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Update of the APEC Baseline Study: Regulations of Products Derived from Innovative Agricultural Technologies and Identification of Ways to Promote Greater Efficiencies and Alignment

APEC High-Level Policy Dialogue on Agricultural Biotechnology

November 2018

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Part 1: Decision Frameworks

Exposure Draft

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EXECUTIVE SUMMARY

The use of biotechnology in agriculture continues to rapidly expand, particularly in key globally traded commodities such as maize, soybean, cotton and canola. More recently, new breeding technologies offer a paradigm shift in food production, including challenges to food regulation.

The regulation of products from biotechnology varies widely across the Asia-pacific region, largely based on local economic, political and societal motives. However, all regulatory agencies, regardless of geography, share the same mandate–to ensure the health and safety of consumers and protect the environment.

The diversity of regulatory frameworks has resulted in some jurisdictions having highly functional and well-resourced regulatory systems, while others have relatively weak systems or no formal regulations at all. This diversity has also resulted in wide differences in the degree and level of protection afforded to the populations across the region and is a major constraint to the introduction of new and novel food products that can address some of the region's most pressing needs (e.g. food security, environmental sustainability and socio-economic improvement). Further, the rapid development and introduction of new biotech products add pressure to those economies where regulatory systems are weak and/or poorly resourced.

Over the past 20 years, more than 1260 food safety decisions across 28 economies have been made from the assessment of agricultural biotechnology products[1]. Often the assessments have been made about the same products or proteins with many years of safe use. In all cases, without exception, the agencies have arrived at the same conclusion on a product's safety. This high level of agreement suggests there is a more efficient way to regulate biotechnology products.

Regulatory convergence and cooperation are recognised as mechanisms to reduce the burden on individual economies, extend the reach beyond borders and drive continuous improvement of domestic regulatory systems. Regulatory convergence represents a process where the regulatory requirements across economies or regions become more similar or aligned over time as a result of the gradual adoption of internationally recognised technical guidance documents, standards and scientific principles. It does not necessarily represent the harmonisation of laws and regulations, which is not a prerequisite

[1] Data provided by CropLife International

for allowing the alignment of technical requirements and greater regulatory cooperation.

This report outlines Part 1 of a project that provides an update to the Regulations of Products Derived from Innovative Agricultural Technologies: Baseline Review of APEC Member Economies. The report provides an outline of APEC economies' decision frameworks in order to inform which economies could be further assessed for compatibility to identify ways to promote greater efficiencies and alignment.

1. INTRODUCTION

This project arose from the APEC High Level Policy Dialogue for Agricultural Biotechnology (HLPDAB) Terms of Reference along with an agreement made by economies at the APEC HLPDAB Meeting in Piura, Peru and concurred within Can Tho. This project provides an update to the Regulations of Products Derived from Innovative Agricultural Technologies: Baseline Review of APEC Member Economies.

The scope of this project aims to identify regulatory best practices among APEC economies and develop tools to build upon the work of international fora and standards. The ultimate goal is to promote greater alignment of APEC economies while making regulatory processes more efficient.

This report outlines Part 1 of the project, providing an outline of APEC economies' decision frameworks in order to demonstrate which economies could be further assessed for compatibility to work together towards regulatory cooperation and is aligned to the scope of services as outlined in Appendix 1.

The focus of this project is limited to food and feed derived from genetic engineering and on outlining decision frameworks that identify the governing regulatory regimes at the economy level in economies where it is present.

Specifically, this report:

- Builds on the baseline review of regulations of products derived from innovative agricultural technologies – with a focus on food and feed. This report is limited to a subset of APEC economies
- Provides foundational information to be able to identify economies with regulatory regimes compatible to regulatory cooperation.

2. BACKGROUND

2.1 Regulatory cooperation

Since the introduction of genetic modification (GM) technology over 20 years ago, there have been more than 1260 submissions for food safety approvals. For all submissions, across 28 economies, no request for approval has been disallowed on safety grounds. Regulatory agencies around the world have access to the same data via applicants' dossiers and, without exception, have always arrived at the same conclusion of a products safety.

Increased familiarity with GM technology and the recognition of the similarity of data inputs and processes and the consistency in food safety submission outcomes creates opportunities for regulatory cooperation between and among governments to reduce redundancy, encourage innovation, facilitate trade, and allow scarce government resources to be employed most effectively. Regulatory cooperation to increase the efficiency and confidence of regulatory decisions does not compromise sovereignty or protection goals of regulatory agencies. All regulatory agencies have equivalent protection goals - protecting human health and the environment.

2.2 The opportunities and benefits to regulatory cooperation

In addition to basing their reviews on Codex guidelines, governments tend to follow similar processes in conducting safety assessments. Consistency in outcomes and the similarity of data inputs and dossiers provided by applicants creates opportunities for cooperation between and among governments to reduce redundancy and employ resources more efficiently and effectively.

Regulatory cooperation is not a novel concept. The European Union recognizes a single food safety assessment for the entire 28 economy bloc and recently Health Canada (HC) and Food Standards Australia New Zealand (FSANZ) have tested a safety assessment sharing program.

Regional cooperation efforts are also actively exploring ways to increase their cooperation around safety assessment sharing (e.g. MERCOSUR in Central America[2]; the COMESA region in East Africa[3]).

Recognition and use of like-minded economy safety assessments for GM crops during the regulatory approval process has proven to provide benefits to both technology providers and regulatory agencies without impacting sovereignty.

Across Asia, Viet Nam has incorporated the principle of mutual recognition by allowing products to go through an expedited review process provided the product has received approval by at least five OECD economies.

Other benefits to cooperation include reduced resource requirements for regulatory agencies allowing for the re-allocation of those resources to new and/or future needs (e.g. training of regulators). Further, a reduction in regulatory costs and timelines mean a clear and predictable path to

[2] Prado and Bertrand (2015) Regulatory cooperation in Latin America: the case of MERCOSUR. 78 LAW & CONTEMP. PROBS. 4 (FALL 2015)
[3] COMESA - Common Market for Eastern and Southern Africa

commercialization for technology providers and reduced risk of trade disruption and a practical solution to addressing issues related to Low-Level-Presence (LLP).

2.3 The APEC Baseline Study

The APEC Baseline Study: Regulations of Products Derived from Innovative Agricultural Technologies was completed in 2006 and updated in 2016[4].

The baseline review prepared for the HLPDAB presented 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 was further disaggregated with regard to the intended application of the biotech product or process. For each APEC Member Economy, regulatory approach details were presented in a consistently

[4] Baseline Review of APEC Member Economies' Regulations of Products Derived from Innovative Agricultural technologies

constructed matrices. Syntheses of similarities and differences were highlighted, and a number of opportunities to embark on an APEC-wide path of regulatory harmonization in this area were also suggested.

Part 1 of this project, as detailed in this report, follows a similar structure to ensure consistency with the Baseline Review.

3. DECISION FRAMEWORKS FOR MEMBER ECONOMIES

3.1 Decision framework

The baseline review prepared for the HLPDAB presented information in a consistent format on agricultural biotechnology regulations. This has been updated and modified to form decision framework that will inform identification of candidate economies for a further compatibility assessment for regulatory cooperation. A summary table for each economy is presented.

3.2 Australia

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for Processing	Comments
Regulatory framework in place?	International standards (e.g. Codex/OECD)	✓	Domestic guidelines are in line with the Codex Guidelines in conducting safety assessment of GM food.			Australia has not signed the Cartagena Protocol
	Domestic laws and regulations	✓	Australia New Zealand Food Standards Under Standard 1.5.2 – Food produced using Gene Technology	*Gene Technology Act 2000* if viable GMOs used; otherwise no special provisions (Specific legislation for GMOs) Viable products may require an import permit under the Biosecurity Act 2015 For products with pesticidal activity (e.g. Bt): Agricultural and Veterinary Chemicals Code Act 1994.	Australia New Zealand Food Standards Code under Standard 1.5.2 – Food produced using Gene Technology Imported Food Control Act 1992 *Gene Technology Act 2000* if viable GMOs to be imported for processing Some viable GM products may require an import permit under the Biosecurity Act 2015	The Gene Technology Act 2000 and Gene Technology Regulations 2001 were recently reviewed. FSANZ are reviewing whether products from new breeding technologies are appropriately captured under the current framework or whether to review the Food Stands Code.
	Implementing Agencies	✓	• Food Standards Australia New Zealand (FSANZ) • Office of the Gene Technology Regulator (OGTR) • The Australian Pesticides and Veterinary Medicines Authority (APVMA) • Department of Agriculture and Water Resources (DAWR)			
Coverage of legislation?	Legislative trigger?	✓	FSANZ regulates the Product of gene technology	Process and product. OGTR regulates the process, APVMA/DAWR regulate the product	FSANZ/APVMA/DAWR regulate the product	
	Specifies organisms covered?	✓	GM Plants, animals and microorganisms	Viable GM Plants, animals and microorganisms	Viable GM Plants, animals or microorganisms	
	Dossier for food safety assessment required?	✓	An application to amend the Food Standards	No separate feed approval is required. If a	If importing viable GMOs (e. g., whole grain, oil	

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for Processing	Comments
			Code is submitted to FSANZ for assessment. Requirements are outlined in the FSANZ Application Handbook	viable GMO, then a licence from OGTR can impose conditions on feed use.	seeds) a license is required from OGTR Some viable GM products may require an import permit under the Biosecurity Act 2015	
Process for assessment and approval?	Timeframes specified?	✓	Approximately 9-12 months	An OGTR licence assessment requires up to 255 working days	An OGTR licence assessment requires up to 255 working days Import permits are variable	
	Processing fees applicable?	✓	FSANZ provide an estimate up front following an administrative assessment. Cost dependent on complexity of application. Refunds are provided for unused time	OGTR does not currently charge fees	OGTR does not currently charge fees An import permit fee is payable (variable)	
	Public consultation?	✓	Preliminary Safety Assessment released for public comment. Public information via publication in Commonwealth Gazette	OGTR releases a Risk Assessment Risk Management Plan for public comment and seek input from interested stakeholders Outcomes are published on the OGTR website	OGTR releases a Risk Assessment Risk Management Plan for public comment and seek input from interested stakeholders Outcomes are published on the OGTR website DAWR does not provide public information for import permits issued	
	Socio economic considerations?	X				Individual State and Territory

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for Processing	Comments
						governments are able to restrict activities with GM crops for market and trade reasons. This only relates to GMOs, not food products.
	Length of approval specified?	✓	Valid until the approval is removed from the Food Standards Code	OGTR license is valid either for a specific duration or until revoked, cancelled or surrendered	Valid until food/feed is removed from sale OGTR license is valid either for a specific duration or until revoked, cancelled or surrendered Import permits are typically valid for 12-24 months	
	Renewal options?	✓			Applications for renewal can be made on a case-by case basis	
Outputs from assessment	Food safety assessment?	✓	Safety Assessments are published on the FSANZ website	RARMPs and Safety Assessments are published on the OGTR website	RARMPs and Safety Assessments are published on the OGTR and FSANZ websites	
	Assessments/Decision made public?	✓	Safety Assessment outcomes and recommendations are published on the FSANZ website Incorporated into the Code as amendments (Becomes part of the	RARMPs and Safety Assessments are published on the OGTR and FSANZ websites	Outcomes are published on the FSANZ and OGTR websites	

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for Processing	Comments
			foods approved under Standard 1.5.2)			
Historical assessments and approvals?	GM Cotton?	✓	HT/IR, Stacked			Applications and current status Soybean, maize and other GM food (i.e. potato, alfalfa, wheat, rice, and sugar beet) approvals described relate only to GM foods, not to feed or import of viable GMOs.
	GM Canola?	✓	HT, Omega-3, hybrid breeding			
	GM Soybean?	✓	HT/IR, stacked, high oleic			
	GM Maize	✓	HT/IR, stacked, high lysine, amylase modified, drought tolerant			
	Other GM foods?	✓	Potato, alfalfa, wheat, rice, sugar beet			
Any special conditions / considerations?	Restrictions to distribution and use?	✓		Adhere to risk management conditions imposed through OGTR license Must comply with any other applicable State or Commonwealth law; State and Territory laws may restrict activities with GMOs within their boundaries for trade and marketing reasons.	Adhere to risk management conditions imposed through OGTR license Must comply with any other applicable State or Commonwealth law; State and Territory laws may restrict activities with GMOs within their boundaries for trade and marketing reasons. Must comply with any conditions associated with an import permit	

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for Processing	Comments
	Labelling requirements?	✓	GM foods and ingredients (including food additives and processing aids) that contain novel DNA or novel protein must be labelled with the words 'genetically modified' GM foods that do not contain any novel DNA or novel protein, and do not have an altered characteristic, do not require GM labelling. The decision not to label these foods was made because the composition and characteristics of these foods is exactly the same as the non-GM food. These foods are typically highly refined foods, such as sugars and oils, where processing has removed the DNA and protein from the food, including novel DNA and novel protein. GM flavourings that are present in food in a concentration of no more than 0.1% are also exempt from labelling. Labelling is also not required when there is no more than 1% (per ingredient) of an approved GM food unintentionally present in a non-GM food. This means labelling is not required when a manufacturer genuinely orders non-GM ingredients but finds that up to 1% of an approved GM ingredient is accidentally mixed with the non-GM ingredient.			

3.3 Brunei Darussalam

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Regulatory framework in place?	International standards (e.g. Codex/OECD)	X				Brunei Darussalam has not signed the Cartagena Protocol
	Domestic laws and regulations	X	Brunei Darussalam currently has no specific guidelines for regulating GMOs. Biotech-related activities are headed by the Department of Agriculture and Agrifood (DAA), under the Ministry of Industry and Primary Resources, and the University of Brunei Darussalam. 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.			
	Implementing Agencies	X	• Ministry of Development–sets the standards and regulations for food • 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			
Coverage of legislation?	Legislative trigger?	X				
	Specifies organisms covered?	X				
Process for assessment and approval?	Dossier for food safety assessment required?	X				
	Timeframes specified?	✓	If the required information is complete, the registration letter is issued within 5-7 working days from the date of submission.			
	Processing fees applicable?	✓	Application for registration to food import is free.			
	Public consultation?	X				
	Socio economic considerations?	✓	GM food products must be safe and conform to *halal* regulations.			
	Length of approval specified?	X				

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
	Renewal options?	X				
Outputs from assessment	Food safety assessment?	X				
	Assessments/Decision made public?	X				
Historical assessments and approvals?	GM Cotton?	X				
	GM Canola?	X				
	GM Soybean?	X				
	GM Maize	X				
	Other GM products?	X				
Any special conditions / considerations?	Restrictions to distribution and use?	X				
	Labelling requirements?	X				

3.4 Canada

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Regulatory framework in place?	International standards (e.g. Codex/OECD)	✓	Domestic guidelines are in line with the Codex Guidelines in conducting safety assessment of GM food.			Canada has not signed the Cartagena Protocol
	Domestic laws and regulations	✓	*Food and Drugs Act and Regulations Division 28: Novel Foods* 1999 Guidelines for the Safety Assessment of Novel Foods Derived from Plants and Microorganisms 2006 (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))	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.
	Implementing Agencies	✓	• Canadian Food Inspection Agency (CFIA) • Health Canada (HC)			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
			• Environment and Climate Change Canada (ECCC)			
Coverage of legislation?	Legislative trigger?	✓	CFIA, ECCC, and Health Canada regulate Novel Products (novel traits, novel feeds and novel foods)			
	Specifies organisms covered?	✓	Novel Products (Plants with Novel Traits (PNT), animals and microorganisms)			
Process for assessment and approval?	Dossier for food safety assessment required?	✓	Petitioners must submit a premarket notification package which demonstrates that the novel food is as safe as its non-modified variety for human consumption	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	

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
					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	
	Timeframes specified?	✓	410 calendar days			
	Processing fees applicable?	✓	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.	
	Public consultation?	✓	Applicants voluntarily post "notices of submission" on the CFIA website for public comment		No	
	Socio economic considerations?	X				For plants: Not part of the formal or informal regulatory process For animals and microorganisms: only if risk management needed
	Length of approval specified?	✓	Valid indefinitely unless new information arises		For plants: 1 year For animals and	

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
					microorganisms: Under CEPA 1999 and NSNR(O), no expiry unless new information arises	
	Renewal options?		Not applicable	Not applicable	Not applicable	
Outputs from assessment	Food safety assessment?	✓	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 website	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)	
	Assessments/Decision made public?	✓	Decision document posted on the *Novel Foods and Ingredients* page of Health Canada website	Decision document posted on the *CFIA* website		
Historical assessments and approvals?	GM Cotton?	✓	HT/IR, Stacked			Applications and current status
	GM Canola?	✓	HT, hybrid breeding			
	GM Soybean?	✓	HT/IR, stacked, high oleic			
	GM Maize	✓	HT/IR, stacked, high lysine, amylase modified, drought tolerant			
	Other GM products?	✓	Potato, alfalfa, wheat, rice, sugar beet, apple, salmon, sunflower			
Any special conditions / considerations?	Restrictions to distribution and use?	X				
	Labelling requirements?	✓	Health Canada shares the responsibility for food labelling with CFIA under the Food and Drugs Act and the Consumer Packaging and Labelling Act36. The CFIA is responsible for non-health and safety aspects of			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
			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.			

3.5 Chile

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Regulatory framework in place?	International standards (e.g. Codex/OECD)	✓	Domestic guidelines are in line with the Codex Guidelines in conducting safety assessment of GM food.			Chile has signed but not ratified the Cartagena Protocol
	Domestic laws and regulations	✓	Approvals of events to be used by the food industry for human consumption and labelling of food containing ingredients derived from GM crops are under regulation of the Ministry of Health (MoH). Decree 115 (2003), of the Food Safety Rule, through the Administrative Technical Norm number 83 (2007) entitles the Public Health Institute (ISP) of the Ministry of Health to evaluate on the differences and similarities of the GM product with the conventional one.		Norm number 83 (2007): regulates import for food	
	Implementing Agencies	✓	• Agricultural and Livestock Service (SAG) • Public Health Institute (ISP) • Ministry of Health (MoH)			
	Legislative trigger?	✓	MoH regulates the product of gene technology			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Coverage of legislation?	Specifies organisms covered?	✓	Viable GM Plants, animals and microorganisms	Viable GM Plants, animals and microorganisms	Viable GM Plants, animals or microorganisms	
Process for assessment and approval?	Dossier for food safety assessment required?	✓	ISP must determine toxicity, allergenicity and long-term effects of the events. After that, ISP communicates its determination to the Ministry of Health. The Ministry then issues an official resolution indicating when an event receives approval to be used in the food industry. Since 2008 ISP has received many events for food safety assessment. The Ministry of Health has not published any final Resolution with approvals to date.			
	Timeframes specified?	✓	MoH: 30 days to resolve if it is admissible. ISP: 180 days.	Not applicable	Not applicable	
	Processing fees applicable?	X	Not required	Not required	Not required	
	Public consultation?	✓	Yes, for 60 days.			
	Socio economic considerations?	X				
	Length of approval specified?	X	No final Resolution with approvals to date			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
	Renewal options?	X	No final Resolution with approvals to date			
Outputs from assessment	Food safety assessment?	✓	Safety Assessments are conducted by ISP, but none published	Approval of commercial seed production activity	Safety Assessments are conducted by ISP, but none published	
	Assessments/Decision made public?	✓	No final Resolution with approvals to date	Case-by-case resolution	No final Resolution with approvals to date	
Historical assessments and approvals?	GM Cotton?	X				
	GM Canola?	X				
	GM Soybean?	✓	For feed			
	GM Maize	✓	For feed			
	Other GM products?	X				
Any special conditions / considerations?	Restrictions to distribution and use?	X				
	Labelling requirements?	✓	The Ministry of Health is also in charge of GM food labelling. By Decree 115, the Food Safety Rule (article 107, letter n) requires labelling for processed foods only if GM food/raw material is substantially different to the conventional product. Currently, labelling of GM food has been one of the main issues related to GM crops discussed at the political level. Seven bills related to GM crops within Chile's Congress have dealt with labelling. However, no decisions have been made up to now.			

3.6 China

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Regulatory framework in place?	International standards (e.g. Codex/OECD)	✓	Domestic guidelines are in line with the Codex Guidelines in conducting safety assessment of GM food.			China has signed and ratified the Cartagena Protocol
	Domestic laws and regulations	✓	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 State Council's "Administrative Rules for Safety of Agriculture GMO" of 2001 (revised in 2017)	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	✓	• Ministry of Agriculture (MOA) • Office for biosafety administration of agricultural GMOs (OBA) • National Biosafety Committee (NBC)			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Coverage of legislation?	Legislative trigger?	✓	The MoA regulates the process of gene technology			
	Specifies organisms covered?	✓	Animals, Plants, microorganism			
Process for assessment and approval?	Dossier for food safety assessment required?	✓	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 admin and precautionary measures Safety certificate and relevant variety registration; Appropriate safety management measures	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 admin and precautionary measures Safety certificate and relevant variety registration; Appropriate safety management measures.	Declaration Form of Import Commodities; Safety Certificate; Acknowledgment and Approval of Labeling of GMO Safety Assessment materials in accordance with “Implementation Regulations 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	

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
					safety management measures	
	Timeframes specified?	✓	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	
	Processing fees applicable?	✓	None specified		None specified	
	Public consultation?	X	China's Biosafety Clearing House; Local agricultural department to supervise safety of agricultural GMOs within its respective areas Local public health department to supervise hygiene and safety of GM food			
	Socio economic considerations?	X				
	Length of approval specified?	✓			3~5 years	
	Renewal options?	X			Unknown	
Outputs from assessment	Food safety assessment?	✓	Biosafety certificate Import Permit Production License		Import Permit/Transit Permit of GM commodity Biosafety Certificate Import Permit/Safety Certificate Production License	
	Assessments/Decision made public?	X				

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Historical assessments and approvals?	GM Cotton?	✓	HT/IR, Stacked			
	GM Canola?	✓	HT, hybrid breeding			
	GM Soybean?	✓	HT/IR, stacked, high oleic			
	GM Maize	✓	HT/IR, stacked, quality traits, drought tolerant			
	Other GM products?	✓	sugar beet			
Any special conditions / considerations?	Restrictions to distribution and use?	✓	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 \ after the GMOs passes AQSIQ Must comply with provisions of Implementation Regulations on Labeling of GMOs:	
	Labelling requirements?	✓	Regulations on Labelling of GMOs: • GMOs - genetically modified (GM) • 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, but no longer contains GM ingredients OR The raw materials of this product contain GM, but the product itself no longer contains GM ingredients • For special requirements on marketing scope –"only for 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.			

3.7 Hong Kong, China

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Regulatory framework in place?	International standards (e.g. Codex/OECD)	X	Domestic guidelines are in line with the Codex Guidelines in conducting safety assessment of GM food, but not a member			Hong Kong, China has not signed the Cartagena Protocol, however, implemented measures pursuant to China's membership
	Domestic laws and regulations	✓	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, March 2011			
	Implementing Agencies	✓	• The Hong Kong Food and Health Bureau (FHB) determines the policy direction of GE food regulation • The Food and Environmental Hygiene Department (FEHD) is the FHB's department for food safety, which administers programs through its Center for Food Safety (CFS) • Administration of policies relating to agricultural production falls under the portfolio of the Agriculture, Fisheries, and Conservation Department (AFCD) within FHB.			
Coverage of legislation?	Legislative trigger?	✓	Process trigger for regulation			
	Specifies organisms covered?	✓	GM ingredients, plants, animals, fisheries and marine species, dairy			
Process for assessment and approval?	Dossier for food safety assessment required?	✓	General: Health Certificates, Plant Import License and Phytosanitary Certificates, Certificate of Origin			No specific requirement regarding the form of

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
			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.			documentation accompanying LMO shipments is supplied. The use of a commercial invoice or other documents required or utilized by existing documentation systems, or documentation as required by other local legislation and/or administrative frameworks is acceptable as documentation to accompany the LMO shipments. In addition to commercial invoices, other forms of documentation that are acceptable include import/export manifests; and licenses or certificates issued or required under other legislation (e.g. phytosanitary certificates).
	Timeframes specified?	X	Not specified			
	Processing fees applicable?	X	Not specified			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
	Public consultation?	✓	Public comments are sought for any new Regulations			
	Socio economic considerations?	✓	Voluntary labeling at 5% threshold, negative labeling discouraged			
	Length of approval specified?	X	Not specified			
	Renewal options?	X	Not specified			
Outputs from assessment	Food safety assessment?	✓	No additional assessment made if product approved overseas by authorities following Codex Alimentarius principles (documentation required).			
	Assessments/Decision made public?	✓	The AFCD maintains a LMO online register which keeps non-confidential information received pertaining to the LMO approval applications.			
Historical assessments and approvals?	GM Cotton?	X				
	GM Canola?	X				
	GM Soybean?	X				
	GM Maize	X				
	Other GM products?	✓	The Genetically Modified Organisms (Control of Release) Exemption Notice made under the Genetically Modified Organisms (Control of Release) Ordinance took effect on June 23, 2012. The Notice exempts certain varieties of genetically engineered papaya and LMOs contained in certain veterinary vaccines (live recombinant veterinary vaccines) from the pre-arrival/pre-production AFCD approval requirement.			
Any special conditions / considerations?	Restrictions to distribution and use?	✓	As specified by approval document			
	Labelling requirements?	✓	Mandatory labelling for GE foods or feeds is not required. Guidelines were formulated by a working group established under the Center for Food Safety The guidelines are based on the following four principals: 1. The labeling of GE food will comply with existing food legislation. 2. The threshold level applied in the guidelines for labeling purpose is 5 percent, in respect to individual food ingredients.			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
			3. Additional declaration on the food label is recommended when significant modifications of the food, e.g. composition, nutrition value, level of anti-nutritional factors, natural toxicant, presence of allergen, intended use, introduction of an animal gene, etc., have taken place. 4. Negative labeling is not recommended.			

3.8 Indonesia

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Regulatory framework in place?	International standards (e.g. Codex/OECD)	✓	Domestic guidelines are in line with the Codex Guidelines in conducting safety assessment of GM food.			Indonesia has signed and ratified the Cartagena Protocol
	Domestic laws and regulations	✓	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 Horticulture (No.015A/NMenegPHOR/09/1999) Regulation 36/2016 established risk assessment guidelines for feed safety	BPOM Regulation No. HK.03.1.23.03. 12.1563/2012 on the Guidelines of Food Safety Assessment for Genetically Engineered Products, 2012 Amendment 19/2016 requirements for the evaluation of GE processing aids. 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,	Regulation 36/2016 established risk assessment guidelines for feed safety, completing the risk assessment framework along with environmental and food safety guidelines. BPOM's amendment to their guidelines for food safety evaluation (regulation 19/2016). This regulation includes the new requirements for the evaluation of GE processing aids.
	Implementing Agencies	✓	• Minister of Agriculture			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
			• 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)			
Coverage of legislation?	Legislative trigger?	✓	Process of gene technology is the trigger; assessment of the product of gene technology			The GOI has not decided whether the regulations for innovative biotechnologies will follow the regulatory framework of GE products
	Specifies organisms covered?	✓	Animals, Fish, Bacteria, Plants			
Process for assessment and approval?	Dossier for food safety assessment required?	✓	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	
	Timeframes specified?	✓	173 days if documentation complete and no objections posed by public during public comment period			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
	Processing fees applicable?	✓	None specified			
	Public consultation?	✓	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			
	Socio economic considerations?	✓	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			
	Length of approval specified?	✓	Valid until revoked			
	Renewal options?		N/A			
Outputs from assessment	Food safety assessment?	✓	Decision on the distribution of the GM foods also serving as food safety certificate; issued by the Head of BPOM			
	Assessments/Decision made public?	✓	Posting in Biosafety Clearing House website and other easily accessed sites			
Historical assessments and approvals?	GM Cotton?	X				Applications and current status
	GM Canola?	X				
	GM Soybean?	✓	HT/IR, stacked, high oleic			
	GM Maize	✓	HT/IR, stacked, amylase modified, drought tolerant			
	Other GM products?	✓	Potato, sugarcane			
Any special conditions / considerations?	Restrictions to distribution and use?	✓			Compliance with other existing requirements for food importation: (i) Health/safety certificates (ii) Product registration (iii) Pre-import Notification	

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
					Label for packaged and/or retail food products at 5% threshold for GM ingredients: “Food Containing Genetically Modified Material”	
	Labelling requirements?	✓	BPOM issued the regulation on food labeling controls for GE products in March 2012, implementing a 1999 regulation that requires labels and special logos for food containing GE ingredients. According to this regulation, packaged food that contains at least five percent of GE products must be labelled with the statement “Food Containing Genetically Engineered Material.” The five percent threshold level is measured as the content percentage of DNA of GE product against the DNA of non-GE product. No food products containing five percent GE materials have been registered to BPOM.			

3.9 Japan

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Regulatory framework in place?	International standards (e.g. Codex/OECD)	✓	Domestic guidelines are in line with the Codex Guidelines in conducting safety assessment of GM food.			Japan has signed and ratified the Cartagena Protocol
	Domestic laws and regulations	✓	Cartagena Law (2004) Food Sanitation Law (1947 plus amendments up to 2003) Food Safety Basic Law (2003) Labelling 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 Health, Labor and Welfare (MHLW), Food Safety Commission (FSC) of the Cabinet Office; Ministry of Environment (MOE); Food Labeling Division of the Consumer Affairs Agency (if applicable)	Ministry of Agriculture Forestry and Fisheries (MAFF); FSC	MOE, MAFF, MHLW, Ministry of Economy, Trade and Industry (METI), Ministry of Finance (MOF) if alcohol produced GMOs, other import-regulatory agencies	
Coverage of legislation?	Legislative trigger?	✓	Process trigger for regulation. Product assessment			
	Specifies organisms covered?	✓	Plants, animals, microorganisms			
Process for assessment and approval?	Dossier for food safety assessment required?	✓	Petition to MHLW for Food safety Assessment detailing characteristics	Petition to MAFF for Feed Safety Assessment detailing any changes in	Petition for import and cultivation, food safety approval from MHLW,	

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
			of GM food, nutritional quality, toxicity and allergenicity if any	feed composition, feed use, potential toxicity, and any potential harm to humans consuming livestock products from animal fed with GM feed	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	
	Timeframes specified?	✓	FSC sets the standard processing time from the reception of dossier to approval as 12 months			
	Processing fees applicable?	X	No fee charged			
	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	
	Socio economic considerations?	✓	Considers consumer preferences and rights, invites public comments	Considers consumer preferences and rights	Considers consumer preferences and rights, invites public comments	

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
			Labelling at 5% threshold for consumers' right to know		Labelling at 5% threshold for consumers' right to know	
	Length of approval specified?	✓	Until revoked			
	Renewal options?					
Outputs from assessment	Food safety assessment?	✓	Undertaken 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 Food Safety Approval from MHLW	Undertaken 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 Feed Safety Approval from MAFF	Undertaken 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 Food Safety Approval from MHLW Feed safety approval from MAFF Environmental Safety approval from MOE	

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
					Approvals from other relevant agencies (dependent on use of imported material)	
	Assessments/Decision made public?	✓	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	
Historical assessments and approvals?	GM Cotton?	✓	HT/IR, Stacked			Applications and current status
	GM Canola?	✓	HT, hybrid breeding			
	GM Soybean?	✓	HT/IR, stacked, high oleic			
	GM Maize	✓	HT/IR, stacked, high lysine, amylase modified, drought tolerant			
	Other GM products?	✓	Potato, alfalfa, papaya			
Any special conditions / considerations?	Restrictions to distribution and use?	✓	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	

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
					presence) Imported commodities may be tested at importation sites before accepted	
	Labelling requirements?	✓	Japan has a labelling law with a 5% GM threshold for each ingredient used in food. Labelling policies and strategies for identity preservation and segregation are handled by the Food Labelling division of the Consumer Affairs Agency (CAA). Created in 2010 to protect and enhance consumer rights, CAA implements the labelling 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.			

3.10 Republic of Korea

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Regulatory framework in place?	International standards (e.g. Codex/OECD)	✓	Domestic guidelines are in line with the Codex Guidelines in conducting safety assessment of GM food.			Korea has signed and ratified the Cartagena Protocol
	Domestic laws and 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 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	

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
	Implementing Agencies	✓	• Ministry of Trade, Industry and Energy (MOTIE) • Biosafety Committee (policy; under MOTIE) • Ministry of Food and Drug Safety (MFDS) • Ministry of Agriculture, Food, and Rural Affairs (MAFRA's) Rural Development Administration (RDA) for environmental risk assessment • Ministry of Environment's (MOE) National Institute of Ecology (NIER), consulted if necessary • Ministry of Health and Welfare's (MHW) Korea Center for Disease Control and prevention (KCDC) consulted as necessary	• MOTIE • Biosafety Committee (policy; under MOTIE) • MAFRA 's National Agricultural Products Quality Management Service (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: o RDA o NAQS o Animal, Plant and Fisheries Quarantine & Inspection Agency (QIA) • NFRDI, as necessary • MFDS • MOE's NIER, consulted if necessary	
Coverage of legislation?	Legislative trigger?	✓	Process trigger and product assessment			
	Specifies organisms covered?	✓	Animals, Bacteria, Plants			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Process for assessment and approval?	Dossier for food safety assessment required?	✓	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 economy, 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 economy, 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 economy, safety assessments overseas, detection methods, and any other importation documents required; documentation on identity preservation (IP), GMO content, testing and segregation methods for IP	
	Timeframes specified?	✓	Acknowledgement of application within 90 days from receipt; Processing time 270 days			
	Processing fees applicable?	✓			Follows a fee schedule and includes import duties	
	Public consultation?	✓	Information posted on BCH and agency websites; Public comments invited on proposals, public consulted about regulations and pending applications			
	Socio economic considerations?	✓	Bioethical considerations, public opinion and perception, potential marketability, over-all acceptability, labeling policy for consumer preference and right to know			
	Length of approval specified?		Not specified			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
	Renewal options?					
Outputs from assessment	Food safety assessment?	✓	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)	
	Assessments/Decision made public?	✓	Information posted on BCH and agency websites; Public comments invited on proposals, public consulted about regulations and pending applications			Biotechnology crops, whether grown domestically or imported, are required to undergo a food safety assessment and an ERA. Of note, the ERA is sometimes referred to as a feed approval, though the review is largely focused on the impact to the

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
						environment, not animal health.
Historical assessments and approvals?	GM Cotton?	✓	HT/IR, Stacked			Food Approvals: 160 Feed Approvals: 147
	GM Canola?	✓	HT, hybrid breeding			
	GM Soybean?	✓	HT/IR, stacked, high oleic			
	GM Maize	✓	HT/IR, stacked, high lysine, amylase modified, drought tolerant			
	Other GM products?	✓	Potato, alfalfa, sugar beet			
Any special conditions / considerations?	Restrictions to distribution and use?	✓	Labelling required as implemented by MFDS for processed foods containing GM ingredients, or as implemented by MAFRA for unprocessed biotech crops	Labelling 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. Labelling required by MFDS: Mandatory labelling 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; Threshold for unintentional presence is 3% Label required if one of top 5 ingredients derived from corn, soybean, cotton, canola, or	

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
					sugarbeets, and DNA or protein detected in these ingredients.	
	Labelling requirements?	✓	MFDS is responsible for establishing biotech labelling guidelines for both unprocessed and processed products and enforcing guidelines in the market place. Both unprocessed biotech crops for human consumption and certain processed food products containing biotech ingredients must carry "genetically modified" (GM) food labels. The stated purpose behind biotech labelling is to respond to the consumers' right to know. Currently, there are very few products on the market with a "GM" label. MFDS implemented new biotech labelling requirements beginning February 4, 2017, expanding mandatory to all detectable products. It also prohibits a non-GMO or GMO-free claim on products that do not have biotech counterparts. However, it allows non-GMO or GMO-free claims for products containing a non-GM ingredient that is more than 50% of total ingredients if it does not contain any trace of a biotech component (zero tolerance). The revision continues to exempt mandatory biotech labelling for products that do not contain foreign DNA or protein.			

3.11 Malaysia

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Regulatory framework in place?	International standards (e.g. Codex/OECD)	✓	Domestic guidelines are in line with the Codex Guidelines in conducting safety assessment of GM food.			Malaysia has signed and ratified the Cartagena Protocol
	Domestic laws and 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) Food Regulations 1983, 1985	
	Implementing Agencies	✓	• Ministry of Environment and Natural Resources (MONRE) • National Biosafety Board (NBB) • Genetic Manipulations Advisory Committee (GMAC) • Department of Biosafety (DBS) • Food Safety and Quality Division of the Ministry of Health (FSQD-MOH)			
Coverage of legislation?	Legislative trigger?	✓	Process trigger with product assessment			
	Specifies organisms covered?	✓	Plants, Microorganism, Animals			
Process for assessment and approval?	Dossier for food safety assessment required?	✓	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			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
			Emergency response plan Other information specified by the NBB			
	Timeframes specified?	✓	180 days if information complete			
	Processing fees applicable?	✓	RM 5000			
	Public consultation?	✓	Public disclosure via specifically formatted Fact Sheets Invitation for written submissions sent to NBB through DBS (regular or electronic mail, FAX)			
	Socio economic considerations?	✓	Considers consequences in case of spills during unloading and transit. May consider effects on market of goods, social norms, and religious concerns			
	Length of approval specified?	✓	Valid until revoked or withdrawn			
	Renewal options?					
Outputs from assessment	Food safety assessment?	✓	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			There is no specific regulatory status of innovative biotechnologies as all biotechnologies are treated the same
	Assessments/Decision made public?	✓	Public disclosure via specifically formatted Fact Sheets Invitation for written submissions sent to NBB through DBS (regular or electronic mail, FAX)			
Historical assessments and approvals?	GM Cotton?	✓	HT/IR, Stacked			
	GM Canola?	✓	HT			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
	GM Soybean?	✓	HT/IR, stacked			
	GM Maize	✓	HT/IR, stacked			
	Other GM products?	✓	Potato			
Any special conditions / considerations?	Restrictions to distribution and use?	✓	Review of approval if new information identifies new risks Requires that transit provisions on spills are followed Mandatory labelling regulations to be implemented later. Fines and/or imprisonment as penalties for non-compliance.			
	Labelling requirements?	✓	In April 2013, the Food Safety and Quality Division of the Ministry of Health (MOH) published new "Guidelines on Labelling of Foods and Food Ingredients Obtained through Modern Biotechnology." The document can be found here: http://fsq.moh.gov.my/v5/ms/guidelines-on-labelling-of-foods-and-food-ingredients-obtained-through-modern-biotechnology/			

3.12 Mexico

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Regulatory framework in place?	International standards (e.g. Codex/OECD)	✓	Domestic guidelines are in line with the Codex Guidelines in conducting safety assessment of GM food.			Mexico signed the Cartagena Protocol in May 2000 and ratified it in September 2003
	Domestic laws and regulations	✓	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 Organismos Genéticamente Modificados 2009	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 Genéticamente Modificados 2009	
	Implementing Agencies	✓	• Inter-Ministerial Commission on GMO Biosafety (CIBIOGEM; policy and coordination) • Ministry of Health (SSA) • Ministry of Agriculture, Livestock, Rural Development, Fisheries and Food (SAGARPA), through its National Service of Health, Food Safety, and Food Quality (SENASICA) • Ministry of Finance and Public Credit (SHCP; for commodity importation, customs and labeling of GMO and products)			
	Legislative trigger?	✓	Process is the trigger for regulation			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Coverage of legislation?	Specifies organisms covered?	✓	GM ingredients, plants, animals, microorganisms			
Process for assessment and approval?	Dossier for food safety assessment required?	✓	Completed application form for each GMO (in 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 parent material Other information as determined by Official Mexican Standards for the organism or food in question Two electronic copies of application and attachments also submitted		Completed application form for each GMO (in Spanish) 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 parent material	

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
					Other information as determined by Official Mexican Standards for the organism or food in question Two electronic copies of application and attachments also submitted	
	Timeframes specified?	✓	Six months			
	Processing fees applicable?	✓	Required but not specified			
	Public consultation?	✓	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			
	Socio economic considerations?	✓	Special consideration for ethnic group preferences for landraces, areas reserved for organic production Mandatory labelling in those cases where GMO food composition or their nutritious properties are significantly different from the respective conventional products			
	Length of approval specified?	✓	Authorised until revoked			
	Renewal options?	✓	Authorised until revoked			
Outputs from assessment	Food safety assessment?	✓	Risk assessment performed by SSA with input from SAGARPA through SENASICA Science-based, case by case			
	Assessments/Decision made public?	✓	Immediate posting of application, invitation of written opinions, comments from public via regular or electronic mail			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
			Scientifically-based public input incorporated in decision-making process			
Historical assessments and approvals?	GM Cotton?	✓				Mexico has authorised for food and feed 164 GE events from nine species. Considering that these are equivalent to conventional products, imports are not labelled.
	GM Canola?	✓				
	GM Soybean?	✓				
	GM Maize	✓	Some cultivation restrictions			
	Other GM products?	✓	Alfalfa; potato; rice, sugar beet, tomato			
Any special conditions / considerations?	Restrictions to distribution and use?	✓	Some cultivation restrictions			
	Labelling requirements?	✓	The Biosafety Law does not require labelling for packaged foods and feeds (commodities) that are equivalent in health and nutritious characteristics to the conventional food and feed (i.e. grains).			

3.13 New Zealand

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Regulatory framework in place?	International standards (e.g. Codex/OECD)	✓	Domestic guidelines are in line with the Codex Guidelines in conducting safety assessment of GM food.			New Zealand signed the Cartagena Protocol in May 2000 and ratified it in May 2005
	Domestic laws and regulations	✓	Food Act of 1981 Australia New Zealand Food Standards Code 1991 - Standard 1.5.2 - Food Produced Using Gene Technology Hazardous Substances and New Organisms Act 1996 (HSNO; 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	Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 ACVM Regulations 2001 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	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 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	

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
			Processing: Plant Health Requirements) 2011			
	Implementing Agencies	✓	• Food Standards Australia New Zealand (FSANZ) • Environmental Protection Agency (EPA) • Ministry for Primary Industries (MPI) • Ministry for the Environment (MfE)– responsible for the management and maintenance of the HSNO Act			MPI is responsible for enforcing the conditions for genetic engineering imposed by the EPA on approved field tests and conditionally released organisms. MPI is also responsible for administering standards for safety, labelling, and composition of food sold in New Zealand, including imported food and foods produced using gene technology.
Coverage of legislation?	Legislative trigger?	✓	Process of gene technology is the legislative trigger FSANZ regulates the Product of gene technology			
	Specifies organisms covered?	✓	All genetically modified organisms A High Court Ruling in 2014, effectively established that organisms resulting from breeding techniques utilizing gene editing techniques, such as Zinc Finger Nuclease type 1 (ZFN-1) and Transcription Activator-Like Effectors (TALEs) systems, would be considered new organisms under the HSNO Act and would be subject to the HSNO Regulations			
Process for assessment and approval?	Dossier for food safety assessment required?	✓	An application to amend the Food Standards Code is submitted to FSANZ for assessment. Requirements are outlined in the FSANZ Application Handbook	Undertaken by MPI-Agricultural Compounds and Veterinary Medicines (ACVM) Group. Consideration given to history of safety in	New Zealand permits the import of GE food products that have been approved by Food Standards Australia New Zealand (FSANZ).	Import Permit from MPI Plant Imports, Plant, Food & Environment Directorate

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
				context of use, listing in other registries, suitability for target animal etc.	The EPA makes all decisions on the importation and domestic use of living modified organisms (LMOs) that are GE on the basis of a thorough assessment of the potential risks and benefits posed by the organisms, under the requirements of the HSNO Act 1996	
	Timeframes specified?	✓	FSANZ Approximately 9-12 months		Import permit from MPI (all agricultural commodities): 15 working days after receipt of import permit application	
	Processing fees applicable?	✓	FSANZ provide an estimate up front following an administrative assessment. Cost dependent on complexity of application. Refunds are provided for unused time		Application for permit to import biological products, microorganisms, and cell cultures from MPI, as of Nov 2018 NZ$220.74*	*If processing your application takes longer than one-and-a-half hours, additional time will be charged at an hourly rate of $102.27 excluding GST or $117.61 including GST.
	Public consultation?	✓	Preliminary Safety Assessment released for public comment. Public information via publication in Commonwealth Gazette	Public notification by posting in MPI website and inviting public submissions for 15 working days	Public notification with invitation for public submissions	Consultation with the public is an integral component in the case-by-case decision-making process. The HSNO Act requires EPA to notify the public of applications it

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
						considers likely to be of significant public interest. The public notice provides a means by which any person may make a written submission in the application. A public hearing of an application may also be held if one is requested by the applicant, by a person who has made a submission, or if EPA considers that a hearing is necessary to ensure due consideration of all the relevant matters.
	Socio economic considerations?	✓	New Zealand is unique in its requirement that the benefits must be considered alongside the risks. Public submissions considered in decision making process In line with recommendations from a 2001 Royal Commission, the HSNO Act was amended to give greater recognition to the knowledge and experience of Māori values by those involved in the decision-making process on new organisms, including GE organisms. When EPA considers applications for the release of GE materials in New Zealand, the HSNO Act requires that the Māori culture and traditions as they relate to their ancestral lands, water, sites, flora and fauna be taken into account. This means that EPA must assess the potential impact of the organisms on indigenous plants and animals – as well as introduced ones – that are valued by the Māori.			
	Length of approval specified?	✓	Valid until the approval is removed from the Food Standards Code	Valid until feed is removed from sale	Valid until food is removed from sale	
	Renewal options?					

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Outputs from assessment	Food safety assessment?	✓	Safety Assessments are published on the FSANZ website			
	Assessments/Decision made public?	✓	Safety Assessment outcomes and recommendations are published on the FSANZ website Incorporated into the Code as amendments (Becomes part of the foods approved under Standard 1.5.2)			
Historical assessments and approvals?	GM Cotton?	✓	HT/IR, Stacked			A GE equine influenza vaccine is the only GE product approved for a controlled release in New Zealand. No other organization has submitted an application for a conditional or full-scale release of a GE product.
	GM Canola?	✓	HT, Omega-3, hybrid breeding			
	GM Soybean?	✓	HT/IR, stacked, high oleic			
	GM Maize	✓	HT/IR, stacked, high lysine, amylase modified, drought tolerant			
	Other GM foods?	✓	Potato, alfalfa, wheat, rice, sugar beet			
Any special conditions / considerations?	Restrictions to distribution and use?	✓			Must comply with any conditions associated with an import permit	
	Labelling requirements?	✓	GE foods and ingredients can only be sold in New Zealand if they have been assessed for safety by FSANZ and approved by the Legislative and Governance Forum on Food Regulation, a council of Australian and New Zealand health ministers.			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
			Under Standard 1.5.2 of the Australia New Zealand Food Standards Code, which outlines the legal requirements for the sale and labelling of GE food, all GE foods sold in New Zealand must be labelled. This means that any food, food ingredient, food additive, food processing aid, or flavoring that contains genetically engineered DNA or protein must have this fact noted on the label with at least the specific wording “genetically modified”. If a food or ingredient has altered characteristics, the same wording “genetically modified” must be on the label. For example, if oil was made from a plant that had been GE so that its oil boils at a higher temperature, the oil would have to be labelled, even though no GE material would be present. A GE ingredient does not have to be listed on the label when: 1. It is a flavoring in the food and makes up less than 0.1% of that food; or 2. An ingredient unintentionally contains GE material at levels of less than 1% of that ingredient; or 3. It is a highly refined food, other than that with altered characteristics, where the effect of the refining process is to remove novel DNA and/or novel protein; 1. 4. It is a processing aid or food additive, except where novel DNA and/or novel protein from the processing aid or food additive remains present in the food to which it has been added.		

3.14 Peru

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Regulatory framework in place?	International standards (e.g. Codex/OECD)	✓	Domestic guidelines are in line with the Codex Guidelines in conducting safety assessment of GM food.			Peru has signed and ratified the Cartagena Protocol
	Domestic laws and regulations	✓	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. In 2011, Peru approved Law 29,811 establishing a ten-year moratorium on genetically engineered organisms.			
	Implementing Agencies	✓	• Instituto Nacional de Innovacion Agraria (INIA) • Servicio Nacional de Sanidad Agraria (SENASA); Agriculturalsanitationrequirements). • General Direction of Environmental Health (DIGESA) • Vice Ministry of Fisheries (PRODUCE)			
Coverage of legislation?	Legislative trigger?	✓	Process trigger with product assessment			
	Specifies organisms covered?	✓	All GMOs			
Process for assessment and approval?	Dossier for food safety assessment required?	✓	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	
	Timeframes specified?	X	None specified			
	Processing fees applicable?	X	None specified			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
	Public consultation?	✓	Publication of summary of application information in two media with domestic circulation; public then invited to provide comments or additional information which may be factored in the risk assessment or approval process			
	Socio economic considerations?	✓	Sustainability and conservation of cultural and biodiversity			
	Length of approval specified?	X	None specified			
	Renewal options?	X	None specified			
Outputs from assessment	Food safety assessment?	✓	Scientific, case-by-case; in accordance with Cartagena Protocol on Biosafety, Codex Alimentarius Guidance documents on foods derived from biotechnology			
	Assessments/Decision made public?	✓	Publication of summary of application information in two media with domestic circulation; public then invited to provide comments or additional information which may be factored in the risk assessment or approval process			
Historical assessments and approvals?	GM Cotton?	X				Peru imports GM crops such as soybeans, corn, and cotton
	GM Canola?	X				
	GM Soybean?	X				
	GM Maize?	X				
	Other GM products?	X				
Any special conditions / considerations?	Restrictions to distribution and use?	✓	Consumer Defense Code of 2011 requires mandatory labelling of GMOs, but labelling provisions not yet published			
	Labelling requirements?	✓	Article 37 of the Consumer Defence Code (March 2011) mandates the labelling of GE content in processed products. The code's implementing regulation, which should be published within 180-days, is still pending after five years. Reportedly INDECOPI (Peru's consumer defence body) has encountered problems drafting a non-trade restrictive implementing regulation.			

3.15 Philippines

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Regulatory framework in place?	International standards (e.g. Codex/OECD)	✓	Domestic guidelines are in line with the Codex Guidelines in conducting safety assessment of GM food.			The Philippines has signed and ratified the Cartagena Protocol The Philippine Senate concurred through its Resolution No. 92 s. 2000: Concurring in the Ratification of the Cartagena Protocol on Biosafety to the UN Convention on Biological Diversity
	Domestic laws and regulations	✓	EO No. 514 s. 2006: Establishing the National Biosafety Framework RA No. 3639 of 1930: Creating the Bureau of Animal Industry PD No. 1144 s. 1977: Creating the Fertilizer & Pesticide Authority PD No. 1433 s. 1978: Plant Quarantine Law *DA-AO No. 8 s. 2002: Approval Process for the Importation of Regulated Articles for Direct Use as Food or Feed, or for Processing* - superseded by DOST-DA-DENR-DOH-DILG		EO 514 2006 EO No. 514 s. 2006: Establishing the National Biosafety Framework RA No. 3639 of 1930: Creating the Bureau of Animal Industry PD No. 1144 s. 1977: Creating the Fertilizer & Pesticide Authority DA-AO No. 22 s. 2007: Amended Approval Process for Importation of Regulated Articles for Direct Use as Food or Feed, or for Processing	

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
			JDC No. 1, Series of 2016 but its relevant MCs are still enforced for implementation DA-AO No. 22 s. 2007: Amended Approval Process for 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 RA No. 10611 2013: Food Safety Act DOST-DA-DENR-DOH-DILG JDC No. 1 s. 2016: Joint Department Circular entitled Rules and Regulations for the Research and Development, Handling and Use, Transboundary Movement, Release into the Environment, and Management of Genetically-Modified Plant and Plant Products Derived from the Use of Modern Biotechnology) http://biotech.da.gov.ph/upload/Signed_DOST-DA-DENR-DOH-DILG_JDCs2016.pdf		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 RA 10611 2013: Food Safety Act DOST-DA-DENR-DOH-DILG JDC No. 1 s. 2016 s: Joint Department Circular entitled Rules and Regulations for the Research and Development, Handling and Use, Transboundary Movement, Release into the Environment, and Management of Genetically-Modified Plant and Plant Products Derived from the Use of Modern Biotechnology) http://biotech.da.gov.ph/upload/Signed_DOST-DA-DENR-DOH-DILG_JDCs2016.pdf	
	Implementing Agencies	✓	• Philippine Department of Agriculture (DA) • Department of Science and Technology (DOST) • Department of Environment and Natural Resources (DENR) • Department of Health (DOH) • DA-Bureau of Plant Industry (BPI) • DA-Bureau of Animal Industry (BAI)			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
			• DA-Fertilizer and Pesticide Authority (FPA) • DOH-Food and Drugs Administration (FDA)-if processed food National Committee on Biosafety of the Philippines (NCBP) – monitoring of the overall process and coordinating all biosafety related matters			
Coverage of legislation?	Legislative trigger?	✓	Process trigger with product assessment			
	Specifies organisms covered?	✓	GM Plants		GM Plants and GM commodities	
Process for assessment and approval?	Dossier for food safety assessment required?	✓	Completed application form according to JDC 01, technical dossier on GMO 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		Completed application form according to JDC 01, technical dossier on GMO 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. Declaration of GM content	
	Timeframes specified?	✓	85 days if documentation is complete and no additional safety issue is raised by the Scientific and Technical Review Panel (STRP) assessment, biosafety committees (BC) of DENR and DOH, BPI-Plant Product Safety Services Division (BPI-PPSD), or the public.			FPA is included if the GM crop has plant-incorporated protectant (PIP)
	Processing fees 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			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
			Nominal application fee for import permit of food commodity (if applicable)			
	Public consultation?	✓	Publication of PIS in two newspapers of domestic circulation, public comments invited within 30-day period Public comments considered for approval of permit application			
	Socio economic considerations?	✓	For final approval, efficacy, risk-benefit analysis, and economic considerations factored in after risk assessment			
	Length of approval specified?	✓	5 years from date of issuance of permit for Direct Use as food or feed or for processing			
	Renewal options?	✓	May apply for another 5-year extension of permit. Renewal depends on compliance with any restrictions imposed on original permit			
Outputs from assessment	Food safety assessment?	✓	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-BPI-PPSD 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-BPI-PPSD Further feed safety review done by DA-BAI Consolidated safety reports evaluation done by DA-Biosafety Committee (BC) For processed food, food safety review done by Food and Drug Administration unless unprocessed ingredients are part of Registry for Approved GMOs	DENR- and DOH-BCs are included for evaluation of environmental and health impact, respectively

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
	Assessments/Decision made public?	✓	5-year Biosafety Permit for Direct Use as Food or Feed or for Processing Import permit (as necessary) Inclusion in registry of Approved GMOs The Philippine Bureau of Plant Industry is in-charge of preparing consolidated summary of technical reports (assessments). These reports are posted on the NCBP and BPI websites for public comment.			
Historical assessments and approvals?	GM Cotton?	✓	HT/IR, Stacked			
	GM Canola?	✓	HT, hybrid breeding			
	GM Soybean?	✓	HT/IR, stacked, high oleic			
	GM Maize	✓	HT/IR, stacked, high lysine, amylase modified, drought tolerant			
	Other GM products?	✓	Potato, alfalfa, rice, sugar beet			
Any special conditions / considerations?	Restrictions to distribution and use?	✓	Permit is for both food and feed uses May not be used for propagation unless separate permit has been issued.			
	Labelling requirements?	✓	Currently, there are no labelling requirements for GE food products. In its "Draft Guidelines on Labelling of Pre-packaged Foods Derived from or Containing Ingredients from Modern Biotechnology," the Philippine Food and Drug Administration (PFDA) indicated that it will not require labelling for GE packaged foods. The PFDA position is largely based on the Codex Alimentarius standards on labelling as described in the "Compilation of Codex Texts Relevant to Labelling of Foods Derived from Modern Biotechnology." The PFDA in late 2013 issued a statement attesting to the safety of GE and GE-derived foods, adding that GE foods were substantially equivalent to conventional counterparts. In 2018, there are proposals in the Congress of the Philippines to enforce labelling requirements when their contents exceed the 0.9% percent threshold. Philippine regulations require shipments of imported bulk commodities to be accompanied by a "Declaration of GMO Content"			

3.16 Papua New Guinea

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Regulatory framework in place?	International standards (e.g. Codex/OECD)	✓	Domestic guidelines are in line with the Codex Guidelines in conducting safety assessment of GM food.			Papua New Guinea has ratified the Cartagena Protocol on Biological Diversity in 2005 and is party to the Convention on Biological Diversity.
	Domestic laws and regulations and Implementing agencies	X	A Draft Biosafety and Biotechnology Policy and Bill (2005) has been developed. This framework was generated by the National Biosafety and Biotechnology Committee (NBBC). The mandate of this policy sits with the National Focal Point, which is the Environment Conservation and Protection Authority (ECPA); however, currently the NBBC remains dormant. Nonetheless, PNG has an active National Codex Committee (NCC), in which the ECPA is represented. The NCC is responsible for addressing Agro Food safety and Codex standards development and other related technical issues such as GM-Platform and Sanitary and Phytosanitary issues under the Sanitary and Phytosanitary Compliance Policy (2011) under the auspice of the Department of Agriculture & Livestock, which emphasises the integrated and/or coordinated approach mechanism. PNG adopts the Codex Alimentarius Commission guidelines and codes of practices for the conduct of safety assessment of food materials derived from genetically modified organisms (GMOs) or Living Modified Organisms (LMOs) developed through the use of modern biotechnology and uses the Codex Principles for risk analysis on food derived from such organisms. 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.		

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Coverage of legislation?	Legislative trigger?	X	Not specified-likely process for cultivation, product for others			
	Specifies organisms covered?	✓	All organisms			
Process for assessment and approval?	Dossier for food safety assessment required?	X	However, would follow the relevant Codex Guidelines or domestic/regional guidelines that are in line with the Codex Guidelines in conducting safety assessment of GM food			
	Timeframes specified?	X	Variable and dependent on the product			
	Processing fees applicable?	✓	Depends on organism, type of permit and action required from quarantine officers			
	Public consultation?	X	Not specified			
	Socio economic considerations?	X	Dependent on importance to PNG agriculture			
	Length of approval specified?	✓	Depends on conditions within the import permit			
	Renewal options?	✓	Depends on conditions within the import permit			
Outputs from assessment	Food safety assessment?	✓	Standard Pest Risk Analysis and phytosanitary criteria			
	Assessments/Decision made public?	X	Not specified			
Historical assessments and approvals?	GM Cotton?	X				
	GM Canola?	X				
	GM Soybean?	X				
	GM Maize	X				
	Other GM products?	X				
Any special conditions / considerations?	Restrictions to distribution and use?	✓	Subject to inspection			
	Labelling requirements?	✓	Aligned to Codex			

3.17 Russia

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Regulatory framework in place?	International standards (e.g. Codex/OECD)	✓	The development of the GMO safety assessment currently used in Russia started in 1995–1996. The methodological approaches to comprehensive complex medical and biological assessment of GMOs were developed in Russia with due regard for international and domestic experience as well as new scientific approaches based on the achievements of contemporary fundamental science.			Russia has not signed the Cartagena Protocol
	Domestic laws and regulations	✓	At present agricultural biotech policy is being regulated by the Decisions of the Eurasian Economic Union (EAEU) – so called "technical regulations" of the Customs Union (CU), Russian federal laws, government resolutions and orders of the heads of the Russian regulation ministries, agencies and services. • CU Technical Regulation No 021/2011 on Safety of Food Products (adopted in December 2011, came into force on July 1, 2013) • CU Technical Regulation No 022/2011 on Food Labeling • CU Technical Regulation No 015/2001 on the Safety of Grain (adopted in December 2011, came to force on July 1, 2013): The Technical Regulation determines requirements for information on grain/oilseeds during transportation either in bulk or in consumer packs (for feed purposes). • CU Technical Regulation No. 024/2011 on Fat and Oil Products (adopted December 2011, came into force on July 1, 2013): This technical regulation requires labeling of oil and fat products released into circulation for human consumption, and labels shall include information on the presence of "GMOs." • CU Technical Regulation No 023/2011 "On Fruit and Vegetable Juices and Their Products" (came into force on July 1, 2013): The EAEU Technical Regulation on Juices and their products bans the use of "GMOs" in baby food (fruit and vegetable juice products for babies) and requires state registration of any product that was processed using methods of genetic modification. **Federal Laws of Russia** • Federal Law No. 358 of July 3, 2016 (FL 358 - in Russian) "On amendments to certain legislative acts of Russia concerning the improvement of state regulation in the sphere of genetic-engineering activities." FL 358 bans the cultivation of GE crops, formalizing the previous de-facto ban resulting from the lack of a regulatory framework.			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
			• 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. This is a foundational federal law on genetic engineering in Russia, but the law does not provide instruments for implementation. There were several amendments to this federal law, including the last one, made by FL 358 of July 3, 2016, which emphasized the role of state control over the release of genetically-engineered organisms into the environment, state monitoring of the effects of such release on the environment and also on the health of human beings. The amendments add the responsibility of control and monitoring, as well as registration, of genetically engineered organisms and products, including imported goods, to the state. The amendments broaden the meaning of "safety control in the sphere of genetic engineering," and emphasize that, based on the results of monitoring the effects of GE organisms and products on the environment and on human health; the authorized bodies of the executive power can ban imports of genetically-engineered organisms and/or products derived from GE organisms into Russia. • 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 Consumer Rights with amendments. The amendment of October 25, 2007 sets the threshold for mandatory labeling of food ingredients made from biotech material at 0.9 percent. Prior to this amendment, trace amounts of biotech food ingredients required labeling • The Federal Law No. 7-FZ of January 10, 2002, "On Protection of the Environment" with amendments made in 2011 and in 2016. Amendment made by FL 358 of July 2016, to Article 50.1 adds the following text: "it is prohibited to grow or breed plants and animals whose genetics have been modified by using genetic-engineering methods and which contain genetic-engineering materials that cannot be introduced as a result of natural (spontaneous) processes, with exception of growing and breeding such plants and animals in the course of expert examination and research activities." • Federal Law of December 17, 1997, No. 149-FZ "On Seed Industry" as amended by FL 358 of July 3, 2016, bans imports of GE planting seeds into Russia, with the exception of sowing (planting) such seeds for research			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
			activities." "It is prohibited to import into Russian territory, or to use for sowing (planting), the seeds of plants which have modified genetics through the application of gene-engineering methods and which contain gene-engineering material that cannot be introduced as a result of natural (spontaneous) processes, with the exception of sowing (planting) such seeds in the course of expert examination and research activities." • Russian Federation Code of Administrative Violations, as amended by FL 358, under Article 6.3. Article 6.3 "Violation of the legislation of the Russian Federation in the Area of Genetic Engineering Activity." **Resolutions of Russia** • Resolution of the Government of Russia No. 988 of December 21, 2000, On State Registration of New Food Products, Materials, and Goods with amendments. The resolution authorizes registration of GE foods • Resolution of the Russian Government No. 717 of July 14, 2012, "On the State Program for Development of Agriculture and Regulation of Agricultural and Food Markets in 2013-2020." The program outlines the main directions of development of agricultural science, including biotechnology, although agricultural biotechnology is not a priority • Resolution of the Russian Government No. 839 of September 23, 2013, "On the State Registration of Genetically-Engineered-Modified Organisms Intended for Release into the Environment as well as Products Derived from the Use of Such Organisms or Containing Such Organisms." • Resolution of the Russian Government No. 548 of June 16, 2014, "On the Amendments to the Resolution No. 839 of September 23, 2013" postpones the implementation of Resolution 839 from July 1, 2014 to July 1, 2017. • On June 29, 2017, the Government of Russia issued Resolution No. 770 "On Amending the Resolution of the Government of Russia No. 839 of September 23, 2013". Resolution No. 770 amends Russia's framework of rules for the registration of GE organisms and products derived or containing such organisms. The Resolution conforms to Federal Law No 358 of July 3, 2016, which bans cultivation and breeding of GE plants and animals within the territory of Russia.			
	Implementing Agencies	✓	• Russian Federal Rospotrebnadzor (Federal Service on Customers' Rights Protection & Human Well-Being Surveillance)			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
			o Conducts state registration of new GE lines for food use and new food products containing GE organisms, including those that are imported into Russia for the first time o Conducts surveys and control of turnover of GE food products in accordance with Russian and EAEU legislation o Develops legislation on GE food products; and o Monitors the influence of GE crops and products on people and the environment. • The Ministry of Agriculture of Russia o Participates in the development of agricultural biotechnology policy o Overall policy development for the use of GE crops and organisms in agriculture o Overall legal regulation of veterinary and phytosanitary conditions of agricultural production and the use of agricultural products • Federal Service for Veterinary and Phytosanitary Surveillance (VPSS) o Subordinated to the Ministry of Agriculture of Russia o Conducts state registration of new GE lines for feed use and new feed containing GE organisms, including those that are imported into Russia for the first time o Issues certificates of registration for GE feed o Currently in the process of developing regulations for the use and monitoring of GE crops, including for cultivation, and GE animals o Monitors the influence of GE crops, animals and products on people and the environment • The Ministry of Industry and Trade of Russia o Participates in the development of domestic standards and technical regulations which set requirements for the biological safety of regulated items • The Ministry of Economic Development of Russia o Monitors the implementation of the Comprehensive Program on Development of Biotechnology in Russia through 2020 • The Russian Academy of Sciences (RAN) o Coordinate fundamental science and research and expertise on science-related programs and projects, including in the field of agricultural biotechnology. • The Eurasian Economic Union (EAEU)		

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
			o Unites Kazakhstan, Russia, Belarus, Armenia and Kyrgyzstan. The EAEU develops and adopts common customs and technical regulations for all member economies.			
Coverage of legislation?	Legislative trigger?	✓	All genetically modified organisms			
	Specifies organisms covered?	✓	All genetically modified organisms			
Process for assessment and approval?	Dossier for food safety assessment required?	✓	GMO safety assessment is carried out for the state registration. Any novel food derived from plant GMO produced in Russia or imported into Russia for the first time is subject to the state registration. Guidance for safety assessment is specified in MU 2.3.2.2306-07 “Medico-Biological Safety Assessment of Plant Genetically Modified Organisms”. According to the accepted regulations, the human health assessment of a novel GMO to be placed on the domestic market includes the following: ■ Molecular assessment includes analysis of genetic construction, genetic modification method, and the gene expression level. ■ Technological assessment includes determination of organoleptic and functional properties, analysis of technological characteristics of the finished products. ■ Human health safety assessment includes several sections of required assessments: analysis of compositional equivalence and toxicological, genotoxicological, and allergological safety studies. ■ Methods for identification include qualitative and quantitative assay of GMO in food (studies targeted at determination of correspondence of these methods to those used in Russia in order to provide monitoring of use and labeling of GM food). The list and the scope of required studies is determined on the basis of analysis of information of the GMO submitted for registration; however, the above-mentioned studies are required. If significant changes in the GMO’s genome, proteome, or metabolome are shown, additional studies may be required to determine: biological value and absorbency reproductive effect; gonadotoxic, embryotoxic, teratotoxic effect; potential carcinogenic effect; lifetime, etc.			
	Timeframes specified?	✓	Approx. 15 months for new GM products, shorter processing time for food products and ingredients if GM component already in the registry			
	Processing fees applicable?	✓	Fees are required. Amount depends on whether the product is already in the registry. *Rospotrebnadzor’s* charges for all examinations and related services, including comprehensive studies required to register biotech events for food use. The fee varies, depending on the range of examinations and studies, but averages around 4.5 million rubles (approximately $US76,300) for the approval of new events for			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
			an unlimited period. Registration of food products that contain a previously registered biotech event is 20,000 rubles ($US338).			
	Public consultation?	X	Not specified			
	Socio economic considerations?	X	Not specified			
	Length of approval specified?	✓	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 options?	✓	Not applicable	Order 366 states that the registration is issued for the period from one up to 10 years	Renewal required for feed products as required	
Outputs from assessment	Food safety assessment?	✓	Applicant submits an application and dossier to Rospotrebnadzor; Rospotrebnadzor assigns a safety assessment study to the Federal Research Center of Nutrition, Biotechnology and Food Safety or former Federal State Budget Enterprise "Science and Research Institute of Nutrition" (ION), which may coordinate with other Russian science institutes and laboratories in the field of biotechnology and microbiology	Registration for feed use has been effectively suspended since the adoption of FL 358 in July 2016, largely due to the reorganization of the research institute that was previously subordinated to VPSS according to the amendments to GOR # 839 that came into force starting July 1, 2017, the procedure for registration of GE crops for feed use has changed. The responsibilities of VPSS in feed registration were confirmed by Order No. 366 of the Russian Ministry of Agriculture on July 26, 2017 " On Approving Administrative Regulation of Federal	Follows CU TRs and certificates issued by *Rospotrebnadzor* and FSVPS	

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
			The applicant concludes an agreement for the food safety assessment with this Center; and - Based on the Institute's assessment, Rospotrebnadzor issues a certificate of registration and registers the product.	Veterinary and Phytosanitary Service for Providing Services on State Registration of Genetically-Engineered-Modified Organisms, Used for Production of Pharmaceuticals for Veterinary Use, as well as Feeds and Feed Additives for Animals, Received from Genetically-Engineered-Modified Organisms or Containing such Organisms. http://www.garant.ru/products/ipo/prime/doc/71651236/		
	Assessments/Decision made public?	X	Not specified			
Historical assessments and approvals?	GM Cotton?	✓				
	GM Canola?	✓				
	GM Soybean?	✓				
	GM Maize	✓				
	Other GM products?	✓	Rice; sugarbeet, potato (Bt potato "Elizaveta" and "Lugovskoy" are registered for food use only for Russia, because these two potato varieties were not registered for the EAEU.			
Any special conditions / considerations?	Restrictions to distribution and use?	✓	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	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	Declaration of food and feed as GM if thresholds are exceeded	

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
			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	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		
	Labelling requirements?	✓	Labelling and information for consumers on the presence of GE ingredients in food products is regulated by the technical regulations of the EAEU on safety and labelling of food products. These regulations require that in any of the EAEU member states, products must be labelled if the presence of GE lines is over 0.9 percent. For food products imported into Russia, *Rospotrebnadzor* has the right to conduct sample tests to detect the presence of biotech components. In 2016, the EAEU notified the WTO of the draft amendments to the TR on Food Labeling ("GMO" sign on food label shall be of the same size and next to the Unified mark of products circulating in markets of EAEU member states). However, the draft is still pending EAEU approval. Information on the composition of feed, including the presence of biotech components is provided on the shipping documents, but so far Russia has not required labeling of presence of "GMOs" in feed on consumer packs of feed.		

3.18 Singapore

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Regulatory framework in place?	International standards (e.g. Codex/OECD)	✓	Domestic guidelines are in line with the Codex Guidelines in conducting safety assessment of GM food.			Singapore has not signed the Cartagena Protocol
	Domestic laws and regulations	✓	Singapore Guidelines on the Release of Agriculture-Related GMOs (GMAC Release Guidelines) 1999 Consolidated version of the Control of Plants Act (Chapter 57A) Consolidated version of the Sale of Food Act (Chapter 283) Consolidated version of the Food Regulations (2005 Edition)			A new statutory board, to be called the Singapore Food Agency (SFA), will be formed in April 2019 year under the Ministry of Environment and Water Resources (MEWR) to oversee food safety and security. The agency will bring together food-related functions currently carried out by three other agencies - the Agri-Food and Veterinary Authority of Singapore (AVA), the National Environment Agency (NEA) and the Health Sciences Authority (HSA)
	Implementing Agencies	✓	• Genetic Manipulation Advisory Committee (GMAC) • Agri-Food & Veterinary Authority (AVA) for relevant import permit and formal approval			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Coverage of legislation?	Legislative trigger?	✓	Process trigger with product assessment			
	Specifies organisms covered?	✓	GM organisms and their food products (fresh or processed)			
Process for assessment and approval?	Dossier for food safety assessment required?	✓	Proposal prepared according to GMAC Release Guidelines; 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		Proposal prepared according to GMAC 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	
	Timeframes specified?	✓	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			
	Processing fees applicable?	✓	No processing fees for GMAC endorsement and AVA approval			
	Public consultation?	✓	Public consultations done during drafting of the guidelines Public informed of approvals through registry			
	Socio economic considerations?	X	None specified			
	Length of approval specified?	X	None specified			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
	Renewal options?	X	None specified			
Outputs from assessment	Food safety assessment?	✓	Scientific and case-by-case taking into consideration human health and environment Done by GMAC Subcommittee on the Release of Agri-Related GMOs, using GMAC Release Guidelines Recommendation of subcommittee considered by GMAC before submitting endorsement to AVA. AVA considers endorsement and conduct further assessment and issues formal approval; Risk assessment uses substantial equivalence approach and based on Codex Guidelines.			
	Assessments/Decision made public?	✓	GMAC endorsement Formal approval by AVA Import permit Entry into GMAC and AVA registry of GMOs approved for food, feed and/or processing			
Historical assessments and approvals?	GM Cotton?	✓	HT/IR, Stacked			21 products for use as food or as food ingredients
	GM Canola?	✓	HT			
	GM Soybean?	✓	HT/IR, stacked, high oleic			
	GM Maize	✓	HT/IR, stacked			
	Other GM products?	✓	Alfalfa, sugar beet			
Any special conditions / considerations?	Restrictions to distribution and use?	✓	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 reported immediately to the GMAC and AVA.			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
			AVA may take necessary risk management measures if there are any new information that may change outcome of original risk assessment			
	Labelling requirements?	✓	There is no specific legislation or guidelines on labelling of GE foods. GMAC subcommittee on labelling was created to consider the issue of labelling of GE products. In recognition that it is a complex issue with no internationally agreed upon threshold on GE material in food, Singapore has no plans to draft guidelines on labelling anytime soon.			

3.19 Chinese Taipei

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Regulatory framework in place?	International standards (e.g. Codex/OECD)	X	Domestic guidelines are in line with the Codex Guidelines in conducting safety assessment of GM food, but not a member			Chinese Taipei has not signed the Cartagena Protocol
	Domestic laws and regulations	✓	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	TFDA is working with a research institute to draft regulatory guidelines for innovative biotechnologies, such as gene editing. Reportedly, a draft guideline on Zinc Finger Nucleases (ZFN) technology, Oligonucleotide-directed Mutagenesis (ODM), RNA-dependent DNA Methylation (RdDM), and Grafting has been completed for the agency's regulatory policy preparedness.
	Implementing Agencies	✓	• Taiwan Food and Drug Administration, Ministry of Health and Welfare (TFDA) • Council of Agriculture COA (allows GMO approved for food to be used also as animal feed)			
Coverage of legislation?	Legislative trigger?	✓	Process trigger for regulation			
	Specifies organisms covered?	✓	GM Plants			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Process for assessment and approval?	Dossier for food safety assessment required?	✓	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 (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		Valid Registration and Pre-Market Approval for use as food or animal feed, submitted to TFDA	
	Timeframes specified?	X	Not specified			
	Processing fees applicable?	✓	Not specified			
	Public consultation?	✓	None specified, but TFDA publishes regulations and list of registration approvals in its website			
	Socio economic considerations?	X	Not specified			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
	Length of approval specified?	✓	Five years			
	Renewal options?	✓	Renewal registration prior to expiration of approval			
Outputs from assessment	Food safety assessment?	✓	Case by case risk assessments done by Genetically Modified Food Advisory Committee (GMFAC) with 21 non-governmental experts 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 Chinese Taipei 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.	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)	

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
			A separate food safety assessment done if stacked traits affect the same biochemical pathway			
	Assessments/Decision made public?	✓	Certificate of Approval. None specified, but TFDA publishes regulations and list of registration approvals in its website			
Historical assessments and approvals?	GM Cotton?	✓	HT/IR, Stacked			129 products. This includes 58 single biotech events (16 soybean, 23 corn, 13 cotton, 5 canola, and 1 sugar beet events), and 71 stacked events (10 soybean, 45 corn, 12 cotton and 4 canola stacked events).
	GM Canola?	✓	HT, hybrid breeding			
	GM Soybean?	✓	HT/IR, stacked, high oleic			
	GM Maize	✓	HT/IR, stacked			
	Other GM products?	✓	sugar beet			
Any special conditions / considerations?	Restrictions to distribution and use?	✓	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	
	Labelling requirements?	✓	Primary products made from raw materials are required to be labelled as GE. “Secondary” products made with GE primary products, such as beverages containing corn syrup, are exempted from GE labelling.			

3.20 Thailand

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Regulatory framework in place?	International standards (e.g. Codex/OECD)	✓	Domestic guidelines are in line with the Codex Guidelines in conducting safety assessment of GM food.			Thailand has ratified the Cartagena Protocol
	Domestic laws and regulations	✓	The Notification of the Ministry of Agriculture and Cooperative (MOAC) on Specification of plant from certain sources as prohibited articles, of exceptions and conditions under the Plant Quarantine Act B.E. 2507 (1964) (No. 10) B.E. 2553 (2010)	The Notification of MOAC on Specification of plant from certain sources as prohibited articles, of exceptions and conditions under the Plant Quarantine Act B.E. 2507 (1964) (No. 10) B.E. 2553 (2010)	The Notification of MOAC on Specification of plant from certain sources as prohibited articles, of exceptions and conditions under the Plant Quarantine Act B.E. 2507 (1964) (No. 10) B.E. 2553 (2010) The Notification of the Ministry of Public Health (MOPH) (No. 251) B.E. 2545 (2002) Re: Labelling of Food Obtained Through Certain Techniques of Genetic Modification / Genetic Engineering	The Technical Biosafety Committee (TBC) has been assigned to be the TFDA's technical arm for food safety assessment for food derived from GMOs. No specific timeframe for finalizing this mandatory regulation has been set
	Implementing Agencies	✓	• Department of Agriculture (DOA), Ministry of Agriculture and Cooperatives (MOAC) • Thai Food and Drug Administration (FDA), Ministry of Public Health (MOPH) • National Bureau of National Agricultural Commodity and Food Standards (ACFS) • Department of Trade Negotiations • Department of Foreign Trade			
Coverage of legislation?	Legislative trigger?	✓	Process trigger with product assessment			
	Specifies organisms covered?	✓	Plants			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Process for assessment and approval?	Dossier for food safety assessment required?	✓	Voluntary food safety assessment performed by TBC follows CODEX guidelines			
	Timeframes specified?	X	Not specified			
	Processing fees applicable?	X	Not specified			
	Public consultation?	X	Not specified			
	Socio economic considerations?	X	Not specified			
	Length of approval specified?	X	Not specified			
	Renewal options?	X	Not specified			
Outputs from assessment	Food safety assessment?	✓	Follows Codex guidelines			
	Assessments/Decision made public?	X	Not specified			
Historical assessments and approvals?	GM Cotton?	X				GM food safety assessment in Thailand is voluntary process
	GM Canola?	X				
	GM Soybean?	✓	HT/IR			
	GM Maize	✓	HT/IR			
	Other GM products?	X				
Any special conditions / considerations?	Restrictions to distribution and use?	✓	Soya and corn only GM food containing Cry9C DNA Sequence and food containing such GM food are prohibited via the Notification of MOPH (No.345)	Soya and corn only	Soya and corn only GM food containing Cry9C DNA Sequence and food containing such Genetically modified food are prohibited via the Notification of MOPH (No.345)	

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
					The Notification of MOPH (No. 251) under the Food Act. enforces the labeling of food containing the 5% threshold level of novel DNA or protein from GM soybean, GM corn, and their products	
	Labelling requirements?	✓	The TFDA under the MOPH enforces the labelling requirement for processed foods containing GE plant materials. Effective in 2002, Only GM soybean, corn, and their products (22 items) have to be labelled. The threshold level has been determined to be 5% of DNA or protein from each of the product's top three ingredients, and each ingredient should be more than 5% by weight of the product.			

3.21 United States

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Regulatory framework in place?	International standards (e.g. Codex/OECD)	✓	Domestic guidelines are in line with the Codex Guidelines in conducting safety assessment of GM food.			The United States has not signed the Cartagena Protocol
	Domestic laws and regulations	✓	**Environmental Protection Agency** • Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) o Prevent and eliminate unreasonable adverse effects on the environment o For plant incorporated pesticides (PIPs) plus amendments • Federal Food, Drug, and Cosmetic Act (FDCA) o Ensure that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information. o novel protein or GM product considered as food additives, flavorants, dietary supplements plus amendments • Toxic Substances Control Act (TSCA) o Prevent the manufacture, processing, distribution in commerce, use, or disposal of chemical substances, or any combination of such activities with such substances, from presenting an unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible population, without consideration of costs or other non-risk factors. **Food and Drug Administration** • Federal Food, Drug, and Cosmetic Act (FDCA) • Public Health Service Act (PHSA) o Ensure the safety, purity, and potency of biological products **United States Department of Agriculture** • Animal Health Protection Act (AHPA) o Protect livestock from animal pest and disease risks • Plant Protection Act (PPA)			FDA currently regulates most GE animals under the FDCA's new animal drug provisions by treating genetic material that is integrated into the animal as a new animal drug. FDA's new animal drug risk assessment considers a drug's safety and effectiveness to the animal and, in the case of food-producing animals, whether food derived from the animal is safe for consumption. The 2017 update to the Coordinated Framework describes FDA's programs for protecting consumers from risks from eating food derived from GE animals.

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
			o Protect agricultural plants and agriculturally important natural resources from damage caused by organisms that pose plant pest or noxious weed risks. • Federal Meat Inspection Act o Ensure that the United States' commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labelled. • Poultry Products Inspection Act o Ensure that the United States' commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labelled. • Egg Products Inspection Act • Virus-Serum-Toxin Act			
	Implementing Agencies	✓	• Food and Drug Administration (FDA) • Environmental Protection Agency (EPA) • United States Department of Agriculture (USDA)			
Coverage of legislation?	Legislative trigger?	✓	Product based system			
	Specifies organisms covered?	✓	All genetically modified organisms			
Process for assessment and approval?	Dossier for food safety assessment required?	✓	Undertaken by FDA-Center for Food Safety and Applied Nutrition (CFSAN) using substantial equivalence and the Codex Alimentarius Guidelines Food safety evaluation dossier prepared in consultation with FDA, in the prescribed format.	Undertaken by FDA-Centre for Veterinary medicine (CVM) using substantial equivalence; approval for feed use contingent also on approval for food use Food safety evaluation dossier prepared in consultation with FDA, in the prescribed format.	Undertaken by APHIS staff following 7CFR § 340 Undertaken by FDA-CFSAN and FDA-CVM using substantial equivalence and/or Codex Alimentarius guideline; approval for feed use contingent also on approval for food use	

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
			Dossier explains "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 toxicity and allergenicity properties of the GMO's novel protein.	Dossier explains "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 toxicity and allergenicity properties of the GMO's novel protein; also considers suitability of GM product as feed	Animal and Plant Health Inspection Service (APHIS): Import Permit (if applicable) Food safety evaluation dossier prepared in consultation with FDA, in the prescribed format. Dossier explains "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 toxicity and allergenicity properties of the GMO's novel protein; also considers suitability of GM product as feed	
	Timeframes specified?	✓	120-135 days			
	Processing fees applicable?	✓	Not specified			
	Public consultation?	✓	Submissions posted in the FDA website for public comment, except for sections marked as confidential		APHIS: Notification of States and Territories	

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
					Submissions posted in the FDA website for public comment, except for sections marked as confidential	
	Socio economic considerations?	X	None specified			
	Length of approval specified?	X	None specified			
	Renewal options?	X	None specified			
Outputs from assessment	Food safety assessment?	✓	FDA food safety evaluation	FDA feed safety evaluation	FDA food and/feed evaluation	
	Assessments/Decision made public?	✓	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	
Historical assessments and approvals?	GM Cotton?	✓				
	GM Canola?	✓				
	GM Soybean?	✓				
	GM Maize	✓				
	Other GM products?	✓				
Any special conditions / considerations?	Restrictions to distribution and use?	✓	Case-by case restrictions may apply		Must adhere to confinement and/or reporting requirements as per APHIS notification	

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
					Case-by case restrictions may apply	
	Labelling requirements?	✓	Foods derived from GE plants, FDA does not consider the mere fact of a modification to be a "material fact" that must be disclosed in food labelling. FDA requires disclosure only if there is a food quality or safety issue, and FDA bears the burden of substantiating such issues. In July 2016, President Obama signed a bill amending the Agricultural Marketing Act of 1946 to require USDA to establish labelling requirements for food products containing bioengineered or genetically modified organisms (i.e. establish the domestic mandatory bioengineered (BE) food disclosure standard). In May 2018, the Agricultural Marketing Service (AMS) proposed a new rule that would require food manufacturers and other entities that label foods for retail sale to disclose information about BE food and BE food ingredient content. The proposed rule is intended to provide a mandatory uniform domestic standard for disclosure of information to consumers about the BE status of foods. More information can be found on the Federal Register https://www.federalregister.gov/documents/2018/05/04/2018-09389/national-bioengineered-food-disclosure-standard.			

3.22 Viet Nam

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
Regulatory framework in place?	International standards (e.g. Codex/OECD)	✓	National guidelines are in line with the Codex Guidelines in conducting safety assessment of GM food.			Viet Nam has signed but not ratified the Cartagena Protocol
	Domestic laws and 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: 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		
	Implementing Agencies	✓	• Ministry of Agriculture and Rural Development (MARD)			
Coverage of legislation?	Legislative trigger?	✓	Process trigger with product assessment			
	Specifies organisms covered?	✓	GM Crops	GM Crops	GM Crops and products	
Process for assessment and approval?	Dossier for food safety assessment required?	✓	(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	(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	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	

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
			about the GMO (description of transformation, inserted genes and sequences, GM characteristics, method of detection), 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 economies	food and feed, information about the GMO (description of transformation, inserted genes and sequences, GM characteristics, method of detection), 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 economies		
	Timeframes specified?	✓	227 working days if developed within Viet Nam; 107 working days if imported as commodity. Estimated processing time includes entry of GMO into registry of GMOs approved for food use	227 working days if developed within Viet Nam; 107 working days if imported as commodity. Estimated processing time includes entry of GMO into registry of GMOs approved for feed use	Usual processing time for commercial importation of commodities	
	Processing fees applicable?	✓	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	Usual fees for commercial importation; no additional fees specified for GMOs		Circular 186/2016/TT-BTC regarding the regulation on "Collection, Payment and Management and Use of Fees paid for the Appraisal for the

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
						Bio-Certification of a Genetically Modified Organisms (GMO)." Accordingly, the fee for each appraisal is VND 70 million
	Public consultation?	✓	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	No additional requirements specified for GMOs if already included in an approved list		
	Socio economic considerations?	X	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		
	Length of approval specified?	X	None specified; certificate valid unless withdrawn	None specified		
	Renewal options?	X	None specified			
Outputs from assessment	Food safety assessment?	✓	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	No additional assessments specified for GMOs if already included in an approved list		
	Assessments/Decision made public?	✓	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 food 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	
Historical assessments	GM Cotton?	X				MARD has received 51 applications for the registration for approval for GE events for
	GM Canola?	X				

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments
and approvals?	GM Soybean?	✓	HT/IR, stacked, high oleic			food and feed use. However, MARD has only approved 21 applications to date with 30 cases still pending. The approved submissions were for GE corn and soybean events, with pending cases including GE events for soybeans, corn, canola, sugar beets, and alfalfa. The lists of approved GE events and the List of received GE dossiers are available at MARD's website: http://www.agrobiotech.gov.vn/web/default.aspx?Lang=vi-VN
	GM Maize	✓	HT/IR, stacked, high lysine, amylase modified, drought tolerant			
	Other GM products?	X				
Any special conditions / considerations ?	Restrictions to distribution and use?	✓	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 proven to have insufficient scientific basis Labeling required if any GM ingredient in food exceeds 5%	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 proven to have insufficient scientific basis Labeling required if any GM ingredient in animal feed exceeds 5%	No additional conditions specified for GMOs if already included in an approved list.	
	Labelling requirements?	✓	Decree 43/2017/ND-CP on Good Labelling, with the decree taking took effect on June 1, 2017 but it does not specify a threshold for GE ingredients containing food that is required to labelled as GE food products. After CropLife Viet Nam raised concerns to MOST on this lack of a threshold, the GVN stated that GE food labelling is still subject to regulation stipulated by the Inter- Ministerial Circular 45/2015/TTLT-BNNPTNT-BKHCN dated November 23, 2015. Inter-Ministerial Circular 45 is applied to pre-packaged foods containing at least one GE ingredient having a content of five percent or higher of the total ingredients forming the product.			

Decision Element	Decision Options	Yes/No	Food	Feed	Importation for processing	Comments

4. CONCLUSIONS AND NEXT STEPS

A first step in identifying candidate economies for compatibility in regulatory cooperation is to capture their current regulatory status. Once detailed, a candidate economies can be selected for further comparative analysis towards a regulatory cooperation program.

This report builds on the APEC Baseline Review of Regulations of Products Derived from Innovative Agricultural Technologies – with a focus on food and feed and a subset of APEC economies. The update and decision frameworks provide foundational information to be able to identify economies with regulatory regimes compatible to regulatory cooperation.

5. APPENDICIES

Appendix 1. Scope of Services

The following outline the key elements of the Scope of Services for the Update of the APEC Baseline Study – Regulations of Products Derived from innovative Agricultural Technologies and Identification of Ways to promote Greater Efficiencies and Alignment; High Level Policy Dialogue on Agricultural Biotechnology Project HLPDAB 01 2017T.

Activity description

Under this activity, the contractor will assist the HLPDAB in completing an update to the APEC Baseline Study: Regulations of Products Derived from Innovative Agricultural Technologies, which was completed in 2006 and updated in 2016. The update will capture the most recent efforts in the region to promote agricultural biotechnology, as well as identify ways to promote greater efficiencies and alignment with APEC economies. The update will also highlight the regions good practices, suggest tools to share across APEC economies, and integrate results into the APEC HLPDAB work plan. The initial outcome of the update will be presented at the HLPDAB workshop, slated for August 2018 in Brisbane, Australia.

To narrow the updates focus, it will be limited to food and feed derived from genetically engineering and will focus on outlining a decision framework that identifies the governing regulatory regimes at the economy level in economies where it is present. Understanding that some APEC economies do not have decision frameworks, the contractor will focus efforts on those economies that have a framework in place through a compatibility assessment. Please see the Attachments A and B. The two tables in Attachment B include the framework for the information collected and can be shared on the APEC website.

The capability assessment will examine existing regulatory food approvals systems with systems engaged in the recognition of safety assessments. This includes the legal and regulatory framework approval process, timeframe, and associated responsibilities therein. The can be summarized in the categories below and evaluated for compatibility:

1. Legal Requirements
    a. Regulatory Timelines
    b. Data Requirements

2. The Decision Making Process
    a. Public Consultations
    b. Decision Process
3. Public Information
    a. Safety Assessment Summary Documents
    b. Data Release

The compatibility assessment is intended to be a concise document that is focused on being informative and digestible for all economies to be able to utilize the results. For this reason, the contractor will ensure the format, content and structure are the most efficient and effective in transmitting findings.

Activity deliverables

Under their APEC contract, the contractor will deliver the following:

- An outline of economies' decision framework to demonstrate which economies require further research in the compatibility assessment
- A draft compatibility assessment and accompanying research notes
- A detailed presentation to encompass the findings, as well as best practices for possible inclusion into the HLPDAB work plan where appropriate and agreed, which will be delivered at the HLPDAB meeting in Port Moresby, Papua New Guinea.

The outputs of this activity will also be self-funded. The self-funded portion will deliver the following outputs:

- Complete a final compatibility assessment (with accompanying research notes) which will be based on comments from the draft assessment mentioned above
- A detailed presentation to encompass the findings, as well as best practices to advance regional efforts, which will be delivered at the HLPDAB workshop in Brisbane Australia.

Milestones

1. An outline of economies' decision framework to demonstrate which economies require further research in the compatibility assessment (31 August 2018).
2. A draft compatibility assessment with accompanying research notes (31 October 2018).

NOTES:

Update the APEC HLPDAB Study (completed in 2016 started in 2011): APEC Baseline Study: Regulations of Products Derived from Innovative Agricultural Technologies; 2) Identify ways (and tools) to promote greater efficiencies and alignment by exploring APEC economy's' policies, regulations, best practices, and trade of agricultural biotechnology along with other international for a and standards; and 3) Develop a work plan for the APEC HLPDAB forum incorporating 1) and 2) listed above including specific actions economies may take to implement the best practices and tools. The goal is to improve regulatory efficiencies which will increase the use of the technology to reap production, environmental and economic benefits for APEC economies. More broadly, the outcome is to promote transparent, science-based regulations in order to advance science and reap the benefits of agricultural innovation in the context of global trade with an emphasis on trade among APEC economies.

Asia-Pacific
Economic Cooperation

Update of the APEC Baseline Study: Regulations of Products Derived from Innovative Agricultural Technologies and Identification of Ways to Promote Greater Efficiencies and Alignment

Part 2: Compatibility Assessment

Exposure Draft

APEC High-Level Policy Dialogue on Agricultural Biotechnology

November 2018

CONTENTS

Acknowledgements

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EXECUTIVE SUMMARY

Regulatory convergence and cooperation are recognised as mechanisms to reduce the burden on individual economies, extend the reach beyond borders and drive continuous improvement of domestic regulatory systems. Regulatory convergence represents a process where the regulatory requirements across economies or regions become more similar or aligned over time as a result of the gradual adoption of internationally recognised technical guidance documents, standards and scientific principles. It does not necessarily represent the harmonisation of laws and regulations, which is not a prerequisite for allowing the alignment of technical requirements and greater regulatory cooperation.

This study investigated the compatibility of regulatory regimes in the sharing of food safety assessments and/or the mutual recognition of safety assessments from economies with trusted regulatory frameworks aligned to international standards. More specifically, the study has aimed to explore areas in which APEC economies have scope to improve, and in which other, comparable economies are leading in terms of a range of relevant outcome indicators.

The study has highlighted the significant supplication of GM food and feed assessment following the same international standards and codes of practice. Despite this, there is diversity in how APEC Members apply these within their respective regulatory systems.

Significant benefits for embarking on regulatory coherence and regulatory cooperation activities are evident and across society (i.e. for governments and regulators, for developers and importers, and importantly for consumers and citizens). However, the study has identified several preconditions to successful regulatory cooperation activities.

Through a compatibility assessment of APEC Member regulatory systems for GM food products and GM feed, this study identified areas of commonality as well as five distinct areas of difference, namely:

1. Predictability.
2. Transparency.
3. Certainty and consistency.
4. History of assessment and approval.
5. Agency autonomy in decision making.

Finally, the study has presented a case study whereby two APEC economies have collaborated to demonstrate regulatory cooperation.

FINDINGS

Finding 1. Almost all APEC Members indicate that they adhere to international standards for the assessment of GM food products. However, there is variability in the decision-making process for GM food products. This is largely in the predictability of assessment, transparency of the process, certainty of an approval and the historical experience of economies in undertaking assessments and issuing approvals.

Finding 2. Regulatory cooperation and harmonisation do not compromise domestic autonomy but do require political will to implement. GM products are still regarded as controversial by many actors and as such there is often a lack of desire to change the status quo and maintain a precautionary approach, despite the overwhelming evidence that supports the more than 20 years of benefits.

Finding 3. In implementing a precautionary approach, regulatory agencies often seek more data from developers (as is a requirement under the SPS Agreement). However, for GM food products, there is a lack of evidence that more data, at higher cost, provides a higher level of safety or certainty.

Finding 4. The familiarity of GM food products, particularly with certain trait and species combinations should enable streamlined approaches for regulatory assessment. The Health Canada (HC) / Food Standards Australia New Zealand (FSANZ) GM food safety assessment sharing model highlights the benefits of regulatory cooperation and serves to highlight the opportunities and benefits for those economies that are prepared to embark on a cooperation program.

Finding 5. Four key tenets to regulatory cooperation have been identified: Trust, benefit, fairness and control.

Finding 6. The regulatory systems of APEC Members were compared to identify economies suitable for regulatory cooperation activities. Differences between regulatory systems were classified into five categories.

Finding 7. Two economies (Malaysia and Singapore) stood out with potential to explore a program of work similar to HC and FSANZ. This approach provides a model for food safety assessment sharing that could also be adopted by other APEC Members. However, it is noted that preconditions to this approach

include: regulatory coherence of each economy, a willingness and commitment to cooperate from senior leaders within each regulatory agency, a program of works that builds trust, and an allocation of time and resources to ensure program momentum is maintained.

Finding 8. Many APEC Members would benefit from further regulatory coherence activities that lay a foundation for future regulatory cooperation and ultimately regional harmonisation.

1.0 INTRODUCTION

The use of biotechnology in agriculture continues to rapidly expand, particularly in key globally traded commodities such as maize, soybean, cotton and canola. More recently, new breeding technologies offer a paradigm shift in food production, including challenges to food regulation.

The regulation of food products from biotechnology varies widely across the Asia-pacific region, largely based on local economic, political and societal motives. However, all food regulatory agencies, regardless of geography, share the same mandate–to ensure the health and safety of consumers.

This project arose from the APEC High Level Policy Dialogue for Agricultural Biotechnology (HLPDAB) Terms of Reference along with an agreement made by economies at the APEC HLPDAB Meeting in Piura, Peru and concurred within Can Tho. This project provides an update to the Regulations of Products Derived from Innovative Agricultural Technologies: Baseline Review of APEC Member Economies.

The scope of this project aims to identify regulatory best practices among APEC economies and develop tools to build upon the work of international fora and standards. The ultimate goal is to promote greater alignment of APEC economies while making regulatory processes more efficient.

This report outlines Part 2 of the project, examining the compatibility of regulatory food approvals systems for engaging in regulatory cooperation and identification of economies that could benefit from regulatory coherence and is aligned to the scope of services as outlined in Appendix 1.

The focus of this project is limited to food and feed derived from genetic engineering [1] and on the compatibility of regulatory frameworks towards regulatory cooperation.

Specifically, this report:

- Builds on the baseline review of regulations of products derived from innovative agricultural technologies – with a focus on food and feed.
- Identification of economies with regulatory systems compatible to regulatory cooperation and regulatory coherence.

[1] Genetic engineering (GE) and genetic modification (GM) are used interchangeably in this report. Both refer to a process whereby the DNA of an organism is modified though a process of gene technology. This report does not specifically address new innovative technologies (e.g. gene editing) that may or may not require a food or feed safety assessment.

2.0 STUDY OBJECTIVES

2.1 Study objectives

The purpose of this study has been to examine opportunities for regulatory cooperation among APEC food and feed regulators. This study investigated the compatibility of regulatory regimes in the sharing of food safety assessments and/or the mutual recognition of safety assessments from economies with trusted regulatory frameworks aligned to international standards. More specifically, the study has aimed to explore areas in which APEC economies have scope to improve, and in which other, comparable economies are leading in terms of a range of relevant outcome indicators. For that purpose, the study investigated the legal and regulatory framework, approval process, timeframes, and associated responsibilities therein.

Through that comparison, the study has aimed to identify which features of regulatory frameworks are linked to their success, and comparatively which features of appeared to contribute to lower outcomes. The study has also aimed to qualify the extent to which the effectiveness of these regulatory regimes was also linked to other, non-regulatory factors, such as social or economic institutions. Finally, the study has sought to assess the extent to which regulatory features that appeared to contribute to regulatory effectiveness would be transferable to the wider APEC context. While the evidence base for the study has come from a few selected areas and economies, its main purpose has been to draw out cross-cutting findings that may inform reflections across a wide range of economies.

It is worth noting that this report should be read in conjunction with Part one of this study.

2.2 Study approach

The key concept and level of analysis for the study is in terms of the 'regulatory system' of APEC economies. A regulatory system combines the organisations that implement regulation, the frameworks used to set expected behaviours and outcomes, and the systems in place to measure compliance and enforce compliance. In other words, rather than focusing on a specific element, a particular target population, or a particular regulator, this approach encompasses the whole range of features of the regulatory system for food and feed safety.

2.3 Methodology

The methodology of this study had three components:

1. Scoping.
2. Data collection.
3. Compatibility assessment and comparative analysis.

The ***scoping phase*** refers to the steps taken to select regulatory areas and economies for further investigation. In order to characterise the regulatory system of an APEC economy, The APEC Baseline Study: Regulations of Products Derived from Innovative Agricultural Technologies 2016 [2] was updated (Part 1 of this study[3]). The regulatory system for each economy was characterised based on a set of criteria and further disaggregated with regard to the intended application of the biotech product or process. For each APEC Member Economy, regulatory approach details were presented in a consistently constructed matrices. Syntheses of similarities and differences were highlighted, and a number of opportunities to embark on an APEC-wide path of regulatory harmonization in this area were also suggested.

The selection of economies for further review was based on:

(a) Evidence of leading performance in the area of food and feed assessment of products from genetic engineering

(b) Scope and level of detail of the information available on the economies regulatory system; and

(c) Compatibility of the economy with leading regulatory systems such as Canada, Australia and United States.

Evidence on performance was taken from a variety of sources, including indexes and databases held by the OECD and FAO, USDA's Global Agriculture Information Network (GAIN) reports and academic studies. Area-specific sources were also reviewed. Adverse events, such as known delays or inconsistency in application of regulation, were also taken into account.

The ***data collection phase*** involved desktop research to identify and review relevant documentation. This included reports and papers from government bodies, industry stakeholders and international organisations (such as the

[2] Baseline Review of APEC Member Economies' Regulations of Products Derived from Innovative Agricultural technologies

[3] Update of the APEC baseline Study–Regulations of Products Derived from Innovative Agricultural Technologies and Identification of Ways to promote Greater Efficiencies–Part 1 (2018)

OECD), academic reports, articles and book chapters, newspaper articles and articles from specialised outlets, as well as primary legislation.

The analysis of the evidence collected consisted in the first instance in a case study approach: each individual economy/regulatory system was studied as a case, triangulating the information obtained from various sources to describe the regime and qualify its strengths and weaknesses. This was then followed by the third phase a ***compatibility assessment and comparative analysis***, whereby the systems of each economy studied (including Canada, Australia and the United States) in a given area were compared with one another. Finally, the findings emerging from each regulatory area were compared, so as to identify cross-cutting findings.

When interpreting this Report's findings, it is important to note that they are based on secondary evidence from desktop research and expert interviews, rather than on primary evidence. This limitation was partially mitigated by efforts to triangulate evidence from different sources.

Finally, the findings are based on economy cases selected on the basis of their effectiveness, rather than on the sources of efficacy. As such, the report's findings are by necessity tentative and a deeper analysis of an Economy is required to fully explore opportunities for regulatory cooperation.

3.0 REGULATORY SYSTEMS FOR GM FOOD AND FEED

3.1 The importance of regulation and trade agreements

Government agencies are responsible for implementing policies to ensure that markets run effectively and to protect consumers through safety regulations. However, it is important to note that regulation is designed to address domestic public policy considerations and is not a trade barrier *per se*.

Regulation is an important tool of democracies to advance public policy, to improve the lives of citizens, to protect their health and physical integrity and our environment, particularly when markets fail to deliver the expected standards of welfare. The domestic focus of regulators is necessary and good and can serve social expectations whereby governments ensure a certain standard is met. APEC economies have different public policy objectives and therefore adopt different regulations. The regulatory differences observed across APEC are to a large extent a manifestation of democracy and sovereignty.

Regulations are enforced usually by a regulatory agency or agencies formed or mandated to carry out the purpose or provisions of a legislation[4]. More recently, regulatory policy is becoming pivotal in addressing broad societal concerns such as food safety and security, environmental protection, distributional equity and sustainable development.

The widespread commercialisation of GM products for food and feed began in 1996[5]. This is only two years after the establishment of the World Trade Organization (WTO)[6]. Accordingly, trade rules discussed and agreed in the Uruguay Round (1986-1994) did not specifically refer to GM food or feed products. Nevertheless, the question of government action restricting imports of products that could harm the health of humans, animals, and plants or harm the environment played a major role in the Uruguay Round negotiations.

The Agreement on the Application of Sanitary and Phytosanitary Measures (the 'SPS Agreement') entered into force with the establishment of the World Trade Organization on 1 January 1995. It concerns the application of food safety and animal and plant health regulations. The SPS Agreement was seen as a significant step forward in defining the conditions under which governments could restrict imports of products for health reasons, while the Technical Barriers to Trade (TBT) Agreement dealt with technical regulations, standards, including labelling requirements, and conformity assessment. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is also relevant in cases where the issue of the patentability of GM products comes into question. The basic articles of the General Agreement on Tariffs and Trade (GATT), incorporated into the WTO as the GATT-1994, that apply to all trade in goods, has had fundamental implications in the development and implementation of domestic GM policies.

In general, GATT obligations provide a useful starting point for considering GM food regulation. Firstly, a distinction needs to be made between the cultivation of GM crops in an economy versus the importation of products for food and/or feed derived from GM crops. Nothing in GATT would oblige a WTO member to allow GM crops to be grown in that economy. As such, regulation around the

[4] Regulatory policy; retrieved November 2018 from: https://www.oecd-ilibrary.org/governance/regulatory-policy-and-governance/setting-the-scene-the-importance-of-regulatory-policy_9789264116573-4-en
[5] Brief 53: Global Status of Commercialized Biotech/GM Crops: 2017; retrieved November 2018 from: http://www.isaaa.org/resources/publications/briefs/53/default.asp
[6] The World Trade Organization (WTO); retrieved November 2018 from: https://www.wto.org/english/thewto_e/thewto_e.htm

cultivation of GM crops has a domestic focus and is typically not a major impediment to trade.

On the other hand, trade obligations and regulations become directly relevant when there is trade in GM products or ingredients between economies. Most trade rules are by their nature constraints on importing governments while exporting economies by contrast have fewer restrictions on their policies. As such, the basic rules of the GATT apply to imports of GM products. Importantly, these rules are *inter alia* in that the importing economy cannot give to a product of a particular supplier, if from a WTO member economy, less favourable treatment than it affords to a 'like' product from other suppliers. The imported product should also not be treated, once on the market, in a way that is more onerous than a domestic 'like' product.

This has been a constant source of discussion, particularly with respect to the EU and other economies that have a focus on the 'precautionary principle[7]' embedded in law. Similarly, a number of APEC economies consider the principle in decision making around the importation of GM food and/or feed products.

The WTO also addresses domestic regulations governing the health and safety consequences of the importation and internal distribution of GM products. These regulations are subject to the disciplines of the WTO SPS Agreement. A regulation banning or limiting imports of GM products, for example, could be covered by this agreement if it were enacted to protect human health or limit damage from the establishment of pests. However, other conditions of the SPS Agreement remain enforce, particularly the requirement that the regulatory measure be '..based on scientific principles and is not maintained without sufficient scientific evidence' (SPS Agreement, Article 2). There is also provision in Article 5, paragraph 7 that allows provisional restrictions in cases where scientific evidence is 'insufficient'. In these cases, the economy issuing the regulation has an obligation to '..seek to obtain the additional information' necessary to apply an objective assessment of risk.

One approach to such a condition is to base import regulations on multilateral standards. The SPS Agreement specifically encourages the use of standards set by the Codex Alimentarius Commission (Codex), a body jointly managed by the UN Food and Agriculture Organization (FAO) and the World Health Organization (WHO), geared towards setting international food standards,

[7] Precautionary principle: defined in this report as 'discretionary action applied to decision making where there may be uncertainty due to the apparent lack of scientific knowledge". Use of the principle is often considered a social responsibility to protect the public from exposure to harm.

guidelines, and codes of practice related to the safety of international food trade. Codex has established a task force to consider the problems associated with risk assessment in the case of GM foods[8].

3.2 Regulatory mandates differ within and between APEC economies

It is well understood that the political and socio-economic drivers of APEC economies differ markedly. As outlined in Part one of this Study[9], there is considerable difference in the regulatory and decision frameworks for GM food and feed across APEC economies.

However, even within an economy, different government agencies with roles in GM food and feed regulation may have differing regulatory mandates such as different directives or regulatory scope. Such differences can sometimes lead to inconsistency, and in extreme cases conflict, in the implementation of GM food and GM feed regulation.

Inconsistency and can, in some circumstances, be mitigated through transparency and greater levels of engagement with stakeholders. This may include, for example, providing access to safety assessment processes and decision-making policies as well as opportunities for public consultation.

4.0 REGULATORY COHERENCE AND COOPERATION

4.1 Regulatory coherence

Regulatory coherence[10] refers to the use of good regulatory practices in the process of planning, designing, issuing, implementing and reviewing regulatory measures in order to facilitate achievement of domestic policy objectives. Further, it refers to efforts across governments to enhance regulatory cooperation in order to further those objectives and promote international trade and investment, economic growth and employment.

The level of regulatory coherence is an important factor in determining the likelihood of embarking on regulatory cooperation efforts as well as the likelihood of success.

[8] Codex: http://www.fao.org/fao-who-codexalimentarius/en/ Two international standard-setting bodies, the World Organisation for Animal Health (OIE) and the International Plant Protection Convention (IPPC) have both established working groups on GM issues.
[9] Update of the APEC baseline Study–Regulations of Products Derived from Innovative Agricultural Technologies and Identification of Ways to promote Greater Efficiencies–Part 1 (2018)
[10] Regulatory coherence, retrieved November 2018 from: https://ustr.gov/sites/default/files/TPP-Final-Text-Regulatory-Coherence.pdf

Regulatory coherence captures two key concepts – the first relating to process in regulation making – including transparency, impact analysis, cooperation and consultation. This effectively reflects the principles of good regulatory practice as articulated by the OECD. Regulatory coherence also refers to an outcome – coherence – regulation that works closely and well together. Cross-border, this could be in the form of mutual recognition, regulatory harmonization or regulator to regulator cooperation.

Further, while intended to improve the regulation making process, and to ensure that regulation is fit for purpose, regulatory coherence has potential to be used to enforce or promote particular regulatory ideologies. As such, while trade agreements can certainly encourage regulatory coherence, they must be careful to ensure that they do not interfere with an economies' legitimate interest in setting their own policy direction – choosing a policy outcome and choosing the best intervention to achieve that outcome.

Good regulatory practices will help ensure that the interventions – whether rules and laws or other government action – are appropriate, effective and fit for purpose. They also help to mitigate against unintended outcomes of the intervention, by engaging potential stakeholders early in the process.

The absence of good regulatory practices can mean that too much regulation is imposed, and innovation is stifled. With respect to gene technology this can mean a lack of access to advanced and cost-effective products. Without good regulatory practices, unintended consequences of regulation are more likely, and regulation can diverge from international norms or rules for no good reason. It can mean that outdated regulation stays in place and a lack of consideration of consequences for cross-border businesses can result in regulation that impedes trade.

4.2 Regulatory cooperation

Regulatory cooperation is a process where governments from different economies work together to:

- reduce unnecessary regulatory differences
- eliminate duplicative requirements and processes
- harmonise or align regulations
- share information and experiences; and
- adopt international standards.

Regulatory cooperation can apply to a range of regulatory activities across a regulatory system. For example, it may apply to a range of regulatory activities, including: policy development; inspections; certification; adoption and development of standards; and product and testing approvals. In terms of GM food and feed, it may refer to the sharing of safety assessments (described in this report) or even mutual recognition of regulatory decisions (e.g. the GM food and feed approval process in Viet Nam). The level and intensity of cooperation can also vary, with the ultimate cooperation reflected in mutual recognition of regulatory decisions.

Increased familiarity with GM technology and the recognition of the similarity of data inputs and processes and the consistency in food safety submission outcomes creates opportunities for regulatory cooperation between and among governments to reduce redundancy, encourage innovation, facilitate trade, and allow scarce government resources to be employed most effectively. Regulatory cooperation to increase the efficiency and confidence of regulatory decisions does not compromise sovereignty or protection goals of regulatory agencies. All food regulatory agencies have equivalent protection goals - protecting human health.

Cooperation mechanisms and efforts may include regulatory harmonization, mutual recognition and information sharing among regulatory authorities, and through regulatory coherence mechanisms, including regulatory impact assessment and transparency in regulatory process. The mechanisms can be considered as either institutional (e.g. through participation in international organizations and adoption of international standards) or substantive through the improvement of existing obligations and mechanisms of cooperation. Importantly, cooperation is a spectrum from a simple agreement to talk through to mutual recognition of regulatory decisions.

In 2013, Health Canada and Food Standards Australia New Zealand embarked on a substantive project to improve the efficiency as well as the synchronization of GM food safety assessments. This case study highlights the challenges in cooperation efforts, even for regulatory systems that demonstrate strong regulatory coherence. However, it also serves as a model that other APEC economies can consider.

4.3 Drivers and enablers of regulatory cooperation

APEC economies follow international standards and guidelines for the safety assessment of GM food and feed. Since the introduction of genetic modification

(GM) technology over 20 years ago, there have been more than 1260 submissions across 28 economies for food safety approvals[11] (Figure 1). In all cases, no request for a food or feed approval has been disallowed on safety grounds. In many cases, the same genetic elements have been repeatedly assessed.

This level of scrutiny has lead developers to ask regulators for a greater level of cooperation and harmonization to facilitate the pathway to market of GM food and feed products.

Key drivers and enablers of regulatory cooperation for GM food products include:

- Having a common motivation (e.g. the allocation of resources, both human and financial)
- Facilitating international trade (e.g. ensuring market access and avoiding trade disputes.)
- Access to technology for food and nutrition security, improving agricultural sustainability and enabling rural development to remain globally competitive
- Alignment of food safety assessment processes through the use of common standards such as Codex and encourage the sharing of safety assessment information through a common platform (e.g. FAO GM Foods Platform)
- Facilitating and fostering trust and strong working relationships between regulatory agencies

[11] Data provided by CropLife International

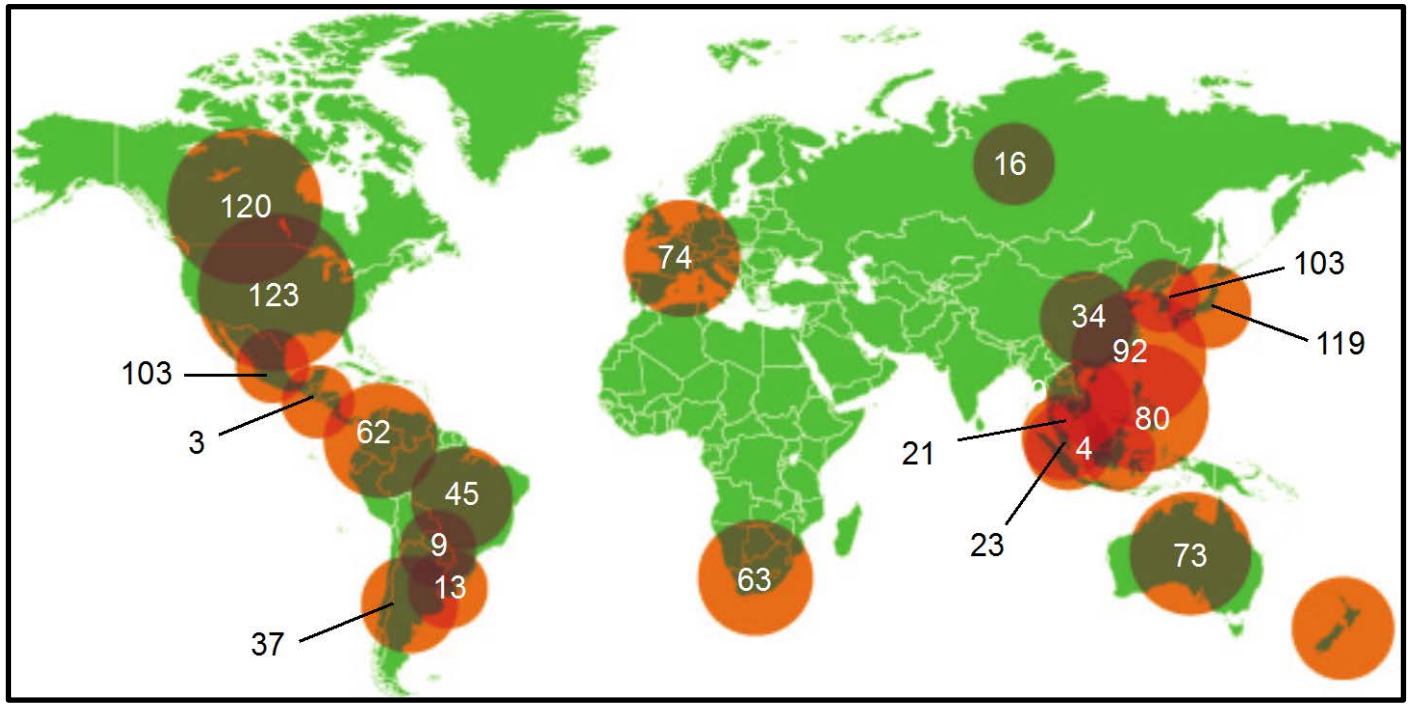

Figure 1. Redundancy and duplication of food safety assessments on GM crops.

Many economies are making food safety decisions–often about the same products. There have been more than 1260 food safety decisions on biotech crops across 28 economies (including the EU)–never with a differing opinion. *Data Source:* CropLife International

4.4 Preconditions for regulatory cooperation

In order for APEC economies to embark on a program of regulatory cooperation, there are several important considerations and prerequisites. Firstly, both economies should have a willingness to cooperate, often motivated by several of the drivers and enablers described above. Secondly, both economies should have effective and transparent domestic regulatory systems (i.e. strong level of regulatory coherence). Thirdly, there is a need for agency level leadership to drive cooperation efforts. Lastly, there needs to be a demand from developers to seek approvals in both markets.

These requirements can be challenging as many regulatory bodies do not have the capability or the resources to undertake the necessary activities towards cooperation and many domestic regulators often work in isolation.

It is a finding from this study that there are four key tenets to regulatory cooperation:

1. **TRUST**
    a. of the domestic regulatory system (protection of an Economies' core values)
    b. Between regulatory agencies/governments/economies.
2. **BENEFITS**
    a. To each economy.
3. **FAIRNESS**
    a. In the application of regulatory cooperation (i.e. along the supply chain, in trade, market access etc.).
4. **CONTROL**
    a. Maintenance of each Economies' sovereignty.

Of these principles, trust is perhaps the most important. In some economies. the public can often distrust regulators and the prospect of regulatory cooperation, in particular the mutual recognition of another Economies' decision. This is perhaps one of the greatest challenges for industry and government to overcome.

Further, it may also be difficult to build trust between potential partners if one of the partners have yet to develop or demonstrate an effective domestic regulatory system. It is critical that trust be established between regulators. This can be achieved through gaining an understanding of how their counterparts'

function, and they need to trust the standards and processes of the partner regulators.

As presented in this report, the shared safety assessment opportunity between Health Canada and FSANZ serves to highlight the importance of building trust. Despite both economies having well-developed and respected domestic regulatory systems and generally strong bilateral relations, it was not until Health Canada and FSANZ officials met together to discuss regulatory cooperation opportunities did the initiative really gain momentum.

Examining the regulatory systems across APEC (Part 1 of this study), it is clear that in addition to basing food and feed safety assessments on Codex guidelines, economies tend to follow similar processes in undertaking safety assessments. Likewise, consistency in the outcomes of assessment, similarity of data inputs and dossiers provided by applicants creates opportunities for regulatory cooperation between and among APEC members to reduce redundancy and employ resources more efficiently and effectively.

4.5 Realizing the benefits of regulatory cooperation

In addition to basing their reviews on Codex guidelines, governments tend to follow similar processes in conducting safety assessments. Consistency in outcomes and the similarity of data inputs and dossiers provided by applicants creates opportunities for cooperation between and among governments to reduce redundancy and employ resources more efficiently and effectively.

Regulatory cooperation is not a novel concept. The European Union recognizes a single food safety assessment for the entire 28 economy bloc and recently Health Canada (HC) and Food Standards Australia New Zealand (FSANZ) have tested a safety assessment sharing program (see the case study presented below).

Food Standards Australia New Zealand (FSANZ) provides a good example of the harmonisation of food regulation. An Agreement between Australia and New Zealand establishing a System for the Development of Joint Food Standards (the Treaty) was signed on 5 December 1995 and has been updated several times since then. This mutual recognition came into effect in 2000.

The Treaty aimed to harmonise food standards, reduce compliance costs and remove regulatory barriers to trade in food between Australia and New Zealand.

Since the establishment of FSANZ, more than 100 safety assessments have been undertaken and approved on GM food products[12].

Regional collaboration efforts are also actively exploring ways to increase their cooperation around safety assessment sharing (e.g. MERCOSUR in Central America[13]; the COMESA region in East Africa[14]).

Recognition and use of like-minded economy safety assessments for GM products during the regulatory approval process has proven to provide benefits to both technology providers and regulatory agencies without impacting sovereignty. Ultimately, cooperation efforts benefit the public and consumers.

Across Asia, Viet Nam has incorporated the principle of mutual recognition by allowing products to go through an expedited review process provided the product has received approval by at least five OECD economies. However, it was noted in Part one of this study that inconsistency in implementation of this policy principle has been challenging for developers.

Other benefits to cooperation include reduced resource requirements for regulatory agencies allowing for the re-allocation of those resources to new and/or future needs (e.g. training of regulators). Further, a reduction in regulatory costs and timelines mean a clear and predictable path to commercialization for technology providers and reduced risk of trade disruption and a practical solution to addressing issues related to Low-Level-Presence (LLP).

The benefits for governments and regulators include:

- Provides a framework for emerging regulatory systems **without unnecessary burden on agency resources**
- Allows **continued growth in scientific credibility** of regulatory assessments
- Leverages extensive experience of risk assessment and years of data generation and safe use to **ensure requirements are commensurate with risk**
- Enables government/agency **resource allocation towards other areas**, including those of higher risk

[12] Current FSANZ GM applications and approvals, retrieved December 2018 from: http://www.foodstandards.gov.au/consumer/gmfood/applications/pages/default.aspx
[13] Prado and Bertrand (2015) Regulatory cooperation in Latin America: the case of MERCOSUR. 78 LAW & CONTEMP. PROBS. 4 (FALL 2015)
[14] COMESA - Common Market for Eastern and Southern Africa

- Maintains **high rigor of safety and security of food supply**
- Promotes **faster domestic deployment and adoption for farmers and consumers of beneficial technologies** to meet challenges such as pests, drought and nutrition
- Creates a **pathway to safety assessment sharing**, collaboration and **mutual recognition** (further streamlining resources).

The benefits for developers and innovators include:

- Reduction in product development costs and timelines **enables smaller and emerging developers to bring products to market**, particularly public sector organisations
- Lowers cost barriers to working on **non-traditional crops and traits**, including local and humanitarian efforts
- Predictability on product launch timelines, **enabling resource streamlining**, patent protection and better, faster deployment
- Educational opportunities for newer developers, **clarity on requirements**, ensures only necessary resources are expended
- Resource redirection **towards additional innovations** for developers of all sizes

The benefits for the public and consumers include:

- Allows **equal access and faster deployment** to beneficial, innovative technologies for producers and consumers
- Increased economic growth and stability resulting from **technology benefits of reducing production costs and increasing yield** [higher farmer returns + downstream industries and rural communities]
- Help **alleviate hunger and poor nutrition**
  - Lower food prices
  - Safe and sustainable supply
- Environmental benefits through **sustainability**
- Ability to **rapidly respond to production threats** (e.g. panama disease of bananas, potato blight, wheat rust Ug99).

5.0 COMPATIBILITY ASSESSMENT

"Regulatory reform, including eliminating unjustifiably burdensome and outdated regulations, can boost productivity and promote job creation, while also protecting the environment and public health, safety, and security. In addition, as trade and investment flows become more globalized, greater alignment in regulatory approaches, including to international standards, is necessary to prevent needless barriers to trade from stifling economic growth and employment." – *2011 APEC Economic Leaders' Declaration*

5.1 Comparative analysis

The regulatory systems for GM food and feed products across APEC were compared to identify economies that could benefit from regulatory coherence and regulatory cooperation.

In order to assess compatibility, qualitative assessment criteria were developed for each of the regulatory system features. The features were summarised into the three key areas and evaluated for compatibility.

1. Legal Requirements
    a. Regulatory timelines
    b. Data requirements
2. The Decision-Making Process
    a. Public consultations
    b. Decision process
3. Public Information
    a. Safety assessment summary documents
    b. Data release

Each of the regulatory features were ranked, scored and then compared.

5.2 Similarities and differences across APEC economies

The majority of APEC economies follow international standards such as Codex and OECD guidelines for food and feed safety assessment and require the submission of an application dossier for assessment. Similarly, most economies have established regulatory frameworks and have defined

implementing agencies. However, the analysis revealed some key differences among APEC economies. These can be generally classified into five categories:

1. **Predictability**–the regulatory system is predictable in terms of an applicant providing all of the necessary information in an application dossier and receiving a favourable outcome.
2. **Transparency**–the regulatory system includes extensive public consultation and communication throughout the application process and post decision.
3. **Certainty and Consistency**–applicants can be certain of the information required for assessment and can expect consistency in the decision-making process
4. **History of Assessment and Approval**–the regulatory system is mature and has assessed a range of GM products and traits.
5. **Agency Autonomy**–the decision-making process is undertaken by the competent authority with outcomes and recommendations implemented.

In consideration of these differences, economies could be assembled into four distinct groups (Table 1). The strengths, weaknesses and opportunities for each of the groups are also presented, noting that these offer insights into some of the issues and potential barriers towards regulatory cooperation.

Table 1. Compatibility analysis

Group	Strengths	Challenges	Opportunities	Economies
1	• Mature regulatory system with history of assessment and approval • Predictable, transparent and consistent • High quality, stable and efficient governments • Highly educated and skilled regulatory work force • Structured regulation • Wealthy and prosperous economies • Case-by-case risk assessment • Highly aligned to international standards • Memberships with international trade organisations (e.g. WTO, OECD, APEC)	• Regulation keeping pace with rapid changes in technology • Some inconsistency in the application of regulations • Duplication of data assessment	• Knowledge and skills transfer to other APEC members • Drivers regulatory cooperation and harmonisation • Utilisation of regulatory cooperation models with other APEC Members • Candidates for mutual recognition of food and feed decisions	• Australia/New Zealand • Canada • Japan • Philippines • Republic of Korea • United States
2	• Functional regulatory systems aligned to international standards • Case-by-case risk assessment • High quality, stable and efficient governments • Highly educated and skilled regulatory work force • Structured regulation • Memberships with international and regional trade organisations (e.g. WTO, OECD, APEC, ASEAN)	• Dependent on imports and exports • Some constraints to implementation of existing frameworks • Uncertainty of how existing systems will handle products from new and emerging technologies • Significant expenditure on testing and detection of GM products • Uncertainty of the new Singapore Food Agency	• Regulatory cooperation programs with Group 1 APEC Members • Provide ASEAN leadership in regulatory assessment	• Malaysia • Singapore

Group	Strengths	Challenges	Opportunities	Economies
3	• Memberships with international and regional trade organisations • Regulatory systems aligned to international standards • Established competent authorities	• Constraints in the implementation of existing frameworks preventing a pathway to market for GM products • Uncertainty of the system impacting innovation • Uncertainty of how existing systems will handle products from new and emerging technologies • Lack of transparency or predictability of the assessment process • Inconsistency in application of regulatory frameworks • Demonstrated restrictions	• Regulatory coherence activities, Regulatory impact analysis • Education and upskilling of regulatory personnel	• Chile • China • Hong Kong, China • Indonesia, • Mexico • Peru • Russia • Chinese Taipei • Thailand • Viet Nam
4	• Memberships with international and regional trade organisations • Internal regulations currently utilised	• No regulatory framework in place • Low interest from government (i.e. not a high priority area)	• Regulatory coherence activities, Regulatory impact analysis • Education and upskilling of regulatory personnel • No need to start from the beginning. Could utilise existing regulatory models without compromising sovereignty	• Brunei Darussalam • Cambodia • Lao • Burma • Papua New Guinea

5.3 Opportunities for regulatory coherence initiatives

Across APEC economies, the need for regulatory coherence for genetically modified food and feed differs markedly. Approval processes for the import of GM products is variable and consistent application of procedures is sometimes lacking. Suffice to say, regulatory coherence is a major limitation to regulatory cooperation across APEC.

Regulatory coherence is not about less regulation nor is it about more regulation. It is about improving the process by which APEC economies develop regulations, generate and apply best practices and in acceptance of common standards and timings in which to implement them. It doesn't require loss of regulatory power or sovereignty. It results in more effective regulation that does not distort markets. Regulatory coherence fosters an optimal regulatory environment that allows the market to be more open, competitive, and innovative.

Regulatory coherence also results in a higher degree of confidence that regulations are providing the appropriate safeguards that are properly enforced, including enhanced confidence in traded products and services. It limits unintended consequences of regulation and increases consumer access to a wide choice of goods and services at better prices while boosting market competitiveness.

Even the most efficient regulation can be a barrier to trade if it is not compatible with or comparable to trading partner economies' regulation; and similarly, if the relevant regulators do not have a cooperative relationship. This is a particular barrier for multi-economy corporations, but regulatory coordination, harmonisation and convergence has benefits and downsides. As such, it must be considered on a sector by sector basis, and considered consistently with good regulatory practice.

The compatibility assessment revealed several economies that would benefit from an increase in regulatory coherence support. Coherence activities could include, for example, development of policy, implementing policy examining regulatory impact assessment and transparency in regulatory process as well as other measures discussed earlier in this report.

APEC has previously sought to improve regulatory coherence in the region through initiatives such as workshops and seminars on gene technology, safety assessment etc. However, greater emphasis is required to gain high level support to enact lessons from such activities.

Moving forward it is important to try to better understand regulation, regulatory principles, and importantly, regulatory concerns. Across APEC we can learn from the mistakes of APEC Members and take notice of these lessons. Trade and its benefits need to be communicated more effectively to populations more than ever before, and part of that is acknowledging risks and trade-offs when regulatory obligations are included in trade agreements. The regulated community needs to better understand trade – to acknowledge that it matters and to continue to consider it in regulatory policy making. Including regulatory coherence provisions in trade agreements is an important layer in ongoing efforts to improve regulatory processes and practices, but trade agreements should not attempt to indiscriminately enforce regulatory harmonization.

5.4 Opportunities for regulatory cooperation

The compatibility analysis identified two APEC economies that could benefit from exploring regulatory cooperation opportunities (i.e. Group 2; Table 1).

A review of the respective agency food approval policies and operational frameworks was undertaken from the perspective of current technology proponents. The review was undertaken for the purpose of identifying what are the similarities and differences between each agency's food assessment and approval processes. A desktop review of the food assessment and approval processes was undertaken (see Part 1 of this study[15]).

This information was collated and assessed for potential harmonisation and cooperation opportunities. Group 2 economies were also compared to Health Canada and FSANZ as these two agencies have recently completed a regulatory cooperation program (see the case study presented below).

Where the differences are mutually exclusive there may be implicit issues and/or barriers that may or may not require the development of either a policy or operational framework change on behalf of one or more of the agencies.

The first step in comparing the food approval systems was to consider the key legislated definitions (see Part 1 of this study). A review of the respective assessment and approval processes identified that there are differences in what triggers the need for an approval based on the definitions of gene technology and the broader definition of novelty as used by Health Canada (Table 2).

[15] Update of the APEC baseline Study–Regulations of Products Derived from Innovative Agricultural Technologies and Identification of Ways to Promote Greater Efficiencies–Part 1 (2018)

There are further differences in how an assessment is undertaken within each agency, but what was found to be common was the approach taken to assess food safety – namely a close adherence to the guidelines developed through the work of the OECD, FAO, WHO and the Codex Alimentarius Commission. Based on this analysis it is clear that the safety assessments undertaken by these agencies is compatible with each other's assessment procedures. As such, the case study described below offers a potential regulatory cooperation model for these APEC economies to explore.

Table 2. Comparative Review of Assessment and Approval Procedures–Policy and Operational Frameworks

Element	Health Canada	FSANZ	Malaysia	Singapore
Legal system	• Food and Drug Regulations (May 2014) under the Food and Drugs Act. • Division B.28 covers novel foods.	• *Food Standards Australia New Zealand Act 1991* (FSANZ Act) • Application for an amendment to the Australia New Zealand Food Standards Code (the Code) ➢ Standard 1.5.2 – Food produced using Gene Technology	• *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*	• *Singapore Guidelines on the Release of Agriculture-Related GMOs (GMAC Release Guidelines) 1999* • *Consolidated version of the Control of Plants Act (Chapter 57A)* • *Consolidated version of Sale of Food Act (Chapter 283)* • *Consolidated version of Food Regulations (2005 Edition)* • *A new statutory board, to be called the Singapore Food Agency (SFA), will be formed in April 2019 year under the Ministry of Environment and Water Resources (MEWR) to oversee food safety and security.*
Trigger for regulation	• Definition of novelty included in Regulation – for products of genetic modification relates to presence of new or altered characteristics. • A novelty determination opinion may be requested prior to submission	• **Standard 1.5.2 - Food** produced using gene technology.	• Malaysia's biosafety law requires that the National Biosafety Board evaluates and approves "living modified organisms" before release onto the market for food, feed, or processing.	• GMAC published the *Guidelines for the Release of Agriculture-Related GE Products* in 1999 to ensure "the safe import, release and use in Singapore of agriculture-related organisms that have been genetically modified." They provide a common framework to assess risks of agriculture-related GE products to human health and environment and approval mechanisms for their release.
Data for submission	• No formal regulation, but expectation for what will be addressed.	• Mandatory data requirements provided in FSANZ Application Handbook	• Completed Application Form C (Non-Research and Development activities involving Higher Plants or products) or Form D (Non-	• Proposal prepared according to GMAC Release Guidelines • template submitted to GMAC; core information requirements

Element	Health Canada	FSANZ	Malaysia	Singapore
	• Pre-submission meeting with outline for expected data to be discussed. • Rationale can be provided for why certain data not generated	• Pre-submission meeting with outline for expected data to be discussed. • Rationale can be provided for why certain data not generated	Research and Development activities involving other LMOs or products) • Risk assessment and risk management report • Emergency response plan • Other information specified by the National Biosafety Board (NBB)	include information on projected consumption pattern, nutritional quality and food safety, and data addressing other criteria set by Codex Alimentarius 2003
Procedure for submission	• No Fee. • Could be submitted online or paper copy, plus two electronic copies. • Health Canada will notify the applicant, in writing, of the decision for the majority of submissions within 410 days of receipt of the submission.	• Applications are formal requests to amend the Australia New Zealand Food Standards Code (the Code). • All applications are subject to an 'Administrative Assessment' which determines whether it is a General or Major procedure application. Applications deemed to provide an "exclusive capturable commercial benefit" for the applicant will be charged a fee, according to the number of hours estimated for the assessment.	• An application for approval must be completed and submitted to the Director General (DG) in the prescribed manner, together with the prescribed fees, and be accompanied with the appropriate documentation	• Under the Guidelines, a proposal has to be submitted to GMAC; then to its *Subcommittee on the Release of Agriculture-Related GMOs* that will review the application, including examining the GE's origin, the experimental procedures used in development and the methods used to prove they are safe for consumption. Following recommendations of the subcommittee, GMAC decides whether to endorse the application. GMAC's decision is then forwarded to AVA for further assessment, which determines final regulatory approval.
Review procedure	• Separate bureau within HC for toxicity, nutrition, and characterization. • Coordination with CFIA on deficiency letters. • 90-day response to deficiency letters required (check)	• FSANZ reviewer appointed to manage application review. • FSANZ is required to complete its assessment of applications either within 9 months (GENERAL) or 12 months (MAJOR). For paid applications, the clock starts on the date the fees are received by FSANZ.	• 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	• 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 using GMAC Release Guidelines • Recommendation of subcommittee considered by

Element	Health Canada	FSANZ	Malaysia	Singapore
				GMAC before submitting the endorsement to AVA. • AVA considers endorsement and conducts further assessment and issues formal approval; Risk assessment uses substantial equivalence approach and based on Codex Guidelines.
Approval process	• Post-review, internal submission to committee for approval. • Simple letter of notification with subsequent publishing of Decision Document on-line for information only. • No approval without CFIA approval for feed (and environmental release).	• Approval is by the FSANZ Board. The FSANZ approval is notified to 'the Forum' (the Council Of Australian Governments [COAG] Legislative and Governance Forum on Food Regulation) for ratification. Once ratified, the approval is gazetted as an amendment to the Code.	• An application for approval must be completed and submitted to the Director General (DG) in the prescribed manner, together with the prescribed fees, and be accompanied with: o risk assessment and a risk management report o emergency responses plan o other information as may be specified by the National Biosafety Board (NBB) • Upon receiving the application, the DG shall: • Refer it to Genetic Modification Advisory Committee (GMAC) for its recommendations, o Refer it to relevant government agencies for specific matters o Invite public participation for purpose of public disclosure • GMAC shall forward its recommendation whether or not the application should be approved and the terms and conditions to be imposed by the NBB, if any, after the assessment. • After having considered the recommendations of the GMAC,	• GMAC endorsement • Formal approval by AVA • Import permit • Entry into GMAC and AVA registry of GMOs approved for food, feed and/or processing

Element	Health Canada	FSANZ	Malaysia	Singapore
			the comments of the relevant department or agency, the views of members of the public, if any, and any additional information, the NBB may grant the application by issuing a certificate of approval or refuse the application.	

6.0 A CASE STUDY OF REGULATORY COOPERATION

6.1 Health Canada and Food Standards Australia New Zealand

In 2013, two APEC economies–Health Canada (HC) and Food Standards Australia New Zealand (FSANZ)–embarked on a joint project to improve the efficiency and synchronisation of GM food safety assessments. This project followed previous cooperation at an international level through Codex and the OECD and was facilitated by a Memorandum of Understanding between the two agencies allowing for the sharing of information associated with GM foods.

The project was further supported by industry, providing information and resources for benchmarking and collaborative assessment.

In the first instance, the agencies needed to establish the ground rules for collaboration. These included:

- Activities and outcomes that would not require changes to existing legislation under which each of the agencies operate
- A process that was flexible and accommodating of the different operating procedures of each agency
- Each agency would continue to make their own independent regulatory and risk management decisions in accordance with their framework and timeframes.

On this basis the agencies undertook a six-stage process towards regulatory cooperation.

6.2 Stage 1. Comparison of regulatory systems

In the first step, HC and FSANZ undertook a comparison of the regulatory approach of each agency (see Appendix 2). The factors considered included:

- What is the trigger for a GM food safety assessment?
- What the timelines were for assessment?
- What data requirements were required by each agency?
- What decision-making process was used by each agency?
- What level of consultation and communication each agency was required to undertake?

6.3 Stage 2: Benchmarking exercises

With an understanding of each regulatory system, the agencies undertook several benchmarking exercises. The purpose of this was to build trust between the agencies and gain an understanding of how each system was implemented for the safety assessment of GM food products. In undertaking this step, the agencies did a comparison of two previously completed safety assessments including the data requirements, general approach to the assessment and the conclusions reached.

Although minor differences in their approach were identified, they did not preclude the agencies undertaking further cooperative work.

6.4 Stage 3: Formulation of a cooperation approach

As discussed previously, the nature of regulatory cooperation is along a continuum from simply talking through to mutual recognition of another agency's decision. HC and FSANZ needed to identify what regulatory cooperation could look like. In simple terms there were four options for cooperation:

1. Undertake a concurrent safety assessment review - simultaneous but separate safety assessment.
2. Undertake a joint safety assessment review where both agencies work on a safety assessment as a joint exercise.
3. Safety assessment sharing where one agency undertakes the safety assessment on behalf of both agencies.

Noting the established ground rules for collaboration, the approach most suited to each agency was to examine a work plan for safety assessment sharing.

6.5 Stage 4: Building trust

With a cooperation strategy identified, the agencies developed a work plan that would build trust between the agencies and consolidate a workable cooperation outcome. The work plan was supported by industry allowing the agencies the opportunity to share information and conclusions. The work plan included:

1. Undertaking a concurrent safety assessment of a relatively simple new application submitted separately but at the same time to each agency.
2. Health Canada evaluation of a FSANZ safety assessment document for a concurrent application submitted separately to each agency.

3. A concurrent safety assessment of a nutritionally complex new application submitted at the same time, but separately, to each agency.

In undertaking this program, the level of trust between the agencies increased, laying the foundations for the development of a formal process.

6.6 Stage 5: Administration and other considerations

Outcomes from the work plan demonstrated that HC and FSANZ could cooperate through the sharing of food safety assessments. A process to allow this to be implemented was developed. This included the need for the staggering of submissions to each agency in order to accommodate differences in timeframes. Submission to the lead agency (the one doing the safety assessment) would occur first, with submission to the second agency only occurring once the safety assessment is completed.

Both agencies are currently working on the development of communication and guidance documentation to clearly articulate to stakeholders how this new cooperative process works in practice.

Further, the outcomes from the joint program are being communicated through relevant senior executives, Ministers, etc.

6.7 Stage 6: Implementation

Finalise the existing MoU with Health Canada, which incorporates provisions for the mutual recognition of food safety assessment sharing.

6.8 Lessons learned

- Operational and structural differences **added to the complexity and time taken** to progress the work
- Likeminded agencies with a strong commitment to collaborative work...but, **important to include trust building exercises** in the project to increase the level of confidence in each others' work
- Geography and time differences challenging, only two face to face meetings (**the most productive**)
- Required the **cooperation and support from industry stakeholders**

- Valuable by-product has been a **stronger working relationship between FSANZ and HC** in all matters related to the regulation of GM food by both agencies

7.0 CONCLUSIONS

APEC Members have a unique opportunity to work together towards a collaborative and harmonised approach to the assessment of GM food and feed products. However, through an assessment and comparative analysis of each of the APEC Members regulatory systems, it is clear that there are a number of barriers and issues that are constraints to this achievement.

The recent project undertaken by Health Canada and Food Standards Australia New Zealand offer insights into the challenges and opportunities in identifying and implementing regulatory cooperation. Such a project serves a potential model for other APEC Members to consider.

A number of APEC Economies are not in a position to undertake active cooperation activities (see Table 1). However, there are opportunities to further develop regulatory coherence, including regulatory impact assessment, improvement in transparency of the regulatory process and the upskilling of policy makers and regulatory personnel (also see Section 4.1). These activities will assist those economies towards a pathway to cooperation and harmonisation.

8.0. APPENDICIES

Appendix 1. Scope of Services

The following outline the key elements of the Scope of Services for the Update of the APEC Baseline Study – Regulations of Products Derived from innovative Agricultural Technologies and Identification of Ways to promote Greater Efficiencies and Alignment; High Level Policy Dialogue on Agricultural Biotechnology Project HLPDAB 01 2017T.

Activity description

Under this activity, the contractor will assist the HLPDAB in completing an update to the APEC Baseline Study: Regulations of Products Derived from Innovative Agricultural Technologies, which was completed in 2006 and updated in 2016. The update will capture the most recent efforts in the region to promote agricultural biotechnology, as well as identify ways to promote greater efficiencies and alignment with APEC economies. The update will also highlight the regions good practices, suggest tools to share across APEC economies, and integrate results into the APEC HLPDAB work plan. The initial outcome of the update will be presented at the HLPDAB workshop, slated for August 2018 in Brisbane, Australia.

To narrow the update focus, it will be limited to food and feed derived from genetically engineering and will focus on outlining a decision framework that identifies the governing regulatory regimes at the economy level in economies where it is present. Understanding that some APEC economies do not have decision frameworks, the contractor will focus efforts on those economies that have a framework in place through a compatibility assessment. Please see the Attachments A and B. The two tables in Attachment B include the framework for the information collected and can be shared on the APEC website.

The capability assessment will examine existing regulatory food approvals systems with systems engaged in the recognition of safety assessments. This includes the legal and regulatory framework approval process, timeframe, and associated responsibilities therein. The can be summarized in the categories below and evaluated for compatibility:

1. Legal Requirements
    a. Regulatory Timelines
    b. Data Requirements

2. The Decision Making Process
    a. Public Consultations
    b. Decision Process
3. Public Information
    a. Safety Assessment Summary Documents
    b. Data Release

The compatibility assessment is intended to be a concise document that is focused on being informative and digestible for all economies to be able to utilize the results. For this reason, the contractor will ensure the format, content and structure are the most efficient and effective in transmitting findings.

Activity deliverables

Under their APEC contract, the contractor will deliver the following:

- An outline of economies' decision framework to demonstrate which economies require further research in the compatibility assessment
- A draft compatibility assessment and accompanying research notes
- A detailed presentation to encompass the findings, as well as best practices for possible inclusion into the HLPDAB work plan where appropriate and agreed, which will be delivered at the HLPDAB meeting in Port Moresby, Papua New Guinea.

The outputs of this activity will also be self-funded. The self-funded portion will deliver the following outputs:

- Complete a final compatibility assessment (with accompanying research notes) which will be based on comments from the draft assessment mentioned above
- A detailed presentation to encompass the findings, as well as best practices to advance regional efforts, which will be delivered at the HLPDAB workshop in Brisbane Australia.

Milestones

1. An outline of economies' decision framework to demonstrate which economies require further research in the compatibility assessment (31 August 2018).
2. A draft compatibility assessment with accompanying research notes (31 October 2018).

NOTES:

Update the APEC HLPDAB Study (completed in 2016 started in 2011): APEC Baseline Study: Regulations of Products Derived from Innovative Agricultural Technologies; 2) Identify ways (and tools) to promote greater efficiencies and alignment by exploring APEC economy's' policies, regulations, best practices, and trade of agricultural biotechnology along with other international for a and standards; and 3) Develop a work plan for the APEC HLPDAB forum incorporating 1) and 2) listed above including specific actions economies may take to implement the best practices and tools. The goal is to improve regulatory efficiencies which will increase the use of the technology to reap production, environmental and economic benefits for APEC economies. More broadly, the outcome is to promote transparent, science-based regulations in order to advance science and reap the benefits of agricultural innovation in the context of global trade with an emphasis on trade among APEC economies.

Appendix 2. Current Food Approval Processes in Canada and Australia

A2.1 Canadian Perspective

Federal responsibility for the regulations dealing with foods sold in Canada, including novel foods, is shared by Health Canada and the Canadian Food Inspection Agency (CFIA). Health Canada is responsible for establishing standards and policies governing the safety and nutritional quality of foods and developing labelling policies related to health and nutrition. The CFIA develops standards related to the packaging, labelling and advertising of foods, and handles all inspection and enforcement duties. The CFIA also has responsibility for the regulation of seeds, veterinary biologics, fertilizers and livestock feeds. More specifically, CFIA is responsible for the regulations and guidelines dealing with cultivating plants with novel traits and dealing with livestock feeds and for conducting the respective safety assessments, whereas Health Canada is responsible for the regulations and guidelines pertaining to novel foods and for conducting safety assessments of novel foods.

A summary procedure with estimated timings for the review of a petition for novel food approval Canada is shown in Figure 2. These timings are not related to any regulatory requirements but represent recent experience. As the initial review and requests for further information are coordinated with CFIA, the timing is related more to the work load in these agencies than to any specific time requirement. Similarly, the time for responding to requests for additional information and having such additional information reviewed is dependent on the petitioner as well as the agencies involved.

The mechanism by which Health Canada controls the sale of novel foods in Canada is the mandatory pre-market notification requirement as set out in Division 28 of Part B of the Food and Drug Regulations[16]. Manufacturers or importers are required under these regulations to submit information to Health Canada regarding the product in question so that a determination can be made with respect to the product's safety prior to sale.

The definition of 'novel food', and the definitions for 'genetically modify' and 'major change' are set out in B.28.001 of the Food and Drug Regulations. In summary, there are 3 types of regulatory triggers for novel foods in Canada, with GM foods falling under the 3rd trigger. In Canada, a novel food is a food that has been genetically modified such that a characteristic is added, or a

[16] Guidelines for the Safety Assessment of Novel Foods, 2006

characteristic is deleted, or a change in a characteristics of a food such that it lies outside the normal range for that characteristic. Food ingredients produced through applications of modern biotechnology trigger a pre-market review if they would meet the definition of novel as per Division 28. It is important to note that Canadian regulations concerning novel foods are not focused on the process used to develop the food, but rather on the final product. Therefore, other methods of intentional modification can also produce a novel food.

In practice, all novel plants produced through genetic modification have to date been sufficiently changed to fall under the definition of a novel food and as such plants are also regulated under feed and environmental regulations, a parallel review is generally undertaken by the Plant Biosafety Office (PBO) and the Animal Feeds Division of CFIA. In order to avoid the potential of a plant being approved for cultivation prior to approval in food or feeds, the agencies have instituted a “no split approval” policy and over time have developed a process of extensive collaboration in the risk/safety assessment procedures. As such, any consideration of the process of novel food approval in Canada has to include the collaboration with CFIA.When a petitioner contacts the Feed Section (CFIA), Novel Foods Section (Health Canada), and/or the Plant Biosafety Office (CFIA) for an opinion on the novelty of a plant and its feed and food products, a meeting will be organized among all three groups to review the case in order to analyse the factors that contribute to its status and provide guidance on the appropriate regulatory oversight. Where a plant variety has been determined to be a Plant with a Novel Trait (PNT), the feed and food products derived from it are most often classified as novel.

The safety criteria for the assessment of novel foods performed by Health Canada were derived from internationally established scientific principles and guidelines developed through the work of the Organization for Economic Cooperation and Development (OECD), Food and Agriculture Organisation (FAO), World Health Organisation (WHO) and the Codex Alimentarius Commission.

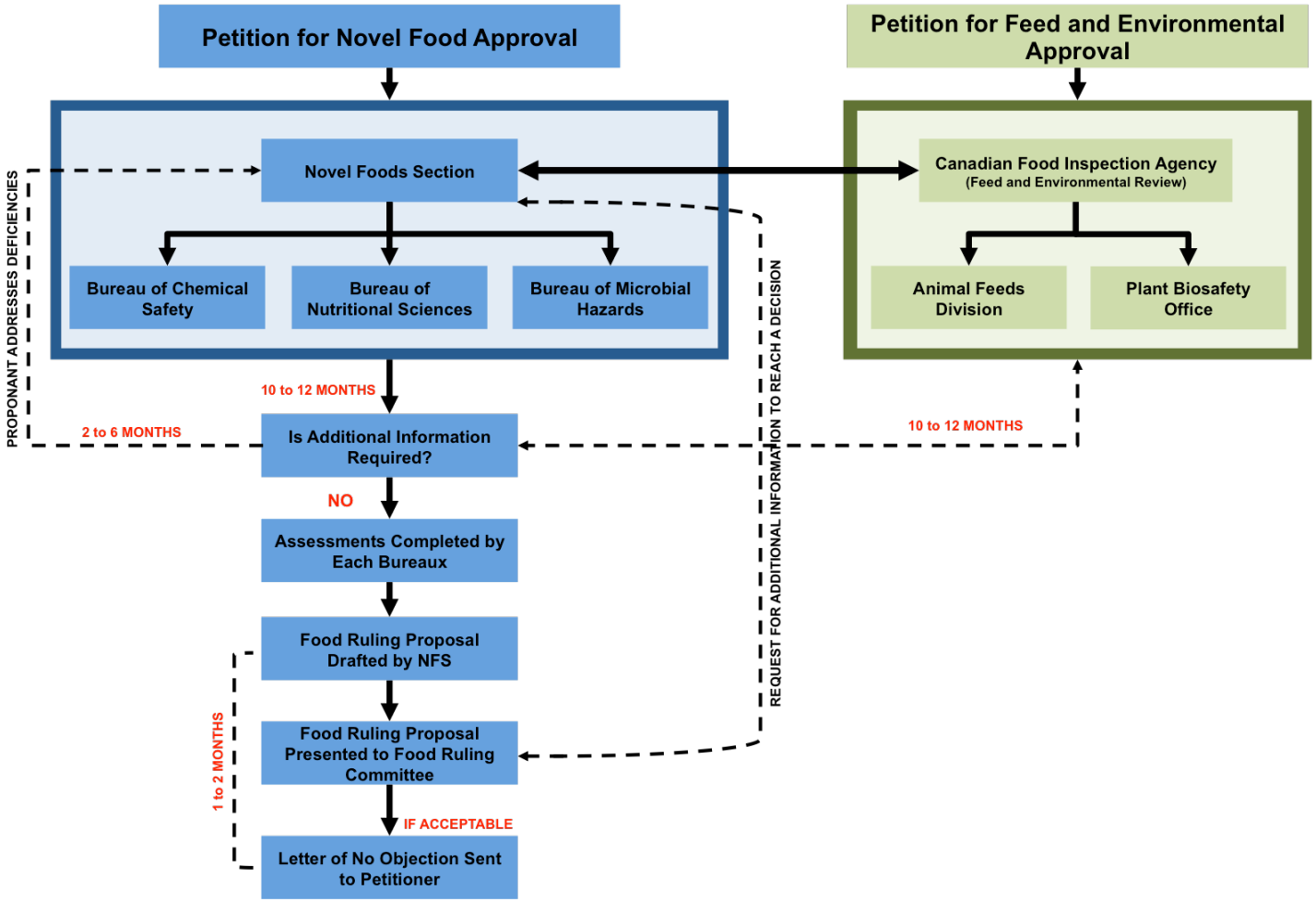

Figure 2. Process for obtaining a novel food approval through Health Canada

Adapted from *Guidelines for the Safety Assessment of Novel Foods* Food Directorate Health Products and Food Branch Health Canada June, 2006

These guidelines provide for both the rigour and the flexibility required to determine the need for notification and to conduct the safety assessment of the broad range of food products being developed. This flexibility is needed to allow novel foods and food products to be assessed on a case-by-case basis and to take into consideration future scientific advances.

Prior to the submission of the petition, product developers commonly request a pre-submission consultation with representatives of all three of the agencies. This process is useful to inform both the agencies on up-coming petitions as well as to provide feedback to the petitioner on the data which is being prepared. Such a meeting can take place quite a long time ahead of submission and is recommended to be held while the data package is being developed such that feedback on the types of data and the way it is presented can be incorporated into the petition.

As parallel applications for approval as a novel feed and for environmental release of a plant with a novel trait have so far always been submitted together with the petition to market a novel food, Health Canada collaborates with each other and with their counterparts in CFIA (Animal Feeds Division, the Plant Biosafety Office and the Plant Biotechnology Risk Assessment Unit) in order to identify any additional information that is needed from the applicant. These requests for information are referred to as deficiency letters and are sent jointly by the collaborating groups so that the applicant does not have to deal with the agencies separately. This process also serves to coordinate approvals between the agencies and implement the “no split approval” policy where a product may have approval for cultivation prior to approval to enter into the food or animal feed chain.

At the completion of the safety assessment, if there are no outstanding concerns regarding any aspect of the safety assessment and it is determined that there are no health risks associated with the consumption of the novel food product in question, a document proposing that the food be permitted for sale is drafted. This proposal, which contains a summary of the scientific reviews conducted by the Food Directorate at Health Canada, is presented to a senior management committee known as the Food Ruling Committee for their consideration.

This Committee is chaired by the Director General of the Food Directorate and consists of Food Directorate senior management and representatives from the Canadian Food Inspection Agency. If the food rulings proposal is found acceptable by the Committee, the petitioner is notified in writing that, based on

the evaluation of the submitted data, Health Canada has no objection to the sale of the novel food product as human food in Canada as specified in the notification.

There are no further steps required prior to marketing of the novel food in Canada and no public consultation as part of the assessment or decision. A novel food decision document is drafted as a summary of the information reviewed to determine safety. This document is made available on the Novel Foods page of the Health Canada website.

A2.2 Australia–New Zealand Perspective

Food Standards Australia New Zealand (FSANZ) is a bi-economy Government agency. FSANZ develops and administers the *Australia New Zealand Food Standards Code* (the Code), which lists requirements for foods such as additives, food safety, labelling and Genetically Modified (GM) foods. However, enforcement and interpretation of the Code is the responsibility of individual state and territory departments and food agencies within Australia and New Zealand.

In Australia, FSANZ is a Commonwealth statutory authority established under the *Food Standards Australia New Zealand Act 1991* (the 'FSANZ Act') and is an independent, expert scientific body. Its functions are stipulated in the FSANZ Act. These functions include developing food standards and variations to food standards that are included in the Code.

Food standards are developed by FSANZ, either by application from any agency, body, or person, or by a proposal of its own initiative. Standards or variations to standards are assessed within FSANZ and then approved by the FSANZ Board. Standards approved by the FSANZ Board are subject to review by '*the Forum*', which is chaired by the Australian Government. The Forum has representatives from all Australian States and Territories, as well as the New Zealand Government. Health Ministers are generally the Lead Ministers, but Ministers from other portfolios such as Agriculture or Food Safety may be nominated by their jurisdiction as the Lead Minister. Other portfolio Ministers contribute as observers.

Once the Forum process is finalised, the variations to the Standards are gazetted and then automatically adopted by reference under the food laws of the Australian States and Territories.

GM Food Regulation in Australia and New Zealand

GM foods are regulated under Standard 1.5.2 – Food produced using Gene Technology[17], contained in the Code. The Standard (an enforceable regulation) has two provisions – mandatory pre-market approval (including a food safety assessment) and mandatory labelling requirements. This Standard ensures that only assessed and approved GM foods enter the food supply.

Comparable with Health Canada, FSANZ assesses the safety of GM foods in accordance with internationally established scientific principles and guidelines developed through the work of the OECD, FAO, WHO and the Codex Alimentarius Commission. These guidelines, which are intended to apply to a broad range of foods, provide both rigour and flexibility to the assessment. Flexibility is needed to allow GM foods to be assessed on a case-by-case basis and to take into consideration future scientific advances.

Further, in relation to foods and animal feeds derived from GM plants, the current approach taken by FSANZ is to avoid 'split use' approvals. A 'split use' approval is where a GM plant receives approval for use as animal feed, but not for human food.

This approach is also practiced in the United States and Canada, which are sources of imported GM foods and food ingredients into Australia and New Zealand. It is now common practice for GM plants intended primarily for feed use to also undergo food safety assessment and approval for human food use. This minimises the risk of unassessed and unapproved products entering the food supply as a result of inadvertent co-mingling of grain/seeds during transport and storage, and also ensures that their use as feed will not pose indirect risks to humans.

FSANZ Food Safety Assessments

The safety assessment process used by FSANZ is described in detail in a guidance document [18] that describes FSANZ's approach to the safety assessment of GM foods and is intended to be read in conjunction with Section 3.5.1 of the FSANZ Application Handbook[19], which outlines the information required to support an application for approval of a GM food.

[17] Standard 1.5.2 – Foods produced using Gene Technology
[18] Safety Assessment of Genetically Modified Foods–Guidance Document (September 2007)
[19] FSANZ Application Handbook
http://www.foodstandards.gov.au/code/changes/pages/applicationshandbook.aspx

The safety assessment of a GM food is conducted within the established risk assessment framework used by FSANZ. In the case of GM food, the primary purpose is to:

- identify new or altered hazards associated with the food as a result of the genetic modification
- assess whether there is any risk associated with these hazards under the intended conditions of use
- determine if any new conditions of use are needed to enable safe use of the food.

Within FSANZ, a team of scientists in the Microbiology and Biotechnology Section routinely conduct robust, risk-based and evidence-based pre-market safety assessment of GM foods. FSANZ has also established an internal working group, the GM Team, to assist with ensuring consistency across GM food safety assessments.

In May 2008, an international expert (notably from Health Canada) was invited to undertake a review[20] of FSANZ's safety assessment procedures for GM foods. The aim of this review was to assess FSANZ's performance in the assessment of GM food safety against international best practice and to identify areas for enhancement.

The review identified six key recommendations for FSANZ to consider in relation to the assessment of GM food. The key recommendations from the report were:

1. Maintain a strong scientific GM team and further strengthen expertise to address future challenges associated with the safety assessment of the next generation of complex GM food.
2. Enhance the engagement of external scientific expertise as appropriate to address future knowledge gaps in assessing the safety of GM food.
3. Investigate the feasibility of managing workload associated with the safety assessment of a GM food application.
4. Continue to engage and establish closer working relationships with other Australian and New Zealand regulatory agencies.

[20] Review of genetically modified food safety assessments (2009)

5. Continue to build on FSANZ's strong international reputation as a leader in GM food safety assessment and explore mechanism(s) to enhance collaboration with international regulatory partners.
6. Continue to provide an open and transparent GM food safety assessment process and enhance the risk communication efforts with key stakeholders.

Making Amendments to the Food Standards Code

Applications to amend the Code are required before a new food produced using gene technology can be approved in Australia and New Zealand. FSANZ is required to assess the safety for human consumption of each GM food prior to giving approval. The safety assessment is applied to the food derived from a GM organism, and is not applied directly to the organism itself, except in so far that the organism is itself the food.

The FSANZ Act and the associated Regulation require FSANZ to make its decisions relating to applications within stipulated periods of time, depending on the Procedure into which an application has been placed (Figure 3):

- **Administrative Assessment** – All applications are subject to an 'Administrative Assessment' on receipt by FSANZ. The main purpose of the Administrative Assessment is to determine whether the application meets the application requirements and the Procedure by which it should be assessed. An assessment is made within 15 business days from receipt of an application to a decision to accept or reject the application.
- **General Procedure** (Subdivision D of the FSANZ Act) – This is the default assessment process and involves one round of public comment. For the purposes of cost-recovery under the Regulations, the General Procedure is split into four levels based on the level of commitment required by FSANZ assessors. It can take up to 9 months from commencement of assessment or receipt of fees to the date of approval of the draft food regulatory measure (Figure 3).
- **Minor Procedure** (Subdivision E of the FSANZ Act) – applies to an application for the variation of a food regulatory measure that, if made, would not directly or indirectly:
- impose, vary or remove an obligation on any person; or

- create, vary or remove a right of any person; or
- otherwise alter the legal effect of the measure.
- One round of consultation is carried out with Government agencies only. An application would fall within this Procedure if its only effect would be:
- correcting a typographical error; or
- updating a reference to another document; or
- amending a cross-reference within a food regulatory measure; or
- omitting provisions of a food regulatory measure that has ceased to have effect; or

any other matters of similar.

It takes up to 3 months from commencement of assessment or receipt of fees to the date of approval of the draft food regulatory measure.

- **Major Procedure** (Subdivision F of the FSANZ Act) – Assessment under the Major Procedure applies to:
    - an application for the development of a new food regulatory measure; and
    - an application for the variation of a food regulatory measure that:

(i) involves such scientific or technical complexity that it is necessary to adopt this procedure in considering it; or

(ii) involves such a significant change to the scope of the food regulatory measure that it is necessary to adopt this procedure in considering it.

A minimum of two rounds of public comment is required and consultation might also require the establishment of external working parties or advisory groups to assist with the assessment.

An application for the development of, or a major variation to, a new food regulatory measure involving:

- developing a new standard; or
- changing a labelling requirement affecting a wide range of foods; or

- changing a compositional requirement for a wide range of foods; or
- adding a new substance affecting a wide range of foods; or
- a pre-market approval, with no similar previous approvals.

This kind of application is likely to:

- involve a very extensive and complex assessment of the risk to public health and safety; or
- have a very broad and significant social or economic impact; or
- require a very extensive and complex toxicological, nutritional, food technology, dietary modelling or microbiological assessment; or
- require a very extensive and complex assessment of risk management measures; or
- involve the development of a very extensive and complex community communications strategy to address public concern; or
- require targeted consultation with key stakeholders or special interest groups; or
- require the development and distribution of community education material; or
- require extensive consultation with government agencies, industry, health professionals and consumer groups; or
- require the establishment of high-level advisory groups to discuss and interpret scientific evidence and social perceptions; or
- require community meetings including public hearings.

It can take up to 12 months from commencement of assessment or receipt of fees to the date of approval of the draft food regulatory measure (Figure 3). This can be extended for up to 6 months by FSANZ.

This statutory timeframe does not include time taken for an applicant to provide additional information or fees (where applicable) and FSANZ has the discretion

to ‘stop the clock’ if it needs more information in order to complete an assessment of an application.

Once FSANZ has completed their assessment and the FSANZ Board has approved an application, a recommendation is made to the Forum. The Forum has one opportunity to request a review of a decision made by FSANZ. Following the Review, the Forum must make one of the following decisions:

- inform FSANZ that it does not intend to amend or reject the draft; or
- amend the draft; or
- reject the draft.

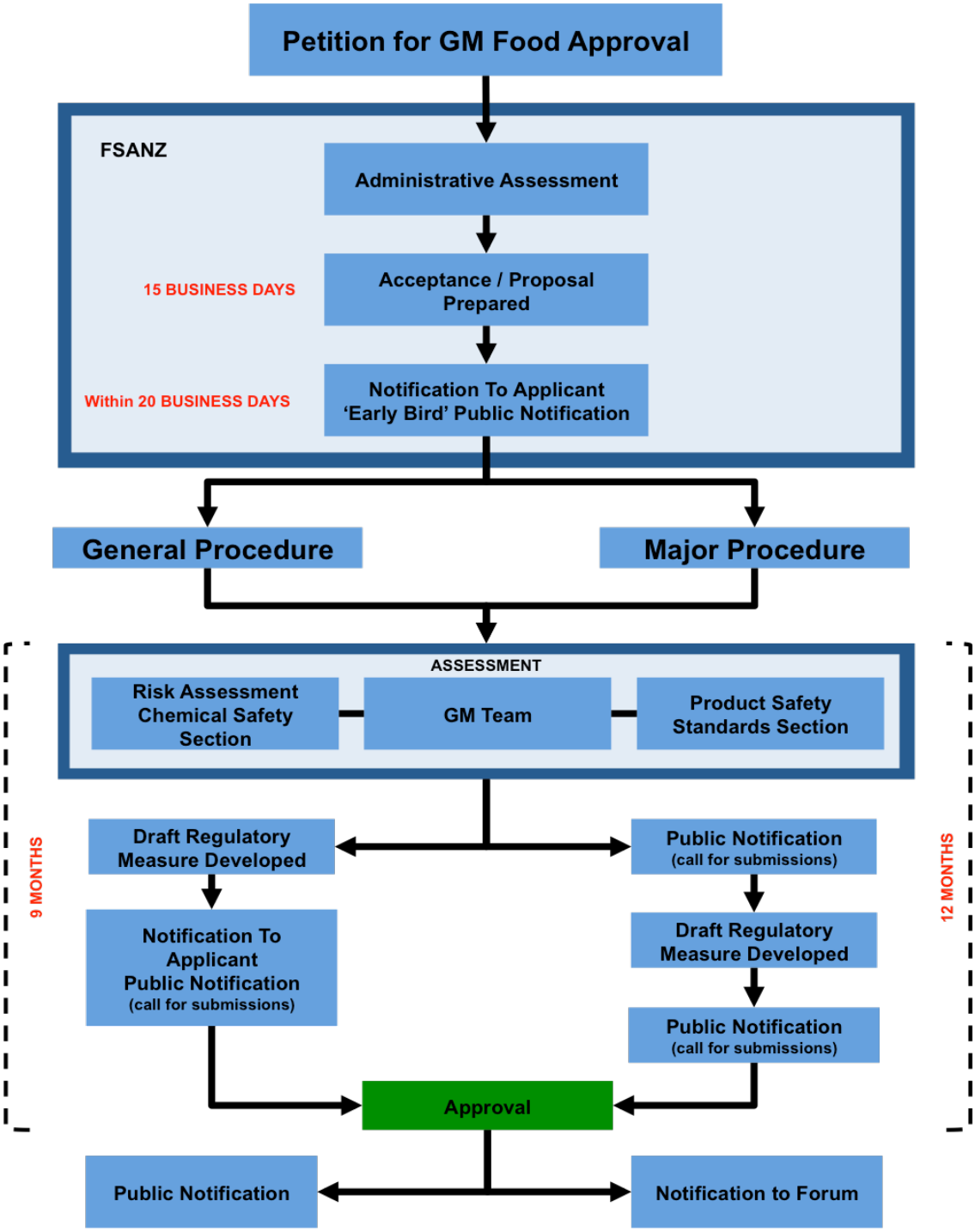

Figure 3. Simplified outline of the FSANZ Food Approval Process.