Standard Operating Procedures Regarding Environmental Risk Assessment and Management of Genetically Modified Plants Based on the Cartagena Act

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Ministry of Agriculture, Forestry and Fisheries

Food Safety and Consumer Affairs Bureau,

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Chapter I: Introduction

I. 1. Introduction

Fourteen years have passed since the world's first commercial cultivation of a genetically modified crop (GM crop) started in the United States, in 1996. Since then, GM crops such as corn and soybeans with herbicide-tolerant or insect-resistant traits have been developed and become prevalent rapidly. In 2006, the total area of GM crop cultivation exceeded 100 million hectares throughout the world.

Meanwhile, the food safety of crops developed by the genetic recombination technique and their effects on biological diversity must be evaluated. An international agreement, the "Cartagena Protocol on Biosafety to the Convention on Biological Diversity" was adopted in 2000 for preventing adverse effects on biological diversity.

Ratifying this Cartagena Protocol, the "Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms" ("Cartagena Act" in short) was enacted in Japan, 2003. Regulatory frameworks are established by this Act, including: before the use of the living modified organism ("LMO" in short), the competent minister approves the use of the LMO only if it is confirmed that the organism has no adverse effect on biological diversity based on a result of the risk assessment.

Currently, crops with new characteristics have been developed and commercially used in the world, for example, some GM crops can produce fatty acid such as docosahexaenoic acid (DHA) contained in fish oil that is said to reduce the risk for heart diseases, and others are more tolerant to drought. The use of GM crops is about to enter a new phase.

It is required to maintain the frameworks to properly conduct environmental risk assessment of GM crops based on the Cartagena Act when GM crops are commercially used with such new traits, in addition to herbicide tolerance and insect resistance. GM crops should not be approved if its adverse effect on biological diversity is confirmed. Only those without any adverse effect should be distributed.

Many people in Japan still have concerns about GM crops. Considering the reasons why, it may be because information dissemination is not sufficient regarding the risk assessment and management framework, besides the framework is complicated and genetic recombination techniques are developed rapidly. These matters should be improved.

As a part of improvements, we decided to formulate Standard Operating Procedures regarding

environmental risk assessment and management of GM crops, so as to contribute to establishing frameworks for reviewing applications, monitoring and so on in a more transparent and consistent manner.

These “Standard Operating Procedures” are developed with reference to the ideas of the risk analysis on food safety. These reveal the standard procedures that are required for the staff in charge of environmental risk management in the Ministry of Agriculture, Forestry and Fisheries (MAFF) to prevent adverse effects of genetically modified plants on biological diversity based on the Cartagena Act.

These “Standard Operating Procedures” will be revised as necessary while they are in place.

I. 2. Definitions

For the purpose of these "Standard Operating Procedures" (SOP in short), the following terms shall have the meaning as defined below.

Term	Definition
Cartagena Act	The Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Act No. 97 of June 18, 2003). The Regulations for Enforcement of this Act (Ministerial Ordinance No. 1 of 2003 of the Ministry of Finance, Ministry of Education, Culture, Sports, Science and Technology; Ministry of Health, Labour, and Welfare; MAFF; Ministry of Economy, Trade and Industry; and Ministry of the Environment) is hereinafter called "Regulations for Enforcement".
Genetically Modified Plant (GM plant)	A plant (including a fruit tree and a flower) whose hereditary properties are modified with the use of genetic recombination technique and which has the capability of self-propagation under natural conditions. This term refers to the plant for agriculture or forestry whose production and distribution are under the jurisdiction of MAFF, among "living modified organisms (LMOs in short)" stipulated in Article 2 (2) of the Cartagena Act.
Biological Diversity	Variability among all living organisms. It includes diversity within species, between species and of ecosystems. Above definition is stipulated in Article 2 of the Convention on Biological Diversity and Article 2 (4) of the Cartagena Act.
Adverse Effect on Biological Diversity	Adverse effect that is caused by the use of LMO and has possibility to impair biological diversity. Above definition is stipulated in Article 3 (i) of the Cartagena Act.
Risk	Possibility and significance of adverse effect on biological diversity caused by the use of LMO.
Risk Analysis	A framework to prevent adverse effects on biological diversity or minimize risks in case there are possibilities of such effects resulting from the use of LMOs. It consists of three elements, that is, risk assessment, risk management,

	and risk communication.
Risk Management	Examination, decision, implementation, of proper policies and measures to reduce risks after consideration on technical feasibility and cost-benefit analysis regarding such policies and measures, in consultation with stakeholders. It also includes revision of the policies and measures.
Risk Manager	The department in charge of the risk management. In the purpose of these SOP, it is the department which is in charge of the Cartagena Act in MAFF.
Risk Assessment	Scientific assessment of the probability and the significance of adverse effect on biological diversity caused by the use of LMO.
Risk Communication	Mutual exchange of information and opinions with stakeholders in the whole process of risk analysis.
Stakeholders	All people who are involved in or affected by the use of GM plants or risk management measures. This term refers to consumers, farmers, enterprises, people who are involved in risk analysis, researchers, developers of GM plants, academia and so on.
Appropriate Level of Protection	A level of protection deemed appropriate to protect biological diversity from adverse effects of GM plant uses, which is considered to set environmental risk management measures.
Use	The act of using GM plants as food, animal feed or other purposes, and cultivating, processing, storing, transporting, and discarding them. Above definition is stipulated in Article 2 (3) of the Cartagena Act.
Type 1 Use	The act of using LMOs outside facilities, equipment or other constructions without containment measures. A definition is stipulated in Article 2 (5) of the Cartagena Act. With regards to GM plants, Type 1 Use covers an experimental use in the field (“confined field trial”) as well as “general use” applied for commercial use such as cultivation in open fields and commercial distribution as foods or feeds.

Type 1 Use Practice

A practice for Type 1 Use such as cultivation of a GM plant. It sets the measures to prevent adverse effects of the GM plant on biological diversity according to its characteristics.

People or companies who wish to conduct Type 1 Use of LMO must stipulate a Type 1 Use practice and must obtain approval for it from the competent ministers. Above definition is stipulated in Article 4 (1) of the Cartagena Act.

Assessment Report

This report states a result of risk assessment concerning adverse effects on biological diversity arising from a Type 1 Use. It contains basic properties of a recipient plant (host) of the GM plant in question; what new gene(s) was introduced to the plant; whether there is any wild fauna and flora in Japan that are likely affected by the Type 1 Use in question; and the possibility of adverse effects on biological diversity, etc.

After an application submitted, following points will be checked in a process of review including consultation with experts: whether there is sufficient data so as to predict adverse effects on biological diversity; whether the contents of application documents are scientifically appropriate, whether they are based on the latest scientific knowledge. Data will be added and/or texts will be improved if they are insufficient.

In Article 4 (2) of the Cartagena Act, the report is stipulated as a "Biological Diversity Risk Assessment Report," but in these SOP, the term "Assessment report" means any types of drafts, that is, from the one before an application to the final one which approval is being discussed.

Risk Assessment Policy

For judging an approval of a Type 1 Use practice, this states a policy of risk assessment regarding the possibility of adverse effects of a GM plant in question on biological diversity. Risk management measures are established taking into account the appropriate level of protection as well as the result of risk assessment which is based on the policy.

Among elements of risk assessment policy, general items are described in "the Guidance for Assessment and Management" (*see the next term*), which are required for risk assessment in a scientific and proper manner, and for drafting an assessment report appropriately.

For example, in case that a host plant or an introduced trait of a GM plant

in question is new so that there is no experience in assessing its risk, the risk managers will consider whether a supplementary risk assessment policy is to formulate. They will also examine how such policy supplements the existing risk assessment policy stipulated in "the Guidance for Assessment and Management".

Guidance for Assessment and Management

Documents that state the general items required for assessing and managing risks in a scientifically appropriate manner.

They state points and procedures of risk assessment, requirements of a confined field trial, and conditions for a monitoring activity. The concrete items are stipulated as the following notifications:

1) "Basic Matters under the provisions of Article 3 of the Cartagena Act" (Ministerial Public Notice No. 1 of 2003 of the Ministry of Finance; Ministry of Education, Culture, Sports, Science and Technology; Ministry of Health, Labour, and Welfare; MAFF; Ministry of Economy, Trade and Industry; and Ministry of the Environment);
2) "Guidance of Implementation of Assessment of Adverse Effects on Biological Diversity of Type 1 Use of LMOs" (Ministerial Public Notice No. 2 of 2003 of the Ministry of Finance; Ministry of Education, Culture, Sports, Science and Technology; Ministry of Health, Labour, and Welfare; MAFF; Ministry of Economy, Trade and Industry; and Ministry of the Environment); and
3) "Concerning the Application for Approval of Type 1 Use Practice with regard to genetically modified plants, their production and distribution which are under the jurisdiction of the Minister of Agriculture, Forestry and Fisheries" (Public Notice No. 19 of the Director-General of the Natural Environment Bureau, Ministry of the Environment; the Director-General of the Food Safety and Consumer Affairs Bureau, the Director-General of the Agriculture, Forestry and Fisheries Research Council, the Director-General of the Forestry Agency, MAFF, December 10, 2007 (hereinafter called "Directors' Notice")).

Application for Approval

Application by people or company who wishes to obtain approval of a Type 1 Use practice. Above definition is stipulated in Article 4 (2) of the Cartagena Act.

Application Document (*Dossier*)	A document necessary for application for approval. To be concrete: 1) An application form for approval of a Type 1 Use practice (the Article 7 of Regulations for Enforcement) 2) A biological diversity risk assessment report (the Article 4 (2) of the Cartagena Act) 3) A plan for emergency measures (the Article 3-1-(4) of the Directors' Notice) Above three documents are mandatory, and a monitoring plan is required when necessary (the Article 3-1-(5) of the Directors' Notice).
Confined Field Trial	An experimental cultivation of a GM plant in question to reveal whether and how biological characteristics of the GM plant, such as cross-ability, may vary when it is grown under natural condition in Japan. The experiment is conducted in the field where certain measures are taken so that outsiders cannot brake in or that the GM plant will not be taken out of the confined field without intention. The Directors' Notice stipulates requirements for a confined field trial such as facilities and equipment in the field and operational procedures of the experiments.
General Use	A Type 1 Use for commercial application such as commercial cultivation, import and transportation of a GM plant to a processing site, in distinction from an experimental Type 1 Use in the confined field.
Experts	Consultation is required by the Cartagena Act with those who have specialized knowledge or experience concerning adverse effects on biological diversity because such effects should be judged based on scientific knowledge. This term refers to selected people who have such expertise on a roster. Above definition is stipulated in Article 4 (4) of the Cartagena Act. Experts are listed as stipulated in Article 10 of Regulations for Enforcement. The list of experts is posted and available on "Japan Biosafety Clearing-House (J-BCH)" (URL: http://www.bch.biodic.go.jp/)

File for Risk Management Information

A file summarizing information on unapproved GM plants that may be brought into Japan, such as their introduced genes, traits, etc. The information in the file is necessary for risk management measures such as development of a detection method and its implementation.

Monitoring

In the SOP, this term refers to the monitoring conducted by an approval holder or a risk manager so as to review the result of risk assessment and effectiveness of risk management measures.

There are two types of the monitoring conducted by an approval holder:

1) Monitoring based on Article 6 (2) of the Cartagena Act

Article 6 (2) of the Cartagena Act stipulates that the competent minister can ask an approval holder for the necessary information on Type 1 Use practice.

Information collection according to this Article includes reports on production in other countries of the GM plant approved for general uses, horizontal gene transfer and so on.

In addition, an information collection plan should be submitted to the risk manager beforehand, when a GM plant is commercially cultivated in Japan. (Regarding soybeans in particular, points to consider for drafting an information collection plan are available because there is a wild relative species to soybean in Japan.)

2) Monitoring stipulated in Director's Notice

A monitoring should be conducted after completing a monitoring plan, when the case falls into the Article 3-1-(5)-1 of the Directors' Notice, including the case for a confined field trial.

With regards to a confined field trial, it is stated in the Directors' notice "If wild fauna and flora that may be affected are grown or live in the area where pollen is dispersed, the monitoring should be conducted in the space including the area." To be precise, in case of genetically modified soybeans, effects on *Glycine soja* should be monitored because it is a wild relative species of soybeans.

A monitoring plan will be publicly available, together with the opinion of experts on an assessment report (except for confidential information).

I. 3. General Principles

I. 3. 1 Purpose of Risk Management

The risk management under the Cartagena Act is implemented in order to prevent adverse effects of GM plants on biological diversity in Japan, with referring to the concept of risk analysis regarding administration of food safety. To be precise, with regards to food safety administration, the Codex Alimentarius Commission established the "Working Principles for Risk Analysis for Food Safety for Application by Governments" in 2007 so as to provide guidelines on three elements of risk analysis (risk management, risk assessment, and risk communication.)

I. 3. 2 Scientific Basis

Risk management measures shall be decided and implemented based on the scientific principles, and must not be maintained without sufficient scientific basis. However, in case significant risk is predicted, tentative measures may be taken even if scientific data is insufficient.

When tentative measures are taken, the risk manager shall collect scientific data, conduct risk assessment properly, and try to take measures that match the level of the risk, so as not to maintain such tentative measures for long time.

When risk management measures are examined, the factors other than scientific basis such as feasibility and cost should also be considered, recognizing that the purpose of the risk management measures is to prevent adverse effects on biological diversity in Japan.

Furthermore, the risk manager should enhance the scientific knowledge that forms the basis of risk management measures.

I. 3. 3 Risk Management Measures According to the Level of Risk

When a risk management measure is taken, it shall match the level of risk and should be sufficient to conserve biological diversity.

I. 3. 4 Archive

Documentary information should be archived in order to secure the transparency of the procedures of risk management and to be referred in the future. When doing so, personal information should be protected and confidentiality should be maintained.

I. 3. 5 Cooperation between Risk Managers

The risk manager should cooperate with risk managers of other aspects (for example, food safety) and people in risk assessment departments (hereinafter called "risk assessors"), through sufficient mutual communication, information sharing on GM plants in Japan and overseas, and sufficient discussion as necessary.

I. 3. 6 Consistency in Risk Management

The risk manager must comply with above-mentioned general principles when they manage risk of GM plants. On the one hand the risk manager must maintain consistency throughout all processes of risk management, including decision-making, on the other hand they should respond to a case appropriately according to a possible affected area, a type of effect, and level of risk.

Chapter II: Reviews and Approval of a Type 1 Use Application

II. 1. Preliminary Information Collection

II. 1. 1 Information Collection on Potential Applications

The risk manager regularly and widely collects information on an application schedule concerning Type 1 Use of GM plants and on the development of GM plants (so called products in the "pipeline") from developers (companies and research institutes which develop GM plants).

The information shall be shared only in the administrative agencies, because it contains confidential information such as patents. This condition is revealed when collecting information.

II. 1. 2 Listing Potential Applications

The risk manager makes a list of potential applications (hereinafter called an "application plan list"), which contains information collected in II. 1. 1.

The application plan list will be used for examining issues, for example, whether the existing guidance for assessment and management is applicable enough to newly developed GM plants. It will also be used in order to review application documents systematically and effectively.

II. 1. 3 Documentation of Basic Information Regarding Recipient Plants

By reference to the information collected in II. 1. 1, the risk manager makes documents summarizing the information on recipient plants that are used as hosts of GM plants. Information on a recipient plant, such as its history, basic characteristic, cultivation method, and wild relative species, is referred to when considering adverse effects on biological diversity. The document is written by plant species. The risk manager also lists other related information such as scientific papers by the recipient plant species, and organizes the lists together with the above-mentioned documents.

II. 1. 4 Documentation of Basic Information Regarding Introduced Traits

By reference to the information collected in II. 1. 1, the risk manager makes documents summarizing the information regarding introduced traits such as information on newly introduced gene, newly expressed protein, its mode and mechanism of action, possible effects by introduced trait on growth of the recipient plant and on wild relative species. The risk manager also lists other related information such as scientific papers by the types of introduced traits, and organizes the list.

II. 1. 5 Examination on the Necessity to Set Additional Conditions for Type 1 Use

By reference to the information organized in II. 1. 3 and II. 1. 4, the risk manager preliminarily examines whether it is necessary to set additional conditions for a Type 1 Use (hereinafter called "Use Condition") for effectively preventing adverse effects on biological diversity in Japan.

Followings are considered for examining the use condition:

1) In case of a confined field trial, it is examined if further use conditions are necessary, taking account of the existing requirements of a confined field, as well as the fact the GM plant is cultivated and used in the field which meets certain requirements stipulated in the Directors' Notice (see also the definition of "Confined Field Trial" in section I.2).
2) In case that it is judged further use condition should be set when using a GM plant in question, the risk manager considers what further use condition prevents adverse effects on biological diversity arising from the Type 1 Use of the GM plant.

II. 2. Prior Consultation Regarding a Confined Field Trial

II. 2. 1 Formulation of Guidance for Environmental Risk Assessment and Management

The risk manager formulates the guidance for environmental risk assessment and management that states necessary points for assessing and managing risks in a scientifically appropriate way. The risk manager consults experts as necessary. The guidance is based on risk assessment policies and contains other issues which are examined by the risk assessor for example test method of toxic substance production. Therefore the risk manager should cooperate with the risk assessor in formulation or revision of the guidance.

The risk manager publishes the contents of the guidance and may inform stakeholders including the developers of GM plants if necessary.

II. 2. 2 Prior Consultation Regarding an Application

The risk manager provides consultation for people who will apply (hereinafter called "prospective applicant") a Type 1 Use practice for the approval as needed (hereinafter called "prior consultation"). Prior consultation can be provided before a prospective applicant makes documents such as an assessment report that is required for the application.

Regarding the information the risk manager obtained, it will be published except for confidential information:

1) at the time of opinion gathering if additional formulation or revision of risk assessment policies is necessary; or
2) at the time of receiving an application for approval of a Type 1 Use practice if additional formulation and revision of risk assessment policies is not necessary.

Above conditions are revealed when prior consultation is provided.

II. 2. 3 Examination on Formulation of an Additional Risk Assessment Policy

Regarding the use of a GM plant that is consulted beforehand, the risk manager examines whether the existing guidance for assessment and management is sufficient so as to take appropriate risk management measures, to be precise, whether there are any points that should be more clarified, or whether the guidance lacks any items.

The additional risk assessment policy should be formulated if the existing guidance for assessment and management is not sufficient to deal with the application on the Type 1 Use of the GM plant. In particular, it should be noted that an additional risk assessment policy should be formulated when the recipient plant or introduced trait is new and has not been assessed yet.

In principle, an additional risk assessment policy should be formulated according to the type of an introduced trait (please refer to II. 2. 4). If a GM plant has a trait which is new but similar to the already reviewed trait, the risk manager examines whether the existing policy is applicable for drafting and reviewing an assessment report of the GM plant. If it is insufficient for risk assessment, the existing policy is revised.

II. 2. 4 Formulation of the Additional Risk Assessment Policy

If the risk manager judges it is necessary to formulate an additional risk assessment policy or revise an existing additional risk assessment policy, such a policy is done so according to the contents of a potential application (for example, basic characteristics of the recipient plant, introduced traits, risk management measures). An additional risk assessment policy contains points that are new or complement the existing guidance (for example, tentative new assessment points or clarification of existing assessment points to add).

Followings are noted for the formulation or the revision:

1) Formulate it according to the type of introduced traits in principle

   In principle, a risk assessment policy should be formulated according to the type of the introduced traits or use (For instance, a basic method to restrict general use of any GM plants which produce pharmaceutical ingredients, or points to consider for the area which is particularly susceptible to adverse effects on biological diversity, can be applicable for same or similar cases). It is also taken into account that data in a confined filed trial is collected for a future application for general use of the same GM plant.

2) Check whether any relevant risk assessment policies exist, and revise them if necessary

   Based on the contents of the potential application, the risk manager examines whether additional risk assessment policies relating to the traits introduced to the GM plant in question are already formulated. If not, it shall be formulated. However, even if additional assessment policies are already formulated, the existing relevant policies shall be revised

if it is predicted that they do not lead a proper assessment, review, and/or decision for risk management measures.

3) Consider to merge an additional policy into the guidance for assessment and management

When the additional risk assessment policy seems common and general after the policy is used for more than one assessment, the risk manager considers whether its contents should be merged into the guidance for assessment and management (For instance, the case that points to consider for a new trait in the additional policy are judged necessary in every assessment, after several time assessment and reviews of the trait).

Regarding the procedures for re-organizing the guidance for assessment and management, the risk manager may consult experts as necessary according to II. 2. 1.

4) Judge necessity of a confined field trial

As stimulated in the guidance for assessment and management, a confined field trial should be conducted in principle when characteristics of a GM plant are known in a laboratory or under natural environment overseas but it is not scientifically clear how it grows in the natural environment in Japan. When the risk manager judge that confined field trial is not necessary from the combination of the recipient plant and characteristics of the introduced trait, previous data, and results of risk assessment of similar GM plants, they write down so in the risk assessment policy.

5) Formulate a risk assessment policy based on more-than-one review

A risk assessment policy should be formulated taking into account more than one review, a combination of a recipient plant and an introduced trait, and whether commercial cultivation of a GM plant in question is expected in Japan. The risk manager writes down in the risk assessment policy the differences of risk management measures, points to consider, or the content of assessment which depend on factors above, if appropriate (for example, the need to conduct a monitoring).

6) Instruction when a confined field trial is necessary

If the risk manager receives an application for a general use without confined field trial in Japan, but if they judge the submitted data or information is not sufficient to approve the general use, they give instruction to the applicant about application for a confined field trial.

II. 2. 5 Opinion Gathering on the Additional Risk Assessment Policy

The risk manager gathers opinions from stakeholders, in cooperation with experts if necessary, on whether the contents of additionally-formulated or revised risk assessment policy are appropriate.

Followings should be considered for gathering opinions:

1) Confidential information concerning the application for approval shall be kept private in principle.
2) For the efficiency of the review, opinions may be gathered in parallel with the review. When doing so, the risk manager pays attention to the process management so as to reflect the result of opinion gathering in risk assessment policies.

II. 2. 6 Revision According to Opinions Gathered

Based on the result of the opinion gathering, the risk manager may revise a risk assessment policy in question as necessary.

In case of formulation or revision of a risk assessment policy in question, the risk manager should inform prospective applicants of the contents that will be added or complemented in the policy and gives them instruction to reflect such changes in a draft assessment report.

II. 3. Review of an Application for a Confined Field Trial

II. 3. 1 Examination of Application Documents (Dossier)

The risk manager checks the completeness of application documents and the validity of their contents[1]. Among application documents, an assessment report should be confirmed whether it is based on the past reviews, points noted by experts, the guidance for assessment and management, and additional risk assessment policies.

When a monitoring is required during the trial as stipulated in the guidance for assessment and management or additional risk assessment policies, it shall be confirmed whether a monitoring plan is drafted.

Based on the check above, the risk manager contacts the applicant and let them know if all necessary documents are submitted, if there is anything exaggerated or omitted in their contents, or if there is any flaw such as factual error in the contents.

When the applicant submits re-drafted documents, the risk manager confirms whether the flaw is properly corrected. If the flaw is not corrected yet, the above process of correction is repeated until it is completed.

[1] To be concrete, the risk manager checks whether all required documents are submitted or not; whether an assessment report contains all necessary information and points to consider listed in the *Guidance of Implementation of Assessment of Adverse Effects on Biological Diversity of Type 1 Use of LMOs (see I.2 Definition)*; whether the assessment report is drafted in accordance with the Guidance above.

II. 3. 2 Review

When the contents of the application documents are confirmed valid, the risk manager presents the documents to experts and gathers opinions from them on the validity of the documents (including an assessment report) in light of the guidance for assessment and management and the additional risk assessment policies.

If risk management measures described in the application documents are insufficient, the risk manager examines what measures are necessary to add.

The risk manager rechecks the validity of the contents of the application documents based on the opinions from experts.

When the contents of the application documents are confirmed appropriate, the risk manager makes a report on the review which contains the process of formulating risk assessment policies, review process, major points noted in the review, the summary of Biological Diversity Risk Assessment Report (excluding confidential information), an emergency plan, opinions from experts, and the result of the review.

II. 3. 3 Opinion Gathering on the Application for the Type 1 Use

The risk manager publishes the review report and gathers opinions from stakeholders.

If the review report is improved according to the opinions gathered, the revised report is also published.

II. 3. 4 Decision on Approval

When it is confirmed that there is no adverse effect on biological diversity in the use complying with the Type 1 Use practice, taking into account the opinions presented by stakeholders, the risk manager shall approve the practice in question.

II. 4. Information Collection on the Confined Field Trial by the Approval Holder

II. 4. 1 Implementation of the Confined Field Trial

The approval holder of the Type 1 Use practice concerning the confined field trial conducts the trial as stipulated in the approved practice.

II. 4. 2 Analysis of the Result of the Confined Field Trial

The approval holder analyzes the results of the confined field trial after it is completed. When a monitoring is conducted, the monitoring result is analyzed together.

II. 5. Prior Consultation Regarding an Application for General Use

II. 5. 1 Prior Consultation Regarding an Application

The risk manager provides prior consultation for a prospective applicant as needed. Prior consultation can be provided before a prospective applicant makes documents such as an assessment report that is required for the application for approval.

Based on the relevant information such as provided by an approval holder and scientific papers, the risk manager organizes such information to judge whether the result of the risk assessment and the risk management measures for the confined field trial have been appropriate.

The information obtained by the risk manager will be published except for confidential information:

1) at the time of opinion gathering, if additional change is necessary in risk assessment policies; or
2) at the time of receiving the application for approval of Type 1 Use practice, in case of no need to change in risk assessment policies.

Above conditions are revealed at the prior consultation.

II. 5. 2 Examination on Changes in the Additional Risk Assessment Policy

According to the results of the confined field trial and the contents of the prior consultation, the risk manager considers whether anything should be changed in the additional risk assessment policy. For example, the risk manager examines whether further information and/or points to consider are required for risk assessment, and whether further risk management measures are necessary.

When an additional risk management policy has not been formulated, the risk manager judges it is necessary to formulate.

II. 5. 3 Changes in the Additional Risk Assessment Policy

Additional risk assessment policies should be changed, taking into consideration the result of the confined field trial and the prior consultation, if the existing guidance for assessment and management, critical points of a risk assessment for confined field trial, or risk management measures are insufficient for risk assessment for approval of a Type 1 Use practice concerning general use.

If an additional risk assessment policy has not been formulated but it is judged necessary, an additional risk assessment policy should be newly formulated.

An additional risk assessment policy should be formulated or amended according to II. 2. 4.

II. 5. 4 Opinion Gathering on Changes in the Additional Risk Assessment Policy

The risk manager gathers opinions from stakeholders, in cooperation with experts if necessary, on whether the contents of the revised or newly formulated additional risk assessment policy are appropriate.

Followings should be considered for gathering opinions:

1) Confidential information concerning the application for approval shall be kept private in principle.
2) For the efficiency of the review, opinions may be gathered in parallel with the review. When doing so, the risk manager pays attention to the process management so as to reflect the results of opinion gathering in risk assessment policies.

II. 5. 5 Revision According to Opinions Gathered

Based on the result of the opinion gathering, the risk manager may revise a risk assessment policy in question as necessary.

If risk assessment policy in question is revised, the risk manager should inform prospective applicants of the additional or amended assessment points or risk management measures, and gives them instruction to reflect such changes in a draft assessment report.

II. 6. Review of the Application for General Use

II. 6. 1 Examination of Application Documents (Dossier)

The risk manager checks the completeness of application documents and the validity of their contents[2]. Among application documents, an assessment report should be confirmed whether it is based on the past reviews, points noted by experts, the guidance for assessment and management, and additional risk assessment policies.

When a monitoring is required in additional risk assessment policies, it shall be confirmed whether a monitoring plan is drafted.

Based on the check above, the risk manager contacts the applicant and let them know if all necessary documents are submitted, if there is anything exaggerated or omitted in their contents, or if there is any flaw such as factual error in the contents.

When the applicant submits re-drafted documents, the risk manager checks whether the flaw is properly corrected. If the flaw is not corrected yet, the above process of correction is repeated until it is completed.

[2] Please also see a footnote in II.3.1 regarding how to check the completeness and the validity of application documents.

II. 6. 2 Review

When the contents of the application documents are confirmed valid, the risk manager presents the documents to experts and gathers opinions from them on the validity of the documents (including an assessment report) in light of the guidance for assessment and management and the additional risk assessment policies.

If risk management measures described in the application documents are insufficient, the risk manager examines what measures are necessary to add.

If the risk manager judges during review a confined field trial should have been conducted in Japan because data or information is not sufficient for risk assessment concerning the general use, the review should be suspended at that point and the risk manager should provide the applicant instructions to apply for a confined field trial.

The risk manager rechecks the validity of the contents of the application documents based on the opinions from experts.

When the contents of the application documents are confirmed appropriate, the risk manager makes a report on the review which contains the process of formulating risk assessment policies, review process, major points noted in the review, the summary of Biological Diversity Risk Assessment Report (excluding confidential information), an emergency plan, opinions from experts, and the result of review.

II. 6. 3 Opinion Gathering on the Application for the Type 1 Use

The risk manager publishes the review report and gathers opinions from stakeholders.

If the review report is improved according to the opinions gathered, the revised report is also published.

II. 6. 4 Decision on Approval

When it is confirmed that there is no adverse effect on biological diversity in the use complying with the Type 1 Use practice, taking into account the opinions presented by stakeholders, the risk manager shall approve the practice in question.

II. 7. Revision of Risk Management Measures

II. 7. 1 Monitoring by the Approval Holder and the Risk Manager

After a Type 1 Use practice is approved for the general use, the approval holder and the risk manager may conduct a monitoring as necessary in the following methods:

1) Monitoring by the approval holder

a) If the application documents include a monitoring plan, the approval holder conducts the monitoring in accordance with the plan.

b) If the risk manager asks the approval holder for the implementation of monitoring as stipulated in Article 6 (2) in the Cartagena Act, the approval holder collects information asked by the risk manager, analyses it and reports the result to the risk manager. The risk manager gives them a specific deadline and methods when asks to provide information.

2) Monitoring and collection of relevant information by the risk manager

The risk manager should survey in the neighboring area of the port of importation or fields where a GM plant was cultivated to examine its growth state. For example, a GM plant whose introduced trait has never been assessed or reviewed may be subject to such survey so as to enhance scientific knowledge. Relevant information such as peer reviewed scientific papers should be collected.

II. 7. 2 Analysis of the Monitoring Result

The risk manager analyses the result of surveys conducted by themselves (please refer to II. 7. 1). In addition, the risk manager collects and analyses the information of the monitoring result provided by the approval holder, and related scientific papers. The risk manager reviews the information above so as to monitor the effectiveness of the risk management measures in operation and the validity of the risk assessment result.

Information obtained by the risk manager may be published except for confidential information.

II. 7. 3 Examination and Decision on Revising Risk Management Measures

The risk manager examines the effectiveness of the existing risk management measures based on II. 7. 1 and II. 7. 2.

If the risk manager judges that it is necessary to revise risk management measures; for instance, in the case that the Type 1 Use in question probably causes adverse effects on biological diversity, the risk manager should consider amending or abolishing the Type 1 Use practice as stipulated in the Article 7 (1) of the Cartagena Act. The risk manager should also revise, as necessary, the information which is collected according to the sections such as II. 1. 3, II. 2. 1, and II. 2. 4 of the SOP. Together with these revised materials, the risk manager drafts revised risk management measures. The risk manager consults experts as necessary.

If the risk manager recognizes emergency measures are necessary, for example in case actual adverse effects on biological diversity are observed, they take necessary measures such as suspension of Type 1 Use based on Article 10 (2) of the Cartagena Act.

II. 7. 4 Opinion Gathering on the Revision

The risk manager publishes the draft for revised risk management measures together with the information that is used to decide the revision, such as the result of the monitoring and the collected information. Then the risk manager gathers opinions from stakeholders on the draft.

Complying with II. 7. 3, the risk manager re-examines the draft as necessary according to the opinions gathered.

II. 7. 5 Implementation of the Risk Management Measures

The risk manager makes a final decision on the revised risk management measures and takes the decided measures.

When the risk management measures in place are judged appropriate according to II. 7. 3, they continue to be applied.

Chapter III: Dealing with Situations of Commingling of an Unapproved Genetically Modified Plant

III. 1. Initial Works

III. 1. 1 Information Collection on Development and Cultivation of GM Plants in Foreign Countries, and their Risk Management Measures

The risk manager collects information such as development and cultivation of GM plants in foreign countries and their risk management measures to the utmost extent so as to cite when considering risk management measures in Japan. The type of the information to collect and the list of the sources should be reviewed on a regular basis. They also should be reviewed at any time if any flaw is found through individual cases, or if there is any other issue to consider.

Followings are included as the sources:

1) Organizations relevant to MAFF (each internal bureau and affiliated agency of MAFF, the Plant Protection Station, and incorporated administrative agencies of research, etc.)
2) Relevant ministries (each ministry relevant to the Cartagena Act (the National Tax Agency, the Ministry of Education, Culture, Sports, Science and Technology, the Ministry of Health, Labour and Welfare, the Ministry of Economy, Trade and Industry, the Ministry of the Environment), the Food Safety Committee, the Ministry of Foreign Affairs, etc.)
3) International Organizations, government agencies overseas, the Japanese Embassies abroad, etc.
4) Academia, study groups, etc.
5) Local public agencies (including research institute)
6) Producers, manufacturers, and distributors of agricultural, forestry or marine products, food, and production materials
7) Consumer groups, etc.

III. 1. 2 Drafting a File for Summarizing Information Collected

Based on the information obtained in III. 1. 1, the risk manager makes out a file for risk management containing information on GM plants whose uses are not approved in Japan but likely to enter into the Japanese territory (hereinafter called “unapproved GM plant”), for example, information for developing a detection method and detecting the GM plant.

Followings are noted when making out the document:

1) Information such as name of introduced genes and base sequence shall be organized as it is necessary for development of a detection method.
2) Information on plant species or products that may be commingled with the unapproved GM plant in question as well as the state of their production and distribution overseas shall

be examined and organized as it is necessary for the detection.

3) Information shall be managed while the sources are specified; but the information whose sources do not wish to be disclosed, for example confidential information, shall be managed separately from the information to publish.
4) When the information is very limited, the risk manager should consider giving high priority to such GM plants in III. 1. 4.

III. 1. 3 Providing Information to Stakeholders

The risk manager should provide the information collected in III. 1. 1 and III. 1. 2 (especially the information on unapproved GM plants) to stakeholders such as producers, manufacturers, and distributors of agricultural, forestry and marine products; organizations relevant to MAFF; and relevant ministries; so as to share the information.

When providing information, the risk manager takes into account the products or plant species in which the GM plant in question may be commingled.

III. 1. 4 Priority Setting of Unapproved GM Plants to Consider Risk Management Measures (Prioritization)

Based on files for risk management information, the risk manager examines the priority of risk management measures, considering the likelihood and possible effects when unapproved GM plants in question are commingled and brought to Japan. The risk manager makes a list of the unapproved GM plants in the order corresponding to the prioritization (hereinafter called "the Priority List").

The risk manager may consult experts about the prioritization when necessary.

III. 1. 5 Formulation of a Risk Assessment Policy

Based on the priority list, the risk manager formulates a risk assessment policy according to each unapproved GM plant in principle.

Followings are noted when formulating a risk assessment policy:

1) A risk assessment policy will be used to consider, based on available data and information, (i) the likelihood that an unapproved GM plant enters Japan for some reasons such as unintentionally commingled goods, and (ii) the necessity of risk assessment if risk management measures are necessary to prevent adverse effects of the unapproved GM plant on biological diversity.
2) If it is urgent, the risk manager may formulate risk assessment policies and examine risk management measures at the same time.

III. 1. 6 Conducting Risk Assessment

The risk manager should conduct a tentative risk assessment of the unapproved GM plant based on the available information, and with consulting experts when necessary.

III. 1. 7 Opinion Gatherings on the Risk Assessment Policy and the Result of Risk Assessment

The risk manager consults stakeholders about whether the priority list, the risk assessment policy, and the result of risk assessment are appropriate.

III. 2. Consideration and Implementation of Risk Management Measures

III. 2. 1 Consideration on Risk Management Measures to Unapproved Genetically Modified Plants

Based on the priority list and risk assessment policies, the risk manager should consider which risk management measures should be taken to prevent adverse effects on biological diversity by the unapproved GM plants.

The risk manager may consult experts as necessary when considering the measures. The risk manager should examine the most efficient and effective way in order to oversee and manage the unapproved GM plants in both aspects of (i) measures to prevent unapproved GM plants from being brought to Japan, including development of detection methods and inspections at quarantine stations, and (ii) measures to prevent unapproved GM plants from spreading after they are brought to Japan. The information on risk management measures abroad that is collected in III. 1 as well as the budget are also taken into account when examining measures.

The risk manager may consult the developers of unapproved GM plants in question as necessary so as to collect information on the GM plants, for example, introduced genes.

III. 2. 2 Implementation of Risk Management Measures

The risk manager decides what risk management measure to take and implements the decided measures, in principle, at a time when commingling of an unapproved GM plant occurs overseas, in order to prevent the unapproved GM plant from being brought.

The risk manager takes the measures according to the level of the risk as stipulated in I. 3.

If an unapproved GM plant is brought into Japan, the risk manager responds to the situation based on “the Food Safety Basic Outline for Emergency Response by the Relevant Ministries” (agreed by the relevant ministries and agencies on April 15, 2004) and “the Basic Guidelines for Emergency Response to Food Safety Accidents” (a notification by the Director-General of the Food Safety and Consumer Affairs Bureau, MAFF, formulated on February 27, 2004; the document number is 6530 in 2003 FY).

When deciding risk management measures to take, the risk manager also should decide what further information is necessary to revise and when to revise risk management measures in place. The risk manager may consult experts as necessary.

III. 2. 3 Providing Information to Stakeholders

The risk manager, in a timely and proper manner, should call attention, provide information to stakeholders, and may request the developers to apply for approval etc. if necessary.

III. 3. Revision of Risk Management Measure

III. 3. 1 Information Collection to Revise Risk Management Measures

The risk manager collects information necessary to revise risk management measures in the following ways.

1) Information collection by the risk manager

The risk manager should collect the information such as the results of inspections at quarantine stations, the result of the voluntary test conducted by the private entities, and peer-reviewed scientific papers.

2) Information from the developer and the country concerned

The risk manager should request the developer of the unapproved GM plant and the competent authority of the country concerned (including the embassy of the country in Tokyo) where the issue occurred to provide necessary information such as introduced genes of the unapproved GM plant in question, the introduced traits, environmental risk assessment report, and the states of management regarding the unapproved GM plant and the recipient plant in the country concerned.

III. 3. 2 Analysis of Collected Information

The risk manager analyzes the information collected by them or provided by the developer and the country concerned. Then they organize the information to examine whether the risk management measures in place is balanced against the risk in question.

The information obtained by the risk manager may be published except for confidential information.

III. 3. 3 Examination and Decision on Revising the Risk Management Measures

After the period which is determined at a time when risk management measures are decided as stipulated in III. 2. 2, the risk manager examines whether the risk management measures in place are effective and whether files for risk management information are valid by taking into account the result of III. 3. 1 and III. 3. 2.

The risk manager may consult experts as necessary when they consider revising the risk management measures, risk assessment policies and documents for information management.

III. 3. 4 Opinion Gathering on the Decision regarding the Revision

The risk manager should publish a draft of the revised risk management measures together with the information used for the revision, and gather opinions from stakeholders on the draft.

According to III. 3. 3, the risk manager should re-examine the draft as necessary based on the opinions gathered.

III. 3. 5 Implementation of the Risk Management Measures

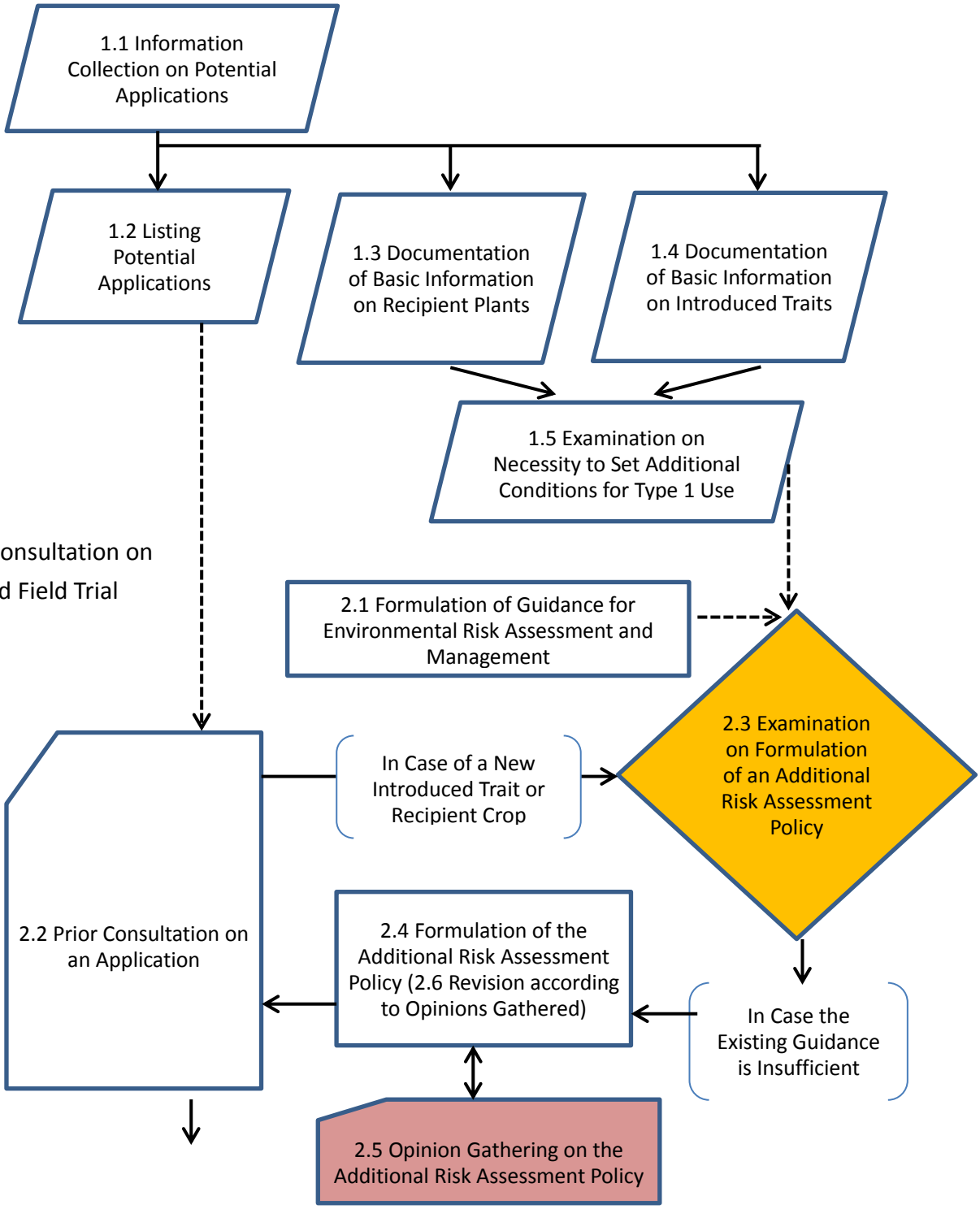
The risk manager makes a final decision on the draft of the revised risk management measures and takes the decided measures.

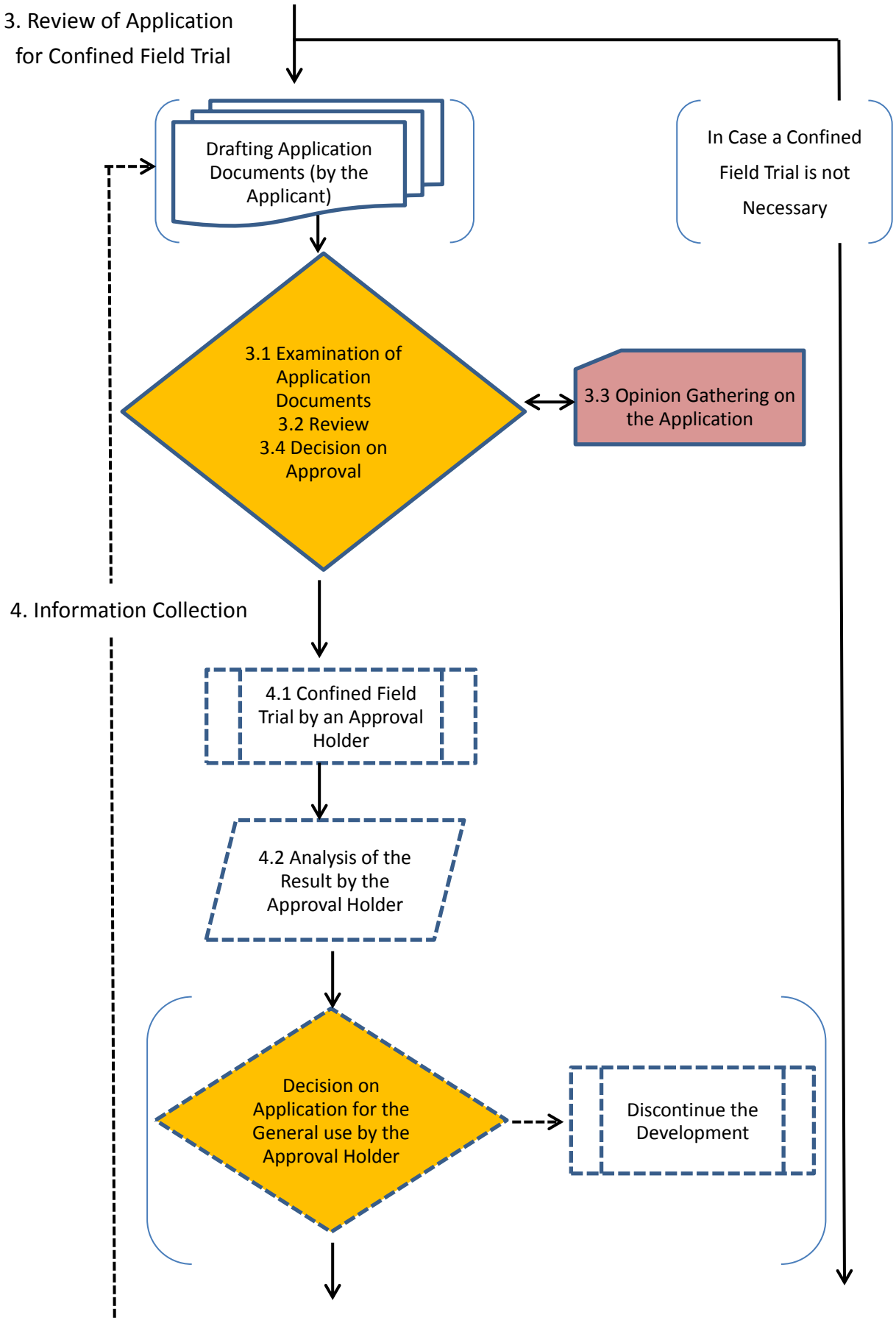
When the risk management measures in place are judged appropriate according to III. 3. 3, they continue to be applied.

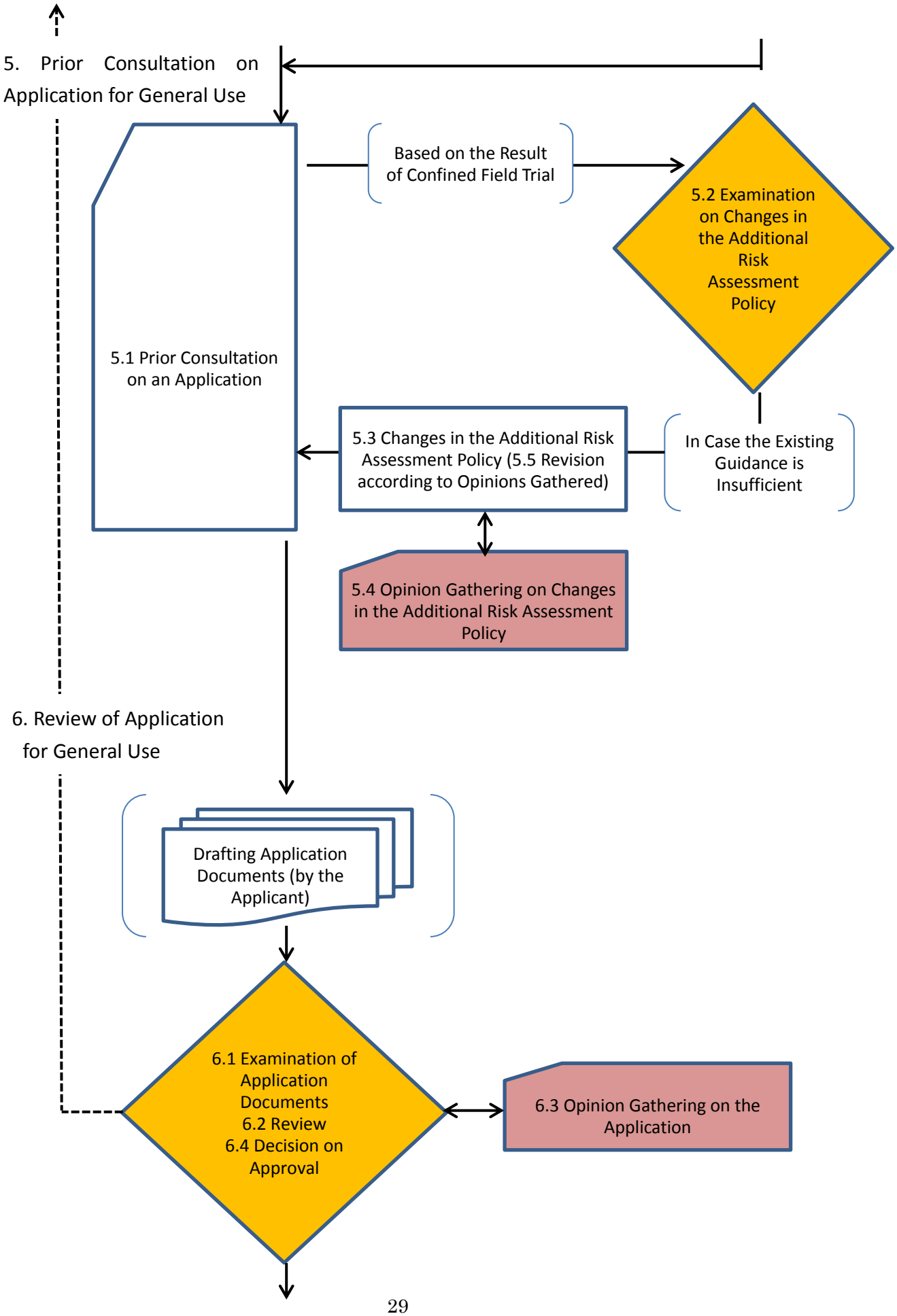
Annex - Flowcharts of the Standard Operating Procedures regarding Environmental Risk Assessment and Management of Genetically Modified Plants Based on the Cartagena Act (SOP)

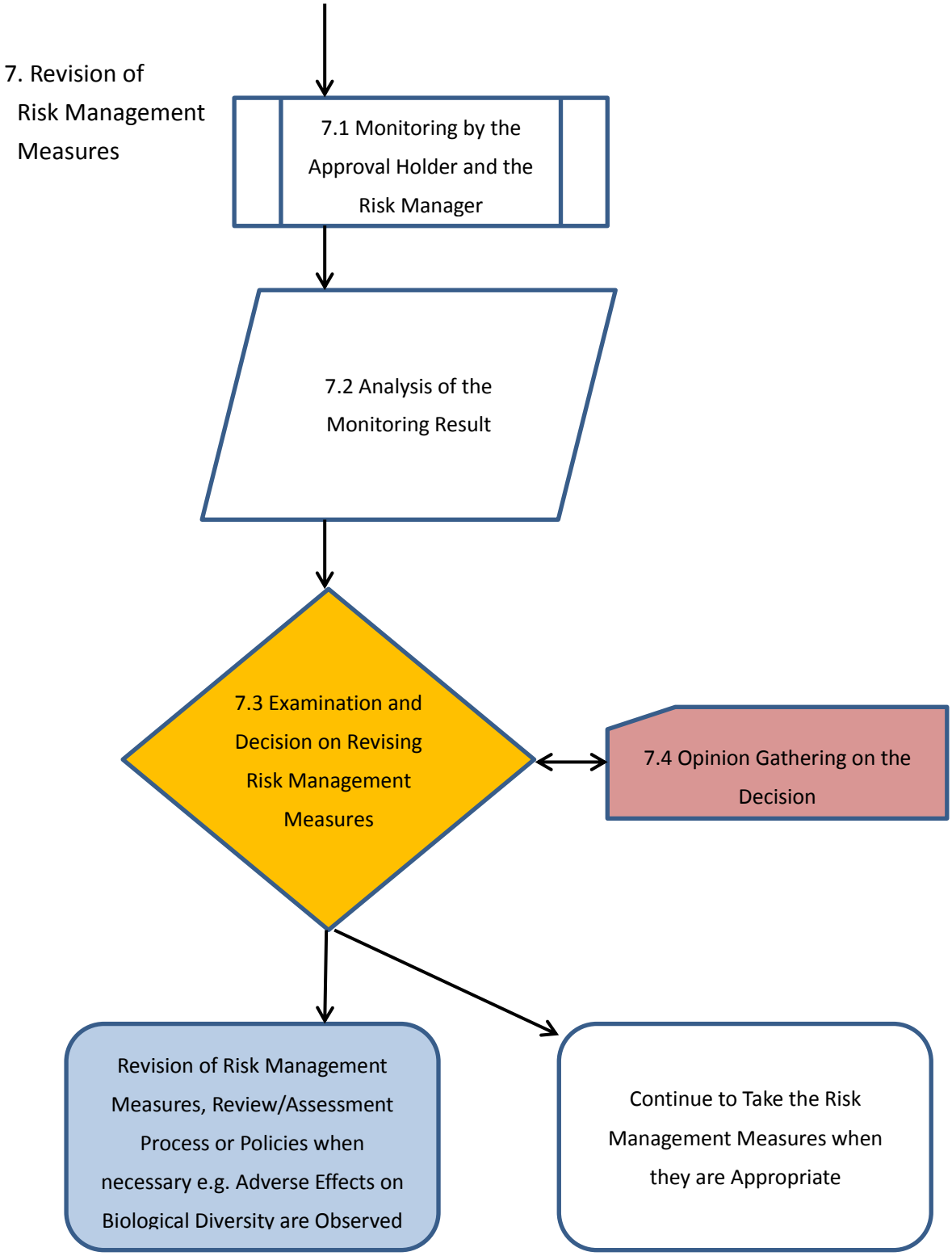
I. Flowchart for Review and Approval of Type 1 Use Application

1. Preliminary Information Collection

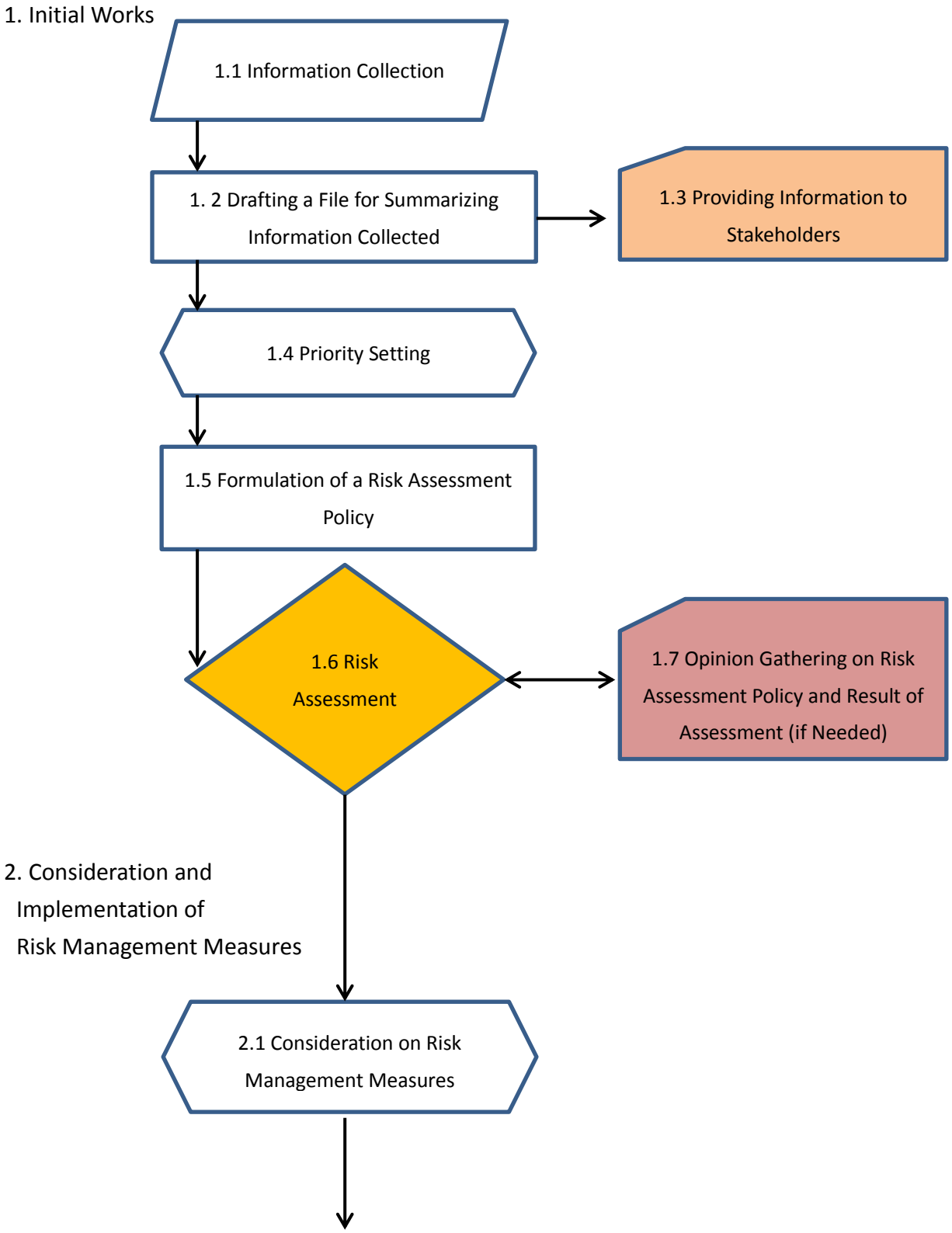


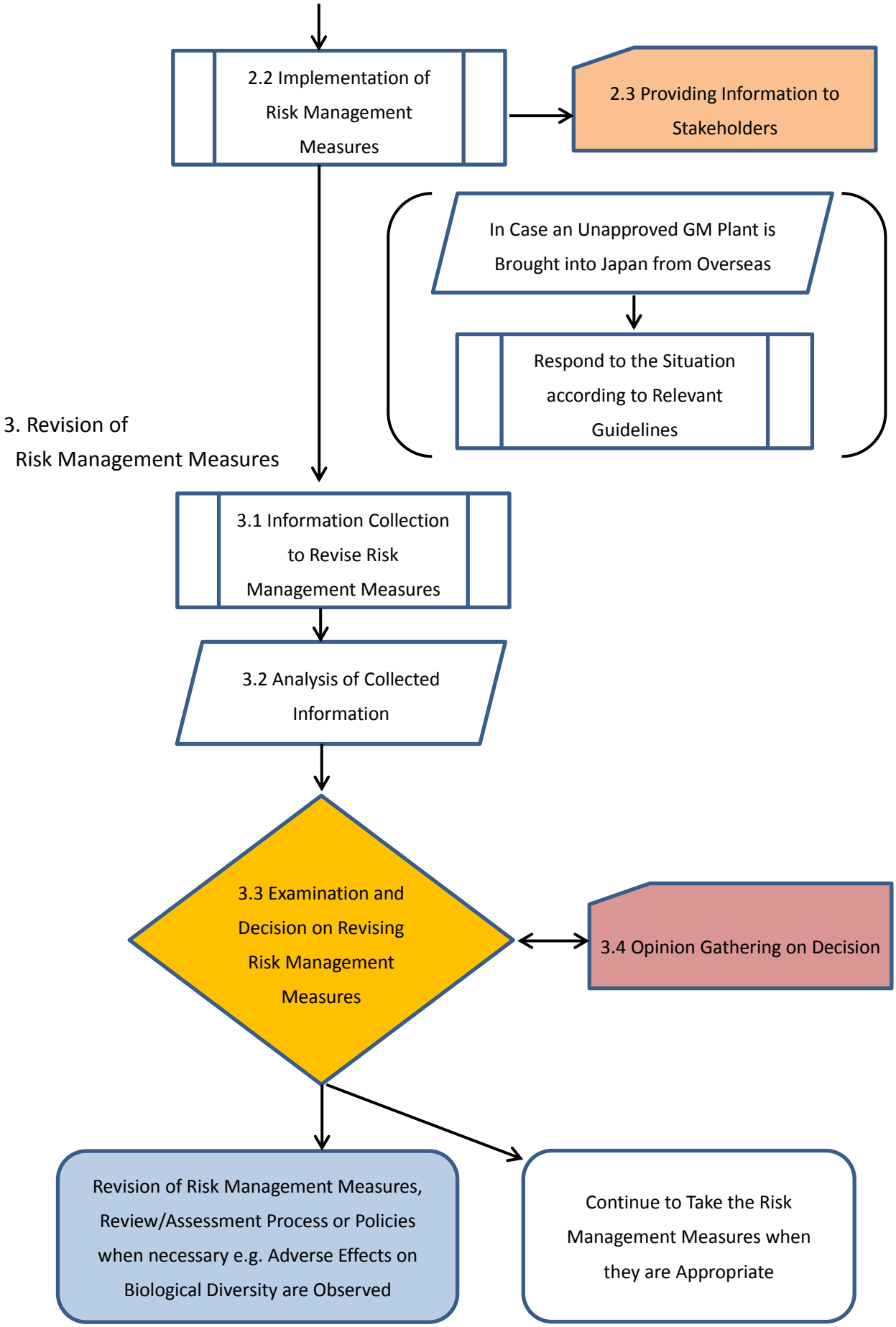

3. Review of Application for Confined Field Trial
Drafting Application Documents (by the Applicant)
In Case a Confined Field Trial is not Necessary
3.1 Examination of Application Documents
3.2 Review
3.4 Decision on Approval
3.3 Opinion Gathering on the Application
4. Information Collection
4.1 Confined Field Trial by an Approval Holder
4.2 Analysis of the Result by the Approval Holder
Decision on Application for the General use by the Approval Holder
Discontinue the Development


5. Prior Consultation on Application for General Use
5.1 Prior Consultation on an Application
Based on the Result of Confined Field Trial
5.2 Examination on Changes in the Additional Risk Assessment Policy
In Case the Existing Guidance is Insufficient
5.3 Changes in the Additional Risk Assessment Policy (5.5 Revision according to Opinions Gathered)
5.4 Opinion Gathering on Changes in the Additional Risk Assessment Policy
6. Review of Application for General Use
Drafting Application Documents (by the Applicant)
6.1 Examination of Application Documents
6.2 Review
6.4 Decision on Approval
6.3 Opinion Gathering on the Application


7. Revision of Risk Management Measures
7.1 Monitoring by the Approval Holder and the Risk Manager
7.2 Analysis of the Monitoring Result
7.3 Examination and Decision on Revising Risk Management Measures
7.4 Opinion Gathering on the Decision
Revision of Risk Management Measures, Review/Assessment Process or Policies when necessary e.g. Adverse Effects on Biological Diversity are Observed
Continue to Take the Risk Management Measures when they are Appropriate

II. Flowchart for Dealing with Situations of Commingling of an Unapproved Genetically Modified Plant




2.2 Implementation of Risk Management Measures
2.3 Providing Information to Stakeholders
In Case an Unapproved GM Plant is Brought into Japan from Overseas
Respond to the Situation according to Relevant Guidelines
3. Revision of Risk Management Measures
3.1 Information Collection to Revise Risk Management Measures
3.2 Analysis of Collected Information
3.3 Examination and Decision on Revising Risk Management Measures
3.4 Opinion Gathering on Decision
Revision of Risk Management Measures, Review/Assessment Process or Policies when necessary e.g. Adverse Effects on Biological Diversity are Observed
Continue to Take the Risk Management Measures when they are Appropriate