Marshall Islands Biosafety Legislative Review

National Biosafety Framework
(RMI NBF-Biosafety Project)

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I. OVERVIEW

Living Modified Organisms pose a potentially large threat to the Marshall Islands because a large percentage of the population is engaged in fishing and agriculture as a primary source of income. As a signatory to both the Convention on Biological Diversity (CBD) and the subsequent Cartagena Protocol, the RMI has a number of international obligations with respect to biosafety. In 2002, the National Biodiversity Strategic Action Plan (NBSAP) was finalized as a roadmap to fulfillment of the CBD obligations. With the guidance of the NBSAP, the foundation of a National Biosafety Framework (NBF) is being formed that includes five central components: 1. A coherent government policy; 2. A regulatory regime; 3. A permitting system; 4. A monitoring and enforcement regime; and 5. A public awareness, education and participation program.

While there is a need for a larger and more complete NBF, this report focuses on a proposed structure for the regulatory regime on biosafety in the RMI. To this end, there are several components of the report: Section II reviews the extent of international obligations as they relate to biosafety; Section III outlines current domestic regulatory instruments that may in some way interact with potential fulfillment of international obligations; Section IV considers the gaps between the obligations outlined in Section II and the current set of domestic tools already available in Section III; Section IV recommends the structure and proposed procedure for developing an appropriate and effective regulatory regime for biosafety in the Marshall Islands. In the short term, a minimal amount of coordination is suggested to begin communications between crucial agencies concerning biosafety issues. In the medium term it is suggested that regulations are drafted and placed in the jurisdiction of the quarantine department of the Ministry of Resources and Development. In the long term, the regulations should empower a workgroup at the national level to continue to address educational, research and political work with respect to the future of biosafety related issues in the RMI.

II. IDENTIFICATION OF RELEVANT INTERNATIONAL OBLIGATIONS AND INSTRUMENTS

The RMI is a member to many international conventions and organizations, however only a few of these are potentially relevant to biosafety. This section outlines the obligations that result from these treaties as they relate to biosafety, the vast majority of which remain to be fulfilled by the RMI.. It is important to note that the RMI is not a signatory of two conventions that relate very closely to the Biosafety Protocol—the Convention for International Trade in Endangered Species (CITES) and the World Trade Organization (WTO). Little existing structure exists in the RMI to handle trade and environment related international procedures and cooperation. As will become clear in Section III of this report, this is a significant hurdle for the government of the RMI to overcome. In all, fourteen environmental and trade related international agreements were reviewed, five of which have particular articles that relate either directly or indirectly to biosafety.

Cartagena Protocol

The Cartagena Protocol details procedures for the safe transboundary transfer, handling and use of living modified organisms (LMO) that may have adverse effects on biological diversity. One of the central mechanisms is detailed in the Advanced Informed Agreement Procedure, which places obligations on both the exporting and importing countries. Complete details of the obligations required by the convention are available in Appendix I. What follows is a summary of the most important requirements.

Articles 7 through 12: Requirements of Advanced Informed Agreement Procedure

Prior to transboundary shipment of LMOs, the exporter must notify the proper national authority of the importer. The importer must acknowledge receipt of the notification and then inform the exporter of its written consent. Within 270 days of receipt of the notification, the importer must report also to the Biosafety Clearing House the notice of decision. If consent is given, the Biosafety Clearing House must be informed if the LMOs are intended for direct use as food or feed. Responsibility for the accuracy of this information is on the party making the decision. This decision can be based on the national legal framework if it is consistent with this Protocol. All laws applicable to LMOs must be provided to the Clearing House. Developing countries that do not have a regulatory framework can comply by declaring that a risk assessment will be undertaken and a decision made within 270 days. Review of decisions is available if a change in circumstances or additional relevant scientific evidence can be demonstrated.

Article 15 Risk Assessment

Risk assessments must be done in a scientifically sound manner taking into account the possible adverse effects of LMOs and risks to human health. The Parties must establish and maintain appropriate measures to control risks identified in the risk assessment. Measures must also be taken to prevent unintentional transboundary movement.

Article 17 Unintentional Transboundary Movements and Emergency Measures

Any release that leads to an unintentional transboundary movement must be reported through an appointed point of contact to the Biosafety Clearing House and any jurisdiction affected by the release if it is likely to have significant adverse effects.

Article 18 Handling, transporting, packaging and identification

LMOs must be handled, transported and packaged safely according to international rules and standards. LMOs intended for direct use as food, feed or processing must clearly state that they "may contain" LMOs and are not intended for introduction into the environment. If the LMOS are intended for introduction to the environment, they must be identified and give instructions on their safe handling, storage, transport and use.

Article 20 Biosafety Clearing House purpose

The purpose of the Clearing House is to facilitate exchange of information regarding LMOs and assist parties in implementation of the Protocol.

Article 23 Public awareness

Parties are required to promote and facilitate public awareness, education and participation regarding all aspects of LMOs. The public must be consulted regarding LMO related decision-making and the Biosafety Clearing House informed.

Article 25 Illegal transboundary movements

Each Party shall adopt laws and/or regulations regarding penalties for illegal transboundary movements. If there is an illegal transboundary movement, the affected Party can request the violating Party to dispose of the LMO at its own expense and all incidents must be reported to the Biosafety Clearing House.

Convention on Biological Diversity

Numerous aspects of biological diversity related issues are covered in this framework convention, including: biodiversity conservation, habitat protection, genetically modified organisms, intellectual property rights, among others, are covered. Importantly, the right of countries to exploit their own resources in accordance with their environmental policies, provided the environment of other sovereign states is unaffected, is recognized. Two central outputs of this convention are the utilization of the Global Environment Facility to fund conservation related projects, and the signing of the Cartagena Protocol.

Article 8 In – situ conservation

This article mandates parties to establish laws or regulations to manage and control the risks associated with the use and release of LMOs that are likely to adversely affect the environment taking into account the risk to human health

Article 18 Technical and scientific cooperation

The need of protocols for procedures regarding the safe transfer, handling and use of any LMO that may have adverse affects on the environment are mandated to be considered by signatories. Additionally, information concerning the use and safety regulations and any potential adverse effects of LMOs must be provided by exporters to recipient countries. .

International Treaty on Plant Genetic Resources for Food and Agriculture

This treaty concerns conservation and sustainable use of plant genetic resources for food and agriculture and the sharing of the benefits from their use in conjunction with the Convention of Biological Diversity

Article 5 Conservation, Exploration, Collection, Characterization, Evaluation and Documentation of Plant Genetic Resources for Food and Agriculture

The promotion of an integrated approach to the exploration, conservation and sustainable use of plant genetic resources is required by this Article. This includes a survey and inventory of plant genetic resources, promotion of plant genetic resource collection, and monitoring the maintenance of collections of plant genetic resources.

Article 6 Sustainable Use of Plant Genetic Resources

Appropriate policy and legal measures that promote the sustainable use of plant genetic resources are to be implemented. These include, among others, strengthening research concerning genetic variation, applying ecological principles in maintaining soil, pest and disease management, and promoting plant breeding of locally acclimated genetic strains.

Article 7 National Commitments and International Cooperation

International cooperation is required to establish or strengthen the capabilities of developing countries and countries with economies in transition with respect to conservation and sustainable use of plant genetic resources and enhance international activities to promote conservation, evaluation, documentation, genetic enhancement, plant breeding, and seed multiplication.

Article 9 Farmers' Rights

National governments must enforce farmers' rights, including equitable participation in sharing benefits of plant genetic resources and the right to participate in making decisions at the national level on matters related to the conservation and sustainable use of plant genetic resources.

Article 10, 11, 12, 13 Multilateral System of Access and Benefit-sharing

The sovereign rights of other jurisdictions over their own plant genetic resources, including the authority to determine access to those resources rests with that national governments and is subject to national legislation. To facilitate access to and benefits from plant genetic resources, each party must establish a multilateral system. This system is meant to provide that access to plant genetic resources is solely for food and agricultural uses and not financially restrictive. However, persons responsible for plant genetic resources under development have discretion as to whether said resource is available and part of such a system.

The benefits arising from the use, including commercial use, of plant genetic resources are to be shared by the exchange of information, access to and transfer of technology, capacity-building, and the sharing of the benefits arising from commercialization.

United Nations Convention on the Law of the Sea

This treaty establishes a regime for governance of a multiplicity of activities in the near shore and the high seas. The subject matter ranges from piracy to the definition of marine resource rights to military and commercial rights and restrictions throughout the worlds' oceans. Only a small portion can be interpreted as applicable to Biosafety related issues.

Part II, Section I, Article 194 Protection and preservation of the marine environment

Measures to prevent, reduce and control pollution of the marine environment from any source must be taken. Additionally, all transboundary polluting activities are specifically prohibited.

Part II, Section I, Article 196 Use of technologies or introduction of alien species

This section specifically states that parties must control the introduction of species that may harm the environment.

Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal

This treaty controls the movement and disposal of hazardous waste. It can be considered applicable only to the extent in which a particular LMO or GMO might be defined as a "hazardous waste." Most likely this interpretation would be unacceptable to parties, however, the obligations are similar to some of the Cartagena Protocol and thus worth mentioning in short.

Article 4 General Obligations

All member states are obliged to prohibit the export of hazardous wastes and other wastes to other parties to the treaty that have prohibited the import of such wastes. The generation of hazardous wastes and other wastes is mandated to be reduced to a minimum, taking into account social, technological and economic aspects. Adequate disposal facilities must be available, for the environmentally sound management of hazardous and other wastes. Transboundary movements of hazardous and other wastes are to be reduced to the minimum and conducted in a manner that will

protect human health and the environment. Packaging, labeling, and transportation of the materials must be in conformity with generally accepted and recognized international rules and standards

Note: The remaining terms regarding shipment echo the Cartagena Protocol

Compact of Free Association as amended 2003

This bilateral agreement defines the totality of rights and responsibilities for both the RMI and the US. All aspects of the economic and political relationship are defined, including environmental protection and trade. Again, no specific mention of biosafety is mentioned, but a number of related topics are discussed.

Title I Government Relations, Article VI Environmental Protection

This section obligates the US to follow domestic legislation under the US National Environmental Protection Act (NEPA), Endangered Species Act, Clean Water and Clean Air Acts, Marine Protection and Sanctuaries Act, Toxic Substances Control Act, Solid Waste Disposal Act and "other environmental protection laws of the US and the RMI…" The RMI is itself obligated to increase its level of environmental protection to the standards of the US.

Title II Economic Relations

The US pledges to make grant assistance available for the purposes of environmental protection in the RMI. Specifically, and inflation adjusted $200,000 is guaranteed for "increased participation of the (RMI EPA) in the annual (USAKA) Environmental Standards Survey and to promote a greater (RMI) capacity for independent analysis of the Survey's findings and conclusions."

With respect to trade relations, the US is granted most favoured nation status, "treatment no less favourable than that accorded like products of any foreign country with respect to …laws and regulations relating to importation, exportation…etc." Thus, products imported and exported to and from the US are not subject to any special treatment beyond which is granted to any other country.

Other Treaties Reviewed

The following treaties were reviewed for potential relation to biosafety related issues and found to have no pertinent Articles or language:

Vienna Convention for the Protection of the Ozone Layer
Montreal Protocol on Substances that Deplete the Ozone Layer
United Nations Framework Convention on Climate Change
Kyoto Protocol
South Pacific Regional Trade and Economic Cooperation
Convention for the Protection of Natural Resources & Environment in the South Pacific
Protocol for the Prevention of Pollution in the South Pacific by Dumping
Protocol on Cooperation in Combating Pollution Emergencies in the South Pacific
Convention on Chemical Weapons

II. CURRENT STATUS OF REGULATORY INSTRUMENTS RELATED TO BIOSAFETY

No single domestic regulation or legislation explicitly mentions the topic of biosafety or GMOs. However, for the purpose of understanding the breadth of RMI legislation that relate to all sides of the National Biosafety Framework all laws have been reviewed to test for the inclusion of any mention of the following topics: LMOs, Import/Export of Living Organisms, Food Safety, Human Health, Plant/Animal Quarantine, Pesticide/Herbicide Use, Introduction of New Species, Invasive Species, Biodiversity, Endangered Species, Socio-economic Impact, Intellectual Property Rights, and Indigenous People. Table 1 provides a summary of this review in which it is made clear that while GMOs are not specifically mentioned – there are several levels of coverage for most of the above topics, excluding LMOs and Intellectual Property Rights.

Level 1 - Legislation: *Includes legal instruments approved by the legislative branch of government, such as a parliament, congress, legislature, or house of assembly, which are then promulgated with binding effect. Names commonly used for these kinds of instruments include 'primary legislation', 'law', 'statute', 'act', 'ordinance' and 'code'.*

Public Health and Sanitation Act 7(1)

This Act provides for the general scope and powers of the Ministry of Health (MOH). The labeling and safety of food for Public Health is the central component of this legislation that interrelates with biosafety. §103(b) provides that the Secretary may establish regulations concerning the "adulteration and misbranding of food, drugs, or milk." §103(q) provides for regulation of "food, drugs, and cosmetics, and the manufacture, compounding, processing, extracting, preparing, storing, selling and offering for sale or offered for human consumption or use." As well, per §112, standards for and inspection of food are authorized by the Act.

To date, no such regulations or standards have come into effect in the Republic, and *de facto* enforcement of the sections has been moved to the RMI Environmental Protection Authority (EPA). The EPA has used this act to inspect restaurant and school sanitation, as well as survey food stores for expired or spoiled food products. However, a Memorandum of Understanding is currently in the works that will take responsibility of this Act and return it to the Ministry of Health. This should occur some time in the second quarter of FY '06.

Quarantine Restrictions Act 8(1)

This Act deals with all aspects of animal and plant quarantine upon entering the republic. §103, adopted in 2000, empowers the Chief of Agriculture to adopt regulations. No specific mention is made to biosafety or GMOs in this Act. However, the Chief of Agriculture is provided with the power to undertake emergency measures for any situation that is not explicitly mentioned in the Act or subsequent regulations (§105).

This act resulted in the Agricultural Quarantine Department of the Ministry of Resources and Development, and the related regulations that are detailed under Level 2 regulations below.

Endangered Species Act 8(3)

§304 provides for the prevention of the risk of extinction of local plant and animals of the Marshall Islands. The act is under the direction of the Secretary of Resources and Development. §307

provides exceptions for, among other things, traditional purposes. §308 provides for regulations to be issued by Secretary of R&D. To date, these regulations have yet to be issued. §309 bans the import of rare or endangered species and §310 bans, with exceptions, the import of living exotic plants and animals. No mention is made explicitly to biosafety.

This Act lies dormant in the Marshall Islands. Though the Ministry of Resources and Development and the Environmental Protection Authority have identified it as an area that needs more program and resource support, nothing has yet been done. As a result there are several species on the list from the original act, but no policies, technical abilities or administrative procedures exist within the RMI to implement the legislation.

EPPSO Act 10(1)

This Act relates to biosafety solely in its mandate of for socio-economic impact in certain policy and planning decisions (§105). The office focuses mostly on data collection for policy advice to the central government, as well as economic planning and budgetary assistance to the Cabinet.

National Environmental Protection Act 35(1)

This broad Act generally empowers the EPA to handle many aspects of biosafety in the Republic, though none specifically related to GMOs. §19 provides as the objects of the EPA to study environmental impacts, improve national policy, make regulations and consider human health as they all relate to the environment. §21(d) and §24 explicitly empowers the Authority to make regulations and standards for the utilization of pesticide. These regulations to date remain to be implemented. §21(f) empowers the Authority to "make regulations with respect to… other aspects of the environment which, in the opinion of the Authority, require regulation." This is a very open-ended power that could easily be utilized for biosafety. §33 and §34 provide for the need of Environmental Impact Assessments (EIA) "in all matters where there is or may be an environmental impact." The subsequent EIA regulations broaden this requirement from solely the public sector to also include the activities of the private sector.

Many provisions of the Act have been enabled through policies, programs and regulations, some very recently. However, other aspects of the Act have yet to be addressed. For example, the legislation calls for the formation of an Environmental Advisory Council, which to date does not exist. Many mandates under the Act are unfulfilled, including the development of a land use scheme (§28), a basic policy on the management of natural resources (§29), and a policy for fisheries management (§30) among others. Instead of being driven by national priority, the mandate of the EPA has been driven by the priority of international donations over the years. Hence, the strongest program areas are those that have in the past been funded by some outside interest, while those mandates that are required by the NEPA tend to lie dormant.

OEPPC Act 35(4)

The Act establishes OEPPC as the advising and coordinating agency for all international environmental agreements. §308 specifically mentions the biodiversity convention. No other references are made to biosafety issues.

Taxation and Import Duties 48(2)

This Act enables the Ministry of Finance to impose import duties of various rates on certain products. Procedures and powers are defined as well as a schedule of import duty rates. The only section of particular interest to biosafety issues is §220, which specifies that the Minister may enter into interagency agreements to properly implement various duties and import responsibilities with; Public Safety, Local Government, MIMRA, EPA, Sea Patrol, Under Cover Investigations Division, Marshall Islands Postal Service, Immigration, Quarantine and any other government agency or statutory independent entity. This section will become important when it is decided what department will specifically be in charge biosafety related procedures.

Marine Resources Authority Act 51(1)

§119(1) (k) empowers MIMRA to: "regulate the processing, marketing and export of fish and fish products;" Otherwise this act does not mention any biosafety relevant issues. MIMRA is potentially very useful in the marine realm; however, their mandate erodes as issues become more terrestrial in nature. Thus, the role of MIMRA cannot be overlooked, but certainly cannot be the central agency charged with biosafety related issues.

Fisheries Act 51(2)

While the preceding Act deals with the formation and powers of MIMRA, this Act describes the fisheries policy of the RMI, and touches upon several biosafety related areas. §209 generally and several other sections specifically deal with the protection of certain endangered species. §210 provides for the promotion and protection of artesenal fisheries. §219 provides that any introduced fish into the waters of the RMI requires a permit from MIMRA. §226 provides for the protection of any species declared endangered by the Authority. §227 bans the export of live fish from the Republic.

The enforcement of this Act is not specifically enabled in any written regulatory system. Instead, if an individual would like to introduce a species to the waters of the RMI, they must first receive an approval letter from MIMRA. In recent years there have been several cases of this happening, including the introduction of seaweed from Kiribati and Fiji for aquaculture, and the importation of freshwater goldfish for pets. There are no official species declared endangered by the Authority – independent of other acts (such as the Trochus Act, Marine Mammal Protection Act and Endangered Species Act). There has also been a moratorium on the extraction of live rock for a period of years. Contrary to § 227, live reef fish trade is permitted for both food fish and aquaria species provided the Authority grants a letter of permission. Currently, there are no live fish food operators on island, though several aquarium fish operators regularly export products off-island. Additionally, a single clam farm exports aquacultured ornamental clams and corals from several farms. These companies are required to have permits from MIMRA to export their products. The permit requires that an inventory of species and numbers being exported are provided. A coastal fisheries management specialist is coming to the RMI in early 2006 to help develop a management plan for the extraction and export of these live species. Likely, an increased level of restrictions will be placed on the exporters once the plan is implemented.

Level 2 - Regulations : *Includes legal instruments that are created under delegated authority by an individual or group, who then present them back to the legislature for approval; these instruments are then promulgated with binding effect. Names commonly used for these kinds of instruments include: 'secondary legislation', 'decree', or 'regulation'.*

Environmental Impact Assessment (EIA) (EPA 1994)

The EIA regulations provide an existing legal instrument to deal with the potential impacts of GMO importation should it raise biosafety concern. In order for an EIA to result, the General Manager of the EPA must determine that a "significant effect" may result from a particular activity (§8). Under §4(s) the term "significant effect" is defined, among other things, as:

> (i) the degree to which public health and safety are affected;
> (iii) the degree to which effects on the environment are likely to involve controversy;
> (iv) the degree to which unique or unknown risks are taken;
> (ix) the potential to threaten the existence of rare or endangered species, or their critical habitats;

These undoubtedly would raise the potential that if a particularly sensitive GMO derived product were to be introduced to the RMI, an EIA may be required by the RMI EPA. The current status of EIA regulations in the RMI is improving. For fifteen years, there was only one EIA solicited by the EPA and completed by a proponent (independent of any outside requirements such as US funding), while in this calendar year, six EIAs have been initiated, with four reaching their completion. The potential for the use of the EIA as a risk management tool should not be overlooked

Plant and Animal Quarantine Regulations (R&D 2000)

These extensive regulations detail the import, quarantine and export requirements for the RMI, including certain species that are prohibited. In the "Second Schedule" (derived from §46) the Minister is empowered to prohibit the import of any species "likely to become a nuisance or to cause injury or damage." However, as with all legislation and regulations included in this analysis, there is no explicit mention of GMOs and their import. As with quarantine regulations worldwide, the central focus of these remain with the removal of pests or disease, not on the nature of the safety of the product in and of itself, or the nature in which the product was made.

The regulations establish a regulatory procedure for the import of any plant or animal, living or otherwise. An applicant first completes an *Application for Plant and Animal Quarantine Permit* provided by the Division of Agriculture in the Ministry of R&D. The application requires that the applicant detail the "material and quantity" of the product including the following specifics,

> For plant importations indicate plant part, i.e. whole seedling, root or branch cutting, seeds etc. For animal importation indicate name (pet name if any) or kind of animal (bird, fowl, cat etc.), age, sex and color.

Once approved, the applicant is granted a *Plant & Animal Quarantine Entry Permit*, good for one year to import the detailed goods. This permit details the condition of importation including any restrictions or requirements for specific products. These requirements depend on the individual product. For example fruits and vegetables are required to be accompanied by a phytosanitary certificate from the exporting country and must be surveyed for potential introduction of fruit flies.

Plant specifications are listed under the following headings: plants (general), live plants (or parts thereof), seed, cut flowers and foliage, timber, (grass, bamboo, cane etc.), soil, sand and gravel, dried food products, pacing material, handicrafts, bacteria, viruses, vaccines, cultures and organisms. Animals are listed for the following: animals (general), dogs, cats, cattle, sheep and goats, domestic horses, mules, donkeys, domestic pigs, birds, day-old chicks, hatching eggs, domestic rodents, rabbits, domestic ruminant and pig embryo, semen of domestic ruminant and pigs, non-commercial animal food products, unsterilized meat, eggs, milk, honey bees, and all other animal products.

In the case that a container or shipment arrives via either a sea or airport of entry without a permit, it is held at quarantine until such a permit is acquired, however long it takes to demonstrate the safety of the product.

Level 3 - Binding Guidelines: *Covers instruments that are created under delegated authority by an individual or group, but which do not need further approval by the legislature before promulgation that is binding. Names commonly used for these kinds of instruments include: 'secondary legislation', 'guidance', 'regulation', 'sub decree', or 'guidelines'.*

As of this review, it does not appear that there are any binding guidelines that have been adopted by any governmental agency that relate to biosafety.

Level 4: Judicial Decisions: *Comprises the work of the judicial branch. It can be divided into two parts: Binding decisions on the interpretation of instruments in Levels 1-3 by courts or other adjudicators; Binding decisions creating law by courts. These may include, for example, 'case law', 'precedents', 'recommendations', and 'opinions'.* There has not as of yet been any judicial decisions that relate to biosafety or any of the related topics covered in the legislative review.

Level 5 - Policies: *Includes non-legally binding instruments that are created by an individual or group with delegated power without the need for further approval before promulgation. Names commonly used for these kinds of instruments include 'code of practice', 'best practice', 'recommendations', 'opinion', guidance' and 'guidelines'.*

Millennium Development Goals (MDG)

One of the MDGs refers to the environment and primarily refers to drinking water quality and its importance for human health. No other mention is made of environmental issues that relate to biosafety and GMOs.

Vision 2018

The environmental component of this 15-year plan for the RMI includes, among others, sections on: 1. Institutional strengthening; 2. EIA; 6. Biodiversity and wildlife conservation; 7. Protection of national heritage; and 9. Fisheries conservation. Beyond these sections, short mention is made of the deficiencies of the quarantine and pesticide regulatory regimes and subsequent policies. However, no specific mention is made of biosafety and GMO related topics.

National Biodiversity Strategic Action Plan

A direct result of the Convention on Biodiversity, this document covers numerous biosafety pertinent topics. To simplify matters, only the sections that deal explicitly with biosafety will be reviewed.

Strategic Theme E – Biotechnology and Biodiversity mentions the threats posed to endemic genetic diversity by the potential introduction of non-native and biotechnologically constructed organisms. Central to this goal for conservation of genetic diversity is the establishment of both *in-situ* and *ex-situ* gene banks of organisms of scientific and cultural importance.

Strategic Theme F – Biosafety and Biodiversity directly mentions several relevant goals and actions that relate to the intent of this regulatory review. Three central threats are identified in the area of biosafety, quarantine, field-testing of GMOs, and biosafety of imported foods. Goal F1 calls for the process, which is a review and resulting regulatory and legislative framework. This has resulted in the current work being untaken. This section describes current legislation as outdated, with no mention specifically of biosafety issues and GMOs. However, the NBSAP is incorrect in stating that the current legislation does not provide for either environmental or social impact assessments (EIA and SIA). As is stated in the review of the EPA EIA regulations, environmental and to a certain degree social impact assessments are mandated through this regulation. Goal F1 specifically calls for alteration of: Quarantine regulations, control over field-testing of GMOs, control over importation of food, and provision for EIA and SIA and definition of inter-agency responsibilities. Finally, this goal calls for a strengthening of enforcement procedures for infringement of legislation and regulations.

Goal F2 appears to be the same as Goal F1 in that it calls for new or revised legislation and regulations on biosafety. This goal calls for separate agencies to have defined roles without conflict of interest, adequate training on risk and environmental assessment, awareness raising, increased biosafety funding, and established linkages between national and regional organizations for technical support.

Strategic Themes F and G of the NBSAP include some preliminary analysis that relate directly to the current project. Though not binding in any way, the NBSAP does provide a useful contextual policy map from which to begin gap analysis in the second phase of this project.

National Environmental Management Strategy

Written in 1992, this document does not explicitly mention biosafety. However, many related subject matters are mentioned, as well as a range of proposals for both legislative and policy solutions. The document, endorsed by the Cabinet and President, includes policy suggestions regarding environmental education, marine and coastal resources, the social and built environment, protection of special areas and species, cultural values and practices, strengthening environmental legal instruments, agricultural resources for sustainability (including pesticides), and environmental emergencies. The document proposes and budgets for numerous project level tasks to realize action for these program areas, though none address specifically GMO and biosafety related issues.

Policy and Priority Actions for Sustainable Mariculture Development

This document, produced by a multi-stakeholder group has a number of observations related to biosafety, as well as several policy level recommendations. Central to the work, the MIMRA Fisheries Policy states that in order to develop cultured fisheries, MIMRA is responsible for preparing "Guidelines Relating to the Culture and Translocation of Marine Organisms in the Republic of the Marshall Island." As of the writing of this report, the Guidelines which are to regulate importation of new marine species have yet to be published. The document recognizes that the introduction of genetically modified exotic or native species pose a legitimate threat to the range of actual and potential mariculture activities in the RMI. Other priority issues are the development of a functional EIA system and non-indigenous species requirements.

Table 1. Overview of Environmental Legislation, Regulations and Policies in the RMI

	Office	Date	Subsidiary Regulations	LMOs	Import/Export of Living Organisms	Food Safety	Human Health	Plant/Animal Quarantine	Pesticide/herbicide Use	Introduction of new Species	Invasive Species	Biodiversity	Endangered Species	Socio-economic Impact	Intellectual Property Rights	Indigenous People
Level 1 : Legislation																
Public Health and Sanitation Act 7(1)	MOH	1966	N	N	N	Y	Y	N	N	N	N	N	N	N	N	N
Quarantine Restrictions Act 8(1)	R&D	1966	Y	N	Y	N	N	Y	N	Y	Y	N	N	N	N	N
Endangered Species Act 8(3)	R&D	1975	N	N	Y	N	N	N	N	Y	Y	Y	Y	N	N	Y
EPPSO Act 10(1)	EPPSO	2003	N	N	N	N	N	N	N	N	N	N	N	Y	N	N
National Environmental Protection Act 35(1)	EPA	1984	Y	N	N	N	Y	N	Y	N	N	Y	N	Y	N	N
OEPPC Act 35(4)	OEPPC	2003	N	N	N	N	N	N	N	N	N	Y	N	N	N	N
Taxation and Import DutiesAct 48(2)	Finance	1989	Y	N	N	N	N	N	N	N	N	N	N	N	N	N
Marine Resources Authority Act 51(1)	MIMRA	1988	Y	N	Y	Y	N	N	N	N	N	N	Y	N	N	N
Fisheries Act 51(2)	MIMRA	1997	Y	N	Y	N	N	N	N	Y	Y	N	Y	N	N	Y
Level 2 : Regulations																
Environmental Impact Assessment	EPA	1994	-	N	N	N	Y	N	N	N	N	N	N	Y	N	N
Plant and Animal Quarantine	R&D	1990	-	N	Y	N	Y	Y	N	Y	Y	N	N	N	N	N
Level 3 : Binding Guidelines and Level 4 : Judicial Decisions																
none																
Level 5 : Policies																
Development Goals	EPPSO	2000	-	N	N	N	Y	N	N	N	N	N	N	Y	N	N
Vision 2018	EPPSO	2002	-	N	Y	N	Y	Y	Y	N	N	Y	Y	Y	N	Y
NBSAP	R&D	2000	-	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
NEMS	EPA	1992	-	N	N	N	Y	N	Y	N	N	Y	Y	Y	N	Y
Sustainable Mariculture Policy	multiple	2004	-	Y	Y	N	N	Y	N	Y	Y	Y	Y	N	N	N

III. Analysis of the Current Status of Regulatory Instruments Related to Biosafety

Several assumptions concerning the objectives of the RMI must be made in order to examine the utility of the current regime to address biosafety. This analysis will assume that the goals of the RMI are twofold:

1. The avoidance of major catastrophes that could potentially result from the introduction of unwanted GMOs.
2. The efficient realization of international obligations at the lowest possible cost in terms of financial, bureaucratic and human resources.

The current legal and regulatory system does not adequately address the above goals. Besides the NBSAP and associated treaties, there is not one single reference to biosafety related issues in any language of the current level one and level two regulatory systems. No matter which direction the National Biosafety Framework will steer policy, there is no explicit language as of the publishing of this report that allows for even minimal regulation.

Appendix I specifically demonstrates the gaps that exist with respect to biosafety and the international obligations established primarily under the Cartagena Protocol and the current domestic regime of the Marshall Islands. While two sets of regulations offer some assistance towards the articles and associated obligations dealing with the importation and potential introduction of LMOs and GMOs, EIA and Quarantine, there is no legal language or policies relating to the export of LMOs—some of the central requirements of the Cartagena Protocol. Though it is unlikely that the RMI would become a center for the development of LMOs in the coming years, it is a possibility that in the future, entrepreneurs could utilize this weak regulatory framework to import, reproduce and subsequently re-export LMOs, particularly of a marine nature.

The challenge of meeting the current set of international obligations, and safely protect the country from biosafety threats cannot be understated. The RMI is in a unique situation of having a very small private and export sector that does not currently deal with much regulation. Additionally, the frequency of activities involving LMOs in the near future is surely limited. This decreases the likelihood that new regulations or policies will become part of the regulatory culture and hence understood by the day-to-day units' officers in the important departments.

Currently, as demonstrated in Table 1, the RMI legal system as it relates to environmental concerns in general and more specifically GMO related topics has a great deal of unresolved overlap and procedures that have not as of yet been resolved. In the case of the introduction of a LMO marine species, MIMRA would have jurisdiction over the introduction, while EPA could also have the potential to regulate via an Environmental Impact Assessment, and Plant and Animal Quarantine could decide that the introduction poses a significant threat as an invasive species.

Due to the large amount of overlapping jurisdictions in such a small country as the RMI, it appears that instead of eliminating responsibility – it would be more useful to simply clearly define the roles of respective agencies. The strengths of the existing system, which is very minimal, exist in the fact that the RMI has a highly centralized government and thus effective coordination and cooperation is realistic. Inter-agency groups are common throughout a large amount of program areas, and communication is relatively simple. With this as context, the next sections look0

at several least cost approaches to meeting the RMI's legal obligations under the Cartagena Protocol and other relevant international obligations.

V. RECOMMENDED REGULATORY REGIME

Several challenges need to be overcome to implement a working biosafety regulatory framework in the RMI. First, overlapping responsibilities and roles create the potential for jurisdictional and bureaucratic breakdown. Second, human and financial resources are not widely available at a sustainable level given the area of prioritization biosafety appears to have on the national agenda. Third, more complex and inflexible solutions for the regulatory regime, will heighten the potential for failure. Thus, priorities must be made to fill the most necessary gaps first and increase in sophistication as the resources and needs arise.

There are four categories of options available to the RMI that range from simply re-interpreting the existing legal system to designing a comprehensive new system. These are:

1. *Interpret or guide the existing system* – No legal activity necessary, the current regulatory system can effectively be utilized to meet all international biosafety obligations.
2. *Amend the existing system* – Utilize the current regulatory system and procedures, and modify where necessary to fulfill obligations.
3. *Design a new system* – Pass new regulations and procedures to implement the Protocol, within an existing agency.
4. *Design a comprehensive new system* – Beyond (3) above, build a new department with associated legislation that can coordinate all GMO related issues.

Interpreting the existing system to include biosafety obligations of international treaties would be extremely practical in that it would involve a minimum alteration from the current course of biosafety related regulations. However, because there is no mention of the key components of biosafety as mandated in the Cartagena Protocol, GMOs and LMOs, it would be extremely difficult to utilize this option in the RMI. Also, many of the current regulatory systems are already barely enforced and need a boost to simply fulfill their own mandates independent of biosafety.

Amending the current system is a plausible option, specifically within the EIA and quarantine regulations, however these regulations do not completely cover the necessary international obligations. Thus, the scope of this pair of regulations would have to be expanded a great deal. Considering that many aspects of these regulations cannot completely be enforced, broadening the scope could lead to a diluted implementation of both obligations.

Part of the reason for the lack of fulfillment of RMI legislation in general is the amount of subsequent duties that exist compared to the capable human resources available for their implementation. Given that several pieces of the RMI National Legislation, such as the Endangered Species Act, and many environmental regulations still remain inactive, it is unknown how long it will take to fully implement an entirely new piece of legislation. Additionally, the human capital is certainly not available in the RMI to develop new legislation, and thus if this solution is sought, outside assistance in terms of human and financial resources is necessary.

This said, given the current state of the regulatory system, nothing short of an entirely new set of regulations would effectively fulfill the RMI's obligations and meet the country's needs as suggested in category (3) above. Given that there is little urgency in completing this task at the national level, it is possible that the time can be taken for development of necessary regulations and appropriate training in the long run, while at the same time implementing a short term policy to deal with the pressing aspects of biosafety issues in the RMI until such a time as the complete regulatory system emerges. A comprehensive new system, as suggested in category (4) above, would be superfluous to the level of biosafety related activities, and create much bureaucratic waste and inefficiency.

The advantage of the category (3) solution is the specificity it allows to legally abide by all necessary obligations. However, a major disadvantage lies in the cost of introducing a new system to a human resource scarce environment. The system must prioritize which aspects of the Cartagena Protocol are most necessary to implement in the short term and allow for the phasing in of more long-term obligations as well as those obligations derived from other treaty instruments.

There two advisable solutions for the RMI at this moment:

1. Immediately draft and pass a cookie cutter set of domestic regulations that sit within a government body and allow the RMI to appear to meet its international obligations.

2. Take a slower approach of first establishing an inter-agency working group with respect to biosafety information policies and then integrate this practice into existing departments. At the same time provide necessary training and adopt regulations at the political level.

The recommended process is depicted in figure 1 below:

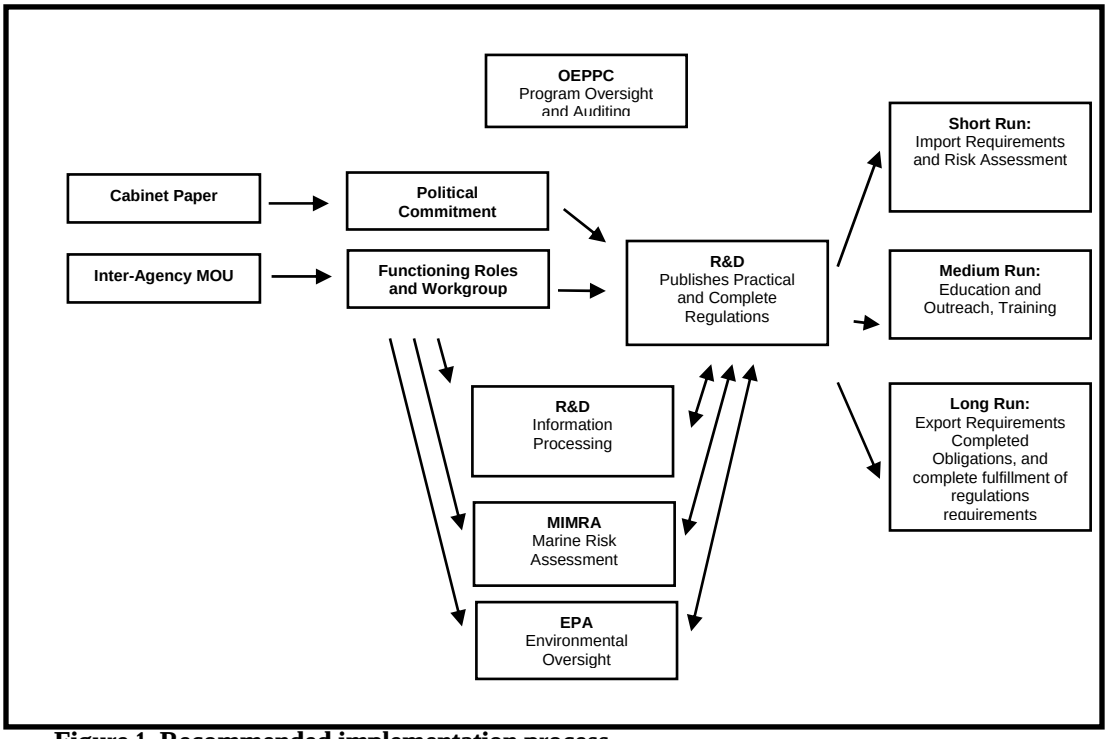

Figure 1. Recommended implementation process

As depicted above, there are four agencies that have potential interests in the regulation of trade in LMOs, notably OEPPC, EPA, MIMRA and R&D. The most appropriate agency to take central regulatory authority is R&D with oversight by EPA, MIMRA, and OEPPC. Given that the two central concerns for the RMI are the potential introduction of LMO marine organisms or the potential of using the RMI as a testing site, a workgroup should be established to assure that this type of biosafety emergency is avoided with or without the necessary regulations. This workgroup should be supported if possible by a Cabinet Paper that identifies the worst-case scenario of the un-regulated introduction of a LMO marine species as a major concern that must be avoided by all potentially involved agencies.

Regulations are recommended to be drafted for the Ministry of Resources and Development Agriculture and Quarantine Department to meet international obligations and mandate interagency cooperation (see Appendix I). A designated representative from MIMRA should clear any marine or coastal species that is potentially imported, while all imports of LMOs other than marine or coastal species should be cleared through the EPA. As well, EPA must have the ability to conduct an EIA if it deems this necessary, independent of any request by R&D, and the regulations should directly reflect such potential. OEPPC should have indirect long-term operational oversight of the entire procedure and ensure via annual review meetings that the procedures are still understood by appropriate officials at each agency such that the procedures do not fade as they lie dormant. Table 2 details the proposed interagency roles.

Table 2. Organizational Roles for Biosafety

Organization	Roles
R&D (Quarantine)	- Pass and enforce Biosafety Regulations - Process permit applications for import/export - Act as contact point for Clearinghouse concerning required information and obligations. - Notify EPA and MIMRA of all applications for relevant risk assessments.
OEPPC	- Oversight and auditing of international obligations and funding.
EPA	- Risk assessment for all products
MIMRA	- Risk assessment for marine products

VI. CONCLUSION

Although a signatory to the Cartagena Protocol, the Convention on Biological Diversity and the International Treaty on Plant Genetic Resources for Food and Agriculture, the RMI does not have the legislative or regulatory framework for their proper implementation. This can be accomplished through a regulatory framework within existing agencies for the highest benefit at the lowest cost. The Quarantine Department within the Ministry of Resources and Development is proposed as the lead regulatory agency for biosafety. Included in these regulations should be direct mention of the mandate of the associated organizations for biosafety processes: OEPPC, EPA and MIMRA. A simultaneous process is proposed to establish a working group including each agency to assure that the inchoate regulatory system is complemented by a functioning and efficient process for meeting Cartagena obligations. The solution will have a greater rate of success the more straightforward and efficient it is able to be, while meeting the dual challenge of meeting all pertinent international obligations.

APPENDIX I.: OBLIGATIONS UNDER THE CARTAGENA PROTOCOL

(*from Annex 1: Implementation Toolkit*)

Obligations	Article(s)	Relevant national Legislation?	Are obligations in line with current legislation or procedure?	Who could be potentially responsible for implementation	How?
Administrative Tasks					
Designate one national authority responsible for liaison with the Secretariat and provide name/address to Secretariat.	19(1),(2)	-	No	R&D	MOU
Designate one or more competent authorities responsible for performing administrative functions under the Protocol and provide name(s)/address(es) to the Secretariat. If more than one, indicate the types of LMOs for which each competent authority is responsible.	19(1),(2)	-	No	R&D	MOU
Provide to the Biosafety Clearing-House: any relevant existing laws, regulations or guidelines, including those applicable to the approval of LMOs-FFP; and any bilateral, regional or multilateral agreements or arrangements.	20(3)(a)-(b), 11(5), 14(2)	-	No	OEPPC	-
Specify to the Biosafety Clearing-House cases in which import may take place at the same time as the movement is notified.	13(1)(a)	No	No	R&D	Regs.
Specify to the Biosafety Clearing-House imports of LMOs exempted from the AIA procedures.	13(1)(b)	No	No	R&D	Regs.
Notify the Biosafety Clearing-House if domestic regulations shall apply with respect to specific imports.	14(4)	No	No	R&D	Regs.
Provide the Biosafety Clearing-House with a point of contact for receiving information from other States on unintentional transboundary movements in accordance with Article 17.	17(2)	No	No	R&D	Regs
Notify the Secretariat if there is a lack of access to the Biosafety Clearing-House and hard copies of notifications to the Clearing House should be provided.	11(1))	No	No	R&D	Regs.
Provide to the Biosafety Clearing-House: Summaries of risk assessments or environmental reviews of LMOs generated by regulatory processes and conducted in accordance with Art. 15 Final decisions concerning the import or release of LMOs; and Article 33 reports.	20(3)(c)-(e)	No	No	R&D	Regs.
Make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements.	25(3)	No	No	R&D	Regs.
Monitor the implementation of obligations under the Protocol and submit to the Secretariat periodic reports at intervals to be determined.	33	No	No	OEPPC	MOU
Notify the Biosafety Clearing-House of any relevant changes to the information provided under part I above.	-	No	No	R&D	Regs.
Legal Requirements and/or Undertakings					
Ensure that the development, handling, transport, use, transfer and release of LMOs are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.	2(2)	EIA & Quarantine	No	EPA & R&D	Regs.
Ensure that there is a legal requirement for the accuracy of information provided by domestic exporters for purposes of notifications for export to another country and by domestic applicants for domestic approvals for	8(2) 11(2)	No	No	R&D	Regs.

LMOs that may be exported as LMOs-FFP.					
Ensure that any domestic regulatory framework used in place of the AIA procedures is consistent with the Protocol.	9(3)	No	No	R&D	Regs.
Ensure that AIA decisions are taken in accordance with Article 15.	10(1)	No	No	R&D	Regs.
Ensure that risk assessments are carried out for decisions taken under Article 10 and that they are carried out in a scientifically sound manner.	15(1),(2)	No	No	EPA & R&D	Regs.
Establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in risk assessments associated with the use, handling and transboundary movement of LMOs under the Protocol.	16(1)	EIA & Quarantine	No	EPA & R&D	Regs.
Take appropriate measures to prevent the unintentional transboundary movements of LMOs, including measures such as requiring a risk assessment prior to the first release of an LMO.	16(3)	EIA & Quarantine	No	EPA & R&D	Regs.
Endeavor to ensure that LMOs, whether imported or locally developed, have undergone an appropriate period of observation that is commensurate with its life cycle or generation time before it is put to its intended use.	16(4)	Quarantine	No	R&D	Regs.
Take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House, and, where appropriate, relevant international organizations, when there is an occurrence within its jurisdiction that leads or may lead to an unintentional transboundary movement of and LMO that is likely to have significant adverse effects on the sustainable use and conservation of biodiversity, taking also into account risks to human health in such States.	17(1)	No	No	OEPPC, MOFA, R&D	Regs.
Take necessary measures to require that LMOs that are subject to transboundary movement under the Protocol are handled, packaged and transported under conditions of safety, taking into account relevant international rules and standards.	18(1)	No	No	R&D	Regs.
Take measures to require that documentation accompanying LMOs-FFP clearly identifies that they “may contain” LMOs and are not intended for intentional introduction into the environment; and provides a contact point for further information.	18(2)(a)	No	No	R&D	Regs.
Take measures to require that documentation accompanying LMOs destined for contained use: Clearly identifies them as LMOs; Specifies any requirements for their safe handling, storage, transport and use; Provides a contact point for further information; and Provides the name and address of individuals or institutions to which they are consigned.	18(2)(b)	No	No	R&D	Regs.
Take measures to require that documentation accompanying LMOs that are intended for intentional introduction in the environment and any other LMOs within the scope of the Protocol: Clearly identifies them as LMOs Specifies the identify and relevant traits and/or characteristics; Provides any requirements for the safe handling, storage, transport and use; Provides a contact point for further information; Provides, as appropriate, the name and address of the importer and exporter; and Contains a declaration that the movement is in conformity with the requirements of the Protocol.	18(2)(c)	No	No	R&D	Regs.
Provide for the designation of confidential information by applicants, subject to the exclusions set forth in Article 21(6).	21(1),(6)	No	No	R&D	Regs.
Ensure consultation with applicants and review of decisions in the event of disagreement regarding claims of confidentiality.	21(2)	No	No	R&D	Regs.
Ensure the protection of agreed-upon confidential information and information claimed as confidential where a notification is withdrawn.	21(3),(5)	No	No	R&D	Regs.
Ensure that confidential information is not used for commercial purposes without the written consent of the notifier.	21(4)	No	No	R&D	Regs.

Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of LMOs, taking also into account risks to human health.	23(1)(a)	No	No	EPA, R&D	Regs./ MOU
Endeavor to ensure that public awareness and education encompass access to information on LMOs identified in accordance with the Protocol that may be imported.	23(1)(b)	No	No	R&D	Regs.
In accordance with relevant domestic laws, consult with the public in decision making under the Protocol, while respecting confidential information.	23(2)	No	No	R&D	Regs.
Endeavour to inform the public about the means of public access to the Biosafety Clearing-House.	23(3)	No	No	R&D	Regs.
Adopt appropriate measures aimed a preventing and, if appropriate, penalizing transboundary movements in contravention of domestic measures to implement the Protocol.	25(1)	No	No	R&D	Regs.
Dispose, at its expense, LMOs that have been the subject of an illegal transboundary movement through repatriation or destruction, as appropriate, upon request by an affected Party.	25(2)	No	No	R&D	Regs.
Procedural Requirements: Advanced Informed Agreement					
Notify, or require the exporter to ensure notification to, in writing, the competent national authority of the Party of import prior to the intentional transboundary movement of a living modified organism that falls within the scope of Article 7, paragraph 1	*8(1)*	No	No	R&D	Regs.
Provide written acknowledgement of receipt of notification to notifier within 90 days, including: - Date of receipt of notification; 9(2)(a) - Whether notification meets requirements of Annex I; 9(2)(b) - That the import may proceed only with written consent and whether to proceed in accordance with the domestic regulatory framework or in accordance with Article 10; OR - Whether the import may proceed after 90 days without further written consent.	10(2)(a), 9(2)(c) 10(2)(b)	No	No	R&D	Regs.
Communicate in writing to the notifier, within 270 days of receipt of notification: Approval of the import, with or without conditions; Prohibition of the import; A request for additional relevant information in accordance with domestic regulatory framework or Annex I; or Extension of the 270 day period by a defined period of time; AND 10(3)(a)-(d) Except where approval is unconditional, the reasons for the decision, including the reasons for the request for additional information or for an extension of time.	10(4)	No	No	R&D	Regs.
Provide in writing to the Biosafety Clearing-House the decision communicated to the notifier.	10(3)	No	No	R&D	Regs.
Respond in writing within 90 days to a request by an Exporting Party for a review of a decision under Article 10 where there has been a change in circumstances or additional relevant scientific or technical information has been made available, providing the reasons for the decision upon review.	12(2), (3)	No	No	R&D	Regs.
Procedural Requirements: Living Modified Organisms for Direct Use as Food, Feed or for Processing					
Upon making a final decision regarding domestic use, including placing on the market, of LMOs that may be subject to transboundary movement for direct use as food or feed, or for processing, inform the Biosafety Clearing-House within 15 days of making that decision, including the information listed in Annex II.	11(1)	No	No	R&D	Regs.
Except in the case of field trials, provide hard copies of the final decision to the National Focal Point of Parties that have notified the Secretariat in advance that they do not have access to the Biosafety Clearing-House.	11(1)	No	No	R&D	Regs.
Provide additional information contained in paragraph (b) of Annex II about					

the decision to any Party that requests it.	11(3)	No	No	R&D	Regs.
In response to the posting of a decision by another Party, a Party that decides to import may take a decision on the import of LMOs-FFP: either as approved under the domestic regulatory framework consistent with the Protocol; OR in the absence of a regulatory framework, on the basis of a risk assessment in accordance with Annex III within no more than 270 days. In this case, a declaration must be made to the Biosafety Clearing-House.	11(4), (6)	No	No	R&D	Regs.

APPENDIX II: APPLICABLE OBLIGATIONS UNDER THE CONVENTION ON BIOLOGICAL DIVERSITY

Obligations	Article(s)	Relevant national Legislation?	Are obligations in line with current legislation or procedure?	Who could be potentially responsible for implementation	How?
Each Party shall require any person under their jurisdiction that are providing LMOs to provide any information concerning the use and safety regulations and any potential adverse effects to any Party into which the LMOs are to be introduced.	16,17	No	No	R&D	Regs.

APPENDIX III: APPLICABLE OBLIGATIONS UNDER THE INTERNATIONAL TREATY ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE

Obligations	Article(s)	Relevant national Legislation?	Are obligations in line with current legislation or procedure?	Who could be potentially responsible for implementation	How?
Procedure for promoting an integrated approach to the exploration, conservation and sustainable use of plant genetic resources	5(1)	No	No	R&D	Regs
Procedure for developing and maintaining appropriate policy and legal measures that promote the sustainable use of plant genetic resources	6	No	No	R&D	Regs
Enhance international activities to promote conservation, evaluation, documentation, genetic enhancement, plant breeding, and seed multiplication	7(2)	No	No	R&D OEPPC	Regs MOA
The national government's responsibility for Farmers' Rights, as they relate to plant genetic resources for food and agriculture	9(2)	No	No	R&D	Regs
In their relationships with other jurisdictions, the Parties recognize the sovereign rights of other jurisdictions over their own plant genetic resources, including that the authority to determine access to those resources rests with national governments and is subject to national legislation	10(1)	No	No	OEPPC	MOA
In the exercise of their sovereign rights, the Parties agree to establish a multilateral system, both to facilitate access to plant genetic resources and to share the benefits arising from the utilization of these resources	10(2)	No	No	R&D OEPPC	Regs MOA
The Parties agree that benefits arising from the use, including commercial use, of plant genetic resources shall be shared by the exchange of information, access to and transfer of technology, capacity-building, and the sharing of the benefits arising from commercialization	11	No	No	R&D OEPPC	Regs MOA