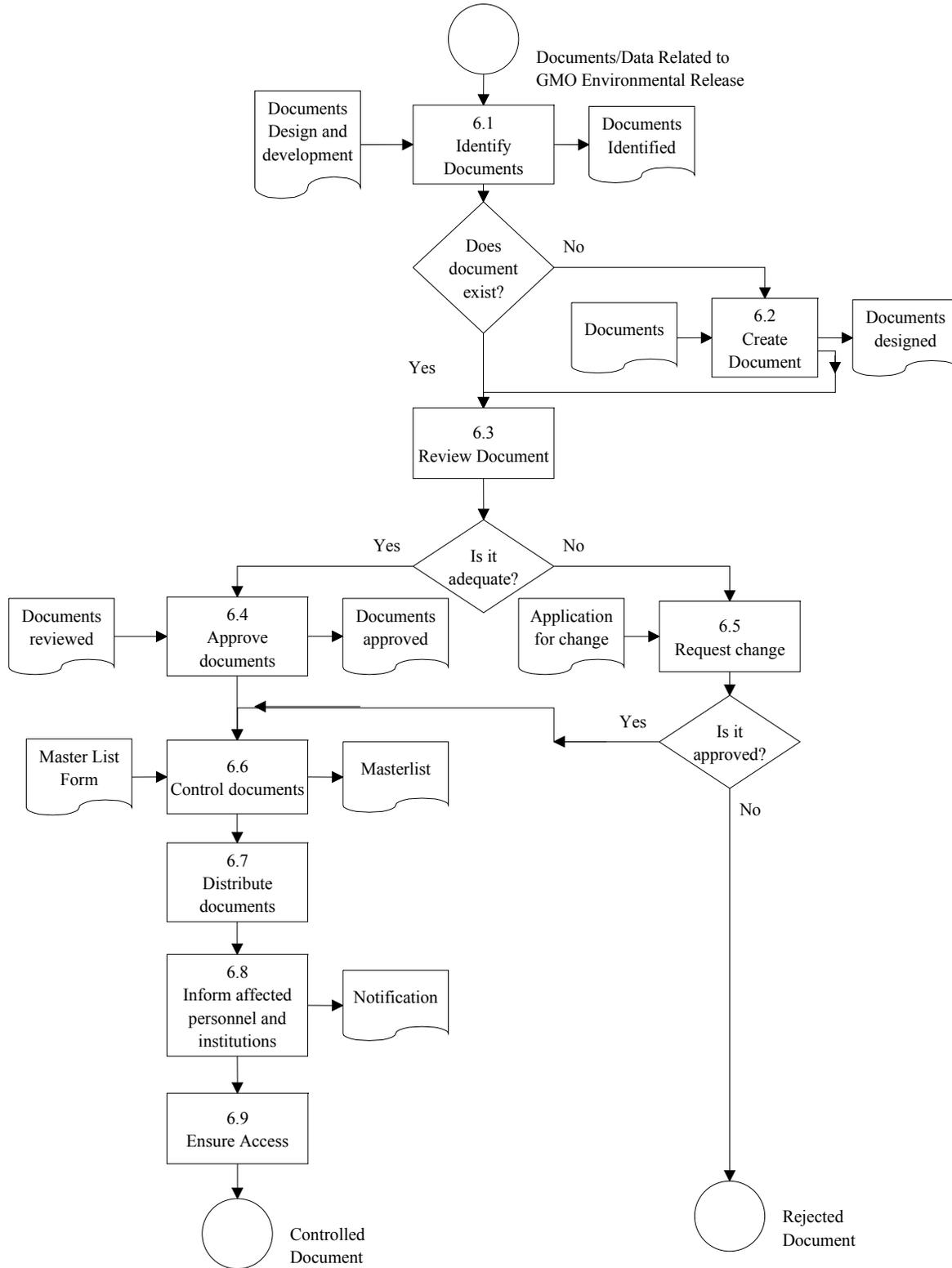
7. Records:

- 7.1 Master List of Controlled Documents.

8. Flowchart and Annexes:

- 8.1 Flowchart.
- 8.2 Annex A: Controlled Documents Master List.
- 8.3 Annex B: Document Change Application.

DOCUMENT CONTROL PROCEDURE FLOWCHART



ANNEX B

DOCUMENT CHANGE APPLICATION

CHANGE REQUESTED BY		APPLICATION DATE:			
DOCUMENT TITLE					
CHANGE REQUESTED					
REASON					
RECOMMENDATION (SELECT ONE)					
<input type="checkbox"/> REJECT (reason)					
<input type="checkbox"/> ACCEPT WITH CHANGES (explain)					
<input type="checkbox"/> ACCEPT					
IF ACCEPTED		SUGGESTED DATE		VALID SINCE	
TRAINING					
RECEIVED BY COORDINATOR OF DOCUMENT CONTROL:			DATE		
AUTHORIZATION			DATE		

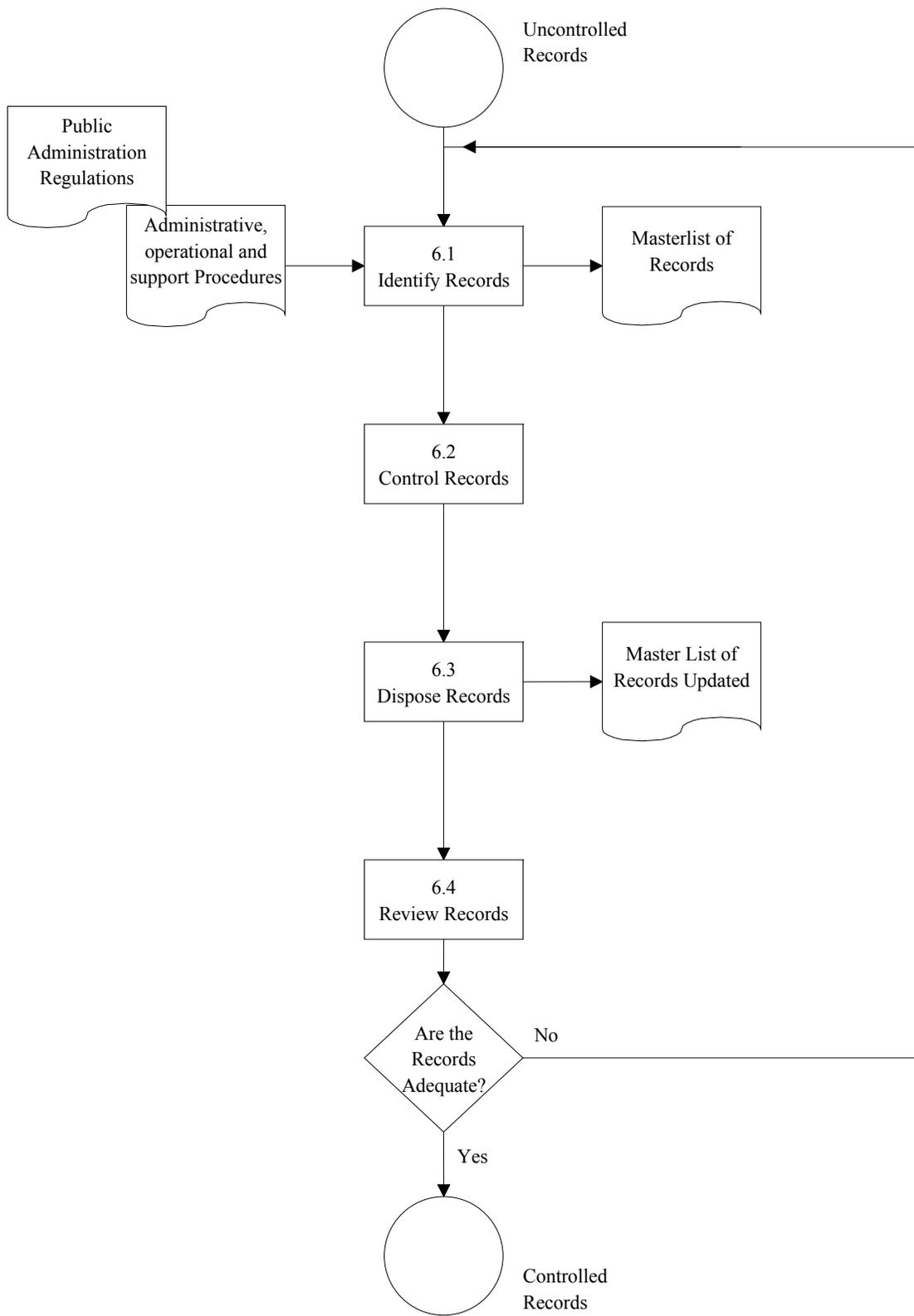
10- RECORD CONTROL PROCEDURE

GOVERNMENT AGENCY

Authorization Date	<input type="text"/>
Effective Date	<input type="text"/>
Created by	<input type="text"/>
Approved by	<input type="text"/>

1. **Purpose:**
 - 1.1 The objective of this procedure is to define the events, actions, interfaces and responsibilities involved in the identification, collection, file, access, storage, maintenance, and discharge of records.
2. **Scope:**
 - 2.1 From records that have been generated through the procedures of release into the environment of GMO's.
3. **References:**
 - 3.1 Administrative, Operational, and Support Procedures.
 - 3.2 Regulations of Public Administration.
 - 3.3 Master List of Records.
4. **Definitions:**
 - 4.1 Record: Document (electronic or print), product or sample statement, which will confirm that a procedure (or part of the procedure) has been carried out.
 - 4.2 Controlled Record: is a record that requires being kept and maintained under safeguard for future reference in an audit and/or for traceability of a result.
5. **Responsibility and Authority:**
 - 5.1 The _____ of GA is responsible to identify, collect, file, store, discharge and review records.
6. **Activities:**
 - 6.1 Identify Records.
 - 6.1.1 The GA will identify the records to be controlled, as indicated by the Administrative, Operational and Support Procedures and the Public Administration Regulation and will be included in the Master List of Records.
 - 6.2 Control Records.
 - 6.2.1 The _____ of GA will collect, file, and keep the records.
 - 6.2.2 The _____ of GA will control the access to the records.
 - 6.3 Dispose Records.
 - 6.3.1 The GA will periodically evaluate the Master List of Records and will dispose of obsolete and unnecessary records.
 - 6.4 Review Records.
 - 6.4.1 The GA will prepare a record review schedule with the purpose of verifying if the records are created and maintained in an adequate manner.
7. **Records:**
 - 7.1 Master List of Records.
8. **Flowchart and Annexes:**
 - 8.1 Flowchart.
 - 8.2 Annex A: Master List of Records.

RECORD CONTROL PROCEDURE FLOWCHART



11- REFERENCES

- Cartagena Protocol on Biosafety to the Convention on Biological Diversity (2000).
- MODEL ACT Proposed Provisions for Transparent, Effective and Workable Biosafety Regulatory Framework. Stanley Abramson, Laura Reifschneider (2002).
- International Technical Guidelines for Safety in Biotechnology. UNEP United Nations Environment Programme (1995).
- Biosafety Frameworks Addressing the Release of Plant LMOs. Crop Life International (2003).
- Biosafety and Risk Assessment in Agriculture Biotechnology, A Workbook for Technical Training. Traynor, Frederick, Koch. (2002).
- Biosafety Regulation: Analysis of International Approaches. MacKenzie, McLean, World Bank Group (2002).
- Report of the Working Group on Harmonization of Regulatory Oversight in Biotechnology, OECD (2000).
- Consensus Document on the Biology of Glycine Max. Series on Harmonization of Regulatory Oversight in Biotechnology OECD (2000).
- The Release of Genetically Modified Crops into the environment. Part I, II. Cornner, Glare and Nap. Plant Journal (2003).
- Genetically Modified Crops L. Fresco FAO Agriculture Department.
- Report of the Inter-Departmental Working Group on Biotechnology to the 17 Session of FAO's Committee on Agriculture COAG (2003).
- Draft Guidelines on Access to Information, Public Participation and Access to Justice to Genetically Modified Organisms. Economic and Social Council UNITED NATIONS (2002).
- Developing National Frameworks for Biosafety Regulation M. McLean Presentation World Bank (2003).
- Genetically Engineered Organism and Products Regulation for Notification and Permits. Department of Agriculture USDA 7CFR Part 340, Animal and Plant Health Inspection Service (1997).
- Guide for Preparing and Submitting a Petition for Genetically Engineered Plants USDA, Animal and Plant Health Inspection Service, (1996).

- Biotechnology Inspection Manual for Notification Field Release USDA, (2002).
- Pesticide Registration and Classification Procedures 40 CFR Parts 152 and 174; Experimental Use Permits 40 CFR Part 172. U.S. Environmental Protection Agency.
- A practical Guide to Containment. Virginia Polytechnic Institute and State University. Traynor, Adair, Irwin (2001).
- Guidelines for Toxicity and allergenicity Evaluation of Transgenic Seeds, Plants and Plants Parts. Ministry of Science and Technology of India (1998).
- Biosafety Regulations of Brazil “Cadernos de Biosseguranza”. (2001).
- Regulations and Guidelines for Biosafety in Biotechnology for Kenya, National Council for Science and Technology (1998).
- Regulation and Guidelines for Biosafety of GMO IN Argentina. CONABIA, SAGPYA (2002).
- Analysis of National Biosafety System: Regulatory Policies and Procedures in Argentina, Burachik, Traynor ISNAR Report (2002).
- Council Directive 90/220/EEC, Directive 2001/18/EC Deliberate Release into the Environment of GMO.
- Genetically Modified Organisms Act N 15/1997 Department of Agriculture South Africa (1997).
- Post Market Oversight of Biotechnology Food. Pew Initiative on Food and Biotechnology. Taylor and Tick (2003).
- An Introduction to the Cartagena Protocol on Biosafety. Secretariat of CBD and UNEP (2003).
- Cartagena Protocol on Biosafety: From Negotiation to Implementation. Secretariat CBD and UNEP (2003).
- Report of the Expert Working Group on PRA for LMO s. Draft Supplement to ISPM11 for the Pest Risk Analysis of LMO s, International Plant Protection Convention, (2002).
- Issues in the Regulation of Genetically Engineered Plants and Animal. Pew Initiative (2004).
- Public Participation in National Biotechnology Policy and Biosafety Regulation. Glover Institute of Development Studies UK (2003).

- Biological Confinement of Genetically Engineered Organisms, National Research Council of National Academies, 2004.
- Glossary of Biotechnology for Food and Agriculture, FAO and Research Technology Paper, by A. Zaid, H. Hughes, E. Porceddu, F. Nicholas, FAO, Rome 2001.

12- GLOSSARY OF TERMS

Applicant: a legal or natural person applying for the authorization for the environmental release of a genetically engineered organism.

Biodiversity: The total variability within and among species of living organisms and their habitats.

Biosafety: the goal of ensuring that the development and use of genetically engineered organisms and products made from them do not negatively affect plant, animal or human health; genetic resources; or the environment.

Biotechnology: the use of biological processes to solve problems or make useful products.

Confinement: isolation of an organism from its environment, including other sexually compatible plants using biological, spatial, temporal and genetic mechanisms.

Construct: an engineered DNA fragment designed to be transferred into a cell or tissue. The construct comprises the gene or genes, a marker gene and appropriate control sequences as a single package.

Containment: a) Physical isolation of an organism from its environment; b) measures and protocols applied to limit contact of genetically engineered organisms with external environment; c) use of physical means (e.g., greenhouses, indoor growth facilities, isolated locations) and/or biological methods (e.g. male sterility, flower removal) to ensure that the organism or genetic material (in form of propagative structures, seeds, pollen) is released into the environment.

Conventional Counterpart: means a related organism/variety, its components and/or products for which there is experience of establishing safety.

DNA: deoxyribonucleic acid, the material of which genes are made, a linear molecule consisting of a sequence of chemical subunits called bases which encodes genetic information in the sequences of bases.

R-DNA: recombinant DNA is a piece of DNA carrying genetic information and is inserted into DNA of a cell, virus or organism by cutting and rejoining in vitro.

Donor: the organism from which genetic material is derived for insertion into or combination with another organism.

Ecosystem: means a dynamic complex of plant, animal and micro-organism communities and their non-living environment interacting as a functional unit.

Environment: components of the earth, including air, land, water, all layers of the atmosphere, all organic and inorganic matter and living organisms and all natural systems that interact with them.

Environmental release: the controlled, intentional testing of genetically engineered organisms outside the confinement structure.

Environment risk assessment: the evaluation of the risk and potential harm to human health and the environment.

Expression: manifestation of a characteristic that is specified by a gene often means the production of a protein by a gene that has been inserted into a host organism.

Event: is the insertion of a particular transgene into a specific location on a chromosome. The term event is often used to differentiate genetically engineered crop varieties.

Familiarity: means having enough information to be able to judge the safety of the introduction or to indicate ways of handling the risks.

Field test: experimentation with crops in a field situation to evaluate several parameters such as phenotype traits and agronomic performance.

Gene: the physical and functional unit of heredity transmitted from generation to generation during sexual and asexual reproduction. Also, the term is used in relation to the transmission and inheritance of particular identifiable traits.

Gene flow: a) the exchange of genes in one or both directions at a low rate between different related and sexually compatible populations; b) the horizontal movement of genes through pollen's transfer among related or unrelated plant species; c) the spread of genes from one breeding population to another population.

Genetic engineering /genetic modification: a) Modifying an organism's genetic makeup by the introduction of a gene or genes into its cells in a way that allows transfer of the gene to successive generations; b) the process of intentionally altering the genetic of an organism, usually by insertion of one or more genes and/or regulatory sequences that may come from the same or any other organism.

Genetically modified organism (GMO): Term used to identify organisms in which the genetic material has been altered by use of molecular techniques. An organism that has been transformed by the insertion of one or more genes.

Genotype: genetic makeup of an individual or group. Compare Phenotype

Genome: the entire complement of genetic material present in each cell of an organism.

Hazard: the potential of an organism to cause harm to human health and/or the environment; also may be referred to as "adverse effect".

Host: a cell or organism used for growth of a virus, plasmid or other form of foreign DNA, or for the production of cloned substances.

Host-vector system: combination of DNA-receiving cells (host) and DNA-transporting substance (vector) used for introducing foreign DNA into a cell.

Isoenzyme: one of the several forms that a given enzyme can take. The forms may differ in certain physical properties, but function similarly as biocatalysts.

Modern Biotechnology: means the application of: a) in vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells and organelles, or b) fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

Nucleic acids: A macromolecule consisting of polymerized nucleotides. Two forms are found, DNA and RNA. Nucleic acids may be linear or circularized and single or double-stranded.

Organism: Any biological entity able to replicate or transfer its own genetic material.

Phenotype: the observable characteristics of an organism, the expression of gene alleles (genotype), as an observable physical or biomedical trait.

Promoter: a short DNA sequence to which the RNA polymerase and certain regulating molecules bind to initiate synthesis from a DNA template. A DNA sequence associated with a gene that determines under what conditions that gene is expressed.

Risk: the combination of the magnitude of the consequences of hazard, if it occurs and the likelihood that the consequences will occur.

Risk assessment: the measures to estimate what harm might be caused, how likely it would be to occur and the scale of the estimated damage.

Risk communication: is an interactive process of risk information and opinion among individuals, groups and institutions.

Risk management: the measures to ensure that the production and handling of an organism are safe.

Trait: one of the many characteristics that define an organism. The phenotype is a description of one or more traits. Synonym: character.

Transformation: The uptake and integration of DNA in a cell, in which the introduced DNA is intended to, change the phenotype of the recipient organism in a predictable manner. The introduction and assimilation of DNA from one organism by another.

Transgenic: An individual in which a transgene has been integrated into its genome. In transgenic eukaryotes, the transgene must be transmitted through meiosis to allow its inheritance by the offspring.

Transgenic organism: an organism formed by the insertion of foreign genetic material into the germ line cells of organisms. Recombinant DNA techniques are commonly used to produce transgenic organisms.

Toxicity: The extent to which a toxic compound negatively affects a given trait.

Toxin: a biological compound produced by one organism that is deleterious to the growth and/or survival of another organism.

Vector: a self-replicating agent (like a plasmid or virus) used to deliver DNA into a cell. An organism or object used to transfer genetic material from a donor to a recipient organism.

Weediness: the plant phenotype of interfering with human activities, being a nuisance in agronomic settings and/or disrupting native ecosystems.