Regulations of Products Derived from Innovative Agricultural Technologies:

Baseline Review of APEC Member Economies

November 2013

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Acronyms

ABRAM	Agricultural Biotechnology Regulatory Approach Matrices
AMM	APEC Ministerial Meeting
BT	Bacillus thuringiensis
CP	Contracting party
GAIN	Global Agriculture Information Network
GE	Genetically engineered
GFSI	Global Food Safety Initiative
GMM	Genetically modified micro-organism
GM	Genetically modified
GMO	Genetically modified organism
HLPDAB	High-Level Policy Dialogue on Agricultural Biotechnology
LLP	Low-level presence
LMO	Living modified organism
OECD	Organization for Economic Cooperation and Development
TPP	Trans-Pacific Partnership Agreement

Acknowledgments

The authors of this report are Dr. Flerida Carono and Mrs. Lynn Salinger. This report was prepared for the Asia-Pacific Economic Cooperation (APEC) organization as part of the APEC Technical Assistance and Training Facility (TATF) program. APEC TATF is managed by USAID, with funding and strategic direction provided by the U.S. State Department Bureau of East Asian and Pacific Affairs, Office of Economic Policy.

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Executive Summary

The use of biotechnology has been endorsed by APEC as one tool to increase agricultural productivity, and hence promote food security. A wide range of microorganisms, agricultural inputs, feeds, food ingredients and additives, commodities, and processed foods can be derived from innovative technologies. For this assessment, the authors focused on recombinant-DNA plants. Expansion of global land area devoted to recombinant-DNA plants has increased significantly since the first recombinant-DNA plant events were approved in the early 1990s. While recombinant DNA techniques have been applied to over 25 different plants, the most widely produced recombinant-DNA plants are widely traded field crops such as corn and soybeans.

As multilateral and preferential trade agreements continue to grow, facilitation of trade, not only by reductions in tariffs but also in non-tariff measures, i.e., technical barriers to trade, becomes an increasing priority. The APEC High-Level Policy Dialogue on Agricultural Biotechnology (HLPDAB) is one forum by which Member Economies can pursue opportunities to harmonize or converge on accepted good regulatory practices in order to promote trade in agricultural products derived from innovative agricultural technologies.

The 21 Member Economies of APEC represent a diverse set of agricultural interests. Global leaders in export of agricultural commodities and net food-importing countries have developed different approaches to the regulation of recombinant DNA plant products for contained work (usually in laboratories), confined release (usually research field trials), commercial release, use as food or feed, or as imported, either for processing or imported in final processed form. Some countries take the position that rules for assessing the safety of genetically engineered food/feed ingredients and products are already encompassed in existing laws and regulations assessing conventional foods with regard to animal, plant, environmental, and human health and safety, while others have passed legislation that specifically considers the potential risks posed by genetically engineered, or “novel,” food products. Regulatory dimensions differ across APEC Member Economies and may include: regulations regarding applications for safety review and approval; public agencies responsible for implementation; the range of organisms covered by regulations; documents and information required for submission; the extent of public participation in policy decision making; the extent of consideration of socioeconomic variables; and scientific criteria.

In order to begin to understand the range of regulatory approaches being implemented by APEC Member Economies, identify good practices that may serve as role models for other Member Economies within APEC, and launch a dialogue about next steps to take to promote regulatory harmonization in this area, this baseline review was prepared for the HLPDAB. Several other examples of comparative analyses of regulatory frameworks for recombinant DNA plant are reviewed in order to see the variables covered. Among these, results of a 60-nation survey are examined in which regulatory approaches in six core areas are compared, scored, and used to derive a recombinant DNA plant inded – referred to as a Genetically Modified or GM regulatory index - of the extent to which countries are less or more open to recombinant-DNA plants.

For each APEC Member Economy, regulatory approach details are presented in consistently constructed matrices. Syntheses of similarities and differences are highlighted, and a number of

opportunities to embark on an APEC-wide path of regulatory harmonization in this area are suggested.

Introduction

Context

Since its inception in 2001 the Asia-Pacific Economic Cooperation (APEC) forum has endorsed the use of biotechnologies[1] – including plant and animal breeding techniques and nanotechnology[2] – as one tool to increase agricultural productivity, protect the environment, and promote food security. Today the manufacture of a wide range of consumer products around the world benefits from new industrial biotech processes, from personal care and cosmetics to clothing and textiles, fuels, furniture, and medicines.[3] The list of agricultural products derived from biotechnologies includes microorganisms, agricultural inputs (e.g., seeds, agro-chemicals, breed stock, etc.), feeds, food ingredients and additives, commodities, and processed foods.[4] While a study of innovative agricultural technology regulation could also examine breed stock, additives, and other new developments, for this assessment, in keeping with direction from the Agricultural Technical Cooperation Working Group, the authors focused on recombinant-DNA plants.[5]

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[1] Article 3 of the Cartagena Protocol on Biosafety defines a "living modified organism" as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;" "modern biotechnology" is defined as a) the application of *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or b) fusion of cells beyond the taxonomic family that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

[2] See reporting from the 2013 World Trade Organization's Public Forum on Trade and Innovation in International Food & Agricultural Trade Policy Council, "IPC Alert: Innovative Agricultural Production Techniques Face Regulatory Barriers," October 3, 2013, http://www.agritrade.org/pressroom/documents/InnovativeAgriculturalProductionTechniquesFaceRegulatoryBarriers.pdf (accessed 23 October 2013).

[3] Examples of consumer products made with industrial biotechnology can be found from the Biotechnology Industry Organization website, http://www.bio.org/sites/default/files/ConsumerProducts060409.pdf.

[4] For example, Canada defines a "novel food" as a) a substance, including a micro-organism, that does not have a history of safe use as a food; b) a food that has been manufactured, prepared, preserved, or packaged by a process that i) has not been previously applied to that food, and ii) causes the food to undergo a major change (a change that may have an adverse affect on the composition, structure, or nutritional value of the food or its generally recognized physiological effects; the manner in which the food is metabolized in the body, or the microbiological safety, chemical safety, or safe use of the food); and c) a food derived from a plant, animal, or micro-organism that has been genetically modified such that i) characteristics are exhibited that were not previously observed, ii) characteristics are no longer exhibited that were previously observed, or iii) one or more characteristics of the plant, animal, or micro-organism no longer fall within the anticipated range for that plant, animal, or micro-organism; see MacKenzie (2000).

[5] Since the development of recombinant-DNA plants, a number of terms have been used to describe these and other genetically engineered organisms. These terms or references include GM (genetically modified), GMO (genetically modified organism), and GE (genetically engineered) among others. While the paper attempts to use the term recombinant DNA plant, in order to maintain consistency with the Codex Alimentarius Commission where possible, the terms GE, GM, and GMO are used when they appear in the literature, in guidance, regulation or law of member economies, or when a member economy has used one of those terms in its contribution to the report.

The United States is the world's largest producer of recombinant-DNA plants. Of the 18 "biotech mega-countries" identified by James (2012) as growing biotech crops on 50,000 hectares or more of land in 2012, seven APEC Member Economies figure prominently. As seen in Table 1, the expansion of land area devoted to recombinant DNA plant cultivation, by country and globally, has been rapid over the last 16 years.

As trade promotion continues to be an economic priority around the globe, multilaterally and within regional trading blocs, and as progress continues to be made in lowering average tariff levels that govern access to foreign markets, elimination of non-tariff measures becomes an increasing priority for trade negotiations. APEC's Subcommittee on Standards and Conformance is promoting regulatory cooperation, as articulated at the July 2013 7th APEC Conference on Good Regulatory Practices.[6] In the ongoing negotiations of the Trans-Pacific Partnership (TPP) Agreement, in which 12 of the 21 APEC Member Economies currently participate, "regulatory coherence" is one of several cross-cutting issues being addressed (Fergusson et al. 2013, 46).

Table 1: Global Cultivation of Biotech Crops by Area and by Country

Rank	Country	Area (million hectares)		Biotech Crops Cultivated
		1996	2012	
1	United States *	1.5	69.5	Maize, soybean, cotton, canola, sugar beet, alfalfa, papaya, squash
2	Brazil		36.6	Soybean, maize, cotton
3	Argentina	0.1	23.9	Soybean, maize, cotton
4	Canada *	0.1	11.6	Canola, maize, soybean, sugar beet
5	India		10.8	Cotton
6	People's Republic of China *	1.1	4.0	Cotton, papaya, poplar, tomato, sweet pepper
7	Paraguay		3.4	Soybean, maize, cotton
8	South Africa		2.9	Maize, soybean, cotton
9	Pakistan		2.8	Cotton
10	Uruguay		1.4	Soybean, maize
11	Bolivia		1.0	Soybean
12	Philippines *		0.8	Maize
13	Australia *	< 0.1	0.7	Cotton, canola
14	Burkina Faso		0.3	Cotton
15	Myanmar		0.3	Cotton
16	Mexico *	< 0.1	0.2	Cotton, soybean
17	Spain		0.1	Maize
18	Chile *		< 0.1	Maize, soybean, canola
TOTAL		2.8	170.3	

*Note: * Denotes an APEC Member Economy.*

Source: Adapted from James (1997, 2012).

APEC's High-Level Policy Dialogue on Agricultural Biotechnology (HLPDAB), a senior officials' forum for dialogue, information exchange, and capacity building on this issue, works to build consensus among the 21 Member Economies on approaches to regulatory frameworks, facilitate

[6] See "Support for good regulatory practices in APEC will foster growth: experts," Medan, Indonesia, 27 June 2013, http://www.apec.org/Press/News-Releases/2013/0627_growth.aspx.

technology transfer, encourage investment, and strengthen public confidence regarding biotechnology.[7] The HLPDAB dialogue work plan for 2010-2012 agreed to advance policy discussion on strategies for regulatory harmonization and coordination of technical approaches.[8]

In its 2012 Food Security Declaration APEC affirmed the need to increase agricultural production and productivity and decrease post-harvest losses, primarily through increased investment and adoption of innovative technologies in agriculture (APEC Ministerial Meeting (AMM) 2012).[9,10] Innovative technologies are also recognized in the Declaration for their contribution to mitigate and adapt to the impact of climate change on agricultural development and product quality. The APEC Food Security Declaration underscores Members' agreement to promote more intense development and capacity-building in the area of agricultural biotechnologies, regulatory harmonization with regard to biotechnologies, science-based risk assessments of agricultural biotechnology, and improved transparency in regulatory decision-making. Member Economies approved an HLPDAB Action Plan at the 2012 AMM meetings to facilitate trade in products derived from innovative agricultural technologies.[11] The Action Plan endorsed the notion of transparent, science-based regulatory approaches that are consistent with international commitments by Member Economies and encouraged Member Economies to:

- Publicize regulatory approaches applicable to innovative agricultural technologies;
- Conduct periodic self-reviews of regulatory approaches in order to ensure transparency and build further confidence in regulatory systems;
- Provide for meaningful and transparent public consultation processes; and
- Identify and begin to deliver capacity-building activities to assist Member Economies in achieving the goals of regulatory transparency.

The most recently adopted HLPDAB work plan for 2013-2015 recommits to work on regulatory harmonization.[12] HLPDAB deliverables will promote the exchange of information in any areas related to agricultural biotechnology, continue to promote public understanding of and build confidence in regulatory systems, establish transparent and functioning regulatory systems that promote regulatory consistency and facilitate trade, and put more emphasis on farmers' welfare as a consideration in transferring innovative technologies.

This baseline review of regulations of products derived from innovative agricultural technologies – with a focus on recombinant-DNA plants - aims to provide foundational information to be able to identify regulatory approaches across Member Economies.

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[7] Taken from HLPDAB, http://www.apec.org/Groups/Other-Groups/Agricultural-Biotechnology.aspx.

[8] APEC HLPDAB Steering Committee: Innovative Agricultural Technologies Forum, "APEC HLPDAB – Dialogue Work Plan 2010-2012," San Francisco, U.S., 23 September 2011.

[9] 2012 APEC Ministerial Meeting on Food Security, "Kazan Declaration on APEC Food Security," Kazan Russia, 30-31 May 2012.

[10] "Innovative agricultural technologies" are defined in the APEC Food Security Declaration to include: improving animal genetics; development of biotechnologies; extension services; adaptation of effective pest and disease management measures; and use of resource-saving technologies and equipment.

[11] 11th HLPDAB, "Action Plan – Facilitating Trade in Products Derived from Innovative Agricultural Technologies," Kazan, Russia, 26-27 May 2012.

[12] HLPDAB Meeting, "HLPDAB Work Plan 2013-2015," Medan, Indonesia, 27 June 2013.

Conceptual Framework

National governments express policy objectives through national laws, which in turn are implemented through codes or regulations by various government agencies. In the case of regulation of recombinant-DNA plants, risk analysis may be conducted before approval is given to work on or commercialize a product, to assess its likely impact on the environment and animal, plant, and human health.

The APEC-OECD Integrated Checklist on Regulatory Reform (2005) elaborates a number of criteria to be considered when undertaking reforms or when reviewing the effectiveness of approaches to regulation, summarized in Figure 1 and Figure 2 below:

Figure 1: Elements of National Regulatory Approaches

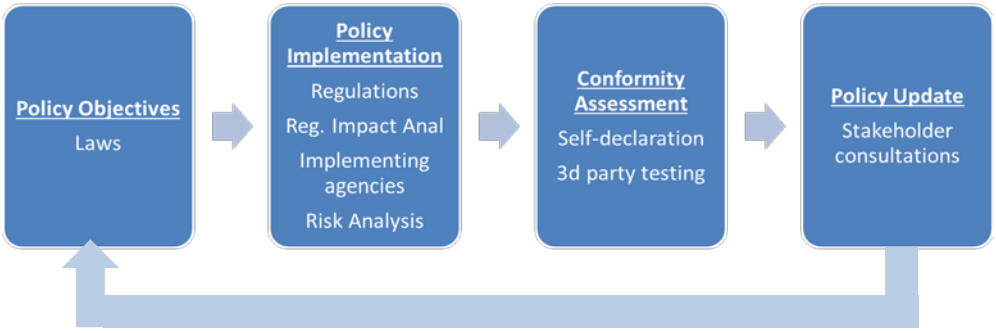

Figure 2: Summary of Regulatory Reform Criteria

Horizontal Criteria Concerning Regulatory Reform	Design of Regulatory Policies
• Existence of an integrated policy • Strength of political support expressed for regulatory reform • Mechanisms to assure accountability and effective implementation of policies • Extent of discriminatory policy elements and willingness to eliminate them • Extent of cross-government coordination regarding regulatory reform • Degree of transparency, consistence, comprehensibility, and accessibility of regulatory framework to all users • Degree of timing and sequencing coherence • Extent of inter-ministerial regulatory reform coordination mechanisms • Depth of available human and technical resources within government to develop and implement regulations • Availability of capacity-building programs for regulators to ensure utilization of best-practice approaches • Existence of credible due process mechanisms for those affected by regulatory framework	• Existence of consistent and coherent application of quality regulation principles • Review of legal basis and economic/social impacts is undertaken when drafting new regulations; performance measurement is considered for reviewing economic/social impacts of new regulations • Review of legal basis and economic/social impacts is undertaken for existing regulations; performance measurement is incorporated in reviewing economic/social impacts of existing regulations • Transparency and predictability of rules, regulatory institutions, and the regulatory management process for users within and outside of government • Effectiveness of public/stakeholder consultation processes • Use of transparent methodologies to analyze regulatory impacts • Assessment of regulatory alternatives is undertaken to promote choice of most efficient and effective policy tool • Extent to which regulatory compliance and enforcement are assured

Source: OECD and APEC (2005)

Responsibility for implementation falls to one or more national- or federal-level government agencies; in addition, sub-national regulations may also be applied. Compliance of farms and firms with the regulatory framework is assessed under conformity assessment rules also established by government.[13] Reviews of new regulations or revisions of existing regulations may be undertaken with varying degrees of stakeholder consultation and public transparency.

[13] In addition to mandatory compliance with regulations, economic actors may also be expected to comply with voluntary industry standards; these are outside the scope of this paper.

In addition to national approaches to regulation, governments affirm their policy commitments through membership in international organizations and adherence to international conventions. Table 2 details the status, by APEC Member Economy, of those commitments, and distinguishes between those to which all or most APEC Members belong and those adherence to which is less widespread among the 21 Members. For example, all or most Economies are members of the FAO and WHO and hence adhere to the Codex Alimentarius, established by the Food & Agriculture Organization and the World Health Organization to harmonize food standards,[14] and the WTO. However, membership or adherence to biotechnology-related protocols or treaties, such as the Convention on Biological Diversity and its accompanying Cartagena and Nagoya protocols, or the International Treaty on Plant Genetic Resources, is not as widespread.

Table 2: Participation by APEC Member Economies in Relevant International Bodies

	Broad Membership Across APEC							Limited Membership Among APEC Member Economies				
	Convention on Biological Diversity	Codex Alimentarius	Food & Agriculture Organization	Int'l Plant Protection Convention	World Health Organization	World Organization of Animal Health	World Trade Organization	Asia & Pacific Plant Protection Commission	Cartagena Protocol on Biosafety	Nagoya Protocol on Access and Benefit-Sharing	International Convention for Protection of New Plant Varieties (UPOV)	Int'l Treaty on Plant Genetic Resources for Food & Agriculture
Australia	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes	Yes	Yes
Brunei Darussalam	Yes	Yes		NCP	Yes	Yes	Yes					
Canada	Yes	Yes	Yes	Yes	Yes	Yes	Yes				Yes	Yes
Chile	Yes	Yes	Yes	Yes	Yes	Yes	Yes				Yes	Yes
China	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes	
Hong Kong, China							Yes					
Indonesia	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes
Japan	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes	Yes	Yes	Yes
Malaysia	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes			Yes
Mexico	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes	Yes	Yes	
New Zealand	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes		Yes	
Papua New Guinea	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes			
Peru	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes	Yes	Yes	Yes
Philippines	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes			Yes
Republic of Korea	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes	Yes	Yes
Russian Federation	Yes	Yes	Yes	Yes	Yes	Yes	Yes				Yes	
Singapore	Yes	Yes	Yes	Yes	Yes	Yes	Yes				Yes	
Chinese Taipei						Yes	Yes					
Thailand	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes

[14] In 2003 principles were established by Codex regarding risk analysis of foods derived from modern biotechnology and guidelines were issued for the conduct of food safety assessment of foods derived from and produced using recombinant-DNA plants or microorganisms. In 2008 Codex issued guidelines for the conduct of food safety assessment of foods derived from recombinant-DNA animals. Codex has also compiled texts relevant to the labeling of foods derived from modern biotechnology (2011). A standard regarding labeling of foods with GM content has not been established. For a list of all standards, including those mentioned here, see http://www.codexalimentarius.org/standards/list-of-standards/.

	Broad Membership Across APEC							Limited Membership Among APEC Member Economies				
	Convention on Biological Diversity	Codex Alimentarius	Food & Agriculture Organization	Int'l Plant Protection Convention	World Health Organization	World Organization of Animal Health	World Trade Organization	Asia & Pacific Plant Protection Commission	Cartagena Protocol on Biosafety	Nagoya Protocol on Access and Benefit-Sharing	International Convention for Protection of New Plant Varieties (UPOV)	Int'l Treaty on Plant Genetic Resources for Food & Agriculture
United States		Yes	Yes	Yes	Yes	Yes	Yes				Yes	Yes
Viet Nam	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes		Yes	
TOTAL Number	18	19	18	18*	19	20	21	9	11	7	13	11

*Note: NCP = Non-contracting party; * = Contracting parties only*

Comparing Agricultural Biotechnology Regulatory Approaches

In order to frame the baseline review of APEC Member Economies' approaches to regulation of trade in products derived from innovative agricultural technologies, a literature survey was undertaken to identify other initiatives that compare recombinant DNA plant regulations across economies. Synthetic overviews of some of the findings of this baseline review are also presented in this section.

Examples of Other Comparative Approaches

Several papers have attempted to compare and contrast country approaches to regulation of agricultural biotechnology and products derived therefrom. For example, Escaler et al. (2012) differentiate APEC Member Economies' agricultural biotechnology regulatory systems according to a number of criteria:

- Is the Economy a significant producer of recombinant-DNA plants or animals?
- Is the Economy a significant importer of recombinant-DNA plants or animals/animal products?
- Is the Economy a signatory to the Cartagena Protocol on Biosafety, which governs the movement of Living Modified Organisms (LMOs) across boundaries?
- What is the extent of coverage of the Economy's regulations, i.e., how many recombinant-DNA plants and how many recombinant DNA plant events[15] are authorized?
- Are the regulations directed to *products* or *processes* by which the products were created?
- Does the Member Economy's regulatory approach stipulate requirements and thresholds for labeling of recombinant DNA plant products?
- Does the Economy's body of biotechnology regulations specifically address low-level presence (LLP) of unapproved recombinant DNA events?

[15] From www.gmo-compass.org: "When scientists develop transgenic plants, plant cells are transformed with foreign DNA individually. Every cell that successfully incorporates the gene of interest represents a unique 'event.' "

- What is the Economy's position regarding stacked events, i.e., do stacked events require separate assessment or if built from previously-approved events, are these *de facto* accepted?[16]
- Does the Member Economy include non-safety, e.g., socioeconomic, considerations in its decision-making process?
- What is the role of public participation in the Member Economy's biotechnology regulatory process?

The authors find that all APEC Member Economies share the same goal of delivering safe food to consumers and into the environment. They differ, however, in their stages of development regarding research and commercialization of recombinant DNA plant products, as well as with regard to their relationship to global food commodity markets (net food exporters versus net food importers). These differences lead them to differ in their approach to regulation of recombinant DNA plant products. Escaler et al. further notes that exporters' fears of product rejection in destination markets that restrict or ban recombinant DNA plant products (e.g., Europe, Japan, Republic of Korea) affects policy decision-making in those food-exporting countries.[17]

MacKenzie (2000) undertook for the Canadian Biotechnology Advisory Committee a comparison of regulatory frameworks for food products of biotechnology in Argentina, Australia, Japan, United Kingdom, and United States. He reviewed regulations from four perspectives: research level ("innovation and scientific discovery"), environmental release, food safety, and market considerations (such as product segregation or labeling requirements, and requirements to engage in market surveillance of the potential adverse or beneficial impacts of the genetically modified foods). Further, he considered the legislative basis and public accountability of the regulatory process, philosophical approaches to regulation, regulatory decision-making transparency, approaches to risk assessment, and the independence of the regulatory decision-making process.

Jaffe (2006) compares national biosafety regulatory systems in East Africa, and proposes a framework of "components and characteristics of a functional and protective biosafety regulatory system." He proposes that the ideal system would be or include:

- *Comprehensive,* i.e., covers all of the different stages of GMO's development, release, and transaction;
- *Adequate legal authority,* i.e., appropriate institutional authority to undertake risk assessments prior to unconfined release into the environment or into markets;
- *Clear safety standards,* i.e., availability of transparent definitions of the safety standards required for government approval;
- *Proportionate risk-based reviews,* i.e., regulatory flexibility exists to treat products on a case-by-case, risk-based basis;
- *Participatory,* i.e., opportunities exist for public engagement with policymakers in the regulatory process;

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[16] The combination of two or more transgenic traits in one plant as a result of conventional breeding.

[17] In addition to public regulation, Gruère and Sengupta (2009) also note the rise of private food processor and retailer standards regarding GM-free products, especially in Europe, leading to fears (both real and unfounded) of commercial risks by developing country exporters.

- *Transparent and understandable*, i.e., availability of readily digestible information to the public regarding all steps in the regulatory process and identification of those opportunities for public engagement in that process;
- *Post-approval oversight* of impacts of GM release continues after government approval;
- *Commitment to flexibility and adaptability* of the regulatory process to accommodate changes in technology, products, and implementation experiences;
- *Efficiency, workability, and fairness* of the regulatory process to that it minimizes time/costs borne by actors, and applies similar considerations to similar products.

A report prepared for the Organization for Economic Cooperation and Development (OECD) provides an overview of modern biotechnology regulatory tools and frameworks applicable across sectors (including, but not limited to, agriculture and food) (Cantley 2007). Across a sample of OECD and non-OECD countries, the report highlights different government approaches to biotechnology policy coherence and coordination across the government and different priorities; different interests in different sectors, depending on whether one is a producer, importer, or not; and varying levels of adherence to regional or international commitments.

One comparison of recombinant DNA plant regulation and its determinants, undertaken across 60 countries (including 19 of 21 APEC Member Economies[18]), produced a "GM regulatory index" referenced below (Vigani and Olper 2013). The Vigani-Olper index, built largely from information discerned from U.S. Department of Agriculture (USDA) Global Agriculture Information Network (GAIN) reports published by the USDA's Foreign Agricultural Service, is developed for six qualitative criteria: 1) approval process; 2) risk assessment; 3) labeling;[19] 4) traceability; 5) coexistence; and 6) membership in international agreements on GMOs. It uses scales in each category, leading to a composite index ranging in rank from 1 (least restrictive regulatory framework) to 15 (most restrictive GMO regulation). The relative ranks estimated for APEC Member Economies range from 1 for Hong Kong to 13 for Japan, as seen in Table 3. While this comparison is fairly current, specialists in the field and member economy experts have noted that it may not adequately capture the complexity of the regulatory frameworks of different economies.

Table 3: GMO Regulatory Index for 19 APEC Member Economies

Rank	Member Economy	Index Value	Rank	Member Economy	Index Value
1	Hong Kong, China	0.10	5	Mexico	0.35
2	Peru	0.15	5	United States	0.35
4	Canada	0.30	6	Thailand	0.40
4	Philippines	0.30	7	Republic of Korea	0.45
4	Singapore	0.30	7	Russian Federation	0.45
4	Chinese Taipei	0.30	8	China	0.50
4	Viet Nam	0.30	9	Australia	0.55
5	Chile	0.35	11	New Zealand	0.65
5	Indonesia	0.35	13	Japan	0.70
5	Malaysia	0.35			

Source: Excerpted from Table 1 (Vigani and Olper 2013)

[18] Missing were Brunei Darussalam and Papua New Guinea.

[19] For example, 0 = no labeling policies, 1 = voluntary GMO labeling, 2 = mandatory GMO label without threshold or with threshold > 1%, 3 = mandatory GMO label with threshold < 1%, 4 = countries declared "GM-free."

Synthesis of Baseline Review Approach & Findings

This baseline review prepared for the HLPDAB presents information in a consistent format on agricultural biotechnology regulations, including:

- Laws and implementing regulations that govern biotechnology-derived products in each Member Economy, with dates of promulgation of these laws and regulations and dates of amendment or revision, where applicable;
- Government agencies with responsibility for implementing and overseeing compliance with the laws and regulations on biotechnology-derived products;
- Broad categories of organisms covered by the laws and regulations;
- Paperwork required for submission;
- Associated processing fees and times;
- Rules regarding risk assessment;
- Rules regarding public participation in the regulatory process;
- Inclusion of "other" considerations, e.g., social or economic factors, in policy decision-making;
- Form of the approval document;
- Restrictions or conditions that may be applied to the approval document;
- Expiration of approval document;
- Provisions for approval renewal.

Each of these criteria is further disaggregated across the columns with regard to the intended application of the biotech product or process. The bullets below represent gradually increasing applicability or utilization in the environment, to which different laws and regulations may apply:

- Contained work (i.e., use in a confined space, as in a laboratory or greenhouse);
- Confined environmental release (i.e., use in research trials, field trials);
- Unconfined or deliberate release into the environment (i.e., use in broader situations, as in risk assessment trials, commercial cultivation, or as seed or animal breedstock);
- Commercial use as food or feed;
- Importation for processing or as a processed feed or food commodity (typically applies to important of cereals, oilseeds, and feed grains for milling, pressing, etc.).

In a few APEC Member Economies, the intended applications (i.e., the column headings) are defined somewhat differently because of specific definitions in the Economy's regulatory approach.

Some APEC Member Economies take the position that biosafety or regulation of recombinant-DNA plants represents a new regulatory challenge, and pass laws specific to that charge. Others, such as Singapore and the United States, take the position that biotechnology is adequately covered in existing laws and regulations on animal, plant, and food safety. Only one Member Economy, Brunei Darrusalam, does not have any recombinant DNA plant-specific regulation in place. Regulatory frameworks in Chile and the Russian Federation are still under development. Papua New Guinea, which does not have specific legislation dealing with recombinant-DNA plants, has drafted a National Biosafety Framework, which includes a Biosafety and Biotechnology Bill; the latter has not yet been enacted by the Cabinet. In 2011 Peru enacted a ten-year moratorium on GMOs, with exceptions for

GMO imports for confined research, use in pharmaceutical or veterinary products, and products imported for direct or processed use as food or feed. Mexico's regulation provides for the designation of recombinant DNA plant (GM) free zones, and Australia's Gene Technology Act allows individual states and territories to designate recombinant DNA plant (GM) and non -GM crop areas.

Regulations may focus on 1) the specific biotechnology *process* used to produce an organism, i.e., requiring approval for specific events or, when presented in combination, for stacked traits; 2) the traits expressed in the new organism; or 3) the *new product* itself. Canada, for example, defines "novelty" as the trigger of a regulatory review. A "plant with a novel trait" is a new variety of a species with one or more traits that are novel to that species in Canada, i.e., 1) it is new to stable, cultivated populations of the same plant species in Canada, and 2) it could potentially have an effect on the environment.[20] The regulatory frameworks in some countries include the term "living modified organism (LMO), defined in the Cartagena Protocol on Biosafety as "any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology."[21]

Nine of the 21 APEC economies are considered extremely biodiverse (megadiverse countries) by Conservation International, and protection of biodiversity is an important consideration in all the regulatory framework of APEC economies. Among the megadiverse countries, four (United States, Philippines, Mexico and Australia) allow commercial scale cultivation of at least one GMO crop. Australia and Mexico have identified areas where specific GM crops may be cultivated. At the other extreme, Peru, another economy with the megadiversity tag, has imposed a 10-year moratorium on the entry and production of GM crops in 2011.

Key guidelines, regulations, laws, and directives from each Member Economy and national implementing agencies are listed in Table 4, in chronological (laws, regulations) and alphabetical (agencies) order. Dates represent original dates of promulgation. For further detail regarding dates of subsequent amendments and areas of applicability and responsibility, see the Economy-specific matrices that follow.

Table 4: Key Agricultural Biotechnology Guidelines, Regulations, Laws, and Directives in APEC Member Economies

	Key Guidelines, Regulations, Laws, & Other Directives	National Implementing Agencies
Australia	• 1992 Imported Food Control Act • 1991 Australia New Zealand Food Standards Code • 2000 Gene Technology Act • 2001 Gene Technology Regulations	• Office of Gene Technology Regulator, Dept of Health, & OGTR Institutional Biosafety Committee • Food Standards Australia New Zealand • Australian Quarantine & Inspection Service
Brunei Darussalam	*No specific guidelines regulating GMOs.*	

[20] CFIA, " 'Novelty' and Plants with Novel Traits," http://www.inspection.gc.ca/plants/plants-with-novel-traits/general-public/novelty/eng/1338181110010/1338181243773. Not all novel agricultural products are the result of ***genetic*** engineering, however.

[21] Cartagena Protocol on Biosafety, Article 3, http://bch.cbd.int/protocol/text/.

	Key Guidelines, Regulations, Laws, & Other Directives	National Implementing Agencies
Canada	• Seeds Act and Regulations • Plant Protection Act and Regulations • Feeds Act and Regulations • Food and Drugs Act and Regulations • Standard for Voluntary Labeling and Advertising of Foods that Are and Are Not Products of Genetic Engineering • Guidelines for Safety Assessment of Novel Foods • Guidelines for Safety Assessment of Novel Feeds • Human Pathogens and Toxins Act • Human Pathogens Importation Regulations • Health of Animals Act and Regulations	• Canadian Food Inspection Agency • Environment Canada • Health Canada • Public Health Agency of Canada
Chile	• 1993 Resolution of exemption 1927/93 of the Agriculture and Livestock Service (specific for GMOs) • Sanitary and Phytosanitary regulations for importation of plant materials (existing regulations, coverage is extended to include GMOs)	• Ministry of Agriculture, Advisory Committee on Release of Transgenic Organisms • Ministry of Agriculture, Agriculture & Livestock Service • Ministry of Agriculture, Office of Studies & Agricultural Policies • National Commission for the Environment
China	• Regulations on Safety of GMOs 2001 • Implem.Regs. on Safety Assessment of GMOs 2002 • Implem.Regs. on Safety of Import of GMOs 2002 • Implem.Regs. on Labeling of GMOs, 2002 • Regs. on Inspection & Quarantine of M/X of GM Products 2004 • 2009 Food Safety Law	• General Administration of Quality, Inspection, & Quarantine • Ministry of Agriculture • National Biosafety Committee • Office of Biosafety Administration of Agricultural GMOs • State Council (agricultural admin department)
Hong Kong, China	• 2008 Guidelines on Biosafety in the Clinical Laboratory • 2011Genetically Modified Organisms (Control of Release) Ordinance • Part V (Food and Drugs) of the Public Health and Municipal Services Ordinance • 2011 Genetically Modified Organisms (Documentation for Import and Export) Regulation • Hong Kong Agriculture, Fisheries and Conservation Department; Plant Ordinance, Cap. 207 (Importation and Pest Control: for importation of Plants	• Food Health Bureau, Agricultural, Fisheries, & Conservation Department • Hong Kong Center for Food Safety, Food & Environmental Hygiene Department • Hong Kong Customs & Excise Department • Universities, R&D institutions
Indonesia	• Act No. 7 of 1996, regarding food (PP 7/1998, amended 2012) • 1999 Joint decree of Ministers on Biosafety and Food Safety of Genetically Engineered Agricultural Products • Act No. 29 of 2000, regarding protection of plant varieties (PP 29/2000) • Act No. 28 of 2004, regarding food safety, quality, and nutrition (PP 28/2004) • Act No. 21 of 2005, Safe Utilization of Genetically Engineered Biological Products (PP 21/2005) • Ministry of Agriculture Regulation No. 61/2011 (procedures of testing, evaluating, releasing, and withdrawing of transgenic crop variety} • 2012 BPOM Regulation No. K.03.1.23.03.12.1563 on the Guidelines of Food Safety Assessment for Genetically Engineered Products	• Agency for Agricultural Research and Development • Biosafety Commission for Transgenic Products • Biosafety Committee • Bureau for Biotechnology and Genetics Resources • Ministry of Agriculture • Ministry of Environment State • Ministry of Marine & Fisheries Affairs • National Agency of Drug & Food Control (BPOM) • Other government agencies

	Key Guidelines, Regulations, Laws, & Other Directives	National Implementing Agencies
Japan	• 1947 Food Sanitation Law (amendments up to 2003 • 1953 Feed Safety Law (amendments up to 2003) • 1960 Pharmaceutical Affairs Act (amendments up to 2002) • 1989 Guidelines for Application of Recombinant DNA Organisms in Agriculture, Forestry, Fisheries, The Food Industry and Other Related Industries (revised 1995, 2000) • 2003 Food Safety Basic Law • 2004 Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (Cartagena Law) • 2009 Labeling Standard for GM Food, Japan Agricultural Standards (JAS) Law	• Consumer Affairs Agency, Food Labeling Division • Food Safety Commission • Ministry of Agriculture, Forestry, & Fisheries • Ministry of Economy, Trade, & Industry • Ministry of Education, Culture, Sports, Science & Technology • Ministry of Environment • Ministry of Finance (if alcohol produced GMOs) • Ministry of Health, Labor, & Welfare • Relevant prefecture agencies
Republic of Korea	• 2008 Act on Transboundary Movements of Living Modified Organisms (LMO Act) • Enforcement Ordinance of LMO Act • Guidelines for Research & Handling of Recombinant Organisms rel to Agric Research • Guidelines for Research of Recombinant Organisms for crops developed by universities & private sector • Guidelines for export & import of LMOs intended for agricultural use, environmental release, food/feed/processing, & other • 1991 Food Sanitation Act • Agricultural Products Quality Control Act	• Biosafety Committees • Ministry of Education, Science, & Technology (MEST) • Ministry for Agriculture, Food, and Rural Affairs (MAFRA) • MAFRA Animal & Plant Quarantine Agency (APQA) • MAFRA, National Agriculture Product Quality Service (NAQS) • Ministry of Environment (MOE), National Institute of Environment Research (NIER) • Ministry of Health & Welfare (MHW) • MHW, Korea Food & Drugs Administration (KFDA) • MHW, Korea Center for Disease Control & Prevention (KCDC) • Ministry of Knowledge Economy (MKE) • Ministry of Land, Transport, & Maritime Affairs (MLTM) • National Fisheries Research & Development Institute (NFRDI)
Malaysia	• 1983 Food Regulations • 2007 Biosafety Act • 2010 Biosafety Regulations • 2010 Biosafety Guidelines for Contained Work Activity of Living Modified Organisms • 2010 Guidelines for Institutional Biosafety Committees • 2010 Exemption under S68 of Biosafety Act	• Genetic Manipulations Advisory Committee • Institutional Biosafety Committees • Ministry of Health, Food Safety & Quality Division • Ministry of Natural Resources & Environment • National Biosafety Board & Dept of Biosafety
Mexico	• 1990 General Health Law • 2005 Law on Biosafety of GMOs • 2007 Federal Law of Seeds Production, Certification, and Sale • 2007 Federal Law of Animal Health • 2008 Biosafety of GMOs Regulations • 2009 Decree proposing reform of GMOs Biosafety Regulations • 2011 Agreement on informational requirements for notification & approval of confined use activities • 2012 Agreement to Determine the Centers of Origin and Centers of Genetic Diversity of Corn in Mexico • 2014 Official Mexican Norm that establish characteristics and content of the report or results of releases of GMO	• Inter-Ministerial Commission on GMO Biosafety (CIBIOGEM) • Ministry of Agriculture, Livestock, Rural Dev, Fisheries & Food (SAGARPA) through National Service of Health, Food Safety, and Food Quality (SENASICA) • Ministry of Environment & Natural Resources (SEMARNAT) • Ministry of Health (SSA) through Federal Commision for the Protection against Sanitary Risks (COFEPRIS) • Ministry of Finance & Public Credit (Imports, customs, labeling of GMO products)

	Key Guidelines, Regulations, Laws, & Other Directives	National Implementing Agencies
New Zealand	• 1981 Food Act • 1991 Australia New Zealand Food Standards Code • 1993 Biosecurity Act • 1996 Hazardous Substances and New Organisms (HSNO) Act • 1997 Agricultural Compounds & Veterinary Medicines (ACVM) Act • 2001 ACVM Regulations • 2003 HSNO (Low-Risk GM) Regulations • 2005 Imports & Exports of Living Modified Organisms Prohibition Order • 2008 HSNO Information Requirements for Segregation & Tracing Regulations • 2011 Environmental Protection Authority Act • 2011 BNZ-GCFP-PHR Standard (Biosafety New Zealand Importation of Grains/Seeds for Consumption, Feed or Processing: Plant Health Requirements)	• Australia New Zealand Food Standards Council • Environmental Protection Authority • Food Standards Australia New Zealand • Institutional Biological Safety Committee • Ministry for the Environment • Ministry for Primary Industries • New Zealand Food Safety Authority
Papua New Guinea	• 1986 Plant Disease & Control Act & Regulations • 1991 Food Sanitation Act • 1997 National Agriculture Quarantine & Inspection Authority Act • 2003 Food Safety Code • Draft National Biosafety Framework, with draft National Biosafety and Biotechnology bill	• Food Sanitation Council • National Agriculture Quarantine & Inspection Authority • National Health Department
Peru	• 1999 Law for Prevention of Risks from Use of Biotechnology, No. 27104 • 2002 Reg. for Prevention of Risks from Use of Biotechnology • 2010 Code of Protection and Defense to the Consumer, Nº 29571 • 2011 Law Establishing a 10-Year Moratorium on Entrance and Production of LMOs, No. 29811 • 2012 Reg. Establishing a 10-Year Moratorium on Entrance and Production of LMOs	• General Direction of Environmental Health (DIGESA) • Ministry of Environment (MINAM) • Ministry of Foreign Trade & Tourism (MINCETUR) • National Institute for Agricultural Innovation (INIA) • National Institute for the Defense of Competition and Intellectual Property Protection (INDECOPI) • National Service for Agricultural Sanitation (SENASA) • National Superintendancy of Customs & Tax Administration (SUNAT) • Vice Ministry of Fisheries • Single Window for Foreign Trade (VUCA)

	Key Guidelines, Regulations, Laws, & Other Directives	National Implementing Agencies
Philippines	• 1930 Act creating the Bureau of Animal Industry (RA-3639) • 1977 Fertilizer & Pesticide Authority Presidential Decree (PD-1144) • 1978 Presidential Plant Quarantine Decree (PD-1433) • 1990 Philippine Biosafety Guidelines • 1997 Agriculture Fisheries & Modernization Act (RA 8435) • 1998 Guidelines on the Planned Release of GMOs and Potentially Harmful Exotic Species • 2002 DA-Administrative Order on Rules & Regulations for Importation & Release into Environment of Plants/Plant Products Derived from Use of Modern Biotechnology (DA-AO-8) • 2006 Executive Order Establishing the National Biosafety Framework (EO 514) • 2007 DA-AO 22 Approval Process for Importation of Regulated Articles for Direct Use as Food or Feed, or for Processing • 2008 DA-AO 31 Adoption of Codex Principles for Risk Analysis of Foods Derived from Modern Biotechnology & Codex Guideline for Conduct of Food Safety Assessment of Foods from Recombinant-DNA Plants	• Department of Agriculture, Bureau of Agricultural & Fisheries Product Standards (DA-BAFPS) • Department of Agriculture, Bureau of Animal Industry (DA-BAI) • Department of Agriculture, Bureau of Plant Industry (DA-BPI) • Department of Agriculture, Fertilizer & Pesticide Authority (FPA) • Department of Environment & Natural Resources • Department of Health, Food & Drugs Administration • Department of Science & Technology, Biosafety Committee (DOST-BC) • Institutional Biosafety Committees • National Committee on Biosafety of the Philippines (NCBP)
Russian Federation	• 1992 Federal Law 2300-1 on Protection of Consumer Rights • 1996 Federal Law 86-FZ on State Regulation of Genetic Engineering Activities • 1999 Federal Law 52-FZ on Sanitary & Epidemiological Well-Being of the Population • 2000 Federal Law 29-FZ on the Quality & Safety of Food Products • 2000 Resolution on State Registration of New Food Products, Materials, & Goods • 2001 Customs Union Technical Resolution on Safety of Grain (adopted 2011) • 2002 Resolution on State Registration of GMO Feeds • 2006 Resolution on Transfer of Testing & Registration of Biotech Feeds from the Ministry of Agriculture to the Veterinary & Phytosanitary Surveillance Service • 2011 Customs Union Technical Resolution on Safety of Food Products	• Customs • Federal Service for Veterinary & Phytosanitary Surveillance (FSVPS) • Ministry of Agriculture, Variety Testing Commission • Russian Federal *Rospotrebnadzor* (Federal Service for Control in the Sphere of Protection Consumers' Rights & Well-Being of Humans)
Singapore	• 1965 Animals & Birds Act • 1977 Infectious Diseases Act • 1985 Sale of Food Act • 1993 Control of Plants Act • 1998 Food Regulations • 1998 Control of Vectors & Pesticides Act • 1999 Guidelines on Release of Agriculture-Related GMOs (GMAC Release Guidelines) • 2005 Biological Agents & Toxins Act • 2006 Singapore Biosafety Guidelines for Research on GMOs • 2006 Workplace Safety & Health Act	• Agri-Food & Veterinary Authority (AVA) • Genetic Manipulations Advisory Committee (GMAC) • Institutional Biosafety Committees (IBCs) • Ministry of Health (MOH) • Ministry of Manpower (MOM) • National Environment Agency (NEA)

	Key Guidelines, Regulations, Laws, & Other Directives	National Implementing Agencies
Chinese Taipei	• 1973 Feed Control Act • 1988 Plant Varieties & Plant Seeds Act • 2002 Regulations for Field Trial of Transgenic Breeding Livestock & Biosafety Assessment • 2005 Regulations for Approving Import/Export of Transgenic Plants • 2008 Guideline for Food Safety Assessment of Foods Derived from GM Plants with Stacked Traits • 2009 Regulation governing field trials on GM fish & aquatic plants • 2010 Guidelines for Food Safety Assessment of GM Foods derived from Recombinant DNA organisms • 2012 Regulations for Field Testing of Transgenic Plants	• Council of Agriculture (COA) • COA Bureau of Animal & Plant Health Inspection & Quarantine (BAPHIQ) • Department of Health, Food & Drugs Administration (TFDA) • National Science Council
Thailand	• 1964 Thai Plant Quarantine Act • 1992 National Biosafety Committee Guidelines on Genetic Engineering & Biotechnology for Laboratory Work • 1992 National Biosafety Committee Guidelines on Genetic Engineering & Biotechnology for Field Work & Planned Release • 1999 Cabinet decision • 2003 Ministry of Public Health labeling law	• Institutional Biosafety Committees (IBCs) • Department of Agriculture (DA) • Department of Foreign Trade • Department of Trade Negotiations • National Biosafety Committee (NBC) • National Bureau of National Agricultural Commodity & Food Standards (ACFS) • National Center for Genetic Engineering & Agricultural Biotechnology (BIOTEC) • Ministry of Agriculture & Cooperatives (MOAC) • Ministry of Public Health (MOPH) • Ministry of Science & Technology (MOST) • Thai Food & Drug Administration (FDA) • Universities, research institutions
United States	• 1939 Federal Food, Drug, & Cosmetic Act (FFDCA) • 1947 Federal Insecticide, Fungicide, & Rodenticide Act (FIFRA) • 1976 Toxic Substances Control Act (TSCA) • 1986 Coordinated Framework for Regulation of Biotechnology • 1986 National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules • 2000 Plant Protection Act (PPA) • 2009 Guidance for Industry Regulation of GE Animals Containing Heritable Recombinant DNA Constructs (non-binding)	• National Science Foundation (NSF) • National Institutes of Health (NIH) • U.S. Department of Agriculture (USDA), Animal & Plant Health Inspection Services (APHIS) • U.S. Environmental Protection Agency (EPA) • U.S. Food & Drug Administration (FDA), Center for Food Safety & Applied Nutrition (CFSAN) • U.S. Food & Drug Administration (FDA), Center for Veterinary Medicine (CVM)
Viet Nam	• 2009 Circular on Risk Assessment of GM Crops to Biodiversity & Environment • 2010 Decree 69 on Biosafety of GMOs, Genetic Specimens, and Products Derived from GMOs • 2012 Decree 108 amending some articles of Decree 69 • 2013 Circular stipulating the order, procedures for granting & revoking biosafety certificates for GM crops	• Ministry of Agriculture & Rural Development (MARD) • Ministry of Natural Resources & Environment (MONRE) • Ministry of Science & Technology (MOST)

APEC Member Economies' policies regarding trade in products derived from innovative agricultural technologies are shaped by each Economy's position in the global market for the commodities that are most likely to be GMOs (corn and soybeans), e.g., whether the Economy is a net importer of corn and soy for food, feed, or as ingredients for processing into one or the other. APEC Economies dependent

on global markets for imports of corn include China, Peru, and Republic of Korea, while those dependent on global markets for imports of soybeans or soybean cake include China, Indonesia, Japan, Mexico, Peru, Philippines, Republic of Korea, Chinese Taipei, Thailand, and Viet Nam.[22] The three largest global suppliers of both corn and soybeans are the United States, Brazil, and Argentina, all of which are major recombinant DNA plant producers.

Recombinant DNA plant trade requirements across the 21 APEC Member Economies may include GM-specific import declarations (China, Hong Kong China, Philippines; in Peru, seed importers must declare that their products contain no GM material); submission of health, biosafety certificates (China, Indonesia, Japan, Mexico, Republic of Korea); domestic approval documentation (Malaysia, from National Biosafety Board; Mexico; inclusion in Philippines' registry of approved GMOs; approval by Federal customers' rights service or Veterinary and Phytosanitary Surveillance Service; endorsement by Singapore's Genetic Modification Advisory Committee and approval from Agri-Food & Veterinary Authority; Taiwan Food and Drug Administration issues and registers premarket approvals for GM products; Thailand's Department of Agriculture issues import approvals, based on National Biosafety Committee recommendations; the United States Food and Drug Administration issues food and feed safety evaluations; Viet Nam's Ministry of Agriculture and Rural Development issues GMO food and feed safety certificates); documentation confirming approval from overseas authorities (Hong Kong China, Philippines); inspection/ quarantine (China); labeling requirements (*see following paragraph*); licensing and permits (Australia, Canada, Hong Kong China, Mexico, New Zealand, Papua New Guinea, Peru, Philippines, Russian Federation, Singapore, Thailand); as well as compliance with general requirements (e.g., sanitary, phytosanitary, safety, labeling, etc.) that apply to the import of conventional foods and feeds.

Recombinant DNA plant abeling requirements may be mandatory or voluntary.[23] A few APEC Member Economies, such as Australia, Japan, and the Republic of Korea, take the position that all or most genetically modified foods and feeds, or foods or feeds derived from genetic engineering processes, except those in which a below-threshold share of the food is represented by a GM substance, should be labeled. Canada's regulations require labeling of GM foods or ingredients in cases where that presence represents a known health risk, for example, in the case of introduction of a known allergen. China requires compliance with labeling management rules, which are formulated by agricultural authorities under the State Council. Hong Kong China allows for voluntary labeling at 5% threshold, and discourages negative labeling. Mexico has passed a mandatory labeling requirement, but it is not yet implemented. New Zealand requires labeling of imported flavorings (< 0.1% threshold) and ingredients (<1% threshold), but not of highly processed imported foods. In Russia, labeling of GM foods and feeds is required, subject to a 0.9% content threshold (in the case of feeds, the threshold is 0.5% for unapproved crops). Chinese Taipei requires mandatory labeling of any products that exceed a 5% threshold. The United States Food & Drug Administration is working to

[22] Source: U.S. Department of Agriculture, Foreign Agricultural Service, "Grains: World Markets and Trade" and "Oilseeds: World Markets and Trade," both September 2013.

[23] According to the Center for Food Safety's global map, a number of other APEC Member Economies – China, Indonesia, Malaysia, Peru, Republic of Korea, Chinese Taipei, Thailand, and Viet Nam – require mandatory labeling of "many" GE foods (as distinct from "nearly all"), with a GM content threshold of greater than 1% triggering that requirement. See Center for Food Safety, "Genetically Engineered Food Labeling Laws," http://www.centerforfoodsafety.org/ge-map/ (accessed 10/24/2013).

finalize guidelines on voluntary labeling of recombinant DNA plant products.[24] Viet Nam requires labeling if any GM ingredient in food, feed, or imported goods exceeds 5%.

Most Economies assign implementation responsibility to a combination of national departments or ministries, usually including the ministries of agriculture (and, if separate, animal and fisheries production), environment, and health (or the regulatory authority overseeing foods and drugs, which may be within or outside of ministries of health). Ministries of science and technology may also play a role. Specific organizations for quarantine and inspection, either from agriculture or trade ministries may also play a role.

Product coverage in the APEC Member Economies' agricultural biotechnology laws and regulations may be broad or specific. Eleven Economies apply the same broad coverage definition to regulations in all application categories ("all recombinant DNA organisms," "Animal, bacteria, plants"), while the other nine nuance the coverage, depending on the intended application. For example, in Chinese Taipei all GMOs are covered in regulations of contained work, but only GM corn & GM soybean are covered in regulations for use as food or feed, or to be imported for processing.

In addition to scientific concerns about the potential impact of a recombinant DNA plant on animal, plant, environmental, and human health, some APEC Member Economies integrate other socioeconomic considerations into their recombinant DNA plant policy-making process:[25]

- Hong Kong China's regulations allow exemptions for some GM varieties already grown in small-scale backyard contexts;
- Indonesia's risk assessment protocols are to be carried out in accordance with religious, ethics, socio-cultural, and aesthetic values;
- Japan takes bioethical and cultural considerations, as well as consumer rights and preferences, into account;
- Malaysia's regulations explicitly require consideration of costs (of eradication or remediation in case of "escape"), effects on biodiversity, markets, social norms, and religious concerns; in
- Mexico gives special consideration to protected, ecologically sensitive areas, areas of origin, and areas reserved for organic production;
- In addition to risk-benefit assessment and effects on bio- and cultural diversity, New Zealand's GM regulatory framework also protects the relationship of the Māori people and their culture with the environment;
- Papua New Guinea's draft National Biosafety Framework, in addition to health and environmental impacts of GMOs, considers the contribution of GMOs to sustainable development, all socioeconomic impacts, and conformity with ethical, cultural, and traditional values and norms of the PNG people;

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[24] See FDA, "Center for Food Safety and Applied NutritionPlan for Program Priorities 2013-2014," proposed activity 4.1.11, "Publish final guidance to help manufacturers who wish to voluntarily label their foods as being made with or without the use of bioengineered ingredients." http://www.fda.gov/aboutfda/centersoffices/officeoffoods/cfsan/whatwedo/ucm366279.htm.

[25] A resource book on socioeconomic considerations in biosafety decisionmaking (Horna, Zambrano, and Falck-Zepeda, eds. 2013) defines "socioeconomic considerations" as focused on impacts on farmers, the national economy, and trade, although future work may expand the definition to include intellectual property rights, impacts on traditional knowledge, and environmental impacts.

- Peru considers sustainability and preservation of cultural and biodiversity;
- Economic considerations are incorporated into GM regulations in the Philippines;
- Korea's regulatory framework takes bioethical, public opinion, and marketability considerations into account; and
- Russia's approach to GM regulation must contend with strong public pre-disposition against genetic engineering.

For each APEC Member Economy, detailed Agricultural Biotechnology Regulatory Approach Matrices and country-specific bibliographic references sources are elaborated in the following section. These were compiled using information culled from the Internet. Two sources of multi-country information were particularly useful: 1) the Convention on Biological Diversity's Biosafety Clearing-House, and 2) the U.S. Department of Agriculture, Foreign Agricultural Service's Global Agricultural Information Network reports from overseas posts regarding biotechnology policies and practices. In addition, Member Economies' own websites and other sites were also consulted.

In the following section, column headings correspond to the recombinant DNA plant-related activities covered by regulations, and also reflect the typical sequence of events involved in the development of new recombinant-DNA plants, from research to commercial production to utilization. The row labels aim to address the bulk of the information needed by Member Economies in international trade involving recombinant-DNA plants and their products; detailing the relevant regulations and government agencies tasked with their implementation. Specifics are also provided on the regulations in place. Taken together, the information provided in the matrices may be of particular use to (potential) trading partners; allowing them to determine/estimate the necessary time and financial resources required for shepherding products through the various regulatory regimes. Furthermore, the commonalities and differences reflected may be useful in determining common grounds for future discussions relating to recombinant DNA plant issues, particularly in harmonizing regulations across member economies.

Agricultural Biotechnology Regulatory Approach Matrices, by Member Economy

AUSTRALIA

Primary responsibility for regulation of Australia's food system falls to the Department of Health, under the Food Regulation Agreement of 2008, and is overseen by the Australia and New Zealand Food Regulation Ministerial Council, comprised of the Commonwealth Health Minister and ministers from each State and Territory. The Office of the Gene Technology Regulator (OGTR), within Australia's Department of Health, oversees the development and environmental release of GM organisms; safety evaluations for GM foods are under the purview of Food Standards Australia New Zealand (FSANZ). Australia and New Zealand share one food standards agency. FSANZ is a bi-national government agency that administers the Australia New Zealand Food Standards Code.

Each State and Territory within Australia also has its own laws to implement and enforce the FSANZ standards. Sections 19-27 of the Food Regulation Agreement of 2008 allow for the possibility that States and Territories may adopt food standards that vary from those adopted under FSANZ, provided that the Lead Minister of the State or Territory notifies FSANZ. In addition, section 21 of the Gene Technology Act 2000 states that a State or Territory "may choose to designate, under its own law, areas as GM crop areas or non-GM crop areas as a means of preserving the identity for these crops for marketing purposes." Thus Australian States and Territories may place a moratorium on GM crops throughout their jurisdiction or limit the deployment of GM crops to certain locales within their jurisdictions to ensure that identity preservation and market are not compromised. This State and Territory prerogative was highlighted when the OGTR approved commercial-scale planting of canola in 2003; a ban on GM canola was put in place by the government. The latest legislative review occurred in 2011, with the moratorium still in force (Australian Government, Department of Health). The status of State and Territory regulation is provided in a separate matrix below.

GM cotton, canola, and roses are the only crops approved for commercial release by the OGTR. To date, 6 GM commodities – specific varieties of corn, potato, soybean, sugar beet, canola and cotton – have been approved for the food supply in Australia and New Zealand. Some research on animal biotechnology is currently underway in Australia, mainly on chicken and sheep, but these are still in the early stages under contained conditions; OGTR classified these activities under Notifiable Low Risk Dealings (NLRD),[26] defined in Part 3, Division 2 of the Gene Technology Regulations 2001.

[26] The term "dealings," defined in the Gene Technology Act 2000, refers to any interaction with GMOs: conducting experiments, producing, breeding, propagating, using in the course of manufacture, growing/raising/culturing, importing, transporting, disposing, or possessing/supplying/using in the course of any of these.

	Contained Work			Dealings Involving Intentional Release (DIR)		Use as Food	Use as Feed	Importation for processing/ as processed commodity
	Exempt Dealings[a]	Notifiable Low Risk Dealings (NLRD)[b]	Dealings Not involving Intentional Release (DNIR)[c]	Limited Field Tests[d]	Commercial Release[d]			
Key Laws & Regulations	Gene Technology Act 2000 Gene Technology Regulations 2001 (Statutory Rules 2001 No. 106 as amended)	Gene Technology Act 2000 Gene Technology Regulations 2001	Gene Technology Act 2000 Gene Technology Regulations 2001 (Schedule 3, Part 3), classification as amended 2007, 2011	Gene Technology Act 2000, Gene Technology Regulations 2001 (Schedule 3, Part 3), classification as amended 2007, 2011	Gene Technology Act 2000, Gene Technology Regulations 2001 (Schedule 3, Part 3), classification as amended 2007, 2011	Australia New Zealand Food Standards Under Standard 1.5.2 – Food produced using Gene Technology	Gene Technology Act 2000 Gene Technology Regulations 2001 (Statutory Rules 2001 No. 106 as amended) if viable GMOs used; otherwise no special provisions (Specific legislation for GMOs)	Australia New Zealand Food Standards Code under Standard 1.5.2 – Food produced using Gene Technology Imported Food Control Act 1992
Implementing Agencies	Institutional Biosafety Committee (IBC)	IBC has assessment and oversight functions	OGTR IBC has pre-assessment functions	OGTR	OGTR		OGTR, Australian Quarantine and Inspection Service (AQIS)	Australian Quarantine and Inspection Service (AQIS)
Organisms covered	Only well-understood organisms and processes for creating and studying GMOs	Plants, animals and microorganisms, classified according to containment requirements	Plants, animals and microorganisms not within exempt or NLRD categories: GM pathogenic organisms, GM organisms containing higher risk genes from pathogens, genes for toxins, or genes conferring oncogenic modification or immuno-modulatory function)	GMOs that will be intentionally released to environment during field trials	GMOs that have undergone limited field tests and intended for commercial scale cultivation		Viable GMO material	Importation of live, viable GMOs (e. g., whole grains, oilseeds) needs a separate license from the OGTR
Required submissions[27]	Notification of the IBC; Completed application form/work proposal submitted to IBC Accredited Organization required to	Detailed information about the proposed dealings with the GMO submitted to Organizations' IBC's.	Completed application formd first submitted IBC for consideration; application form signed by IBC chair, head of organization and project supervisor, then submitted to OGTR	Completed application formd first submitted IBC for consideration Application form is signed by IBC chair, head of organization and project supervisor,	Completed application formd first submitted to IBC, then to OGTR IBC chair and Organization provides supporting information		If importing viable GMOs (e. g., whole grain, oil seeds) a separate license required from OGTR, import permit applications to Australian Quarantine Inspection Service	

[27] Forms, guidelines, and operational policies of OGTR may be found at http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/forms-guidelines-1.

	Contained Work			Dealings Involving Intentional Release (DIR)		Use as Food	Use as Feed	Importation for processing/ as processed commodity
	Exempt Dealings[a]	Notifiable Low Risk Dealings (NLRD)[b]	Dealings Not involving Intentional Release (DNIR)[c]	Limited Field Tests[d]	Commercial Release[d]			
	provide list of exempt dealings to the OGTR annually			then submitted to OGTR Completed application form includes detailed information on number of GMOs to be released, proposed number of releases and proposed completion date			must indicate presence of GM material and relevant authorizations	
Processing Fee	None	None	None	None	None	None	OGTR: None specified,	None
Processing time	Not Applicable	Depends on IBC assessment; IBC provides written notification to proponent	90 working days from OGTR's date of receipt of Application	150 days for a limited and controlled field tests applications where no significant risk has been identified 170 days if significant risk has been identified	255 working days for commercial scale cultivation		Variable	
Risk Assessment	Assessed over time as posing negligible risk		OGTR identifies any hazards posed by GMO and level of risk based on assessment of likelihood and consequence of the hazard occurring.[28] Risk Assessment and Risk Management Plan (RARMP) prepared by OGTR, may seek advice from Gene Technology Technical Advisory Committee (GTTAC),	Risk Assessment and Risk Management Plan (RARMP) prepared by OGTR May seek advice from prescribed experts, agencies and authorities on matters relevant to risk assessment and management restrictions that will be specified in license.	Risk Assessment and Risk Management Plan (RARMP) prepared by OGTR after consultation with: (i) The public (ii) All State and Territory Governments (iii) Relevant local council(s); relevant Australian Government		OGTR will consider any risks of using non-viable products of Australian field trials as feed and will apply conditions or disallow the product to be used as necessary. Otherwise no special assessments done.	

[28] Further information on the OGTR risk assessment process is available at http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/content/riskassessments-1. Australia's Risk Analysis Framework was revised in 2013 (OGTR 2013).

	Contained Work			Dealings Involving Intentional Release (DIR)		Use as Food	Use as Feed	Importation for processing/ as processed commodity
	Exempt Dealings[a]	Notifiable Low Risk Dealings (NLRD)[b]	Dealings Not involving Intentional Release (DNIR)[c]	Limited Field Tests[d]	Commercial Release[d]			
			GTEC, States and Territories, or others, as necessary; qualification of personnel and Organization considered in RA-RMP	Public is consulted during preparation of RARMP. Suitability of applicant Organization considered in granting license	Departments and agencies (iv) The Commonwealth Minister for the Environment (v) The Gene Technology Technical Advisory Committee Suitability of applicant Organization considered in granting license			
Public participation	At any time, any member of the public may make a submission to OGTR proposing that certain dealings with GMOs be removed from or included in the list of exemptions. Public comment is requested on proposed changes to exempt dealings with GMOs	At any time, any member of the public may make a submission to OGTR proposing that certain dealings with GMOs be removed from or included in the list of NLRDs Public information is available via OGTR's GMO Record Public comment is requested on proposed changes to NLRDs	Public information via OGTR's GMO Record Application and license posted in GMO record Public comment or public hearing is held as necessary	Public information via publication in Commonwealth Gazette, direct mail to registered subscribers Posting in the public GMO record Comments invited on the draft RARMP from the public through notices in national and regional newspapers, the Government Gazette, OGTR website and direct mail to those registered with the OGTR	Public information via publication in Commonwealth Gazette, direct mail to registered subscribers; Public consultation; Public comment or public hearing as necessary; posting in GMO record. Comments invited on draft RARMP from the public via notices in national and regional newspapers, the Government Gazette, OGTR website and direct mail to those registered with the OGTR. 30-50 days		Follows OGTR procedures[29]	

[29] For information on public participation in the assessment of gene technology, see fact sheet prepared by OGTR, http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/factpublic-htm.

	Contained Work			Dealings Involving Intentional Release (DIR)		Use as Food	Use as Feed	Importation for processing/ as processed commodity
	Exempt Dealings[a]	Notifiable Low Risk Dealings (NLRD)[b]	Dealings Not involving Intentional Release (DNIR)[c]	Limited Field Tests[d]	Commercial Release[d]			
				30-50 days provided for invited submissions	allowed for invited submissions			
Socioeconomic considerations	None	None	Depends on scale and restrictions imposed by prevailing state laws	States and Territories may impose moratorium on field tests of GM crops within their boundaries to address concerns about market (domestic and foreign), socioeconomics, and trade implications[30]		None	Depends on scale and restrictions imposed by prevailing state laws	None
Approval Document	None required	IBC assessment	License issued to accredited Organization that submitted application	License issued to accredited Organization submitting application	License issued to accredited Organization submitting application	Incorporated into the Code as amendments (Becomes part of the foods approved under Standard 1.5.2)	OGTR license if viable material or generated from field trials	Incorporated into the Code as amendments (Becomes part of the foods approved under Standard 1.5.2)
Restrictions or conditions	No intentional release to environment.	Conducted by competent personnel (appropriate training and experience) containment facility certified as PC1, PC2 or PC3; transported, stored and disposed according to OGTR Guidelines; must be part of Organization's annual report to OGTR	Stringent containment in certified facilities ranging from PC2 to PC4, no intentional release to environment; monitoring & audit by OGTR as necessary; license may be revoked, cancelled or surrendered; OGTR notified of new information that may affect original RA-RMP; annual report submitted to OGTR; other restrictions or conditions as necessary (case by case)	Adhere to Risk management conditions imposed on license; Need to comply with any other applicable State or Commonwealth law; OGTR may impose restriction on number or GMOs to be released and number of releases	Adhere to risk management conditions imposed on license; Need to comply with any other applicable State or Commonwealth law; State and Territorial laws may bar or limit deployment of GMO within their boundaries.		No special labeling requirement	If importing viable GMOs (e. g., whole grain, oil seeds) a separate license required from OGTR, import permit applications to Australian Quarantine Inspection Service must indicate presence of GM material and relevant authorizations; labeling requirements for processed products apply
Expiration of Approval Document	Not Applicable		Valid until revoked, cancelled or surrendered	Valid until date specified on license	Valid until revoked, cancelled or surrendered	Valid until food is removed	Not applicable	Valid until food is removed

[30] See Australian Government, Department of Agriculture, Fisheries, and Forestry, "Genetically Modified Crop fact sheet," http://www.daff.gov.au/agriculture-food/biotechnology/pamphlets/genetically_modified_crop_fact_sheet.

	Contained Work			Dealings Involving Intentional Release (DIR)		Use as Food	Use as Feed	Importation for processing/ as processed commodity
	Exempt Dealings[a]	Notifiable Low Risk Dealings (NLRD)[b]	Dealings Not involving Intentional Release (DNIR)[c]	Limited Field Tests[d]	Commercial Release[d]			
Renewal provisions	Not Applicable	Not Applicable	Not Applicable	New application for further limited releases after expiration	Not Applicable	Not applicable	Not applicable	Not applicable

Notes:

[a] *Exempt dealings are those involving work using well understood organisms and processes for creating or studying GMOs.*

[b] *Notifiable Low Risk Dealings are dealings that have been assessed over time as posing low risk to human health and environment provided certain risk management conditions are met. They must be contained within a certified facility within an accredited organization and if transported must be transported within the guidelines issued by the OGTR for transport of GMOs.*

[c] *Dealings with GM organisms that do not fall within exempt or NLRD classification. Requires license issued by OGTR.*

[d] *Australian regulations cover "Limited Field Tests" and "Commercial Release" as part of Dealings Involving Intentional Release (DIR)*

[d] *Completed application form may contain information marked Confidential Commercial Information. OGTR approves which items may be classified as Confidential Commercial Information. Confidential Commercial information is not posted in the GMO record.*

[e] *Includes the Department of Agriculture, Fisheries and Forestry; (DAFF); DAFF Biosecurity (formerly the Australian Quarantine and Inspection Service); Food Standards Australia New Zealand; the Australian Pesticides and Veterinary Medicines Authority; the Therapeutic Goods Administration; the National Industrial Chemical Notification and Assessment Scheme and the Department of Foreign Affairs and Trade*

Australian State and Territory Regulation of GMOs

New South Wales, Victoria, Western Australia, South Australia, Tasmania, and the Australian Capital Territory have enacted legislation imposing moratoria on commercial cultivation of GM crops, while Queensland and the Northern Territory have not. The following table summarizes the present status of State and Territory regulations on the commercial cultivation of GMOs.

State/territory	Regulation	Provision	Present status	Remarks
Australian Capital Territory (ACT)	Gene Technology (GM Crop Moratorium) Act 2004	Moratorium on GM commercial cultivation in ACT ACT Minister of health can grant exemptions to moratorium	Moratorium still in effect	
New South Wales	Gene Technology Act of 2003 (GM Crop Moratorium)	Moratorium on commercial cultivation of GM crops except for non-food items (carnations, cotton); limited field tests allowed with restrictions	Reviewed in 2007, moratorium lifted for GM canola, but remains for others, unless approved by Minister for Primary Industries	Application for state approval submitted by representative from the specific industry

State/territory	Regulation	Provision	Present status	Remarks
Northern Territory	No legislation on moratorium.	No moratorium imposed on the commercial cultivation of GM crops	No moratorium imposed on the commercial cultivation of GM crops	
Queensland	No legislation on moratorium.	No moratorium imposed on the commercial cultivation of GM crops	No moratorium imposed on the commercial cultivation of GM crops	
South Australia	GM Crops Management Act 2004. Genetically Modified Crops Management Regulations 2008.	Ban on planting GM crops in South Australia; field trials allowed to continue with restrictions	Moratorium on GM food crops for an indefinite period	Exempts non-viable GM products or non-food GM crops such as ornamental flowers; Kangaroo Island and Eyre Peninsula designated as GM-free zone
Tasmania	Genetically Modified Organisms Control Act 2004.	Preserve GM-free nature of crops in Tasmania, but supports field trials of GM poppy	GM moratorium until November 2014 was passed in 2008 by Tasmanian Government to ban GM crops, animals, and microbes: supported by all political parties.	
Victoria	Control of Genetically Modified Crops Act 2004	State moratorium orders over GM crops on a case by case basis. Limited field tests allowed with restrictions	Moratorium on GM canola allowed to lapse in 2008. Act remains in place and provides for future moratoriums other GM crops	OGTR approval is sufficient, unless state imposes prohibition, moratorium or other restrictions
Western Australia	Genetically Modified Free Crops Act 2003	Prohibits commercial growing of GM crops on commercial scale, but state Minister for Agriculture can make discretionary exemptions for trials and certain GM crops	In 2008, cultivation of GM cotton was allowed in specific areas GM canola trials allowed in 2009; in early 2010, State Agriculture and Food Minister approved exemption to allow commercial cultivation of OGTR-approved GM canola.	

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BRUNEI DARUSSALAM

Brunei's economy primarily relies on its rich petroleum reserves and the economy. It does not have a large agricultural sector and, as a result, only has minimal domestic activities in agricultural biotechnology. Moreover, the economy imports most of its food commodities.

Brunei Darussalam currently has no specific guidelines for regulating GMOs and to date is not a Party to the Cartagena Protocol on Biosafety. It did not participate in the UNEP-GEF National Biosafety Frameworks (NBF) Development Project. Any biotech-related activities are spearheaded by the Department of Agriculture and Agrifood (DAA), under the Ministry of Industry and Primary Resources, and the University of Brunei Darussalam. The economy's main concern about GM food is that products generated by this technology are safe and conform to *halal* regulations.

Brunei's food regulatory system is as follows:

- The Ministry of Development is responsible for setting standards and regulations for food. Importers and traders have to comply with the provisions of the Public Health (Food) Act of 1998 and Public Health (Food) 2000. Application for registration to food import is free. If the required information is complete, the registration letter is issued within 5-7 working days from the date of submission.

- The Department of Agriculture and Agrifood under the Ministry of Industry and Primary Resources issues import permits for food, and the Plant Quarantine unit implements phytosanitary regulations.
- The Department of Health Services' Food Quality Division is responsible for food quality and Food safety, and in promoting public awareness of these topics.

Brunei Darussalam's government has no official stance on GM technology. Nonetheless, Brunei's DAA considers GM technology as an avenue that the economy should explore to keep abreast with scientific developments globally. In order to do this, relevant policies need to be put in place. The biotechnological activities in the Economy are mainly on plant tissue culture to improve desired traits and for mass propagation and germ plasma collection.

Initiatives towards the development of a biosafety framework for regulating GMOs in Brunei are currently underway. On 3 May 2012, Brunei's DAA announced its intentions to advance research and capacity in biotechnology through the formulation of a master plan for biotechnology. The master plan will include recommendations for a legal framework concerning GM agri-products and the possible establishment of a centre for agriculture biotechnology in Brunei. The undertaking is expected to result in recommendations on a legal framework and regulatory system for future agricultural biotechnology activities, as well as on short, medium and long-term strategies to develop agriculture biotechnology in Brunei.[31] The project seeks to attract the active involvement and assistance that can be solicited from the private sector to boost biotech activities in the economy.

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[31] Although reference to this master plan was found in May 2012, no subsequent evidence of a completed master plan has been found.

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CANADA

In Canada, the regulation of biotechnology products, depending on their intended use, falls under the mandate of the Canadian Food Inspection Agency (CFIA), Health Canada and Environment Canada. At the border, the Canada Border Services Agency also plays a role in frontline inspections. Health Canada is responsible for regulation of foods, drugs, cosmetics, and medical devices, including those derived through biotechnology, while pest control products are overseen by Health Canada's Pest Management Regulatory Agency, and the CFIA oversees regulation of feeds, seeds (including "plants with novel traits)," fertilizer and other novel supplements, and veterinary biologics. Environmental and indirect human health aspects of biotech animals including fish products and all other animate products of biotechnology not covered by the CFIA and Pest Management Regulatory Agency are jointly overseen by Environment Canada and Health Canada through the Canadian Environmental Protection Act 1999.

Canada's regulatory framework was established through agreement among federal regulatory bodies and was announced in 1993. The need for an investment in this regulatory strategy to meet new challenges was recognised when the Canadian Biotechnology Strategy was renewed in 1998. The principles from this strategy, which are still in place, include reflecting Canadian values; engaging Canadians in open, ongoing, dialogue; promoting sustainable development, competitiveness, public health, scientific excellence, and an innovative economy; and, ensuring responsible action and co-operation domestically and internationally. These principles established that the practical benefits of biotechnology products and processes would be balanced with the need to protect health, safety and the environment. This framework also set out that regulators should build on existing legislation and institutions rather than developing new legislation or establishing a separate agency for biotechnology. The approach outlined in the framework was based on the use of science-based safety assessments and risk management with the goals of protecting human health, animal health, and the environment while contributing to the prosperity and well-being of Canadians.

Canadian regulatory oversight may be triggered solely by the novelty of traits expressed by plants or the novel attributes of the agricultural products, irrespective of the means by which the novelty was introduced. This "product-based" approach to regulation has been validated by numerous scientific bodies and expert consultations. In Canada the same regulatory framework and assessment approach is applied to products of biotechnology and "non-biotechnology" products. This avoids duplication of effort and ensures that similar products are regulated in a consistent manner by the federal departments and agencies that house the required subject matter expertise. Depending on the characteristics of the product and its intended uses, agricultural products may trigger a range of regulatory instruments. The relevant statutes are the *Seeds Act, Feeds Act, Fertilizers Act, Food and Drugs Act, Health of Animals Act*, and the *Canadian Environmental Protection Act, 1999 (CEPA 1999)* and the Regulations associated with these Acts.

Because the scope of Canada's regulatory approach is broader than just genetic engineering, Canadian regulators have adopted unique terminology and definitions. Rather than referring to GM plants, GM feeds or GM foods, the guidelines and regulations refer to plants with novel traits, novel feeds and novel foods, respectively. Following are the Canadian definitions of a novel food, a plant with a novel trait and a novel feed.

Novel Food

A novel food is any food that does not have a history of safe use as a food, or has been manufactured or packaged in a way not previously applied to that food and which causes a major change in the properties of the food or that has been derived from an organism that has been genetically modified such that:

1) the organism exhibits characteristics that were not previously observed in that organism,
2) the organism no longer exhibits characteristics that were previously observed in that organism, or
3) one or more characteristics of the organism no longer fall within the anticipated range for that organism[33].

Novel foods include all GM foods, whether derived from recombinant DNA methods or from conventional breeding but can also include other foods, such as novel oils (camelina oil), or high pressure processed foods.

Plant with a Novel Trait

Similarly, a plant with a novel trait can be any plant that that has one or more traits that are novel to that species in Canada. A **trait is considered to be novel** when it has both of these characteristics:

- it is new to stable, cultivated populations of the plant species in Canada, and
- it has the potential to have an environmental effect[34].

This can include plants produced through genetic engineering as well as plants produced through accelerated mutagenesis, cell fusion, wide out-crossing, or even conventional cross-breeding.

Novel Feed

Novel feeds are considered to be those derived from an organism or organisms, or parts or products thereof that:

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[33] See http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/FullText.html#h-144.

[34] http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._1400/index.html

- are not approved as livestock feed in Canada (i.e. are not listed in Schedule IV or V of the *Feeds Regulations*), and/or
- contain a novel trait[35].

Schedules IV and V of the *Feeds Regulations* list feed ingredients approved for use in livestock feed in Canada. Schedule IV comprises a range of ingredients such as forages and roughages, energy feeds, protein sources, vitamins, minerals, fermentation products and other products, while Schedule V is restricted to flavouring ingredients.

A novel trait is a heritable characteristic of a feed that is not substantially equivalent in terms of its specific use and safety to a characteristic of a similar feed that is set out in Schedule IV or V of the *Feeds Regulations*. In other words, for novel feeds derived from plant sources, a novel trait is a heritable characteristic that is new to a plant species, or is an endogenous trait that has been modified such that it differs from conventional parameters for that plant species.

Food Labelling Policies

Various regulations under the *Food and Drugs Act* and the *Consumer Packaging and Labelling Act* require manufacturers of food products to include on the labels certain information about the nutrient content (if nutrient claims are made) or the presence of compounds that could result in allergic reaction. Both types of labelling requirements are intended to make the product labels useful to consumers by providing clear, relevant, accurate, readable, informative and non-misleading information. The overall purpose is to enable informed decision making about healthy eating in managing relevant dietary needs.

Health Canada shares the responsibility for food labelling with CFIA under the *Food and Drugs Act* and the *Consumer Packaging and Labelling Act*[36]. The CFIA is responsible for non-health
and safety aspects of labelling, with a focus on consumer protection against fraud and misrepresentation. Health Canada is responsible for health and safety.

In terms of Health Canada's mandate regarding health and safety under the *Food and Drugs Act*, mandatory labelling would be required for novel foods where safety concerns related to potential allergenicity or major composition and/or nutritional changes may be mitigated through labelling. In this situation, such labels would alert consumers or susceptible groups in the population.

In the case of a food demonstrated to be safe, similar in composition, and nutritionally equivalent to traditional foods already available, neither Health Canada nor the CFIA has a legal mandate to require additional labelling statements.

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[35] http://laws-lois.justice.gc.ca/eng/regulations/SOR-83-593/index.html

[36] http://www.inspection.gc.ca/food/labelling/other-requirements/method-of-production/ge-factsheet/eng/1333373177199/1333373638071

	Contained Work	Limited Field Test	Commercial Release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
Key Laws & Regulations	2009 Canadian Biosafety Standards and Guidelines (standards are binding and guidelines are voluntary) *Human Pathogens and Toxins Act* *Human Pathogens Importation Regulations* *Health of Animals Act and Regulations* *Canadian Environmental Protection Act* (CEPA) 1999 / *New Substances Notification Regulations (Organisms)* (NSNR (O))	For plants with novel traits (PNTs): Directive 2000-07: Environmental Release of Plants with Novel Traits within Confined Research Field Trials in Canada; Directive 2009-09: Plants with novel traits regulated under Part V of the Seeds Regulations: Guidelines for determining when to notify the Canadian Food Inspection Agency; *Plant Protection Act 1990* and *Plant Protection Regulations 1995*; *Seeds Act 1985* and *Seeds Regulations Part V* *2012* For animals and some microorganisms: *Canadian Environmental Protection Act 1999* (CEPA 1999) ; *New Substances Notification Regulations (Organisms)* (NSNR (O))	For plants with novel traits (PNTs): Directive 94-08: Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits, 2000; Biology Documents (Companion Documents for Dir94-08); Directive 2009-09: Plants with novel traits regulated under Part V of the Seeds Regulations: Guidelines for determining when to notify the Canadian Food Inspection Agency; *Plant Protection Act* *1990* and *Plant Protection Regulations 1995*; *Seeds Act 1985* and *Seeds Regulations Part V* *2012* For animals and some microorganisms: *Canadian Environmental Protection Act 1999* (CEPA 1999); *New Substances Notification Regulations (Organisms)* (NSNR (O))	*Food and Drugs Act and Regulations Division 28: Novel Foods* 1999 Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms 2003 (Health Canada, nonbinding guidance document)	*Feeds Act Feeds Regulations,* 1983 Regulatory Guidance 1 (Canadian Food Inspection Agency non-binding guidance document including the Guidelines for Safety Assessment of Novel Feeds: Plant and Microbial Sources)	Directive 96-13: Import Requirements for Plants with Novel Traits, including Transgenic Plants and their Viable Plant Parts Permit Application 201037 *Plant Protection Act, S.C. 1990*, c. 22 *Plant Protection Regulations* 1995, SOR/95-212 Canadian Food Inspection Agency Fees Notice, Canada Gazette: Part I 2000 (as amended from time to time) *Seeds Act*, R.S., 1985 c. s.-8 *Seeds Regulations, Part V*, C.R.C., c. 1400, 2012 *Canadian Environmental Protection Act 1999* (CEPA 1999) *New Substances Notification Regulations (Organisms)* (NSNR (O))

	Contained Work	Limited Field Test	Commercial Release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
Implementing Agencies	Canadian Food Inspection Agency , Environment Canada, Public Health Agency of Canada	Canadian Food Inspection Agency, Environment Canada, Health Canada	Canadian Food Inspection Agency, Environment Canada), Health Canada	Canadian Food Inspection Agency, Health Canada	Canadian Food Inspection Agency	Canadian Food Inspection Agency
Organisms covered	Plants, animals, microorganisms, fisheries	Plants with Novel Traits (PNTs), animals, microorganisms	Plants with Novel Traits (PNTs), animals, microorganisms	Plants, animals, microorganisms	Plants, animals, microorganisms	Plants including transgenic plants and their viable plant parts, animals and microorganisms
Required submissions	Import Permit Requests as necessary For CEPA 1999 and NSNR (O), a Notification is required as per the Regulations.	For PNTs: Confined Research Field Trial filled up Application Form Fee Submission For animals and microorganisms: a Notification is required as per CEPA1999 and NSNR (O) Regulations	For PNTs: Fee Submission CFIA Detection and Identification Method Criteria; Completed application for Authorization of Environmental Release of PNTs as per the Guidelines and Regulations For animals and microorganisms: a Notification is required as per CEPA1999 and NSNR (O) Regulations	Completed application form with the following information: How food crop was developed Molecular biological data Composition of the novel food Nutritional data for novel food Potential for new toxins Potential for allegenicity Expected dietary exposure by population and subgroups	Applicants must provide a notification with satisfactory evidence in order to demonstrate that the feed is safe (in terms of animal health, human health via food residues and worker/by-stander exposure, and the environment) and effective for its intended purpose prior to marketing	For plants: Completed application for Permit to Import Plants and Other Things under the Plant Protection Act (CFIA/ACIA 5256) PNTs (and/or products derived from them) are subject to the same phytosanitary import requirements as their unmodified counterparts Other applications may be required to comply with other regulations, as necessary: D-97-04: Application, procedures, issuance and use of a permit to import under the *Plant Protection Act* D-08-04: Plant Protection Import Requirements for Plants and Plant Parts for Planting: Preventing the Entry and Spread of Regulated Plant Pests Associated with the Plants for Planting Pathway D-96-13: Import Requirements for Plants with Novel Traits, including Transgenic Plants and their Viable Plant Parts For animals and microorganisms: Notification is required as per CEPA 1999 and NSNR (O) Regulations
Processing Fee	None	For PNTs: $400 per submission, $100 per trial site, $100 per qualified renewal submission (in addition to $100 per trial site for renewal)	For PNTs: $2000 per submission For animals and some microorganisms: no fee is required	No fee required	$450 + tax per submission	For plants: CFIA fees in accordance with the CFIA fees notice. Fees charged will depend on the type, nature, and number of risk assessments required by the application.

	Contained Work	Limited Field Test	Commercial Release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
		For animals and some microorganisms: no fee is required				For animals and microorganisms: no fee is required
Processing time	For CEPA 1999 and the NSNR (O): 30 days	For PNTs: 30 days at minimum For CEPA 1999 and the NSNR (O),animals and microorganisms: 90 days	For PNTs: Variable For CEPA 1999 and the NSNR (O),animals and microorganisms: 120 days	120 days		For plants: Variable For CEPA 1999 and the NSNR (O), animals and microorganisms: 30 days
Risk Assessment	Scientific, case-by-case, based on guidelines, as per CEPA 1999 and the NSNR (O) or applicable pathogen-specific regulatory scheme	For PNTs: Scientific, case-by-case; largely based on biology documents and data submitted by applicants. For animals and microorganisms: as per CEPA 1999 and the NSNR (O)	For PNTs: Scientific, case-by-case; largely based on biology documents and data submitted by applicants on gene stability, impact on non-target and biodiversity, and potential for being pest. For animals and microorganisms: as per CEPA 1999 and the NSNR (O)	Pre-market safety assessment; Scientific, case-by-case; places emphasis on nutritional quality, toxicity, allergenicity and consumption pattern.	The feed must be safe (in terms of animal health, human health via food residues and worker/by-stander exposure, and the environment) and effective for its intended purpose prior to marketing.	For plants: No For animals and microorganisms: as per CEPA 1999 and the NSNR (O)
Public Participation	No	No	For PNTs: Applicants voluntarily post "notices of submission" on the CFIA website for public comment For animals and microorganisms: No	Applicants voluntarily post "notices of submission" on the CFIA website for public comment	Applicants voluntarily post "notices of submission" on the CFIA website for public comment	No
Socioeconomic considerations	Not part of the formal or informal regulatory process, unless risk management is required under CEPA 1999 and NSNR (O)	For PNTs: Not part of the formal or informal regulatory process. For animals and microorganisms: only if risk management needed.	For PNTs: Not part of the formal or informal regulatory process. For animals and microorganisms: only if risk management needed.	Not part of the formal or informal regulatory process	Not part of the formal or informal regulatory process	For plants: Not part of the formal or informal regulatory process For animals and microorganisms: only if risk management needed.
Approval Document	Import permit, if necessary	For PNTs: Import permit, if necessary; authorization from CFIA For animals and some microorganisms: Not required under CEPA 1999 and NSNR (O)	For PNTs: Authorization from CFIA For animals and some microorganisms: Not required under CEPA 1999 and NSNR (O)	Letter of No Objection sent to applicant, detailing any restrictions, additional requirements Decision document posted on the *Novel Foods and Ingredients* page of Health Canada Web site	Authorization letter to the applicant. Letter can include risk management / mitigation measures Decision document posted on the *CFIA website*	For plants: Import permit For animals and microorganisms: Not required under CEPA 1999 and NSNR (O)
Restrictions or conditions	Activities done by qualified personnel in facilities complying with Physical Containment Levels appropriate for activity, or as required if part of risk management under	For PNTs: General and species-specific terms and conditions for confined research field trials Restrictions on the size and number of confined research field trial sites Reproductive isolation of confined	For PNTs: Plant varieties produced through biotechnology cannot be registered and sold in Canada until authorized for environmental, livestock feed and food safety	Labeling is mandatory if there is a health issue with food; otherwise voluntary labeling		For plants: Restrictions and conditions to ensure containment as specified in the import permit For animals and microorganisms: Only if a part of risk management under CEPA 1999 and NSNR(O)

	Contained Work	Limited Field Test	Commercial Release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
	CEPA 1999 and NSNR(O)	research field trials Records and reportorial requirements Disposal and storage of plant material from confined field trials Post-harvest land use restrictions For animals and microorganisms: Only if a part of risk management under CEPA 1999 and NSNR(O)	Stewardship plans may be required for PNTs expressing either a novel herbicide tolerance or a novel insect resistance For animals and microorganisms: Only if part of risk management under CEPA 1999 and NSNR(O)			
Expiration of Approval Document	Under *Human Pathogens Importation Regulations*, import permits are valid for 1 year for risk group 2 multiple entry and for 3 months for a single entry for risk group 3 and 4. Under CEPA 1999 and NSNR(O), no expiry unless new information arises	For PNTs: 1 year For animals and microorganisms: Under CEPA 1999 and NSNR(O), no expiry unless new information arises	For PNTs: Valid indefinitely unless new information arises For animals and microorganisms: Under CEPA 1999 and NSNR(O), no expiry unless new information arises	Valid indefinitely unless new information arises	Valid indefinitely unless new information arises	For plants: 1 year For animals and microorganisms: Under CEPA 1999 and NSNR(O), no expiry unless new information arises

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CHILE

In November 1993 the Advisory Committee on the Release of Transgenic Organisms (CALT) in the Ministry of Agriculture and Livestock was created to provide technical support to the Ministry of Agriculture's Agricultural and Livestock Service (SAG) with regard to the introduction and environmental release of transgenic organisms. The National Commission for the Environment (CONAMA), the Office for Agricultural Studies and Agricultural Policies (ODEPA), the Institute for Nutrition and Food Technology of the University of Chile (INTA), and the Department of Fisheries in the Ministry of Fisheries also maintain and design of programs to monitor and regulate the management of GMOs. GM products that are substantially different from the conventional versions of the same products must be registered with the Ministry of Health; they must also be labeled if different (Ramirez 2013). Chile imports GM corn, soybeans, and animal feed and derived products from Brazil, Argentina, and the United States.

The Chilean regulatory system for products of biotechnology is still in its infancy, with several proposed new laws/regulations pending. The formal Regulations currently in place are the Resolution of Exemption 1927/93 of the SAG (statutory instruments, specific for GMOs) and the Decree-Law 3554/81 (statutory instruments, non-specific for GMOs). The regulatory system for field trials is essentially operating under sanitary and phytosanitary regulations for

importation of plant materials. The law allows field trials of imported transgenic materials only. There is as yet no system in place for the regulation of transgenic products developed domestically, and for approval of any products for commercial use. A few plant products have received approval for large-scale cultivation, but these are restricted to multiplication of seeds and subsequent re-export for use elsewhere. None of the seeds produced are made available to Chilean farmers and consumers.

Dossiers of transgenic plants produced at INIA, the national agro-fisheries research institute, have been voluntarily submitted to CALT for review. Chilean regulators have taken "a wait-and-see approach" in developing domestic regulations for GMOs, hoping to benefit from international initiatives such as the Cartagena Protocol on Biosafety.

Chilean regulators are mainly focused on preserving the unique indigenous species found in the distinct ecozones that divide the economy. The primary role of the SAG is the protection of the zones through quarantine procedures, and regulation is focused on invasive alien species. Chile is currently drafting a National Biosafety Framework; at present, the document is still in draft form.

	Contained Work	Limited Field tests	Use as Food/Feed	Importation for processing/as processed commodity
Key Laws & Regulations	Resolution of exemption 1927/93 of the Agriculture and Livestock Service, 1993 (specific for GMOs)	Sanitary and Phytosanitary regulations for importation of plant materials (existing regulations, coverage is extended to include GMOs)		Sanitary and Phytosanitary regulations for importation of plant materials (existing regulations, coverage is extended to include GMOs)
Implementing Agencies	CALT	CALT , CONAMA and SAG	CALT, CONAMA, ODEPA and SAG	
Organisms covered	Plants	Plants	Plants	
Required submissions	Information on proposed work with GMOs under containment Dossiers of locally developed transgenic plants submitted to CALT voluntarily	Import Permit Requests, as necessary Dossier of materials to be imported for field trials	Import Permit Requests, as necessary Dossier of materials to be imported for commercial seed production	
Processing Fee	No available information	No available information	No available information	
Processing time	No available information	No available information	No available information	
Risk Assessment	No available information	No available information	No available information	
Public participation	No available information	No available information	No available information	
Socioeconomic considerations	None specified	Biodiversity and preservation of unique species; management of invasive alien species	Biodiversity and preservation of unique species; management of invasive alien species	
Approval Document	None specified	Import permit, if necessary, approval of field test of imported material	Import permit, approval of commercial seed production activity	
Restrictions or conditions	None specified	Field trials for imported materials only No provisions for locally developed GM plant	Restricted to multiplication of seed and re-export for use elsewhere	

	Contained Work	Limited Field tests	Use as Food/Feed	Importation for processing/as processed commodity
			Seeds not available for use by local farmers	
Expiration of Approval Document	None specified	None specified	None specified	
Renewal provisions	None specified	None specified	None specified	

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CHINA

In 2001 the State Council of China established an inter-ministerial joint conference for the administration of agricultural GMOs safety. The table below gives an overview of China's existing GM regulatory system (People's Republic of China, Ministry of Agriculture 2001). The State Council of China's joint ministry conference for the safety administration of agricultural GMOs consists of the following agencies: AQSIQ - General Administration of Quality, Inspection, and Quarantine; MOST – Ministry of Science and Technology; MOA – Ministry of Agriculture; NDRC-National Development and Reform Commission; NHFPC-National Health and Family Planning Commission; CFDA-China Food and Drug Administration; MEP-Ministry of Environmental Protection; MOC-Ministry of Commerce; MOE-Ministry of Education; State Forestry Administration; CAS-Chinese Academy of Science. The Ministry of Agriculture sets up an office for biosafety administration of agricultural GMOs (OBA), which will be in charge of the administration of the safety assessment of agricultural GMOs. OBA is affiliated with the Department of Science, Technology and Education, MOA. A national biosafety committee (NBC) shall be established by MOA and in charge of safety assessment of agricultural GMOs. The NBC shall be composed of experts who are engaged in biological research, production, processing,

inspection and quarantine with respect to agricultural GMOs, as well as experts in the fields of public health and environmental protection. These regulators administer China's regulatory regime for GMOs and emerging agricultural technology.

China is currently the sixth largest producer of biotechnology-enhanced plants (by acreage), cultivated on 3.9 million hectares in 2011 (Lagos and Jie 2012). Eight GM plants (cotton, tomatoes, sweet peppers, petunias, poplar, rice, corn and papaya) were approved for commercial distribution. However, six of these are not currently produced, and their biosafety certificates were not renewed due to a lack of commercial markets. At present, Bt (Bacillus thuringiensis
)[32] cotton is the largest GM crop produced in China. In 2011 over 71.5% of the 5.45 million hectares planted to cotton in China was produced with Bt cotton varieties (Lagos and Jie 2012). New GM crops (resistant insect rice and phytase corn) were approved in 2009. The Ministry of Agriculture's Department of Science, Technology, and Education provides a Chinese-language list of approved GM crops, referenced by Lagos and Jie.[33]

As noted by Huang and Yang (2011), China's biosafety regulatory framework addresses both domestic GM crop commercialization and imports. Imports of both GM soybeans and GM maize figure importantly in China's trade profile; with the U.S., Brazil, and Argentina serving as China's key suppliers of soybeans, and the U.S. as China's key supplier of maize. Import approval depends on demonstration of prior regulatory approval in the country of origin. China's regulatory stance includes zero threshold for LLP in imports. Although China has approved several GM crops for commercialization, with a "significant number in the research and regulatory pipeline," so far China has not sought approvals of any of its GM crop events in foreign countries, a policy that could affect China's GM crop exports (e.g., rice, processed rice products) in the future (Huang and Yang 2011).

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[32] Refers to the introduction of genes from the soil bacterium, *Bacillus thuringiensis*, to improve pest resistance of genetically modified crops.

[33] See http://www.moa.gov.cn/ztzl/zjyqwgz/

	Contained Work	Limited Field Test (Restricted, Enlarged, Productive)[34]	Commercial Release	Use as Food	Use as Feed	Importation for processing/as processed commodity
Key Laws & Regulations	Regulation on Inspection and Quarantine of Import and Export of GM products, 2004 Implementation Regulations on Safety Assessment of GMOs, 2002 Implementation Regulations on the Safety of Import of GMOs, 2002 Regulations on Safety of Agricultural GMOs, 2001	Implementation Regulations on Safety Assessment of GMOs, 2002 Implementation Regulations on the Safety of Import of GMOs, 2002 Regulations on Safety of Agricultural GMOs, 2001	Implementation Regulations on Safety Assessment of GMOs, 2002 Implementation Regulations on the Safety of Import of GMOs, 2002 Regulations on Safety of Agricultural GMOs, 2001	Implementation Regulations on Safety Assessment of GMOs, 2002 Implementation Regulations on the Safety of Import of GMOs, 2002 Regulations on Safety of Agricultural GMOs, 2001 Food Safety Law, 2009	Implementation Regulations on Safety Assessment of GMOs, 2002 Implementation Regulations on the Safety of Import of GMOs, 2002 Regulations on Safety of Agricultural GMOs, 2001	Regulation on Inspection and Quarantine of Import and Export of GM products, 2004 Implementation Regulations on Labeling of GMOs, 2002 Implementation Regulations on Safety Assessment of GMOs, 2002 Implementation Regulations on the Safety of Import of GMOs, 2002 Implementation Regulations on the Processing of GMOs, 2002 Regulations on Safety of Agricultural GMOs, 2001 Food Safety Law, 2009
Implementing Agencies	AQSIQ, MOA, OBA, NBC, competent agricultural administrative department of the State Council	MOA, OBA, NBC, competent agricultural administrative department of the State Council	MOA, OBA, NBC	MOA, OBA, NBC	MOA, OBA, NBC	AQSIQ, MOA, OBA, NBC; State Council agricultural authorities (labeling)
Organisms Covered	Animals, Plants, microorganism	Animals, Plants, microorganism	Animals, Plants, microorganism	Animals, Plants, microorganism	Animals, Plants, microorganism	Animals, Plants, microorganism
Required Submissions	Declaration Form of Import Commodities; Safety Certificate; Acknowledgment & Approval of Labeling of GMO Application for Safety Assessment Completed safety registration form for imported	Application for Safety Assessment; Safety class of GMO and justification; Inspection report from technical inspection body; Appropriate safety admin & precautionary measures; Summary report of the previous stage	Application for Safety Assessment; Safety class of GMO and justification; Inspection report from technical inspection body; Appropriate safety admin & precautionary measures; Summary report of the testing stages	Application for safety assessment Application qualification documents; Completed safety registration form for imported GMO; Certification that related research and testing has been completed abroad; Appropriate safety	Application for Safety Assessment Application qualification documents; Completed safety registration form for imported GMO; Certification that related research and testing has been completed abroad; Appropriate safety	Declaration Form of Import Commodities; Safety Certificate; Acknowledgment and Approval of Labeling of GMO Safety Assessment materials in accordance with "Implementation Regulations

[34] Prior to commercial release and issuance of safety certificate, a GM crop has to go through three stages of field releases: 1) Restricted, 2) Enlarged and 3) Productive Release - alternatively designated as Medium Testing, Environmental Testing and Commercializing Testing.

	Contained Work	Limited Field Test (Restricted, Enlarged, Productive)[34]	Commercial Release	Use as Food	Use as Feed	Importation for processing/as processed commodity
	GMO; Certification that related research and testing has been completed abroad; Appropriate safety admin & precautionary measures	Completed safety registration form for imported GMO; Certification that related research and testing has been completed abroad; Appropriate safety administrative & precautionary measures	Safety registration form for imported GMO; Certification of permitted marketing from exporting economy; Scientific testing data of exporting economy verifying that the GM products have no significant harm; Safety mgt measures during export	admin and precautionary measures Safety certificate and relevant variety registration; Appropriate safety management measures	admin and precautionary measures Safety certificate & relevant variety registration; Appropriate safety mgt measures	on Safety of Import of GMOs" Completed safety registration form for imported GMO; Completed application form for safety evaluation of GMOs; Certification of permitted marketing from exporting economy; Scientific testing data of exporting economy verifying that the GM products have no significant harm; Safety inspection report; Appropriate safety admin and precautionary measures Safety certificate and relevant variety registration; Appropriate safety mgt measures
Processing Fee	None specified	2500 CNY per application(Enlarged field testing)/3000 CNY per application (Productive testing)	5000 CNY per application	None specified	None specified	5000 CNY per application
Processing Time	270 business days 3 months after the application deadlines (March 31 & September 30 every year)	3 months after the application deadlines (March 31 & September 30 every year)	3 months after the application deadlines (March 31 & September 30 every year)	3 months after the application deadlines (March 31 & September 30 every year)	3 months after the application deadlines (March 31 & September 30 every year)	270 business days 30 days 3 months after the application deadlines (March 31 & September 30 every year) 270 days
Risk Assessment	Scientific and case- by-case basis; by safety classes and work stages	Scientific and case- by-case basis; by safety classes and work stages	Scientific and case- by-case basis; by safety classes and work stages[35]	Scientific and case-by-case basis; by safety classes and work stages	Scientific and case- by-case basis; by safety classes and work stages	Scientific and case- by-case bases; by safety classes and work stages
Public Participation/ Comment	China's BCH; local agricultural department to supervise safety of	China's BCH; local agricultural department to supervise safety of	China's BCH; local agricultural department to supervise safety of	China's BCH; l local agricultural department to supervise safety of	China's BCH; local agricultural department to supervise safety of	China's BCH; local agricultural department to supervise safety of

[35] Shall go through the 3 testing stages prior to import and commercial cultivation, i. e., restricted field testing, enlarged field testing and productive testing

	Contained Work	Limited Field Test (Restricted, Enlarged, Productive)[34]	Commercial Release	Use as Food	Use as Feed	Importation for processing/as processed commodity
	agricultural GMOs within its respective areas Local public health department to supervise hygiene and safety of GM food	agricultural GMOs within its respective areas Local public health department to supervise hygiene and safety of GM food	agricultural GMOs within its respective areas Local public health department to supervise hygiene and safety of GM food	agricultural GMOs within its respective areas Local public health department to supervise hygiene and safety of GM food	agricultural GMOs within its respective areas Local public health department to supervise hygiene and safety of GM food	agricultural GMOs within its respective areas Local public health department to supervise hygiene and safety of GM food
Socioeconomic Considerations			Comprehensive evaluation report of production and application aims to assess impact on aspects of production, trade and social etc.	Consumer right to choose		
Approval Document	Import Permit/ Transit Permit of GM Commodity Import Permit	Biosafety certificate Import Permit Safety Certificate (for application for enlarged/productive testing)	Biosafety certificate Import Permit after restrictive field test; Safety certificate after enlarged/productive field test Marketing License	Biosafety certificate Import Permit Production License	Biosafety certificate Import Permit Production License	Import Permit/Transit Permit of GM commodity Biosafety Certificate Import Permit/Safety Certificate Production License
Restrictions or conditions	Biosafety certificate must be issued by a special agency within the territory; proponent must have full-time technical staff; appropriate equipment and facilities and qualified IBC	Biosafety certificate must be issued by a special agency within the territory; proponent must have full-time technical staff; appropriate equipment and facilities and qualified IBC	Marketing license requires full-time managerial and marketing files and implementation of all appropriate safety management measures that may be specified Advertisement of GMOs may be broadcasted, published or posted only after examination and approval of MOA	Production license also stipulates compliance with provisions of Food safety Law and labeling provisions	Production license also stipulates compliance with provisions of Food safety Law	Introducing organization can only apply to the Customs only after the GMOs passes AQSIQ Must comply with provisions of Implementation Regulations on Labeling of GMOs: • GMOs - genetically modified (GM) x x • Products directly processed from agricultural GMOs - GM product (finished product) OR processed w/GM as raw material • products made/ processed with GMOs but show no traces of GM ingredients – This product is made from GM X X but no longer contains GM ingredients OR The raw materials of this product contain GM X X, but the product itself no longer contains GM ingredients • for special requirements on marketing scope –

	Contained Work	Limited Field Test (Restricted, Enlarged, Productive)[34]	Commercial Release	Use as Food	Use as Feed	Importation for processing/as processed commodity
						"only for X X sale (production, processing or use); • Language on the label shall be standard Chinese • Labels of domestic GMOs shall not be used by the producer/packer until after approval of local agricultural admin department
Expiration of Approval Document	1~2 years	1~2 years	5 years	None specified	None specified	3~5 years
Provision for Renewal	None specified	Simplified procedure	Bulletin No. 736, MOA	None specified	None specified	None specified

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HONG KONG, CHINA

The Hong Kong Government (HKG) began implementing its new GM regulations in March 2011 with a 6-month transition period for items already present in the Hong Kong environment and food market. Exempted from its new regulations are two varieties of GM papaya grown in backyards on a small scale by residents, presumably from seeds of fruits imported as commodity. The territory is not a major agricultural producer and imports a large percentage of its food requirements. At present, agricultural biotechnology-related activities are largely carried out under containment. Although collaborative research on GM rice is being done in government laboratories, the field trials for these are done in Mainland China. No field trials of locally developed GMOs have been conducted in Hong Kong. The source of living modified organisms (LMOs) that may be cultivated in the territory are exclusively from importation of viable LMOs.

Currently, the HKG does not have any specific biotechnology regulations with regard to the mandatory labeling of GM food products. It makes no distinction between conventional or GM foods, subjecting them to the same food safety regulation. GM-ingredient specific regulation is, however, being proposed. The HKG introduced voluntary labeling of GM products as a viable alternative for the trade. Guidelines on voluntary labeling for biotech foods were published in 2006 by the HKG Center for Food Safety; they are advisory in nature with no legal effect. The threshold level applied in the guidelines for labeling purpose is 5 percent of individual food ingredient. The HKG discourages negative labeling.

The HKG has announced its intention to regulate GM foods by putting in place a Pre-Market Safety Assessment Scheme (PMSAS) by the second half of 2013. Under this scheme, a GM food developer needs to submit an application and provide supporting documentation to the Center for Food Safety (CFS) for evaluation in the context of Codex principles and guidelines. The GM food should pass the CFS safety assessment before it can be sold in Hong Kong. The PMSAS regulation will cover foods derived from GM plants, animals, and microorganisms. The CFS has not determined whether any application fees will be required. The HKG anticipates no significant impact arising from the implementation of this proposed regulation, stating that the GM commercial ingredients present in Hong Kong foods should have been evaluated by other regulatory authorities overseas. For these ingredients, future assessment procedures applied by PMSAS will be simplified, provided the principles and procedures adopted by the overseas authorities "are similar" to those of Codex. For GM ingredients that have not been approved overseas, the Government does not anticipate that Hong Kong will be the selected as the first market to which such ingredients will be introduced.

The proposed PMSAS requires GM food developers to include all overseas safety assessments, evaluation findings, and approval certificates in their submissions. The CFS indicated that they will evaluate the application by making reference to the safety assessment conducted by other regulatory authorities. Suitable transitional arrangements will be made for GM ingredients already present in the Hong Kong market. After implementation of PMSAS,

the CFS will upload the list of approved GM food and on its homepage for the reference. Hong Kong food manufacturers and importers will be responsible for ensuring that only approved GM ingredients are contained in their products.

	Contained Work	Limited Field tests	Commercial release	Use as Food/Feed	Importation for processing/ as processed commodity
Key Laws & Regulations	Guidelines on Biosafety in the Clinical Laboratory, February 2008 Genetically Modified Organisms (Control of Release) Ordinance, 2011	Genetically Modified Organisms (Control of Release) Ordinance, 2011	Genetically Modified Organisms (Control of Release) Ordinance, 2011	Part V (Food and Drugs) of the Public Health and Municipal Services Ordinance (Cap.132); Hong Kong Agriculture, Fisheries and Conservation Department; Plant Ordinance, Cap. 207 (Importation and Pest Control: for importation of Plants Genetically Modified Organisms (Documentation for Import and Export) Regulation, 2011	Part V (Food and Drugs) of the Public Health and Municipal Services Ordinance (Cap.132); Hong Kong Agriculture, Fisheries and Conservation Department; Plant Ordinance, Cap. 207 (Importation and Pest Control: for importation of Plants Genetically Modified Organisms (Documentation for Import and Export) Regulation, 2011
Implementing Agencies	Universities, R&D Institutions Agricultural, Fisheries, and Conservation Department (AFCD) within the Food Health Bureau (FHB)	AFCD within FHB	AFCD within FHB	Food and Environmental Hygiene Department (FEHD) Hong Kong Center for Food Safety (CFS) for implementation of territory-wide food safety control policies and enforcing food related legislation; AFCD for importation of Plants and Line Animals; Hong Kong Customs and Excise Department (issues license for imported dutiable commodities)	FEHD-CFS for implementation of territory-wide food safety control policies and enforcing food related legislation; AFCD for importation of Plants and Line Animals; Hong Kong Customs and Excise Department (issues license for imported dutiable commodities)
Coverage	Recombinant Bacteria, Viruses, Fungi, plants, animals	LMOs	LMOs	GM ingredients, plants, animals, fisheries and marine species, dairy	GM ingredients, plants, animals, fisheries and marine species, dairy
Required submissions	Documentation detailing common name, scientific name and, where available, commercial name of LMO Name, address and contact details of consignee and exporter or importer Any requirement for safe handling of the LMO; characteristics and unique identifier of LMO to aid in Biosafety Clearing house (BCH) referencing	Documentation detailing common name, scientific name and, where available, commercial name of LMO Name, address and contact details of consignee and exporter or importer Any requirement for safe handling of the LMO Characteristics and unique identifier of LMO to aid in Biosafety Clearing house (BCH) referencing Risk class and import approval for the first trans-	Documentation detailing common name, scientific name and, where available, commercial name of LMO Name, address and contact details of consignee and exporter or importer Any requirement for safe handling of the LMO Characteristics and unique identifier of LMO to aid in Biosafety Clearing house (BCH) referencing Risk class and import approval for the first trans-	General: Health Certificates, Plant Import License and Phytosanitary Certificates, Certificate of Origin GM specific: declaration that shipment contains LMO or if identity of LMO is not known, that shipment may contain LMO Declaration that LMO is not intended for release into the environment Documentation specifying common name, scientific name and, where available, commercial name of the LMO Transformation event code of the LMO or, where available, its unique identifier code	General: Health Certificates, Plant Import License and Phytosanitary Certificates, Certificate of Origin GM specific: declaration that shipment contains LMO or if identity of LMO is not known, that shipment may contain LMO Declaration that LMO is not intended for release into the environment; documentation specifying common name, scientific name and, where available, commercial name of the LMO Transformation event code of the LMO or, where available, its unique identifier code Name, address and contact information on importer or exporter

	Contained Work	Limited Field tests	Commercial release	Use as Food/Feed	Importation for processing/ as processed commodity
		boundary movements of LMO Declaration that the movement of the LMO is in conformity with the requirements of the Protocol applicable to the exporter Details of contact point for additional information in case of emergency	boundary movements of LMO Declaration that the movement of the LMO is in conformity with the requirements of the Protocol applicable to the exporter Details of contact point for additional information in case of emergency	Name, address and contact information on importer or exporter	
Processing Fee	None specified	None specified	None specified	None specified	No additional fees specified
Processing time	Not specified	Not specified	Not specified	Not specified	Not specified
Risk Assessment	Scientific, case-by-case	Context of Cartagena Protocol on Biosafety; other international approvals are considered in the risk assessments	Context of Cartagena Protocol on Biosafety; other international approvals are considered in the risk assessments	No additional assessment made if product approved overseas by authorities following Codex Alimentarius principles (documentation required)	No additional assessment made if product approved overseas by authorities following Codex Alimentarius principles (documentation required)
Public participation	Invited comments on new regulations	Invited comments on new regulations	Invited comments on new regulations	Invited comments on new regulations	Invited comments on new regulations
Socioeconomic considerations	None Specified	None Specified	Exemption granted for GM papaya varieties already prevalent in Hong Kong, and grown in backyards on small scale	Transition period for GM ingredients already sold in Hong Kong markets; Limited trade disruptions; Voluntary labeling at 5% threshold, negative labeling discouraged	Transition period for GM ingredients already sold in Hong Kong markets; Limited trade disruptions; Voluntary labeling at 5% threshold, negative labeling discouraged
Approval Document	None Specified	AFCD approval	AFCD approval	Phytosanitary Certificate from the Country of Origin and Import permit; Health Certificate, CFS approval posting in CFS website as part of approved list of GM products	Phytosanitary Certificate from the Country of Origin and Import permit; Health Certificate, CFS approval posting in CFS website as part of approved list of GM products
Restrictions or conditions	No environmental releases	As specified by approval document	As specified by approval document	As specified by approval document	Not for cultivation
Expiration of Approval Document	None specified	None specified	None specified	None specified	None specified

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INDONESIA

In recent years, the Government of Indonesia (GOI) has issued a variety of new regulations pertaining to biotechnology. In 2005, the GOI released Regulation No. 21 on Biosafety of Genetically Engineered Products, referred to as PP 21/2005. This regulation covers the whole spectrum of agricultural biotechnology-related activities, but the commercial cultivation of GM crops in Indonesia awaits the finalization of procedures and requirements for this activity. In October 5, 2011 the Ministry of Agriculture issued Regulation No. 61/2011 on the procedures of testing, evaluating, releasing, and withdrawing of transgenic crop varieties. This regulation allows limited field trials for the environmental safety assessment to be done in parallel with the adaptation trial for variety release.

Two transgenic feed enzymes, two GM soybean, seven GM corn, and one GM sugar cane varieties have been approved for food use by the Indonesia Food Safety Agency (known by its local acronym BPOM). Two other GM sugarcane varieties have been submitted for food safety evaluation by BPOM. A GM corn product (NK603) has also been approved for feed uses. Three GM sugarcane varieties are currently approved for environmental release by the Ministry of Environment, furthermore the Ministry of Agriculture has released one variety of drought tolerance sugarcane approval thru the MOA Decree No. 4571/Kpts/SR.120/8/2013 . The Ministry of Agriculture's approval is required for commercial cultivation of these sugar cane varieties in Indonesia.

The GOI has conducted confined field tests of several transgenic crops, including rice (resistant to biotic stress), sugarcane (tolerant to a-biotic stress and modification of high glucose content), cassava (modification of amylase), potato (resistant to biotic stress), and tomato (resistant to biotic stress). Additional research projects on transgenic plants include virus resistance for tomatoes and potatoes, delayed ripening for papaya, sweet potato pest resistance, drought tolerant rice, and pest resistant soybeans are also ongoing.

Although regulations regarding transgenic animals are in place, Indonesia does not currently produce or commercialize transgenic animals. Some research institutions and universities have conducted studies on animal molecular markers, using molecular markers in cattle breeding and for the identification of desirable characteristics like heat tolerance, feed efficiency, and disease resistance in cattle and chicken. The general consensus is that Indonesia will not be deploying transgenic animals in the near future.

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
Key Laws & Regulations	1999 Joint decree of Ministers on Biosafety and Food Safety of Genetically Engineered Agricultural Products[36] Act No. 21 of 2005, Safe Utilization of Genetically Engineered Biological Products (PP 21/2005)	PP 21/2005 Ministry of Agriculture Regulation No. 61/2011 (procedures of testing, evaluating, releasing, and withdrawing of transgenic crop variety)	Covered by PP 21/2005, but no final implementing rules and regulations yet Presidential Regulation Number 39/2010	PP 21/2005 Act No. 7 of 1996, regarding food (PP 7/1998, amended 2012) BPOM Regulation No. K.03.1.23.03.12. 1563/2012, on the Guidelines of Food Safety Assessment for Genetically Engineered Products	PP 21/2005 Act No. 29 of 2000, regarding protection of plant varieties (PP 29/2000) Act No. 28 of 2004, regarding food safety, quality, and nutrition (PP 28/2004) Joint Decree on Biosafety and Food Safety of GE Agricultural Products, 1999 (Ministry of Agriculture (No. 998.1/Kpts/OT .210/9/99), Ministry of Forestry and Estate (No. 790.a/Kpts-IX/ 1999), Ministry of Health (No.1145A/ MENKES/SKB/IX/1999), and State Ministry of Food and	BPOM Regulation No. HK.03.1.23.03. 12.1563/2012 on the Guidelines of Food Safety Assessment for Genetically Engineered Products, 2012 PP 29/2000 BPOM Regulation No. HK.03.1.23.03. 12.1564/2012 BPOM Regulation No. HK 27/2013 on Importation Control of Drug & Food BPOM Regulation No. 28/2013 Importation Control of Drug,

36 Joint Decree of the Minister of Agriculture, the Minister of Forestry and Estate Crops, the Minister of Health, and the State Minister of Food and Horticulture on Biosafety and Food Safety of Genetically Engineered Agricultural Products.

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
					Horticulture (No.015A/NMenegPHOR/09/1999)	Traditional Medicine, Health Supplement, & Food Materials
Implementing Agencies	Agency for Agricultural Research and Development Bureau for Biotechnology and Genetics Resources Biosafety Committee Ministry of Environment State Other government agencies	Agency for Agricultural Research and Development Ministry of Environment State Other government agencies	Commission of Biosafety for Genetically Engineered Products (KKH-PRG37) with the assistance of the Technical Team of Bio-safety of Genetically Engineered Products Process (TTKH) and the Indonesian Biosafety Clearing House of Genetically Engineered Products (BKKH) Ministry of Agriculture Ministry of Marine and Fisheries Affairs Ministry of Environment State Ministry of Health BPOM Other government agencies	Minister of Agriculture Minister of Marine and Fisheries Affairs National Agency of Drug and Food Control (BPOM) Commission of Biosafety for Genetically Engineered Products (KKH-PRG) with the assistance of the Technical Team of Bio-safety of Genetically Engineered Products Process (TTKH) and the Indonesian Biosafety Clearing House of Genetically Engineered Products (BKKH)	Minister of Agriculture Minister of Marine and Fisheries Affairs	Minister of Agriculture Minister of Marine and Fisheries Affairs BPOM KKH-PRG, with the assistance of the TTKH and the BKKH
Organisms covered	Animals, Fish, Bacteria, Plants	Animals, Fish, Bacteria, Plants	Animals, Fish, Bacteria, Plants	Animals, Fish, Bacteria, Plants	Animals, Fish, Bacteria, Plants	Animals, Fish, Bacteria, Plants
Required submissions	Application for the Assessment of Biosafety and Food Safety of Genetically Engineered Agricultural Products	Application for the Assessment of Biosafety and Food Safety of Genetically Engineered Agricultural Products requires a certificate of Contained Work before environmental release application	Application for the Assessment of Biosafety and Food Safety of Genetically Engineered Agricultural Products requires a certificate of completion of limited field tests	Completed Application form for GM food safety assessment submitted to BPOM	Completed Application form for GM feed safety assessment submitted to Ministry of Agriculture or Ministry of Marine and Fisheries Affairs	Application of genetically engineered product food safety assessment (to be conducted by KKH-PRG) Other existing requirements for food importation: (i) Health/safety certificates (ii) Product registration (iii) Pre-import Notification

[37] PRG is the Indonesian acronym for “genetically engineered products.”

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
Processing Fee	None specified	None specified	None specified	None specified	None specified	None specified
Processing time	88 days	221 days if documentation complete and no objections posed by public during public comment period	221 days if documentation complete and no objections posed by public during public comment period	173 days if documentation complete and no objections posed by public during public comment period	173 days if documentation complete and no objections posed by public during public comment period	173 days if documentation complete and no objections posed by public during public comment period
Risk Assessment	Scientific; precautionary approach in accordance with religion, ethics, socio-cultural and aesthetics	Scientific; precautionary approach in accordance with religion, ethics, socio-cultural and aesthetics	Scientific; precautionary approach in accordance with religion, ethics, socio-cultural and aesthetics	Scientific; precautionary approach in accordance with religion, ethics, socio-cultural and aesthetics	Scientific; precautionary approach in accordance with religion, ethics, socio-cultural and aesthetics	Scientific; precautionary approach in accordance with religion, ethics, socio-cultural and esthetics
Public Participation	None specified	After technical assessment of TTKH, KKH forwards summary of assessment to BKKH for posting in BCH website and other easily accessed sites for public comment for 60 days	After technical assessment of TTKH, KKH forwards summary of assessment to BKKH for posting in BCH website and other easily accessed sites for public comment for 60 days	After technical assessment of TTKH, KKH forwards summary of assessment to BKKH for posting in BCH website and other easily accessed sites for public comment for 60 days	After technical assessment of TTKH, KKH forwards summary of assessment to BKKH for posting in BCH website and other easily accessed sites for public comment for 60 days	After technical assessment of TTKH, KKH forwards summary of assessment to BKKH for posting in BCH website and other easily accessed sites for public comment for 60 days
Socioeconomic considerations	None specified	None specified	Requires Food and feed safety approvals; Includes all considerations covered by Food and feed safety assessments; effects on biodiversity	Prior to scientific risk assessment, KKH determines if GM foods or components contain elements that run contrary to religious, ethics, socio-cultural, aesthetic and environmental norms Application recommended for outright rejection by BPOM head if found to be non-compliant with above criteria	Prior to scientific risk assessment, KKH determines if GM foods or components contain elements that run contrary to religious, ethics, socio-cultural, aesthetic and environmental norms Application recommended for outright rejection by BPOM head if found to be non-compliant with above criteria	Prior to scientific risk assessment, KKH determines if GM foods or components contain elements that run contrary to religious, ethics, socio-cultural, aesthetic and environmental norms Application recommended for outright rejection by BPOM head if found to be non-compliant with above criteria
Approval Document	Approval from the head of the Indonesian Agency for Agricultural Research and Development	Certificate for Environmental safety Approval from Minister of Environment and Head of Non-Department Govt Institutions	Food safety certificate and environmental safety approvals	Decision on the distribution of the GM foods also serving as food safety certificate; issued by the Head of BPOM	Decision on the distribution of the GM foods also serving as food safety certificate; issued by the Head of BPOM	Decision on the distribution of the GM foods also serving as food safety certificate; issued by the Head of BPOM

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
Restrictions or conditions			Approval for food and feed safety required; certificate of environmental safety also required before commercial cultivation			Compliance with other existing requirements for food importation: (i) Health/safety certificates (ii) Product registration (iii) Pre-import Notification Label for packaged and/or retail food products at 5% threshold for GM ingredients: "Food Containing Genetically Modified Material"
Expiration of Approval Document	None specified	None specified	None specified	Valid until revoked	Valid until revoked	Valid until revoked

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JAPAN

Japan has an active and functional regulatory system for the regulation of GMOs. Japan is the largest per capita importer of GM food and feeds and its government has approved more than 130 transgenic events for food use and more than 95 events for environmental release, which includes commercial-scale cultivation. No commercial cultivation of GM food crops takes place in Japan. Only Suntory's blue rose, released in 2009, is commercialized for cultivation in its territory. However, commercial-scale cultivation of high-value biotech plants does take place under containment. The National Institute of Advanced Industrial Science and Technology's (AIST) has a 291sq m, completely closed facility that grows transgenic strawberry under strict containment. The strawberries produce interferon used to treat canine periodontal disease. Two varieties of biotech silkworm developed by National Institute of Agricultural Science (NIAS)) are grown by six farmers in Gunma Prefecture to produce "protein A," a protein used for medical diagnostic agents.

Commercialization of GM products requires food, feed, and environmental approvals, on top of other requirements set by standards for various commodities. The key Ministries involved in GMO regulation are the Ministry of Environment, Ministry of Health, Labor and Welfare (MHLW), Ministry of Agriculture Forestry and Fisheries (MAFF), Ministry of Education, Culture, Sports, Science and Technology (MEXT), and Ministry of Economy, Trade and Industry (METI).

Japan does not grant separate approvals for importation for food, feed, and industrial use and for intentional releases into the environment. Food and feed importers are required to conduct a limited field test in an isolated plot on Japanese soil prior to the actual commercial importation of the commodity, even if the said commodity will not be cultivated in Japan. These limited field trials on isolated sites are known as Stage 3 Field Trials (S3-FT), and are required for

each biotech event that will be imported into Japan. The same requirements are imposed for seeds imported for commercial cultivation and grains imported for food, feed and industrial use.

Separate environmental approvals are required for stacked events, although it is generally not necessary to perform S3-field trials for their importation. Existing data and information on parental lines are usually sufficient for evaluation. The Food Safety Commission (FSC) of the MHLW requires a safety approval for stacked genes if the crosses are above subspecies level. Safety approvals are also required if the parental traits are for insect resistance, herbicide tolerance or virus resistance, or if consumption patterns differ between the parental lines and the stacked-trait offspring

Japan has a labeling law with a 5% GM threshold for each ingredient used in food. Labeling policies and strategies for identity preservation and segregation are handled by the Food Labeling division of the Consumer Affairs Agency (CAA). Created in 2010 to protect and enhance consumer rights, CAA implements the labeling requirement of the Food Safety Sanitation Law and the Japan Agricultural Standards Law (JAS). There is zero tolerance for the presence of unapproved events in shipments and commodities reaching Japanese soil. To ensure that only approved events are present in the foodstuff, MAFF performs constant monitoring of the import sites and of the market.

	Contained Work		Limited Field tests	Commercial release/Propagation	Use as Food	Use as Feed	Importation for processing/ as processed commodity
	Research and Development	Contained Commercial Cultivation					
Key Laws & Regulations	Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms, 2004 (Cartagena Law) Guidelines for Application of Recombinant DNA Organisms in Agriculture, Forestry, Fisheries, The Food Industry and Other Related Industries, 1989 (revised 1995, 2000)	Cartagena Law (2004) As defined by commercial use: (i) Food Sanitation Law (1947 plus amendments up to 2003); Food Safety Basic Law (2003) (ii) Feed Safety Law (1953 plus amendments up to 2003) (iii) Pharmaceutical Affairs Act (1960 plus amendments up to 2002)	Cartagena Law (2004) Guidelines for Application of Recombinant DNA Organisms in Agriculture, Forestry, Fisheries, The Food Industry and Other Related Industries (1989, revised 1995)	Cartagena Law (2004) Food Sanitation Law (1947 plus amendments up to 2003) Food Safety Basic Law (2003) Pharmaceutical Affairs Act (1960 plus amendments up to 2002)	Cartagena Law (2004) Food Sanitation Law (1947 plus amendments up to 2003) Food Safety Basic Law (2003) Labeling Standard for GM Food, Japan Agricultural Standards (JAS) Law, if applicable (2009)	Cartagena Law (2004) Feed Safety Basic Law (2003)	Cartagena Law (2004) Food Sanitation Law (1947 plus amendments up to 2003) Food Safety Basic Law (2003) Pharmaceutical Affairs Act (1960 plus amendments up to 2002)
Implementing Agencies	Ministry of Education, Culture, Sports, Science and Technology (MEXT):	Ministry of Agriculture Forestry and Fisheries (MAFF), Ministry of Environment (MOE), and, depending on commercial use,	MAFF and MOE	MOE, MAFF, MHLW, METI, Ministry of Finance (MOF) if alcohol produced GMOs, relevant prefecture agencies	MHLW, Food Safety Commission (FSC) of the Cabinet Office; MOE; Food Labeling Division of the Consumer Affairs Agency (if applicable)	MAFF; FSC	MOE, MAFF, MHLW, METI, Ministry of Finance (MOF) if alcohol produced GMOs, other import-regulatory agencies

	Contained Work		Limited Field tests	Commercial release/Propagation	Use as Food	Use as Feed	Importation for processing/ as processed commodity
	Research and Development	Contained Commercial Cultivation					
		Ministry of Economy, Trade and Industry (METI) or Ministry of Health, Labor and Welfare (MHLW),					
Organisms covered	Plants, animals, microorganisms	Plants, animals, microorganisms	Plants, animals, microorganisms	Plants, animals, microorganisms	Plants, animals, microorganisms	Plants, animals, microorganisms	Plants, animals, microorganisms
Required submissions	Petition to MEXT providing details of activity, facilities and characteristics of the GM construct	Petition to MAFF and MOE for approval for commercial production under containment, providing details of activity, facilities, characteristics of GMO, previous overseas approvals (if any) and commercial utilization Petition to relevant ministry for approval of agricultural utilization (MAFF), Industrial utilization (METI) or pharmaceutical utilization ; import permits if necessary	Petition for isolated field cultivation detailing data generated in containment, characteristics of GMO, inserted gene(s), gene stability, potential gene flow, potential impact on biodiversity, details of selected site for isolated field test, specification of facilities, equipment, procedures and personnel	Petition for import and cultivation, food safety approval from MHLW, feed safety approval from MAFF, Approval from MHLW for pharmaceutical use, data/report from isolated field test for first importation (Stage 3 Field Trial), Biological Diversity Risk Assessment Report from isolated field test	Petition to MHLW for Food safety Assessment detailing characteristics of GM food, nutritional quality, toxicity and allergenicity if any	Petition to MAFF for Feed Safety Assessment detailing any changes in feed composition, feed use, potential toxicity, and any potential harm to humans consuming livestock products from animal fed with GM feed	Petition for import and cultivation, food safety approval from MHLW, feed safety approval from MAFF, Approval from MHLW for pharmaceutical use, data/report from isolated field test for first importation (Stage 3 Field Trial), Biological Diversity Risk Assessment Report from isolated field test
Processing Fee	No fee charged	No fee charged	No fee charged	No fee charged	No fee charged	No fee charged	No fee charged
Processing time	None specified	None specified	None specified	None specified	None specified	None specified	None specified

	Contained Work		Limited Field tests	Commercial release/Propagation	Use as Food	Use as Feed	Importation for processing/ as processed commodity
	Research and Development	Contained Commercial Cultivation					
Risk Assessment	Done by Expert Panel on Recombinant DNA technology; Bioethics and Biosafety Commission, Council for Science and technology and MEXT Uses scientific principles, international and national guidelines for Good laboratory Practices and Guidelines for Application of Recombinant DNA Organisms in Agriculture, Forestry, Fisheries, The Food Industry and Other Related Industries	Done by Expert Panel on Recombinant DNA technology; Bioethics and Biosafety Commission, and other expert panels specified by relevant Ministries responsible for approval of commercial utilization of GMO produced under containment	Done by Biodiversity Impact Assessment Group and experts selected by MAFF and MOE ministers whose special knowledge and experience are suited for the proposed activity Uses scientific principles, comparative approach; assesses potential to harm environment through, among others, enhanced competitiveness, production of new or more toxins, gene flow	Done by Biodiversity Impact Assessment Group of MAFF and MOE plus experts selected by other relevant agencies Utilizes data from Stage 3 Field trial, submitted dossiers on characteristics of GMO, food safety, feed safety and/or use in pharmaceuticals; takes into consideration changes in competitiveness of GMO, persistence in environment, any production of new or more toxins production, gene flow	Done by FSC with Genetically Modified Food Expert Committee Considers safety of host plants, introduced genes, vectors, novel proteins' potential allergenicity and toxicity, and any changes in food composition that may alter nutrient quality; and human consumption patterns Essentially follows FSC published standards and Codex guidelines for comparative and weight of evidence approach	Done by Expert Panel on Recombinant DNA Organisms (part of Agricultural Materials Committee) and FSC GM Foods expert Committee for review of safety of animal products from livestock that consumed GM feeds Considers changes in feed conversion efficiency, feed use, possible new toxins in food, and potential adverse effects of animal products from livestock fed with GM feeds	Done by Biodiversity Impact Assessment Group of MAFF and MOE plus experts selected by other relevant agencies; utilizes data from Stage 3 Field trial, submitted dossiers on characteristics of GMO, food safety, feed safety and/or use in pharmaceuticals Takes into consideration changes in competitiveness of GMO, persistence in environment, any production of new or more toxins production, gene flow
Public Participation/ Comment	Japan Biosafety Clearing House (BCH) website and MEXT websites inform public of research activities	Japan BCH website and MAFF, MOE, METI, and/or MHLW websites inform public of production activities	Japan BCH to inform public of isolated trials; Publicize information about the isolated field trial through web pages, media and face-to-face meeting with local residents Public comment invited	Japan BCH Publication/posting of Expert's Assessment; Public Consultation	Japan BCH Publication/posting of Expert's Assessment; Public Consultation or invites Comment as needed Review of Experts' assessment by Advisory groups with broad stakeholder representation	Japan BCH Publication/posting of Expert's Assessment; Public Consultation or invites Comments as needed	Japan BCH Publication/posting of Expert's Assessment; Public Consultation
Socioeconomic considerations	Bioethical and cultural considerations; prefecture ordinances that may restrict conduct of activities	Bioethical and cultural considerations; prefecture ordinances that may restrict conduct of activities	Public reaction in trial site, prefecture ordinances may restrict conduct of activities, possible use of GMO as food, feed, industrial or pharmaceutical material		Considers consumer preferences and rights, invites public comments Labeling at 5% threshold for consumers' right to know	Considers consumer preferences and rights	Considers consumer preferences and rights, invites public comments Labeling at 5% threshold for consumers' right to know
Approval Document	MEXT approval based on	MAFF approval (for agricultural	Joint MAFF and MOE Environment Safety	Food safety approval from MHLW	Food Safety Approval from MHLW	Feed Safety Approval from MAFF	Food safety approval from MHLW

	Contained Work		Limited Field tests	Commercial release/Propagation	Use as Food	Use as Feed	Importation for processing/ as processed commodity
	Research and Development	Contained Commercial Cultivation					
	recommendation of expert panel	utilization); METI approval (for industrial utilization) or MHLW for Pharmaceutical Utilization	Approval for isolated field trial	Feed safety approval from MAFF Environmental Safety approval from MOE Approvals from other relevant agencies (dependent on use of imported material)			Feed safety approval from MAFF Environmental Safety approval from MOE Approvals from other relevant agencies (dependent on use of imported material)
Restrictions or conditions	For research and development small scale Laboratory or Greenhouse use only Need to conform with local prefecture laws, restrictions and ordinances	Indoor commercial cultivation for agricultural, industrial or pharmaceutical utilization	Isolated field cultivation only Need to establish crop-specific buffer zones Devise safety management system Need to conform with local laws, restrictions and ordinances	Identity preservation if necessary, must comply with prefecture restrictions on activity May require buffer zones to be established	Labeling requirements may be imposed at 5% threshold, or if GM is one of top 3 components of food item Zero tolerance of contamination with unapproved event.	Labeling requirements may be imposed at 5% threshold, or if GM is one of top 3 components of food item Zero tolerance of contamination with unapproved event.	Must comply with other import requirements (standard declarations based on Food Hygiene Law) Labeling at 5% threshold, no unapproved GM component (zero tolerance for low level presence) Imported commodities may be tested at importation sites before accepted
Expiration of Approval Document	None specified	None specified	As specified in Petition	Until revoked	Until revoked	Until revoked-	Until revoked
Renewal Provision	None specified	None specified	None specified	None specified	None specified	None specified	None specified

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REPUBLIC OF KOREA

The Republic of Korea imports GM crops and products for food, feed, and processing (FFP), but not for cultivation. South Korea depends heavily on imported foods, which supply about 70% of the country’s food consumption needs. The bulk of its animal feed is made from GM corn and GM soybean meal, but a limited amount of food products is made using ingredients of GM origin. No GM crop has been commercially cultivated in South Korea, but the government and the private sector have invested heavily in the development of GM crops.

Local development of GM crops is currently underway by various government agencies, universities, and private industry, with substantial investment coming from the government. In 2010, the Ministry for Food, Agriculture, Forestry, and Fisheries, which became the Ministry of Agriculture, Food, and Rural Affairs in 2013, announced that it intended to invest approximately US$6.5B over the next 10 years in the economy’s life sciences infrastructure. Capacity-building activities include plans to “1) upgrade the risk assessment system for biotech crops; 2) strengthen the bio-resource management; 3) develop energy crops, like marine algae, and 4) increase genomic research and bio-organ production” (Chung 2012). Research on GM crops has mainly focused on drought and disease-resistance, nutrient enrichment, transformation techniques, and gene expression in crops such as rice, pepper, bean, potatoes, Chinese cabbage, watermelon, apples and sweet potato. Among the GM crops under development, resveratrol-enriched rice (for treatment of metabolic syndrome and related conditions) is perhaps closest to generating a comprehensive dossier that will address all the information required by the regulatory process.

South Korea is also actively doing research on transgenic animals, with a view of utilizing these for the development of biomedicines and bio-organs. Work is underway to develop chicken and swine producing high-value proteins, anti-virus materials, and anti-oxidant substances. Work on transformed mini-pigs is underway to produce bio-compatible organs, and silkworms have been transformed to produce human therapeutics or silk of various natural colors.The bulk of the economy's animal feed is made from GM corn and GM soybean meal, but a limited amount of food products is made using ingredients of GM origin. No GM crop has been commercially cultivated in South Korea, but the government and the private sector have invested heavily in the development of GM crops.

GM regulation in South Korea is based mainly on the Living Modified Organism (LMO) Act, "The Act on Transboundary Movements of Living Modified Organisms" (Law No. 6448), and on other pre-existing laws and regulations meant to address food safety and sanitation concerns, quarantine, trade and transport requirements, pharmaceutical concerns, and health issues. South Korea is a party to the Cartagena Protocol on Biosafety and the Living Modified Organisms Act (LMO Act) of 2008 was enacted to comply with the requirements of the Protocol. The LMO Act specifies identical requirements for importation of GM crops and products for seed (cultivation) and for food, feed, and processing (FFP). In both cases, environmental risk assessments must be carried out before the commodities enter the local food or feed market. Several government agencies from different Ministries regulate work involving GMOs in South Korea, as specified in the matrix below. Pursuant to the LMO Act (Article 31), the Biosafety Committee chaired by the Prime Minister sets policies and reviews factors relevant to the implementation of the Cartagena Protocol. To date, South Korea has approved 77 out of 100 events submitted for food safety evaluations and 76 out of 104 events submitted for use as feed.

Stacked events do not undergo a full safety assessment if the combined traits have already been approved separately, if the expression and consumption patterns do not change because of the stacking, and if no cross-breeding is observed among sub-species. An environmental risk assessment is, however, conducted if the available information indicates interactions among the traits present in the parental lines.

South Korea requires mandatory labels for both unprocessed GM crops for human consumption and processed foods that contain GM-derived ingredients. GM labels are required "for 27 categories of foods if biotech crops are among the top five ingredients in the finished product and if a foreign protein or DNA is present in the finished product. Foods containing refined ingredients derived from these crops, such as soybean oil, high fructose corn syrup, and raw sugar are currently exempt from labeling" (Chung 2011, 2012b). Retail packaged animal feeds are also required to carry a GMO label if they contain GM ingredients. Bulk shipments of grains are also required to carry appropriate GM labels if they are 1) 100% GM; 2) known to contain some GM, or 3) likely to contain GM crops. South Korea's labeling requirements allow for a 3% threshold level of unintentional GM presence. Negative labeling is voluntary and is discouraged by regulatory authorities.

To implement the labeling requirement and facilitate testing of products at ports and in the local market, South Korea has devised a system of accreditation of laboratories for testing for the presence of GM in bulk and processed commodities prior to shipment to South Korea. Regulations for foreign laboratory accreditation standards are specified in Korean Food & Drug Administration (KFDA) Notice No. 2011-21 (Chung 2012a). The 2013 reorganization of government offices has dissolved the KFDA and has vested the implementation of labeling requirements to the Ministry of Food and Drug Safety, directly under the Prime Minister's Office (Chung and Wixom 2013).

	Contained Work	Field tests	Commercial release/Propagation	Use as Food	Use as Feed	Importation for processing/ as processed commodity
Key Laws & Regulations	The Act on Transboundary Movements of Living Modified Organisms (Law No. 6448, LMO Act) 2008, revised Dec. 2012 The Enforcement Ordinance of the Act on Transboundary Movements of Living Modified Organisms "Guidelines for Research and Handling of Recombinant Organisms Related to Agricultural Research (for RDA-developed crops)" "Guidelines for Research of Recombinant Organisms (for crops developed by Universities and the private sector)" from the Ministry of Health and Welfare (MHW)	The Act on Transboundary Movements of Living Modified Organisms (Law No. 6448, LMO Act) 2008, revised Dec. 2012 The Enforcement Ordinance of the Act on Transboundary Movements of Living Modified Organisms "Guidelines for Research and Handling of Recombinant Organisms Related to Agricultural Research (for RDA-developed crops)" "Guidelines for Research of Recombinant Organisms (for crops developed by Universities and the private sector)" from MHW	The Act on Transboundary Movements of Living Modified Organisms (Law No. 6448, LMO Act) 2008, revised Dec. 2012 The Enforcement Ordinance of the Act on Transboundary Movements of Living Modified Organisms Consolidated Notice: provides guidelines for export and import of LMOs for intended for agricultural use, intended for environmental release, intended for food, feed and processing and other use. Food Sanitation Act Agricultural Products Quality Control Act:	The Act on Transboundary Movements of Living Modified Organisms (Law No. 6448, LMO Act) 2008, revised Dec. 2012 The Enforcement Ordinance of the Act on Transboundary Movements of Living Modified Organisms Consolidated Notice: provides guidelines for export and import of LMOs for intended for agricultural use, intended for environmental release, intended for food, feed and processing and other use. Food Sanitation Act	The Act on Transboundary Movements of Living Modified Organisms (Law No. 6448, LMO Act) 2008, revised Dec. 2012 The Enforcement Ordinance of the Act on Transboundary Movements of Living Modified Organisms Consolidated Notice: provides guidelines for export and import of LMOs for intended for agricultural use, intended for environmental release, intended for food, feed and processing and other use. Agricultural Products Quality Control Act	The Act on Transboundary Movements of Living Modified Organisms (Law No. 6448, LMO Act) 2008, revised Dec. 2012 The Enforcement Ordinance of the Act on Transboundary Movements of Living Modified Organisms Consolidated Notice: provides guidelines for export and import of LMOs for intended for agricultural use, intended for environmental release, intended for food, feed and processing and other use. Food Sanitation Act Agricultural Products Quality Control Act of 1998
Implementing Agencies	Ministry of Trade, Industry and Energy (MOTIE) Biosafety Committee (policy; under MOTIE) Ministry of Science, ICT and Future Planning (MSIP) Ministry of Health & Welfare (MHW) (voluntary guidelines) Ministry of Agriculture, Food, and Rural Affairs (MAFRA) agencies: • Rural Development Administration (RDA); and if necessary,	MOTIE Biosafety Committee (policy; under MOTIE) MSIP MHW (voluntary guidelines) MAFRA agencies: • RDA, and as necessary, • QIA National Fisheries Research and Development Institute (NFRDI, under Ministry of Oceans and Fisheries, MOF, as necessary) Ministry of Environment's (MOE) National Institute of Environmental Research	MOTIE Biosafety Committee (policy; under MOTIE) MAFRA agencies: • RDA • National Agriculture Product Quality Service (NAQS), and as necessary, QIA and NFRDI Ministry of Food and Drug Safety (MFDS) MOE's NIER for approvals of non-agricultural GMOs and consulted for environmental risk assessment)	MOTIE Biosafety Committee (policy; under MOTIE) MFDS MAFRA's RDA for environmental risk assessment MOE's NIER, consulted if necessary MHW's Korea Center for Disease Control and prevention (KCDC) consulted as necessary	MOTIE Biosafety Committee (policy; under MOTIE) MAFRA 's NAQS for Feed safety and RDA for Environmental risk assessment, as necessary: MOE's NIER, consulted if necessary	MOTIE Biosafety Committee (policy; under MOTIE) MAFRA agencies: • RDA • NAQS • QIA NFRDI, as necessary MFDS MOE's NIER, consulted if necessary

	Contained Work	Field tests	Commercial release/Propagation	Use as Food	Use as Feed	Importation for processing/ as processed commodity
	• Animal, Plant and Fisheries Quarantine and Inspection Agency (QIA)	(NIER, for approvals of non-agricultural GMOs and consulted for environmental risk assessment) MHW's Korea Center for Disease Control and prevention (KCDC) consulted as necessary	MHW's Korea Center for Disease Control and prevention (KCDC) consulted as necessary			
Organisms covered	Animals, Bacteria, Plants	Animals, Bacteria, Plants	Animals, Bacteria, Plants	Animals, Bacteria, Plants	Animals, Bacteria, Plants	Animals, Bacteria, Plants
Required submissions	Proposed activities with description of GMO submitted to MSIP, MAFRA (RDA and QIA) and MSIP	Completed application with complete information on GMO, activities and trial sites submitted to MOE (NIER), MAFRA (RDA and QIA), and MSIP	Completed application submitted to RDA, MFDS, KCDC, NAQS, and NIER, with complete dossiers on, among others, GMO, gene inserted, food and feed safety data, environmental assessment data, data from field tests conducted in exporting country, safety assessments overseas, detection methods, and any other importation documents required; documentation on identity preservation (IP), GMO content, testing and segregation methods for IP	Completed application submitted to RDA, MFDS, KCDC, and NIER, with complete dossiers on, among others, GMO, gene inserted, food and feed safety data, environmental assessment data, data from field tests conducted in exporting country, safety assessments overseas, detection methods, and any other importation documents required; documentation on identity preservation (IP), GMO content, testing and segregation methods for IP	Completed application submitted to RDA, NAQS, and NIER, with complete dossiers on, among others, GMO, gene inserted, food and feed safety data, environmental assessment data, data from field tests conducted in exporting country, safety assessments overseas, detection methods, and any other importation documents required; documentation on identity preservation (IP), GMO content, testing and segregation methods for IP	Completed application submitted to MOTIE, RDA, MFDS, KCDC, NAQS, and NIER, with complete dossiers on, among others, GMO, gene inserted, food and feed safety data, environmental assessment data, data from field tests conducted in exporting country, safety assessments overseas, detection methods, and any other importation documents required; documentation on identity preservation (IP), GMO content, testing and segregation methods for IP
Processing Fee	None specified	None specified	None specified	US$3656 (unverified)	US$3656 (unverified)	None specified but follows a fee schedule and includes import duties
Processing time	None specified	None specified	None specified; all approvals must be issued before commercial cultivation	Acknowledgement of application within 90 days from receipt; Processing time 270 days	Acknowledgement of application within 90 days from receipt; Processing time 270 days	Acknowledgement of application within 90 days from receipt; Processing time 270 days
Risk Assessment	Done by RDA and MSIP plus technical experts. Scientific, case-by-case, considers containment requirements for design of risk management protocols ; generally done by RDA and expert committees of institutions	Scientific, case-by-case, considers containment requirements for design of risk management protocols; generally done by RDA and expert committees of institutions	Primarily done by RDA and MFDS, using precautionary approach for environment; generally follows Codex guidelines on Food safety (includes feed safety); considers results of assessments done elsewhere, but may require independently conducted assessments by local agencies; rigorous environmental risk assessment focusing on	Precautionary approach for environment; Food and health safety assessment done by MFDS with input from KCDC generally follows Codex guidelines on Food safety; considers results of assessments done elsewhere, but may require independently conducted assessments by local agencies	Precautionary approach for environment; feed evaluations done by NAQS, with input from MFDS and KCDC; generally follows Codex guidelines on food safety and FAO guidelines on animal feed; considers results of assessments done elsewhere, but may require independently conducted assessments by local agencies	Precautionary approach for environment; Food and health safety assessment done by MFDS with input from KCDC-generally follows Codex guidelines on Food safety and FAO guidelines for animal feed; considers results of assessments done elsewhere, but may require independently conducted

	Contained Work	Field tests	Commercial release/Propagation	Use as Food	Use as Feed	Importation for processing/ as processed commodity
			biodiversity effects expected (No commercial scale application has been approved to date)			assessments by local agencies
Public Participation/ Public Comment	Information posted on BCH and agency websites; Public comments invited on proposals, public consulted about regulations	Information posted on BCH and agency websites; Public comments invited on proposals, public consulted about regulations	Information posted on BCH and agency websites; Public comments invited on proposals, public consulted about regulations and pending applications	Information posted on BCH and agency websites; Public comments invited on proposals, public consulted about regulations and pending applications	Information posted on BCH and agency websites; Public comments invited on proposals, public consulted about regulations and pending applications	Information posted on BCH and agency websites; Public comments invited on proposals, public consulted about regulations and pending applications
Socioeconomic considerations	Bioethical considerations, public opinion and perception, potential marketability	Bioethical considerations, public opinion and perception, potential marketability	Bioethical considerations , public opinion and perception, potential marketability, over-all acceptability, labeling policy for consumer preference and right to know	Bioethical considerations, public opinion and perception, potential marketability, over-all acceptability, labeling policy for consumer preference and right to know	Bioethical considerations, public opinion and perception, potential marketability, over-all acceptability, labeling policy for consumer preference and right to know	Bioethical considerations, public opinion and perception, potential marketability, over-all acceptability, labeling policy for consumer preference and right to know
Approval Document	MSIP and RDA approval for Contained Work, import permit if applicable	RDA approval for field testing domestically developed GM crops in designated government fields, or RDA approval (with NIER input) for in-economy field testing GMOs that will be used as seed	Food safety approval from MFDS Feed safety approval from NAQS; environmental safety approval from RDA with input from NIER; import permit and other permits related to food or feed imports	1 of 3 types of food safety approvals issued by MFDS: (i) Full approval for GM crops currently produced or imported in commercial scale (ii) Conditional approval for discontinued crops (iii) Conditional approval for crops not grown commercially for human consumption Approval for environmental safety from RDA and MOE/ NIER Import permit from relevant agency (non-GM specific)	Approval for feed safety from NAQS Approval for environmental safety from RDA and MOE/ NIER Import permit from relevant agency (non-GM specific)	Approval for feed safety from MFDS (full or conditional) Approval for Feed safety from NAQS Approval for Environmental safety from RDA and MOE/ NIER Import permit from relevant agency (non-GM specific)
Restrictions or conditions	Contained Work only	Field test in government approved sites only; 1-3 years allowed depending on GM crop.	None specified (still no GM crop under commercial cultivation)	Labeling required as implemented by KFDA for processed foods containing GM ingredients, or as implemented by MIFAFF for unprocessed biotech crops	Labeling required for packaged animal feed products that contain GM ingredients Conventional Bulk shipments with unintentional GM presence below 3% exempt from label if with import permit or government certificate. Otherwise, label required.	In economy field test required for LMOs imported for use as seeds; for FFP, RDA will review the data from field trials conducted in the exporting economy, but may also require in economy field trials. Labeling required by MFDS: Mandatory labeling for 27 categories of foods if biotech crops are among

	Contained Work	Field tests	Commercial release/Propagation	Use as Food	Use as Feed	Importation for processing/ as processed commodity
						the top five ingredients in the finished product and if a foreign protein or DNA is present in the finished product; Threshold for unintentional presence is 3% Label required if one of top 5 ingredients derived from corn, soybean, cotton, canola, or sugarbeets, and DNA or protein detected in these ingredients.
Expiration of Approval Document	None specified	One year after approval	None specified	None specified	None specified	None specified
Renewal Provision	None specified	Yearly application for renewal	None specified	None specified	None specified	None specified

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MALAYSIA

Malaysia’s Biosafety Act of 2007 (Act 678) established the National Biosafety Board (NBB) to regulate the release, importation, exportation and contained work of LMOs and the release of products of such organisms. The Biosafety Act seeks to “protect human, plant, and animal health, the environment, and biological diversity” (as stated in the Act’s preamble), and specifically references the precautionary approach to biosafety matters “where there are threats of irreversible damage.”

The NBB is chaired by the Secretary-General of the Ministry of Natural Resources and Environment (MONRE), with representatives from six Ministries and no more than four other persons with “knowledge or experience or both in any of the disciplines or matters” relevant to the Act. The NBB appoints a Director General to facilitate the process and head the Department of Biosafety, which acts as the Secretariat and implementing arm of the NBB. The NBB is advised by the Genetic Manipulations Advisory Committee (GMAC) which also performs risk assessments and recommends risk management measures. At the institutional level, Institutional Biosafety Committees (IBCs) perform oversight functions to ensure compliance with any conditions imposed under Malaysian law and regulation.

Malaysia's existing regulations do not include specific provisions on the commercial scale cultivation or propagation of GMOs (Malaysia uses the term Living Modified Organisms, LMOs), although there are provisions that may allow field tests covering more than 10 hectares. Specific provisions in the Act also detail requirements for deliberate release of GMOs for sale and marketing, "as gift, prize or free item, Disposal, Remediation purposes", and "any other activity which does not amount to Contained Work" (Second Schedule, Section 3). Labeling of all GMOs and their products is mandatory according to Section 61 of the Act, and regulations were scheduled to be implemented in July 2012. Implementation of labeling regulations, however, has been deferred to an unspecified date. In its present form, the guidelines for labeling has a 3% threshold for each ingredient and exempts highly refined foods, products that do not contain novel proteins or novel DNA, animal products from animals fed with GM feeds, fermentation products from GM microorganisms and products using enzymes produced by GM organisms.

Malaysia has no regulation that specifically covers the commercial cultivation of any GM crop. The Ministry of Agriculture, through the Malaysia Agricultural Research and Development Institute (MARDI), is actively researching GM rice (tungro-virus resistance), papaya (ring spot virus resistance and prolonged shelf-life), pomelos (skin color), and passion fruit (resistance to mosaic virus). The Palm Oil Board and private companies are using modern biotechnology techniques to develop palm oil with high carotenoid and tocotrienol levels (Wahab 2012). Pineapples have been genetically modified for resistance to black heart disease, and work is ongoing to develop virus-resistance in chili peppers and delayed ripening in bananas.

Malaysia's Ministry of Agriculture & Agro-Based Industry and Ministry of Science, Technology and Innovations support biotechnology and actively seek investors to develop this sector, but MONRE actively advocates stricter regulations for biotechnology- derived crops and their products. To date, Malaysia has approved the importation of 6 corn and three soybean events for food and feed use, together with the approval of the Glacein™-Ice-Structuring Protein produced by modern biotechnology. Malaysia has likewise approved the importation of cut flowers of GM carnations, and the importation and use of GM technology-derived, trypsin-modulating oostatic factor (TMOF) peptide, formulated into a mousticide, and the importation of cut flowers of GM carnations. Limited work on GM animals has been done in Malaysia, although the NBB has approved the Institute of Medical Research's application for the Limited-Mark-Release-Recapture of a strain of genetically modified *Aedes aegypti* (L.) in October 2010.

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
Key Laws & Regulations	Biosafety Act of 2007 (Act 678) (promulgated 2009) Biosafety (Approval and Notification) Regulations 2010 Biosafety Guidelines for Contained Work Activity of Living Modified Organism (LMO) 2010 Guidelines for Institutional Biosafety Committees 2010	Biosafety Act of 2007 (Act 678) (promulgated 2009) Biosafety (Approval and Notification) Regulations 2010 Exemption under S68 of the Biosafety Act (5 October 2010)	Not covered by existing regulations	Biosafety Act of 2007 (Act 678) (promulgated 2009) Biosafety (Approval and Notification) Regulations 2010 Exemption under S68 of the Biosafety Act (5 October 2010)	Biosafety Act of 2007 (Act 678) (promulgated 2009) Biosafety (Approval and Notification) Regulations 2010 Exemption under S68 of the Biosafety Act (5 October 2010)	Biosafety Act of 2007 (Act 678) (promulgated 2009) Biosafety (Approval and Notification) Regulations 2010 Exemption under S68 of the Biosafety Act (5 October 2010) Food Regulations 1983, 1985

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
	Exemption under S68 of the Biosafety Act (5 October 2010)					
Implementing Agencies	Ministry of Environment and Natural Resources (MONRE) National Biosafety Board Genetic Manipulations Advisory Committee (GMAC) Department of Biosafety (DBS) Registered Institutional Biosafety Committees (IBCs)	MONRE NBB GMAC DBS IBCs	*Not Applicable, per above*	MONRE NBB GMAC DBS Food Safety and Quality Division of the Ministry of Health (FSQD-MOH)	MONRE NBB GMAC DBS Food Safety and Quality Division of the Ministry of Health (FSQD-MOH)	MONRE NBB GMAC DBS Food Safety and Quality Division of the Ministry of Health (FSQD-MOH)
Organisms covered	Plants, animals, arthropods, aquatic organisms, microorganisms	Plants, animals, arthropods, aquatic organisms, microorganisms	Not Applicable	Plants, Microorganism, Animals	Plants, Microorganism, Animals	Plants, Microorganism, Animals
Required submissions	Completed Notification Form from proponent submitted by IBC to NBB via the DBS[38] Emergency Response Plan (from Proponent and IBC) Specific measures for the Contained Work activity	Completed Application Form A (Research and Development activities involving Higher Plants) or Form B (Research and Development activities involving other organisms). Risk Assessment and Risk Management Report (from IBC) Emergency Response Plan (from Proponent and IBC) Other Information required by NBB	Not Applicable	Completed Application Form C (Non-Research and Development activities involving Higher Plants or products) or Form D (Non-Research and Development activities involving other LMOs or products) Risk assessment and risk management report Emergency response plan Other information specified by the NBB	Completed Application Form C (Non-Research and Development activities involving Higher Plants or products) or Form D (Non-Research and Development activities involving other LMOs or products) Risk assessment and risk management report Emergency response plan Other information specified by the NBB	Completed Application Form C (Non-Research and Development activities involving Higher Plants or products) or Form D (Non-Research and Development activities involving other LMOs or products) Risk assessment and risk management report Emergency response plan Other information specified by the NBB
Processing Fee	Required but amount not schedule of fees	< 5 ha: RM 100	Not Applicable	RM 5000	RM 5000	RM 5000

[38] NBB/N/CU/10/Form E: Notification for Contained Use and Import for Contained Use Activities Involving Living Modified Organism (LMO) for Biosafety Levels 1, 2, 3 and 4

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
		5 – 10 ha: RM 250 > 10 ha: 500 RM All others not covered by above schedule: RM 5000				
Processing time	90 days if information complete	180 days if information complete	Not Applicable	180 days if information complete	180 days if information complete	180 days if information complete
Risk Assessment	Initially performed by IBCs and subsequently reviewed by GMAC and other relevant government agencies	Initially performed by IBCs and subsequently reviewed by GMAC and other relevant government agencies Final assessment and decision made by NBB	Not Applicable	Review done by Food Safety and Quality Division of the Ministry of Health (FSQD-MOH) and GMAC. Considered as a deliberate release requires description of response measures in case of spills during unloading and transit. Final assessment and decision done by NBB	Review done by Food Safety and Quality Division of the Ministry of Health (FSQD-MOH) and GMAC. Considered as a deliberate release requires description of response measures in case of spills during unloading and transit. Final assessment and decision done by NBB	Review done by Food Safety and Quality Division of the Ministry of Health (FSQD-MOH) and GMAC. Considered as a deliberate release requires description of response measures in case of spills during unloading and transit. Final assessment and decision done by NBB
Public consultation/ Public Comment	None specified	Public disclosure via specifically formatted Fact Sheets Invitation for written submissions sent to NBB through DBS (regular or electronic mail, FAX)	Not Applicable	Public disclosure via specifically formatted Fact Sheets Invitation for written submissions sent to NBB through DBS (regular or electronic mail, FAX)	Public disclosure via specifically formatted Fact Sheets Invitation for written submissions sent to NBB through DBS (regular or electronic mail, FAX)	Public disclosure via specifically formatted Fact Sheets Invitation for written submissions sent to NBB through DBS (regular or electronic mail, FAX)
Socioeconomic considerations	Mainly addressed by funding agencies according to perceived national needs. Considers risk management and emergency response measures to ensure GMO containment	Considers effect of release on biodiversity, effects on existing crop production technologies in trial sites, cost of eradication or remediation in case of "escape" May consider effects on market of goods, social norms, and religious concerns	Not Applicable	Considers consequences in case of spills during unloading and transit. May consider effects on market of goods, social norms, and religious concerns	Considers consequences in case of spills during unloading and transit. May consider effects on market of goods, social norms, and religious concerns	Considers consequences in case of spills during unloading and transit. May consider effects on market of goods, social norms, and religious concerns
Approval Document	Notification accepted or additional measures (including cessation of activities) imposed by NBB; Import permit if necessary	Certificate of Approval from NBB; Import permit if necessary	Not Applicable	Certificate of Approval from NBB; Import permit if necessary Approval certificate valid for subsequent similar release activity involving the same LMO or products of such organisms or importation involving the same LMO	Certificate of Approval from NBB; Import permit if necessary Approval certificate valid for subsequent similar release activity involving the same LMO or products of such organisms or importation involving the same LMO	Certificate of Approval from NBB; Import permit if necessary Approval certificate valid for subsequent similar release activity involving the same LMO or products of such organisms or importation involving the same LMO

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
				when undertaken by the same approved person	when undertaken by the same approved person	when undertaken by the same approved person
Restrictions or conditions	Strictly for research and development purposes only Strict containment in facilities designated for appropriate Biosafety levels Fines and/or imprisonment as penalties for non-compliance	Strictly for research and development purposes only Strict confinement to trial sites Strict adherence to conditions of field trials Fines and/or imprisonment as penalties for non-compliance	Not Applicable	Review of approval if new information identifies new risks Requires that transit provisions on spills are followed Mandatory labeling regulations to be implemented later. Fines and/or imprisonment as penalties for non-compliance.	Review of approval if new information identifies new risks Requires that transit provisions on spills are followed Mandatory labeling regulations to be implemented later. Fines and/or imprisonment as penalties for non-compliance.	Review of approval if new information identifies new risks Requires that transit provisions on spills are followed Mandatory labeling regulations to be implemented later. Fines and/or imprisonment as penalties for non-compliance.
Expiration of Approval Document	None specified	As specified in the Certificate of Approval	Not Applicable	Valid until revoked or withdrawn	Valid until revoked or withdrawn	Valid until revoked or withdrawn
Renewal provisions	None specified	May apply for variation in application or submit new application	Not Applicable	Not Applicable	Not Applicable	Not Applicable

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MEXICO

Mexico's Law on the Biosafety of Genetically Modified Organisms provided for the formation of the Inter-Secretarial Commission on Biosafety of Genetically Modified Organisms (CIBIOGEM), and establishes "the foundation of biosafety regulations in Mexico and the institutional structure needed for this purpose" (Izaguirre et al. 2008). CIBIOGEM is made up of the heads of the Secretariats of: Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA); Environment and Natural Resources (SEMARNAT); Health (SAS); Public Education (SEP); Finance and Public Credit, and Economy (SHCP) and the General Director of the National Council for Science and Technology (CONACyT). CIBIOGEM is tasked with the formulation and

coordination the policies necessary for the implementation of the law. To carry out these functions, the Commission is aided by a Technical Committee of experts from the member Secretariats, a Scientific Advisory Committee made up of independent experts from various institutions, and a Mixed Advisory Committee made up of representatives from associations and societies from the private and public sectors.

The Biosafety law covers all activities related to the use of GMOs, from contained to commercial use, as well as the utilization of their products. The law and its accompanying regulations provides for special considerations to be given to ecologically sensitive areas, protected areas, centers of origins, and areas for organic agriculture. Such special considerations may provide for the declaration of special GMO-free zones based on the precautionary approach.

Activities involving releases are jointly regulated by SAGARPA and SEMARNAT, and use for food and feed of GMOs and their products are mainly regulated by SSA. The shared responsibility of regulating the introduction of GMOs into the environment is meant to create a check and balance in the decision-making process. For example, if the permit for the introduction of a new GMO is to be issued by SAGARPA (plants, animals and aquatic organisms), it must consider SEMARNAT's resolution on the GMO's potential impact on the environment and biological diversity. Likewise, if the issuance of the permit falls under SEMARNAT's purview (wildlife and biodiversity related), it must take into account SAGARPA's assessment of the GMO's safety. This process aimed "to guarantee transparency and impartiality" in the decision-making (Izaguirre et al. 2008).

The Biosafety Law on GMOs stipulates that any GMO for release must undergo a three-step process: experimental, pilot scale and commercial scale releases. Any GMO that will be imported into Mexico must also satisfy the official Mexican standards that apply to the specific product that is imported. The law also requires mandatory labeling of GM foods that are not equivalent to the conventional.

	Contained Work	Limited Field tests		Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
		Experimental Release	Release within Pilot Program				
Key Laws & Regulations	Law on Biosafety of GMOs 2005 Biosafety of GMOs Regulations 2008 Acuerdo por el que se determina la información y documentación que debe presentarse en caso de realizar actividades de utilización confinada y se da a conocer el formato único de avisos de utilización confinada de	Law on Biosafety of GMOs 2005 Biosafety of GMOs Regulations 2008 Decreto por el que se reforman, adicionan y derogan diversas disposiciones del Reglamento de la Ley de Bioseguridad de Organismos Genéticamente Modificados 2009 2012 Agreement to Determine the Centers	Law on Biosafety of GMOs 2005 Biosafety of GMOs Regulations 2008 Decreto por el que se reforman, adicionan y derogan diversas disposiciones del Reglamento de la Ley de Bioseguridad de Organismos Genéticamente Modificados 2009 2012 Agreement to Determine the Centers	Law on Biosafety of GMOs 2005 Biosafety of GMOs Regulations 2008 Decreto por el que se reforman, adicionan y derogan diversas disposiciones del Reglamento de la Ley de Bioseguridad de Organismos Genéticamente Modificados 2008 Ley Federal de Producción,	Law on Biosafety of GMOs 2005 Biosafety of GMOs Regulations 2008 Ley General de Salud 1990 Decreto por el que se reforman, adicionan y derogan diversas disposiciones del Reglamento de la Ley de Bioseguridad de Organismos	Law on Biosafety of GMOs 2005 Biosafety of GMOs Regulations 2008 Ley General de Salud 1990 Ley Federal de Sanidad Animal 2007 Decreto por el que se reforman, adicionan y derogan diversas disposiciones del Reglamento de la Ley de Bioseguridad de	Law on Biosafety of GMOs 2005 Biosafety of GMOs Regulations 2008 Ley General de Salud 1990 Decreto por el que se reforman, adicionan y derogan diversas disposiciones del Reglamento de la Ley de Bioseguridad de Organismos

	Contained Work	Limited Field tests		Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
		Experimental Release	Release within Pilot Program				
	organismos genéticamente modificados 2011 Ley General de Salud (applies to experiments and research related to human health) 1990	of Origin and Centers of Genetic Diversity of Corn in Mexico 2014 Official Mexican Norm that establish characteristics and content of the report or results of releases of GMO	of Origin and Centers of Genetic Diversity of Corn in Mexico 2014 Official Mexican Norm that establish characteristics and content of the report or results of releases of GMO	Certificación y Comercio de Semillas 2007 2012 Agreement to Determine the Centers of Origin and Centers of Genetic Diversity of Corn in Mexico	Genéticamente Modificados 2009	Organismos Genéticamente Modificados 2009	Genéticamente Modificados 2009
Implementing Agencies	Inter-Ministerial Commission on GMO Biosafety (CIBIOGEM; policy and coordination) Ministry of Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA), through its National Service of Health, Food Safety, and Food Quality (SENASICA) Ministry of Environment and Natural Resources (SEMARNAT) Ministry of Health (SSA), through the Federal Commission for the Protection against Sanitary Risk (COFEPRIS), if applicable	CIBIOGEM (policy and coordination) SAGARPA SEMARNAT SSA/COFEPRIS	CIBIOGEM (policy and coordination) SAGARPA SEMARNAT SSA/COFEPRIS	CIBIOGEM (policy and coordination) SAGARPA SEMARNAT SSA/COFEPRIS	CIBIOGEM (policy and coordination) SSA	CIBIOGEM (policy and coordination) SSA	CIBIOGEM (policy and coordination) SSA SAGARPA through SENASICA Ministry of Finance and Public Credit (SHCP; for commodity importation, customs and labeling of GMO and products)
Coverage	Recombinant Bacteria, Viruses, Fungi, plants, animals; for teaching, research and commercial production under containment	All Genetically Modified Organisms (GMO) released into the environment	All Genetically Modified Organisms (GMO) released into the environment	All Genetically Modified Organisms (GMO) released into the environment	GM ingredients, plants, animals, microorganisms	GM ingredients, plants, animals, microorganisms	GM ingredients, plants, animals, microorganisms
Required submissions	Notification document reviewed	Completed application form (in Spanish) for	Completed application form (in Spanish) for	Completed application form (in Spanish) for	Completed application form for each GMO (in	Completed application form for each GMO (in	Completed application form for each GMO (in

	Contained Work	Limited Field tests		Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
		Experimental Release	Release within Pilot Program				
	and endorsed by Internal Biosafety Commission (IBC) to SENASICA (format specified by Acuerdo…") Document detailing description of inserted gene(s), host, GM characteristics, planned activities, containment measures and facilities for handling, storage, importation (if necessary), transport, destruction and disposal, and actions to be taken in case of accidental release to environment	permit for the experimental release of GMO (also providing information about applicant) GMO characterization Identification of the zone(s) where the GMO release is intended Potential risks to the environment and biological diversity Biosafety monitoring measures and procedures Background of release in other countries Authorization number from SSA (if applicable) Documentation of release in country of origin (if applicable) Other information as determined by Official Mexican Standards for the organism in question Two electronic copies of application and attachments also submitted Report of results of the environmental release (2014 NOM)	permit to release GMOs in a pilot program (also providing information about applicant) Identification data of the experimental release permit or copy of experimental release permit Report on results of experimental releases Quantity of GMO to be released Handling conditions for GMO Identification of the zone(s) where the GMO release is intended Biosafety monitoring measures and procedures Authorization number from SSA (if applicable) Documentation of release in country of origin (if applicable) Proposal for the term of permit Other information as determined by Official Mexican Standards for the organism in question Two electronic copies of application and attachments also submitted	permit to release GMOs in commercial scale (also providing information about applicant) Identification data of the experimental release permit and of the release Permit in the pilot program, or copy of permit Description of the area where the release shall be performed (municipality, state) Report on results for experimental release and pilot program release Specific instructions or recommendations for transportation in accordance with Official Mexican standards for the specific commodity, as well as for storage and handling Conditions for commercial release (if applicable) Considerations about the risks of alternative technological options Information on marketing of same GMO in other countries If imported, legal documents that prove the GMO is approved	Spanish) for authorization of use of GMO for food (also providing information about applicant) Assessment of potential risks to human health due to consumption of GMO (includes data on host, donor, gene and GMO characteristics; nucleotide sequences, gene stability, protein expression and characteristics, allergenicity and toxicity, nutritive value, substantial equivalence to conventional counterpart, (if applicable), conventional use and consumption patterns, storage characteristics For combination of genes, additional information on GM parental characteristics, metabolic pathways, gene stability in parentals Other information as determined by Official Mexican Standards for the organism or food in question Two electronic copies of application and attachments also submitted	Spanish) for authorization of use of GMO for feed (also providing information about applicant) Assessment of potential risks to human health due to consumption of GMO (includes data on host, donor, gene and GMO characteristics; nucleotide sequences, gene stability, protein expression and characteristics, allergenicity and toxicity, nutritive value, substantial equivalence to conventional counterpart, (if applicable), conventional use and consumption patterns, storage characteristics For combination of genes, additional information on GM parental characteristics, metabolic pathways, gene stability in parentals Other information as determined by Official Mexican Standards for the organism or food in question Two electronic copies of application and attachments also submitted	Spanish) for authorization of use of GMO for processing for human consumption (also providing information about applicant) Assessment of potential risks to human health due to consumption of GMO (includes data on host, donor, gene and GMO characteristics; nucleotide sequences, gene stability, protein expression and characteristics, allergenicity and toxicity, nutritive value, substantial equivalence to conventional counterpart, (if applicable), conventional use and consumption patterns, storage characteristics For combination of genes, additional information on GM parental characteristics, metabolic pathways, gene stability in parentals Other information as determined by Official Mexican Standards for the organism or food in question Two electronic copies of application and attachments also submitted

	Contained Work	Limited Field tests		Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
		Experimental Release	Release within Pilot Program				
			Report of results of the environmental release (2014 NOM)	for release in the country of origin Other information as determined by Official Mexican Standards for the organism in question Two electronic copies of application and attachments also submitted			
Processing Fee	None specified	Required but amount not specified	Required but amount not specified	Required but amount not specified	Required but amount not specified	Required but amount not specified	Required but amount not specified
Processing time	None specified	6 months	3 months	4 months	6 months	6 months	6 months
Risk Assessment	Performed by the proponent and IBC, may be reviewed by SAGARPA (through SENASICA) and/or SEMARNAT SSA may make independent review as appropriate Science-based, case by case	Performed by SAGARPA if GMO permit to be issued SEMARNAT Performed by SEMARNAT if GMO permit to be issued SAGARPA Inputs from SSA if applicable Science-based, case-by-case	Performed by SAGARPA if GMO permit to be issued SEMARNAT Performed by SEMARNAT if GMO permit to be issued SAGARPA Inputs from SSA if applicable Science-based, case-by-case	Performed by SAGARPA if GMO permit to be issued SEMARNAT Performed by SEMARNAT if GMO permit to be issued SAGARPA Inputs from SSA if applicable Science-based, case-by-case	Performed by SSA with input from SAGARPA through SENASICA Science-based, case by case	Performed by SSA with input from SAGARPA through SENASICA Science-based, case by case	Performed by SSA with input from SAGARPA through SENASICA Science-based, case by case
Public participation	None specified	Public comments invited for each new regulation Immediate posting of application, invitation of written opinions, comments from public via regular or electronic mail Scientifically-based public input incorporated in decision-making process	Public comments invited for each new regulation Immediate posting of application, invitation of written opinions, comments from public via regular or electronic mail Scientifically-based public input incorporated in decision-making process	Public comments invited for each new regulation Immediate posting of application, invitation of written opinions, comments from public via regular or electronic mail Scientifically-based public input incorporated in decision-making process	Public comments invited for each new regulation Immediate posting of application, invitation of written opinions, comments from public via regular or electronic mail Scientifically-based public input incorporated in decision-making process	Public comments invited for each new regulation Immediate posting of application, invitation of written opinions, comments from public via regular or electronic mail Scientifically-based public input incorporated in decision-making process	Public comments invited for each new regulation Immediate posting of application, invitation of written opinions, comments from public via regular or electronic mail Scientifically-based public input incorporated in decision-making process

	Contained Work	Limited Field tests		Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
		Experimental Release	Release within Pilot Program				
Socioeconomic considerations	None specified	Special consideration for protected areas, ecologically sensitive areas, areas of origin, areas reserved for organic production	Special consideration for protected areas, ecologically sensitive areas, areas of origin, areas reserved for organic production	Special consideration for protected areas, ecologically sensitive areas, areas of origin, areas reserved for organic production	Special consideration for ethnic group preferences for landraces, areas reserved for organic production Mandatory labeling in those cases where GMO food composition or their nutritious properties are significantly different from the respective conventional products	Special consideration for ethnic group preferences for landraces, areas reserved for organic production Mandatory labeling in those cases where GMO food composition or their nutritious properties are significantly different from the respective conventional products	Special consideration for ethnic group preferences for landraces, areas reserved for organic production Mandatory labeling in those cases where GMO food composition or their nutritious properties are significantly different from the respective conventional products
Approval Document	Acknowledgment of notification sufficient unless “activity is cancelled,” work is prohibited, or more stringent biosafety measures are imposed.	Permit for experimental release issued by SAGARPA or SEMARNAT, depending on GMO being released	Permit to release GMOs in a pilot program issued by SAGARPA or SEMARNAT, depending on GMO being released	Permit to release GMOs in a commercial scale issued by SAGARPA (Through SENASICA) or SEMARNAT, depending on GMO being released	Authorization	Authorization	Authorization Import permit
Restrictions or conditions	Strictly for Contained Work Transport of GMO to unapproved facilities prohibited Import/export require permits Record keeping strictly required Notification required for facilities used for the first time SENASICA may conduct random inspection	As specified by permit. SAGARPA or SEMARNAT may impose additional isolation, measurement or monitoring measures to enhance material management Additional restrictions on maize Report required upon completion of activities	As specified by permit. SAGARPA or SEMARNAT may impose additional isolation, measurement or monitoring measures to enhance material management Additional restrictions on maize Report required upon completion of activities	As specified by permit Seeds certified prior to commercial cultivation Mandatory labeling for GM seeds Additional restrictions on maize	As specified by approval document	As specified by approval document	As specified by approval document Not for cultivation
Expiration of Approval Document	None specified; may be specified in notification	As specified by proponent and approved by office issuing permit	As specified by proponent and approved by office issuing permit	Valid until revoked	Valid until revoked	Valid until revoked	Valid until revoked

	Contained Work	Limited Field tests		Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
		Experimental Release	Release within Pilot Program				
Provisions for renewal	None specified	None specified, but may apply for variation in the permit issued or reapply for new permit	None specified, but may apply for variation in the permit issued or reapply for new permit	Not applicable	Not applicable	Not applicable	Not applicable

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NEW ZEALAND

New Zealand's regulation of activities dealing with GMOs falls mainly under the Hazardous Substances and New Organisms (HSNO) Act of 1996, which has been revised several times to reflect changes in government ministries and public sentiments. All regulations dealing with new organisms (GM is classified as a new organism) undergo public notification or hearing before implementation. All applications for the use of new organisms are available to the public, except for sections that contain confidential information. The New Zealand regulations consider several socioeconomic points in approving activities involving the study, development, cultivation, and use of GMOs.

HSNO regulations are implemented by the Environmental Protection Authority (EPA), with the Ministry for Primary Industries (MPI) mainly responsible for regulating the use of GMOs for food, feed and processing. The HSNO Act specifically requires that the EPA consider the principles of the Treaty of Waitangi in making decisions, i.e., that HSNO decision-makers act in good faith to make informed decisions that protect the interests of the Māori people in New Zealand.[39]

Use of GMOs and GM-derived foods are regulated by the Food Act and the Australia New Zealand Food Standards Code under Standard 1.5.2 Food Produced Using Gene Technology. Animal feed is classified as an Oral Nutritional Compound (ONC) and as such is regulated under the Agricultural Compounds and Veterinary Medicines (ACVM) Act of 1997 and the ACVM Regulations of 2001. New Zealand has not approved any large-scale environmental releases of GMOs, and so far has confined GMO activities to the use of GM technology for research. To date, canola, corn, cotton, alfalfa, potato, rice, soybean and sugar beets have been approved as food or feed in New Zealand.

	Contained Work	Limited Field tests (Outdoor containment)	Commercial release		Use as Food	Use as Feed	Importation for processing/ as processed commodity
			Release with controls	Release without controls			
Key Laws & Regulations	Hazardous Substances and New Organisms Act 1996 (HSNO Act) (as amended, as of October 2012) Environmental Protection	HSNO Act 1996 (as amended, as of October 2012) Environmental Protection Authority Act 2011 Biosecurity Act 1993	HSNO Act 1996 (as amended, as of October 2012) Environmental Protection Authority Act 2011 Biosecurity Act 1993 HSNO (Genetically Modified Organisms -	HSNO Act 1996 (as amended, as of October 2012) Environmental Protection Authority Act 2011 Biosecurity Act 1993	Food Act of 1981 Australia New Zealand Food Standards Code 1991 - Standard 1.5.2 - Food Produced Using Gene Technology HSNO Act 1996 (as amended, as of October	Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 ACVM Regulations 2001	Food Act of 1981 Australia New Zealand Food Standards Code 1991 - Standard 1.5.2 - Food Produced Using Gene Technology HSNO Act 1996 (as amended, as of

[39] As per Chapter 3, "Treaty Principles, Rights, and Obligations" of the Waitangi Treaty; see http://www.waitangi-tribunal.govt.nz/reports/viewchapter.asp?reportID=8B60D3D9-A7F5-45B4-9605-F065D6645155&chapter=4. To ensure that Māori interests are addressed, at least one of the 6-8 members of the EPA Board is a person with expertise on Māori customary values and practices as defined by the Treaty of Waitangi. The EPA also has an external Māori statutory advisory committee, comprised of 4-8 people.

	Contained Work	Limited Field tests (Outdoor containment)	Commercial release		Use as Food	Use as Feed	Importation for processing/ as processed commodity
			Release with controls	Release without controls			
	Authority Act 2011 HSNO (Low-Risk Genetic Modification) Regulations 2003 Biosecurity Act 1993		Information Requirements for Segregation and Tracing) Regulations 2008		2012)- for live or viable GMOs Biosecurity Act of 1993 - for live or viable GMOs Imports and Exports (Living Modified Organisms) Prohibition Order 2005 BNZ-GCFP-PHR Standard (Biosafety New Zealand Importation of Grains/Seeds for Consumption, Feed or Processing: Plant Health Requirements) 2011	HSNO Act as amended (as of October 2012)- for live or viable GMOs Biosecurity Act of 1993 - for live or viable GMOs Imports and Exports (Living Modified Organisms) Prohibition Order 2005 BNZ-GCFP-PHR Standard (Biosafety New Zealand Importation of Grains/Seeds for Consumption, Feed or Processing: Plant Health Requirements) 2011	October 2012)- for live or viable GMOs Biosecurity Act of 1993 - for live or viable GMOs Imports and Exports (Living Modified Organisms) Prohibition Order 2005 BNZ-GCFP-PHR Standard (Biosafety New Zealand Importation of Grains/Seeds for Consumption, Feed or Processing: Plant Health Requirements) 2011
Implementing Agencies	Ministry for the Environment (MFE) Environmental Protection Authority (EPA) Ministry for Primary Industries (MPI) Institutional Biological Safety Committee (IBSC)	Ministry for the Environment (MFE) Environmental Protection Authority (EPA) Ministry for Primary Industries (MPI)	Ministry for the Environment (MFE) Environmental Protection Authority (EPA) Ministry for Primary Industries (MPI)	Ministry for the Environment (MFE) Environmental Protection Authority (EPA) Ministry for Primary Industries (MPI)	Food Standards Australia New Zealand (FSANZ) Australia New Zealand Food Standards Council EPA (if GMO is live or viable) MPI -NZ Food Safety Authority (NZFSA) MPI (More prominent role expected if new Food Bill is passed by Parliament)	MPI-ACVM Group NZFSA EPA (if GMO is live or viable)	FSANZ Australia New Zealand Food Standards Council EPA (if GMO is live or viable) MPI Food Safety Authority MPI (More prominent role expected if new Food Bill is passed by Parliament)
Organisms covered	All genetically modified organisms (GMO)	All GMOs	All GMOs	All GMOs	All GMOs	All GMOs	All GMOs

	Contained Work	Limited Field tests (Outdoor containment)	Commercial release		Use as Food	Use as Feed	Importation for processing/ as processed commodity
			Release with controls	Release without controls			
Required submissions[40]	Completed application form with information on: • Applicant • Proposed activity • Location and description of facility • Purpose of activity • Information on Genetically modified organism (biology, relationship to relevant NZ organisms, description of genetic modifications) • Proposed containment (physical, biological and operational) • Details of engagement with Maori (if applicable) • Assessment of risks and benefits from the proposed activity with the GM organism • References	Completed application form with information on: • Applicant • Proposed activity • Purpose of activity • Information on Genetically modified organism (biology, relationship to relevant NZ organisms, description of genetic modifications) • Nature and method of field test • Proposed containment (physical, biological and operational) within field site • Details of engagement with Māori (if applicable) • Assessment of risks and benefits from the proposed activity with the GM organism • Possible effects resulting from the transfer of genetic elements to other organisms in or around the site of the field test • References	Completed application form with information on: • Applicant • Proposed activity • Purpose of activity • Information on Genetically modified organism (biology, relationship to relevant NZ organisms, description of genetic modifications) • Nature and method of field test • Proposed containment (physical, biological and operational) within field site • Details of engagement with Māori • Assessment of risks and benefits from the proposed activity with the GM organism • Proposed controls to manage or mitigate risks • Segregation and tracing measures • References	Completed application form with information on: • Applicant • Proposed activity • Purpose of activity • Information on Genetically modified organism (biology, relationship to relevant NZ organisms, description of genetic modifications) • Nature and method of field test • Proposed containment (physical, biological and operational) within field site • Details of engagement with Māori • Assessment of risks and benefits from the proposed activity with the GM organism • Reference	Detailed information on genetic material, new protein characteristics (particular attention on toxicity and allergenicity), food composition and nutritional quality[41] Import Permit from MPI Plant Imports, Plant, Food & Environment Directorate	Filled up Application form for Alteration of the Register of Substances Generally Recognized as Safe (GRAS) for oral nutritional compounds, providing information on, as applicable: • Applicant • Substance information • Safety information including listing in safety registers of other economies • Rationale and data to support the inclusion of the substance on the GRAS register other economies • Suitability as feed to target animal • Declaration on status of the GMO as food or feed in country of origin • History of safety in the context of use • References	Detailed information on genetic material, new protein characteristics (particular attention on toxicity and allergenicity), food composition and nutritional quality Import Permit from MPI Plant Imports, Plant, Food & Environment Directorate
Processing Fee	Pre-application consultation fees: variable, case-by-case Publicly notified (as determined by chief	Pre-application consultation fees: variable, case-by-case Publicly notified (as determined by chief executive, invites	Pre-application consultation fees: variable, case-by-case Negotiated	Pre-application consultation fees: variable, case-by-case Negotiated	FSANZ: US$ 10,225 for import. Not fixed, extra fee may apply depending on the duration of safety assessment Import Permit from MPI Plant Imports, Plant, Food	None for the application as GRAS, but fees charged for consultations Import Permit from MPI Plant Imports, Plant, Food & Environment	FSANZ: US$ 10,225 for import. Not fixed, extra fee may apply depending on the duration of safety assessment

	Contained Work	Limited Field tests (Outdoor containment)	Commercial release		Use as Food	Use as Feed	Importation for processing/ as processed commodity
			Release with controls	Release without controls			
	executive, requires public submissions or hearing) application: NZ$11,500 + disbursements Not Publicly notified (determined as low risk) application: NZ$1,150 Import by rapid assessment [based on HSNO (Low-Risk Genetic Modification) Regulations 2003] application: NZ$ 575 Fees for IBSC delegation: NZ$ 575, + separate fees for amendments and renewals Fees for audit of implementation of delegation (IBSC): NZ$ $4,600	public submissions or hearing) application: NZ$11,500 + disbursements Not Publicly notified application: NZ$2,300			& Environment Directorate: NZ$166.62	Directorate: NZ$166.62	Import Permit from MPI Plant Imports, Plant, Food & Environment Directorate: NZ$166.62

[40] Forms may be found at the following: http://www.epa.govt.nz/new-organisms/find-application-form/application-finder/Pages/default.aspx

[41] Applications are usually finalized following a series of consultations with regulators. Details may be obtained from the FSANZ Applications Handbook downloadable from http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx

	Contained Work	Limited Field tests (Outdoor containment)	Commercial release		Use as Food	Use as Feed	Importation for processing/ as processed commodity
			Release with controls	Release without controls			
Processing time	Exclusive of time for pre-application discussions, compliance with requests for additional information: If publicly notified, 100 working days after receipt of application If non-notified 60 working days after receipt of application For rapid assessment, 10 working days after receipt of application	Exclusive of time for pre-application discussions, compliance with requests for additional information: If publicly notified, 100 working days after receipt of application If non-notified 60 working days after receipt of application For rapid assessment, 10 working days after receipt of application	Exclusive of time for pre-application discussions, compliance with requests for additional information, 100 working days after receipt of application. Time may be variable depending on complexity of application	Exclusive of time for pre-application discussions, compliance with requests for additional information, 100 working days after receipt of application. Time may be variable depending on complexity of application.	Variable duration of assessment by FSANZ Import permit from MPI (all agricultural commodities): 15 working days after receipt of import permit application	Variable duration of assessment by ACVM and NZFSA Import permit from MPI (all agricultural commodities): 15 working days after receipt of import permit application	Variable duration of assessment by FSANZ Import permit from MPI (all agricultural commodities): 15 working days after receipt of import permit application
Risk Assessment	Review of risk assessment done by qualified IBSC or by Advisors who evaluate the application and submissions. A report or draft decision is then forwarded to the Decision-Making Committee or the Decision Maker Assessment based on possible effects on NZ biodiversity, suitability of containment facilities, procedures and management to prevent escape from containment,	Review of risk assessment done by Advisors who evaluate the application and submissions. A report or draft decision is then forwarded to the Decision-Making Committee or the Decision Maker Assessment based on possible effects on NZ biodiversity, suitability of containment facilities, procedures and management to prevent escape from containment, biology of GM organism, and consequences of possible gene flow Assessment considers risks and benefits that may result from the	Review of risk assessment done by Advisors who evaluate the application and submissions. A report or draft decision is then forwarded to the Decision-Making Committee or the Decision Maker Assessment based on possible risks to human health and environment and to bio- and cultural diversity; favorable risk-benefit ratio; protection of biodiversity and sustainable utilization of resources; protection of Māori's and Māori culture's relationship with environment Release approvals granted if GMO will not significantly displace any native species, destroy habitats, reduce biodiversity , or cause	Review of risk assessment done by Advisors who evaluate the application and submissions. A report or draft decision is then forwarded to the Decision-Making Committee or the Decision Maker Assessment based on possible risks to human health and environment and to bio- and cultural diversity; favorable risk-benefit ratio; protection of biodiversity and sustainable utilization of resources; protection of Māori's and Māori culture's relationship with environment Release approvals granted if GMO will not significantly displace any native species, destroy habitats, reduce biodiversity , or cause	Case-by-case according to FSANZ's approved safety assessment criteria. FSANZ safety standards based on concepts and principles developed through international organizations such as the World Health Organization; considers new genetic material, new proteins, and new properties of food	Done by ACVM and second party peer review by NZFSA Considers history of safety in context of use, listing in other registries, suitability for target animal	Case-by-case according to FSANZ's approved safety assessment criteria. FSANZ safety standards based on concepts and principles developed through international organizations such as the World Health Organization; considers new genetic material, new proteins, and new properties of food

	Contained Work	Limited Field tests (Outdoor containment)	Commercial release		Use as Food	Use as Feed	Importation for processing/ as processed commodity
			Release with controls	Release without controls			
	biology of GM organism. Assessment considers risks and benefits that may result from the proposed activity	proposed activity. Steps in the risk assessment include identification of points that may concern Māori ways how to address such issues	harm to human health and environment Control measures imposed in cases GMO presence poses a threat to an existing industry	harm to human health and environment			
Public Participation / Public Comment	All applications uploaded in EPA website. EPA may require public notification or public hearing based on nature of proposed activity and of GMO Notification usually done by publication in four main newspapers- EPA then invites submissions from the public	All applications uploaded in EPA website. EPA may require consultation with Māori, public notification or public hearing based on nature of proposed activity and of GMO. Notification usually done by publication in four main newspapers - EPA then invites submissions from the public	Consultation with the Māori required 30-day public notification with invitation for submissions from public required. All applications uploaded in EPA website. Public hearing may be requested by public, applicant or EPA	Consultation with the Māori required 30-day public notification with invitation for submissions from public required. All applications uploaded in EPA website. Public hearing may be requested by public, applicant or EPA	Public notification with invitation for public submissions	Public notification by posting in in NZFSA website and inviting public submissions for 15 working days	Public notification with invitation for public submissions
Socioeconomic considerations	All decisions on the import to New Zealand of GMOs, take into account socioeconomic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity and possible adverse effects on indigenous communities	All decisions on the import to New Zealand of GMOs, take into account socioeconomic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity and possible adverse effects on indigenous communities.	Risk-benefit assessment is a major consideration for approval GMO effect on bio- and cultural diversity is considered Māori's and Māori culture's relationship with environment protected	Risk-benefit assessment is a major consideration for approval GMO effect on bio- and cultural diversity is considered Māori's and Māori culture's relationship with environment protected	Public submissions considered in decision making process	Public submissions considered in decision making process	Public submissions considered in decision making process

	Contained Work	Limited Field tests (Outdoor containment)	Commercial release		Use as Food	Use as Feed	Importation for processing/ as processed commodity
			Release with controls	Release without controls			
Approval Document	Approvals given by decision-makers (selected members of the HSNO Decision Making Committee) Approval posted in EPA website	Approvals given by decision-makers (selected members of the HSNO Decision Making Committee) Approval posted in EPA website	Approvals given by decision-makers (selected members of the HSNO Decision Making Committee) Approval to be posted in MPI website	Approvals given by decision-makers (selected members of the HSNO Decision Making Committee) Approval to be posted in MPI website	Incorporated into the Food Code as amendments (Becomes part of the list of foods approved under Standard 1.5.2)	GM feed component added to Gras Register via New Zealand Gazette.	Incorporated into the Food Code as amendments (Becomes part of the list of foods approved under Standard 1.5.2)
Restrictions or conditions	Proposed activities may be done only in facilities approved by MPI Strict adherence to containment requirements Movement of GMO outside approved containment facilities need prior approval from EPA Export of GMO generated in containment require prior approval from MFE and MPI	Field trial should be done under conditions similar to those of the environment into which the new organisms are likely to be released; GMO or any heritable material arising from them should be retrieved or destroyed at the end of the field test. Procedures and activities should ensure that the GMO or the introduced genes do not escape the test site. All field tests inspected and monitored regularly to ensure compliance with imposed conditions Viable biological material must be destroyed at the end of the contained field test Movement of GMO outside approved containment facilities need prior approval from EPA Export of GMO generated from site	Control measures observed (may include restrictions on location and area planted, buffer zones, physical or biological barriers to gene flow; temporal, biological or physical isolation) Segregation and tracing measures followed. Export of GMO generated from site require prior approval from MFE and MPI	No restrictions in New Zealand under HSNO Act Export of GMO generated from site require prior approval from MFE	Labeling requirement implemented by MPI Food Safety Authority < 0.1% labeling threshold for approved flavoring from GM <1% labeling threshold for approved GM ingredient No label required for approved highly processed food Zero tolerance for GM food not approved listed in food code Requires import permit from MPI Plant Imports, Plant, Food & Environment Directorate	None specified if GM component classified as GRAS	Labeling requirement implemented by MPI Food Safety Authority < 0.1% labeling threshold for approved flavoring from GM <1% labeling threshold for approved GM ingredient No label required for approved highly processed food Zero tolerance for GM food not approved listed in food code Requires import permit from MPI Plant Imports, Plant, Food & Environment Directorate

	Contained Work	Limited Field tests (Outdoor containment)	Commercial release		Use as Food	Use as Feed	Importation for processing/ as processed commodity
			Release with controls	Release without controls			
		require prior approval from MFE and MPI					
Expiration of Approval Document	As specified in the approval document	As specified in the approval document	As specified in the application and approval document, or if none specified in the application, five years after approval is granted	Not specified	Valid until food is removed from list	Valid while GM feed is in the GRAS register	Valid until food is removed from list
Renewal Provisions	May be renewed by submitting an amendment to original application or submitting a new application	May be renewed by submitting an amendment to original application or submitting a new application	Application for new approval	Not specified	Not applicable	Not applicable	Not applicable

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PAPUA NEW GUINEA

Biotechnology-related activities in Papua New Guinea are limited. Few of its research and academic institutions have advanced biotechnology capabilities. Most research and academic institutions use tissue culture technology extensively, and only a few laboratories are equipped to perform molecular diagnostics, DNA fingerprinting and DNA sequencing (Komolok 2004). No local transformation has been carried out in any of the research laboratories, although local plant varieties have undergone molecular transformations in laboratories abroad. Papua New Guinea's Second National Report to the Biosafety Clearing-House states that there is "anecdotal evidence of intentional and unintentional introduction of GMOs/LMOs but no legal mechanism to enforce"[42] restrictions on unsanctioned introductions.

Papua New Guinea does not have specific legislation that deals with genetically modified organisms or their uses, but a National Biosafety Framework (NBF) has been drafted, including a draft Biosafety and Biotechnology Bill. The NBF was endorsed by the National Executive Council in 2009, but the draft Bill is yet to be enacted by the Cabinet. The draft Biosafety & Biotechnology Bill identifies the Department of Environment and Conservation (DEC) as the National Competent Authority in charge of implementing the provisions of the Bill. In its current form, the draft bill requires creation of the Biosafety and Biotechnology Council (NBBC), administered by the DEC. The draft Bill also includes the set of regulations that specifies information required for a Genetically Modified Organism License, a Risk Assessment Plan, and Field Testing Regulations. It does not include any provisions for the commercial propagation and use of GMOs.

The Papua New Guinea NBF highlights the biological and cultural diversity of the Economy, and places emphasis on conservation and sustainable use of its resources. It specifies a precautionary approach to the introduction of GMOs into the environment, and highlights the requirement for an advanced informed agreement for import and export of GMOs. The NBF also includes provisions for public information and participation via oral or written submissions. The risk assessment and risk management provisions of the NBF specifically requires due consideration be given to impacts to human health, environment, other organisms, contribution to sustainable development, all socioeconomic impacts, and conformity with ethical, cultural, and traditional values and norms of the PNG people (paragraph 32 of the NBF), as well as inputs from other government agencies. The bill also stipulates that "a performance bond in the prescribed form shall be lodged with a bank approved by the Competent National Authority by a license holder."

According to Papua New Guinea's Biosafety Clearing-House report, the DEC is presently designated as the Competent National Authority, and "there are existing legislations that are not specific to LMO's but are broad enough to accommodate LMO concerns such as existing quarantine laws that may be applicable in the case of an illegal transboundary movement of exotic organisms that may include LMO's." The DEC also administers the Environment Act 2000, which "provides the administrative mechanism for environmental impact assessment and evaluation of activities regulating impacts on the receiving

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42 http://bch.cbd.int/database/record.shtml?documentid=102486.

environment through an established environment approval and permitting system." No local transformation, field trials, or commercial propagation of GMOs have been done in Papua New Guinea, nor has the Economy received any application for such a purpose. As such, the Environment Act 2000 has not yet been applied to any GMO-related activity.

Use of GMOs for food is presumably regulated by the National Health Department, which administers the Food Safety Code and the Food Sanitation Act. Most of the food laws of PNG are adopted from Australian food laws. The Codex Alimentarius reported that, as of 2006, the PNG was finalizing its food regulations "and is using Codex standards for this purpose" (Codex Alimentarius 2007, 8).

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
Key Laws & Regulations	National Agriculture Quarantine and Inspection Authority Act 1997	National Agriculture Quarantine and Inspection Authority Act 1997 Plant Disease and Control Act 1986 & Regulations	Not specified	Food Safety Code 2003 Food Sanitation Act 1991 National Agriculture Quarantine and Inspection Authority Act 1997	National Agriculture Quarantine and Inspection Authority Act 1997	National Agriculture Quarantine and Inspection Authority Act 1997
Implementing Agencies	National Agriculture Quarantine and Inspection Authority	National Agriculture Quarantine and Inspection Authority	*Not applicable, per above*	Food Sanitation Council; National Health Department National Agriculture Quarantine and Inspection Authority	National Agriculture Quarantine and Inspection Authority	Food Sanitation Council; National Health Department National Agriculture Quarantine and Inspection Authority
Organisms covered	All organisms	All organisms	*Not applicable, per above*	All organisms	All organisms	All organisms
Required submissions	Completed application form for specific for the organism and exporting economy (for import only)	Completed application form for specific for the organism and exporting economy (for import only)	*Not applicable, per above*	Completed application form for specific for the organism and exporting economy (for import only)	Completed application form for specific for the organism and exporting economy (for import only)	Completed application form for specific for the organism and exporting economy (for import only)
Processing Fee	Depends on organism, type of permit and action required from quarantine officers	Depends on organism, type of permit and action required from quarantine officers	*Not applicable, per above*	Depends on organism, type of permit and action required from quarantine officers	Depends on organism, type of permit and action required from quarantine officers	Depends on organism, type of permit and action required from quarantine officers
Processing time	variable	variable	*Not applicable, per above*	variable	variable	variable
Risk Assessment	Standard Pest Risk Analysis and phytosanitary criteria	Standard Pest Risk Analysis and phytosanitary criteria	*Not applicable, per above*	Standard Pest Risk Analysis and phytosanitary criteria	Standard Pest Risk Analysis and phytosanitary criteria	Standard Pest Risk Analysis and phytosanitary criteria
Socioeconomic considerations	Depends on importance of organism to PNG agriculture	Depends on importance of organism to PNG agriculture	*Not applicable, per above*	Depends on importance of organism to PNG agriculture	Depends on importance of organism to PNG agriculture	Depends on importance of organism to PNG agriculture
Approval Document	Import permit	Import permit	*Not applicable, per above*	Import permit	Import permit	Import permit
Restrictions or conditions	Subject to inspection at all times; Containment according to International Plant Protection Convention (IPPC) containment standards; seed labels according to quarantine restrictions	Subject to inspection at all times; Containment according to International Plant Protection Convention (IPPC) containment standards; seed labels according to quarantine restrictions	*Not applicable, per above*	Subject to inspection at all times; labels according to Food Safety Code and Food Sanitation Act (not specific for GM)	Subject to inspection at all times	Subject to inspection at all times; Containment according to International Plant Protection Convention (IPPC) containment standards; seed labels according to quarantine restrictions

Expiration of Approval Document	Depends on application submitted	Depends on application submitted	*Not applicable, per above*	Depends on application submitted	Depends on application submitted	Depends on application submitted
Renewal Provisions	Not specified	Not specified	*Not applicable, per above*	Not specified	Not specified	Not specified

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PERU

According to the Law for Prevention of Risks from Use of Biotechnology, Nº 27104, in Peru there are three National Competent Authorities to regulate the use of LMO. Primary responsibility for regulation of LMO involved in Agriculture falls to the National Institute of Agricultural Innovation (INIA), which belongs to the Ministry of Agriculture (MINAGRI). Vice Ministry of Fisheries is responsible for regulation of LMO in hybro-biological resources. Finally, the General Direction of Environmental Health (DIGESA), which belongs to the Ministry of Health, is responsible for the use of LMO in processed food.However, all thesesectorial regulations, at present, are still in draft form.

The approvals for the commercial release of LMO into the environment, confinement and intended use as feed and primary food are granted by the INIA, but the risk analysis is carried out by Sectorial Technical Groups (GTS), comprised of Ministry of Environment (MINAM), General Direction of Environmental Issues Agriculture (MINAGRI), National Agricultural Sanitary and Phytosanitary Service (SENASA) and local Universities.

The Code of Protection and Defense to the Consumer, Law Nº 29571, requires mandatory labeling for GM food, but it has not been implemented yet. The National Institute for the Defense of Competition and Intellectual Property Protection (INDECOPI) is the main National Implementing Agency for labeling. The regulations for commercialization of GM food do not consider the cases of Low Level Presence (LLP) or the Adventitious Presence.

On November 14, 2012, the Government of Peru passed Supreme Decree 008-2012-MINAM establishing implementing regulations (IR) to enforce a ten-year moratorium on planting biotech crops anywhere in the country. The Ministry of Environment (MOE) is the main agency responsible for the aforementioned Decree. Nolte (2012) noted that the U.S. Department of Agriculture's Foreign Agricultural Service has been advised that comments from these institutions, along with those from the Ministry of Trade, have not been incorporated in the IR.

According to the original moratorium law (Law 29811), MOE's rationale for implementing the moratorium is to strengthen national capabilities, develop infrastructure, and establish the baselines on native biodiversity in order to allow the Government of Peru to evaluate the risk of releasing GM crops into the environment. In the baseline, for example, the IR aim to develop a nationwide inventory of animals, plants, insects (target and non-target), and soil microorganisms (fungi and bacteria) that could be affected by GM crops. This inventory, to be completed within an ambitious 10-year timeline, will also include a full survey of organic farms and biodiversity areas.

The moratorium allows three exceptions to the biotech prohibition. These are for imports of: 1) GMOs for research in a confined environment, 2) GMOs used for pharmaceutical or veterinary products, and 3) GM crops imported for food, feed, or processing. These products are still subject to a risk assessment before being authorized and must comply with the Cartagena Protocol on risk evaluation, management, and communication. The implementing regulations do not detail what is the risk assessment procedure or how long it would take.

The IR assign new oversight and enforcement responsibilities to several government agencies including SUNAT (Customs), SENASA, INIA (national research institute), and ITP (Fisheries Institute under the Ministry of Production). The IR require that all seed importers file an affidavit declaring that their product does not contain GM material. They also mandate that Peru's Sanitary and Phytosanitary Authority, SENASA, conduct random sampling and testing to enforce compliance. The regulations for commercialization of seeds do not consider the cases of Low Level Presence (LLP) or the Adventitious Presence (AP) of GM seeds in conventional lots. There are three classes of offenses under the IR: mild, serious, and very serious. The IR do not specify what constitutes each type of offense, but establishes a maximum fine of $14 million (10,000 tax units, currently at 3,650 soles). Lastly, the IR required that all institutions adapt their procedures to comply with their new responsibilities within 120 days.

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
Key Laws & Regulations	Ley 27104, Ley de Prevención de Riesgos Derivados del Uso de la Biotecnología 2003 Reglamento de la Ley de Prevención de Riesgos Derivados del Uso de la Biotecnología - DS No. 108-2002-PCM 2002 Cartagena Protocol on Biosafety to the Convention on Biological Diversity	Ley 27104, Ley de Prevención de Riesgos Derivados del Uso de la Biotecnología 2003. Reglamento de la Ley de Prevención de Riesgos Derivados del Uso de la Biotecnología - DS No. 108-2002-PCM 2002. Cartagena Protocol on Biosafety to the Convention on Biological Diversity	Cartagena Protocol on Biosafetyto the Convention on Biological Diversity (Rescinded by Law Nº 29811). Law for Prevention of Risks from Use of Biotechnology, Nº 27104(Rescinded by Law Nº 29811). Ley Nº29811, Ley que establece la Moratoria al Ingreso y Producción de Organismos Vivos Modificados al Territorio Nacional por un período de 10 años, 2011. Reglamento de la Ley Nº29811, Ley que establece la Moratoria al Ingreso y Producción de Organismos Vivos Modificados al Territorio Nacional por un período de 10 años, DECRETO SUPREMO (DS) Nº008-2012-MINAM, 2012	Cartagena Protocol on Biosafety to the Convention on Biological Diversity Ley 27104, Ley de Prevención de Riesgos Derivados del Uso de la Biotecnología 2003. Reglamento de la Ley de Prevención de Riesgos Derivados del Uso de la Biotecnología - DS No. 108-2002-PCM 2002.	Cartagena Protocol on Biosafety to the Convention on Biological Diversity Ley 27104, Ley de Prevención de Riesgos Derivados del Uso de la Biotecnología 2003. Reglamento de la Ley de Prevención de Riesgos Derivados del Uso de la Biotecnología - DS No. 108-2002-PCM 2002.	Cartagena Protocol on Biosafety to the Convention on Biological Diversity Ley 27104, Ley de Prevención de Riesgos Derivados del Uso de la Biotecnología 2003. Reglamento de la Ley de Prevención de Riesgos Derivados del Uso de la Biotecnología - DS No. 108-2002-PCM 2002.
Implementing Agencies	Ministerio del Ambiente (MINAM) Instituto Nacional de Innovacion Agraria (INIA) Servicio Nacional de Sanidad Agraria (SENASA);	Ministerio del Ambiente (MINAM) Instituto Nacional de Innovacion Agraria (INIA) Servicio Nacional de Sanidad Agraria (SENASA);	Ministerio del Ambiente (MINAM) Instituto Nacional de Innovacion Agraria (INIA) Servicio Nacional de Sanidad Agraria (SENASA);	Instituto Nacional de Innovacion Agraria (INIA) Servicio Nacional de Sanidad Agraria (SENASA); Agriculturalsanitationrequirements).	Instituto Nacional de Innovacion Agraria (INIA) Servicio Nacional de Sanidad Agraria (SENASA); Agriculturalsanitationrequirements).	Instituto Nacional de Innovacion Agraria (INIA) Servicio Nacional de Sanidad Agraria (SENASA); Agriculturalsanitationrequirements).

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
	Agriculturalsanitationrequirements). Superintendencia Nacional de Aduanas y de Administracion Tributaria (SUNAT; customs and dutiesforimported GMO) Vice Ministry of Fisheries (PRODUCE)	Agriculturalsanitationrequirements). Office of Environmental Evaluation and Control (OEFA) Vice Ministry of Fisheries (PRODUCE)	Agriculturalsanitationrequirements). Office of Environmental Evaluation and Control (OEFA) Vice Ministry of Fisheries (PRODUCE) SENASA (for imports) SUNAT (for imports)	General Direction of Environmental Health (DIGESA) Vice Ministry of Fisheries (PRODUCE)	General Direction of Environmental Health (DIGESA) Vice Ministry of Fisheries (PRODUCE)	General Direction of Environmental Health (DIGESA) Vice Ministry of Fisheries (PRODUCE) MINCETUR; for incorporating GMO-related requirements into VUCA electronic applications
Organisms covered	All GMOs	All GMOs	All GMOs	All GMOs	All GMOs	All GMOs
Required submissions	Application providing details on description of GMOs, purposes of planned activity; inserted genes, gene functions, emergency plan	All seed importers file affidavit declaring that their product does not contain GM material	All seed importers file affidavit declaring that their product does not contain GM material	Application providing details on GMOs, Inserted genes and expression products; expected use of GMO as food; toxicity, allergenicity and other data specified by Codex Alimentarius guidance documents	Application providing details on GMOs, Inserted genes and expression products; expected use of GMO as food; toxicity, allergenicity and other data specified by Codex Alimentarius guidance documents	DIGESA food safety approval or registry entry (when operational) Import application via VUCA
Processing Fee	None specified	None specified	None specified	None specified	None specified	None specified
Processing time	None specified	Not applicable (Due to Law Nº 29811)	Not applicable (Due to Law Nº 29811)	None specified	None specified	None specified
Risk Assessment	Scientific, case-by-case; in accordance with Cartagena Protocol on Biosafety and specific provisions of Ley 27104; Performed by Sectoral Technical Groups (GTS)	Not applicable (Due to Law Nº 29811)	Not applicable (Due to Law Nº 29811)	Scientific, case-by-case; in accordance with Cartagena Protocol on Biosafety, Codex Alimentarius Guidance documents on foods derived from biotechnology	Scientific, case-by-case; in accordance with Cartagena Protocol on Biosafety, Codex Alimentarius Guidance documents on foods derived from biotechnology	Scientific, case-by-case; in accordance with Cartagena Protocol on Biosafety, Codex Alimentarius Guidance documents on foods derived from biotechnology
Public Participation/ Public Comment	Publication of summary of application information in two media with national circulation; public then invited to provide comments or additional information which may be factored in the risk assessment or approval process	Not applicable (Due to Law Nº 29811)	Not applicable (Due to Law Nº 29811)	Publication of summary of application information in two media with national circulation; public then invited to provide comments or additional information which may be factored in the risk assessment or approval process	Publication of summary of application information in two media with national circulation; public then invited to provide comments or additional information which may be factored in the risk assessment or approval process	Publication of summary of application information in two media with national circulation; public then invited to provide comments or additional information which may be factored in the risk assessment or approval process
Socioeconomic considerations	None specified	Sustainability and conservation of cultural and biodiversity	Sustainability and conservation of cultural and biodiversity	Sustainability and conservation of cultural and biodiversity	Sustainability and conservation of cultural and biodiversity	Sustainability and conservation of cultural and biodiversity

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
Approval Document	Authorization from MINAM and import-related agencies	Not applicable (Due to Law Nº 29811)	Not applicable (Due to Law Nº 29811)	Authorization from INIA for primary foods DIGESA food safety approval SENASA, SUNAT import permit and assessment of duties	Authorization from INIA for primary foods DIGESA feed safety approval SENASA, SUNAT import permit and assessment of duties	DIGESA food or feed safety approval SENASA, SUNAT import permit and assessment of duties
Restrictions or conditions	Strictly for Contained Work in facilities specified in application Post entry (if imported) subject to inspection and monitoring by SENASA and INIA and OEFA Management systems in place to prevent escape of GMO from approved facilities	Imported seeds can be inspected, sampled and tested by SENASA Upon entry, some oversight and enforcement functions by SUNAT and INIA	Imported seeds can be inspected, sampled and tested by SENASA Upon entry, some oversight and enforcement functions by SUNAT and INIA	Consumer Defense Code of 2011 requires mandatory labeling of GMOs, but labeling provisions not yet published	Consumer Defense Code of 2011 requires mandatory labeling of GMOs, but labeling provisions not yet published	Consumer Defense Code of 2011 requires mandatory labeling of GMOs, but labeling provisions not yet published
Expiration of Approval Document	None specified	Not applicable (Due to Law Nº 29811)	Not applicable (Due to Law Nº 29811)	None specified	None specified	None specified
Renewal provisions	None specified	Not applicable (Due to Law Nº 29811)	Not applicable (Due to Law Nº 29811)	None specified	None specified	None specified

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PHILIPPINES

The Philippines remains a regional biotechnology leader and continues to be looked to for guidance on biotechnology policy by other developing countries. The Philippine biotechnology regulatory system remains science-based. Under the current regulatory regime as provided for by the Philippine Department of Agriculture’s Administrative Order No. 8 (DA-AO 8)**,** 32 transformation events (TEs) and 28 stacked-trait products are approved for direct use as food, feed, or for propagation. As of June 7, 2012, eight (8) GM crop varieties were approved for commercial production, unchanged from the previous year’s level. This consisted of five (5) TEs and three (3) stacked or combined trait products. All the GM crop varieties approved for propagation were corn.

GM corn was planted on 27% (685,000 hectares) of the total Philippine corn area by an estimated 300,000 farmers in 2011. Both land area and the number of farmers involved in GM corn cultivation are likely to have increased again in 2012 as the benefits and profits of GM technology become more apparent. Field

tests of Bt eggplant have been carried out and Golden Rice,[43] produced by the International Rice Research Institute (IRRI), is undergoing multilocational field trials expected to be completed by 2015.[44]

In 2011 U.S. exports to the Philippines of genetically engineered (GE) products (e.g. soybean meal, feeds and fodders, etc.) grew by 8% to reach $527 million (Corpuz 2012). No biotechnology-related trade disruptions were experienced in 2011; however, some international anti-GMO groups have stepped up activities in the Philippines, including efforts to pass a mandatory GMO labeling bill and block commercialization of *Bt* eggplant and Golden Rice.

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
Key Laws & Regulations	Executive Order (EO) No. 514: Establishing the National Biosafety Framework 2006 Philippine Biosafety Guidelines 1990 (full containment) Guidelines on the Planned Release of Genetically- Modified Organisms (GMOs) and Potentially Harmful Exotic Species (PHES). NCBP Ser. 3 (Confined tests) 1998 Republic Act No. 3639 1930 (RA-3639): An act creating the Bureau of Animal Industry, defining its powers and functions, providing for its personnel; making appropriation for its organization and operation; changing the name of the Bureau of Agriculture to Bureau of Plant Industry, and other purposes.	EO 514 2006 RA 3639 1930 PD-1433 1978 DA-Administrative Order (AO)- 8 s 2002: Rules and Regulations for the Importation and Release into the Environment of Plants and Plant Products Derived from the Use of Modern Biotechnology, plus all the relevant Memorandum Circulars issued for implementation	EO 514 2006 RA 3639 1930 PD-1433 1978 DA- AO- 8 2002 and relevant MCs issued for implementation DA-AO 22 s. 2007: Amending Specific Sections of Part V of D.A. Administrative Order No. 8, s. 2002, "Approval Process for the Importation of Regulated Articles for Direct Use as Food or Feed, or for Processing" DA-AO 31 s. 2008: Adoption of Codex Principles for the Risk Analysis of Foods Derived from Modern Biotechnology and the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants	EO 514 2006 RA 3639 1930 PD-1433 1978 DA- AO- 8 2002 and relevant MCs issued for implementation DA-AO 22 s. 2007: Amending Specific Sections of Part V of D.A. Administrative Order No. 8, s. 2002, "Approval Process for the Importation of Regulated Articles for Direct Use as Food or Feed, or for Processing" DA-AO 31 s. 2008: Adoption of Codex Principles for the Risk Analysis of Foods Derived from Modern Biotechnology and the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants	EO 514 2006 RA 3639 1930 PD-1433 1978 DA- AO- 8 2002 and relevant MCs issued for implementation DA-AO 22 s. 2007: Amending Specific Sections of Part V of D.A. Administrative Order No. 8, s. 2002, "Approval Process for the Importation of Regulated Articles for Direct Use as Food or Feed, or for Processing" DA-AO 31 s. 2008: Adoption of Codex Principles for the Risk Analysis of Foods Derived from Modern Biotechnology and the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants	EO 514 2006 RA 3639 1930 PD 1433 1978 DA- AO- 8 2002 and relevant MCs issued for implementation RA 9711 of 2009: Food and Drugs Administration (FDA) Act (for processed foods) DA-AO 22 s. 2007: Amending Specific Sections of Part V of D.A. Administrative Order No. 8, s. 2002, "Approval Process for the Importation of Regulated Articles for Direct Use as Food or Feed, or for Processing" DA-AO 31 s. 2008: Adoption of Codex Principles for the Risk Analysis of Foods Derived from Modern Biotechnology and the Codex Guideline for the Conduct of Food Safety Assessment of Foods

[43] So-called because of the insertion of beta carotene to supply 50% of the recommended daily allowance of vitamin A with a one-cup serving of the rice.

[44] See IRRI, "When will Golden Rice be available to farmers and consumers?" September 2013, http://irri.org/index.php?option=com_k2&view=item&id=12108:when-will-golden-rice-be-available-to-farmers-and-consumers?&lang=en.

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
	Presidential Decree No. 1433 (PD-1433): Plant Quarantine Decree of 1978		RA 8435: Agriculture Fisheries and Modernization Act of 1997 PD- 1144 of 1977: Presidential Decree creating the Fertilizer and Pesticide Authority	RA 8435: Agriculture Fisheries and Modernization Act of 1997	RA 8435: Agriculture Fisheries and Modernization Act of 1997	Derived from Recombinant-DNA Plants RA 8435: Agriculture Fisheries and Modernization Act of 1997
Implementing Agencies	National Committee on Biosafety of the Philippines (NCBP; policy matters) Department of Science and Technology (DOST)-Biosafety Committee (BC) Department of Agriculture (DA)-Bureau of Plant Industry (BPI) - through membership in the DOST-BC and through quarantine responsibilities Department of Environment and Natural Resources (DENR) - through membership in the DOST-BC Department of Health Food and Drugs Administration (DOH) - through membership in the DOST-BC Institutional Biosafety Committees (IBC)	NCBP (policy matters) DA-BPI DOST-BC IBC for each test site	NCBP (policy matters) DA-BPI DA Bureau of Agricultural and Fisheries Product Standards (BAFPS) DA Bureau of Animal Industry (BAI) DA Fertilizer and Pesticide Authority (FPA)	NCBP (policy matters) DA-BPI DA-BAFPS DA-BAI	NCBP (policy matters) DA-BPI DA-BAFPS DA-BAI	NCBP (policy matters) DA-BPI DOH-FDA (if processed food) DA-BAFPS DA-BAI
Organisms covered	All GMOs	GM Plants	GM Plants	GM Plants	GM Plants	GM Plants and GM commodities
Required submissions	Project proposal (as specified in the Philippine Biosafety Guidelines,) detailing host and donor species, inserted gene(s), GMO characteristics, proposed activities, biosafety measures,	Certificate of completion of contained test from DOST-BC (All events must undergo contained and/or confined tests under supervision of DOST-BC) Completed application form according to DA-AO 8, technical dossier detailing	BPI certificate that GMO event has undergone satisfactory field testing in the appropriate sites representing relevant climate classifications Completed application form according to DA-AO 8, technical dossier on GMO	Completed application form according to DA-AO 8, technical dossier on GMO event (including references and other supporting documents), copy of PIS, and proponent's duly accomplished risk assessment matrix	Completed application form according to DA-AO 8, technical dossier on GMO event (including references and other supporting documents), copy of PIS, and proponent's duly accomplished risk assessment matrix	Completed application form according to DA-AO 8, technical dossier on GMO event (including references and other supporting documents), copy of PIS, and proponent's duly accomplished risk assessment matrix

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
	references, facilities, personnel and time frames endorsed by IBC and submitted to the DOST Biosafety Committee (DOST-BC) through the proponent's IBC For materials to be imported: Application for import permit submitted to DA's Bureau of Plant Industry (BPI); application should provide details GMO, on quantity, means of transport, receiving facility, and purpose of importation	host and donor characteristics, inserted gene(s), proposed activities in each field test site, biosafety, management and isolation measures that will be in place, risk assessment matrix duly accomplished by IBC, personnel and time frames. Supporting documents and references attached to application. For materials to be imported: certification that material has been approved by exporting economy, plus notification that GM movement is in accordance with existing international obligations For materials to be imported: Application for import permit submitted to DA's Bureau of Plant Industry (BPI); application should provide details GMO, on quantity, means of transport, receiving facility, purpose of importation	event (including references and other supporting documents), copy of PIS, and proponent's duly accomplished risk assessment matrix For materials to be imported: certification that material has been approved by exporting economy, plus notification that GM movement is in accordance with existing international obligations	For materials to be imported: certification that material has been approved by exporting economy, plus notification that GM movement is in accordance with existing international obligations	For materials to be imported: certification that material has been approved by exporting economy, plus notification that GM movement is in accordance with existing international obligations	For materials to be imported: certification that material has been approved by exporting economy, plus notification that GM movement is in accordance with existing international obligations Declaration of GM content
Processing Fee	None required by DOST BC, but proponent defrays costs associated with inspection and monitoring of activities, facilities and test sites. Nominal application fee for import permit	PhP1000/application filed, plus Risk Assessment Review Costs determined by negotiations between applicant and DA-BPI in Risk Assessment Review Work and Financial Plan Applicant shoulders costs of public information, public consultation and/or public hearing Nominal application fee for import permit of seeds (if applicable)	PhP1000/application filed, plus Risk Assessment Review Costs determined by negotiations between applicant and DA-BPI in Risk Assessment Review Work and Financial Plan Applicant shoulders costs of public information, public consultation Nominal application fee for import permit of seeds (if applicable)	PhP1000/application filed, plus Risk Assessment Review Costs determined by negotiations between applicant and DA-BPI in Risk Assessment Review Work and Financial Plan Applicant shoulders costs of public information, public consultation Nominal application fee for import permit of food commodity (if applicable)	PhP1000/application filed, plus Risk Assessment Review Costs determined by negotiations between applicant and DA-BPI in Risk Assessment Review Work and Financial Plan Applicant shoulders costs of public information, public consultation Nominal application fee for import permit of food commodity (if applicable)	PhP1000/application filed, plus Risk Assessment Review Costs determined by negotiations between applicant and DA-BPI in Risk Assessment Review Work and Financial Plan Applicant shoulders costs of public information, public consultation Nominal application fee for import permit of food commodity (if applicable)
Processing time	15-30 days if information complete	120 days if documentation is complete and no additional safety issue is raised by Scientific and Technical Review Panel (STRP) assessment or public participation	90 days if documentation is complete and no additional safety issue is raised by STRP assessment or public participation	60 days if documentation is complete and no additional safety issue is raised by STRP assessment or public participation	60 days if documentation is complete and no additional safety issue is raised by STRP assessment or public participation	60 days if documentation is complete and no additional safety issue is raised by STRP assessment or public participation

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
Risk Assessment	Scientific, case-by-case risk assessment done by DOST Biosafety committee that includes representatives from DA, DENR and DOH; may involve external experts as necessary	Initial risk assessment done by applicant and applicant's IBC Review and independent case-by-case assessment done by STRP using risk assessment templates applicable for GMO and novel traits	Initial risk assessment done by applicant Review and independent case-by-case assessment done by STRP using risk assessment templates applicable for GMO and novel traits Further food safety review done by DA -BAFPS Further feed safety review done by DA-BAI Further environmental safety review done by DA-BPI If pest protected, review also done by FPA	Initial risk assessment done by applicant Review and independent case-by-case assessment done by STRP using risk assessment templates applicable for GMO and novel traits Further food safety review done by DA -BAFPS Further feed safety review done by DA-BAI	Initial risk assessment done by applicant Review and independent case-by-case assessment done by STRP using risk assessment templates applicable for GMO and novel traits Further food safety review done by DA -BAFPS Further feed safety review done by DA-BAI	Initial risk assessment done by applicant Review and independent case-by-case assessment done by STRP using risk assessment templates applicable for GMO and novel traits Further food safety review done by DA -BAFPS Further feed safety review done by DA-BAI For processed food, food safety review done by Food and Drug Administration unless unprocessed ingredients are part of Registry for Approved GMOs
Public Participation	None for activities within a physical structure (laboratory or greenhouse). For confined test, public participation invited through Public Information sheet (PIS) posted in conspicuous place in local government unit where confined test is to be conducted.	Public consultation through IBC and comments also invited through Public Information Sheet (PIS) posted in conspicuous place in local government unit where field test is to be conducted. Public hearing (facilitated by IBC) may be required if the STRP reports that significant risk associated with activity.	Publication of PIS in two newspapers of national circulation, public comments invited within 30-day period Public comments considered for approval of permit application	Publication of PIS in two newspapers of national circulation, public comments invited within 30-day period Public comments considered for approval of permit application	Publication of PIS in two newspapers of national circulation, public comments invited within 30-day period Public comments considered for approval of permit application	Publication of PIS in two newspapers of national circulation, public comments invited within 30-day period Public comments considered for approval of permit application
Socioeconomic considerations	Sentiments of residents taken into account in selection of sites for confined tests; no confined tests approved for environmentally critical areas as designated by DENR	Sentiments of residents taken into account in selection of sites for field tests; no field tests approved for environmentally critical areas as designated by DENR	For final approval, efficacy, risk-benefit analysis, and economic considerations factored in after risk assessment	For final approval, efficacy, risk-benefit analysis, and economic considerations factored in after risk assessment	For final approval, efficacy, risk-benefit analysis, and economic considerations factored in after risk assessment	For final approval, efficacy, risk-benefit analysis, and economic considerations factored in after risk assessment
Approval Document	Approval letter from DOST Biosafety Committee Endorsement letter to BPI if material is to be imported	Biosafety permit for Field Testing Import permit from BPI (if necessary)	5-year Biosafety Permit for Propagation 5-year Biosafety Permit for Direct Use as Food or Feed Inclusion in registry of Approved GMOs	5-year Biosafety Permit for Direct Use as Food or Feed or for Processing Import permit (as necessary) Inclusion in registry of Approved GMOs	5-year Biosafety Permit for Direct Use as Food or Feed or for Processing Import permit (as necessary) Inclusion in registry of Approved GMOs	5-year Biosafety Permit for Direct Use as Food or Feed or for Processing Import permit (as necessary) Inclusion in registry of Approved GMOs

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
	Import permit from BPI if necessary		Import permit (as necessary)			
Restrictions or conditions	Work with GMOs only in approved facilities or sites; movement requires notification of IBC and DOST-BC and may require BPI (Quarantine) supervision. Access to facilities or confined test sites limited to authorized personnel DOST-BC monitoring teams may conduct inspection/monitoring activities during implementation of activities	GMO should have undergone contained or confined tests under DOST-BC supervision If imported, GMO must be approved for field tests from economy of origin GMO planted only in approved test sites Strict material management and destruction of viable biomass at the end of the field test Specific restrictions imposed by DA-BPI	GMO should have undergone field tests under DA-BPI supervision Concurrent or prior approval of GMO for food and feed If imported, GMO must be approved from economy of origin GMO field tested in sites representing the climate classifications where deployment is planned Compliance with any monitoring requirements imposed in the Propagation Permit Other specific restrictions imposed by DA-BPI	Permit is for both food and feed uses May not be used for propagation unless separate permit has been issued.	Permit is for both food and feed uses May not be used for propagation unless separate permit has been issued.	Permit is for both food and feed uses May not be used for propagation unless separate permit has been issued.
Expiration of Approval Document	Activities must commence within two years after issuance of approval letter	Activities must commence within two years after issuance of approval letter	5 years from date Propagation Permit is issued	5 years from date of issuance of permit for Direct Use as food or feed or for processing	5 years from date of issuance of permit for Direct Use as food or feed or for processing	5 years from date of issuance of permit for Direct Use as food or feed or for processing
Renewal provision	May apply for extension, or reapply for new approval	May apply for extension, or reapply for new approval	May apply for another 5-year extension of permit Renewal depends on compliance with any restrictions or monitoring requirements imposed on original permit	May apply for another 5-year extension of permit. Renewal depends on compliance with any restrictions imposed on original permit	May apply for another 5-year extension of permit. Renewal depends on compliance with any restrictions imposed on original permit	May apply for another 5-year extension of permit. Renewal depends on compliance with any restrictions imposed on original permit

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RUSSIAN FEDERATION

The Russian Federation does not produce GM crops, but Russian scientists are actively conducting laboratory research on agricultural crops. GM plants resulting from such research have yet to reach a stage where they can be field-tested. Under Federal Law No. 7-FZ of January 10, 2002 on Environmental Protection, as amended January 1, 2011, Article 50.1, "it is prohibited to produce, grow and use plants, animals and other organisms not typical for natural ecological systems, or created artificially, without developing effective measures to prevent their uncontrolled reproduction, obtaining a positive state ecological expert's conclusion, and permission from the federal bodies of executive power that conduct the state management of environment, and other federal bodies of executive power in accordance with their competence and legislature of the Russian Federation." The Federation has not yet identified the relevant regulatory agency that will oversee these activities. Likewise, regulations to cover these activities have not yet been adopted.

In 2012 Russia adopted the State Program on the Development of Biotechnology (including agricultural biotechnology) through 2020, anticipating the adoption of a number of legislative documents that will build a foundation for a biotech-oriented economy by 2020. The program calls for the establishment of a National Biotechnology Council to function as a steering group to reach the program's strategic goal of increasing biotechnology's contribution to the economy (around 1 % of GDP by 2020, and 3 % by 2030, according to Vassilieva 2012b). The adoption of this program, coupled with the Russian Federation's membership in the Eurasian Economic Commission in 2012, calls for the drafting of new regulations, revisions of some existing procedures, and reorganization of agencies responsible for regulating GMOs and their products. This process of updating rules and assigning roles as to various regulatory agencies is on-going.

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
Key Laws & Regulations	Federal Law No. 86-FZ of June 5, 1996: On the State Regulation in the Sphere of Genetic Engineering Activities" with amendments made in 2000	Federal Law No. 86-FZ of June 5, 1996: On the State Regulation in the Sphere of Genetic Engineering Activities" with amendments made in 2000 and in 2010 *Note: The 2010 amendment authorizes government to develop procedures for release into the environment, but regulations have not yet been issued.*	Federal Law No. 86-FZ of June 5, 1996: On the State Regulation in the Sphere of Genetic Engineering Activities" with amendments made in 2000 and in 2010 *Note: The 2010 amendment authorizes government to develop procedures for release into the environment (regulations not yet issued)* Ministry of Economic Development 2011 draft resolution on the state registration of genetically modified organisms for release into environment (not yet adopted)	Federal Law No 52-FZ of March 30, 1999, On the Sanitary-Epidemiological Well-being of the Population Federal Law No. 29-FZ of January 2, 2000, On the Quality and Safety of Food Products with amendments made in 2001 – 2008 Federal Law No. 2300-1 of February 7, 1992, On the Protection of Consumers Rights with October 25, 2007 amendments setting the threshold for mandatory labeling of food ingredients made from biotech material to 0.9 percent Resolution of the Government of the Russian Federation No. 988 of December 21, 2000, On State Registration of New Food Products, Materials, and Goods with amendments (registration of GMO food)	Resolution of the Government of the Russian Federation No 26 of January 18, 2002, On the State Registration of GMO Feeds Resolution of the Government of the Russian Federation No. 422 of July 14, 2006 that transferred testing and registration of biotech feeds from the Ministry of Agriculture of the Russian Federation to the Federal Service for Veterinary and Phytosanitary Surveillance (VPSS)	Customs Union[45] Technical Resolution (CU TR) No 021/2011 on Safety of Food Products CU TR No 015/2001 on the Safety of Grain (adopted 2011) Other CU TRs issued requirements for importation
Implementing Agencies	Variety Testing Commission at the Ministry of Agriculture	Not yet identified	Not yet identified	Russian Federal *Rospotrebnadzor* (Federal Service on Customers' Rights Protection & Human Well-Being Surveillance)	Federal Service for Veterinary and Phytosanitary Surveillance (VPSS)	Customs Union of Belarus, Kazakhstan, and Russia
Organisms covered	All GMOs	All GMOs	All GMOs	All GMOs	All GMOs	All GMOs
Required submissions	Not available	Not available	Not available	Completed application form and dossier, proof of payment of fees	Completed application form and dossier, proof of payment of fees	Completed application form, certificate issued by *Rospotrebnadzor* and/or VPSS, proof of payment of fees
Processing Fee	Not available	Not available	Not available	Variable, but averages around US$100,000 for new events	Variable, but averages around US$100,000 for new events registered for 5 years	Not available

[45] "Customs Union" here refers to the Russia-Kazakhstan-Belarus Customs Union (CU).

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
				About US$645 for food products containing GM already in the registry	Renewal costs essentially the same	
Processing time	Not available	Not available	Not available	Approx. 15 months for new GM shorter processing time for food products and ingredients if GM component already in the registry	Not available	Not available
Risk Assessment	Not available	Not available	Not available	Done by Institute of Nutrition of the Academy of Medical Sciences, but certificate issued by Russian Federal *Rospotrebnadzor*; includes results of laboratory tests one by the Institute and specified laboratories	Done by Experts Council on the safety (non-safety) of the GMO feed, but FSVPS makes final decision based on the Council's Conclusion Approval usually issued only if event has also been approved as food by the *Rospotrebnadzor*	Follows CU TRs and certificates issued by *Rospotrebnadzor* and FSVPS
Socioeconomic considerations	Not available	Strong public sentiment against GM	Strong public sentiment against GM	None specified	None specified	None specified
Approval Document	Import permit, if necessary Information on other approvals not available	Import permit, if necessary Information on other approvals not available	Import permit, if necessary Information on other approvals not available	Certificate of registration Inclusion in registry of food assessed as safe Import permit, if necessary	Certificate of registration Inclusion in registry of feed assessed as safe Import permit, if necessary	Import permit
Restrictions or conditions	Not available	Cultivation without permission from government prohibited	Cultivation without permission from government prohibited	Registration required for new crops as well as products that contain the approved crops if GM content exceed 0.9% Labeling required with 0.9% threshold Separate registration of products containing registered GM required if GM content exceeds 0.9% If imported, must follow other Technical regulations issued by Customs Union of Eurasian Economic Commission	Registration required for new crops as well as products that contain the approved crops if GM content exceed 0.9%; 0.5% is threshold for GM feed ingredients that has not yet been approved If imported, declared as GM if 0.9% threshold exceeded for approved crops, 0.5% threshold for unapproved crops If imported, must follow other Technical regulations issued by Customs Union of Eurasian Economic Commission	Declaration of food and feed as GM if thresholds are exceeded

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
Expiration of Approval Document	Not available	Not available	Not available	No expiration but may be recalled based on new information	Five years	No expiration for food but may be recalled based on new information; 5 years for feed, subject to renewal
Renewal provisions	Not available	Not available	Not available	Not applicable	Renewal required every 5 years	Feed required every 5 years for feed use

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SINGAPORE

Singapore does not produce any GMO crops, and existing regulations address various types of activities involving GMOs. Singapore therefore does not have any GMO-specific legislation, opting instead to use existing regulations and agencies to regulate GMO use.

To help implement regulatory schemes Singapore formed a Genetic Manipulation Advisory Committee (GMAC) that is tasked "to oversee and to provide scientifically-sound advice on the research and development, production, release, use and handling of genetically modified organisms (GMOs) in Singapore."[46] GMAC has issued the Singapore Biosafety Guidelines for Research on GMOs and the Singapore Guidelines on the Release of Agriculture-Related GMOs. These were adapted from existing international guidelines and regulations, and issued after consultations with relevant local stakeholders and regulatory authorities. The Guidelines have undergone several revisions and are continuously being reviewed to keep abreast with developments in GM technology.

There is no specific labeling requirement for GM foods in Singapore.

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
Key Laws & Regulations	Singapore Biosafety Guidelines for Research on Genetically Modified Organisms (GMOs) 2006 and revisions as of 2013 Workplace Safety and Health Act 2006 and revisions as of 2009 For regulating importation of biological materials: (i) Control of Plants Act (implemented by Agri-Food and Veterinary Authority,	Singapore Guidelines on the Release of Agriculture-Related GMOs (GMAC Release Guidelines) 1999 For importation and formal approval of activities by relevant regulatory agencies: (i) Control Act of Plants (AVA) 1993 and revisions as of 2000 (ii) Animals and Birds Act (AVA) 1965 and revisions as of 2002	Singapore Guidelines on the Release of Agriculture-Related GMOs (GMAC Release Guidelines) 1999 For importation and formal approval of activities by relevant regulatory agencies: (i) Control Act of Plants (AVA) 1993 and revisions as of 2000 (ii) Animals and Birds Act (AVA) 1965 and revisions as of 2002	Singapore Guidelines on the Release of Agriculture-Related GMOs (GMAC Release Guidelines) 1999 Control Act of Plants (for importation and formal approval) 1993 and revisions as of 2000 Sale of Food Act (Chapter 283) 1985 revised edition, with amendments as of 2002 Food Regulations 1998 with amendments as of 2005	Singapore Guidelines on the Release of Agriculture-Related GMOs (GMAC Release Guidelines) 1999 Control Act of Plants (for importation and formal approval) 1993 and revisions as of 2000 Sale of Food Act (Chapter 283) 1985 revised edition, with amendments as of 2002 Food Regulations 1998 with amendments as of 2005	Singapore Guidelines on the Release of Agriculture-Related GMOs (GMAC Release Guidelines) 1999 Control Act of Plants (for importation and formal approval) 1993 and revisions as of 2000 Sale of Food Act (Chapter 283) 1985 revised edition, with amendments as of 2002 Food Regulations 1998 with amendments as of 2005

[46] See GMAC, "About us," http://www.gmac.gov.sg/Index_About_Us.html.

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
	AVA) 1993 and revisions as of 2000 (ii) Animals and Birds Act (implemented by AVA) 1965 and revisions as of 2002 (iii) Biological Agents and Toxins Act (regulated by Ministry of Health, MOH) 2005 and revisions as of 2006 (iv) Infectious Diseases Act (implemented by National Environmental Authority, NEA) 1977 and revisions as of 1990 (v) Control of Vectors and Pesticides Act (implemented by NEA) 1998 and revisions as of 2002	(iii) Biological Agents an Toxins Act (MOH) 2005 and revisions as of 2006 (iv) Infectious Diseases Act (NEA) 1977 and revisions as of 1990 (v) Control of Vectors and Pesticides Act (NEA) 1998 and revisions as of 2002	(iii) Biological Agents an Toxins Act (MOH) 2005 and revisions as of 2006 (iv) Infectious Diseases Act (NEA) 1977 and revisions as of 1990 (v) Control of Vectors and Pesticides Act (NEA) 1998 and revisions as of 2002			
Implementing Agencies	Genetic Manipulation Advisory Committee (GMAC); Institutional Biosafety Committees (IBCs) Ministry of Manpower (MOM) for regulation of Workplace Safety and Health Ministry of Health (MOH) for relevant import permit and formal approval Agri-Food & Veterinary Authority (AVA) for relevant import permit and formal approval National Environment Agency (NEA), for relevant import permit and formal approval	GMAC Agencies that issue formal Permit: • MOH • NEA • AVA	GMAC AVA	GMAC AVA	GMAC AVA	GMAC AVA
Organisms covered	All GMOs and GMO products for research	All GMOs intended for release to environment	All GMOs intended for release to environment	GM organisms and their food products (fresh or processed)	GM organisms and their food products (fresh or processed)	GM organisms and their food products (fresh or processed)
Required submissions	Proposal prepared according to GMAC	Proposal prepared according to GMAC	Proposal prepared according to GMAC	Proposal prepared according to GMAC	Proposal prepared according to GMAC	Proposal prepared according to GMAC

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
	template submitted by proponent to IBC; proposal contains information about the DNA that will be manipulated, hosts and vectors, description of proposed activities, procedures and facilities to ensure containment, procedures for disposal, and IBC assessment and assignment to Category A, B, or C If proposed activities fall under Category A or B according to IBC assessment, copy of proposal and IBC assessment submitted to GMAC If material is to be imported, copy of proposal and IBC decision and if necessary, GMAC endorsement submitted to NEA, MOH, or AVA application of Import permit	template submitted to GMAC; information requirement variable for different organisms, core information include GMO characteristics, eventual use, data from contained activities, location, frequency, and quantity of releases, description of site of release, changes in autecology, planned activities, contingency plans, material management and disposal procedures	template submitted to GMAC; information requirement variable for different organisms, core information include GMO characteristics, eventual use, data from contained activities, location, frequency, and quantity of releases, description of site of release, changes in autecology, planned activities, contingency plans) If GMO will be used as food, must provide information on projected consumption pattern, nutritional quality and food safety, and data addressing other criteria set by Codex Alimentarius 2003 guidance document	template submitted to GMAC; core information requirements include information on projected consumption pattern, nutritional quality and food safety, and data addressing other criteria set by Codex Alimentarius 2003	template submitted to GMAC; core information requirements include information on projected consumption pattern, nutritional quality and food safety, and data addressing other criteria set by Codex Alimentarius 2003 Feed data requirements as set by AVA	template submitted to GMAC; core information requirements include information on projected consumption pattern, nutritional quality and food safety, and data addressing other criteria set by Codex Alimentarius 2003 Other supporting documents, e.g., bills of lading, airway bills, and invoices, as necessary Phytosanitary certificates, as necessary
Processing Fee	None specified for GMAC endorsement	None specified for GMAC endorsement	None specified for GMAC endorsement	None specified for GMAC endorsement	None specified for GMAC endorsement	None specified for GMAC endorsement
Processing time	10 working days to acknowledge receipt of IBC decision; Processing time for GMAC endorsement may be variable	GMAC endorsement within 150 days from receipt of proposal, unless more information is required by Risk assessors or GMAC; Processing time not specified for formal approval from specific regulatory agency	GMAC endorsement within 150 days from receipt of proposal, unless more information is required by Risk assessors or GMAC; Processing time not specified for formal approval from specific regulatory agency	GMAC endorsement within 150 days from receipt of proposal, unless more information is required by Risk assessors or GMAC; Processing time not specified for formal approval from specific regulatory agency	GMAC endorsement within 150 days from receipt of proposal, unless more information is required by Risk assessors or GMAC; Processing time not specified for formal approval from specific regulatory agency	GMAC endorsement within 150 days from receipt of proposal, unless more information is required by Risk assessors or GMAC; Processing time not specified for formal approval from specific regulatory agency
Risk Assessment	Scientific and case-by-case Done by researcher and Institutional Biosafety Committees (IBCs) according to the Guidelines	Scientific and case-by-case taking into consideration human health and environment Done by GMAC Subcommittee on the Release of Agri-Related GMOs, expert panel or relevant regulatory agency	Scientific and case-by-case taking into consideration human health and environment Done by GMAC Subcommittee on the Release of Agri-Related GMOs, , expert panel or relevant regulatory agency	Scientific and case-by-case taking into consideration human health and environment Done by GMAC Subcommittee on the Release of Agri-Related GMOs, , expert panel or relevant regulatory agency	Scientific and case-by-case taking into consideration human health and environment Done by GMAC Subcommittee on the Release of Agri-Related GMOs, , expert panel or relevant regulatory agency	Scientific and case-by-case taking into consideration human health and environment Done by GMAC Subcommittee on the Release of Agri-Related GMOs, , expert panel or relevant regulatory agency

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
	IBC classifies proposal as significant risk (A) , low risk(B) or exempt(C) If Category B, IBC does risk assessment, approves proposal and informs GMAC of decision If category A, IBC does initial assessment, notifies GMAC and GMAC does a further assessment before endorsement; GMAC informs relevant regulatory agencies as necessary Relevant regulatory agencies considers GMAC recommendation, but may require further assessment as necessary	using GMAC Release Guidelines Recommendation of subcommittee considered by GMAC before endorsement to NEA, MOH, or AVA NEA, MOH or AVA considers endorsement and issues formal approval or requires further review	using GMAC Release Guidelines Recommendation of subcommittee considered by GMAC before endorsement to NEA, MOH, or AVA NEA, MOH or AVA considers endorsement and issues formal approval; agency may require further review If for commercial propagation and use as food, risk assessment uses substantial equivalence approach	using GMAC Release Guidelines Recommendation of subcommittee considered by GMAC before endorsement to AVA Food Control Division AVA considers endorsement and issues formal approval; AVA may require further review Risk assessment uses substantial equivalence approach and based largely on Codex guidance documents	using GMAC Release Guidelines Recommendation of subcommittee considered by GMAC before endorsement to AVA Food Control Division AVA considers endorsement and issues formal approval; AVA may require further review Risk assessment uses substantial equivalence approach and based largely on Codex guidance documents	using GMAC Release Guidelines Recommendation of subcommittee considered by GMAC before endorsement to AVA Food Control Division AVA considers endorsement and issues formal approval; AVA may require further review Risk assessment uses substantial equivalence approach and based largely on Codex guidance documents
Public Participation / Public Comment	Public consultations done during drafting of the guidelines	Public consultations done during drafting of the guidelines Public to be informed of planned releases	Public consultations done during drafting of the guidelines Public to be informed of planned releases	Public consultations done during drafting of the guidelines Public informed of approvals through registry	Public consultations done during drafting of the guidelines Public informed of approvals through registry	Public consultations done during drafting of the guidelines Public informed of approvals through registry
Socioeconomic considerations	None specified	None specified	None specified	None specified	None specified	None specified
Approval Document	IBC approval and GMAC notification (Category A: Regulated Experiments with Significant Risks) IBC approval (Category B: Notifiable Experiments with Low Risks) GMAC positive recommendation to NEA, AVA, or MOH, if necessary Import permit, if necessary	GMAC endorsement Formal approval by NEA, MOH or AVA Import permit (if necessary) Entry into GMAC registry of GMOs approved for limited release	GMAC endorsement Formal approval by NEA, MOH or AVA Import permit (if necessary) Entry into GMAC registry of GMOs approved for commercial release Entry into GMAC registry of GMOs approved for food (if applicable)	GMAC endorsement Formal approval by AVA Import permit (if necessary) Entry into GMAC registry of GMOs approved for food	GMAC endorsement Formal approval by AVA Import permit (if necessary) Entry into GMAC registry of GMOs approved for feed	GMAC endorsement Formal approval by AVA Import permit Entry into GMAC registry of GMOs approved for food, feed and processing
Restrictions or conditions	Medical surveillance of personnel may be required for some activities under Category A as stipulated by WHO Laboratory Biosafety Manual Annual report submitted to GMAC by IBC	Proponent must submit report after release Post- or post-introduction monitoring by relevant regulatory agency may be required Any new information regarding potential risks to	Proponent must submit report after release Post-introduction or post-marketing Monitoring by proponent and regulatory agency may be required. Any new information regarding potential risks to	Post-introduction or post-marketing Monitoring by proponent and regulatory agency may be required. Any new information regarding potential risks to the environment or to human health must be	Post-introduction or post-marketing Monitoring by proponent and regulatory agency may be required. Any new information regarding potential risks to the environment or to human health must be	Post-introduction or post-marketing Monitoring by proponent and regulatory agency may be required. Any new information regarding potential risks to the environment or to human health must be

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
	Medical surveillance of personnel may be required for specific activities All activities with GMO limited to designated laboratories; transport requires specific packaging and approval of IBC and government regulatory agencies (if transboundary movement)	the environment or to human health must be reported immediately to the GMAC.	the environment or to human health must be reported immediately to the GMAC. GMAC may recall GMOs based on new information that may change outcome of original risk assessment	reported immediately to the GMAC. GMAC may recall GMOs based on new information that may change outcome of original risk assessment	reported immediately to the GMAC. GMAC may recall GMOs based on new information that may change outcome of original risk assessment	reported immediately to the GMAC. GMAC may recall GMOs based on new information that may change outcome of original risk assessment
Expiration of Approval Document	All experiments must be completed within 3 years	None specified	None specified	None specified	None specified	None specified
Renewal Provisions	May request for extension of GMAC endorsement for 3 more years	None specified	None specified	None specified	None specified	None specified

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CHINESE TAIPEI

Chinese Taipei has been developing its domestic biotechnology capabilities, with an emphasis on pharmaceuticals. Local research on agricultural crops, ornamentals, and fish is also very active. Its biotechnology research and development community has developed promising GM varieties of rice, broccoli, potato, bitter gourd, tomato, papaya, banana, calla lily, and orchids (*Phalaenopsis* and *Oncidium*). Some of these GM constructs have reached field trial stage but no local GM construct has gone through the regulatory system to reach the commercial propagation stage. Nor has any locally developed GM undergone regulatory food safety assessment. Chinese Taipei has been rather reticent to encourage applications for domestic cultivation largely because of the issue co-existence and the small size of the average farm. Regulations on the propagation and production of GM crops are currently being drafted, but an ornamental fish or an ornamental non-food GM plant is the GMO most likely to be approved for commercial propagation.

Chinese Taipei uses an inter-agency coordination approach for regulating agricultural biotechnology and extends the mandate of its existing regulatory agencies by amending existing laws, promulgating new ones, or issuing regulatory announcements to address specific issues on genetically modified organisms and related products (Perng 2013). The Taiwan Food and Drug Administration (TFDA), within Taiwan's Ministry of Health and Welfare, is the lead regulatory agency, responsible for food safety assessment for premarket approval and food labeling policies. Regulatory guidelines exist for the safety assessment of products of recombinant DNA technology, but to date such guidelines only have been applied to GM soybean and GM corn. GM corn and GM soybeans approved for food are also allowed to be used for animal feed. Chinese Taipei's regulatory system requires separate safety assessments for stacked traits, especially when the introduced genes bear on the same metabolic pathway.

Chinese Taipei is a major importer of GM commodities and has approved several single event and stacked traits corn and soybeans. Chinese Taipei requires pre-market approval of all GMOs that will be used as food and requires mandatory labeling of products where any GM component exceeds the 5% threshold. Chinese Taipei also imports large quantities of cotton and canola oils, but this commodity is not subject to any food safety assessment.

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
Key Laws & Regulations	Regulations for Approving Import/Export of Transgenic Plant 2005	Plant Varieties and Plant Seeds Act 2005 (prohibits cultivation of any unapproved GM plant) Regulations for Approving Import/Export of Transgenic Plant 2005 Administrative Regulations for the Field Testing of the Transgenic Plants 2005 Regulation governing field trials on GM fish and aquatic plants 2009, revised 2012 Regulations for the Field Trial of Transgenic Breeding Livestock (Fowl) and the Bio-Safety Assessment 2002	Plant Varieties and Plant Seeds Act 2005 (prohibits cultivation and marketing of any unapproved GM plant; regulations governing propagation and production of GM crops still being drafted)	Guidelines for Food Safety Assessment of GM Foods Derived from recombinant DNA organisms 2010 Guideline for Food Safety Assessment of Foods Derived from GM plants with Stacked Traits 2008	Feed Control Act (not yet amended but COA likely to adopt a policy that all approved products for food use are also eligible for animal feed use) 1973	Guidelines for Food Safety Assessment of GM Foods Derived from recombinant DNA organisms 2010 Guideline for Food Safety Assessment of Foods Derived from GM plants with Stacked Traits 2008

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Implementing Agencies	National Science Council (NSC) Bureau of Animal and Plant Health Inspection and Quarantine (BAPHIQ - under COA), for importation materials and quarantine requirements)	COA and affiliated research institutes	COA	Taiwan Food and Drug Administration, Ministry of Health and Welfare (TFDA)	TFDA (also approves GMO for food use) COA (allows GMO approved for food to be used also as animal feed)	Taiwan Food and Drug Administration, Ministry of Health and Welfare (TFDA)
Organisms covered	All GMOs	GM plants (terrestrial and aquatic), GM fish and GM fowl	All GMOs	GM corn and GM soybean only (WTO notified of intention to expand coverage in near future)	GM corn and GM soybean only, but WTO already notified of expanded coverage in near future	GM corn and GM soybean only, but WTO already notified of expanded coverage in near future
Required submissions	For NSC-funded activities: Proposal for research activities detailing expertise of personnel, available and procurable facilities and equipment and methodology ensuring good laboratory practices (GLP) Import Permit from BAPHIC (if applicable) For greenhouse activities: application form detailing characteristics of GMO (including host, donor and transgene characteristics), location of the testing facility and a plan map with an appropriate scale; the established isolation facility; the available inspection equipment; a map of the layout of facilities and equipment within the testing area; operating management standards list of professional personnel and their assignments; organization of biosafety committee and a list of members	Application for Permit to field test with: (i) Detailed dossier for GM organism (host, gene, transgene characteristics, transformation particulars, life cycle and reproductive characteristics, genetics and gene expression profiles and copy numbers), (ii) Description of available facilities and characteristics of sites for field test (iii) Isolation strategies, management and operating procedures including monitoring and disposal methodologies (iv) Detailed experimental procedures (v) Verifying documents attesting that application and methodologies have been reviewed and approved by the field testing institution's biosafety committee (vi) Declaration that the GMO has been studied under containment prior to field test (vii) Import Permit from BAPHIQ, if necessary	Not applicable	Application for safety assessment of single event GM food and GMO dossier detailing: (i) Host organism and history of safe use as food (ii) Donor organism, inserted genes and use of gene and donor organism (iii) Molecular data and transformation method (including copy number, sequences and stability of transformation) (iv) Expression profile (v) Field trial data and variability of nutritional composition (vi) Allergenicity and toxicity data (vii) Other available data on adverse effects (including data appropriate animal tests, if necessary) Application for safety assessment of GM food with stacked traits and GMO dossier detailing: (i) Comparative molecular profile of stacked GMO and parental varieties (ii) Comparative expression profiles of stacked GMO and parental varieties	Application for safety assessment of single event GM food and GMO dossier detailing: (i) Host organism and history of safe use as food (ii) Donor organism, inserted genes and use of gene and donor organism (iii) Molecular data and transformation method (including copy number, sequences and stability of transformation) (iv) Expression profile (v) Field trial data and variability of nutritional composition (vi) Allergenicity and toxicity data (vii) Other available data on adverse effects (including data appropriate animal tests, if necessary) Application for safety assessment of GM food with stacked traits and GMO dossier detailing (i) Comparative molecular profile of stacked GMO and parental varieties (ii) Comparative expression profiles of stacked GMO and parental varieties	Valid Registration and Pre-Market Approval for use as food or animal feed, submitted to TFDA

				(iii) Comparative compositional analysis and agronomic variation of stacked GMO and parental varieties (iv) If same biochemical pathway is affected, a complete stacked GMO dossier is required	(iii) Comparative compositional analysis and agronomic variation of stacked GMO and parental varieties (iv) If same biochemical pathway is affected, a complete stacked GMO dossier is required	
Processing Fee	None specified	None specified	Not applicable	NT $322,500 (approximately $10,750 USD) per registration case including dossier reviewing and product identification	Not specified	Not specified
Processing time	None specified; NSC funded activities undergo two rounds of review	None specified	Not applicable	Not specified	Not specified	Not specified
Risk Assessment	If NSC-funded, done by scientific reviewers of NSC For greenhouse activities, done by 9-13 member committee appointed by COA for a term of two years; Committee includes technical expects	Scientific and case-by-case. Review done by Institutional Biosafety Committee of certified trial agency and by 9-13 member committee appointed by COA for a term of two years; Committee includes technical expects	Not applicable	Case by case risk assessments done byGeneticall Modified Food Advisory Committee (GMFAC) with 21 non-governmenal expers appointed by TFDA for 2-year terms. Essentially follows Codex Alimentarius Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (with annexes), taking into account food consumption data of Taiwan or the Food Balance Sheets issued by COA Safety assessment for stacked trait GMO done to ascertain absence of interaction among inserted genes. If interaction present, additional data required for safety assessment. A separate food safety assessment done if stacked traits affect the same biochemical pathway	GM foods assessed as safe also available for use as animal feeds.	Codex guidelines (comparative approach) although not a member Cartagena Protocol on Biosafety (comparative approach)
Public Participation/	None required	None specified, but COA will make public the approved biosafety	Not applicable	None specified, but TFDA publishes regulations and	Not specified	None specified, but TFDA publishes regulations and

Public Comment		assessment plans, including applicant, institution implementing field testing, characteristics of GMO, date of plan approval, and implementation deadline of the planned activities.		list of registration approvals in its website		list of registration approvals in its website
Socioeconomic considerations	None required	None specified	Not applicable	None specified, but only applications for GM soybean and GM corn are accepted by TFDA	None specified, but only applications for GM soybean and GM corn are accepted by TFDA	None specified, but only applications for GM soybean and GM corn are accepted by TFDA
Approval Document	Approval document for NSC funding	Certificate of Approval by COA Permit for Conducting Field Trial Import/Export Approval for Environmental release (BAPHIQ) Permit for Transboundary Movement from COA Fishery Administration if applicable)	Not applicable	Certificate of Approval	Not specified	Certificate of Approval
Restrictions or conditions	GM kept in contained facilities (laboratories or approved greenhouses) only Limited access to facilities	Field trials must be conducted in COA-accredited field trial sites and facilities only COA may send qualified personnel for unannounced inspection and monitoring Field testing implemented in accordance with instruction manual for operation and management of field testing Reportorial requirements as specified in approval document	Not applicable	Regulations and assessment for corn and soybeans only Labeling required for foods where GM content of any one component exceeds 5% Stacked traits obtained by conventional breeding goes through separate assessment Presence of any unapproved event is illegal	Labelling for GM feeds is not currently required	Regulations and assessment for corn and soybeans only Labeling required for foods where GM content of any one component exceeds 5% Stacked traits obtained by conventional breeding goes through separate assessment Presence of any unapproved event is illegal
Expiration of Approval Document	None specified	Ten years (For approval as a field testing institution)	Not applicable	Five years	Five years	Five years
Renewal Provision	None specified	May apply for new certificate of approval; application submitted 3 months prior to expiration and should include copy of original certificate.	Not applicable	Renewal registration prior to expiration of approval	Renewal registration prior to expiration of approval	Renewal registration prior to expiration of approval

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THAILAND

Officially, no genetically modified crop is cultivated on a commercial scale in Thailand. Prior to 2003, field trials were carried out on Flavr Savr tomato, *Bt* cotton, *Bt* corn, Roundup Ready® cotton, Roundup Ready® corn, antisense RNA tomato, and ringspot virus-resistant papaya. In 2003, the government imposed a blanket ban on further field trials of any GM plant. The ban was revoked 25 December 2007, but new restrictions were imposed, including restricting trials to government properties, conducting public hearings before any new field trials are approved, requiring approval from the Ministerial Cabinet for every trial, and strict surveillance of each GM implementation. As of July 2012, no new field trials have been approved.

At present, Thailand is in the process of enacting a biosafety law that details provisions for working with GMOs. As of 2012, Thailand's draft Biosafety Law passed the government's legal office review and had gone through public comment. The provisions of the draft law are perceived to be less burdensome than what presently is in operation, but the draft has not yet been submitted to the Ministerial Cabinet. Once approved by the Ministerial Cabinet, Parliament subsequently will have to enact the draft into law.

The draft law specifies provisions on a range of activities involving GMOs, i.e., 1) contained work of GMOs; 2) field experiment in confined areas; 3) intentional release of GMOs to the environment; 4) placing GMOs on the market; 5) import, export, and transit of GMOs; 6) suspension, revocation, and cancellation of licenses; 7) handling, transport, relocation, storage, packaging, and identification of GMOs; and 8) emergency and unintentional release of GMOs to the environment" (Preechajarn 2011). Until this law is passed, the formal commercialization of agricultural biotechnology in Thailand cannot proceed. In 2013 it was reported that no change in Thailand's biotechnology regulatory framework had been introduced since the last update (Preechajarn 2013).

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
Key Laws & Regulations	National Biosafety Committee's (NBC) Guidelines in Genetic Engineering and Biotechnology for Laboratory Work (1992, revised 2004)	National Biosafety Committee's (NBC) Guidelines in Genetic Engineering and Biotechnology for Field Work and Planned Release (1992, revised 2004)	None; importation and propagation in commercial quantities is not allowed	Cabinet's decision, 1999 policy statement Thai Plant Quarantine Act, promulgated in 1964 and amended in 1994	Cabinet's decision, 1999 policy statement Thai Plant Quarantine Act, promulgated in 1964 and amended in 1994	Cabinet's decision, 1999 policy statement Ministry of Public Health labeling law 2003
Implementing Agencies	NBC National Center for Genetic Engineering and	NBC, BIOTEC, MOAC, DA, MOST, universities	*N/a, per above*	Thai Food and Drug Administration (FDA)	National Bureau of National ACFS	Thai FDA

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
	Agricultural Biotechnology (BIOTEC) Ministry of Agriculture and Cooperatives (MOAC) Department of Agriculture (DA) Ministry of Science and Technology (MOST) Universities and research institutions Institutional Biosafety Committees (IBC)	and research institutions. IBCs		National Bureau of National Agricultural Commodity and Food Standards (ACFS) Ministry of Public Health (MOPH)		Department of Trade Negotiations Department of Foreign Trade MOPH
Organisms covered	Plants, animals, fisheries	Plants, animals, fisheries		Plants	Plants	Plants
Required submissions	Import Permit Requests as necessary; Approval of Director-general of the DA (with recommendations from NBC)	Import Permit Requests as necessary; Approval of Director-general of the DA (with recommendations from NBC)		Import Permit Requests; Approval of Director-general of the DA (with recommendations from NBC)	Import Permit Requests; Approval of Director-general of the DA (with recommendations from NBC)	Import Permit Requests; Approval of Director-general of DA (with recommendations from NBC)
Processing Fee	None specified	None specified	N/A	None specified	None specified	None specified
Processing time	None specified	1-2 years	N/A	None specified	None specified	None specified
Risk Assessment	Scientific, case-by case, “based on precautionary principle”	Scientific, case by case, “based on precautionary principle”	N/A	Follows Codex guidelines		Follows Codex guidelines
Socioeconomic considerations	N/A	N/A	N/A	N/A	N/A	N/A
Approval Document	Import permit, if necessary	Import permit, if necessary		Import permit	Import permit	Import permit
Restrictions or conditions	Strict containment (laboratory and greenhouse); for research purposes only	Government owned land only; for research purposes only		Soya and corn only; certain foods prohibited via notification by MOPH	Soya and corn only	Processed foods, cotton lint only; “Voluntary” post-marketing labeling of processed food if GM ingredient exceeds 5%; certain foods prohibited via notification by MOPH
Expiration of Approval Document						
Renewal Provision						

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Ministry of Public Health. 2012. Notification No. 251 B.E. 2545 (2002) "Re: Labeling of Food Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering." http://www.asianfoodreg.com/regulations

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UNITED STATES

In the United States, the safe use of agricultural biotechnology and its products are regulated through existing federal regulatory agencies by adapting existing laws that “govern the health, safety, efficacy, and environmental impacts of similar products derived by more traditional methods” (Pew Initiative on Food and Biotechnology 2001). The United States first addressed this issue in 1986 with the Coordinated Framework for Regulation of Biotechnology. The Coordinated Framework contributors found that existing statutes provide agencies with sufficient authorities to regulate the safe use of a wide range of biotechnology products, not only rDNA products. As with other laws, additional legislation may be drafted if the existing authorities are found to be wanting. Should agency jurisdictions overlap, the framework assigns a lead agency to address concerns related to the product, and allows the lead agency to request additional scientific expertise from other USG agencies to address a particular issue or product.

Several factors determine which laws and regulations apply to products derived through the use of Biotechnology, including rDNA products. These include the stage of development (contained research, field test, commercial use), its intended use (e.g., food, feed, pesticides, veterinary biologic, type of possible hazards (pest, pollutant issues), and type of organisms (plant, animal, microorganism). In general, early research in contained facilities (e.g., laboratories, contained greenhouses, vivaria, or other structures housing genetically engineered organisms) is concerned with ensuring that containment is secure, and differs in kind depending on the nature and type of organism that is being developed. Much of this early research, particularly concerned with human health (e.g., microorganisms to produce medical products, genetically engineered laboratory animal models) are covered by guidelines established by the National Institutes of Health (NIH. The penalty for non-adherence to NIH guidelines is loss of all NIH funding for the institution in which significant infractions are found.

U.S. federal law requires that the label and labeling of all foods (for man or other animals) regardless of the method of production be truthful and not misleading. Because foods derived from GE organisms do not as a class differ from other foods in any meaningful or uniform way, or present any different or greater safety concern than foods developed by conventional means, the method of development of a new food variety (including the use of new techniques such as rDNA technology) is generally not material information that would be required to be disclosed in the labeling for the food. The FDA, allows producers to label their foods as having been or not having been produced using modern biotechnology, provided such labeling is truthful and not misleading.

In 2001 the U.S. Food & Drug Administration (FDA) issued draft guidance for industry regarding voluntary labeling indicating whether foods have or have not been developed using biotechnology. [47]

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
Policy Guidance, Laws & Regulations	National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules or similar guidelines 2013	Plants: Plant Protection Act (PPA, for potential weeds and plant pests) 2000; Federal Insecticide, Fungicide and Rodenticide Act (FIFRA, for plant incorporated pesticides[PIPs]) 1947 plus amendments; and the Toxic Substances Control Act (TSCA; for plants producing compounds that are not regulated as drugs or pesticides) 1976 plus amendments Animals: Federal Food, Drug and Cosmetic Act (FFDCA, under new animal drug provisions, 1938 plus	Plants: PPA for potential weeds and plant pests 2000; FIFRA for PIPs 1947 plus amendments, and TSCA for plants producing compounds that are not regulated as drugs or pesticides) 1976 plus amendments Animals: Federal Food, Drug and Cosmetic Act (FFDCA, under new animal drug provisions, 1938 plus amendments, and the non-binding "Guidance for Industry: Regulation of Genetically Engineered Animals Containing	FFDCA (novel protein or GM product considered as food additives, flavorants, dietary supplements) 1938 plus amendments FIFRA for plant incorporated pesticides (PIPs) 1947 plus amendments	FFDCA (novel protein or GM product considered as food additive, flavorants, dietary supplements) 1938 plus amendments FIFRA for plant incorporated pesticides (PIPs) 1947 plus amendments	Plants: PPA for potential weeds and plant pests 2000 FFDCA (novel protein or GM product considered as food additive, flavorants, dietary supplements) 1938 plus amendments FIFRA for plant incorporated pesticides (PIPs) 1947 plus amendments

[47] U.S. FDA, "Center for Food Safety and Applied Nutrition Program Priorities, 2013-2014,"

http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CFSAN/WhatWeDo/ucm366279.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery ■

U.S. FDA,"Guidance for Industry: Voluntary Labeling Indicating Whether Foods Have or Have Not Been Developed Using Bioengineering; Draft Guidance" 2001;

http://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/labelingnutrition/ucm059098.htm

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
		amendments, and the non-binding "Guidance for Industry: Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs), issued 2009 Microorganisms: TSCA for "new" microbes (included in broad definition of new chemical substances) 1976 plus amendments	Heritable Recombinant DNA Constructs), issued 2009 Microorganisms: TSCA for "new" microbes (included in broad definition of new chemical substances) 1976 plus amendments FFDCA (for pre-marketing consultation on food safety) 1939 plus amendments			
Implementing Agencies	Government funding agency, if applicable (e.g., National Science Foundation, National Institutes of Health, etc.) Institutional Biosafety Committees (IBCs) registered with National Institute of Health's Office for Biotechnology Activities	Plants: USDA-APHIS (APHIS; for import, interstate movement and environmental release) (Biotechnology Regulatory Services BRS); Environmental Protection Agency (EPA) Animals: Food and Drug Administration (FDA) Microorganisms: EPA and APHIS (if a potential plant pest)	Plants: USDA-APHIS (BRS); EPA for PIPs; FDA Center for Food Safety and Applied Nutrition (CFSAN, consulted by USDA-APHIS) Animals: FDA Microorganisms: EPA and APHIS (if a potential plant pest)	FDA-CFSAN USDA Food Safety and Inspection Service (USDA-FSIS for meat, eggs and poultry)	FDA- Center for Veterinary Medicine (CVM)	FDA-CFSAN FDA-CVM USDA-APHIS
Organisms covered	All GMOs	GMOs as definted in 7 CFR 340	GMOs as definited in 7 CFR 340	All GMOs	All GMOs	All GMOs
Required submissions	Research Proposal for funding and/or IBC Assessment	APHIS: (i) Notification document (plant species not a potential pest, gene integration stable, function of inserted gene known does not cause plant disease, gene product not infectious nor produce infectious entities, inserted gene not from human or animal pathogens); OR (ii) Application for permit (for plant species that	APHIS: Petition for determination of non-regulated status stating "factual grounds why the organism should not be regulated under 7 CFR part 340". Including scientific literature, unpublished data, field trial data in support of the petition, and information, if any, "unfavorable to the petition." Information submitted for notification or permit applications for field trials	Food safety evaluation dossier prepared in consultation with FDA, in the prescribed format. Dossier should explain "scientific evaluation of the food safety of the new protein by providing a synopsis of the safety data and information and conclusions about potential food safety concerns if the protein inadvertently entered the food supply." Data requirements are focused in determining	Food safety evaluation dossier prepared in consultation with FDA, in the prescribed format. Dossier should explain "scientific evaluation of the food safety of the new protein by providing a synopsis of the safety data and information and conclusions about potential food safety concerns if the protein inadvertently entered the food supply." Data requirements are focused in determining	APHIS: Import Permit (if applicable) Food safety evaluation dossier prepared in consultation with FDA, in the prescribed format. Dossier should explain "scientific evaluation of the food safety of the new protein by providing a synopsis of the safety data and information and conclusions about potential food safety concerns if the protein inadvertently entered the food supply."

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
		may pose a pest risk to environment) including, gene donor organisms, vectors used when needed to clarify the order of genetic compoments, molecular mechanisms involved in production of expressed material, purpose of genetic modification and proposed steps to control GMO and associated biological materials (including confinement) EPA, under FIFRA: (i) Notification document (for >10 acres land or >1 acre water, plus some confinement) (ii) Application for "experimental use permit" under FIFRA, including dossier detailing effectiveness, chemistry, toxicology, environmental fate, and effect on non-target species. EPA under TSCA: "pre-manufacture notification" for product of genetic transformation (for microbials or plants) FDA: Investigative New Animal Drug (INAD) Application or New Animal Drug Application (NADA) data detailing characteristics of GM animal, ploidy and zygosity, molecular modifications (including inserted gene sequence details of gene construct, purpose of modification, stability of heritability, food and feed safety assessments,	also part of submitted dossier EPA under TSCA: "Microbial Commercial Activity Notice (MCAN)" for product of genetic transformation (for microbials or plants) FDA: New Animal Drug Application (NADA) data detailing characteristics of GMO animal, ploidy and zygosity, molecular modifications (including inserted gene sequence details of gene construct, purpose of modification, stability of heritability, food and feed safety assessments, environmental assessments, effectiveness, and any INAD data generated	toxicity and allergenicity properties of the GMO's novel protein	toxicity and allergenicity properties of the GMO's novel protein; also considers suitability of GM product as feed	Data requirements are focused in determining toxicity and allergenicity properties of the GMO's novel protein; also considers suitability of GM product as feed

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
		environmental assessments, and effectiveness				
Processing Fee	None	None specified	None specified	None specified	None specified	None specified
Processing time in law or regulation	None	APHIS: (i) Notification: 30 days (ii) Permit: 120 days EPA under TSCA: 90 days after submission of notification EPA under NEPA: if document for compliance with NEPA is necessary, application must be submitted 1 year prior to any planned environmental release.	APHIS: 180 days after receipt of petition EPA under TSCA: 90 days FDA: None specified	120-135 days FDA vs EPA?	120-135 days FDA vs EPA?	120-135 days
Risk Assessment	For non-government research institutions, done in-house IBC (follows RAC guidelines) Done in house by government research institutions (voluntary compliance with RAC guidelines; mandatory compliance for NIH funded research)	Done by APHIS staff following 7CFR § 340 Done by EPA staff under FIFRA following 40CFR parts 152, 172 and 174 (plants) or 40CFR part 725 (microorganisms) Done by EPA staff under TSCA 40 CFR 725 and NEPA 40 CFR§1501.3 and 1501.4, and 40 CFR § 1508.9	Done by APHIS staff following 7CFR § 340, taking into account public comments received Done by EPA staff, taking into consideration "potential to cause unreasonable risks to human health and environment", using TSCA criteria for risk assessment Done by FDA Center for Veterinary Medicine (CVM) taking into account risks for human health and environment, food and feed safety, including concerns about effectiveness, residues and effects on the receiving population	Done by FDA-CFSAN using substantial equivalence and the Codex Alimentarius Guidelines	Done by FDA-CVM using substantial equivalence; approval for feed use contingent also on approval for food use	Done by APHIS staff following 7CFR § 340 Done by FDA-CFSAN and FDA-CVM using substantial equivalence and/or CodexAlimentarius guideline; approval for feed use contingent also on approval for food use
Public Participation/ Public Comment	None required	APHIS: Notification of States and Territories Public comment may be required by EPA for activities that require NEPA document	APHIS: 30-day public comment period for petition for nonregulated status under 7 CFR 340 EPA: none specified except for those that require NEPA document	Submissions posted in the FDA website for public comment, except for sections marked as confidential	Submissions posted in the FDA website for public comment, except for sections marked as confidential	APHIS: Notification of States and Territories Submissions posted in the FDA website for public comment, except for sections marked as confidential

	Contained Work	Limited Field tests	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
			FDA-CVM: Public advisory committee meetings prior to approval; summary of information used for safety assessment posted after completion of NADA			
Socioeconomic considerations	None specified	None specified	None specified	None specified	None specified	None specified
Approval Document	Approval for funding (if applicable)	Acknowledged notification or issued permit for field trial (APHIS), and/or experimental use permit (EPA under FIFRA) Acknowledged Pre-Manufacture Notice (PMN) from manufacturer	APHIS: Determination of nonregulated status under 7 CFR 340 EPA: MCAN approval document FDA-CVM: NADA approval document with or without restrictions	FDA food safety evaluation	FDA feed safety evaluation	FDA food and feed safety evaluations
Restrictions or conditions	Must adhere to Good Laboratory Practice (GLP) and use appropriate containment facilities	APHIS: Must adhere to confinement and/or reporting requirements FDA-CVM: INAD recordkeeping and reports required EPA: TSCA reporting requirements, especially when interstate shipping is involved	FDA-CVM: As specified in approval document, and post approval commitments on registration, recordkeeping and reports	Case-by case restrictions may apply	Case-by case restrictions may apply	APHIS: Must adhere to confinement and/or reporting requirements Case-by case restrictions may apply
Expiration of Approval Document	None specified	APHIS: Notifications valid 12 months; Permits are case by case	None specified	None specified	None specified	None specified
Renewal Provision	None specified		None specified	None specified	None specified	None specified

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VIET NAM

At present, no commercial cultivation of GM crops or trade in GM seeds has been approved in Viet Nam. Viet Nam, however, imports soybean and corn as bulk commodities and such imports likely contain GM varieties.

Viet Nam's initial biosafety regulations of GMOs were issued in 2005 in the form of guidelines to cover scientific research, technology development, and use of GMOs (Nampompeth 2010). Some of the provisions in the early guidelines were later incorporated in subsequent decrees and circulars issued by the Government and the different Ministries tasked with implementing regulations concerning GMOs.

The current regulatory system in place in Viet Nam is Decree of Government No. 69/2010/ND-CP on Biosafety of Genetically Modified Organisms, Genetic Specimen, and Products Derived from Genetically Modified Organisms, which covers the entire range of activities relating to research, development, and use of GMOs and their products in Viet Nam. Implementation of this decree is guided by a series of circulars issued by the designated government agencies, detailing specific requirements and procedures for contained and confined use, field trials, commercial cultivation and use of GMOs and their products for food, feed, and processing. The decree regulates GMO by event, but does not require a new assessment for stacked events generated by crossing previously approved events, unless the stacked traits were created by simultaneous transfer of multiple genes in one event.

Prior to the issuance of Decree of Government No. 69/2010/ND-CP, the Ministry of Agriculture and Rural Development (MARD) issued Circular No. 69 /2009/TT-BNNPTNT on risk assessment of GM crops to biodiversity and environment to set procedures for confined tests and field trials. No new circular has been issued by MARD after the 2010 decree. Presumably, the same procedures outlined in Circular No. 69 will be used by MARD in regulating confined tests and field trials. Under Circular 69, MARD issued the first permit for conducting confined field trials of GM corn to two companies in March 2010. In August of the same year, a third company was granted a permit for conducting confined field trials of GM corn. All confined field trials of were successfully completed in late 2010. MARD subsequently granted permission allowing the same three biotech companies to conduct multi-location field trials, and all multi-location field trials of *Bt* corn were completed in late 2011. On November 16, 2012, MARD issued another permit to a company to conduct a confined field trial for an additional GM corn variety. The local scientific community is reportedly working on the introduction of various traits into rice, maize, cotton, soybean, papaya, cabbage, cassava, sweet potato, potato, tomato, sugarcane, ornamental flowers (carnation, chrysanthemum, gladiolus), and forest trees using the tools of modern biotechnology, but none of these have been subject to confined tests or small-scale field trials.

Circular No. 08/2013/TT-BTNMT stipulating the order of procedures for granting and revoking biosafety certificates for GM crops has been issued by the Ministry of Natural Resources and Environment to accommodate wide-scale cultivation of GM crops. In Viet Nam, confined tests and field trials are conducted by MARD-certified agencies nominated by the proponents. Confined and small field tests require isolation, while large-scale field tests require only "appropriate management and monitoring measures." Results of the field tests are required for applications for biosafety certificate under Decree No. 69/2010/ND-CP and Circular No. 08/2013/TT-BTNMT.

Circulars for implementing regulations for use of GM crops and their products for food, animal feed, and processing are yet to be issued by MARD, although drafts have reportedly been prepared and are undergoing public comment. In the interim, the labeling requirements stipulated in Decree of Government No. 69/2010/ND-CP have not yet been implemented.

	Contained Work	Limited field tests a large scale trials	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
Key Laws & Regulations	Decree of Government No. 69/2010/ND-CP on Biosafety of Genetically Modified Organisms, Genetic Specimen and Products Derived from Genetically Modified Organisms, 2010	Decree of Government No. 69/2010/ND-CP on Biosafety of Genetically Modified Organisms, Genetic Specimen and Products Derived from Genetically Modified Organisms, 2010 Circular No. 69 /2009/ TT-BNNPTNT on risk assessment of genetically modified crops to biodiversity and environment	Circular No. 08/2013/TT-BTNMT (*stipulating the order, procedures for granting and revoking biosafety certificate for genetically modified crops)*, 2013	Decree of Government No. 69/2010/ND-CP on Biosafety of Genetically Modified Organisms, Genetic Specimen and Products Derived from Genetically Modified Organisms, 2010 Decree of Government No: 108/2011/ND-CP Amending some articles of the Decree No. 69/2010/ ND-CP, 2011 (promulgated January 2012)	Decree of Government No. 69/2010/ND-CP on Biosafety of Genetically Modified Organisms, Genetic Specimen and Products Derived from Genetically Modified Organisms, 2010	Decree of Government No. 69/2010/ND-CP on Biosafety of Genetically Modified Organisms, Genetic Specimen and Products Derived from Genetically Modified Organisms, 2010
Implementing Agencies	Ministry of Science and Technology (MOST)	Ministry of Agriculture and Rural Development (MARD)	MoNRE Vietnam Environment Administration (VEA)	Ministry of Agriculture and Rural Development (MARD)	MARD	MARD
Organisms covered	All GMOs	GM crops	GM crops	GM crops	GM crops	GM crops and products
Required submissions	3 sets of applications submitted to MOST for laboratory certification declaring availability of appropriate professional staff, equipment and detailing laboratory's functions and duties, track record, capacity, and laboratory operating procedures that satisfy biosafety requirements Explanation statements on projects of science research and technology development involving GMOs (according to prescribed information requirements), details of biosafety management procedures	For Certification of Trial Agency: (i) Application for issuance of certificate of Trial Agency (ii) Copies of decisions on applicant's functions and duties (iii) Explanation on capacity (equipment, facilities and technical manpower, safe operating practices) of Trial Agency according to form prescribed by MARD (iv) Documents to prove compliance with conditions set by MARD For Permit for Field Trial:	(i) Application for Biosafety Certificate according to prescribed format (ii) 10 copies of report on Field trial results accompanied by official document on field trial results from MARD (iii) 10 copies of Risk Assessment Report in prescribed format plus electronic file of the same (details on host, inserted DNA, transformation method, GM characteristics, proposed use, risks to human health, environment and biodiversity, risk management	(i) Application for issuance of Certificate of GMOs that satisfy conditions for food, according to specified format (ii) Report of risk assessment of GMOs in relation to human health with dossier describing recipient organism, presence of inherent toxicants, allergens and anti-nutrients, history of use as food, information about the GMO (description of transformation, inserted genes and sequences, GM characteristics, method of detection),	(i) Application for issuance of Certificate of GMOs that satisfy conditions for animal feed, according to specified format (ii) Report of risk assessment of GMOs in relation to its suitability as animal feed with dossier describing recipient organism, including its adverse impacts on human and livestock health, history of use as food and feed, information about the GMO (description of transformation, inserted genes and sequences, GM characteristics, method of detection),	Certificate for GMOs satisfying conditions to be used as food plus inclusion in list of GMOs that satisfy conditions to be used as food. -or- Certificate for GMOs satisfying conditions to be used as animal feed plus inclusion in list of GMOs that satisfy conditions to be used as animal feed

	Contained Work	Limited field tests a large scale trials	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
		(i) Application for issuance of a permit for field trial according to format specified by MARD (ii) Dossier on GMO detailing host, donor and GMO characteristics, genetic modification, detection methods, history of previous approvals and use, location, map, size and description of field trial site, trial methodologies, number/volume of GMO in field trial, duration of trial, projected risks, risk management, safety measures, and disposal plans (iii) Field trial plan according to specified format (iv) Copy of Certificate of Trial Agency (v) If GMO is to be imported, document declaring that said GMO is permitted to be used for the same purpose in the exporting economy (vi) If application is for a large scale trial, document from MARD accepting results of confined trials	measures, plan for monitoring risks) (iv) Electronic file containing information on environmental and biodiversity risk assessment report in prescribed format (v) Additional information that may be requested as deemed necessary	history of approval and use as food, (iii) Comparative nutritional composition, toxicity and allergenicity data, and possibility of other ill effects if used as food, and proposed measures for risk management. (iv) If imported, documents to prove that GMOs have been used as food in five developed countries	history of approval and use, comparative nutritional composition, metabolic performance and information on risks when unintentionally used as food. (iii) If imported, documents to prove that GMOs have been used as animal feed in five developed countries	
Processing Fee	None specified	None specified for certification of Trial Agency Fees required for Applications for permit for Field ; actual fees to be determined by the Ministry of Finance and MARD	Required but amount not specified in circular	Fees required for Application for issuance of Certificate of GMOs satisfy conditions for food; actual fees to be determined by the Ministry of Finance and MARD	Fees required for Application for issuance of Certificate of GMOs that satisfy conditions for animal feed; actual fees to be determined by the Ministry of Finance and MARD	Usual fees for commercial importation; no additional fees specified for GMOs
Processing time	82 working days	For certification of Trial Agency: 82 working days	Approximately 200 working days	227 working days if developed within Vietnam;	227 working days if developed within Vietnam;	Usual processing time for commercial importation of commodities

	Contained Work	Limited field tests a large scale trials	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
		For Permit for Field Trials: 97 working days		107 working days if imported as commodity. Estimated processing time includes entry of GMO into registry of GMOs approved for food use	107 working days if imported as commodity. Estimated processing time includes entry of GMO into registry of GMOs approved for animal feed use	
Risk Assessment	Assessment of laboratory's suitability done by committee appointed by MOST to examine applications	For certification of Trial Agency and for Permit for field trials: Examination of submissions done by Committee established by MARD	Scientific and technical assessment performed by applicant and reviewed by Technical Advisory Team (TAT) formed by VEA. ecommendation of TAT discussed by Biosafety Committee formed by Minister of MONRE	Evaluation of submitted documents and review of risk assessment done by Committee for food safety of GMOs established by MARD; Committee advises Minister of MARD on results of evaluation	Evaluation of submitted documents and review of risk assessment done by Committee for animal feed safety of GMOs established by MARD; Committee advises Minister of MARD on results of evaluation	No additional assessments specified for GMOs if already included in an approved list
Public consultation or Public comment	None required	None required for Certification of Trial Agency and for Permit for Field trials	Within 5 days of receipt of dossier, information on report on risk assessment on effect of GMO on environment and biodiversity (item d above)published in Vietnam Biosafety Clearing House (BCH) for 30 day public comment; public comments summarized by VEA and forwarded to Biosafety Committee	Upon receipt of complete and valid documents, report of risk assessment of GMOs in relation to human health published in MARD website for 30-day public comment	Upon receipt of complete and valid documents, report of risk assessment of GMOs in relation to its suitability as animal feed published in MARD website for 30-day public comment	No additional requirements specified for GMOs if already included in an approved list
Socioeconomic considerations	None required	None required for Certification of Trial Agency and for Permit for Field trials	None specified for risk assessment but may play role in final decision by Minister of MONRE	None specified for risk assessment but together with public comment may play role in final decision by Minister of MARD	None specified for risk assessment but together with public comment may play role in final decision by Minister of MARD	No additional requirements specified for GMOs if already included in an approved list.
Approval Document	Certificate of laboratory for science research on GMO issued by Minister of MOST; Ministry of Natural Resources and Environment (MONRE) informed of certification	Certification of Trial Agency and Permit for Field Trial issued by MARD Minister; MONRE informed of issuance of Certification and Permit	Biosafety Certificate	Certificate for GMOs satisfying conditions to be used as food plus inclusion in list of GMOs that satisfy conditions to be used as food	Certificate for GMOs satisfying conditions to be used as animal feed plus inclusion in list of GMOs that satisfy conditions to be used as animal feed	No additional documents specified for GMOs if already included in an approved list
Restrictions or conditions	Certificate may be withdrawn; each activity in certified facilities needs approval from MOST; MOST may stipulate specific contents of biosafety management within facility	MARD provides detailed guidance, monitors operation of trial agencies; certification may be withdrawn if Trial Agency fails to comply with operating conditions on infrastructure, professional	Biosafety certificate may be revoked if new scientific evidence for harm becomes available, upon discovery of false information provided by applicant, or presentation of evidence for erroneous	Certificate may be withdrawn if warranted by new science-based evidence of potential risk, if false information has been provided, or if the conclusion of the Committee for food safety of GMOs has been	Certificate may be withdrawn if warranted by new science-based evidence of potential risk, if false information has been provided, or if the conclusion of the Committee for food safety of GMOs has	No additional conditions specified for GMOs if already included in an approved list.

	Contained Work	Limited field tests a large scale trials	Commercial release	Use as Food	Use as Feed	Importation for processing/ as processed commodity
		staff, and safety operating procedures	conclusion made by Biosafety Committee Certificate holder must submit annual report of production status of GM crop in Vietnam and report must be circulated to MONRE, MARD, and the People's Committees in localities where GM crop is cultivated	proven to have insufficient scientific basis Labeling required if any GM ingredient in food exceeds 5%	been proven to have insufficient scientific basis Labeling required if any GM ingredient in animal feed exceeds 5%	Labeling required if any GM ingredient in goods exceeds 5%
Expiration of Approval Document	None specified	For Certification of Trial Agency, no specified expiration Permit for Field Trials valid for period specified	None specified; certificate valid unless revoked	None specified; certificate valid unless withdrawn	None specified; certificate valid unless withdrawn	None specified
Renewal Provisions	None specified	None specified	None specified	None specified	None specified	None specified

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Conclusions & Next Steps

- Twenty out of twenty-one APEC Member Economies have in place a regulatory framework to address the products derived from innovative agricultural technologies within national boundaries, including regulations that address their importation as an ingredient for processing into food or feed. For some economies the information is readily available; in other economies this information is difficult to find. The survey exposes the complexity of the regulations regarding agricultural products derived from innovative technologies and the myriad of regulating agencies. The information contained here represents the most up-to-date, comprehensive, and accurate information available on each member economy, with the exception of Brunei Darussalam. This economy is yet to have a regulatory system in place.

- It is recommended that the High-Level Policy Dialogue on Agricultural Biotechnology publish the survey on the APEC website for use by APEC economies. This is in accordance with the APEC 2013 Joint Ministerial Statement point 75. Acknowledging that agricultural biotechnology advances APEC economies' agricultural sustainability and goals for food security, we agreed to promote the sharing of information and experience on the creation and fostering of science-based regulatory structures….

- Publishing of the survey on the APEC website will provide an opportunity for APEC economies to glean from other economies' regulatory practices that they may adopt to improve their systems. To this end it would make sense for the HLPDAB to follow-up with fora that allow economies to share their efficiencies and successes of their regulatory systems. In addition, there must be an effort to keep the information accurate, up to date, and endeavor to assure transparency of all national regulatory information. At this point, there is no mechanism (or funding) in place to do this. Further, at some point it would make sense to evaluate economies use of the survey to determine the usefulness of the information.

- It may also be useful include at an APEC HLPDAB forum examples of economies making changes to their regulatory practices based on adopting efficiencies in other economies and more challenging regulatory topics Another step may to be to expand the survey to include links to international clearing-houses of multi-country biosafety regulatory information and registries of safety approvals.

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