CropLife International/Global Industry Coalition

Implementation Guide

to the

NAGOYA – KUALA LUMPUR SUPPLEMENTARY PROTOCOL ON LIABILITY AND REDRESS TO THE CARTAGENA PROTOCOL ON BIOSAFETY

April 2013

CropLife INTERNATIONAL

Table of Contents

Foreword 3

Introduction 4

General Considerations 5

Explanation of the Guide Format and Notations 7

Implementation Guide 8

Annex I: Determination of Damage (with alternative texts) 19

Annex II: Response Measures (with alternative texts) 21

Compiled Example Text with Selected Alternatives 24

CropLife International is the global federation representing the research-based plant science industry that develops, manufactures and sells products and services designed to improve the global production of food, feed, fibre and fuel in a sustainable way. As a global network, CropLife International acts as an ambassador for the plant science industry, encouraging understanding and dialogue whilst promoting sound science and agricultural technology in the context of sustainable agriculture and development. CropLife International represents a network of regional and national associations in 91 countries and is led by the major R&D-driven plant science companies such as BASF, Bayer CropScience, Dow AgroSciences, DuPont Pioneer, FMC, Monsanto, Sumitomo Chemical and Syngenta.

The **Global Industry Coalition** (GIC) for the Cartagena Protocol on Biosafety receives input and direction from trade associations representing thousands of companies from all over the world. Participants include associations representing and companies engaged in a variety of industrial sectors such as plant science, seeds, agricultural biotechnology, food production, animal agriculture, human and animal health care, and the environment.

Foreword

In our capacity as Co-chairs of the international negotiating process that culminated with the adoption on October 15th, 2010, of the Nagoya – Kuala Lumpur Supplementary Protocol, it is a pleasure to acknowledge by means of the present foreword the contribution made by CropLife International and the Global industry Coalition to the discussions and to the final outcome.

For more than eight years a working group comprised of Government representatives, members of the academic sector, industry representatives and Non-Governmental Organisations engaged together in a long dialogue in the context of the Cartagena Protocol on Biosafety. As a result, rules and procedures in the field of liability and redress relating to living modified organisms were developed.

However, international negotiating processes often imply that the texts that finally achieve the consensus of all participants are not as clearly drafted and as straightforward as one would wish. These instruments define terms in a way that sometimes differ from their common use, they often include expressions that seem redundant or even contradictory to a layman, and they incorporate provisions that, without a clear understanding of the *travaux préparatoires*, would be very difficult to read.

It is for that reason that we welcome the publication of this Guide which, in our view, constitutes a valuable tool for Governments to better understand and consequently better apply at the domestic level the provisions of the Supplementary Protocol. The authors have done an excellent job in making accessible to a broader public, in an orderly and friendly manner, the provisions of the Supplementary Protocol and therefore promoting and facilitating the understanding of the Treaty for the benefit of the conservation and sustainable use of biological diversity around the world.

René Lefeber
Co-chair

Jimena Nieto
Co-chair

[1] For more information on The Compact, see www.biodiversitycompact.org.

Introduction

The primary purpose of this Implementation Guide is to assist countries that do not have existing mechanisms to address damage to the conservation and sustainable use of biodiversity to develop a system for identifying responsible operators and requiring response measures in conformity with the Nagoya-Kuala Lumpur Supplementary Protocol (Supplementary Protocol) to the Cartagena Protocol on Biosafety (Protocol) under the Convention on Biological Diversity (Convention).

Every attempt has been made to retain as much as possible the exact language of the Supplementary Protocol. Changes have been made only where necessary to convert text for use as a domestic regulation. The Supplementary Protocol itself, however, heavily relies on domestic law to fill in important definitions and provisions. Where domestic law in a country does not exist on the various points identified in the Supplementary Protocol or is inconsistent with the Supplementary Protocol, this Guide provides examples of text that could be considered by the government in amending or creating domestic law. The sources of most of the content, which are specified in the explanations, are: (a) the European Union's Directive 2004/35 of the European Parliament and of the Council on environmental liability with regard to the prevention and remedying of environmental damage (ELD); or (b) The Compact: A Contractual Mechanism for Response in the Event of Damage to Biological Diversity Caused by the Release of a Living Modified Organism (Compact)[1].

[1] For more information on The Compact, see www.biodiversitycompact.org.

General Considerations

Redress for damage to biodiversity:
The Supplementary Protocol provides a framework, including key definitions, to be used by countries to put in place systems at the national level to ensure that persons (operators) responsible for damage (an adverse effect on the conservation and sustainable use of biodiversity as defined in Supplementary Protocol, Art. 2, hereafter "damage") caused by living modified organisms (LMOs) undertake or pay for response measures to address that damage.

The scope of the Supplementary Protocol is limited to damage caused by LMOs that find their origin in a transboundary movement. However, the same system can (and should, for reasons of implementing the "polluter pays" principle and to also ensure compliance with WTO obligations) also apply to damage caused by domestic activities with LMOs.

To avoid a situation of non-compliance, a country that becomes Party to the Supplementary Protocol should have the necessary legal measures and administrative systems in place upon entry into force of the Supplementary Protocol for that country.

The starting point for any country to implement the Supplementary Protocol is a detailed analysis of existing domestic law. The following step-wise approach is suggested:

Countries should first examine their domestic laws to determine whether sufficient domestic rules and procedures already exist to address potential damage to the environment or to biological diversity. If applicable rules exist, they should be carefully analysed for compliance and consistency with all aspects of the Supplementary Protocol.

- Does national legislation already provide for liability and response in the case of any damage to the environment or biodiversity? A general instrument applying to damage to the environment or biodiversity (from any cause), and which provides for notification, assessment of damage and identification of those responsible for it, as well as governmental authority to order operators that cause damage to undertake appropriate response measures, would likely comply with the Supplementary Protocol. In addition, such an instrument has the added advantage of ensuring that those responsible for any damage to the environment or biodiversity must redress it, not only in the case of biotechnology. This is more consistent with the Convention and provides better protection for the environment.
- Where rules providing for redress for damage to the environment or biodiversity do not exist, are insufficient, or are contrary to the requirements of the Supplementary Protocol, a comprehensive plan for amendment or creation of new legal instruments should be developed. This includes review and consideration of numerous specific areas left by the Supplementary Protocol to domestic law. A country's ratification plan therefore should include systematic consideration of all references in the Supplementary Protocol to domestic law.

General Principles:
In considering the relationship of the Supplementary Protocol with domestic law and the applicability of domestic laws in implementing the Supplementary Protocol, countries should apply general principles for protecting the environment and biodiversity and establish a system for the fair, efficient and predictable resolution of claims of damage. Considerations include:

- Protection of biodiversity as a "public good" by the state.
- Science-based evidence and decisions.
- Responsibility channeled to the "operator" who caused the damage (the "polluter" pays).
- Legal due process.
- Independent unbiased decision-makers.
- Recognition of existing jurisprudence or legislation: Where there is developed jurisprudence and law, there is no reason to change basic approaches to liability and redress in relation to a new, but thoroughly assessed and regulated technology.
- Practical and fair application.
- Social responsibility: Balance risks and benefits by adequately protecting biodiversity while appropriately enabling the use of technology that contributes to food and agricultural security.

Civil Liability:
The Supplementary Protocol requires that its Parties provide in their domestic law for civil liability for material or personal damage (also known as "traditional damages") related to damage as defined in the Supplementary Protocol. Since virtually every country in the world already has civil law covering traditional damages[2], they can simply apply existing law to meet this obligation as foreseen in Article 12.2(a).

Caveats:
Transposing international frameworks into national law is a complex process. In the case of the Supplementary Protocol, the process may appear even more complex because the Supplementary Protocol framework defers to domestic law in 18 instances. On the other hand, the many references to domestic law may be seen as facilitating ratification and implementation because they provide flexibility for countries with different legal systems.

[2] See Prof. Lucas Bergkamp, Liability and Redress: Existing Legal Solutions for Traditional Damage (January 2004). http://www.ecoconsult.ch/uploads/1144-CropLife_Handbook.pdf

Compliance with the Cartagena Protocol on Biosafety:

The Supplementary Protocol obviously builds on the Protocol and national biosafety legislation put in place to implement the Protocol. Thus, compliance with the Supplementary Protocol follows and flows from compliance with the Protocol. This situation gives rise to a number of fundamental points that should be well-considered and addressed:

- If legally binding domestic biosafety legislation exists, it should be evaluated to determine the extent to which it is consistent with the Protocol. For example, definitions in domestic legislation should be the same as those found in the Protocol (the Supplementary Protocol incorporates by reference all Protocol definitions). If definitions in domestic law differ from the Protocol or the Convention, inconsistencies, misunderstandings and misinterpretation will likely result.
- Other aspects of Protocol compliance should also be considered. For example, timeframes for procedures should be within stated Protocol limits; provisions consistent with the Protocol on the treatment of confidentiality should be incorporated; and information requirements and risk assessment should be consistent with the Protocol requirements and annexes.
- The Implementation Toolkit developed as part of capacity building work under the Protocol provides a useful checklist to assess compliance with Protocol obligations[3]. Deficiencies or inconsistencies in national biosafety legislation can be identified using this Toolkit. Any deviations should be addressed prior to or as part of the plan to implement and comply with the Supplementary Protocol.
- Once Protocol-compliant national biosafety legislation is in place, it should be placed on the Biosafety Clearing House along with a declaration pursuant to Protocol Article 14.4 that the domestic regulation applies.

Relationship between Protocol and Supplementary Protocol Implementation:

- If a law is already in place that is compliant with the Protocol, it may be possible to implement the Supplementary Protocol through a separate regulation, order or decree pursuant to that law. If the biosafety law is not Protocol compliant, one may consider merging the two processes and addressing both Protocol and Supplementary Protocol obligations and compliance in a single instrument.
- This Guide provides explanations and example texts to implement the Supplementary Protocol in a new stand-alone legal instrument. With slight modifications, the texts also could be incorporated into existing biosafety law.
- Regardless of the approach that is chosen, it is imperative that all the related legal instruments are consistent with the Protocol, the Supplementary Protocol and each other, and that they do not redefine terms or overlap. The relationship between a new legal instrument and those already in existence should be clear in the text and any provisions in previously existing legislation that are being replaced should be explicitly revoked.

[3] See UNEP/CBD/BS/COP-MOP/1/15, Annex III (p. 73).

Explanation of the Guide Format and Notations

Supplementary Protocol Text:

The text of the Supplementary Protocol is set out in blue print and placed in text boxes in the Guide for ease of reference. Underlining has been added to highlight references to domestic law.

Example Text:

- An example of possible text to implement the provisions of the Supplementary Protocol is provided.
- For a limited number of provisions, two alternative examples are provided for countries to consider. Example Text is presented in two colours. Blue print indicates that the text can be found in the Supplementary Protocol.
- Any deletions or insertions suggested to implement the Supplementary Protocol at the national level are clearly marked in red.
- Throughout the Guide, capital letters have been used for defined terms (e.g., Living Modified Organism). These edits are not marked as changes in the Example Text.
- Curly brackets { } are used where information specific to a country needs to be inserted, i.e., the name of the country or a reference to an existing domestic law.
- Square brackets [ ] mark text that may be deleted depending on the existence of relevant domestic law.
- The term "regulation" is used in these Guidelines but should be replaced by the relevant national term (e.g., law, decree, order or other legal measure).

Explanation:

Commentary and guidance concerning possible text to implement each relevant provision of the Supplementary Protocol are provided in italicised text following the Example Text.

Implementation Guide

NAGOYA – KUALA LUMPUR SUPPLEMENTARY PROTOCOL ON LIABILITY AND REDRESS TO THE CARTAGENA PROTOCOL ON BIOSAFETY

Example text:

Regulation No. ___ (Liability and Redress relating to Living Modified Organisms) 2012

Explanation: The title of the Regulation should appear with relevant citations, numbering, date, etc.

The Parties to this Supplementary Protocol,

***Being* Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, hereinafter referred to as "the Protocol",**

***Taking into account* Principle 13 of the Rio Declaration on Environment and Development,**

***Reaffirming* the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development,**

***Recognising* the need to provide for appropriate response measures where there is damage or sufficient likelihood of damage, consistent with the Protocol,**

***Recalling* Article 27 of the Protocol,**

Have agreed as follows:

Example text:

Whereas

~~*The Parties to this Supplementary Protocol,*~~

~~*Being* Parties to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, hereinafter referred to as "the Protocol",~~

{name of country} is Party to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity hereinafter referred to as the "Protocol" pursuant to *{cite national legal measure related to ratification or accession}* and has ratified/acceded to the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety, hereinafter referred to as the "Supplementary Protocol" pursuant to *{cite national legal measure related to ratification or accession}*,

Recalling {e.g., Biosafety Law No. __ of 20__ and Regulation No. __ of 20__},

Taking into account Principle 13 of the Rio Declaration on Environment and Development,

Reaffirming the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development,

Recognising the need to provide for appropriate response measures where there is damage or sufficient likelihood of damage, consistent with the Protocol,

~~*Recalling Article 27 of the Protocol,*~~

~~Have agreed as follows:~~

Hereby adopts the following:

Explanation: The Supplementary Protocol language should be replaced with preambular clauses appropriate for this type of national legislation. Reference should be made to the country's status as a Party to the Protocol and Party to the Supplementary Protocol, taking due regard for ensuring that legal measures and administrative systems are in place prior to depositing an instrument of ratification/accession. See Introductory Note for further explanation of the relationship between the Protocol, the Supplementary Protocol and existing domestic legislation.

Reference also should be made to existing national biosafety laws, regulations, etc.

Article 1 Objective

The objective of this Supplementary Protocol is to contribute to the conservation and sustainable use of biological diversity, taking also into account risks to human health, by providing international rules and procedures in the field of liability and redress relating to living modified organisms.

Example text:

Article 1 Objective

The objective of this ~~Supplementary Protocol~~ Regulation is to contribute to the conservation and sustainable use of Biological Diversity, taking also into account risks to human health, by providing ~~international~~ rules and procedures in the field of liability and redress relating to Living Modified Organisms in accordance with the Supplementary Protocol.

Explanation: It is necessary to convert the Supplementary Protocol language for domestic law to state the objective of the Regulation.

Article 2 Use of terms

1. The terms used in Article 2 of the Convention on Biological Diversity, hereinafter referred to as "the Convention", and Article 3 of the Protocol shall apply to this Supplementary Protocol.

Example text:

Article 2 Use of terms

1. The following terms ~~used in Article 2 of the Convention on Biological Diversity, hereinafter referred to as "the Convention", and Article 3 of the Protocol~~ shall apply to this Regulation and its annexes: ~~Supplementary Protocol~~.

a. "Convention" means the Convention on Biological Diversity;
b. "Protocol" means the Cartagena Protocol on Biosafety to the Convention on Biological Diversity;
c. "Supplementary Protocol" means the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety;
d. "Biological Diversity" means the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems;
e. "Habitat" means the place or type of site where an organism or population naturally occurs;
f. "Ecosystem" means a dynamic complex of plant, animal and micro-organism communities and their non-living environment interacting as a functional unit;
g. "Contained use" means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;
h. "Living Modified Organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;
i. "Living Organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;
j. "Modern Biotechnology" means the application of:
    i. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
    ii. 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.

Explanation: For ease of reference and to assure consistency, the key terms from the Convention and Protocol are incorporated into this text. Alternatively, reference could be made to domestic law if all the relevant Convention and Protocol terms are found therein without change. It would be helpful to reorder the terms alphabetically in actual legislation.

2. In addition, for the purposes of this Supplementary Protocol:
a. "Conference of the Parties serving as the meeting of the Parties to the Protocol" means the Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol;
b. "Damage" means an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health, that:
i. Is measurable or otherwise observable taking into account, wherever available, scientifically-established baselines recognised by a competent authority that takes into account any other human induced variation and natural variation; and
ii. Is significant as set out in paragraph 3 below;

(Article 2 Use of terms continued….)

Example text:

~~2. In addition, for the purposes of this Supplementary Protocol~~:
~~a.~~ ~~"Conference of the Parties serving as the meeting of the Parties to the Protocol" means the Conference of the Parties to the Convention serving as the meeting of the Parties to the Protocol;~~
k. "Damage" means an adverse effect on the conservation and sustainable use of Biological Diversity, taking also into account risks to human health, that:
    i. Is measurable or otherwise observable taking into account, wherever available, scientifically-established Baselines recognised or established by a Competent Authority under this Regulation that takes into account any other human induced variation and natural variation; and
    ii. Is significant as set out in paragraph 2~~3~~ below;

Explanation: Supplementary Protocol Article 2.a. is not relevant to domestic regulations so has not been included in the Regulation.

To ensure consistency with the Supplementary Protocol, the definition of Damage is incorporated into the Regulation. Paragraph b.i. refers to Baselines "recognised" by the Competent Authority. In cases where a Baseline already exists, it may be recognised. Where that is not yet the case, the Competent Authority may establish a Baseline as part of its work to identify Damage, etc. Accordingly, the words "or established" have been added to the Supplementary Protocol definition.

c. "Operator" means any person in direct or indirect control of the living modified organism which could, as appropriate and as determined by domestic law, include, inter alia, the permit holder, person who placed the living modified organism on the market, developer, producer, notifier, exporter, importer, carrier or supplier;

(Article 2 Use of terms continued….)

Example text:

l) "Operator" means any person in direct or indirect control of the Living Modified Organism [in accordance with ~~which could, as~~ {citation to appropriate ~~and as determined by~~ domestic law}]. ~~, include, inter alia, the permit holder, person who placed the living modified organism on the market, developer, producer, notifier, exporter, importer, carrier or supplier,~~

Explanation: Article 2.2.c of the Supplementary Protocol defers to domestic law and provides a non-exhaustive list of examples of persons who could be held responsible as the "Operator". If the term "operator" already is defined in a relevant existing national law, the text in square brackets should be retained and completed with a reference to the law. In cases where appropriate domestic law does not exist, the text in square brackets should be deleted.

In countries where the term is not defined or the definition is not appropriate for this context, "Operator" needs to be explicitly defined in the Regulation. To operationalize the "polluter pays principle," the term "Operator" should focus on the person in direct or indirect control of the product or the activity that caused the Damage (i.e., the person who in fact and legally caused or should have prevented the Damage). Examples of who might be an operator (i.e., the developer who created the LMO, the grower who planted it in a proscribed area, etc.) are not necessary or appropriate in the regulation, as the "control" test will establish the identity of the Operator.

d. "Response measures" means reasonable actions to:
- **i. Prevent, minimise, contain, mitigate, or otherwise avoid damage, as appropriate;**
- **ii. Restore biological diversity through actions to be undertaken in the following order of preference:**
  - **a. Restoration of biological diversity to the condition that existed before the damage occurred, or its nearest equivalent; and where the competent authority determines this is not possible;**
  - **b. Restoration by, inter alia, replacing the loss of biological diversity with other components of biological diversity for the same, or for another type of use either at the same or, as appropriate, at an alternative location.**

(Article 2 Use of terms continued….)

Example text (part i):

m. "Response Measures" means reasonable actions to:
- i. Prevent, minimise, contain, mitigate, or otherwise avoid Damage, as appropriate;
- ii. Restore Biological Diversity through actions to be undertaken in the following order of preference:
  - a) Restoration of Biological Diversity to the Baseline C~~e~~ondition ~~that existed before the damage occurred,~~ or its nearest equivalent; and where the Competent Authority determines this is not possible;
  - b) Restoration by, inter alia, replacing the loss of Biological Diversity with other components of Biological Diversity for the same, or for another type of use either at the same or, as appropriate, at an alternative location;

Explanation: The Supplementary Protocol definition of "Response Measures" is incorporated. Reference also is made to the "Baseline Condition", which has also been included as a new defined term. The Baseline Condition is an essential concept in the application of Response Measures since the state of Biological Diversity to be achieved with the application of the Response Measures will be determined by the specific circumstances of the Damage and the resulting effects on the viability and sustainability of the affected species and ecosystem, and the Baseline is no longer the relevant end point in that determination.

Example text (part ii):

n. "Competent Authority" for purposes of this Regulation means {name of minister, agency or office};

Explanation: It is necessary to specify the office or agency that will make determinations and carry out the obligations of the Regulation for the government (e.g., Ministry of Agriculture; National Agriculture Institute, etc.). Additional details about the Competent Authority may be placed in Article 15 below.

Example Text (part iii):

o. "Baseline" means the condition at the time of the Damage of the natural resources and services that would have existed had the Damage not occurred, estimated on the basis of the Best Information Available;

p. "Baseline Condition" means the state of Biological Diversity that is the goal of the restoration plan for the species or Ecosystem alleged to be Damaged and that represents the condition that existed before Damage occurred to that species or Ecosystem, which is satisfied when:

i. population dynamics data for the species alleged to be Damaged demonstrate that the species can maintain itself on a long-term basis as a viable component of the Ecosystem;
ii. the natural range of the species has been increased to a sustainable level;
iii. a sufficient Habitat exists to maintain the species on a long-term basis; or
iv. one or more other species in the affected Ecosystem related to or dependent upon the species alleged to be Damaged can maintain itself on a long-term basis as a viable component of the Ecosystem;

Explanation: The term "Baseline" has been added because it is essential to the assessment of potential Damage. The Example Text is adapted from Article 2(14) of the ELD. The term "Baseline Condition" has been added because it is important in the determination of appropriate and sufficient Response Measures. These terms, which are not defined in the Supplementary Protocol, help clarify the determination and application of Response Measures.

Example text (part iv):

q. "Best Available Information" means the peer-reviewed or peer-reviewable information obtained through the generally accepted scientific methodology used in the relevant scientific community of endeavour (such as genetics, ecology, microbiology, species population dynamics, and social sciences), including such information found on the Biosafety Clearing House of the Protocol. This methodology must consist of a testable hypothesis, existence and maintenance of standards controlling the technique's operation, and an acceptable known or potential rate of error, and the results must be repeatable. Best Available Information must be used in the determination of each element of a claim for Response Measures.

Explanation: "Best Available Information" is a term used in the ELD, however, it is not defined in that instrument. To increase clarity and predictability, in the Example Text, the ELD terminology is used and is defined based on language from the Compact. Also incorporated in this definition is the reference to the Biosafety Clearing House found in Article 5.3 of the Supplementary Protocol.

3. A "significant" adverse effect is to be determined on the basis of factors, such as:
a. The long-term or permanent change, to be understood as change that will not be redressed through natural recovery within a reasonable period of time;
b. The extent of the qualitative or quantitative changes that adversely affect the components of biological diversity;
c. The reduction of the ability of components of biological diversity to provide goods and services;
d. The extent of any adverse effects on human health in the context of the Protocol.

(Article 2 Use of terms continued….)

Example text:

2~~3~~. Damage is established only in the case of a significant adverse effect:
a. ~~A "significant" adverse effect is to be determined on the basis of factors, such as:~~An effect is adverse if it is a qualitative or quantitative change~~s~~ that:
~~b.~~ ~~The extent of the adversely~~ Negatively affects the components of Biological Diversity;
~~c.~~ ~~The reduction of~~ Reduces the ability of components of Biological Diversity to provide goods and services; or
~~d.~~ ~~The extent of any adverse~~ Negatively affects ~~on~~ human health in the context of the Protocol.
b. An adverse effect is significant based upon the extent of the adverse effects in 2.a., above, and if it results in~~The~~ long-term or permanent change, to be understood as change that will not be redressed through natural recovery within a reasonable period of time.

Explanation: The Supplementary Protocol provides various factors that may be considered by Parties to determine when a change is both adverse and qualifies as "significant". The text is revised to provide greater clarity about these two distinct elements.

Article 3 Scope

1. This Supplementary Protocol applies to damage resulting from living modified organisms which find their origin in a transboundary movement. The living modified organisms referred to are those:
a. Intended for direct use as food or feed, or for processing;
b. Destined for contained use;
c. Intended for intentional introduction into the environment.
2. With respect to intentional transboundary movements, this Supplementary Protocol applies to damage resulting from any authorised use of the living modified organisms referred to in paragraph 1 above.

Example text:

Article 3 Scope
1. This Regulation ~~Supplementary Protocol~~ applies to Damage resulting from authorised import or use of Living Modified Organisms intended for ~~which find their origin in a transboundary movement. The living modified organisms referred to are those:~~
a. ~~Intended for d~~Direct use as food or feed, or for processing;
b. ~~Destined for c~~Contained use; and
c. ~~Intended for i~~Intentional introduction into the environment.

~~2. With respect to intentional transboundary movements, this Supplementary Protocol applies to damage resulting~~

~~from any authorised use of the living modified organisms referred to in paragraph 1 above.~~

Explanation: When Damage occurs, it is irrelevant whether it was caused by domestic or foreign operators. Accordingly, the liability and redress provisions of the Regulation should apply equally to Damage caused by domestic activities and foreign activities, thus avoiding any WTO implications or violations. The proposed text covers all approved activities, whether domestic or involving a transboundary movement.

3. This Supplementary Protocol also applies to damage resulting from unintentional transboundary movements as referred to in Article 17 of the Protocol as well as damage resulting from illegal transboundary movements as referred to in Article 25 of the Protocol.

(Article 3 Scope continued…)

Example text:

~~3~~. 2. This Regulation ~~Supplementary Protocol~~ also applies to Damage resulting from:

a. U~~u~~nintentional transboundary movements as referred to in Article 17 of the Protocol;~~as well as damage resulting from~~
b. I~~i~~llegal transboundary movements as referred to in Article 25 of the Protocol; and
c. Unintentional or illegal introduction of Living Modified Organisms into the environment under national law.

Explanation: This text follows the Supplementary Protocol text but, in addition, clarifies in paragraph that the Regulation also applies to Damage resulting from unapproved activities and activities that are illegal under national law.

4. This Supplementary Protocol applies to damage resulting from a transboundary movement of living modified organisms that started after the entry into force of this Supplementary Protocol for the Party into whose jurisdiction the transboundary movement was made.

(Article 3 Scope continued…)

Example text:

~~4~~. 3. This Regulation ~~Supplementary Protocol~~ applies to Damage resulting from the release of ~~a transboundary movement of~~ a Living Modified Organism as specified in paragraphs 1 or 2 that occurred ~~started~~after the entry into force of this Regulation.~~Supplementary Protocol for the Party into whose jurisdiction the transboundary movement was made~~

Explanation: New rules can only be applied on a prospective basis.

5. This Supplementary Protocol applies to damage that occurred in areas within the limits of the national jurisdiction of Parties.

(Article 3 Scope continued…)

Example text:

~~5.~~ 4. This Regulation ~~Supplementary Protocol~~ applies to Damage that occurs~~ed~~ in areas within the limits of the national jurisdiction of {name of country}~~Parties~~.

Explanation: Domestic regulations may only apply to Damage that occurs within national jurisdiction.

6. Parties may use criteria set out in their domestic law to address damage that occurs within the limits of their national jurisdiction.
7. Domestic law implementing this Supplementary Protocol shall also apply to damage resulting from transboundary movements of living modified organisms from non-Parties.

Explanation: The example texts provided in this Guide ensure that liability and redress provisions apply equally to Damage caused by domestic activities and foreign activities, thus avoiding any WTO implications or violations. No further text is required in relation to Supplementary Protocol paragraphs 6-7.

Article 4 Causation

A causal link shall be established between the damage and the living modified organism in question in accordance with domestic law.

Example text:

Article 4 Causation

1. A causal link shall be established by the Competent Authority between the Damage and the Living Modified Organism in question.

Alternative A, where causation is established by domestic law:

[2. Causation shall be established in accordance with {citation to appropriate domestic law}].

Alternative B, where domestic law does not provide clear guidance on causation:

[2. The Competent Authority shall determine that:

a. General causation exists, i.e. the change can generally be caused by the Living Modified Organism in question;
b. Specific causation exists, i.e. the Damage would not have occurred but for the release of the Living Modified Organism in question, and results directly from the phenotypic or genotypic modification of

the Living Modified Organism in question; and
c. No superseding event alters the chain of events that otherwise might have connected the release of the Living Modified Organism in question to the Damage.]

Explanation: The prevention and remedying of Damage should be implemented through the application of the "polluter pays" principle. The fundamental principle should therefore be that an Operator whose activity has caused the Damage is held responsible. Various "causation" tests ensure that this is the case.

Nearly every country's civil laws will provide guidance on establishing causation. In this case, Alternative A can be used with a citation to the relevant law.

In cases where appropriate domestic law does not exist, the second alternative provides and explains the key components of causation. At a minimum, an Operator should be held responsible only when the three distinct elements of causation are proven: (a) general causation, (b) specific causation, and (c) the lack of any superseding event.

Article 5 Response measures

1. Parties shall require the appropriate operator or operators, in the event of damage, subject to any requirements of the competent authority, to:
a. Immediately inform the competent authority;
b. Evaluate the damage; and
c. Take appropriate response measures.

Example text:

Article 5 Response Measures

1. ~~Parties shall require t~~In the event of Damage, t~~T~~he appropriate Operator ~~or operators, in the event of damage, subject to any requirements of the competent authority,~~ shall ~~to~~:
a. Immediately inform the Competent Authority;
b. Evaluate the Damage; and
c. Take appropriate Response Measures.

Explanation: In defining the appropriate Response Measures, countries first need to assess whether Response Measures complying with the principles as set out in the Supplementary Protocol already exist. If that is not the case or only partly the case, countries should include detailed provisions on how Response Measures, in the form of restoration or compensation, will be identified.

In paragraph 1), the plural term "Operators" is not necessary (and does not appear elsewhere in the Supplementary Protocol) and therefore has been removed to avoid interpretation problems elsewhere. Under the Supplementary Protocol and this Regulation, one or more than one Operator can be held responsible while using only the singular term. In addition, the text is streamlined for domestic use but maintains the obligation on the Operator to notify the Competent Authority and take action as appropriate.

2. The competent authority shall:
a. Identify the operator which has caused the damage;
b. Evaluate the damage; and
c. Determine which response measures should be taken by the operator.

(Article 5 Response Measures continued…)

Example Text:

2. The C~~c~~ompetent A~~a~~uthority shall:
a. Identify the Operator which has caused the Damage in accordance with Article 4 and Article 6 of the Regulation;
b. Evaluate the Damage in accordance with Annex I; and
c. Determine which Response Measures should be taken by the Operator in accordance with Annex II.

Explanation: The Supplementary Protocol text has been used for paragraph 2 but references to relevant provisions in the Regulation are added for clarity. In addition, it may be necessary to create Standard Operating Procedures to guide the Competent Authority in making determinations and implementing them. This can be done by governmental decree or order following the creation of the Regulation. See also Article 15.

Reference is also made in this provision to the two annexes that have been added to provide detailed provisions on determining Damage (Annex I) and on identifying the appropriate Response Measures (Annex II).

3. Where relevant information, including available scientific information or information available in the Biosafety Clearing-House, indicates that there is a sufficient likelihood that damage will result if timely response measures are not taken, the operator shall be required to take appropriate response measures so as to avoid such damage.
4. The competent authority may implement appropriate response measures, including, in particular, when the operator has failed to do so.

(Article 5 Response Measures continued…)

Example Text:

3. Where relevant Best Available Information~~, including available scientific information or information available in the Biosafety Clearing House,~~ indicates that there is a sufficient likelihood that Damage will result if timely Response Measures are not taken, the Operator shall be required to take appropriate Response Measures so as to avoid such Damage.

4. The Competent Authority may implement appropriate Response Measures, including, in particular, when the Operator has failed to do so.

Explanation: Paragraph 3 uses the term "Best Available Information" found in the ELD and, as noted previously, has been defined to include scientific information on the Biosafety Clearing House.

5. The competent authority has the right to recover from the operator the costs and expenses of, and incidental to, the evaluation of the damage and the implementation of any such appropriate response measures. Parties may provide, in their domestic law, for other situations in which the operator may not be required to bear the costs and expenses.

(Article 5 Response Measures continued…)

Example Text:

5. The Competent Authority has the right to recover from the Operator the costs and expenses of, and incidental to, the evaluation of the Damage and the implementation of any such appropriate Response Measures. ~~Parties may provide, in their domestic law, for other situations in which the operator may not be required to bear the costs and expenses.~~ The Competent Authority shall not recover costs or expenses of Response Measures in situations where the Damage in question is the result of an event defined as an exemption in Article 6 of the Regulation or a superseding event as defined in Article 4 of the Regulation.

Explanation: The first sentence of paragraph 5 of the Supplementary Protocol has been included in the Example Text without change. The second sentence of paragraph 5 permits Parties to include additional situations in which an Operator may not be required to bear costs. Nothing has been added. Instead, the Example Text simply refers to Articles 4 and 6 of the Regulation which identify cases in which an Operator is not held responsible.

6. Decisions of the competent authority requiring the operator to take response measures should be reasoned. Such decisions should be notified to the operator. Domestic law shall provide for remedies, including the opportunity for administrative or judicial review of such decisions. The competent authority shall, in accordance with domestic law, also inform the operator of the available remedies. Recourse to such remedies shall not impede the competent authority from taking response measures in appropriate circumstances, unless otherwise provided by domestic law.

(Article 5 Response Measures continued…)

Example Text:

6. Decisions of the Competent Authority requiring the Operator to take Response Measures must ~~should~~ be reasoned. Such decisions shall ~~should~~ be notified in writing to the Operator. ~~Domestic law shall provide for remedies, including the opportunity for administrative or judicial review of such decisions.~~ The Competent Authority shall~~, in accordance with domestic law, also~~ inform the Operator of the available remedies, including administrative and judicial review.

Explanation: The permissive language of the Supplementary Protocol ("should") has been changed to mandates ("shall") since only this formulation is possible in domestic legislation. Article 5, paragraph 6 of the Supplementary Protocol requires Parties to inform Operators of available remedies. These should include both administrative review (review of a decision by the Competent Authority on request by the Operator) and judicial review (provision for an Operator to access a court of law to review the results of an administrative review). Reference may be made to domestic law.

7. In implementing this Article and with a view to defining the specific response measures to be required or taken by the competent authority, Parties may, as appropriate, assess whether response measures are already addressed by their domestic law on civil liability.
8. Response measures shall be implemented in accordance with domestic law.

Explanation: No provisions are necessary in domestic regulations.

Article 6 Exemptions

1. Parties may provide, in their domestic law, for the following exemptions:
a. Act of God or force majeure; and
b. Act of war or civil unrest.

Example text:

Article 6 Exemptions

Alternative A

1. ~~Parties may provide, in their domestic law, for the following exemptions.~~
An Operator shall not be held liable upon proof that the Damage was caused by:
a. An Act of God or force majeure; or
b. An act of war or civil unrest.

Explanation: The primary defenses found in most liability systems are included in the Example Text as permitted under Article 6.1 of the Supplementary Protocol. The word "or" between paragraphs (a) and (b) is necessary to ensure that both standard defenses are available.

2. Parties may provide, in their domestic law, for any other exemptions or mitigations as they may deem fit.

Example text:

Article 6 Exemptions

Alternative B

~~Parties may provide, in their domestic law, for any other exemptions or mitigations as they may deem fit.~~

1. An Operator shall not be held liable upon proof that the Damage was caused by:
   a. An Act of God or force majeure; or
   b. An act of war or civil unrest.

2. In addition, an Operator shall not be held liable upon proof that the Damage was caused by:

   a. An act or omission that was the subject of a compulsory order by the government;
   b. Realisation of a risk:
      i Specifically assessed in compliance with Annex III of the Protocol (including those risks for which management measures were proposed in the risk assessment), where:
         a) the risk assessment was accepted by the governmental authority responsible for the proposed activity with the Living Modified Organism; and
         b) an authorisation for the Living Modified Organism in question was granted; and
      ii The Damage is consistent with the type, magnitude and probability of harm presented in the risk assessment; or
   c. Realisation of a risk posed by an activity specifically authorised or specifically permitted by applicable law or regulations.

Explanation: The Supplementary Protocol gives wide discretion to Parties to include additional defenses. The first defense arises when Damage occurs because of compulsory compliance by an Operator with a governmental order or mandate.

The three additional defenses included in the Example Text Alternative B relate to risk or conduct specifically approved by the government (these are taken from the Compact). Each of these defences is grounded in full and complete compliance by the Operator with the requirements imposed by the Competent Authority, whether through compulsory order, under to the requirements for risk assessment pursuant to the Protocol and national law, or by law or regulation. Fairness dictates that the Operator be exonerated from responsibility given proof of full compliance with all requirements imposed by the Competent Authority.

Article 7 Time limits

Parties may provide, in their domestic law, for:
   a. Relative and/or absolute time limits including for actions related to response measures; and
   b. The commencement of the period to which a time limit applies.

Example text:

Article 7 Time Limitations

~~Parties may provide, in their domestic law, for:~~
   ~~a. Relative and/or absolute time limits including for actions related to response measures; and~~

~~The commencement of the period to which a time limit applies.~~

The Competent Authority shall notify the Operator of a decision in relation to Response Measures no later than the earliest date of:

   a. Three (3) years from the date on which the Competent Authority knew or should have known of the Damage; or
   b. Twenty (20) years after the first authorisation or release in the environment (whichever is earliest) of the Living Modified Organism in question alleged to have caused the Damage; provided, that this twenty year time limitation shall be tolled (suspended) if the Living Modified Organism in question has caused Damage for which Response Measures have been ordered.

Explanation: Time limitations are central to all administrative and civil justice systems; they require timely action by those with rights or obligations and provide finality for all concerned. The three year relative time limit provides a Competent Authority with sufficient time to make the necessary determinations when Damage is discovered or alleged. The absolute time limit of twenty years to notify an Operator of a finding of responsibility runs from the first release of the Living Modified Organism anywhere in the world. This provides sufficient time for any Damage to materialise and the Competent Authority to act. Both the relative and absolute time limits suggested in the Example Text are standard in existing administrative and civil liability systems.

Article 8 Financial limits

Parties may provide, in their domestic law, for financial limits for the recovery of costs and expenses related to response measures.

Example text:

Article 8 Financial limits

~~Parties may provide, in their domestic law, for financial limits for the recovery of costs and expenses related to response measures.~~

In the event that an Operator is ordered to provide Response Measures, the following financial limits will apply for Incidents of Damage:

a. For a single of incident of Damage caused by an LMO, a maximum sum of [enter amount]; and
b. For all incidents of Damage caused by that LMO, a maximum sum of [enter the amount].

Explanation: Financial limits create a balance between the risk of any potential Damage and the benefits offered by LMOs, such as enhanced production of food, feed, fiber and fuel.

Financial limits should take into account:

1) potential costs of Response Measures (which would currently be purely speculative and cannot be estimated because there are no incidents of Damage by an LMO and no experience on which to base an actuarial calculation); and
2) the ability of all potential Operators to pay or to obtain insurance or provide some other form of financial security as provided by applicable corporate and business law (applied without discrimination to domestic and foreign enterprise); and
3) how insurability of potential liability under this law, decree or regulation may be best facilitated.

Article 9 Right of recourse

This Supplementary Protocol shall not limit or restrict any right of recourse or indemnity that an operator may have against any other person.

Example text:

Article 9 Right of recourse

This Regulation ~~Supplementary Protocol~~ shall not limit or restrict any right of recourse or indemnity that an Operator may have against any other person.

Explanation: This provision preserves existing rights under corporate or civil law.

Article 10 Financial security

1. Parties retain the right to provide, in their domestic law, for financial security.
2. Parties shall exercise the right referred to in paragraph 1 above in a manner consistent with their rights and obligations under international law, taking into account the final three preambular paragraphs of the Protocol.
3. The first meeting of the Conference of the Parties serving as the meeting of the Parties to the Protocol after the entry into force of the Supplementary Protocol shall request the Secretariat to undertake a comprehensive study which shall address, inter alia:
a. The modalities of financial security mechanisms;
b. An assessment of the environmental, economic and social impacts of such mechanisms, in particular on developing countries; and
c. An identification of the appropriate entities to provide financial security.

Explanation: The Supplementary Protocol does not mandate Parties to impose financial security requirements. If a Party were to elect to do so, however, any such requirements imposed exclusively on biotechnology would need to be supported by a justification that can withstand WTO scrutiny. In fact, most countries already have in place legal requirements for doing business. These requirements automatically apply to any business activity that takes place in the country and also can be relied on in the context of implementing the Supplementary Protocol. Hence, in most cases, there is no need for any additional, specific requirements related to the release of an LMO. Where general corporate or business law establishing the required capitalisation, assets, insurance or other financial security to conduct the particular business activity is lacking, it should be developed and equitably applied to all enterprises.

Article 11 Responsibility of States for internationally wrongful acts

This Supplementary Protocol shall not affect the rights and obligations of States under the rules of general international law with respect to the responsibility of States for internationally wrongful acts.

Explanation: No provisions are necessary in domestic regulations.

Article 12 Implementation and relation to civil liability

1. Parties shall provide, in their domestic law, for rules and procedures that address damage. To implement this obligation, Parties shall provide for response measures in accordance with this Supplementary Protocol and may, as appropriate:
a. Apply their existing domestic law, including, where applicable, general rules and procedures on civil liability;
b. Apply or develop civil liability rules and procedures specifically for this purpose; or
c. Apply or develop a combination of both.

2. Parties shall, with the aim of providing adequate rules and procedures in their domestic law on civil liability for material or personal damage associated with the damage as defined in Article 2, paragraph 2 (b):
   a. Continue to apply their existing general law on civil liability;
   b. Develop and apply or continue to apply civil liability law specifically for that purpose; or
   c. Develop and apply or continue to apply a combination of both.
3. When developing civil liability law as referred to in subparagraphs (b) or (c) of paragraphs 1 or 2 above, Parties shall, as appropriate, address, inter alia, the following elements:
   a. Damage;
   b. Standard of liability including strict or fault-based liability;
   c. Channelling of liability, where appropriate;
   d. Right to bring claims.

Explanation: As noted previously, where existing law already addresses an issue to which the Supplementary Protocol defers to domestic law, that law should be referenced or incorporated. This Regulation proposes provisions for domestic regulation where current law is silent on the relevant points.

Since nearly every country already has a system providing for civil liability and redress, countries should identify their own systems and can chose to simply apply them to establish liability and provide for redress in the case of traditional damage. Please see Introductory Note.

Article 13 Assessment and review

The Conference of the Parties serving as the meeting of the Parties to the Protocol shall undertake a review of the effectiveness of this Supplementary Protocol five years after its entry into force and every five years thereafter, provided information requiring such a review has been made available by Parties. The review shall be undertaken in the context of the assessment and review of the Protocol as specified in Article 35 of the Protocol, unless otherwise decided by the Parties to this Supplementary Protocol. The first review shall include a review of the effectiveness of Articles 10 and 12.

Explanation: No provisions are necessary in domestic regulations.

Article 14 Conference of the Parties serving as the meeting of the Parties to the Protocol

1. Subject to paragraph 2 of Article 32 of the Convention, the Conference of the Parties serving as the meeting of the Parties to the Protocol shall serve as the meeting of the Parties to this Supplementary Protocol.
2. The Conference of the Parties serving as the meeting of the Parties to the Protocol shall keep under regular review the implementation of this Supplementary Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Supplementary Protocol and, *mutatis mutandis*, the functions assigned to it by paragraphs 4 (a) and (f) of Article 29 of the Protocol.

Explanation: No provisions are necessary in domestic regulations.

Article 15 Secretariat

The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Supplementary Protocol.

Explanation: No provisions are necessary in domestic regulations.

Article 16 Relationship with the Convention and the Protocol

1. This Supplementary Protocol shall supplement the Protocol and shall neither modify nor amend the Protocol.
2. This Supplementary Protocol shall not affect the rights and obligations of the Parties to this Supplementary Protocol under the Convention and the Protocol.
3. Except as otherwise provided in this Supplementary Protocol, the provisions of the Convention and the Protocol shall apply, mutatis mutandis, to this Supplementary Protocol.
4. Without prejudice to paragraph 3 above, this Supplementary Protocol shall not affect the rights and obligations of a Party under international law.

Explanation: No provisions are necessary in domestic regulations.

Article 17 Signature

This Supplementary Protocol shall be open for signature by Parties to the Protocol at the United Nations Headquarters in New York from 7 March 2011 to 6 March 2012.

Explanation: No provisions are necessary in domestic regulations.

Article 18 Entry into force

1. This Supplementary Protocol shall enter into force on the ninetieth day after the date of deposit of the fortieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organisations that are Parties to the Protocol.
2. This Supplementary Protocol shall enter into force for a State or regional economic integration organisation that ratifies, accepts or approves it or accedes thereto after the deposit of the fortieth instrument as referred to in paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organisation deposits its instrument of ratification, acceptance, approval, or accession, or on the date on which the Protocol enters into force for that State or regional economic integration organisation, whichever shall be the later.
3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organisation shall not be counted as additional to those deposited by member States of such organisation.

Example text:

Article 10 Entry into Force

1.This Regulation shall enter into force on the __ day following its publication.

2.{Articles x – y of Biosafety Law N. __} concerning liability and redress shall be revoked upon entry into force of this Regulation.

Explanation: A provision providing for the entry into force of the Regulation needs to be included. If existing biosafety law or regulation addresses liability relating to Living Modified Organisms, those provisions should be explicitly revoked upon entry into force of this Regulation.

Article 19 Reservations

No reservations may be made to this Supplementary Protocol.

Article 20 Withdrawal

1. At any time after two years from the date on which this Supplementary Protocol has entered into force for a Party, that Party may withdraw from this Supplementary Protocol by giving written notification to the Depositary.
2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.
3. Any Party which withdraws from the Protocol in accordance with Article 39 of the Protocol shall be considered as also having withdrawn from this Supplementary Protocol.

Explanation: No provisions are necessary in domestic regulations.

Article 21 Authentic texts

The original of this Supplementary Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorised to that effect, have signed this Supplementary Protocol.

DONE at Nagoya on this fifteenth day of October two thousand and ten.

Example text:

Adopted ….

Explanation: Any formalities for the adoption of the Regulation in accordance with domestic law can be inserted.

Annex I: Determination of Damage

Explanation: *These provisions help to guide the process of determining the Damage for which an Operator may be held liable.*

Two alternatives are provided for this Annex. Alternative A is based on ELD language and Alternative B is based on Compact language. Changes to the original ELD text are marked in red. Citations in the original text to EU law have been omitted.

Example text:

Annex I: Determination of Damage

[Alternative A (taken from the ELD, Annex I):

1) Damage is determined by comparing the nature and quantum of change in the species or Ecosystem from the Baseline. To determine if there is a measurable change in Biological Diversity, the Baseline must first be established. Then the conditions alleged to represent ~~change or~~ Damage must be compared to that Baseline to verify that there has been a measurable change from the Baseline. If measurable change has occurred, it must then be determined whether the measurable change is significant and adverse.

2) The significance of any Damage that has adverse effects on reaching or maintaining the favourable conservation status of Habitats or species has to be assessed by reference to the conservation status at the time of Damage, the services provided and their capacity for natural regeneration.

3) The Competent Authority shall base its determination of the Baseline and the comparison of the Baseline to the conditions alleged to represent Damage on Best Available Information, including an assessment of *inter alia* the following:

   a) the number of species, their density or the area covered,
   b) the role of the particular species or of the damaged area in relation to the species or the Habitat conservations, the rarity of the species or Habitat (assessed at local; regional and higher level including Community level);
   c) the species capacity for propagation (according to the dynamics specific to that species or to that population), its viability or the Habitat's capacity for natural regeneration (according to the dynamics specific to its characteristic species or to their populations);
   d) the species' or Habitat's capacity, after Damage has occurred, to recover within a short time, without any intervention other than increased protection measures, to a condition which leads, solely by virtue of the dynamics of the species or the Habitat, to a condition deemed equivalent or superior to the Baseline Condition.

4) The following are examples of changes to a species that are <u>not</u> significant and adverse changes *per se*:

   a) Negative variations that are smaller than natural fluctuations regarded as normal for the species or Habitat in question;
   b) Negative variations due to natural causes or resulting from intervention relating to the normal management of sites, as defined in Habitat records or target documents or as carried on previously by owners or Operators;
   c) Damage to species or Habitats for which it is established that they will recover, within a short time and without intervention, either to the Baseline Condition or to a condition which leads, solely by virtue of the dynamics of the species or Habitat, to a condition deemed equivalent or superior to the Baseline Condition.]

[Alternative B (paragraphs 2), 3), 4) and the subparagraphs of 5) taken from the Compact)

1) Damage is determined by comparing the nature and quantum of change in the species or Ecosystem from the Baseline. To determine if there is a measurable change in Biological Diversity, the Baseline must first be established. Then the conditions alleged to represent ~~change or~~ Damage must be compared to that Baseline to verify that there has been a measurable change from the Baseline. If measurable change has occurred, it must then be determined whether the measurable change is significant and adverse.

2) The Competent Authority shall base its determination of the Baseline and the comparison of the Baseline to the conditions alleged to represent Damage on Best Available Information, taking into account *inter alia* the following:

   (a) the nature and characteristics of the species;
   (b) the functionality or natural resource service provided by the species;
   (c) any other human induced variation; and
   (d) any other natural variation, including

      a. the natural range/distribution of species and the naturally occurring fluctuation in numbers and distribution of the species over time;

b. the interaction of the species within the Ecosystem and the species' capacity for natural regeneration;
c. the species' capacity for propagation;
d. the species' capacity for recovery within a reasonable period of time under natural restorative forces.

3) A measurable change is a significant and adverse change only when, as a result of that change:

(a) population dynamics data for the species alleged to be Damaged demonstrate that the species cannot maintain itself on a long-term basis or a reliable component of its natural Habitat;
(b) the natural range of the species has been reduced to an unsustainable level;
(c) a sufficient Habitat no longer exists to maintain the species on a long-term basis; or
(d) one or more other species in the affected Ecosystem related to or dependent upon the species alleged to be Damaged cannot maintain itself on a long-term basis as a viable component of the Ecosystem.

4) In assessing whether there has been significant and adverse change, the Competent Authority shall take into consideration the life histories of the species, on a qualitative and quantitative basis, which may demonstrate naturally occurring changes over time (increases and decreases) in population census, geographical distribution, gene frequency, and other biological parameters. Such naturally occurring changes in these or other parameters are not significant and adverse change *per se*, as they may be necessary for the adaptation of the species or the natural evolution of the Ecosystem. Also, such changes may be a factor in the determination of whether significant and adverse change has occurred but are not sufficient in and of themselves to establish such significant and adverse change.]

5) The following are examples of changes to a species that are <u>not</u> significant and adverse changes *per se*:

(a) a change in Biological Diversity which is within the historical or expected range of fluctuations regarded as "normal" for the species;
(b) a change in Biological Diversity due to natural causes or resulting from intervention relating to the normal management of the Ecosystem;
(c) a change in Biological Diversity for which it is determined that any resulting reduction in numbers or distribution of species will be reversed or will recover due to natural restorative forces to the Baseline Condition or to a condition which leads, solely by virtue of the dynamics of the species or its Ecosystem, to a condition at least equivalent to the Baseline Condition;
(d) a change in Biological Diversity which is consistent with the risk assessment, and results from the intended use, of the Living Modified Organism in question authorised (e.g. the reduction or loss of the target pest species);
(e) a change in the genetic content of a species that does not significantly impact its functionality, interactions within its Ecosystem or its conservation status;
(f) the mere presence of the Living Modified Organism in question or unique genetic elements from the Living Modified Organism in question in the species or within the Ecosystem; or
(g) a change in Biological Diversity resulting from actions, activities or events which would have occurred even if the Living Modified Organism in question's unmodified counterpart was used (e.g. the conventional crop of the same species as the Living Modified Organism in question).]

Annex II: Response Measures

Explanation: *This annex provides a detailed overview of the elements to be taken into consideration in selecting Response Measures for the restoration plan and for compensation if restoration is not possible.*

Two alternatives are provided for this Annex. Alternative A is based on ELD language and Alternative B is based on Compact language. Changes to the original ELD text are marked in red. Citations in the original text to EU law have been omitted.

Example text:

Annex II: Response Measures

[Alternative A, (adapted from the ELD)

This Annex sets out a common framework to be followed in order to choose the most appropriate measures to ensure the ~~remedying~~ restoration of ~~environmental~~ Damage.

1) ~~Remediation~~ Restoration of Damage to water or protected species or natural Habitats Remedying of ~~environmental~~Damage, in relation to water or protected species or natural Habitats, is achieved through the restoration of the environment to its Baseline Condition by way of primary, complementary and compensatory ~~remediation~~ restoration, where:

   (a) 'Primary' ~~remediation~~ restoration is any ~~remedial~~ response measure which returns the damaged natural resources and/or impaired services to, or towards, Baseline Condition;
   (b) 'Complementary' ~~remediation~~ restoration is any ~~remedial~~ Response Measure taken in relation to natural resources and/or services to compensate for the fact that primary ~~remediation~~ restoration does not result in fully restoring the damaged natural resources and/or services;
   (c) 'Compensatory' ~~remediation~~ restoration is any action taken to compensate for interim losses of natural resources and/or services that occur from the date of Damage occurring until primary ~~remediation~~ restoration has achieved its full effect;
   (d) 'Interim Losses' means losses which result from the fact that the damaged natural resources and/or services are not able to perform their ecological functions or provide services to other natural resources or to the public until the primary or complementary measures have taken effect. It does not consist of financial compensation to members of the public.

Where primary ~~remediation~~ restoration does not result in the restoration of the environment to its Baseline Condition, then complementary ~~remediation~~ restoration will be undertaken. In addition, compensatory ~~remediation~~ restoration will be undertaken to compensate for the Interim Losses.
~~Remedying~~ Restoration of ~~environmental~~Damage, in terms of Damage to water or protected species or natural Habitats, also implies that any significant risk of human health being adversely affected be removed.

1.1. *~~Remediation~~ Restoration objectives*
Purpose of primary ~~remediation~~ restoration
1.1.1. The purpose of primary ~~remediation~~ restoration is to restore the damaged natural resources and/or services to, or towards, Baseline Condition.

Purpose of complementary ~~remediation~~ restoration
1.1.2. Where the damaged natural resources and/or services do not return to their Baseline Condition, then complementary ~~remediation~~ restoration will be undertaken. The purpose of complementary ~~remediation~~ restoration is to provide a similar level of natural resources and/or services, including, as appropriate, at an alternative site, as would have been provided if the damaged site had been returned to its Baseline Condition. Where possible and appropriate the alternative site should be geographically linked to the damaged site, taking into account the interests of the affected population.

Purpose of compensatory ~~remediation~~ restoration
1.1.3. Compensatory ~~remediation~~ restoration shall be undertaken to compensate for the Interim Loss of natural resources and services pending recovery. This compensation consists of additional improvements to protected natural Habitats and species or water at either the damaged site or at an alternative site. It does not consist of financial compensation to members of the public.

1.2. *Identification of ~~remedial~~ ~~Restoration~~ Response Measures*
Identification of primary ~~remedial~~ Response Measures
1.2.1. Options comprised of actions to directly restore the natural resources and services towards Baseline Condition on an accelerated time frame, or through natural recovery, shall be considered.

Identification of complementary and compensatory ~~remedial~~ Response Measures
1.2.2. When determining the scale of complementary and compensatory ~~remedial~~ Response Measures, the use of resource-to-resource or service-to-service equivalence approaches shall be considered first. Under these approaches, actions that provide natural resources and/or services of the same type, quality and quantity as those damaged shall be considered first. Where this is not possible, then alternative natural resources and/or services shall be provided. For example, a reduction in quality could be offset by an increase in the quantity of ~~remedial~~ Response Measures.

1.2.3. If it is not possible to use the first choice resource-to-resource or service-to-service equivalence approaches, then alternative valuation techniques shall be used. The Competent Authority may prescribe the method, for example monetary valuation, to determine the extent of the necessary complementary and compensatory ~~remedial~~ Response Measures. If valuation of the lost resources and/or services is practicable, but valuation of the replacement natural resources and/or services cannot be performed within a reasonable time-frame or at a reasonable cost, then the Competent Authority may choose ~~remedial~~ Response Measures whose cost is equivalent to the estimated monetary value of the lost natural resources and/or services.

The complementary and compensatory ~~remedial~~ Response Measures should be so designed that they provide for additional natural resources and/or services to reflect time preferences and the time profile of the ~~remedial~~ Response Measures. For example, the longer the period of time before the Baseline Condition is reached, the greater the amount of compensatory ~~remedial~~ Response Measures that will be undertaken (other things being equal).

1.3. *Choice of the ~~remedial options~~ Response Measures*
1.3.1. The reasonable *~~remedial options~~ Response Measures* should be evaluated, using best available technologies, based on the following criteria:
— The effect of each option on public health and safety,
— The cost of implementing the option,
— The likelihood of success of each option,
— The extent to which each option will prevent future Damage, and avoid collateral damage as a result of implementing the option,
— The extent to which each option benefits to each component of the natural resource and/or service,
—The extent to which each option takes account of relevant social, economic and cultural concerns and other relevant factors specific to the locality,
— The length of time it will take for the restoration of the Damage to be effective,
— The extent to which each option achieves the restoration of site of the ~~environmental~~Damage,
— The geographical linkage to the damaged site.

When evaluating the different identified *~~remedial options~~ Response Measures*, primary ~~remedial~~ Response Measures that do not fully restore the damaged water or protected species or natural Habitat to the Baseline Condition or that restore it more slowly can be chosen. This decision can be taken only if the natural resources and/or services foregone at the primary site as a result of the decision are compensated for by increasing complementary or compensatory actions to provide a similar level of natural resources and/or services as were foregone. This will be the case, for example, when the equivalent natural resources and/or services could be provided elsewhere at a lower cost. These additional ~~remedial~~ Response Measures shall be determined in accordance with the rules set out in section 1.2.2.

1.3.3. Notwithstanding the rules set out in section 1.3.2~~, and in accordance with Article 7(3),~~ the Competent Authority is entitled to decide that no further Response Measures should be taken if:

(a) the ~~remedial~~ Response Measures already taken secure that there is no longer any significant risk of adversely affecting human health, water or protected species and natural Habitats, and
(b) the cost of the Response Measures that should be taken to reach Baseline Condition or similar level would be disproportionate to the environmental benefits to be obtained.

2. ~~Remediation~~ Restoration of land Damage
The necessary Response Measures shall be taken to ensure, as a minimum, that the relevant contaminants are removed, controlled, contained or diminished so that the contaminated land, taking account of its current use or approved future use at the time of the Damage, no longer poses any significant risk of adversely affecting human health. The presence of such risks shall be assessed through risk-assessment procedures taking into account the characteristic and function of the soil, the type and concentration of the harmful substances, preparations, organisms or micro-organisms, their risk and the possibility of their dispersion. Use shall be ascertained on the basis of the land use regulations, or other relevant regulations, in force, if any, when the Damage occurred.

If the use of the land is changed, all necessary Response Measures shall be taken to prevent any adverse effects on human health.

If land use regulations, or other relevant regulations, are lacking, the nature of the relevant area where the Damage occurred, taking into account its expected development, shall determine the use of the specific area.

A natural recovery option, that is to say an option in which no direct human intervention in the recovery process would be taken, shall be considered.]

[Alternative B (adapted from the Compact)

1) Restoration is the preferred form of response. The Competent Authority shall propose a restoration plan and the Operator may offer an alternative restoration plan. Absent agreement on the restoration plan between the Operator and the Competent Authority, the restoration plan will be determined by the Competent Authority in accordance with the following:
   (a) The restoration plan shall be designed to achieve the Baseline Condition and be based on Best Available Information. The restoration plan shall not exceed that which is necessary to achieve the

Baseline Condition.

(b) The restoration plan shall take into account the characteristics of the Ecosystem in which Damage is alleged to have occurred, such as whether it is (i) a protected area, (ii) a centre of origin, or (iii) a developed, industrialised or degraded Ecosystem.

(c) The restoration plan shall take into account negative impacts, if any, on public health or on an Ecosystem proven to have been caused by the Damage.

(d) The determination based on Best Available Information of the scope, methods and processes of a restoration plan may consider as appropriate the precautionary approach as it is described in Principle 15 of the Rio Declaration. For the restoration plan to include a different scope, method or process for a related or dependent species (Ecosystem approach) than the scope, method or process for the Damaged species, the Competent Authority must demonstrate through Best Available Information that impacts to related or dependent species require such a different scope, method or process.

(e) The restoration plan shall take into account benefits from the release of the Living Modified Organism in question.

(f) Where the Competent Authority determines that restoration of the biological diversity to the Baseline Condition of the Damaged species or Ecosystem is not possible, the Competent Authority shall articulate the reasons for the determination. If the Competent Authority and the Operator agree, the restoration plan may instead provide for restoration by replacing the loss of biological diversity with other components of biological diversity for the same, or for another type of use either at the same, or as appropriate, at an alternative location;

(g) The restoration plan shall include detailed costs of implementing the restoration plan;

(h) The restoration plan shall incorporate a mechanism for the Competent Authority to address any future requests for amendments to the restoration plan that are agreed to by the Operator and the Competent Authority or are the subject of contention between the Operator and the Competent Authority.

2) Compensation is only available when:

(a) restoration is not possible;

(b) it is not technically or financially feasible to achieve the Baseline Condition; or

(c) the cost of implementing the restoration plan exceeds the economic value of the Damage.

3) Where the Competent Authority seeks compensation, the amount of compensation shall be determined through a valuation method[4] based on objective processes and objective criteria. The valuation:

(a) shall be supported by evidence based upon the Best Available Information;

(b) shall take into account an assessment of the loss of functionality, value, use or natural resource services from the species resulting directly from and attributable only to the change from the Baseline and any projected future loss of function, value, use and natural resource services; the effect of such loss on established domestic customs and the characteristics of the ecosystem where Damage has occurred, such as whether it is (i) a protected area, (ii) a centre of origin, or (iii) a developed, industrialised or degraded Ecosystem;

(c) shall take into account negative impacts, if any, on public health or on an Ecosystem proven to have been caused by the Damage;

(d) shall take into account benefits from release of the Living Modified Organism in question;

(e) shall take into account the cost of restoration; and

4) The Competent Authority shall take into account:

(a) all benefits resulting from the release of the Living Modified Organism, including any increase in the function, value, or natural resource services of or to the species, any other species or the Ecosystem compared to any loss of function, value, or natural resource service of the Damaged species;

(b) the natural restorative processes of the species or Ecosystem would reverse any such loss; and

(c) whether restoration would eliminate or substantially reduce the benefits from the release of the Living Modified Organism.

5) Any restoration plan shall be tailored to preserve the benefits from the Release of the LMO. Where any Damage is determined by a Competent Authority to be sufficiently reversible or repairable to a Baseline Condition by natural restorative processes within a reasonable time, there shall be no obligation by the Operator for restoration. If Response Measures cannot be so tailored, the Competent Authority shall determine Response Measures *ex aequo et bono*, including appropriate restoration, a combination of restoration and compensation, compensation instead of restoration or no compensation or restoration.]

---

[4] The Secretariat of the Convention on Biological Diversity has published a manuscript entitled, *An Exploration of Tools and Methodologies For Valuation of Biodiversity and Biodiversity Resources and Functions*," as Convention Technical Series No. 28, containing case studies of the application of valuation methodologies described in the manuscript and which may be applicable in the Assessment and Arbitration Process if consistent with the terms and conditions of the Compact.

Compiled Example Text with Selected Alternatives

Regulation No. ___ (Liability and Redress relating to Living Modified Organisms) 2012

Whereas

{name of country} is Party to the Cartagena Protocol on Biosafety to the Convention on Biological Diversity hereinafter referred to as the "Protocol" pursuant to {cite national legal measure related to ratification or accession} and has ratified/acceded to the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety, hereinafter referred to as the "Supplementary Protocol" pursuant to {cite national legal measure related to ratification or accession},

Recalling {e.g., Biosafety Law No. __ of 20__ and Regulation No. __ of 20__},

Taking into account Principle 13 of the Rio Declaration on Environment and Development,

Reaffirming the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development,

Recognising the need to provide for appropriate response measures where there is damage or sufficient likelihood of damage, consistent with the Protocol,

Hereby adopts the following:

Article 1 Objective

The objective of this Regulation is to contribute to the conservation and sustainable use of Biological Diversity, taking also into account risks to human health, by providing rules and procedures in the field of liability and redress relating to Living Modified Organisms in accordance with the Supplementary Protocol.

Article 2 Use of terms

1. The following terms shall apply to this Regulation and its annexes:

   a. "Convention" means the Convention on Biological Diversity;
   b. "Protocol" means the Cartagena Protocol on Biosafety to the Convention on Biological Diversity;
   c. "Supplementary Protocol" means the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety;
   d. "Biological Diversity" means the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems;
   e. "Habitat" means the place or type of site where an organism or population naturally occurs;
   f. "Ecosystem" means a dynamic complex of plant, animal and micro-organism communities and their non-living environment interacting as a functional unit;
   g. "Contained use" means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;
   h. "Living Modified Organism" means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;
   i. "Living Organism" means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;
   j. "Modern Biotechnology" means the application of:
      i. *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
      ii. 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.
   k. "Damage" means an adverse effect on the conservation and sustainable use of Biological Diversity, taking also into account risks to human health, that:
      i. Is measurable or otherwise observable taking into account, wherever available, scientifically-established Baselines recognised or established by a Competent Authority under this Regulation that takes into account any other human induced variation and natural variation; and
      ii. Is significant as set out in paragraph 2 below;
   l. "Operator" means any person in direct or indirect control of the Living Modified Organism [in accordance with {citation to appropriate domestic law}];
   m. "Response Measures" means reasonable actions to:
      i. Prevent, minimise, contain, mitigate, or otherwise avoid Damage, as appropriate;
      ii. Restore Biological Diversity through actions to be undertaken in the following

order of preference:

a) Restoration of Biological Diversity to the Baseline Condition or its nearest equivalent; and where the Competent Authority determines this is not possible;
b) Restoration by, inter alia, replacing the loss of Biological Diversity with other components of Biological Diversity for the same, or for another type of use either at the same or, as appropriate, at an alternative location;

n. "Competent Authority" for purposes of this Regulation means {name of minister, agency or office};
o. "Baseline" means the condition at the time of the Damage of the natural resources and services that would have existed had the Damage not occurred, estimated on the basis of the Best Information Available;
p. "Baseline Condition" means the state of Biological Diversity that is the goal of the restoration plan for the species or Ecosystem alleged to be Damaged and that represents the condition that existed before Damage occurred to that species or Ecosystem, which is satisfied when:
    i. population dynamics data for the species alleged to be Damaged demonstrate that the species can maintain itself on a long-term basis as a viable component of the Ecosystem;
    ii. the natural range of the species has been increased to a sustainable level;
    iii. a sufficient Habitat exists to maintain the species on a long-term basis; or
    iv. one or more other species in the affected Ecosystem related to or dependent upon the species alleged to be Damaged can maintain itself on a long-term basis as a viable component of the Ecosystem;
q. "Best Available Information" means the peer-reviewed or peer-reviewable information obtained through the generally accepted scientific methodology used in the relevant scientific community of endeavour (such as genetics, ecology, microbiology, species population dynamics, and social sciences), including such information found on the Biosafety Clearing House of the Protocol. This methodology must consist of a testable hypothesis, existence and maintenance of standards controlling the technique's operation, and an acceptable known or potential rate of error, and the results must be repeatable. Best Available Information must be used in the determination of each element of a claim for Response Measures.

2. Damage is established only in the case of a significant adverse effect:

    a. An effect is adverse if it is a qualitative or quantitative change that:
        i. Negatively affects the components of Biological Diversity;
        ii. Reduces the ability of components of Biological Diversity to provide goods and services; or
        iii. Negatively Affects human health in the context of the Protocol.

    b. An adverse effect is significant based upon the extent of the adverse effect in 2.a above and if it results in long-term or permanent change, to be understood as change that will not be redressed through natural recovery within a reasonable period of time.

Article 3 Scope

1. This Regulation applies to Damage resulting from authorised import or use of Living Modified Organisms intended for:

    a. Direct use as food or feed, or for processing;
    b. Contained use; and
    c. Intentional introduction into the environment.

2. This Regulation also applies to Damage resulting from:

    a. Unintentional transboundary movements as referred to in Article 17 of the Protocol;
    b. Illegal transboundary movements as referred to in Article 25 of the Protocol; and
    c. Unintentional or illegal introduction of Living Modified Organisms into the environment under national law.

3. This Regulation applies to Damage resulting from the release of a Living Modified Organism as specified in paragraphs 1 or 2 that occurred after the entry into force of this Regulation.

4. This Regulation applies to Damage that occurs in areas within the limits of the national jurisdiction of {name of country}.

Article 4 Causation *(Alternative B)*

1. A causal link shall be established by the Competent Authority between the Damage and the Living Modified Organism in question.

2. The Competent Authority shall determine that:

a. General causation exists, i.e. the change can generally be caused by the Living Modified Organism in question;
b. Specific causation exists, i.e. the Damage would not have occurred but for the release of the Living Modified Organism in question, and results directly from the phenotypic or genotypic modification of the Living Modified Organism in question; and
c. No superseding event alters the chain of events that otherwise might have connected the release of the Living Modified Organism in question to the Damage.

Article 5 Response Measures

1. In the event of Damage, the appropriate Operator shall:

   a. Immediately inform the Competent Authority;
   b. Evaluate the Damage; and
   c. Take appropriate Response Measures.

2. The Competent Authority shall:

   a. Identify the Operator which has caused the Damage in accordance with Article 4 and Article 6 of the Regulation;
   b. Evaluate the Damage in accordance with Annex I; and
   c. Determine which Response Measures should be taken by the Operator in accordance with Annex II.

3. Where relevant Best Available Information indicates that there is a sufficient likelihood that Damage will result if timely Response Measures are not taken, the Operator shall be required to take appropriate Response Measures so as to avoid such Damage.

4. The Competent Authority may implement appropriate Response Measures, including, in particular, when the Operator has failed to do so.

5. The Competent Authority has the right to recover from the Operator the costs and expenses of, and incidental to, the evaluation of the Damage and the implementation of any such appropriate Response Measures. The Competent Authority shall not recover costs or expenses of Response Measures in situations where the Damage in question is the result of an event defined as an exemption in Article 6 of the Regulation or a superseding event as defined in Article 4 of the Regulation.

6. Decisions of the Competent Authority requiring the Operator to take Response Measures must be reasoned. Such decisions shall be notified in writing to the Operator. The Competent Authority shall inform the Operator of the available remedies, including administrative and judicial review.

Article 6 Exemptions *(Alternative B)*

1. An Operator shall not be held liable upon proof that the Damage was caused by:

   a. An Act of God or force *majeure*; or
   b. An act of war or civil unrest.

2. In addition, an Operator shall not be held liable upon proof that the Damage was caused by:

   a. An act or omission that was the subject of a compulsory order by the government;
   b. Realisation of a risk:
      i. Specifically assessed in compliance with Annex III of the Protocol (including those risks for which management measures were proposed in the risk assessment), where:

         a) the risk assessment was accepted by the governmental authority responsible for the proposed activity with the Living Modified Organism; and
         b) an authorisation for the Living Modified Organism in question was granted; and

      ii. The Damage is consistent with the type, magnitude and probability of harm presented in the risk assessment; or
   c. Realisation of a risk posed by an activity specifically authorised or specifically permitted by applicable law or regulations.

Article 7 Time Limitations

The Competent Authority shall notify the Operator of a decision in relation to Response Measures no later than the earliest date of:

a. Three (3) years from the date on which the Competent Authority knew or should have known of the Damage; or
b. Twenty (20) years after the first authorisation or release in the environment (whichever is earliest) of the Living Modified Organism in question alleged to have caused the Damage; provided, that this twenty year time limitation shall be tolled (suspended) if the Living Modified Organism in question has caused Damage for which Response Measures have been ordered.

Article 8 Financial limits

In the event that an Operator is ordered to provide Response Measures, the following financial limits will apply for Incidents of Damage:

a. For a single of incident of Damage caused by an LMO, a maximum sum of [enter amount]; and
b. For all incidents of Damage caused by that LMO, a maximum sum of [enter amount].

Article 9 Right of recourse

This Regulation shall not limit or restrict any right of recourse or indemnity that an Operator may have against any other person.

Article 10 Financial Security

1. This Regulation shall enter into force on the __ day following its publication.

2. {Articles x – y of Biosafety Law N. __} concerning liability and redress shall be revoked upon entry into force of this Regulation.

Adopted ….{any necessary formalities}

Annex I: Determination of Damage
(to be completed based on choice of alternatives)

Annex II: Response Measures
(to be completed based on choice of alternatives)

CropLife International aisbl
326 Avenue Louise, Box 35
1050 Brussels
Belgium

tel +32 2 542 04 10
fax +32 2 542 04 19
croplife@croplife.org
www.croplife.org

Date of publication: April 2013

Design: cambridgemarketing.co.uk