Comparing international approaches to food safety regulation of GM and Novel Foods

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Introduction

Novel foods and genetically modified organisms (GMOs) are subject to a large variation in regulatory approaches around the world, with some countries being more open to the cultivation and use of GMOs and new or novel substances, whilst others take a more cautious approach and have specifically developed regulatory frameworks to control the placement of such products on their markets. In addition, there are varying definitions and classifications applied across different parts of the world to both categories.

The specific objective of this report is to help provide an understanding as to how specified non-EU countries regulate “novel foods” and GMOs compared to the European Union and what their regulatory system comprises of, including their approaches to authorisation processes.

The report also considers with respect to international trade, how non-EU countries with different regulatory systems are able to protect public health and trust whilst facilitating trade agreements and build upon the basic minimum food safety measures recognised by the World Trade Organization and Codex Alimentarius.

The overall objective of the research is to identify different regulatory approaches and processes deployed by non-EU countries and to assess how these differences in regulation affect trade.

Executive summary

Campden BRI was commissioned by the FSA to conduct a qualitative assessment of how the regulation of novel food and genetically modified organisms in selected non-EU countries differs from the current requirements in the United Kingdom and also to identify what systems are in place to regulate international trade in such commodities.

For the purpose of comparing the regulatory systems of non-EU countries to the UK, we will consider the situation of the UK prior to 1 January 2021, where the UK still acted as an EU Member State. This allows for a more straightforward baseline comparison, rather than comparing other countries to the UK system which has only operated since 2021. This is especially useful when exploring disputes raised in the past regarding the EU regulatory approach. As of 1 January 2021, the FSA assumed the Central Competent Authority role from the European Commission for regulated products in the UK. The UK retained EU law relating to regulation of GMOs and novel foods and therefore operates in a similar way to the EU system explored in this report. This means comparisons to the current position of the UK remain relevant.

To account for substantial differences in the scope of regulation between the countries, reasonably relevant concepts outside of what is considered “novel food” or “genetically modified” in the EU were also reviewed.

The first part of the report deals with the regulation and authorisation of “novel foods” in selected non-EU countries compared to the EU, reviewing their approaches to “novelty” determination and authorisation processes, differences in terminology, safety standards, and evidence-based requirements. Australia, Canada, Japan, and the United States were agreed with the FSA as the countries of interest for “novel foods”.

In the EU, a “novel food” is any food or substance that has not been used for human consumption to a significant degree within the EU before 15 May 1997. Any such food requires approval before placing on the market although not all require a risk assessment. The Novel Food legislation specifically excludes foods with technological function such as food additives and genetically modified foods from its scope.

In Japan and the United States, novel foods or food ingredients are not particularly addressed in legislation. Neither country has an equivalent regulatory concept for novel foods. In contrast, Australia and Canada have a regulatory regimen that more closely reflects the position in the EU, however, with significant differences when it comes to the definitions, what falls under the novel food legislation, and the authorisation procedures. In both markets, approval is required before such food is placed on the market.

The second part of the report discusses how different non-EU countries regulate and authorise GMOs compared to the EU. Argentina, Australia, Brazil, Canada, and the United States were deemed to represent best the key differences in the regulatory approaches to GMOs.

The six markets reviewed have substantial differences in how GMOs and products derived from GMOs are regulated. One significant difference is that the EU and Australia place emphasis on the process used to derive the product while Argentina, Canada, and the US may not regulate a product as a GMO if the product is substantially equivalent to the product derived by more conventional techniques. Canada and the US do not have legislation specifically dedicated to reviewing GMOs – genetically modified products are regulated under the same legal provisions as their conventional counterparts.

The focus on the final product rather than on the processes used to derive the product in Argentina, Canada, the US, and partially in Brazil allows for a flexible approach to accommodate new techniques. The Australian approach relies on the Regulator periodically reviewing the lists of techniques that generate or do not generate GMOs. As a result of the ruling by the Court of Justice in 2018, the regulatory system in the EU ensured all organisms obtained by new mutagenesis techniques are automatically considered GMOs in so far as the techniques and methods of mutagenesis alter the genetic material of an organism in a way that does not occur naturally.

The labelling of GM foods is an area where the differences between the countries assessed within the scope of this report are the most obvious to the consumer. Argentina and Canada have no mandatory requirements for labelling GM content in foods. Such labelling is mandatory in Australia, Brazil, and the EU but the rules have substantial

differences. Although GM foods in the United States are largely considered to be substantially equivalent to the conventional counterparts, mandatory labelling requirements for “bioengineered foods” have recently been introduced.

The last part of the report considers the role of international trade agreements in the establishment and operation of regulations concerning “novel foods” or foods derived from genetically modified organisms. Relevant treaties at a global level considered here are the General Agreement on Tariffs and Trade (GATT), World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and the WTO Agreement on Technical Barriers to Trade (TBT Agreement) as well as the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. Free trade agreements between two or more jurisdictions adhere to the principles of those at a global level and further liberalise trade between the signatories.

A review of global agreements indicated that there was no reference to either “novel foods” or foods from genetically modified organisms. In the absence of specific provisions, of particular relevance is the SPS Agreement which establishes the parameters within which food safety can be assured without being considered to be a barrier to trade. Under this agreement, each country has the right to take measures to prioritise protection of human, animal and plant health over trade, provided it can be demonstrated that the measures are based on science, are necessary, and do not discriminate between the countries. The SPS Agreement also promotes harmonisation of SPS measures through adoption of international scientific consensus which is usually articulated by organisations such as the Codex Alimentarius Commission. Notably, in its guidance documents on the risk and safety assessments of foods produced from genetically modified organisms, the Codex Alimentarius Commission adopted the definitions of genetically modified organisms set out in the Cartagena Protocol.

The EU approach to regulating genetically modified crops at the turn of the twenty-first century has been the subject of a dispute arbitrated in the WTO. In its final opinion, the WTO panel considered that the EU had operated an effective moratorium on GM products between June 1999 and August 2003 that was disproportionate, concluding both the then approval processes and regulatory comitology were neither transparent nor timely and that there was sufficient scientific knowledge available which disqualified the

use of the precautionary principle. Although not the subject of a dispute at WTO level, the EU's definition of what constitutes a novel food has been the subject of discussion, particularly with South American states. The issue has to some degree been assuaged through the adoption of the concept of "traditional foods from third countries" in the current Novel Food regulation.

Trade agreements made by the EU with Canada and Japan, as well as a draft agreement with Mercosur were reviewed. Neither of these makes a specific reference to either "novel foods" or foods from genetically modified organisms within the SPS provisions of the treaties. At a generic level, signatories undertake to have timely and transparent regulatory processes and to give advance notice of any intention to make regulatory changes. However, the one between the EU and Canada does make reference to a discussion forum on the issue of genetically modified organisms in the form of a "Dialogue on Biotech Market Access Issues".

In contrast to the agreements with the EU, the trilateral trade agreement between Canada, the United States, and Mexico (CUSMA) has two relevant chapters – one relating to SPS arrangements and the second to the Agriculture. The later makes specific mention of "agricultural biotechnology", distinguishing it from conventional breeding techniques and re-emphasising the signatories' commitment to ensure transparent and timely processes within the context of an appropriate regulatory regime.

Although attempts were made to assess the effects of trade agreements on the volume of trade in GM crops between the signatories, the efforts were largely prevented by the absence of tariff codes dedicated to GM varieties.

1 Novel foods

1.1 European Union

1.1.1 Competent authorities

The **European Commission** is the central competent authority coordinating the authorisation process, initiating safety evaluations, adopting implementing acts, and disseminating information on the status of novel foods (including traditional foods from third countries).

The **European Food Safety Authority** (EFSA) may be asked by the Commission to carry out a risk assessment. EFSA also gets an opportunity to object a notification regarding a "traditional food from a third country" (see definition in **Section 1.1.3**) and, if notification is transformed into an application, will conduct a safety evaluation.

National authorities of the Member States play a key role in determining whether the food is novel in the first place as they serve as the primary point of contact for the novelty determination. Member States can also trigger an authorisation procedure and have a say whether to endorse the authorisation proposal via country's participation in the **Standing Committee on Plants, Animals, Food and Feed** (SCoPAFF).

The competent authorities for the required inspections and enforcement of novel food legislation differ in each Member State. In the UK, local authorities, including Trading Standards and Environmental Health Officers, are responsible for the inspection of novel foods placed on the market and the enforcement of novel food legislation.

1.1.2 Key legislation

All novel food products and products containing novel foods need to accord with the general safety requirements stipulated in **Regulation (EC) No 178/2002**.

The rules for the placing of novel foods on the market in the European Union are laid down in **Regulation (EU) 2015/2283**.

Procedural steps of the consultation process for determination of novel food status are laid down in **Commission Implementing Regulation (EU) 2018/456**.

Administrative and scientific requirements for novel food applications are laid down in **Commission Implementing Regulation (EU) 2017/2469**.

The positive list of authorised novel foods is established and set out in the Annex to **Commission Implementing Regulation (EU) 2017/2470**.

Specific rules apply to traditional foods from non-EU countries which their food business operators or importers wish to sell in the EU. These are laid down in **Commission Implementing Regulation (EU) 2017/2468**.

EU countries may restrict through specific legislation the marketing of a product on their territory.

1.1.3 Definitions/terminology

Regulation (EU) No 2015/2283 defines “novel food” to mean “any food that was not used for human consumption to a significant degree within the Union before 15 May 1997…”.

The European Commission has published an **Information and Guidance Document** on the interpretation of “human consumption to a significant degree”. The document highlights numerous important aspects to consider and includes a decision tree but does not provide a set of measurable parameters.

The definition lists specific food categories that may be considered novel foods. These would cover newly developed food, innovative food, food produced using new technologies and production processes, as well as food which is or has been traditionally consumed outside of the EU.

Food manufactured using cell or tissue cultures and food consisting of engineered nanomaterials are both specifically covered by the definition. On the other hand, food

exclusively used in food supplements within the EU before 15 May 1997 will only be considered “novel food” if it is intended to be used in foods other than food supplements.

Food intended to be used for technological purposes (i.e. enzymes, additives, flavourings, and extraction solvents) and GM food which are covered by other EU acts are specifically outside the scope of novel food regulation.

“Traditional food from a third country” is defined to mean a novel food (excluding certain food categories) derived from primary production and with a history of safe food use in a third country.

“History of safe food use in a third country” means that the safety of the food in question has been confirmed with compositional data and from experience of continued use for at least 25 years in the customary diet of a significant number of people in at least one third country, prior to a notification to the Commission.

1.1.4 Processes

Food business operators can place a novel food on the European Union market only after the Commission has processed an application for the authorisation of a novel food and has adopted an implementing act authorising the placing on the market of a novel food and updating the Union list.

1.1.4.1 Consultation process on novel food status

Under Article 4 of Regulation (EU) No 2015/2283, it is the duty of food business operators to verify if the food they intend to place on the EU market falls within the scope of the novel food legislation. If unsure, FBOs can consult the competent authorities of the EU country where they first intend to place the food on the market. In drawing conclusion, national authorities may consult colleagues in other EU countries and the European Commission. On the other hand, the Commission may also decide whether a particular food falls within the definition of novel food. Once the conclusion on the novel food status of a food is reached, it is published by the Commission on its website.

Consultation with the national authorities takes up to 4 months from the date on which the Member State decided on the validity of the consultation request. In duly justified cases, it can be extended by up to 4 more months. At the end of the consultation, a conclusion on the novel status is issued. If considered “not novel”, the food may be marketed across the EU Member States.

1.1.4.2 Authorisation process for novel foods

If the food is determined to be novel, an application will need to be made directly to the Commission for authorisation to market and sell the novel food legally in the EU. The authorisation procedure may be triggered either by an applicant (EU country, a non-EU country, or an interested part) or by the Commission.

If the novel food is liable to impact human health, the Commission without delay, and not later than 1 month after having verified the application’s validity, will request the European Food Safety Authority (EFSA) to carry out a risk assessment. EFSA will adopt its opinion within 9 months from the date of receipt of a valid application from the Commission. However, the clock may be stopped if EFSA requests additional information from the applicant.

Within the 7 months from the date of the publication of the EFSA's opinion or, if EFSA’s opinion was not requested, from the date of receiving a valid application, the Commission must submit a draft implementing act to the Standing Committee on Plants, Animals, Food and Feed (SCoPAFF) authorising the placing on the market of a novel food and updating the Union list. SCoPAFF is composed by representatives of all EU countries and presided by a European Commission representative. If the act receives a favourable vote from SCoPAFF and is adopted and published by the Commission, the novel food can be lawfully placed on the European Union market.

The Commission may terminate the authorisation procedure at any stage. In deciding to discontinue the process, the Commission would have to take into account the views of Member States, EFSA’s opinion and any other legitimate relevant factors. Equally, the applicant may also withdraw its application at any time.

The authorisation and entry for a novel food in the Union list includes, where appropriate, specifications, conditions of use, additional special labelling requirements, and post-market monitoring requirements. Otherwise, novel food is subject to the general labelling requirements laid down in Regulation (EC) No 1169/2011.

1.1.4.3 Notification process for traditional foods from third countries

Those intending to place on the market within the Union a traditional food from a non-EU country, instead of following the authorisation procedure, may opt to submit a notification of that intention to the Commission. Without delay, and not later than 1 month after having verified whether the application falls within the scope of the Novel Food Regulation (EU) No 2015/2283 and the requirements set out in Article 14 of that regulation are met, the Commission will forward it to the Member States and to EFSA.

Member States and EFSA will have 4 months to submit to the Commission duly reasoned safety objections to the placing on the market of the traditional food concerned. If the safety of the traditional food in question can be established on the basis of evidence of a history of consumption in the third country and no duly reasoned safety objections have been submitted within that period, the Commission will adopt an implementing act authorising the placing on the market of the traditional food and will update the Union list without delay.

If any duly reasoned safety objections are submitted, the Commission cannot authorise the placing on the market of the traditional food concerned and update the Union list. In that case, the applicant may choose to transform a notification into an application by additionally including the duly reasoned safety objections received as well as the applicant's response to these objections and submitting it to the Commission.

The Commission will forward the valid application to EFSA without delay and will also make it available to Member States. EFSA will have 6 months to adopt its opinion on the application. In certain circumstances, this period may be extended.

Within 3 months of the date of publication of the EFSA's opinion, the Commission must submit to SCoPAFF a draft implementing act authorising the placing on the market within

the Union of the traditional food from a third country and update the Union list. Under certain circumstances, this 3-month period may be extended. The Commission needs a favourable vote from SCoPAFF before it can adopt and publish the implementing act authorising the lawful placing on the European Union market.

1.1.4.4 Additional provisions

Applicants may be granted an individual authorisation for placing on the market of a novel food for 5 years based on newly developed scientific evidence and proprietary data. Otherwise, authorisations are generic.

Food business operators who have placed a novel food on the market have an obligation to inform the Commission of any information of which they become aware concerning any new scientific or technical information which might influence the evaluation of the safety of use of the novel food as well as any prohibition or restriction imposed by a third country in which the novel food is placed on the market.

1.1.5 Dossier requirements

The application for an authorisation of a novel food must include:

- the name and address of the applicant;
- the name and description of the novel food;
- the description of the production process(es);
- the detailed composition of the novel food;
- scientific evidence demonstrating that the novel food does not pose a safety risk to human health;
- where appropriate, the analysis method(s);
- a proposal for the conditions of intended use and for specific labelling requirements which do not mislead the consumer or a verifiable justification why those elements are not necessary.

Additional administrative and scientific data requirements for novel food applications are established in Commission Implementing Regulation (EU) 2017/2469. Specifically, it provides that, on request, the applicant may need to provide the raw data for the individual studies (published and unpublished) undertaken by the applicant, or on their

behalf, to support their application. Toxicological studies must be conducted in facilities following the principles of GLP.

The notification of a traditional food from a third country requires less information compared to novel food application. For instance, the description of the production processes and the analysis methods would not be needed. Also, to demonstrate that the food does not pose a safety risk to human health, it will only be necessary to demonstrate the history of safe food use in a third country.

Administrative and scientific data requirements for notifications and applications concerning traditional foods from third countries are established in Commission Implementing Regulation (EU) 2017/2468. A notification transformed into an application must additionally include the applicant's response to duly reasoned safety objections received in response to the notification.

1.1.6 Safety standard

To be authorised by the Commission, a novel food must not:

- pose a risk to human health, on the basis of the scientific evidence available;
- mislead consumers, especially when it is intended to replace another food and there is a significant change in the nutritional value;
- be nutritionally disadvantageous for the consumer when replacing another food under normal consumption.

The overall evaluation of potential risk to human health must be made in the context of known or likely human exposure.

In assessing the safety of novel foods, EFSA will consider whether:

- the novel food concerned is as safe as food from a comparable food category already existing on the market within the Union;
- the composition of the novel food and the conditions of its use pose a safety risk to human health in the Union;

- a novel food, which is intended to replace another food, differs from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

Where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, the Commission is required to take into account the precautionary principle before forming its final opinion on the authorisation.

In assessing the safety of a traditional food from a third country on application, EFSA would consider whether:

- the history of safe food use in a third country is substantiated by reliable data submitted by the applicant;
- the composition of the food and the conditions of its use pose a safety risk to human health in the Union;
- a traditional food from the third country, which is intended to replace another food, differs from that food in such a way that its normal consumption would be nutritionally disadvantageous for the consumer.

1.1.7 Summary

The EU has a well-established regulatory framework for novel foods which encompasses any food that was not used for human consumption to a significant degree within the EU before 15 May 1997. Nanomaterials, cell culture products, foods previously used as a food supplement, and even traditional foods from third countries are specifically listed as potentially novel foods.

While it is the duty of a food business operator to consider whether their product is a novel food, the competent authorities of Member States can be consulted. The consultation usually takes up to 4 months (potentially up to 8 months). Alternatively, the Commission may also conclude whether a particular food is a novel food. The conclusion of the national authorities or the Commission on the novel status is binding.

If the food is considered novel, it can only be placed on the EU market after the Commission has processed the application for authorisation and adopted a regulation authorising the marketing of a novel food in question.

Since the evidence of “human consumption to a significant degree” is limited to the use on the EU territory, a different set of procedures is established for foods derived from primary production and traditionally consumed outside of the EU. Although these are considered “novel foods”, instead of seeking authorisation via application, the proponent may opt to submit a notification of the intention to place the product on the EU market, provided that the safety of the food can be demonstrated with compositional data and experience of continued use for at least 25 years in the customary diet of a significant number of people in at least one third country. Data requirements for notifications regarding traditional foods from third countries are slightly different.

Risk assessment for novel foods is carried out by EFSA but only if the novel food is liable to have an effect on human health. EFSA also gets an opportunity to submit duly reasoned safety objections on notifications of the intention to place on the EU market a traditional food from third countries. In case of any safety objections, from Member States or EFSA, a notification converted into an application will also be risk assessed by EFSA.

The decision-making regarding novel foods, including traditional foods from third countries, is shared between the European Commission and the national authorities of the Member States, including via their participation in SCoPAFF. Since the process involves multiple parties, the overall process is fairly complex and can take several years.

1.2 Australia

1.2.1 Competent authorities

Food Standards Australia New Zealand (FSANZ) is the central competent authority coordinating the approval process, undertaking the risk-based assessment of all novel food applications, consulting the public on the proposed measure, and amending the list of permitted novel foods in the Food Standards Code for both Australia and New Zealand.

To assist food businesses with the determination of whether the food is “novel”, FSANZ has established the **Advisory Committee on Novel Foods** (ACNF). The ACNF is chaired by FSANZ and representatives from Australian state and territory jurisdictions and the New Zealand Ministry for Primary Industries. It provides non-binding recommendations to food businesses and FSANZ.

All amendments to the Food Standards Code are notified to the **Australia and New Zealand Ministerial Forum on Food Regulation** (Forum). Forum membership is made up of lead ministers (usually health ministers) from Australian state and territory governments and the Australian and New Zealand governments. Other ministers from related portfolios may also participate. The Forum can ask FSANZ to review its decision to approve a variation to a standard on certain grounds.

The New Zealand Government is also able to request a review of FSANZ decisions on certain grounds.

In Australia, implementing, monitoring and enforcing the Food Standards Code, including the Standard for novel foods, is the responsibility of state and territory governments through their respective laws. The responsible agencies vary in each jurisdiction but generally include Departments of Health and sometimes other departments. Local councils are also involved in monitoring and enforcement activities.

The **Department of Agriculture, Water and the Environment** (DAWE) enforces the Food Standards Code at the border in relation to imported foods through the Imported Food Control Act 1992.

1.2.2 Key legislation

All food manufacturers and suppliers are required by law to ensure food sold in Australia is safe and suitable. This requirement is contained in **food legislation** based on Model Food Act 2000 adopted in each Australian state and territory.

Food must also meet all the applicable requirements in the Australia New Zealand **Food Standards Code**. Novel foods and novel food ingredients are regulated under **Standard**

1.5.1 in the Code. It applies to both Australia and New Zealand. The Standard provides the definitions for “novel food” and “non-traditional food” and prohibits the use of novel foods in foods for retail sale in Australia or New Zealand unless these novel foods are on the list of permitted novel foods and their use complies with the conditions set for that novel food. Permitted novel foods are listed in **Schedule 25** of the Code.

FSANZ is currently reviewing the requirements in the Code for novel foods to investigate potential improvements to the identification of foods that should be subject to pre-market regulatory assessment, and the enforceability of the standard’s requirements to ensure compliance (see **Proposal P1024**). FSANZ considered introducing a cut-off date, the benefits of industry self-assessment of safety while ensuring the level of transparency and regulatory oversight, a demonstrated history of safe use of a food in other markets and switching from exclusive permissions to generic approvals.

1.2.3 Definitions/terminology

The definition of novel food in Australia and New Zealand includes two parts. The first is a definition of “non-traditional food”, and the second is a definition of “novel food”, which is a subset of “non-traditional food”.

Standard 1.5.1 of the Code defines “non-traditional food” to mean one of the following:

- a food that does not have a history of human consumption in Australia or New Zealand; or
- a substance derived from a food, where that substance does not have a history of human consumption in Australia or New Zealand other than as a component of that food; or
- any other substance, where that substance, or the source from which it is derived, does not have a history of human consumption as a food in Australia or New Zealand.

The use of a food as or in a food for special medical purposes is explicitly said not to constitute a history of human consumption in Australia or New Zealand in relation to that food for the purposes of novel food regulation.

"Novel food" is further defined to mean a non-traditional food that requires an assessment of the public health and safety considerations having regard to:

- the potential for adverse effects in humans,
- the composition or structure of the food,
- the process by which the food has been prepared,
- the source from which it is derived,
- patterns and levels of consumption of the food,
- any other relevant matters.

Therefore, to be considered novel, a food must first be considered non-traditional. A food that is considered traditional in Australia and New Zealand cannot be considered novel. Importantly, a non-traditional food will only be considered novel if it requires an assessment of the public health and safety.

A non-exhaustive list of possible categories of novel foods in the definition includes:

- plants or animals and their components,
- plant or animal extracts,
- herbs, including extracts,
- dietary macro-components,
- single chemical entities,
- microorganisms, including probiotics,
- foods produced from new sources, or by a process not previously applied to food.

Food sold for technological purposes such as food additives and processing aids, foods produced using gene technology, and nutritive substances added to food are regulated separately from novel foods.

For food manufactured using cell or tissue cultures (e.g. cell-based meat), FSANZ's **view** is that such food would be captured within existing standards in the Food Standards Code and would require pre-market approval. Depending on the composition of cell-based meats, it could potentially fall under the standards covering novel foods, processing aids, food additives, foods produced using gene technology, vitamins and minerals, labelling that indicates the true nature of the food etc.

Nanoscale materials are not specifically addressed within the novel food legislation or any other regulatory framework. Where there is no presumption or demonstration of safety, existing standards for food additives, processing aids, nutritive substances and novel foods added to foods or used in food production require pre-market assessment. These existing standards contain no limitations around particle size. In its **position** on nanotechnology, FSANZ highlighted that, in assessing the safety of foods manufactured using nanotechnologies, it will not focus on the size of the material, but rather on materials that are likely to act in a different way biologically or chemically if present in the final food.

In Australia, dietary supplements are referred to as "complementary medicines" and are regulated as medicines by the **Therapeutic Goods Administration** (TGA). As a result, new substances for use in listed complementary medicines would be evaluated under a separate legal framework. On the other hand, TGA **indicates** that a recent comprehensive review of a substance performed by FSANZ, in the context of recognition as a novel food, could form the basis of an application for evaluation of a substance for use in listed complementary medicines.

In the opposite case, where a substance was previously used in complementary medicines as opposed to the use as a regular part of diet, this will be taken into account when considering whether the food is non-traditional and will weigh towards the food being considered non-traditional.

1.2.4 Processes

1.2.4.1 Consultation process on novel food status

Before placing a food on the market, a food business must determine whether a food is likely to meet the definition of "novel food" to know whether it will be subject to the premarket approval requirements of the novel food standard or if it can be sold without needing to be assessed by FSANZ. If a food business does not consider the food to be a "novel food", they may choose to place the food on the market without needing to seek approval from FSANZ.

If in doubt, an enquiry can be made to the ACNF. The ACNF provides recommendations on whether certain foods are likely to meet the definition of novel food. The recommendation does not constitute a safety consideration, is not legally binding, and is provided only to help enquirers make their own decision on whether they should submit an application seeking to amend the Standard for novel foods. Ultimately, it is the responsibility of the food business to make the final conclusion.

A **record of views** formed by ACNF in response to enquiries is available for public review on the FSANZ website along with the reasons for the recommendation. Notably, not all enquiries will produce a recommendation from the ACNF.

The ACNF uses a **guidance tool** to determine whether a food is novel or not. If a food business chooses to approach the ACNF, a questionnaire included in Appendix 1 of the guidance tool will need to be completed and submitted to the ACNF. The questionnaire includes specific questions relevant to the consideration of whether a food is non-traditional as well as whether an assessment for public health and safety considerations is needed.

However, it is not mandatory for potential applicants to seek the view of the ACNF. Instead, a potential applicant may proceed directly to submitting an application seeking to amend the Food Standards Code to permit a particular food that they believe meets the definition of “novel food”.

Considering the two-part definition of “novel food”, it first needs to be established whether a food should be considered a “non-traditional food”. The questions that help determine that include the length of use, extent of use, quantity (level of intake) of use, and the purpose or context of use. Additionally, confidence in the information provided needs to be considered. In certain cases, overall consideration may balance out a deficiency in one of the four key questions with a strong evidence in another area.

If the food is deemed “non-traditional”, then it is further necessary to establish whether an assessment of public health and safety considerations would be required. If yes, the food is likely to be deemed a “novel food”, and an application to change the Food Standards

Code will need to be submitted to FSANZ before a novel food or a novel food ingredient could be marketed in Australia or New Zealand. On the other hand, if there is evidence that a “non-traditional” food has a long history of safe consumption in other countries, and the composition of the food is well understood, it is perhaps unlikely that further assessment of safety will be required, and, therefore, the food may not be considered “novel”.

Under the current regulatory framework, certain foods that have been consumed by indigenous populations in Australia and New Zealand would be considered to have a history of human consumption in Australia and New Zealand, so do not meet the definition of “non-traditional food” and therefore cannot be considered “novel foods”. Recommendations from the ACNF have often been sought for these foods for clarification of the regulatory standing not only in the domestic market, but also to assist entry into foreign markets.

1.2.4.2 Pre-application assistance

FSANZ encourages potential applicants to contact FSANZ for **pre-application assistance** before formally submitting an application. While requesting pre-application assistance (including providing a draft application to FSANZ) is not mandatory, it can help ensure the application contains the necessary information. All pre-application information provided to FSANZ, including draft applications, is treated as confidential.

Any information or comments provided by FSANZ at the pre-application stage are not legally binding and are not an authoritative statement as to the likely outcome of an assessment of application.

1.2.4.3 Application to change the Food Standards Code

Anyone wishing to sell a novel food, or a novel food ingredient must apply to FSANZ to request that the Standard for novel foods be amended to include the food or ingredient in the list. Novel food applications are subject to a pre-market safety assessment by FSANZ. If the food passes this assessment, it is added to the list in the Standard and the manufacturer can start marketing the novel food, as long as it complies with any specified conditions.

Detailed requirements for the information that is required to support an application for a novel food as well as practical information on the procedure for making an application to FSANZ to vary the code are provided in the **Application Handbook** of FSANZ.

All applications are subject to an “administrative assessment” on receipt by FSANZ. It takes up to 15 working days from receiving application to conduct administrative assessment and accept/prepare proposal.

Within the next 20 working days, the applicant is notified whether the application is accepted or rejected, and an “early bird” public notification is circulated.

The main purpose of the administrative assessment is not only to determine whether the application meets the application requirements but also the procedure under which it should be assessed. While the Application Handbook distinguishes four different procedures, new novel food applications are likely to be assessed under the general procedure.

General procedure is the default assessment procedure which involves at least one round of public comment and takes up to 9 months from commencement of assessment or receipt of fee to the date of approval of the draft food regulatory measure. The clock can be stopped for further information OR while awaiting policy guidelines or principles from the Forum.

Once the draft food regulatory measure is approved, it is published and notified to the Forum within 10 working days. Once FSANZ has notified the Forum of an approval, the Forum has within 60 days one opportunity, by majority decision, to request a review of a decision made by FSANZ based on certain grounds. Following the review by FSANZ, the Forum has again 60 days to either inform FSANZ it does not intent to amend or reject the draft, amend the draft, or reject the draft.

FSANZ gazettes the standard and registers it as a legislative instrument. Gazettal occurs after FSANZ decisions on standards are considered by the Forum. Gazetted standards

or variations are adopted automatically, by reference and without amendment, into Australian state and territory food laws.

The Standard includes a provision for exclusive permissions for novel foods. An applicant may ask FSANZ to grant, for a fee, an exclusive permission for a novel food or novel food ingredient in a specified brand and class of food, subject to any listed conditions. This permission is effective for a period of 15 months. At the end of this period, the exclusive permission reverts to a general permission that is not limited to a specific brand. The granting of an exclusive permission under the Standard does not preclude others from applying to FSANZ for approval of exclusive permissions of their own brand of the same novel food or novel food ingredient in the same class of food, with the brand being the only differentiating feature.

1.2.5 Dossier requirements

According to the Application Handbook, an application to vary the Food Standards Code to approve the use of a new novel food or novel food ingredient must include the following:

- whether the application is seeking exclusivity;
- technical information on the novel food (type of novel food, the purpose of adding a novel food ingredient to food, information on the physical and chemical properties, information on the impurity profile for a typical preparation, manufacturing process, specification for identity and purity, and analytical method for detection of a novel food ingredient);
- information on the safety of the novel food;
- information on dietary exposure to the novel food;
- information on the nutritional and health impact of the novel food;
- information related to potential impact on consumer understanding and behaviour.

Since there are several categories of novel foods, the data requirements for a safety assessment will vary depending on the nature of the novel food. What would be required for each category of novel foods is detailed in the Application Handbook.

Factors to consider in a safety assessment of the novel food include:

- the history of use as a food in other countries,
- the composition of the novel food, particularly the levels of anti-nutrients and naturally occurring toxins,
- the method of preparation and specifications of a novel food ingredient,
- potential for allergenicity of the novel food,
- metabolism/toxicokinetic studies on the novel food ingredient,
- animal toxicity studies on the novel food ingredient,
- human toleration studies on the novel food ingredient.

1.2.6 Safety standard

A risk-based assessment process is undertaken to ensure the safety of novel foods before they can be sold in Australia and New Zealand. In its **publication** on risk analysis in food regulation, FSANZ stipulates that the goal of the safety assessment is to confirm that there is reasonable certainty that no harm will result from the intended use of the food and to determine whether any risk management strategies are warranted to ensure the safe use of the food.

1.2.7 Summary

To be considered novel in Australia and New Zealand, a food or a substance must satisfy a two-prong test – it must be considered non-traditional and must also require an assessment of the public health and safety. There is no strict cut-off date – the “length of use” is considered on a case-by-case basis. A food or a substance without a history of human consumption in either Australia or New Zealand will be considered “non-traditional”, but this does not automatically make the food novel, as only non-traditional foods that require an assessment of the public health and safety are considered novel.

Considering that the term “history of human consumption” is not legally defined, the definition of “non-traditional food” is subject to a certain level of uncertainty and ambiguity. Equally, the phrase “requires an assessment of the public health and safety considerations” is not clearly defined in the Code, meaning that it is a matter of judgement or estimation as to whether an assessment is required (i.e. whether the food is novel).

The ACNF offers only a non-binding recommendation about whether or not a food is novel. Thus, it is always the proponent's responsibility to determine whether it is novel.

A novel food cannot be sold as food or used as a food ingredient in Australia or New Zealand unless it is listed in the Code. Before listing, FSANZ will conduct an in-depth risk-based assessment in order to establish its safety for human consumption, considering a variety of toxicological and nutritional issues as well as information about its chemistry and the expected level of intake.

The decision-making process is extensive as the safety assessment by FSANZ generally takes up to 9 months with a round of comments from the public. Even after the assessment is concluded, the proposal to amend the standard still requires approval by the Forum, representing the Australian and New Zealand governments and also Australian state and territory governments, and that may delay the approval further.

It is worth mentioning that FSANZ is considering modernising the regulatory framework for novel foods by potentially borrowing elements from other regulatory systems, for example, industry self-assessment of safety as in the US, a specific cut-off date, or considering the history of safe use in other markets. However, the publishing of proposals has been delayed.

1.3 Canada

1.3.1 Competent authorities

Health Canada (HC) is responsible for the regulations and guidelines pertaining to novel foods and for the safety assessment of all novel foods, including genetically modified foods, proposed for sale in Canada. Health Canada's **Food Directorate** is the main department dealing with novel foods.

Canadian Food Inspection Agency (CFIA) primarily focuses on inspection and enforcement duties, but provincial/territorial and local agencies are also involved in the inspection and enforcement.

Where necessary, **Environment and Climate Change Canada** is responsible for assessing the impact the novel food has on the environment.

1.3.2 Key legislation

Any food sold in Canada must meet the relevant requirements of the **Food and Drugs Act** (FDA), **Food and Drug Regulations** (FDR), **Safe Food for Canadians Act** (SFCA), and **Safe Food for Canadians Regulations** (SFCR).

The definition and the requirement for pre-market notification are established in **Division 28** of the FDR, while specific requirements and procedures are described in Directives.

1.3.3 Definitions/terminology

Section B.28.001 of the FDR defines “novel food” to mean:

a) a substance, including a microorganism, that does not have a history of safe use as a food;
b) a food that has been manufactured, prepared, preserved or packaged by a process that
   (i) has not been previously applied to that food, and
   (ii) causes the food to undergo a major change; and
c) a food that is derived from a plant, animal or microorganism that has been genetically modified such that
   (i) the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism,
   (ii) the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or
   (iii) one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism.

“Major change” is defined to mean, in respect of a food, a change in the food that, based on the manufacturer’s experience or generally accepted nutritional or food science theory, places the modified food outside the accepted limits of natural variations for that food with regard to

a) the composition, structure or nutritional quality of the food or its generally recognised physiological effects;
b) the manner in which the food is metabolised in the body; or
c) the microbiological safety, the chemical safety or the safe use of the food.

As a result, the process used to manufacture a food may be novel, but the food may be deemed non-novel if the novel process does not cause a major change to the food. In other words, if the food is substantially equivalent to a non-novel food.

Foods with a history of safe use as a food will not be considered novel and the history of use is not geographically limited. There is no cut-off date – each novel food is assessed on a case-by-case basis.

Notably, a food that is derived from genetically modified plants, animals or microorganisms is specifically included under the broader concept of novel food. Here, “genetically modify” means to change the heritable traits of a plant, animal or microorganism by means of intentional manipulation.

Cell-based meat will likely be held to be a novel food in Canada because it does not meet the current definition of meat in Canadian law, certain components that go into making the cell-based meat are novel, and it may be genetically engineered. However, there are currently no guidelines for novel foods derived from animals and there are no recommended regulatory routes for cell-based meat.

Food additives are regulated separately from novel foods.

Natural health products (i.e. food supplements) are regulated separately from conventional foods and therefore are not directly affected by novel food regulations.

Under Health Canada’s **policy**, novel fibres and novel fibre sources are subject to a separate or additional regulatory oversight. For the purposes of novel fibre applications, “novel fibres are ingredients manufactured to be sources of dietary fibre and consist of carbohydrates with a degree of polymerisation of 3 or more that are not digested and

absorbed by the small intestine. They are synthetically produced or are obtained from natural sources which have no history of safe use as dietary fibre or which have been processed so as to modify the properties of the fibre contained therein. Accepted novel fibres have at least one physiological effect demonstrated by generally accepted scientific evidence".

1.3.4 Processes

1.3.4.1 Novelty determination process

Stakeholders may ask Health Canada to **determine** if their food products or ingredients meet the definition of "novel food" in order to understand whether they must submit a novel food pre-market submission for their product.

For foods or food ingredients that are not genetically modified, to request a novelty determination from Health Canada, the stakeholder must complete a Novelty Determination Information Form which can be requested from Submission Management and Information Unit of the Health Canada's Food Directorate. For genetically modified foods and food ingredients, Health Canada should be contacted for assistance on what information would be needed for the novelty determination.

A written response on the novelty status of the food or food ingredient will be received within 60 days of receipt of the request.

If a food or food ingredient is novel, Health Canada will inform that the food or food ingredient requires a pre-market assessment to be sold in Canada. On the other hand, if found to be "non-novel", a "letter of non-novelty" for the product will be issued.

Health Canada started publishing a **list** of non-novel determinations for foods and ingredients including Health Canada's rationale for each determination. The outcomes of some past determinations will only be published after further analysis. Foods and food ingredients on this list were considered not-novel for use as a food or food ingredient and did not undergo a safety assessment by Health Canada for food use. Such foods or food ingredients would still need to comply with all other applicable requirements.

1.3.4.2 Pre-submission consultation

Before submitting a novel food notification, the proponents are strongly encouraged to request a **pre-submission consultation** with Health Canada for assistance on how to make a submission. Depending on proponent's experience, one or more pre-submission consultations may be needed.

The purpose of pre-submission consultation is to improve predictability of the regulatory assessment process and the overall quality of regulatory submissions, effectively increasing the overall efficiency of the assessments and resulting in more timely reviews and decision-making. These consultations may potentially explain why Health Canada is given a fairly short time window to respond to pre-market notification for novel foods.

Notably, pre-submission consultations will not include:

- assessment of data, labels or other information pertinent to the product;
- discussion on the acceptability of a product or other socio-economic or non-safety considerations;
- general policy discussions or requirements;
- providing information regarding pending enforcement actions and/or complaints submitted against the product proponent/company and/or actions pending through any applicable dispute resolution mechanism.

Instead, it will focus on the completeness of the proposed regulatory submission, clarifying the data and/or information requirements specific to the individual product, clarifying the regulatory requirements, policies and administrative processes, and clarifying expectations for data quality and suitability, the use and elaboration of scientific rationale.

Pre-submission consultations for novel foods must be requested 8-12 weeks prior to the desired consultation date from the Novel Food Section of Health Canada's Food Directorate. Relevant information package must be provided to lead Health Canada official at least 4 weeks prior to the consultation.

Pre-submission meetings with Health Canada are also encouraged to identify and assess potential risks and benefits of nanotechnology-based food products and to discuss type of information that may be required for the product's safety assessment.

1.3.4.3 Pre-market notification

According to **B.28.002** of the FDR, a food that meets the definition of “novel food” can be sold or advertised for sale in Canada only if the manufacturer or importer of the novel food has notified Health Canada in writing of their intention to sell or advertise for sale the novel food, and has received a written notice (so called “letter of no objection”) from Health Canada.

B.28.003 of the FDR gives Health Canada 45 days after receiving a notification to review the dossier and to either notify the manufacturer or importer in writing that the information is sufficient or request in writing from the notifier additional scientific information that is necessary to assess the safety of the novel food.

If additional information for safety assessment is requested, Health Canada has 90 days after receiving the additional information to assess it and, if it establishes that the novel food is safe for consumption, notify the manufacturer or importer in writing that the information is sufficient.

Novel food safety assessments are conducted by scientists from the Bureau of Chemical Safety, Bureau of Nutritional Sciences, and Bureau of Microbial Hazards within Heath Canada’s Food Directorate. The team includes chemists, nutritionists, toxicologists, microbiologists, and molecular biologists.

At the completion of the safety assessment, if and only 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 is then presented to the Food Rulings Committee which 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 but 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 (i.e. a “letter of no objection”).

It is noteworthy that his decision is not a legal document but rather an indication that a petitioner’s submission appears reasonable.

To assist the petitioner in preparing a novel food notification and explain what information is considered sufficient for a safety assessment, Health Canada provides detailed **guidelines** for the safety assessment of novel foods derived from plants and microorganisms.

Notably, Health Canada’s **policy** subjects novel fibre sources to an additional regulatory oversight. If a proposed fibre source is a “novel food”, novel food notification will have to be completed and submitted to Health Canada preceding or concurrent with a novel fibre application. Heath Canada publishes a list of dietary fibres reviewed and accepted by Heath Canada’s Food Directorate.

1.3.5 Dossier requirements

According to **B.28.002** of the FDR, notification submitted to Health Canada must be signed by the manufacturer or importer, or a person authorised to sign on behalf of the manufacturer or importer, and must include the following information:

(a) the common name under which the novel food will be sold;
(b) the name and address of the principal place of business of the manufacturer and, if the address is outside Canada, the name and address of the principal place of business of the importer;
(c) a description of the novel food, together with
  (i) information respecting its development,
  (ii) details of the method by which it is manufactured, prepared, preserved, packaged and stored,
  (iii) details of the major change, if any,
  (iv) information respecting its intended use and directions for its preparation,

(v) information respecting its history of use as a food in a country other than Canada, if applicable, and

(vi) information relied on to establish that the novel food is safe for consumption;

(d) information respecting the estimated levels of consumption by consumers of the novel food;

(e) the text of all labels to be used in connection with the novel food; and

(f) the name and title of the person who signed the notification and the date of signing.

To enhance the efficiency of the review process, petitioners are asked to address the following areas, as applicable, in their safety assessment data packages:

- history of use,
- dietary exposure,
- detail of novel process,
- history of organism(s),
- characterisation of derived line/strain,
- genetic modification considerations,
- nutritional considerations,
- toxicology considerations,
- allergenicity considerations,
- chemical considerations,
- microbiological considerations.

Once again, the history of use is not restricted to Canada. Instead, a substance may be considered to have a history of safe use as a food if it has been consistently consumed for a number of generations in a large, genetically diverse human population in ways and levels similar to those expected or intended in Canada. Therefore, traditional foods from other countries are likely to escape being regulated as novel foods in Canada.

While Health Canada seems to rely heavily on data and information provided by the applicant in making its scientific assessment, the requirements for the data to be submitted are quite extensive. The actual data required will depend on the type of novel food.

1.3.6 Safety standard

The purpose of the pre-market safety assessment by Health Canada is to provide assurance that the food is safe when prepared or consumed according to its intended use. Detailed safety assessment criteria and the decision-making process for each parameter are described in **Health Canada's Guidelines** for the Safety Assessment of Novel Foods.

1.3.7 Summary

The Canadian approach does not discriminate the products based on how they are produced. The definition of novel foods is so broad that it covers not only substances without a history of safe use as a food or foods made using new processes that cause a major change, but also GM foods. This creates a level playing field for all products that are new to the market regardless of the production processes used. At the same time, foods, including genetically modified or nanoscale materials, that are substantially equivalent to a non-novel counterpart will not be considered novel.

While it is primarily the proponent's responsibility to consider whether their food or food ingredient is novel before placing it on the Canadian market, the proponent may request a novelty determination from the authorities resulting in either the conclusion that the novel food or food ingredient requires a pre-market safety assessment to be sold in Canada or a letter of non-novelty, provided the information is complete. The determination is conducted on a case-by-case basis and a food that is substantially equivalent to a non-novel food will not be considered novel. Notably, the history of safe use in a food context is not limited to Canada and there is no fixed cut-off date.

If the food or food ingredient is considered novel, a pre-market notification to Health Canada and confirmation that it is safe for consumption will be needed. Although called a notification, a positive safety conclusion by the authorities in response to the submitted notification is mandatory before a novel food can be placed on the Canadian market.

Scientists with expertise in relevant fields conduct a thorough analysis of the data and the protocols provided by the applicant to ensure the validity of the results. The aim of the risk-based scientific assessment is to ensure that the novel food or food ingredient is safe

to consume under expected consumption patterns and of the same nutritional quality as similar products available on the market and also to assess whether it can be toxic or cause allergic reactions. Depending on the product, the scientists will assess how the product was developed but the focus will stay on the novelty of the product itself.

The potential shortcoming of the actual implementation of the approach is that new products before being placed on the market are only subject to a pre-market review process via notification with a narrow time window for the authorities to conclude whether they agree with the proponent's position regarding the product's safety. On the other hand, the data and/or information requirements specific to the individual product is very much in the focus of voluntary but strongly encouraged pre-submission consultations. Consultations provide the authorities with a venue to guide the proponent in the dossier preparation so that the overall quality of the submitted dossier is ensured, potentially justifying the fairly expedient process for the dossier review.

Consider that the authorities are committed to provide a written response regarding the novelty status within 60 days – if deemed not novel, the food can be placed immediately on the market without any special restrictions. A conclusion whether novel food pre-market submission is reasonable can be reached as quickly as within 45 days, provided no additional safety information is requested. Pre-submission consultations may also be taking place thus not showing the true extent of the actual process. Still, it is a well-defined and predictable process, which has a potential to stimulate innovation.

1.4 Japan

1.4.1 Competent authorities

The **Ministry of Health, Labour and Welfare** (MHLW) is the competent authority responsible for food safety. The MHLW has 6 advisory councils, including the Pharmaceutical Affairs and Food Sanitation Council (PAFSC).

Food Safety Commission of Japan (FSC) is a risk assessment organisation for science-based assessment of food safety risk to human health.

The **Consumer Affairs Agency** (CAA) oversees labelling.

Monitoring of compliance and enforcement of the relevant legislation is done by regional bureaus of health and welfare and the quarantine stations of the MHLW, in cooperation with the local governments.

1.4.2 Key legislation

Under the **Food Sanitation Act** and other related acts, the MHLW lays down regulations and sets food safety standards, including for foods and food additives.

FSC operates under the **Food Safety Basic Act**.

CAA administers **Food Labelling Act** and **Health Promotion Act**.

1.4.3 Definitions/terminology

In Japan, there is no equivalent concept of “novel food”.

1.4.4 Processes

A food or food ingredient that is new to the Japanese market generally is not subject to a mandatory pre-market review or approval by the authorities before being marketed in Japan. Although, consulting with the MHLW is recommended to ensure that it can be distributed in Japan.

For all foods (including novel foods) to be imported into Japan, it is mandatory to submit import notification to a quarantine station of the MHLW. At the quarantine station, food sanitation inspectors carry out document examination and inspection to see whether the foods comply with the requirements of the Food Sanitation Act and other food legislation. As part of this, quarantine officials may request additional information from importers, such as ingredient proportions and manufacturing processes prior to granting entry. The product will be allowed entry only once it is determined to be in compliance with Japanese food legislation.

Also, under Article 7 of the Food Sanitation Act, for new food products or food ingredients that have not generally been served for human consumption and for which there is no

certainty that there is no risk of harm to human health, the MHLW may seek the opinion of the PAFSC and may prohibit the sale of such foods.

The MHLW may also seek the opinion of the PAFSC for foods and food ingredients that are not new as such but are being offered for consumption in a completely new way and also in the case where a new food or food ingredient is suspected to have caused a serious damage to health, and may prohibit the sale of affected foods.

The ban may be fully or partially lifted on application from an interested party or on the MHWL's own initiative after receiving the opinion of the PAFSC, if they find that there is no risk to health from affected foods. The MHLW will publish a public notice in the official bulletin regarding prohibiting the sale or lifting the ban.

The recent **amendment** to the Food Sanitation Act introduced some new measures in order to prevent damage to health by creating a designation system for the ingredients and components that require particular care when contained in food, and also a notification system that requires business operators to report the cases of damage to health caused by intake of their food products containing the designated ingredients and components. However, at this point it is unclear what these designated ingredients and components are.

1.4.4.1 Food additives

Application to the MHLW would be necessary if a "novel" food or food ingredient is to be used as a **food additive**. Assuming that there are no issues with the content of the application, MHLW is **committed** to approve a new food additive within 1 year from the date of receiving the results of safety assessment from FSC.

1.4.4.2 Ingredients with drug properties

The MHLW maintains two special lists of new raw materials:

- **drug list** (ingredients (raw materials) used exclusively as drugs),
- **non-drug list** (ingredients (raw materials) that are not deemed to be drugs unless they are labelled as effective).

Companies may choose to register a new ingredient in one of the above two lists by submitting an **application** to the MHLW. However, the purpose of these two lists is to serve as a reference for judging whether the ingredient is likely to be classified as drug, thus, only some novel foods or ingredients are likely to end up on one of the lists.

For ingredients that are difficult to judge whether they could be used in foods or not, manufacturers/importers of products containing ingredients/components not listed in the above two lists can request an assessment from the MHLW (via Prefectural agencies).

1.4.4.3 Foods with Health Claims

Foods making certain health-related claims (collectively known as “Foods with Health Claims”) are subject to special rules, which may require approval or notification but that would be relevant only if health-related claims are made. There are three types of such foods with distinctive requirements.

“**Foods for Specified Health Uses**” (FOSHU) are foods containing an ingredient with functions for health and officially approved to claim physiological effects on the human body. FOSHU are intended to be consumed for the maintenance / promotion of health or special health uses by people who wish to control certain health conditions, including blood pressure or blood cholesterol.

FOSHU must comply with the specifications and standards established by the government and are subject to individual pre-market authorisation. On application, the MHLW will evaluate the claimed effects and the safety of the food. The claim must be approved by the MHLW as well. For the assessment of effectiveness, the MHLW will consult with the PAFSC. The safety assessment will be conducted by the FSC.

The requirements for a food to be approved as FOSHU:

- effectiveness on the human body must be clearly demonstrated;
- no safety issues;
- nutritionally appropriate ingredients must be used (e.g. no excess salt);
- must meet approved product specifications at the time of consumption;
- quality control methods must be established.

"**Foods with Nutrient Function Claims**" (FNFC) refers to any food labelled with one of the nutrient function claims specified by the MHLW. The standards and specifications for the indication of nutritional function are established so far for 17 ingredients (12 vitamins and 5 minerals).

FNFC may be freely manufactured and distributed without any permission from or notification to the national government, provided that the food meets the established standards and specifications. The amount of nutritional ingredient per the recommended daily intake of the product must be within the specified range, the nutrient function claim must use the specified wording, and the product must also display a prescribed warning.

"**Foods with Function Claims**" (FNC) is a new type of "Foods with Health Claims" introduced in 2015.

FNC are subject to shorter pre-market notification procedure. The notification to CAA must be submitted at least 60 days before the planned product launch. While dossier must include scientific evidence on food safety and effectiveness, it will not be evaluated by the government. Food business operators make appropriate function claims based on scientific evidence for which they are responsible. The scientific evidence for function claims must be obtained from clinical trials or systematic literature reviews. An incomplete or inadequate documentation can be rejected.

1.4.4.4 Cell-based meat

The Ministry of Agriculture, Forestry and Fisheries (MAFF) is in the **process** of establishing new rules and regulations for meat alternative products developed using new food technologies such as cellular agriculture and plant-based proteins.

Depending on the interpretation of existing laws, currently it is possible to sell cultivated meat in Japan.

1.4.5 Summary

The concept of novel food is not used in Japan. A new food or food ingredient can be freely placed on the Japanese market without any pre-market approval as long as it is not

used as a food additive, no drug or health-related claims are made, and there is a certainty that it poses no risk of harm to human health.

There is a certain level of oversight at the point of import by quarantine officials and the foods that are not in compliance with Japanese food legislation may be stopped. However, assessment at the border is conducted on a case-by-case basis and does not constitute a full pre-market review as such.

Once the product is on the market, the MHLW may take steps to prohibit the product if new food or new food ingredient in the food is determined to be posing a risk to human health.

1.5 United States

1.5.1 Competent authorities

The **Food and Drug Administration** (FDA) is responsible for regulating the safety of all food ingredients regardless of the jurisdiction of the final product where it is used (i.e. TTB for most alcoholic beverages; USDA FSIS for meat, poultry, and egg products; and FDA for all the other foods).

FDA may enforce against someone for using an unapproved food additive regardless of jurisdiction (e.g. caffeine in alcoholic beverages under TTB) but usually coordinates inspection and enforcement activities with other relevant federal authorities as well as with the authorities on the state and local level.

1.5.2 Key legislation

The Federal Food, Drug, and Cosmetic Act (FD&C Act) and subsequent amending statutes codified into Title 21 Chapter 9 of the United States Code (**21 U.S. Code Chapter 9**) give authority to the FDA to oversee the safety of food, drugs, medical devices, and cosmetics.

FDA publishes regulations implementing the requirements of the statutes related to foods in Title 21 of the Code of Federal Regulations (**21 CFR Parts 1-199**).

1.5.3 Definitions/terminology

In the United States, there is no regulatory concept of “novel food” as such. Instead, new foods or food ingredients are reviewed under one of the existing regulatory pathways. In most cases, new foods and food ingredients are reviewed either as food additives or colour additives by issuing a regulation following a safety assessment by the FDA or are determined to be generally recognised as safe (GRAS) under the intended conditions of use.

This is as a result of a very broad definition of “food additive” in the FD&C Act (**21 U.S. Code §321(s)**) which covers “any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (…), if such substance is not generally recognised, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (…) to be safe under the conditions of its intended use (…)”.

Specifically excluded from the definition are:

- pesticide chemicals and their residues,
- colour additives,
- substances sanctioned prior to 6 September 1958,
- new animal drugs,
- dietary ingredients for use in dietary supplements.

The underlined part in the definition forms the basis for the GRAS (“Generally Recognised as Safe”) exception for a substance from being regulated as a food additive. Notably, GRAS status relates not to the substance as such but to its use. If not covered, any new use automatically requires a new GRAS determination (or a food or colour additive regulation).

The term “substance” in the definition has a broad meaning and includes not only substances in the more traditional meaning of the term but also foods and food ingredients, including compound ones, whether used in other foods or sold as such. As a result, a food or a food ingredient that is new to the United States could potentially be

considered a food additive unless it is considered GRAS under the conditions of its intended use or falls under a separate regulatory framework (e.g. colour additive, dietary ingredient etc.).

Importantly, the process by which the food or food ingredient is produced (e.g. genetic modification) does not play a significant role. New additive regulation or new GRAS status determination would only be needed if the final product is substantially different from a more traditional counterpart or if its intended use changes.

Interestingly, since the properties of materials at nanoscale are often vastly different from the same material at larger scale and there is currently no scientific consensus regarding the safety in the scientific community, nanomaterials may not be considered under GRAS framework. Instead, new nanomaterials would be subject to mandatory review by the FDA under food additive provisions.

In its **guidance for industry**, FDA has indicated that some novel substances, such as added botanical ingredients or their extracts, that have been previously used in dietary supplements but have not been used in conventional foods may be unapproved food additives. Equally, substances that have been present in the conventional foods for many years, if used at levels in excess of their traditional use levels or used in new conventional foods, may also be considered unapproved food additives. The presence of an unapproved (=unsafe) food additive automatically renders the food adulterated (**21 U.S. Code §342**). To avoid this, the new use of a substance must either be approved under a food additive regulation or be considered GRAS for the new intended use.

Equally broad is the definition for “colour additive” as it means “a material which (…), when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (…) of imparting colour thereto (…)” (**21 U.S. Code §321(t)**).

Unlike for food additives, there is no exception for GRAS uses of colour additives – each colour additive must be approved by FDA in a regulation before use. Any unapproved colour in a food is automatically deemed unsafe, and the presence of an unsafe colour additive in the food renders the food adulterated (**21 U.S. Code §342**).

A food additive or a GRAS substance may also impart colour and therefore may need an additional approval as a colour additive unless it is already covered by one of the broader classes of colour additives such as "**fruit juice**" or "**vegetable juice**".

Since dietary ingredients in dietary supplements are specifically excluded from the definition of "food additive", these would be subject to a different regulatory framework. For the purposes of **21 U.S. Code §350b**, "new dietary ingredient" means a dietary ingredient that was not marketed in the United States in a dietary supplement before 15 October 1994.

In terms of cell or tissue culture based products, the US Department of Agriculture (USDA) and the Food and Drug Administration (FDA) have recently signed a **formal agreement** for regulating cell-based meat and poultry aiming to provide a transparent path to market for cell-based meat alternatives.

FDA's **approach** to regulating products derived from cultured animal cells that are not under USDA's jurisdiction will be consistent with what's stipulated in the formal agreement mentioned above except that USDA will not need to be involved. As such, FDA's process will involve a thorough pre-market consultation process and routine inspections of records and facilities.

The FDA's pre-market consultation process will include evaluating the production process and produced biological material, including tissue collection, cell lines and cell banks, manufacturing controls, and all components and inputs.

After a successful pre-market safety consultation, the FDA also intends to conduct routine inspections on an ongoing basis, as well as other oversight activities at cell banks and facilities where cells are cultured, differentiated, and harvested aiming to ensure that potential risks are being managed and that biological material exiting the culture process is safe and not adulterated.

1.5.4 Processes

1.5.4.1 Food additive/colour additive petition

FDA encourages **pre-petition consultations** for food additives and colour additives, including meetings, to facilitate the development of food additive and colour additive petitions. A pre-petition consultation may be used to verify whether a petition is required or to ensure that the quality and quantity of information meets the minimum requirements for filing a petition.

According to FDA's **guidance**, petitions for food and/or colour additives are submitted to FDA Center for Food Safety and Applied Nutrition (CFSAN). Each petition is assigned a Consumer Safety Officer who will be the point of contact for consultation with FDA technical experts, arranging meetings, and updating on the progress of the submission.

Withing 15 days after receipt, FDA will notify the petitioner whether the petition was accepted, and, if not, what are the reasons. Petitioner may supplement a deficient petition after being notified regarding deficiencies.

Once the petitioner is notified, the FDA will publish in the Federal Register within the 30 days from the filing date a notice of the filing, the name of the petitioner, and a brief description of the proposal in general terms.

If the intended uses include uses in meat or poultry products, a copy will be sent to USDA for simultaneous review.

The FDA may request a full description of the production methods, facilities and controls used, as well as a sample of the additive or the food in which the additive is proposed to be used. If not submitted on request, the petition will be considered withdrawn without prejudice.

The Consumer Safety Officer then distributes appropriate parts of the petition to experts for evaluation.

Once safety studies are evaluated, acceptable exposure level is determined, a tentative safety conclusion is reached, advisory committee input is received, the final safety evaluation is made, and the administrative record is compiled, a draft of the final rule to be published is prepared. This concludes the review.

For colour additives, the final rule becomes effective 31 days after the final rule is published in the Federal Register. For food additives, the regulation is effective from the publication date.

The average time between submission until a final rule is published for a direct food additive petition is 24 months. For colour additive petitions, the length of the approval process varies significantly.

1.5.4.2 GRAS determination

Under the definition of “food additive”, any substance that is intentionally added to food is a food additive and therefore subject to premarket review and approval by FDA, unless the substance is generally recognised, among qualified experts, to be safe under the conditions of its intended use.

The use of a food substance may be demonstrated to be GRAS either through scientific procedures or, for a substance used in food before 1 January 1958, through experience based on common use in food.

Under **21 CFR §170.30(c)** and **§170.3(f)**, general recognition of safety through experience based on common use in foods requires a substantial history of consumption for food use by a significant number of consumers before 1958. In practice, this is no longer a viable option because the same level of safety would need to be assured as if it is assessed through scientific procedures and a more recent consumption data would need to be used anyway.

Under **21 CFR §170.30(b)**, general recognition of safety through scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive. But, unlike in the case of asking FDA to

issue or amend a food additive regulation, the proponent may convene his own GRAS panel or use an existing GRAS panel (e.g. **FEMA GRAS program** for flavourings) to conclude whether the substance is GRAS for the intended use.

In convening a GRAS panel, one should refer to FDA's **draft guidance for industry** detailing agency's views on best practices for convening a GRAS panel.

Notification of GRAS determinations to the FDA is voluntary. For this reason, many GRAS self-determinations are never notified to the FDA and are not in public domain. Still, the same GRAS criteria apply regardless of whether a conclusion of GRAS status is submitted to FDA as a GRAS notice or whether it is an independent conclusion of GRAS status that remains with the proponent.

If GRAS notice is submitted, FDA may issue a letter saying that it has no questions, may say that notice does not provide a basis for GRAS determination, or may cease to evaluate the notice at notifier's request. Either way, it is always the manufacturer's responsibility to ensure that all ingredients in the food are either approved by the FDA or considered GRAS and that the food is not adulterated. FDA's response that it has no questions does not constitute an approval.

The GRAS notification procedure required that FDA respond to a GRAS notice within 180 days, with an option to extend by additional 90 days on an as needed basis. FDA usually takes less than 180 days to respond to GRAS notices.

Submitting a GRAS notice to FDA does not prevent the manufacturer from marketing the substance in the United States as long as the manufacturer is correct in concluding that a substance is GRAS under the conditions of its intended use.

1.5.4.3 New dietary ingredient notification

21 U.S. Code §350b requires manufacturers and distributors who wish to a market dietary supplement that contain a "new dietary ingredient" to submit to FDA, at least 75 days before the dietary ingredient is introduced or delivered for introduction into interstate commerce (movement between the states or from abroad), information that is the basis

on which the manufacturer or distributer has concluded that a dietary supplement containing the new dietary ingredient will reasonably be expected to be safe.

FDA will acknowledge its receipt of a notification. For 75 days after the filing date, the manufacturer or distributor of a dietary supplement that contains a new dietary ingredient may not introduce, or deliver for introduction, into interstate commerce the dietary supplement that contains the new dietary ingredient.

This 75-day window is the opportunity for FDA to object to placing the new dietary ingredient or the dietary supplement that contains the new dietary ingredient but the failure of the FDA to respond to the notification within this window does not constitute a finding by the FDA that the new dietary ingredient or the dietary supplement that contains the new dietary ingredient is safe or is not adulterated. Ultimately, it is always the responsibility of the manufacturer or distributor to conclude that it is safe and to ensure that the product is not adulterated.

1.5.5 Dossier requirements

1.5.5.1 Food additive/colour additive petition

Requirements for food and colour additive petitions are described in **21 CFR §171.1** and **21 CFR §71.1**. The following would need to be included:

- identity and composition of the additive (properties, specifications, method of manufacture, stability data etc.),
- proposed use and proposed level of use,
- data establishing the intended effect (for food additives),
- quantitative detection methods,
- full reports of investigations made with respect to the safety of the additive,
- estimated exposure from the proposed use (in food, drugs, cosmetics, or devices, as appropriate),
- proposed tolerances (if needed),
- environmental information (as required by the National Environmental Policy Act),
- if petitioning to alter the existing regulation, full information on the proposed changes,
- fee (for colour additive petitions only).

1.5.5.2 GRAS determination

While the assessment procedure may be different, the content of the dossier for GRAS determination should largely be the same as what would be required for food additive petition.

Importantly, determination of GRAS status through scientific procedures must be based upon the application of generally available and accepted scientific data, information, or methods, which ordinarily are published, as well as the application of scientific principles, and may be corroborated by the application of unpublished scientific data, information, or methods.

Therefore, GRAS determination must be largely based on the information in public domain. This is different from FDA's approval of a food additive where proprietary information is submitted and reviewed by FDA.

1.5.5.3 GRAS notice

A GRAS notice for a substance intended for use in human food must include:

- signed statements and certification;
- identity, method of manufacture, specifications, and physical or technical effect;
- dietary exposure;
- self-limiting levels of use;
- experience based on common use in food before 1958;
- narrative;
- list of supporting data and information in your GRAS notice.

1.5.5.4 New dietary ingredient notification

As indicated in **21 CFR §190.6**, the notification must include information that is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing a new dietary ingredient will reasonably be expected to be safe under the conditions of use recommended or suggested in the labelling.

The notification must include:

- the name and complete address of the manufacturer or distributor of the dietary supplement that contains a new dietary ingredient, or of the new dietary ingredient;
- the name of the new dietary ingredient (if an herb or other botanical, Latin binomial name (including the author) must be included);
- a description of the dietary supplement or dietary supplements that contain the new dietary ingredient, including:
    - the level of the new dietary ingredient in the product;
    - the conditions of use of the product recommended or suggested in the labelling or if no conditions of use are stated, the ordinary conditions of use; and
- the history of use or other evidence of safety establishing that the dietary ingredient, when used under the conditions recommended or suggested in the labelling of the dietary supplement, will reasonably be expected to be safe.
- a signature by a designated person who can be contacted if FDA has questions.

On the other hand, to prove that a dietary ingredient is a “grandfathered” one (i.e. not a “new dietary ingredient”) and therefore exempt from any requirement for FDA approval, a manufacturer must be prepared to supply FDA with written documentation showing use as a dietary supplement in the United States before 15 October 1994.

1.5.6 Safety standard

For foods or food ingredients to be approved as food additives or considered GRAS for the intended use the safety standard is a “reasonable certainty of no harm”. **21 CFR §170.3(i)** specifically says:

“Safe” or “safety” means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the conditions of its intended use. It is impossible in the present state of scientific knowledge to establish with complete certainty the absolute harmlessness of the use of any substance. Safety may be determined by scientific procedures or by general recognition of safety. In determining safety, the following factors shall be considered:

- The probable consumption of the substance and of any substance formed in or on food because of its use;
- The cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substance or substances in such diet;
- Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of food and food ingredients, are generally recognised as appropriate.

The safety standard for colour additives is “convincing evidence of no harm”. **21 CFR §70.3(i)** says:

“Safe” means that there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the colour additive.

Additionally, to the above, food additives and colour additives are subject to Delaney clause prohibiting approving any substances that are known to induce cancer in humans or animals. Delaney clause does not apply to GRAS uses of substances.

Approvals of food and/or colour additives are safety-based only – there is no explicit balancing of risk vs. benefits, and safety, per se, is based on the relevant statutory standard.

New dietary ingredients are subject to a much weaker safety standard of “reasonable assurance of no significant or unreasonable risk of illness or injury” (**21 U.S. Code §342(f)(1)(B)**).

1.5.7 Summary

The FDA sets the rules for the safety of ingredients to be used in the production of all foods (i.e. conventional foods and dietary supplements) for sale in the United States, even if the final product is under USDA or TTB jurisdiction.

Although the concept of “novel food” as such is not used, there are comparable regulatory pathways in place for food additives, colour additives, GRAS uses of substances, and new dietary ingredients.

Notably, the definition of “food additive” is a term of art with artificially broad meaning to avoid loopholes. It is not limited to ingredients used for technological function but rather includes *any* substance that may become a component or may affect the characteristics of the food. Even a source of radiation or a substance migrating from food contact material into food is a food additive.

Since “substance” here also has a much broader meaning than the common understanding of the term, any “novel” food or food ingredient could potentially be considered a food additive, unless considered GRAS for the intended use, or used as a colour additive or as a dietary ingredient.

The FDA now predominantly relies on the industry to conduct their own GRAS self-determinations with an option of voluntary notification of the GRAS conclusion to the FDA, giving the agency 6 months to respond. Although general recognition of safety through scientific procedures for GRAS status requires the same quantity and quality of scientific evidence as in the case of food additive petition, the fact that many GRAS determinations are never notified to the FDA and are therefore not in the public domain might reduce the extent of oversight.

On the other hand, in the US it is always the responsibility of the manufacturer to ensure that the food is safe and not adulterated. The authorities avoid setting any specific parameters to meet. There are also considerable risks of litigation in case of suspected adulteration. Thus, delegating the assessment of safety for most new ingredients to the industry sits naturally within the overall regulatory framework.

Importantly, GRAS status is lost automatically as soon as the scientific consensus on the safety of the substance is lost. Practice shows that it may take as long as 10 years for FDA to act after the consensus on the safety of the substance is lost.

Two additional exceptions from being regulated as food additives are for colour additives and new dietary ingredients. While anything to be used as a food colour is subject to mandatory colour additive approval in the regulation via lengthy notice and comment rulemaking, new dietary ingredients are only subject to a pre-market notification

requirement with 75-day window for the FDA to object the finding of safety based on a limited information provided by the proponent. As there are no official lists of dietary ingredients marketed in the US prior to 15 October 1994, it is not always easy to decide whether the dietary ingredient is “new”.

Notably, the Delaney clause prohibits the authorities from approving any food additive or colour additive that is known to cause cancer in either humans or animals. This blanket prohibition does not directly apply to GRAS uses of substances.

1.6 Comparison

1.6.1 Regulatory approach

Out of the five markets assessed within the scope of this report, novel foods or food ingredients are not particularly addressed in the legislation in Japan and the United States. The remaining three countries use the term “novel food”, however, there are significant differences between the countries when it comes to the definitions, what falls under the novel food legislation, and the procedures for the authorisation. A comparison of different aspects of how “novel” foods or food ingredients are addressed in each of the five countries is provided in **Annex 1**.

In the European Union, “novel food” is any food that was not used for human consumption to a significant degree within the EU before 15 May 1997. Any such food requires approval before placing on the market although not all require risk assessment by EFSA. Novel food legislation specifically excludes foods with technological function and genetically modified foods from the scope. On the other hand, nanomaterials, cell culture products, and foods previously used as a food supplement constitute some of the product categories potentially considered novel food.

In Australia (and New Zealand), the scope of the “novel” concept is narrower as non-traditional foods that do not require an assessment of the public health and safety are automatically not novel and can be freely placed on the market. An assessment of the public health and safety considerations would take into account the potential for adverse effects to humans, the composition or structure of the food, processes used, the source, patterns and levels of consumption, and any other relevant matters.

As in the EU, the evidence of history of human consumption is restricted to the local market – Australia or New Zealand, but, unlike in the EU, no specific cut-off date was ever established. Instead, “length of use” is part of a case-by-case assessment of whether the food is non-traditional, which is a prerequisite for it to be considered novel.

Although the novel food legislation does not specifically exclude foods with technological function or GM foods, these are regulated separately regardless. Also, there is no particular focus on the particle size of materials or cell culture products in the novel food legislation or in the position of the authorities.

The Canadian approach to novel food regulation is very different from the above two as it focuses primarily on the product itself and not on how it was obtained. Yes, a food would be novel if it has been manufactured, prepared, preserved or packaged by a novel process but only if it causes the food to undergo a major change. As such, if the food is substantially equivalent to a conventional counterpart in terms of composition, structure, nutritional quality, physiological effects, the manner in which it is metabolised in the body, microbiological or chemical safety, or the safe use of the food, it is unlikely to be considered novel.

Similarly, a food derived from an organism genetically modified through intentional manipulation will not be considered novel unless the manipulation introduced new or removed existing characteristics or changed the normal range for the characteristics of the organism.

Lastly, a substance can be considered a novel food if it has no history of safe use as a food – this would be relevant to herbal substances and other ingredients that have a history of use in dietary supplements or cultural practices (e.g. plants used for teas in herbal medicine) as opposed to a history of use to satisfy hunger or thirst. Notably, the evidence of a history of safe use is not limited to Canada and there is no specific cut-off date.

Foods with technological function and uses in food supplements (i.e. natural health products) are regulated separately but nanomaterials and cell culture products may well be subject to novel food regulation.

Since Japan does not have a separate regulatory framework for novel foods or food ingredients, these would be subject to the general requirements that apply to all foods. Instead, general food legislation provides for the oversight of novel foods or food ingredients already on the market and acting if these are deemed as posing a risk to human health.

Having said that, foods making certain health-related claims may need to be authorised or at least notified to the authorities before being placed on the market.

There are provisions in place for the oversight of foods and food ingredients that are new to the Japanese market at the point of import, but it does not constitute a full review. The consultation with the MHLW is recommended for both domestic and imported foods and food ingredients to ensure that these can be distributed in Japan.

Foods with technological function are regulated separately, and the authorities are in the process of establishing a regulatory framework for meat alternative products, including the ones produced using cellular agriculture.

In United States, the definition of “food additive” is broad enough to cover any food, ingredient or substance that may become a component or may affect the characteristics of the food, unless it falls under one of the exemptions specifically carved out from the definition of “food additive”.

The biggest and the most important exemption is for substances (including foods and food ingredients) that are generally recognised as safe under the conditions of its intended use. It covers not only substances that were specifically evaluated by GRAS panel but also a wide range of foods such as salt, monosodium glutamate, apples, vinegar, spices or many other common foods or food ingredients that are considered GRAS based on their long history of save use for human consumption. The basic

premise of the GRAS status is that the substance loses GRAS status for the intended use as soon as the scientific community becomes divided regarding its safety. Also, any new intended use requires a new GRAS status determination (or a food additive regulation) as the GRAS status is not the for substance as such but for its intended use. Considering the above, there is really no need or room for a special treatment of “novel foods” – foods with technological function, nanomaterials, foods previously used as a food supplement, cell culture products, and even genetically modified foods could be assessed via GRAS regulatory approach.

Another potentially relevant exemption from the definition of food additive is for dietary ingredients for use in dietary supplements. Particularly, dietary ingredients not marketed in the US in a dietary supplement before 15 October 1994 would be regulated as “new dietary ingredients”.

1.6.2 Approval processes

A comparison of approval processes for novel foods or similar concepts in all five countries is provided in **Annex 2** to this report.

In all three markets with special regulatory framework for novel foods, approval is required before such food is placed on the market.

In the European Union, getting a novel food approved for marketing is a complex process as even novel status determination by the recipient Member State can take up to 4 months from concluding on the validity of the consultation request or even longer if additional information is requested or if an extension of a maximum of 4 months is sought. If the food is considered novel, it can take several years from the moment the application for authorisation is submitted to the European Commission before the Commission adopts a regulation authorising the marketing of a novel food in question. Of course, the procedure may be concluded quicker if the novel food is not liable to impact human health and therefore does not require a risk assessment by EFSA which may take up to 9 months, if no further information is required. Considering the vast breadth of activities undertaken by the Commission, it is not surprising that the Commission is given 7 months (with a possibility of extension) to come up with a draft proposal which then still

requires a favourable vote from SCoPAFF representing all Member States. In the past two years, it took between 7 and 24 months from application to publication of the regulation authorising the placement on the market.

Notifications for traditional foods from third countries, once validated and forwarded, are subject to a potentially quicker procedure as the Member States and EFSA are given only 4 months (if no additional information is requested) to provide their objections. If no objections received, it can be authorised fairly quickly. In case of any objections, EFSA's scientific opinion would be needed which would delay the whole process significantly. While the procedure should be somewhat quicker, in practice, it takes almost the same amount of time from notification to publication as in the case of applications for authorisation.

In Australia, a certain emphasis is on the pre-application assistance by FSANZ so that, once the dossier for novel food application is submitted, it could be reviewed without unnecessary delays. The ACNF of FSANZ can also be asked to issue a non-binding recommendation regarding the novel food status. Both these consultations are not time limited.

Novel food applications are likely to be assessed under the general procedure which takes up to 9 months and includes a single period of public consultation as standard. Once the conclusion is reached, the draft proposal still needs approval of the Forum representing both national governments and the governments of the Australian states and territories, potentially delaying the publication of the amendment to the list of permitted novel foods in the Code. As such, the overall process (excluding the preliminary consultations) easily takes over 1 year, even if not further information is requested. The clock can be stopped if waiting policy guidelines or principles from the Forum.

Canada requires only a pre-market notification for novel foods. To place a novel food on the market, a "letter of no objection" must first be issued by the authorities.

On request, authorities may issue a binding conclusion regarding the novel status. Proponents are also strongly encouraged to consult with the authorities before submitting a notification dossier. This step is aimed at improving the quality of dossiers and improving predictability of the notification review outcome.

The authorities are given only 45 days to conclude whether submission appears reasonable or not, unless additional safety information is requested. If additional safety information is indeed requested, the authorities will have 90 days to conclude whether the provided information establishes that the novel food is safe for consumption and notify the proponent in writing that the information is sufficient. It is important to note that the authorities are only required to conclude whether they agree with the proponent's conclusion that the novel food is safe consumption based on the information submitted. So, this is not a full authorisation process as in the EU or in Australia. On the other hand, the Canadian authorities claim that they keep themselves updated on the newest developments in the production methods and food safety science, and do not rely solely on what is provided by the proponent. Quick turnaround of the notification process is also possible potentially due to all the assistance offered during a well-structured pre-submission consultation stage and due to sufficient staffing of the relevant departments at Health Canada.

In Japan, foods, including novel foods, making certain health-related claims are subject to pre-market review. For instance, "foods for specified health uses" must comply with the specifications and standards established by the government and are subject to individual pre-market authorisation. The claimed effects and the safety of the food will be assessed by the MHLW. For the assessment of effectiveness, the MHLW will consult with the PAFSC. The safety assessment will be conducted by the FSC. The timelines do not seem to be clearly defined.

"Foods with function claims" are subject to shorter pre-market notification procedure. The notification to CAA must be submitted at least 60 days before the planned product launch. Scientific evidence on food safety and effectiveness that must be included in the dossier is not evaluated by the government.

On the other hands, “foods with nutrient function claims” may be freely manufactured and distributed without any permission from or notification to the national government, as long as the food meets the established standards and specifications.

In the United States, before placing a “novel” food or food ingredient on the market, one should consider whether it will be used as a dietary ingredient in dietary supplements, or whether it will be used as a “food additive” within the broader meaning of the term or as a colour additive – in both conventional foods or dietary supplements.

If used as a dietary ingredient in dietary supplement, the proponent needs to consider whether it is “new dietary ingredient”, and, if it is, submit a notification with limited information to the FDA before introducing the new dietary ingredient into the US market.

If not used as dietary ingredient in dietary supplements, then it would be necessary to consider whether the food or food ingredient can be used as a colour additive, and, if it can be used as such, colour additive petition to the FDA to issue a regulation would be needed which can take several years.

If the food or food additive is unlikely to be used as a colour additive, then it is only necessary to choose between submitting a food additive petition which can take on average 2 years or convening a GRAS panel or asking others who have a functioning GRAS panel (e.g. GRAS panel by FEMA for flavourings) to assess the a food or food ingredient whether it is generally recognised, among qualified experts, to be safe under the conditions of its intended use.

Unlike the process for food additives, GRAS procedure does not involve notice and comment rulemaking which is a time-consuming process. For this reason, new substances are predominantly reviewed under the GRAS rules as opposed to using a food additive procedure. The notification of GRAS conclusions to the FDA is entirely voluntary and most determinations are never notified to the FDA. FDA’s review as part of the notification procedure is usually sought for more complex situations where additional review by the authorities is seen as reassurance regarding the safety of a particularly novel food or ingredient.

1.6.3 Conclusions

The approaches to the regulation and oversight of novel foods in the EU and non-EU countries, as reviewed in this part, are merely a reflection of different schools of thinking and food regulatory systems in general. As such, it was not surprising to find that the authorities in Canada, Japan, the United States, and even Australia usually do not particularly concern themselves with foods that are new to these markets as long as these do not pose a risk to human health.

The United States could exemplify a market where the food industry has lots of freedom to innovate without direct involvement from the authorities as long as general requirements of the law regarding food safety are adhered to. The fact that novel foods are not specially regulated does not change the overall responsibilities of the manufacturers.

On the opposite end of the scale, a more cautious approach and a broader interpretation of precautionary principle in the EU dictates that even foods that do not pose a risk to human health, if considered novel, must be reviewed and explicitly authorised by legislation before marketing.

Although explicit approvals before placing on the market are also required in Australia and Canada, the differences in the concept of “novel food” alone ensure that many lower risk foods considered “novel” in the EU can be more easily and more quickly placed on the Australian or Canadian market. This also means that authorities can allocate valuable resources where it is needed the most.

All in all, it is important to find balance and ensure the safety of food supply without unnecessarily stifling product innovation.

2 Genetically modified organisms

2.1 European Union

2.1.1 Competent authorities

The **European Commission** along with the **European Food Safety Authority** (EFSA) and national authorities of EU Member States are involved in the authorisation process of genetically modified organisms (GMOs).

The EFSA undertakes risk assessments of GMO food and feed applications when requested by a national authority following an application submitted by any person in such national territory.

If the application also covers cultivation, EFSA delegates the environmental risk assessment to an EU country which sends EFSA its Environmental Risk Assessment (ERA) report. EFSA submits its opinion to the Commission and to the EU countries. The Commission proposes to Member States to grant or refuse the authorisation. If authorisation is granted, the legislation is written by the European Commission together with Member States Expert Committee.

Member States can decide on cultivation of GMOs and on use of GMOs for food and feed on their territory.

GMOs are regulated in the EU through Directives, which governments of Member States must implement and enforce.

In the EU, the competent authorities for the required inspections and enforcement of GMO legislation differ in each Member State.

2.1.2 Key legislation

All genetically modified food and feed need to accord with the general safety requirements stipulated in **Regulation (EC) No 178/2002**.

Provisions of protection of human life and health, animal health and welfare, environment and consumer interests in relation to genetically modified food and feed, in addition to procedures for the authorisation and supervision of genetically modified food and feed, are laid down in **Regulation (EC) No 1829/2003**.

Requirements for the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms are laid down in **Regulation (EC) No 1830/2003**.

A system for the development and assignment of unique identifiers for genetically modified organisms is established by **Commission Regulation (EC) No 65/2004**.

The deliberate release into the environment of genetically modified organisms is regulated by **Directive 2001/18/EC**.

The provisions for the environmental risk assessment of genetically modified organisms are laid down in **Commission Directive (EU) 2018/350**.

The possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory is provided by **Directive (EU) 2015/412**.

The rules on the contained use of genetically modified micro-organisms are laid down in **Directive 2009/41/EC**.

Transboundary movements of genetically modified organisms are regulated by **Regulation (EC) No 1946/2003.**

Applications for authorisation of genetically modified food and feed are ruled by **Commission Implementing Regulation (EU) No 503/2013**.

EU GMO database can be accessed through the following link: **https://webgate.ec.europa.eu/dyna/gm_register/index_en.cfm**

2.1.3 Definitions/terminology

According to **Regulation (EC) No 1829/2003** along with **Directive 2001/18/EC**, the term “genetically modified organism (GMO)” means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination.

Regulation (EC) No 1829/2003 also provides definitions for the following terms:

- “genetically modified food” means food containing, consisting of or produced from GMOs;
- “genetically modified feed” means feed containing, consisting of or produced from GMOs;
- “produced from GMOs” means derived, in whole or in part, from GMOs, but not containing or consisting of GMOs;
- “control sample” means the GMO or its genetic material (positive sample) and the parental organism or its genetic material that has been used for the purpose of the genetic modification (negative sample);
- “conventional counterpart” means a similar food or feed produced without the help of genetic modification and for which there is a well-established history of safe use.

“Micro-organism” is defined by **Directive 2009/41/EC** as any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, and animal and plant cells in culture.

This Directive also provides definition for “genetically modified micro-organism” (GMM), which means a micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination; within the terms of this definition:

(i) genetic modification occurs at least through the use of the techniques listed in Annex I, Part A;
(ii) the techniques listed in Annex I, Part B, are not considered to result in genetic modification.

"Contained use" means any activity in which micro-organisms are genetically modified or in which such GMMs are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with, and to provide a high level of safety for the general population and the environment.

Regulation (EC) No 1830/2003 defines "unique identifier" as a simple numeric or alphanumeric code which serves to identify a GMO on the basis of the authorised transformation event from which it was developed and providing the means to retrieve specific information pertinent to that GMO.

2.1.4 Scope of regulation

Regulation (EC) No 1829/2003 covers food and feed produced 'from' a GMO but not food and feed 'with' a GMO.

Processing aids (such as enzymes) which are only used during the food or feed production process are not covered by the definition of food or feed and, therefore, are not included in the scope of this Regulation. Nor are food and feed which are manufactured with the help of a genetically modified processing aid included in the scope of this Regulation. Furthermore, Commission **guidance document** on criteria for categorisation of food enzymes states that if the GMM is removed, hence not present in the enzyme, then the enzyme is out of the scope of Regulation (EC) No 1829/2003 on genetically modified food and feed, and, therefore, the statement "produced from genetically modified (name of the ingredient)" does not need to be declared on the labelling of a product produced using such enzyme. However, if the food enzyme is obtained from GMM which is not removed, then it falls under the scope of Regulation (EC) No 1829/2003.

In addition, products obtained from animals fed with genetically modified feed or treated with genetically modified medicinal products will be subject neither to the authorisation requirements nor to the labelling requirements referred to in this Regulation.

Furthermore, mutagenesis and cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods are specifically excluded from the scope, according to Annex I B of Directive 2001/18/EC.

In July 2018, the Court of Justice of the European Union (CJEU) clarified that organisms obtained by new mutagenesis techniques fall within the scope of the EU GMO legislation. The Commission is now working with EU countries and stakeholders to implement the Court's ruling. The latest **Summary Report** (18 September 2020) on the "Member States' Competent authorities - Joint Working Group" meeting on this matter is available at the Commission website under the title of '**New Techniques in Biotechnology**'.

2.1.5 Processes

Applicants can apply for GMO authorisations by submitting a dossier with experimental data and a risk assessment.

Authorisations are valid throughout the EU and may be for:

- Cultivation
- Marketing of food and feed and derived products

If the GMO is to be used in food or feed without cultivation, applying for food and feed purposes is enough. If the GMO is to be used in food or feed with cultivation in the EU, companies need to apply for both cultivation and food/feed purposes under the same Regulation. If the GMO is not to be used in food or feed, applying for authorisation for cultivation is enough.

There are different procedures depending on the intended use.

Regarding field trials, anyone intending to introduce GMOs into the environment for experimental purposes must first get authorisation from the relevant national authority in the country where the release is planned. The **national authority** is

responsible for making a decision on the release based on an environmental risk assessment and an assessment of the health risks according to the rules in Part B of Directive 2001/18/EC on deliberate release of GMOs for any other purpose than for placing on the market.

In relation to GMO authorisations for cultivation in the EU, according to Directive 2001/18/EC, an application for authorisation of a GMO for cultivation must be submitted to a national competent authority. The lead country prepares an assessment report and sends it to the Commission which forwards it to the EU countries for comments. The Commission requests a European Food Safety Agency (EFSA) risk assessment if at least one EU country proposes one or more reasonable objections based on the assessment report. Based on EFSA's assessment, the Commission proposes to EU countries to grant or refuse the authorisation.

Under the new Directive (EU) 2015/412 EU countries have 2 possibilities to restrict or prohibit GMO cultivation on their territory:

- During the authorisation procedure, an EU country may ask to amend the geographical scope of the application to exclude part of or all its territory. The applicant has 30 days to adjust or confirm the scope of its application. Member States are allowed to ask for their territory to be reintegrated into the geographical scope of the authorisation after the GMO authorisation has been granted;
- After a GMO has been authorised for cultivation in the EU, an EU country may adopt national opt out measures restricting or prohibiting the cultivation of a GM crop, by invoking compelling grounds such as environmental or agricultural policy objectives, town and country-planning, land use, coexistence, socio-economic impacts, or public policy.

EU countries can use the new Directive's provisions immediately, meaning that they can launch the procedure to adopt national opt out measures to ban/restrict cultivation of already authorised GMOs; or, during a 6 month transitional period (e.g. until 1 October 2015), they can request to be excluded from the geographical scope

of the GMO applications that have already received an EFSA opinion or are already authorised.

Regarding GMO to be used in food and feed, a GMO or a food product derived from a GMO can only be put on the market in the EU/UK after it has been authorised on the EU level after a scientific assessment of the risks to health and the environment. An application for authorising a GMO for food or feed uses must be submitted to a national authority. The application under Regulation (EC) 1829/2003 must also comply with the requirements set out in Commission Implementing Regulation (EU) No 503/2013 on applications for authorisation of genetically modified food and feed. The national authority then sends the application to EFSA for a risk assessment. If the application also covers cultivation, EFSA delegates the environmental risk assessment to an EU country which sends EFSA its Environmental Risk Assessment (ERA) report. EFSA opinion is submitted to the European Commission and to the EU countries. Once EFSA publishes its risk assessment, the public has 30 days to comment on the Public Consultation on the Commission website. The Commission then proposes to Member States to grant or refuse the authorisation. If the Commission proposal differs from EFSA's opinion, it must be explained why. National representatives approve the Commission's proposal by qualified majority in the Standing Committee on Plants, Animals, Food and Feed. If the Committee does not approve or reject the proposal by a qualified majority, the Commission may summon an Appeal Committee.

If the Appeal Committee fails to reach an opinion by a qualified majority, the Commission has to take the responsibility for the final decision.

The contained use of GM micro-organisms is ruled by Directive 2009/41/EC. Anyone planning to commence contained use activity must notify its competent authorities. The authorities verify that the installation is appropriate for the activity and that the work does not pose any danger to human health and the environment. If the activity involves high risk, i.e. Class 4, the written consent of the authority is necessary before commencing the contained use activity. Contained use activities are classified from level 1 to 4 with assigned containment levels and protective measures:

- Class 1 covers activities of no or negligible risk
- Class 2 covers activities of low risk
- Class 3 covers activities of moderate risk
- Class 4 covers activities of high risk

2.1.6 Regional restrictions

During the authorisation procedure of a given GMO or during the renewal of consent/authorisation, a Member State may demand to exclude all or part of the territory from cultivation.

Once the European Commission approves an application on GMO, Member States can either implement it or adopt national opt-out measures restricting or prohibiting the cultivation of GMOs on their territory, in addition to restricting or prohibiting the use of GMOs for food and feed on their territory, by invoking compelling grounds such as environmental or agricultural policy objectives, town and country-planning, land use, coexistence, socio-economic impacts, or public policy.

Member States can also adopt emergency measures based on new identified risk (on health and environmental grounds).

2.1.7 Labelling

General labelling requirements are laid down in **Regulation (EC) No 1169/2011** on the provision of food information to consumers.

Specific additional requirements for the labelling of a GMO food/ingredient are ruled by Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC. It states in Article 6, that for prepacked products consisting of or containing GMOs a statement must be applied to foodstuffs to make the consumers aware that they are buying a GM food.

Therefore, where genetically modified ingredients have been used in a product, the words “Genetically modified” or “Produced from genetically modified (ingredient)” must appear in the brackets immediately following the name of the ingredient concerned or clearly on the label where there is no list of ingredients. Where the ingredient is designated by the name of a category, the words “Contains genetically modified (organism)” or “Contains (ingredient) produced from genetically modified (organism)” should be used in the list of ingredients.

A footnote to the list of ingredients may be used instead of declaring the presence of GM material directly in the list of ingredients. For small packs and non-prepacked foods offered for sale to the final consumer, the information must be permanently and visibly displayed where the food is sold or on the packaging material.

As specified in the authorisation, the consumer must be informed of any differences from a conventional counterpart in composition, nutritional value or nutritional effects, the intended use of the food, effects on the health of any population segment, and of possible ethical or religious concerns. For completely new products without a conventional counterpart, appropriate information about the nature and the characteristics of the foods concerned must be given.

A labelling threshold of 0.9% is established to exempt from GM labelling the adventitious or technically unavoidable presence of GM material in food or feed. The threshold applies at the level of each individual ingredient. Any presence above 0.9% or any intentional addition of an ingredient requires labelling. Importantly, the threshold only applies where operators can supply evidence of having taken appropriate steps to avoid the presence of GM material and does not apply to the presence of GM varieties not authorised in the EU.

Foods merely produced with the help of GM technology (e.g. GM enzymes) do not have to be labelled as GM. Products obtained from animals fed with GM feed or treated with GM medicinal products will be subject neither to the authorisation requirements nor to the labelling requirements.

The labelling requirement applies irrespective of the detectability of DNA or protein resulting from the genetic modification in the final product.

Further information is available in **Questions & Answers** document published by the Commission containing information about authorised GMOs, labelling and risk assessments.

There exist "GM-free" labels pointing out that, in addition to what is laid down by the EU legislation on GMOs, specific measures have been taken on a voluntary basis to strictly exclude the presence or the use of GMOs in some food or feed products. Such voluntary labels are possible provided that they are not misleading for the consumer.

A **study** on the state of play in the EU on GM-free food labelling schemes and assessment of the need for possible harmonisation has been performed by an external consultant for the Commission, in order to take stock of existing GM free labels in place or in development in the EU, and to analyse their respective features. Case studies can be found **here**.

The use of "non-GMO" claims is not currently covered by any EU harmonised legislation. Each Member State may apply its own legislation and/or guidance in relation to such a claim.

There are third parties who offer certification for "non GM" claims on food products such as non-GMO certification by **FoodChain ID**. In addition, **organic** certification would also ensure the requirements for a "GM-free" claim would be met.

2.1.8 Traceability

"Traceability" in the context of GMOs is defined in Article 3 of **Regulation (EC) No 1830/2003** to mean the ability to trace GMOs and products produced from GMOs at all stages of their placing on the market through the production and distribution chains.

This regulation also establishes specific traceability requirements depending on whether the product consists of or contains GMOs or has been produced from GMOs.

GMOs, or food and feed consisting of or containing GMOs, are assigned a unique identifier and are labelled as such to ensure traceability and enable consumers to make informed choices.

All operators involved, i.e. farmers or food and feed producers who introduce a product in the supply chain or purchases such a product must be able to identify their supplier and the companies to which the products have been delivered.

Operators must provide their customers with the following information, in writing:

- an indication that the product – or certain ingredients – contains, consists of, or is obtained from GMOs;
- information on the unique identifier(s) for these GMOs. In the case of products consisting of or containing mixtures of GMOs to be used only as food or feed or for processing, this information may be replaced by a declaration of use by the operator. It has to be accompanied by a list of the unique identifiers for all those GMOs that have been used to constitute the mixture.

Operators must also ensure that the information is passed on in writing to those who are next in the supply chain.

For a period of five years after every transaction within the supply chain, every operator must keep a record of this information and be able to identify the operator from whom they bought the products and the one to whom he or she supplied them.

In addition, Article 18 of Regulation (EC) No 178/2002 laying down the general principles of food law and food safety states that “the traceability of food, feed, food-producing animals, and any other substance intended to be, or expected to be,

incorporated into food or feed shall be established at all stages of production, processing and distribution".

2.1.9 Low level presence policy

EU has a zero tolerance policy for the low level presence of unapproved GMOs.

Commission Regulation (EU) No 619/2011 establishes the Minimum Required Performance Limit (MRPL), the lowest amount or concentration of analyte in a sample that has to be reliably detected and confirmed by official laboratories. This limit established at 0.1% constitutes the so called technical zero for the low level presence of non-authorised GM material in feed imports. However, this is only applicable to GM feed material authorised in a third country and for which an authorisation has been pending in the EU for more than three months or has expired.

There is no similar technical zero established for the presence of non-approved GMOs in foods.

2.1.10 Monitoring/enforcement

In compliance with Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms, 'following the placing on the market of a GMO as or in a product, the notifier shall ensure that monitoring and reporting on it are carried out according to the conditions specified in the consent. The reports of this monitoring shall be submitted to the Commission and the competent authorities of the Member States. On the basis of these reports, in accordance with the consent and within the framework for the monitoring plan specified in the consent, the competent authority which received the original notification may adapt the monitoring plan after the first monitoring period'. Examples of post-market monitoring plan (PMM) reports are available **here**.

In addition, based on the relevant EU legislation on GMOs Regulation (EU) 2017/625, it is the obligation of the EU countries to carry out official controls for:

- deliberate release of GMOs (e.g. cultivation of GM maize) in the EU;

- presence of GMOs and/or GM material in food, animal feed and seeds at import stage and on the EU market.

These controls are organised based on the Member States' Multiannual National Control Plans (MANCP). Controls may consist of audits, inspections, the latter including documentary, identity and physical checks. Physical checks may comprise sampling and testing. GMO testing for the purpose of official controls is carried out using validated methods of detection. The last version of UK MANCP before leaving the EU can be found **here**. UK guidance and reports on GM inspections are available **here**.

Commission Recommendation 2004/787/EC provides guidance for sampling and detection of GMOs and materials produced from GMOs. For sampling of feed, Regulation (EC) 152/2009 applies. For GM feed material whose authorisation is pending or has expired in the EU, Regulation (EU) 619/2011 provides harmonised methods for sampling and testing.

Upon the detection on the EU market of an unauthorised GMO, a notification is submitted through the **Rapid Alert System for Food and Feed** (RASFF) in order to share relevant information between its members and respond collectively and efficiently to possible risks. Emergency measures can be adopted, and their severity depends on the gravity of the situation.

Furthermore, the Commission carries out **audits** or inspections to ensure that national authorities are fulfilling their legal obligations with regard to official controls. **Audit reports** are published on the Commission website.

Further **reports and studies** on GMOs can be found on the Commission's website.

Regarding enforcement actions, Article 45 of Regulation (EC) No 1829/2003 and Article 11 of Regulation (EC) No 1830/2003 state that 'Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all

measures necessary to ensure that they are implemented. The penalties provided for must be effective, proportionate and dissuasive".

General information on enforcement can be found on the **EU countries' controls webpage**.

2.1.11 Products on the market

The registration status of a GM food and feed can be found in the **Community register of GM food and feed**. GM food and feed that are permitted to be placed on the market in accordance with Regulation (EC) No 1829/2003 include:

- cotton,
- maize,
- oilseed rape,
- soybean,
- sugar beet,
- swede-rape.

In addition, there are two lists of SNIFs (Summary Notification Information Format) submitted to the Member State's Competent Authorities under Directive 2001/18/EC available for deliberate release into the environment of **plants GMOs** and **other than plants GMOs** for any other purposes than placing on the market (experimental releases).

Furthermore, a **list of authorised and pending notifications** under Directive 2001/18/EC related to placing on the market of GMOs as or in products is also available.

2.1.12 Summary

The European Union has a well-developed legal framework to ensure that the development of modern biotechnology, and more specifically of genetically modified organisms (GMOs), takes place in safe conditions.

The framework aims to support the protection of not only human and animal health but also the environment by requiring a high standard of safety assessment at EU level before any genetically modified (GM) substance can be placed on the market.

It lays down harmonised procedures for risk assessment and authorisation of GMOs. Once approved, authorisations are valid throughout the EU and may be for either the cultivation or the marketing of a food and/or feed and derived products.

The legal framework provides a robust environment for the transparent use and placement on the market of GMOs. It recognises that under normal agriculture conditions, the possibility of adventitious presence of authorised GM crops in non-GM crops cannot be entirely excluded but requires putting suitable measures in place throughout production (including at the cultivation, harvest, transport, storage, and processing stages) to ensure GMOs can coexist alongside conventional and/or organic crops.

The legislation also sets out traceability measures to be in place to identify which authorised GMO is used. It also requires the clear labelling to indicate the presence of GMOs in products placed on the market so that consumers and operators throughout the food and feed chain could make an informed choice as to the use of such substances.

2.2 Argentina

2.2.1 Competent authorities

The **Ministry of Agriculture, Livestock, and Fisheries** (MAGyP) is the ministry responsible for designing and executing production, marketing and sanitary plans in the fields of agriculture, fishery, forestry, and agroindustry.

Secretariat for Food and Bioeconomy (SAYBI) of the MAGyP is currently in charge of granting authorisations for the release and commercialisation of GMOs.

National Advisory Committee on Agricultural Biotechnology (CONABIA) is an interdisciplinary and interinstitutional group that includes **representatives** from various government institutions, universities, and industry associations involved in agricultural biotechnology. Some are appointed as observers with no voting rights. The members must disclose their conflicts of interest and must refrain from participating if there is a conflict of interest.

The **Directorate of Biotechnology** (DB) within MAGyP centralises all activities and information related to biotechnology. It assists CONABIA in the evaluation of applications for authorisation for the environmental safety and advises SAYBI on activities related to biotechnology and agricultural biosafety.

National Service of Agricultural and Food Health and Quality (SENASA) is a decentralised body under MAGyP responsible for regulating animal and plant products and by-products, fishery and seafood products. Technical Advisory Committee on the Use of GMOs (CTAUOGM) of SENASA carries out food safety reviews for the GM food applications.

Undersecretariat of Agricultural Markets (SSMA) evaluates commercial impact on export markets by preparing a technical report to avoid a negative impact on Argentine exports.

National Seed Institute (INASE) is the government agency in charge of registering and controlling the seed market and monitoring field trails. New varieties are registered in the National Registry of Cultivars.

2.2.2 Key legislation

Regulatory framework for regulating activities with GMOs is established in **Resolution No. 763/2011** (MAGyP). It puts CONABIA and the Directorate of Biotechnology in charge of conducting the risk assessment, the design of biosecurity measures and risk management.

Resolution No. 44/2019 (SAYBI) establishes procedures for requesting, evaluating and granting of authorisations for contained (e.g. greenhouse) or confined (i.e. field trial) activities with regulated GM plants.

Resolution No. 36/2019 (SAYBI) establishes procedures for risk analysis carried out by CONABIA with respect of plant GMOs and for case-by-case determination by CONABIA on whether a plant obtained from new improvement techniques that use modern biotechnology falls within the scope of GM regulation.

Resolution No. 63/2019 (SAYBI) establishes authorisation procedures for GM animals, including a case-by-case determination by CONABIA on whether GM animals and biological material with reproductive capacity, produced using new improvement techniques that use modern biotechnology and the accumulation of biotechnological events, fall within the scope of GM regulation.

Resolution No. 52/2019 (SAYBI) establishes procedures for the submission of applications for the evaluation of GM microorganisms for commercial release.

Resolution No. 412/2002 (SENASA) (in **English**) establishes the principles and criteria for the assessment of food derived from GMOs, the requirements and the rules of proceedings for the human and animal safety assessment of foods derived from GMOs, and what information is required for the assessment.

Resolution No. 498/2013 (INASE) prohibits activities with regulated GM plants without prior authorisation.

Resolution No. 26/2018 (SAYBI) establishes a temporary procedure to grant commercial authorisation for GMOs to be used for food, feed, or processing and refers for guidance on LLP issues to documents by OECD and Codex Alimentarius.

Resolution No. E 79/2017 (Secretariat for Value Added) establishes the procedure for authorisations to carry out activities that involve the experimental release or

production of GM animals or biological material with reproductive capacity under confinement conditions.

In 2019, the regulatory framework was updated by **Resolution No. 36/2019** to provide that implementation aspects that require quicker turnaround may be addressed via complementary and interpretive Provisions of the Directorate of Biotechnology.

As such, **Provision No. 1/2019** (DB) approves the form for preliminary consultations for plants, animals, and microorganisms obtained through new improvement techniques, streamlining CONABIA's process to decide if a new organism obtained by these techniques is regulated as GMO or not.

Provision No. 3/2019 (DB) clarifies the classification system for biotechnological events authorised or evaluated to date based on their potential to establish synergic effects, effectively simplifying the process for combining technologies that exist separately on the market.

Provision No. 4/2019 (DB) approves special guidelines for crops with protection against insects based on insecticide proteins.

2.2.3 Definitions/terminology

Resolution No. 36/2019 and **Resolution No. 63/2019** provide the following relevant definitions:

- Genetically Modified Organism (GMO) – any biological entity capable of transferring or replicating genetic material that has a new combination of genetic material that has been obtained through the application of modern biotechnology.
  Note: For the purposes of Resolution No. 63/2019, animal GMOs include sterile animals, embryos and all biological material with reproductive capacity.
- Modern biotechnology – application of nucleic acid *in vitro* techniques, including rDNA and direct injection of nucleic acid into cells or organelles, or

fusion of cells beyond the taxonomic family, that exceed natural physiological barriers to reproduction or recombination, and which are not techniques used in traditional breeding and selection.

- Genetic construct or “construct” – nucleic acid segment made up of two or more contiguous nucleotide sequences that have been combined by means of *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA).
- Essentially similar constructs – constructs that share the same characteristics of interest using the same molecular mechanisms.
- Accumulation of events – accumulation by sexual crossing of transformation events that were obtained separately, as well as the retransformation or cotransformation that results in separate inserts.

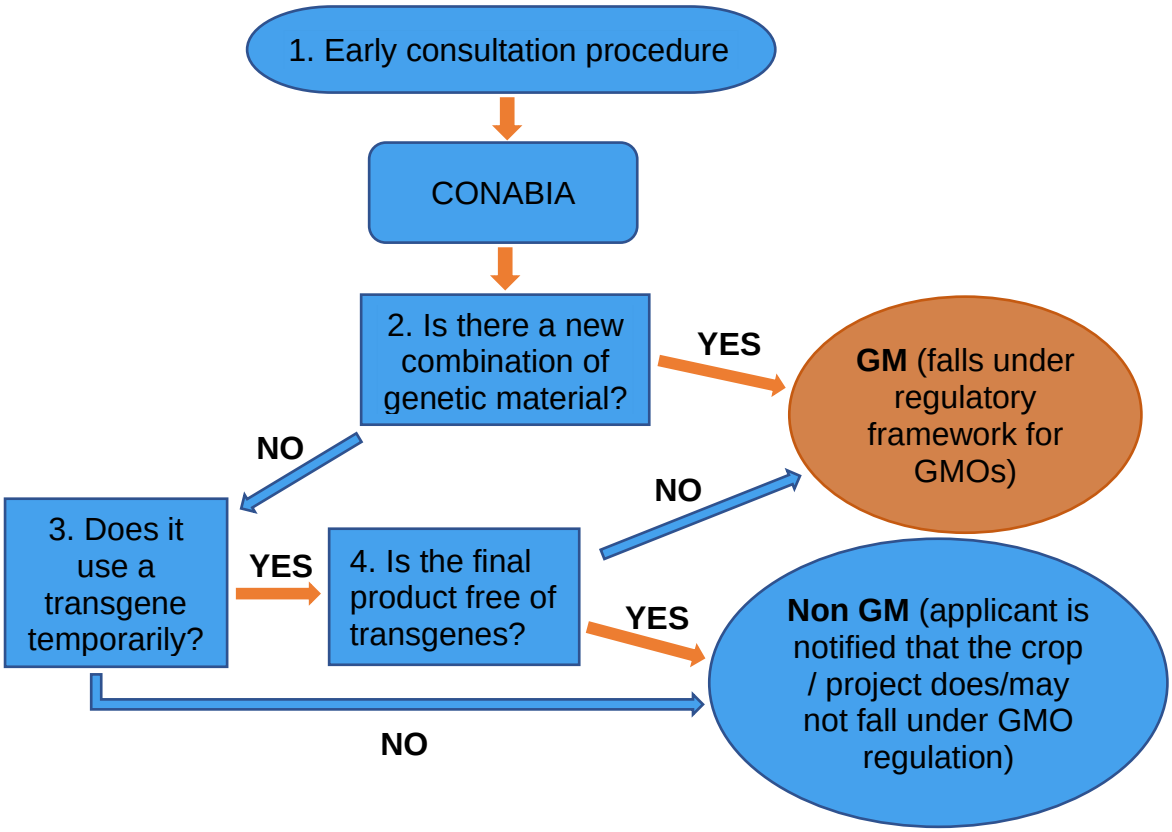
Resolution No. 44/2019 on contained and confined release provides the following additional definitions:

- Regulated material – seed and/or biomass of a regulated plant GMO, including materials that presumably contain them and those that are not GMOs but are present in the regulated area.
- Regulated plant GMO – plant GMO belonging to species for agroindustrial use and/or modified for agroindustrial uses and/or that could be released into the agroecosystem, containing events that do not have authorisation for commercial use.
- Release (of plant GMO) – the introduction of a regulated plant GMO into the agroecosystem.

2.2.4 Scope of regulation

Resolution No. 36/2019 includes the procedures to determine when a crop, obtained from new improvement techniques that use modern biotechnology, is outside the regulatory framework of Resolution No. 763/2011 and its implementing regulations (see **Figure 1**).

Figure 1. Flow chart diagram for new improvement technique applications to determine regulatory status in Argentina



Source: A. Whelan (2018)

To be potentially exempt, the interested party must carry out a pre-submission consultation step, in which they will provide information on the improvement methodology used to obtain and select the crop, on the new trait or characteristic introduced, and evidence of the genetic changes present in the final product. CONABIA will issue an opinion on whether the result of the improvement process meets the definition of plant GMO and, consequently, is covered by the regulatory framework for GMOs.

For a genetic change to be considered a new combination of genetic material, it will be analysed whether there has been an insertion in the genome of a defined genetic construct. Any plant descended from a GM plant will be presumed to be a GM plant unless a contrary conclusion is reached on the basis of scientific information.

Equally, **Resolution No. 63/2019** provides that, for GM animals and GM animal biological material with reproductive capacity obtained using new improvement techniques that use modern biotechnology and the accumulation of biotechnological events, CONABIA will analyse during the pre-submission consultation step, on a case-by-case basis, whether a new combination of genetic material has been generated. CONABIA will also assess whether there is sufficient scientific evidence on the absence of the event(s) temporarily employed during the process of obtaining the animal.

Under both Resolutions, in the event that CONABIA decides that a new combination of genetic material has not been generated and, if applicable, that there are no unauthorised events in the plant or animal, SAYBI will inform the interested party that their product is outside the scope of Resolution No. 763/2011 and its implementing regulations. Therefore, such product would not be regulated as a GM plant or GM animal.

Even if exempt from GMO regulations, CONABIA may recommend to SAYBI, on the basis of a scientific-technical justification, that a special monitoring would be done regarding the plant or animal analysed when characteristics and/or its novelty so merit.

The Resolutions provide for the possibility to make preliminary enquiry still in the development stage, and also establish that accumulations of previously authorised events with low probability of synergism will not require a new authorisation prior to commercialisation.

Similar provisions regarding the exclusion from being regulated as a GMO are contained in **Resolution No. 52/2019** for GM microorganisms.

Therefore, gene-edited crops/animals and foods that do not contain foreign DNA are regulated as conventional counterparts, but only after a dossier on the specific event is submitted to CONABIA to determine if it is exempt.

2.2.5 Processes

All activities that involve GMOs to be used for agro-industrial purposes or in the agricultural context require prior authorisation from SAYBI.

In order to obtain this authorisation, the interested parties must present the corresponding form duly prepared and accompany the documentation that is required, according to the type of activities that are intended to be carried out. They must also designate a legal representative and a technical representative, who will sign the form. The data provided in the application form has the character of a sworn declaration.

All the detailed activities must be carried out under controlled conditions through the application of biosafety measures stipulated by the Directorate of Biotechnology and CONABIA.

2.2.5.1 Contained or confined activities (regulated GM plants)

The procedure for obtaining authorisation for contained or confined activities with regulated GM plants is detailed in Annex I of **Resolution No. 44/2019**.

Pre-submission consultations can be requested. Requests for consultations must be presented to the Directorate of Biotechnology to be evaluated by CONABIA. Both the Directorate and CONABIA may request additional information. All such consultations must conclude within 60 working days unless additional information or documentation is requested.

To apply for authorisation, the applicant must have a current registration in the National Registry of Operators with Genetically Modified Plant Organisms (RNOOVGM). Each applicant is limited to one application per crop (species) per calendar year. Applications must be submitted at least 4 months in advance.

Evaluations are conducted by CONABIA and the Directorate of Biotechnology on a case-by-case basis. The authorities must resolve the application within 80 working days, if the period is not extended or restarted.

If CONABIA's opinion is not received within the indicated period, the principle of "silence in favour of the company" applies. The company may submit to the Directorate of Biotechnology their calculation of the period and request to be informed about the status of CONABIA's opinion. The Directorate must formally reply within 2 working days.

If the deadline is met and the opinion is favourable, the applicant may start the activities but first must submit a notification to INASE four working days in advance, in order to allow inspections.

2.2.5.2 Unconfined activities/commercial release

According to **Resolution No. 763/2011**, authorisations for the commercialisation (i.e. deregulation) of GMOs are granted by SAYBI, based on the technical reports prepared by three competent authorities and their advisory commissions, each addressing the aspects of biosafety, food safety, and impacts on production and commercialisation.

CONABIA, with the support of the Directorate of Biotechnology, evaluates, from a technical and scientific perspective, the potential impact to the environment of the introduction of GMOs into Argentine agriculture.

CTAUOGM of SENASA conducts a technical safety assessment of food products derived from GMOs for human and animal consumption.

SSMA analyses the approval status of the event under study in key destination markets to determine if the addition of this event to Argentina's export supplies might restrict access to these markets. SSMA has 45 days to finish impact evaluation. In

many cases, commercialisation is only authorised if approval is received from the importing country's authorities.

2.2.5.3 Commercial release (GM plants/animals)

Under **Resolution No. 36/2019** and **Resolution No. 63/2019**, CONABIA conducts a risk assessment on a case-by-case basis with the objective to determine and evaluate the possible adverse effects of the release of plant or animal GMOs into the agroecosystem, including the effects on the conservation and sustainable use of biological diversity, taking into account the risks to human health from non-food exposure. The competent authorities will use risk analysis to make informed decisions regarding the commercial authorisation of plant or animal GMOs.

Pre-submission consultations can be requested. Consultations for plant or animal GMOs must be completed within 80 working days unless additional information or documentation is requested.

Once the application is submitted, CONABIA, with the assistance of the Directorate of Biotechnology, evaluates the scientific-technical aspects involved. The applicant may be contacted, if questions, observations, or need for clarification arise.

Notably, the application must include a description of the best and most up-to-date analytical methods available to specifically detect the events included in the application, as well as the reference materials and other materials needed for the method. The applicant also commits to provide required materials if requested by the authorities.

The evaluation must be completed within 180 working days from the date of submission of the application to the Directorate of Biotechnology.

Once the evaluation is completed, the Directorate of Biotechnology and CONABIA will jointly issue a Decision Document in which the relevant aspects of the plant or

animal GMO will be described – the results of risk assessment and, if new or increased risks are identified, a proposal for risk management and communication.

The Decision Document is a non-binding technical opinion for the use of the authorising authority (SAYBI). In itself, the document does not confer any permission or rights, nor does it modify the regulated status of plant or animal GMOs.

The draft Decision Documents generated by CONABIA are made public for 60 days for the purposes of receiving technical, non-binding comments from anyone residing in Argentina. CONABIA may consider the relevant comments before finalising the Decision Document. Once final, the Decision Document is sent to SAYBI and the applicant. SAYBI makes the final decision on whether to authorise it or not.

In the case of events that contain genetic constructs identical or essentially similar to those incorporated in other plant or animal GMOs that already have a risk assessment concluded with a favourable Decision Document, the evaluation may be carried out on a case-by-case basis with the focus on establishing the absence of new or increased risks with respect to the plant or animal GMO previously evaluated.

2.2.5.4 Commercial release (GM microorganisms)

Regulatory provisions for the biosecurity evaluation of GM microorganisms for agroindustrial purposes or uses in the agricultural context stipulated in **Resolution No. 52/2019** are comparable to the above except that the applications have to be submitted via electronic portal to SENASA. Corresponding Directorate within SENASA will complete the assessment within their expertise and forward the file to the Directorate of Biotechnology, who will forward the request to CONABIA or to Advisory Committee on Bio-inputs for Agricultural Use (CABUA), as appropriate.

2.2.5.5 GM food

SENASA has the authority to evaluate the risks to human and animal health of food derived from GMOs. The risk evaluation includes an assessment of whether such food is harmful, its nutritional characteristics, and a comparison between the GM-

derived food and its conventional counterpart. For a GM-derived food to be approved, it must be as safe and nutritious as conventional food already in the market. As new scientific and technical information becomes available, the food's risk assessment is re-evaluated accordingly.

Detailed requirements, forms, and procedures for the safety assessment of food derived from GMOs are included in Annexes II and III of **Resolution No. 412/2002**.

In the assessment, the concept of substantial equivalence is used to identify similarities and differences between the food derived from a GMO and its conventional counterpart, which has a history of safe use as food.

2.2.6 Regional restrictions

No information found.

2.2.7 Labelling

Currently, Argentina has no regulations regarding mandatory labelling of GM products. It is the government's official position that GM foods that are substantially equivalent to a conventional food should not be subject to any different labelling requirements.

2.2.8 Traceability

There is no official traceability system in place.

Some testing for GM material is conducted under the voluntary **Bolsatech** program for the purposes of intellectual property rights.

Testing methods and reference materials must be provided to the authorities as part of the application procedure. The applicants commit to provide materials needed for testing later on request as part of the application.

Resolution No. 147/2016 established the procedure to submit for approval the methods of control, sampling and/or analysis that are used in the trade of grains intended for detection and identification of DNA and quantification of specific proteins.

2.2.9 Low level presence policy

Argentina endorsed the International Statement on Low Level Presence and participates in the Global Low-Level Presence Initiative. It also signed an **agreement** with Brazil, Canada, and the United States on LLP.

It is the first country to address LLP issue in its regulations. **Resolution No. 26/2018** (SAYB) establishes a temporary procedure to grant commercial authorisation for GMOs to be used as a raw material for agro-industrial processing and as a human food or an animal feed but not for sowing and marketing of seeds.

Authorisations under this procedure would only cover GMOs authorised in third countries and authorised for confined activities in Argentina. For situations where only low level presence of the GMO is expected, Article 6 of the procedure refers to **OECD Guidelines** and Annex 3 of Codex Alimentarius Guideline **CXG 45-2003** for recommendations.

Also, **Resolution No. 23/2019** (Mercosur) establishes the mechanism to reduce the occurrence of LLP of GMOs in the Member States. Under this resolution, any new authorisation of a GMO for human food or animal feed use must be notified to other Member States within 30 days of authorisation. The notifying Member State must also send risk assessment report, information on the approval status in the main export markets, and non-confidential part of the information submitted by the applicant. For the implementation of this mechanism, the developers of the authorised event must have previously submitted the request for commercial evaluation of the product in the other Member States.

2.2.10 Monitoring/enforcement

Compliance with the biosecurity measures for authorised releases is monitored by INASE and SENASA, who can order actions to avoid adverse effects to the environment.

2.2.11 Products on the market

Commercially authorised products currently include corn, soy, cotton, safflower, alfalfa.

Recently, drought-resistant GM wheat was **authorised** as well, despite the concerns that it may disrupt the exports of wheat. However, commercialisation is contingent on Brazil's approval as the main export market for Argentinian wheat.

2.2.12 Summary

Argentina has a very well-defined regulatory system for GMOs that is predominantly product-oriented with the main focus on new traits rather than on the process used to obtain the product. Risk assessments are carried out in a timely and efficient manner on a case-by-case basis using scientific-technical criteria, and the final product is regulated rather than the process by which the GMO was developed. The breeding method is taken into consideration only in those instances where the environment, agricultural production, or human or animal health could be at risk.

The techniques used may still play an important role considering that one of the three evaluations required for the authorisation for commercial release relates to assessing the impact a commercialised GMO will have on Argentina's trade with other countries – it is unlikely to be approved if it may negatively affect exports.

For products obtained through the use of new breeding techniques, a consultation procedure is established on a case-by-case basis to consider whether a new organism obtained by these techniques is regulated as GMO or not. As there is no definitive list of new breeding techniques included in the legislation, the approach is flexible enough to potentially accommodate any future techniques.

CONABIA and the Directorate of Biotechnology are main competent authorities for all activities related to biotechnology as both collectively conduct the risk assessment, design biosecurity measures, and decide on risk management options, if necessary. The final decision on the authorisation is with the Secretariat for Food and Bioeconomy of the Ministry of Agriculture, Livestock, and Fisheries.

While the Directorate of Biotechnology sits within the government, CONABIA includes representatives from various government institutions, universities, and industry associations involved in agricultural biotechnology. Therefore, CONABIA tends to be rather favourable to the use of biotechnology in Argentina.

When conducting risk assessment of genetic constructs identical or essentially similar to those incorporated in other plant or animal GMOs that already have a risk assessment concluded with a favourable Decision Document, the focus could be on the possibility of new or increased risks with respect to the plant or animal GMO previously evaluated.

Once the GMO is approved for commercial release, it would still need to be evaluated by the relevant agency depending on the intended use. SENASA is responsible for evaluating the safety of GM food to human and animal health. In the assessment of GM food, the concept of substantial equivalence is used to identify similarities and differences between the food derived from a GMO and its conventional counterpart with a history of safe use as food.

In 2019, the regulatory system was significantly modernised to provide for even more flexibility and quicker turnaround. The update permits the Directorate of Biotechnology to address the aspects of implementation via complementary and interpretive Provisions. This appears to have helped with speeding up establishing and updating the practical provisions for certain processes.

2.3 Australia

2.3.1 Competent authorities

The **Gene Technology Regulator** (the Regulator) is an independent statutory office holder that administers the regulation of all dealings with GMOs (animals, plants, microorganisms etc.) in Australia and ensures compliance with the conditions of any approvals by undertaking monitoring, audits, inspections, and investigations. The Regulator is appointed by the Governor General of Australia only with the agreement of the majority of all jurisdictions (States and Territories). The appointment is for a period of 5 years. The Regulator is supported by the Office of the Gene Technology Regulator (OGTR) which is part of the Department of Health.

The gene technology regulatory scheme is overseen by the Commonwealth, State, and Territory governments through the **Legislative and Governance Forum on Gene Technology** (LGFGT). The **Gene Technology Standing Committee** (GTSC), composed of senior officials from all jurisdictions, provides high-level support to the LGFGT.

Several other Australian government agencies also oversee work with GM products, depending on the use. For instance, **Food Standards Australia New Zealand** (FSANZ) is responsible for setting standards for the safety, content, and labelling of foods. FSANZ also is the central competent authority coordinating the approval process, undertaking the risk-based assessment of applications for foods produced using gene technology, consulting the public on the proposed measure, and amending the list of permitted GM foods for both Australia and New Zealand.

The Australian Pesticides & Veterinary Medicines Authority (APVMA) regulates the use of GM products as pesticides or animal medicines.

The **Department of Agriculture, Water and the Environment** (DAWE) regulates the importation into Australia of all animal, plant and biological products that may pose a quarantine pest and/or disease risk.

While compliance with Australia's legislation on GM products is mostly monitored by the OGTR, additional monitoring and enforcing of relevant legislation is done by State and Territory governments as well as local councils.

2.3.2 Key legislation

Australia applies a process-based approach to regulating products of gene technology. The lists of which techniques constitute or do not constitute gene technology and whether derived organisms are or are not genetically modified organisms are periodically reviewed by the Regulator.

The nationally consistent legislative scheme for gene technology is comprised of the Australian Commonwealth **Gene Technology Act 2000** and **Gene Technology Regulations 2001**, and corresponding State and Territory legislation.

Standard 1.5.2 of the Australia New Zealand Food Standards Code prohibits the sale of a food produced using gene technology or containing an ingredient produced using gene technology unless the food is listed in **Schedule 26** of the Code or is permitted in the Code for use as a food additive or processing aid. The standard also establishes labelling requirements for food produced using gene technology.

Food entering Australia is subject to the **Imported Food Control Act 1992**, which provides for the inspection and control of imported food using a risk-based border inspection program called the Imported Food Inspection Scheme (IFIS), unless the food importer has entered into a food import compliance agreement (FICA) with the DAWE.

GM products used as pesticides or animal medicines are subject to additional requirements under the **Agricultural and Veterinary Chemicals (Administration) Act 1992**.

2.3.3 Definitions/terminology

Gene Technology Act 2000 provides the following important definitions:

“gene technology” means any technique for the modification of genes or other genetic material, but does not include:

a) sexual reproduction; or
b) homologous recombination; or
c) any other technique specified in the regulations for the purposes of this paragraph.

“genetically modified organism” means:

a) an organism that has been modified by gene technology; or
b) an organism that has inherited particular traits from an organism (the initial organism), being traits that occurred in the initial organism because of gene technology; or
c) anything declared by the regulations to be a genetically modified organism, or that belongs to a class of things declared by the regulations to be genetically modified organisms;

but does not include:

d) a human being, if the human being is covered by paragraph (a) only because the human being has undergone somatic cell gene therapy; or
e) an organism declared by the regulations not to be a genetically modified organism, or that belongs to a class of organisms declared by the regulations not to be genetically modified organisms.

“organism” means any biological entity that is:

a) viable; or
b) capable of reproduction; or
c) capable of transferring genetic material.

“GM product” means a thing (other than a GMO) derived or produced from a GMO.

“deal with”, in relation to a GMO, means the following:

a) conduct experiments with the GMO;
b) make, develop, produce or manufacture the GMO;

c) breed the GMO;
d) propagate the GMO;
e) use the GMO in the course of manufacture of a thing that is not the GMO;
f) grow, raise or culture the GMO;
g) import the GMO;
h) transport the GMO;
i) dispose of the GMO;

and includes the possession, supply or use of the GMO for the purposes of, or in the course of, a dealing mentioned in any of paragraphs (a) to (i).

For the purposes of regulating GM food, **Standard 1.5.2** defines the following:

“gene technology” means recombinant DNA techniques that alter the heritable genetic material of living cells or organisms.

“food produced using gene technology” means a food which has been derived or developed from an organism which has been modified by gene technology.

Note: This definition does not include food derived from an animal or other organism which has been fed food produced using gene technology, unless the animal or other organism is itself a product of gene technology.

“genetically modified food” means a food produced using gene technology that contains novel DNA or novel protein or is listed in Section S26—3 as subject to the conditions that its labelling must comply with this section.

“novel DNA” and “novel protein” mean DNA or protein which, as a result of the use of gene technology, is different in chemical sequence or structure from DNA or protein present in counterpart food that has not been produced using gene technology, other than protein that is used as a processing aid or used as a food additive, and has an amino acid sequence that is found in nature.

2.3.4 Scope of regulation

Techniques excluded from the definition of "gene technology" under paragraph (c) are listed in **Schedule 1A** of the Gene Technology Regulations 2001. The list includes chemical or radiation induced mutagenesis, fusion of animal or human cells as long as the fused cells are unable to form a viable whole animal or human, protoplast fusion, *in vitro* fertilisation, natural processes that do not involve GM material (e.g. conjugation, transduction, transformation, transposon mutagenesis), and other techniques.

Introduction of RNA into an organism is also not considered a gene technology as long as the RNA does not translate into a polypeptide, does not alter the organism's genome sequence, and does not give rise to an infectious agent.

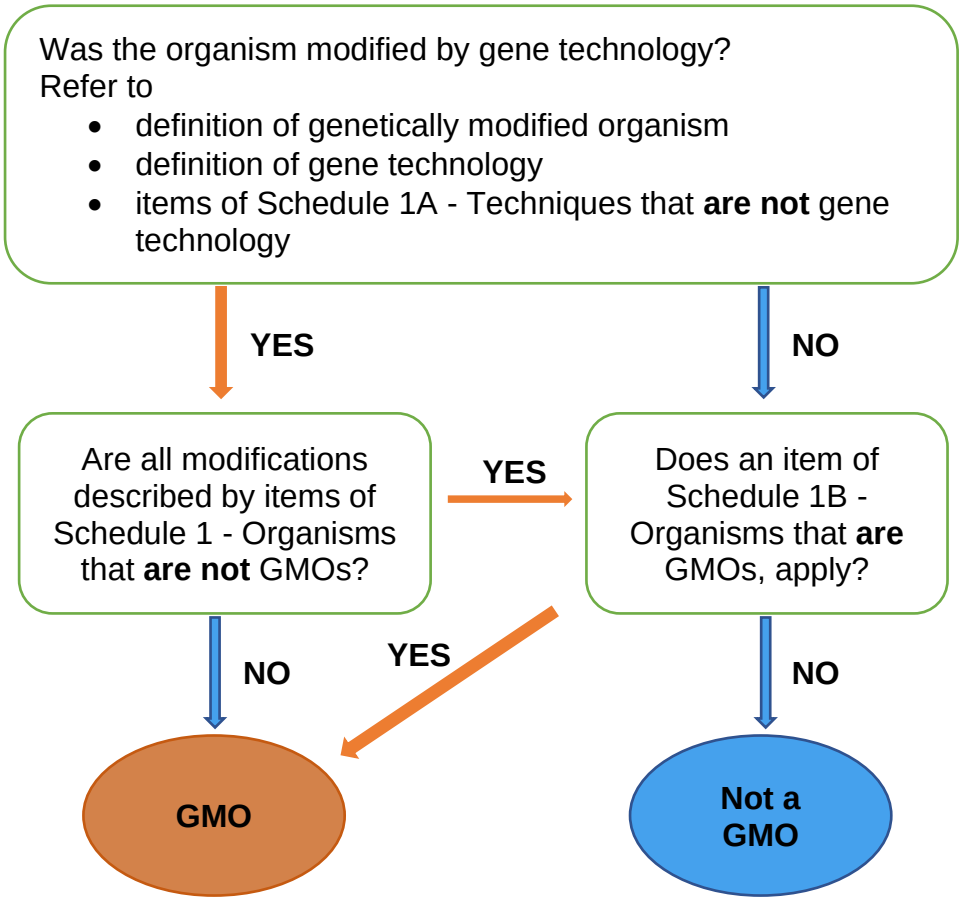
For the purposes of the paragraph (c) in the definition of "genetically modified organism", **Schedule 1B** of the Gene Technology Regulations 2001 specifically lists the following as a GM organism:

- an organism that has had its genome modified by oligonucleotide-directed mutagenesis;
- an organism modified by repair of single-strand or double-strand breaks of genomic DNA induced by a site-directed nuclease, if a nucleic acid template was added to guide homology-directed repair.

Schedule 1 of the Gene Technology Regulations 2001 lists organisms that are declared not to be a genetically modified organism under the paragraph (e) of the definition of "genetically modified organism" as long as the organism has not been modified by gene technology, has not inherited any traits (except Item 9 in Schedule 1) that occurred because of gene technology, and none of the items in Schedule 1B applies.

The diagram in **Figure 2** summarises the approach of the Gene Technology Regulator in considering whether an organism is in scope of the regulations to being determined as a GMO or not.

Figure 2. Flow chart diagram to determine whether an organism is classed as a GMO in Australia



Source: [Office of the Gene Technology Regulator]

The Gene Technology Regulations 2001 are periodically reviewed to provide clarity regarding the new techniques. The Regulator determines after consultations on a case-by-case basis if a specific new genetic modification process and the products derived from such new process is subject to GMO legislation or not.

As an example, the latest **amendments** to the Gene Technology Regulations 2001 excluded SDN-1 organisms from regulation provided that no nucleic acid template was added to cells to guide genome repair following site-directed nuclease application, and the organism has no other traits from gene technology (e.g. cas9 transgene, expressed SDN protein).

The method used to modify an organism is the central consideration in determining whether or not the organism is a GMO. Thus, techniques that are similar to SDN-1 but do not meet the SDN-1 exclusion are not currently excluded from regulation.

Similarly, the scale of resulting nucleotide changes, whether an insertion or deletion, or whether the resulting nucleotide sequence may be found in sexually compatible species, is not a deciding factor.

Notably, such changes to the Commonwealth gene technology legislation are not adopted into the gene technology legislation of States and Territories automatically. Therefore, there might be temporary differences between the Commonwealth and State/Territory legislation.

FSANZ is also **reviewing** how the Food Standards Code applies to food derived using new breeding techniques (NBTs). The final report recommends:

- to revise and modernise the definitions in the Code to make them clearer and better able to accommodate existing and emerging genetic technologies;
- give consideration to process and non-process based definitions and the need to ensure that NBT foods are regulated in a manner that is proportionate to the risk they pose;
- ensure open communication and active engagement with all interested parties and also explore ways to raise awareness about GM and NBT foods.

The public consultation on the new proposal was delayed due to COVID-19.

2.3.5 Processes

Part 4 of the **Gene Technology Act 2000** prohibits all dealings with GMOs unless:

- the person undertaking the dealing is authorised to do so by a GMO licence;
- the dealing is exempt dealing;
- the dealing is a notifiable low risk dealing;
- the dealing is included on the GMO register; or
- the dealing is specified in an emergency dealing determination.

This defines the different pathways to legally deal with GMOs.

There are two types of licences:

- Dealings NOT involving an Intentional Release (DNIR) of GMOs into the environment are dealings with GMOs in contained facilities which do not meet the criteria for classification as Exempt Dealings or Notifiable Low Risk Dealings (NLRDs);
- Dealings involving an Intentional Release (DIR) of GMOs into the Australian environment are dealings with GMOs which take place outside of containment facilities.

2.3.5.1 Exempt dealings

Exempt dealings are a category of dealings with GMOs that have been assessed over time as posing a very low risk (i.e. contained research involving very well understood organisms and processes for creating and studying GMOs) and are therefore exempt from licencing.

The only legislative requirement for exempt dealings is that they must not involve an intentional release of a GMO into the environment. There are no requirements to report exempt dealings to the Regulator.

Exempt dealings, including host/vector systems for exempt dealing, are described in **Schedule 2** of the Gene Technology Regulations 2001.

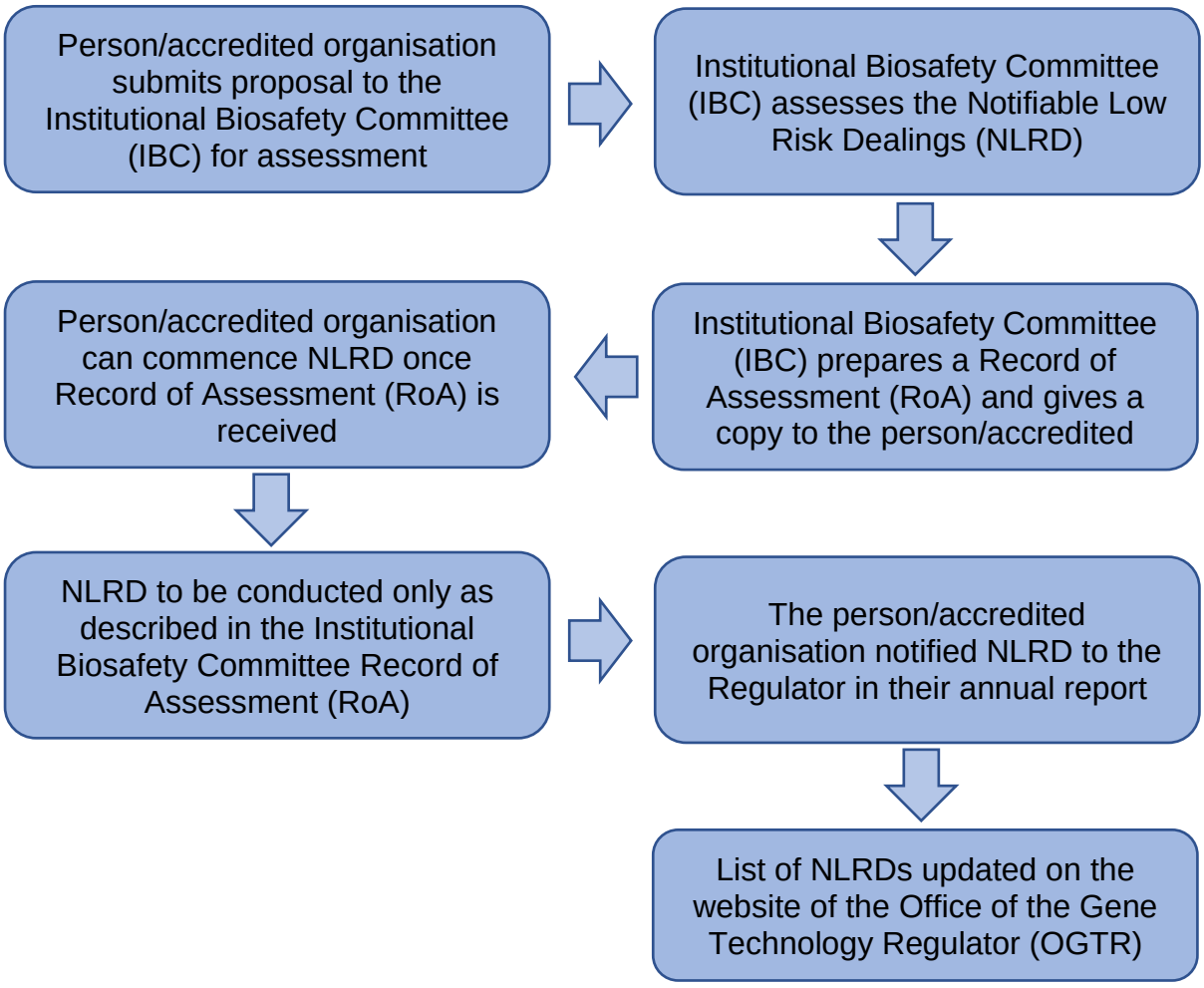
2.3.5.2 Notifiable Low Risk Dealings (NLRDs)

Notifiable Low Risk Dealings are activities with GMOs undertaken in containment that have been assessed as posing low risk to the health and safety of people and the environment provided certain risk management conditions are met.

The types of dealings with GMOs classified as NLRDs are specified in **Schedule 3** of the Gene Technology Regulations 2001.

An NLRD may only be undertaken after it has been assessed as being an NLRD by an **Institutional Biosafety Committee** (IBC) established by an accredited organisation. Once IBC prepares a Record of Assessment, the NLRD can commence but must notify the Regulator of any NLRDs assessed during the financial year in an annual report. The list of NLRDs is then updated on the OGTR website.

The process involves a series of steps for registering and approving Notifiable Low Risk Dealings (NLRDs) activities at a premise.



Source: **Office of the Gene Technology Regulator**

The list of NRLDs notified to the Regulator can be found on the OGTR **website**.

2.3.5.3 Dealings NOT involving an Intentional Release (DNIR licences)

DNIRs are dealings with GMOs in contained facilities that do not meet the criteria for classification as either exempt dealings or NLRDs. According to **Part 3, Schedule 3** of Gene Technology Regulations 2001, DNIRs are considered higher risk dealings than NLRDs and therefore must be licenced by the Regulator.

In general, DNIRs often involve work with GM pathogenic organisms, or GMOs containing higher risk genes from pathogens or genes that encode toxins or confer an oncogenic modification or immunomodulatory effect.

Once a DNIR application is received, the Regulator has 90 working days to make a decision to either issue, or refuse to issue, a licence for the dealings proposed in a DNIR application. This period does not include any days in which the Regulator is seeking further information from the applicant in relation to the application.

The containment facilities used for conducting DNIRs are generally certified by the regulator. The risk group classification of the non-GM parent organism and the risks identified for dealings with the specific GMO will determine the appropriate level of containment. DNIR licences issued by the Regulator specify the facilities in which the dealings may be conducted.

The list of DNIR applications and licences can be found on the OGTR **website**.

2.3.5.4 Dealings involving an Intentional Release (DIR licences)

DIR licences can be issued for experimental field trials (limited and controlled releases), for general/commercial releases of GM plants, or for some other purposes. The release of GM animals would also require a DIR licence.

The process that the Regulator must follow in making a decision about whether or not to issue a licence is established in **Sections 40-67** of the Gene Technology Act 2000. The overall summary of the evaluation process of DIR applications is provided in the **fact sheet**.

The completed **application form** must include supporting information provided by an IBC established by an accredited organisation, usually the organisation applying for the licence.

The Regulator notifies the public of the DIR application being received.

Each DIR licence application is subject to a comprehensive, science-based, case-by-case analysis process. After receiving the application, the Regulator must prepare a risk assessment and risk management plan (RARMP) and make a decision about whether or not to issue a licence.

Each application's prepared RARMP identifies risks to human health and safety, and to the environment, posed by the dealings with GMOs proposed in the application. It also addresses risk management measures (that would be covered by the licence conditions) to manage any identified risks.

In evaluating the DIR application and preparing a RARMP, the Regulator consults with all State and Territory governments, relevant local councils, Australian government departments and agencies (i.e. DAWE, FSANZ, APVMA etc.), the Commonwealth **Minister for the Environment**, and the **Gene Technology Technical Advisory Committee**.

After the draft RARMP is prepared, the Regulator invites submissions about the RARMP from the above groups as well as the public for at least 30 days.

The RARMP is then finalised taking into account advice received on risks to human health and safety and the environment. The final RARMP informs the Regulator's decision to issue or refuse to issue a licence.

The Regulator must decide whether to issue a DIR licence within 255 working days. For limited and controlled release applications, the decision must be made within 150 working days, or, if significant risk is identified, within 170 working days.

The list of DIR applications and authorisations can be found on the OGTR **website**.

As stated in the **fact sheet** on ongoing monitoring of the safety of GM crops in Australia, a risk analysis may be reviewed at any time if there are questions about the ongoing safety of a particular GM crop. The OGTR also reviews the risk analysis for every commercial GM crop after the crop has been grown in Australia for some time. Often, risk analysis reviews are done while evaluating a new variety of GM crop, developed from a previous variety that was approved by the regulator.

2.3.5.5 Dealings included on the GMO register

Licensed dealings with GMOs may be placed on the **GMO Register** if any risks posed by the dealing are minimal, and the Regulator is satisfied that the dealings are sufficiently safe to be undertaken by anyone without the need for a licence.

The Regulator will be satisfied that the risks are minimal if the risk estimates of identified risks are low or negligible, or if there are no identified risks.

2.3.5.6 Emergency Dealing Determinations (EDD)

An **Emergency Dealing Determination** is a legislative instrument made under Part 5A of the Gene Technology Act 2000. The emergency provisions of the Act give the Minister of Health the power to expedite an approval of dealings with a GMO in an emergency. This is usually used for vaccines (see **list of EDDs**).

2.3.5.7 GM pesticides and veterinary medicines

Under the **Agricultural and Veterinary Chemicals (Administration) Act 1992**, the APVMA is required to **consult** with the Regulator before deciding whether to approve an active constituent, register an agricultural and veterinary chemical product, approve a label, vary or reconsider any approvals or registrations, or issue a permit for a GM product, and any advice given by the Regulator must be taken into account.

2.3.5.8 GM feed

Feed from approved Australian-grown GM crops (currently, canola, cotton, and safflower) may be fed to animals. Unprocessed GM products imported as feed (e.g. whole grain) would require a license from the Regulator, as there is a possibility that seed could be released into the environment.

Livestock may not be fed material from GM crop trials, unless specifically approved by the Regulator.

Processed animal feeds are currently not covered by gene technology legislation and do not require prior approval or a license from the Regulator to be imported.

2.3.5.9 GM food

Foods produced using gene technology are regulated under **Standard 1.5.2** of the Food Standards Code. This standard provides for the mandatory pre-market approval (including a food safety assessment). A GM food can only be sold legally in Australia or New Zealand if it has been assessed, found to be safe and approved by FSANZ. Approved GM foods are listed in **Schedule 26** of the Food Standards Code.

Not every approved GM food enters the market as food. Many GM crops approved for use as food, are actually grown for animal feed.

The producer of the GM food must apply to FSANZ for the food to be approved at the commodity level. Until food from a particular commodity has been approved,

products containing food or ingredients derived from that commodity cannot be sold lawfully.

FSANZ encourages contacting them for **pre-application assistance** before formally submitting an application.

The application process is summarised in Part 2.2 of the **Application Handbook**. First, an administrative assessment is conducted on whether to accept the application (up to 15 working days). Once the application is accepted, the applicant is notified, and an early bird notification is published (within the next 20 working days).

GM food applications are likely to be assessed under the general procedure which is the default assessment procedure. It is described in Part 2.2.5 of the Application Handbook. It involves at least one round of public comment and takes up to 9 months from commencement of assessment to the date of approval of the draft food regulatory measure. The clock can be stopped for further information OR while awaiting policy guidelines or principles from the Forum.

Once the draft food regulatory measure is approved, it is published and notified to the **Australia and New Zealand Ministerial Forum on Food Regulation** (Forum) within 10 working days. The Forum then has one opportunity within 60 days, by majority decision, to request a review of a decision made by FSANZ. Following the review by FSANZ, the Forum has again 60 days to either not object, amend the draft, or reject the draft. The New Zealand government may also ask FSANZ to review its decision to approve a variation to a standard on certain grounds.

FSANZ gazettes the standard and registers it as a legislative instrument. Gazettal occurs after FSANZ decisions on standards are considered by the Forum. Gazetted standards or variations are adopted automatically, by reference and without amendment, into Australian state and territory food laws.

The whole process generally takes at least 12 months.

Detailed requirements for the information that is required to support an application for a GM food as well as practical information on the procedure for making an application to FSANZ to vary the code are provided in Guideline 3.5.1 and Part 2.3 of the **Application Handbook**. The safety assessment process used by FSANZ is described in detail in a booklet on the **Safety Assessment of Genetically Modified Foods**.

In conducting **safety assessment** of a GM food, FSANZ aims:

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

Each GM food is assessed on a case-by-case basis. Both the intended and unintended effects of the genetic modification are considered. GM food is compared with conventional foods having an acceptable standard of safety, focusing on the identification of similarities and differences between the GM food and an appropriate comparator, and a characterisation of any of the identified differences in order to determine if they may raise potential safety and nutritional issues.

The safety assessment does not aim to establish the absolute safety of the GM food but rather to consider whether the GM food is comparable to the conventional counterpart food, i.e., that the GM food has all the benefits and risks normally associated with the conventional food.

Since the responsibility for demonstrating the safety of the new GM food lies with the developer, FSANZ does not conduct own independent testing of GM foods. Instead, FSANZ conducts a thorough analysis of the data submitted in the application and of the protocol used to ensure the validity of results. If FSANZ determines that the data are not sufficient, additional information and testing may be requested. FSANZ may

also supplement the information provided by the applicant with any published data that is relevant to the product in question.

2.3.6 Regional restrictions

Several States and Territories had moratoria in place delaying the commercial release of GM crops that are fully licenced by the Regulator. Most are already lifted.

The moratoria that remain are in Tasmania (extended until 2029) and the Australian Capital Territory. New South Wales maintains a moratorium but only on the growing of GM food crops (until 2021).

2.3.7 Labelling

According to **Standard 1.5.2**, a food for sale that is produced using gene technology must include the statement “genetically modified” in conjunction with the name of the GM food.

If the GM food is an ingredient, or is used as a food additive or a processing aid and novel DNA or novel protein from food additive or processing aid remains present in the food, the information that it is genetically modified may be included in the list of ingredients.

For a food for sale that is not in a package form, such information would need to be displayed in connection with the display of the food.

The standard provides the following exemptions:

- GM food that is highly refined to remove novel DNA or novel protein and has no specific conditions established in Schedule 26;
- GM processing aids and food additives with no novel DNA or novel protein remaining in the food;
- GM flavouring substances present in the food at ≤0.1% of food;
- GM food unintentionally present in the food at ≤1% of each ingredient;

- food prepared and sold for immediate consumption from food premises and vending vehicles.

According to **Standard 1.2.1**, food sold to caterers is not exempt from the requirement to be labelled as “genetically modified”.

Additional labelling and information requirements for GM foods that have “altered characteristics” are established in Schedule 26. This would be applicable to any GM foods that differ significantly from their conventional counterparts in terms of composition or nutritional values, cause allergic responses in particular segments of the population, or differ in their intended use.

Importantly, the definition of “gene technology” for the purposes of GM labelling in Standard 1.5.2 is limited to rDNA techniques. As a result, foods produced using any other gene technologies are not required to be labelled as genetically modified.

Claims such as "GM Free" are entirely voluntary but must not be misleading or deceptive.

2.3.8 Traceability

Standard 1.5.2 does not establish any specific requirements for traceability. Nonetheless, as stated in the **National Surveillance Program for Genetically Modified Foods**, majority of businesses in Australia have systems in place to demonstrate efforts to comply with the labelling provisions in the Standard. Verification processes may be required where the manufacturer chooses to make voluntary negative claims regarding the absence of GMOs.

According to FSANZ Application Manual, the dossier for foods produced using gene technology must include the information on the nature and identify of the genetically modified food, including the name, line number and OECD Unique identifier of each of the new lines or strains of GM organism from which the food is derived. Submitting test methods and/or reference materials with an application is not required.

2.3.9 Low level presence policy

While Australia **endorsed** the International Statement on Low Level Presence and participates in the Global Low-Level Presence Initiative, current legislation effectively imposes “zero tolerance” to LLP.

There is a risk-based national **strategy** in place for unintended presence of unapproved GMOs in seed for sowing developed by the inter-departmental Working Group on Unintended Presence. The OGTR is responsible for implementing the strategy and employs a risk management approach focusing on the areas posing the highest likelihood of unintended presence.

If a GMO is **found** in imported seed stock, the OGTR must be contacted as soon as possible. Once the Regulator is satisfied that a person has come into possession of a GMO inadvertently, the Regulator can issue a temporary **Inadvertent Dealing** licence, for no longer than 12 months, for the purpose of disposing of the GMO.

2.3.10 Monitoring/enforcement

The Regulator has substantial powers under the legislation as it includes provisions for compliance and enforcement of authorisations. These are **monitored** by the Monitoring and Compliance Section of the OGTR.

Australia also has a **National Compliance and Monitoring Strategy for Genetically Modified Foods**, which includes the elements of education, surveillance, complaint and incident response, communication, and evaluation.

According to the **Australia and New Zealand Food Regulation Compliance, Monitoring and Enforcement Strategy**, the monitoring and enforcement of food laws in Australia and New Zealand is done by Australian, State and Territory, and New Zealand government food regulators through their own Food Acts and other food related legislation taking a risk-based, graduated and proportionate approach. The DAWE enforces these laws at Australia’s borders in relation to imported food.

Under the **Trans-Tasman Mutual Recognition Arrangement** (TTMRA), signed between the Government of New Zealand and the Commonwealth, State and Territory Governments within Australia, goods that can be lawfully sold in one jurisdiction can also be sold in the others without having to satisfy additional requirements. This principle is captured in the **Trans-Tasman Mutual Recognition Act** 1997. Therefore, monitoring and enforcement in New Zealand also directly affects what's on the market in Australia. Only foods classified as "risk foods" would be subject to Imported Food Inspection Scheme.

2.3.11 Products on the market

Schedule 26 of the Code currently lists 79 distinct GM crop lines for food use. Of these, only GM canola and GM cotton are produced on a commercial agricultural scale in Australia. Foods derived from the remaining GM crop lines are approved in the Code as they could be present in imported foods.

The table of **authorisations** for commercial releases of GM plants lists 17 current authorisations for GM crops (canola, cotton, and safflower). The import of unauthorised unprocessed crops is prohibited.

In 2018, **GM cotton** accounted for over 99.5% of total area planted to cotton in Australia. In 2018, about 20% of the national **canola** crop was GM.

There are **currently** 35 active field trial licences for GM plants (chickpea, sorghum, banana, barley, perennial ryegrass, wheat).

2.3.12 Summary

The distinguishing quality of the gene technology regulatory scheme in Australia is that the regulation, monitoring, audits, inspections, and investigations of all dealings with GMOs is under the responsibility of a single independent statutory office of the Gene Technology Regulatory, acting as a central authority for all dealings with GMOs in Australia. The gene technology regulatory scheme, including the

appointment of the Regulator, is overseen by the Commonwealth, State, and Territory governments.

Another important aspect is that the Commonwealth legislation for gene technology does not automatically apply in all States and Territories – any update still needs to be incorporated into the corresponding State or Territory legislation. Therefore, sometimes there might be temporary differences between the legislation in the Commonwealth and various States or Territories. Also, States and Territories may choose to ban cultivation of federally approved GMOs on their territories.

Although the regulatory approach in Australia is very much process-oriented, unlike in the EU, the regulations are updated from time to time to reflect the progress in science. After consultations, the Regulator may determine on a case-by-case basis whether a specific new genetic modification process and the products derived from such new process is subject to GMO legislation or not. The main drawback is that it's a lengthy process to update regulations – it may take a number of years before the amendments fully enter into force and are also reflected in the corresponding legislation of States and Territories. On the positive side, the conclusion uniformly applies to all products produced using the same technique as long as the end result also meets the relevant conditions as opposed to what perhaps could happen in the case of individual consultation on a case-by-case basis.

Another distinguishing future of the regulatory system in Australia is that some of the dealings with GMOs can or must be assessed by an Institutional Biosafety Committee (IBC). For instance, notifiable low risk dealings (NLRD) with GMOs undertaken in containment under certain risk management conditions can be simply assessed as being NLRD by IBC and notified to the Regulator in an annual report.

Applications for intentional release must also include supporting information provided by an IBC. Each application for international release submitted to the Regulator is subject to a comprehensive, science-based, case-by-case analysis. The Regulator consults the prescribed experts, agencies, and authorities before preparing a risk assessment and risk management plan (RARMP) and also once the draft RARMP is

prepared. The process also includes a round of public comments. The Regulator has up to 255 working days to decide on whether to issue a licence for intentional release or not.

Of course, depending on the intended use of GMOs, other Australian government agencies may also need to get involved. As such, FSANZ would be responsible for the approval of foods produced using gene technology. Approval for food use according to the general procedure will take another year at least.

2.4 Brazil

2.4.1 Competent authorities

The National Biosafety Council (CNBS) is a superior advisory body under the Office of the President, made up of 11 Ministers of State, established with the objective of formulating and implementing the National Biosafety Policy. It establishes the principles and guidelines for the administrative actions of federal agencies and entities involved in biotechnology and may give opinion on certain aspects of requests for commercial release of GMOs and their derivatives.

The **National Technical Commission on Biosafety** (CTNBio) is a multidisciplinary collegiate body, providing technical advisory support to the Federal Government in the formulation. Among other things, it is responsible for establishing technical safety norms and procedures regarding the protection of human health, living organisms and the environment, for activities involving the construction, experimentation, cultivation, manipulation, transportation, commercialisation, consumption, storage, release and disposal of GMOs and derivatives.

The **Ministry of Science, Technology and Innovation** provides technical and administrative support to CTNBio. The Minister of State appoints 27 full members and 27 substitutes to CTNBio. All must be Brazilian citizens of recognised technical competence, with significant scientific knowledge and achievements, with a doctor's degree and an outstanding professional activity in the areas of biosafety, biotechnology, biology, human and animal health, and the environment.

The **Ministry of Agriculture, Livestock, and Food Supply** (MAPA) through its **Secretariat of Animal and Plant Health** (SDA/MAPA) is responsible for the actions of State concerning topics ranging from animal and plant health, to the quality and identification of agricultural inputs, and of animal and plant products and derivatives. MAPA issues authorisations and registrations and supervise products and activities that use GMOs and their derivatives for animal use, in agriculture, livestock, agroindustry and related areas.

The **Secretariat for Aquaculture and Fisheries** (SAP/MAPA) is responsible for authorisations and registrations of products and activities with GMOs and their derivatives intended for use in fishing and aquaculture.

National Health Surveillance Agency (ANVISA) under the Ministry of Health is the competent authority to issue authorisations and registrations and to inspect products and activities with GMOs and their derivatives intended for human consumption.

The **Ministry of the Environment** (MMA) issues authorisations and registrations and inspects products and activities involving GMOs and their derivatives to be released into natural ecosystems, and also deals with environmental licensing in cases where CTNBio determines that the activity is a potential cause of significant degradation of the environment.

Brazilian Institute of Environment and Renewable Natural Resources (IBAMA) under the Ministry of the Environment monitors and inspects the events and their impact on the environment.

2.4.2 Key legislation

Law No. 11,105/2005 (Biosafety Law) outlines the regulatory framework for activities involving GMOs and their derivatives. It sets safety standards and mechanisms for monitoring activities involving GMOs and their derivatives. It also created CNBS, restructured CTNBio, provided for the National Biosafety Policy, and included other measures.

Decree No. 5.591/2005 implements and clarifies the provisions of Law No. 11,105.

Decree No. 4,680/2003 regulates the right to information regarding foods and food ingredients intended for human consumption or animal feed that contain or are produced from GMOs.

Normative Resolution No. 1/2006 provides for the creation and functioning of Internal Biosafety Commissions (CIBios) and establishes criteria and procedure for requesting, issuing, reviewing, extending, suspending and cancelling of Biosafety Quality Certificates (CQB).

Normative Resolution No. 6/2008 establishes rules for the planned release into the environment of GMOs of plant origin and their derivatives.

Normative Resolution No. 7/2009 establishes rules for the planned release into the environment of risk class 1 GM microorganisms and GM animals and their derivatives.

Normative Resolution No. 16/2018 (in **English**) establishes the technical requirements for requesting opinion of CTNBio regarding the GMOs obtained through the use of innovative precision improvement techniques.

Normative Resolution No. 18/2018 establishes classification of risks of GMOs and the levels of biosafety to be applied in activities and projects with GMOs and their derivatives in containment.

Normative Resolution No. 21/2018 provides rules for commercial use activities of GM microorganisms and their derivatives.

Normative Resolution No. 23/2019 establishes simplified rules for the planned release into the environment of GMOs of risk class 1 that have previously been

approved by CTNBio for the purpose of experimental evaluations in planned releases.

Normative Resolution No. 24/2020 lays down the rules for commercial release and monitoring of GMOs and their derivatives.

2.4.3 Definitions/terminology

Law No. 11,105/2005 provides the following relevant definitions:

- "genetic engineering" – activity of production and manipulation of recombinant DNA/RNA molecules;
- "recombinant DNA/RNA molecules" – molecules manipulated outside living cells by modifying natural or synthetic DNA/RNA segments that can multiply in a living cell, or the DNA/RNA molecules resulting from this multiplication; synthetic DNA/RNA segments equivalent to natural DNA/RNA are also considered;
- "genetically modified organism" or "GMO" – organism whose genetic material (DNA/RNA) has been modified by any genetic engineering technique;
- "derived from GMOs" – product obtained from GMOs and which does not have autonomous capacity to replicate or which does not contain a viable form of GMOs.

Normative Resolution No. 6/2008 provides the following definition:

- "planned release" – release into the environment of a GMO of plant origin or its derivatives, for experimental evaluations under monitoring, according to the provisions of this Normative Resolution.

Normative Resolution No. 24/2020 provides the following additional term:

- "similar genetic construct" – non-identical genetic constructs whose differences do not result in changes in the identity of the expression products.

2.4.4 Scope of regulation

Law No. 11,105/2005 specifically excludes from the scope of GM regulation the following:

- mutagenesis;
- formation and use of somatic cells from animal hybridoma;
- cell fusion, including that of protoplasm, of plant cells, which can be produced using traditional culture methods;
- auto cloning of non-pathogenic organisms that occurs naturally.

Products developed using techniques that involve direct introduction of hereditary material into an organism, as long as these do not involve the use of recombinant DNA/RNA molecules or GMOs, including *in vitro* fertilisation, conjugation, transduction, transformation, polyploid induction and any other natural process are excluded from the definition of GMOs.

The category of “GMO derivatives” excludes pure, chemically defined substances obtained through biological processes as long as it does not contain GMOs, heterologous proteins or recombinant DNA.

In 2018, CTNBio published **Normative Resolution No. 16/2018** (in **English**), which includes a not exhaustive list of innovative precision breeding techniques (comprises new breeding techniques) that could generate a product that will not be considered as a GMO, as defined by Law No. 11,105/2005. To determine whether a product obtained using innovative precision breeding techniques and its derivatives would or not be considered a GMO, a letter of enquiry must be submitted to CTNBio. The product will be assessed on a case-by-case basis.

The products in question will have to demonstrate at least one of the below characteristics:

- a product proven to be free from recombinant DNA/RNA, that is obtained by a technique employing GMOs as a parent;

- a product obtained by a technique that uses DNA/RNA that will not multiply in a living cell;
- a product obtained by a technique that introduces targeted site mutations, generating a gain or loss of genic function, but proven to be free from recombinant DNA/RNA;
- a product obtained by a technique where there is a temporary or permanent expression of recombinant DNA/RNA molecules, without the presence or introgression of these molecules in the product;
- a product where techniques employing DNA/RNA molecules are used which, whether absorbed or not in the systemic way, do not cause permanent modification of the genome.

Notably, all 7 requests submitted under this new approach ended up with CTNBio concluding that the products did not fit the legal definition of GMO in Brazil.

2.4.5 Processes

Generally, a GM product must go through four different stages before it can be sold in Brazil. First, a company must submit the project to CTNBio for approval. CTNBio reviews the proposal and, if necessary, makes a site visit to determine whether the conditions exist to carry out the work safely. Once the proposal is approved, development and testing can begin under restricted and controlled conditions. Then, before the GM product's commercial release, CTNBio evaluates whether the data collected correspond to the biosecurity criteria established by CTNBio.

Only public and private entities are allowed to work with GMOs. Any legal person wishing to carry out activities covered by **Decree No. 5,591/2005**, must first request authorisation from CTNBio.

Each entity that uses genetic engineering methods or conducts research on GMOs and their derivatives, must form an **Internal Biosafety Commission** (CIBio), and must also appoint a primary responsible person for each specific project. The rules for this are established in **Normative Resolution No.1/2006** (as amended). CIBio must include at least three specialists from the areas relevant to the company's

activities, with sufficient scientific knowledge and experience to evaluate and supervise the works with GMOs and their derivatives developed at the institution, and may also include a member from outside the scientific community, for example, an employee of the entity, as long as that employee is prepared to consider the broader interests of the community.

CIBio is an essential element for the monitoring and surveillance of activities with GMOs and their derivatives within the entity, for ensuring compliance with the biosafety requirements, and for all the communication with CTNBio.

Each CIBio must be registered with CTNBio, so that a Biosafety Quality Certificate (CQB) could be issued. CTNBio issues CQB within 30 days if submitted documentation is in order, but in some cases, CTNBio may require additional information or may execute an audit of the facilities before issuing CQB.

Under **Law No. 11,105/2005**, two broad categories of activities are distinguished – research activities and commercial use.

Research includes activities carried out in a laboratory, under containment regime, or in a field, as part of the process to obtain GMOs and their derivatives or for the purposes of biosafety assessment of GMOs and their derivatives, which encompasses, within the experimental sphere, the construction, growing, handling, transportation, transfer, import, export, storage, release into the environment, and disposal of GMOs and their by-products.

An activity that does not fit the criteria for a research activity is considered a commercial use of GMOs and their derivatives. That includes cultivation, production, handling, transportation, transfer, marketing, import, export, storage, use, release, or disposal of GMOs and their derivatives for commercial purposes.

2.4.5.1 Research activities

Under Law No. 11,105/2005, CTNBio is responsible for establishing the biosafety requirements for the issuance of permits for laboratories, institutions, or companies carrying out activities related to GMOs and their derivatives.

To this end, **Normative Resolution No. 18/2018** establishes 4 risk classes for GMOs and sets the levels of biosafety to be applied in activities and projects in containment regimes involving the creation, cultivation, production, handling, storage, quality control, and disposal of GMOs, and the research, technological development, and educational activities related to GMOs.

The Resolution also provides details on the presentation of proposals for GMO-related projects and activities, and requirements for laboratory specifications and design, and containment equipment.

Rules for the planned release into the environment of GMOs of plant origin and their derivatives, for the purposes of experimental evaluations under monitoring, are established in **Normative Resolution No. 6/2008**.

The same for the planned release into the environment of risk class 1 GM microorganisms and GM animals and their derivatives is provided in **Normative Resolution No. 7/2009**.

2.4.5.2 Commercial release

Normative Resolution No. 24/2020 lays down the rules and data requirements for commercial release and monitoring of GMOs and their derivatives, and specifically excludes GM microorganisms from the scope as these are covered by a separate Normative Resolution.

Before commercial release of GMOs and their derivatives, the applicant, after approval by CIBio, must send to CTNBio the proposal signed by the legal representative of the entity, a copy of the technical opinion of the CIBio on the

proposal, declaration that the information is true signed by the legal representative, executive summary summarising the proposal, information on the GMO, information on the risk assessment for human and animal health, information on the risk assessment for the environment, simplified risk assessment (if criteria are met), and post-commercial release monitoring plan (if non-negligible risks are identified in the risk assessment).

Risk assessment information for the environment is not required for requests of commercial release of GMOs whose proposed use is only for human and animal consumption. Similarly, risk assessment information for human and animal health is not needed for requests of commercial release of GMOs whose proposed use does not include human and animal consumption.

Proposals for commercial release are published in the official journal and on the website at least 30 days in advance of being placed on the agenda. If requested, a hearing can be arranged with a public notice at least 30 days in advance.

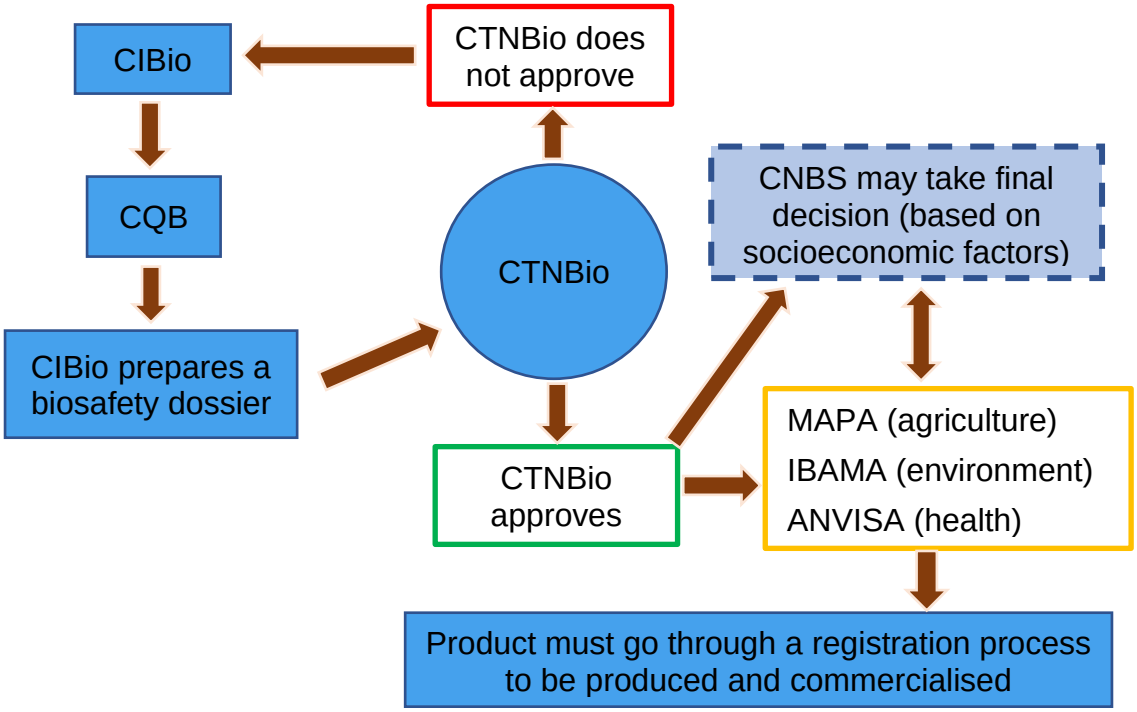
The proposal is then evaluated by all permanent sectorial subcommittees of CTNBio, who may request the advice of external experts. Subcommittees have 90 days to analyse the information and prepare their opinions, unless extended by CTNBio.

CTNBio may request additional information, and the applicant will have 90 days to submit it.

After publication of the favourable technical decision on the proposal for the commercial release of GMOs and their derivatives, CTNBio sends a copy of the process, within 10 working days, to the corresponding registration and inspection bodies and entities, so that they could perform their duties.

An outline of these interactions described for this case-by-case basis approvals process of commercial releases is depicted in **Figure** , with the CTNBio acting as the central authority for approving the commercial release proposal.

Figure 3. Flow chart diagram of the approval process for commercial release in Brazil



- CTNBio – National Technical Commission on Biosafety
- CIBio – Internal Biosafety Commissions
- CQB – Biosafety Quality Certificates
- CNBS – National Biosafety Council
- MAPA – Ministry of Agriculture, Livestock and Food Supply
- IBAMA – Brazilian Institute of Environment and Renewable Natural Resources
- ANVISA – National Health Surveillance Agency

Source: **Nepomuceno *et al.* (2019)**

The rules for commercial use activities for GM microorganisms and their derivatives are established in **Resolution No. 21/2018**.

2.4.5.3 Differential rules based on familiarity

Normative Resolution No. 23/2019 provides for a simplified procedure for the planned release into the environment of risk class 1 GMOs that have previously been approved by CTNBio for the purpose of experimental evaluations in planned

releases. This includes GMOs with accumulated events where all events have previously been individually approved by CTNBio.

Under this procedure, company's CIBio can grant authorisation for planned release into the environment of GMOs of risk class 1 that have been previously approved by CTNBio. CIBio must simply send a notification to CTNBio.

According to **Normative Resolution No. 18/2018**, risk class 1 (low risk to the individual and low risk to the community) includes GMOs that contain DNA/RNA sequences that do not cause harm to human and animal health and adverse effects to plants and the environment.

Normative Resolution No. 24/2020 also provides for a simplified risk assessment of GMOs with identical or similar genetic constructs that are used in GMOs of the same species that have received a technical opinion from CTNBio favourable to commercial release in Brazil.

2.4.5.4 Determination for innovative precision breeding techniques

Under **Normative Resolution No. 16/2018**, to determine whether a product obtained using innovative precision breeding techniques and its derivatives is a GMO, as defined by Law No. 11,105/2005, a letter of enquiry must be submitted to CTNBio. Annex II of the Normative Resolution lists data requirements for the request.

Once the request is filed with the CTNBio, a summary extract will be published in the official journal and distributed to sitting members of CTNBio for assessment and reporting purposes. The final opinion of CTNBio will be based on a case-by-case analysis of evidence of meeting at least one of the prescribed conditions.

The final opinion will be submitted for review to at least one of the Permanent Sectoral Subcommittees, depending on the parental organism and proposed use of the technique under enquiry, and its approval will be submitted to a CTNBio plenary

session for a vote. Subcommittees will have up to 90 days to analyse the submission and draft opinions, but it may be extended by CTNBio.

Additional information or studies may be requested, but CTNBio will have to provide appropriate scientific reasoning for that.

2.4.6 Regional restrictions

Law No. 11,460/2007 prohibits the planting of genetically modified organisms only in environmental protection areas. The proposal to ban the research and cultivation of GMOs in indigenous lands and areas of conservation units was vetoed.

No information found on whether Brazilian states can restrict cultivation.

2.4.7 Labelling

Decree No. 4,680/2003 requires that foods and food ingredients intended for human or animal consumption containing or produced from genetically modified organisms with more than 1% of GMOs in the product to disclose to the consumer the transgenic nature of product. This threshold can be reduced by CTNBio.

Accordingly, the label on the packaging or container must prominently state on the main panel, depending on the case, “transgenic (product name)”, “contains transgenic (name of ingredient or ingredients)” or “product produced from transgenic (product name)”, together with the symbol approved by the Ministry of Justice. The design of the symbol and the graphic requirements were approved by **Ordinance No. 2.658/2003** (see **Figure 4**). Additionally, the consumer must be informed about the donor species of the gene as part of the list of ingredients. The products sold in bulk or fresh are not exempt. Even foods or ingredients derived from animals fed GM feed require corresponding labelling.

Foods and food ingredients that do not contain and are not produced from GMOs can be labelled as “GMO free …”, provided that there are GM varieties on the Brazilian market. For example, “GM-free corn”.

Figure 4. Design of the symbol used in Brazil to disclose the transgenic nature of the product

The symbol consists of a bordered equilateral triangle with the letter ‘T’ housed within coloured in black, this is set against a contrasting-coloured background of either yellow or white.

The research by **Hakim *et al.* (2020)** shows that consumers in Brazil are not familiar with the meaning of this symbol. Nonetheless, all the efforts to date to change labelling requirements were unsuccessful.

2.4.8 Traceability

According to **Decree No. 4,680/2003**, the information that is required to appear on the label must also be provided in the accompanying documentation so that this information accompanies the product or the ingredient throughout all stages of the production chain.

According to Normative Resolution No. 24/2020, application for the authorisation for commercial release must include the information on the relevant general and specific detection techniques for the GMO in question. The reference materials do not seem to be required to be submitted as part of the application.

2.4.9 Low level presence policy

Brazil endorsed the International Statement on Low Level Presence and participates in the Global Low-Level Presence Initiative. It also signed an **agreement** with Argentina, Canada, and the United States on LLP.

Resolution No. 23/2019 (Mercosur) which establishes the mechanism to reduce the occurrence of LLP of GMOs in the Member States also applies in Brazil. Under this resolution, any new authorisation of a GMO for human food or animal feed use must be notified to other Member States within 30 days of authorisation. The notifying Member State must also send risk assessment report, information on the approval

status in the main export markets, and non-confidential part of the information submitted by the applicant. For the implementation of this mechanism, the developers of the authorised event must have previously submitted the request for commercial evaluation of the product in the other Member States.

2.4.10 Monitoring/enforcement

ANVISA inspects primarily the following research institutions:

- those with biosafety level classified as NB-2 or NB-3;
- holding a Biosafety Quality Certificate and conducting active research;
- with a favourable technical decision by CTNBio and involving GMOs or derivatives intended for human use.

Other supervisory bodies, especially MAPA and MMA, also have powers to inspect and monitor.

2.4.11 Products on the market

Brazil is the second largest producer of GM crops in the world. During the 2018/2019 crop season, total area planted with GM corn, cotton, and soybeans was nearly 51.8 million hectares. 95.7% of soybeans, 89.8% of cotton, 90.7% of first-crop corn, and 84.8% of second-crop corn were genetically modified.

Currently, only GM bean, cotton, eucalyptus, corn, soybean, and sugarcane are approved in Brazil.

2.4.12 Summary

The regulatory system in Brazil was supposed to have two layers of oversight – CTNBio for technical advisory support and CNBS for final review. However, almost a decade ago, CNBS declared that it considers all approvals by CTNBio for commercial release of GMOs as conclusive and will only review administrative appeals that relate to national interests or socioeconomic issues. This effectively allows CTNBio to make decisions autonomously on issues related to health,

environment, and agriculture, facilitating the approval of biotech events, potentially weakening the oversight.

Another compounding issue is the composition of CTNBio. Out of 27 members, 12 represent the academic field, 9 are representatives from Ministries, and the remaining 6 are representatives of civil society. Only 14 votes are needed to authorise commercial release of any GM product. Historically, this quorum is easily achieved because the experts from academia as well as the representatives from the Ministries of Agriculture and Science and Technology tend to favour approvals.

While the fundamental legislation on GMOs is fairly old, most aspects of GMOs were lately addressed via Normative Resolutions of CTNBio. As a result, certain parts of the regulatory framework for GMOs received a significant facelift in the past three years to reflect the current state of play.

For instance, the new approach to innovative precision breeding techniques is flexible enough to accommodate new techniques as it does not establish a definitive list of techniques that will or will not generate a product that is considered a GMO or not. Each product is assessed on a case-by-case basis by CTNBio. The focus is mainly on the characteristics and safety of the final product. It considers whether an introduced genetic material is absent, as well as the risk level associated with the modified organism. When applicable, it also takes into account information on the manipulated genes or genetic elements function and whether the product has already been approved for commercialisation in other countries. On the other hand, the above does not change the way products that are not exempt are regulated, effectively creating a hybrid system.

2.5 Canada

2.5.1 Competent authorities

The regulation of products derived from biotechnology is the responsibility of three federal agencies:

- **Canadian Food Inspection Agency** (CFIA)

- **Health Canada** (HC)
- **Environment and Climate Change Canada** (ECCC)

All three work together to monitor the development of plants with novel traits, novel foods, and all plants or products with new characteristics not previously used in agriculture and food production.

The CFIA is responsible for environmental risk assessment, safety of field trials, import permits, variety registration of plants with novel traits, and safety assessment of novel feed.

The review process for plants with novel traits is coordinated and final decision is made by the CFIA's Plant Biosafety Office (PBO). The same for novel feed is done by the CFIA's Animal Feed Division (AFD).

The CFIA's Plant and Biotechnology Risk Assessment (PBRA) Unit provides scientific advice to the PBO and is responsible for the environmental safety assessment of plants with novel traits. It also conducts a molecular characterisation of the plant with novel trait, in co-operation with the Molecular Unit of the AFD and Health Canada's Bureau of Microbial Hazards (BMH).

Health Canada, among other things, is responsible for assessing the human health safety of foods, including novel foods, and approving their use in commerce. Health Canada's Food Directorate is the main department to deal with novel foods. The Bureau of Chemical Safety (BCS), the Bureau of Nutritional Sciences (BNS), and the Bureau of Microbial Hazards (BMH) within the Food Directorate review different aspects of the novel food notifications.

The Submission management and Information Unit (SMIU) of Health Canada is responsible for communicating with applicants and receiving and tracking the progress of all pre-market notifications while the Novel Food Section (NFS) of the BMH coordinates the technical aspects of the pre-market assessment across the three bureaus of the Food Directorate.

Decisions on novel foods are made by the Food Rulings Committee (FRC) which consists of Food Directorate senior management and representatives from the CFIA. The composition of the FRC may change according to the specific novel food proposals that are being considered.

Health Canada's Pest Management Regulatory Agency (PMRA) is responsible for safety assessment and authorisation of pest control products, including biopesticides and plants expressing novel insect resistance and herbicide tolerance traits.

ECCC acts as a regulatory safety net for products of biotechnology for uses not covered under other federal legislation, including organisms and microorganisms that may have been derived through biotechnology. Therefore, ECCC is responsible for environmental risk assessment of genetically modified animals.

Under a memorandum of understanding with the ECCC and Health Canada, new substance notifications for aquatic organisms with novel traits (e.g. fish products of biotechnology) are administered and risk assessments are conducted by Fisheries and Oceans Canada (DFO).

Where necessary, ECCC is also responsible for assessing the impact the novel food has on the environment.

Federal food labelling is regulated by both Health Canada and the CFIA.

Inspection and enforcement of the relevant provisions is mostly done by the CFIA. However, provincial/territorial and local agencies are also involved in the inspection and enforcement.

2.5.2 Key legislation

Canada has no specific legislation on genetically modified materials, and feed or food derived from these materials. Instead, agricultural products of biotechnology are regulated under the same broad legislation and structures as agricultural products

produced in more traditional ways, with some new regulations and administrative procedures added on.

The regulatory framework primarily focuses on the end-product and not on the process used to create the product – the focus is on the traits expressed in the products and not on the method used to introduce those traits. This creates a level playing field for all novel products without impeding the innovation.

The regulation of plants, including plants with novel traits, falls under the scope of **Seeds Act** and **Regulations**.

Plants with novel insect resistance traits and herbicide tolerance traits are also subject to requirements under **Pest Control Products Act** and **Regulations**.

Novel foods, including genetically modified, are regulated under **Food and Drugs Act** and **Regulations**. As any food sold in Canada, novel food will also be subject to requirements under **Safe Food for Canadians Act** and **Regulations**.

Feeds, including novel, fall under the scope of **Feeds Act** and **Regulations**.

Fish products of biotechnology and all other animate products of biotechnology not covered under other federal legislation are regulated within the scope of the **Canadian Environmental Protection Act, 1999**, and **New Substances Notification Regulations (Organisms)**.

The import control of plants with novel traits and/or products derived from such plants is under the **Plant Protection Act** and **Regulations**.

In terms of labelling, there is a **National Standard** on “Voluntary labelling and advertising of foods that are or are not products of genetic engineering”.

The specific procedures and requirements are detailed in various directives or guideline documents.

2.5.3 Definitions/terminology

The Canadian approach to regulating novel products from plant sources is that it is the presence of a novel trait in a plant that potentially poses environmental risk and not the process by which the trait was introduced. Thus, the focus is on the novelty of the end product and not all products of genetic engineering are considered novel.

According to **Directive 94-08**, a "plant with novel trait" (PNT) is a plant where the new trait is not present in stable, cultivated populations of the plant species in Canada, **or** the trait is present at a level significantly outside the range of that trait in stable, cultivated populations of that plant species in Canada, **and** where the new trait has the potential to negatively affect environmental safety.

Seeds Regulations include the following relevant definitions:

"novel trait", in respect of seed, means a characteristic of the seed that

a) has been intentionally selected, created or introduced into a distinct, stable population of cultivated seed of the same species through a specific genetic change, and
b) based on valid scientific rationale, is not substantially equivalent, in terms of its specific use and safety both for the environment and for human health, to any characteristic of a distinct, stable population of cultivated seed of the same species in Canada, having regard to weediness potential, gene flow, plant pest potential, impact on non-target organisms and impact on biodiversity.

"release" means any discharge or emission of seed into the environment or exposure of seed to the environment and includes the growing and field testing of plants.

“confined release” means release under conditions intended to minimise the establishment and spread, in the environment, of seed or of genetic material from plants derived from the seed, and the interaction of the seed or genetic material with the environment.

“unconfined release” means release on an unrestricted basis.

“environment” means the components of the Earth and includes

a) air, land and water,
b) all layers of the atmosphere,
c) all organic and inorganic matter and living organisms, and
d) the interacting natural systems that include components referred to in paragraphs (a) to (c).

Feed Regulations include the following relevant definitions:

“feed” includes a feed derived through biotechnology.

“novel feed” means a feed, comprising an organism or organisms, or parts or products thereof, that

a) is not set out in Schedule IV or V, or
b) has a novel trait.

“novel trait”, in respect of a feed, means a characteristic of the feed that

a) has been intentionally selected, created or introduced into the feed through a specific genetic change, and
b) based on valid scientific rationale, is not substantially equivalent, in terms of its specific use and safety both for the environment and for human and animal health, to any characteristic of a similar feed that is set out in Schedule IV or V.

"release" means any discharge or emission into the environment of a feed or livestock product produced from the feed or exposure of a feed or livestock product produced from the feed to the environment.

The definition of "novel food" in **Section B.28.001** of the FDR specifically includes:

… a food that is derived from a plant, animal or microorganism that has been genetically modified such that

(i) the plant, animal or microorganism exhibits characteristics that were not previously observed in that plant, animal or microorganism,
(ii) the plant, animal or microorganism no longer exhibits characteristics that were previously observed in that plant, animal or microorganism, or
(iii) one or more characteristics of the plant, animal or microorganism no longer fall within the anticipated range for that plant, animal or microorganism.

"Genetically modify" here means "to change the heritable traits by means of intentional manipulation". Therefore, this would include conventional breeding, modern biotechnology techniques (e.g. genetic engineering), gene editing, and mutagenesis.

2.5.4 Scope of regulation

The regulatory oversight is based on the characteristics of the product, regardless of how it was developed, and each product is assessed on a case-by-case basis.

The concept of substantial equivalence is deeply rooted in the Canadian regulatory approach. A product developed using biotechnology will not be subject to additional regulatory oversight, if it is considered substantially equivalent to something that is already in use and generally considered as safe in Canada, based on valid scientific rationale.

For instance, a plant developed using rDNA but not expressing a novel trait would be exempt, even if it is a new or different transformation or insertion event. For example, if a transgenic PNT is assessed and approved, and the plant of the same species is

subsequently transformed with the same DNA construct and expressing the same traits as the approved variety, any cultivars derived from this new event would not trigger regulatory scrutiny as a PNT, as it would not be novel.

Equally, if the food is derived from a genetically modified plant, animal, or microorganism, but it does not exhibit new characteristics, does not lose previously observed characteristics, and the characteristics do not fall outside the anticipated range for that characteristic, the food will not be considered novel.

The potential to have an environmental effect is one of the triggers to classify the crop as a plant with novel trait. If regulated, the assessment takes into account immediate or long-term harmful effects on the environment or its biological diversity, dangers to the environment on which life depends, and dangers in Canada to human life or health. But if it has no effect on the environment, it will not be regulated as a PNT. Although it may still be regulated as a novel food.

2.5.5 Processes

A summary of the Canadian pre-market regulatory process for PNTs and novel foods and novel feeds derived from plant sources in a diagram can be found **here**.

2.5.5.1 Novelty determination (novel food, novel feed, PNT)

It is the responsibility of proponents (e.g. plant breeders, product developers, importers of new plant lines), based on their expertise, on familiarity with their product, and on relevant scientific literature, to determine whether their product fits the definition of a PNT. The PNT status of a plant is determined on a case-by-case basis.

If the PNT will further be used as a human food or animal feed, additionally, the proponent would need to determine whether their feed or food will be novel.

If a proponent requires additional guidance regarding a novelty determination, they should contact PBO for PNTs, NFS for novel foods, and AFD for novel feed.

2.5.5.2 Pre-submission consultation (novel food, novel feed, PNT)

Before any regulatory submissions, including for novel foods, novel feeds, and PNTs developed with the help of biotechnology, the proponents are strongly encouraged to request a **pre-submission consultation** with the CFIA and/or Health Canada for assistance on how to make a submission. Depending on proponent's experience, more than one pre-submission consultations may be needed.

The purpose of pre-submission consultation is to improve predictability of the regulatory assessment process and the overall quality of regulatory submissions, effectively increasing the overall efficiency of the assessments and resulting in more timely reviews and decision-making. Thus, it will focus on the completeness of the proposed regulatory submission, clarifying the data and/or information requirements specific to the individual product, clarifying the regulatory requirements, policies and administrative processes, and clarifying expectations for data quality and suitability, the use and elaboration of scientific rationale.

Pre-submission consultations must be requested 8-12 weeks prior to the desired consultation date. Consultation requests should be sent to the CFIA's PBO (for PNTs), Health Canada's NFS (for novel foods) and/or the CFIA's AFD (for novel feed).

The proponent must submit the relevant information package, including any specific questions that they would like the authorities to address, to lead CFIA or Health Canada official at least 4 weeks prior to the consultation.

2.5.5.3 Contained use (PNT)

Breeders are fully responsible for managing any risks in their research programs as long as the materials remain in contained conditions (e.g. in laboratories or under glass). The formal system takes over only once the breeder has developed a cultivar that shows agronomic or other merit, is genetically unique and stable, and is ready to be examined for registration. Developers are recommended to follow Canadian **biosafety guidelines**.

2.5.5.4 Confined research field trials (PNT)

Authorisations for confined research field trials are granted and renewed by the PBO. The guidance to applicants for authorisation of confined research field trials of PNTs for research purposes is provided in the **Directive 2000-07**. It summarises the information requirements and procedures used by the PBO, and where appropriate, other federal and provincial agencies.

Applications for confined research field trials of PNTs must be sent to the CFIA's Pre-market Application Submission Office (PASO) at least 30 days before the expected planting date. If assessment for risks to food and feed supplies by Health Canada or the CFIA's AFD is necessary, applications will need to be submitted 60 days before the expected planting date.

To minimise the exposure of the PNT to the environment, PBO imposes, on a case-by-case basis, both general and species-specific terms and conditions of authorisation for the confined research field trials to keep the plant material confined.

Although the PBO may exchange information with other departments of the CFIA and Health Canada, it is the applicant's responsibility to ensure that all requirements of these departments are met directly. If in doubt whether other departments need to be involved, applicants should consult with the PBO and provide any necessary data at least 90 days before the anticipated planting date.

The PBO sends non-confidential information about each trial to provincial government contacts in those provinces where proposed trials are going to be done. Provincial governments have a 30-day comment period, and any comments are considered by the PBO in the final evaluation of the application. Provincial governments may request additional information on the proposed trials.

Non-confidential information about confined research field trails is made available to the public upon request and on the PBO's **website**.

CFIA inspectors have the authority to inspect confined research field trial sites without prior notification, as well as the records and methods of disposal and storage of plant material from the confined trial.

If a PNT needs to be imported into Canada to carry out a confined research field trial, an **import permit** will first need to be issued by the CFIA.

The PBO distribute copies of received field trial applications to the CFIA's livestock feed evaluators, if the applicant wants to use material from the trial in a research feeding study, and also shares information with the PMRA in cases involving testing novel herbicide tolerance or insect resistance.

2.5.5.5 Unconfined environmental release (PNT)

According to **Directive 94-08**, all PNTs must be authorised prior to their release into the Canadian environment as per the Seeds Act and Seeds Regulations. In order to obtain an authorisation for unconfined release, proponents must demonstrate that their product is as safe for the Canadian environment as its counterpart(s).

To assist with this, the characteristics of the species are defined in a series of **Biology Documents** published by the PBO. Biology Documents relate to plants with no novel traits of the species in question and provide background information on the biology of a particular plant species, its centres of origin, its related species, the potential for gene introgression from the plant into relatives, as well as details on the life forms with which it interacts.

Where a biology document for a particular PNT's plant species is not available, proponents must notify the PBO at least 1 year prior to anticipated submission of an application for unconfined environmental release so that a biology document could be drafted. A review of an application for a PNT will not be initiated without a finalised biology document.

A proponent must submit a comprehensive package of information that consists of appropriate data and relevant scientific information to describe the environmental risk the PNT may pose relative to its counterpart(s) already present in the Canadian environment.

Importantly, information submitted for previously approved crops with comparable traits can be reused, so that all the relevant data would not need to be generated again.

The PBO reviews the information submitted, determines the level of assessment required and may seek scientific advice from the PBRA before deciding on the product.

The PBRA reviews environmental safety information on the PNT provided by the proponent based on five criteria:

- potential for increased weediness/invasiveness;
- potential for gene flow to sexually compatible plants and its consequences;
- potential of the PNT to become a plant pest;
- potential impacts on non-target species, including humans;
- potential impacts on biodiversity.

If risks are identified, the PBRA will provide scientific advice related to risk management options, otherwise, appropriate risk management conditions on the product are imposed by the PBO.

The PBRA conducts a molecular characterisation of the PNT together with the Molecular Unit of the AFD and Health Canada’s BMH.

After considering the advice provided by the PBRA and any other relevant factors, the PBO makes the final decision on the authorisation of a PNT for unconfined environmental release and whether any risk management conditions are required.

Some crop species (e.g. canola, sunflower) are subject to **variety registration**. Once a PNT of such a crop has been authorised for unconfined environmental release, the new variety must be registered with the CFIA's Variety Registration Office before it can be sold in Canada.

2.5.5.6 Novel feed application

If the product is intended for livestock feed, an additional assessment will be needed under the Feeds Act by the CFIA's AFD.

After receiving a novel feed application, the PASO will pass the file on to the AFD.

AFD verifies that all information needed for review has been received and decided whether to accept the file for review. If accepted, it is given to AFD evaluation officers assigned to the file. Each evaluator assesses a submission according to his/her own area of expertise (e.g. animal nutrition, toxicology, molecular biology).

The AFD lead evaluator shares responsibility with the PBRA for reviewing the method of detection and identification if applicable by the CFIA for PNTs and novel feeds from plant sources and for coordinating writing of the decision document once the final decision for authorisation of the novel plant has been made.

In certain cases, the AFD may request additional information from the applicant and/or other regulatory agencies.

Once submitted information has been reviewed by AFD and the applicant has had the opportunity to respond to all outstanding requests for further information and/or clarification, AFD proceeds with the decision-making step, including risk management, based on the available information.

Once all evaluators within the AFD have finished assessing a submission according to their own expertise, all evaluators work collaboratively to reach a joint final

decision based on all the evidence included in the submission and recommend appropriate risk management options as necessary.

2.5.5.7 Novel food notification

For products intended for human consumption, an additional assessment will be needed under Food and Drugs Act by Health Canada's Food Directorate.

After receiving a novel food notification, the SMIU distributes the material submitted to the three bureaus within the Food Directorate. The BCS is responsible for evaluating the food for chemical, toxicological, and allergenic concerns. The BNS evaluates nutritional aspects of the food and compares compositional data for the novel food with that for its conventional counterpart. The NFS within the BMH is responsible for the evaluation of genetic and microbial considerations.

If one or more bureaus have questions or require clarification from the proponent, the SMIU or the NFS will contact the applicant.

At the completion of the safety assessment, if and only 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. If the food rulings proposal is found acceptable by the FRC, the applicant 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 (i.e. a "letter of no objection").

2.5.5.8 Harmonisation of regulatory decisions (PNT, novel feed, novel food)

If a plant is considered to be a PNT and a source of a novel food and a novel feed, regulatory decisions regarding the use as a novel feed, novel food and environmental release are coordinated and harmonised between the PBO, AFD, and FRC. Once the regulatory decisions have been harmonised, the CFIA and Health

Canada each send a letter to the applicant and post a decision document on their respective websites.

2.5.5.9 New substances notification (fish products of biotechnology)

Under the **New Substances Notification Regulations (Organisms)**, if a living organism, including fish products of biotechnology, is not on the **domestic substances list**, a new substance notification must be submitted to ECCC. Fish products of biotechnology that are on the domestic substances list would also require a notification if they are proposed for a **significant new activity**.

The regulations don't apply to fish products of biotechnology that

- are research and development organisms;
- are imported to or manufactured in a facility from which there's no release into the environment of the organism, the genetic material of the organism, or material from the organism involved in toxicity.

If not exempt from the regulation, the notification must provide information listed in **Schedule 5** to New Substances Notification Regulations (Organisms) at least 120 days before importing or manufacturing the product.

Based on the information provided, DFO will conduct an assessment of a living organism for potential adverse effects on the environment and human health and will recommend to ECCC any necessary risk management measures. The final decision on the notification is with the ECCC.

In the case of GM salmon, the **environmental risk assessment** consisted of an exposure assessment and an environmental hazard assessment. The indirect human health assessment focused on potential human contact with the fish in the environment, should they escape containment. It did not examine human food consumption. Overall, DFO concluded, with reasonable certainty, that the proposal poses low risk to the Canadian environment and low risk to indirect human health.

Notably, DFO conduct their **own research** to support risk assessments on the potential impact of new fish on wild wish, other species, and the surrounding environment.

Separate submissions are needed for fish products of biotechnology to be used as a novel food or a novel feed, as described above. For GM salmon, it was **concluded** that it is as safe and nutritious for humans and livestock as conventional salmon effectively approving GM salmon for sale in Canada. Once approved for use as food and livestock feed, it is considered to be equivalent to its conventional counterparts.

2.5.5.10 New substances notification (other animal biotechnology products, microorganisms)

If a GM microorganism is not on the domestic substances list, it will be subject to a new substance notification requirement under the **New Substances Notification Regulations (Organisms)** as above, except that the **information required** will differ and the risk assessment decisions will be made by ECCC and Health Canada.

For **biotechnology-derived animals** other than fish, proponents should contact ECCC so that the animal could undergo a full safety assessment for potential impacts on the environment. In turn, Health Canada will evaluate the human health aspects of biotechnology-derived animals, including the safety of the people working with the animals. The CFIA may also play a role.

2.5.6 Regional restrictions

A number of municipalities or groups of municipalities have passed a resolution against genetically engineered crops and animals within its jurisdiction. Most of these **GE Free Zones** are in British Columbia. Otherwise, authorisations are valid throughout Canada.

2.5.7 Labelling

Since genetically modified foods are considered to be as safe and nutritious as non-GM foods, there are no specific laws in Canada about labelling of genetically

modified foods. As a result, it is not mandatory to identify the method of production, including genetic modification, used to develop a food product on the label.

General food labelling requirements under the Food and Drugs Act and the Safe Food for Canadians Act require that the labels be truthful, not deceptive, not misleading, not to give an untrue impression of the food's merit, safety, or quality.

Special labelling is required for all foods, including genetically modified, in case of any health and safety concerns such as the potential to cause allergic reactions, changes to the composition of the food, or changes to the nutritional quality of the food. Thus, if a novel food results in a health or safety change or a significant change in nutrition or composition, Health Canada may require a declaration on the label detailing the way it differs from its non-modified counterpart.

Voluntary "method of production" labelling is permitted as long as the information is truthful and not misleading. The requirements for such voluntary labelling on foods that are products of genetic engineering are provided in the **National Standard**.

According to the standard, a claim on a single-ingredient food that it is not a product of genetic engineering should only be made for an ingredient that is obtained from sources of which less than 5% are products of genetic engineering. The unintentional presence at levels below 5% is considered to be adventitious and would not prevent making negative claims.

Equally, a claim that an ingredient is a product of genetic engineering should not be made when less than 5% of the ingredient is a product of genetic engineering. In case of presence at a level between 5% and 95%, it is only permitted to claim that the ingredient comes from both GE and non-GE sources. If more than 95% of an ingredient is a product of genetic engineering, then it would be indicated as a GE ingredient.

Additionally, there are third parties who offer certification for “non GM” claims on food products such as the **Non-GMO Project**. In addition, organic certification would also ensure a “non-GM” claim would be met.

2.5.8 Traceability

There are no universal requirements regarding traceability. On the other hand, authorities may request testing methodology and reference samples to be provided.

For instance, if the CFIA identifies that a method of detection and identification is required as part of the PNT submission to verify compliance with the conditions of authorisation, the CFIA will request appropriate test methodologies for the detection and identification of the PNT, and also a written agreement to provide the CFIA with reference material suitable to support these methods.

Additional requirements to investigate the origin of all ingredients present at 1% or more would apply in case a voluntary claim is made regarding the presence or absence of products of genetic engineering.

2.5.9 Low level presence policy

As a leading producer and exporter of GM agricultural products, Canada **does not advocate** a zero-tolerance policy for LLP. Partially, because GM crops that are likely to be found in international trade have already undergone safety assessments by Health Canada and the CFIA and have been authorised for use in Canada. So, the potential for unauthorised GM crops entering Canada through imports is low.

Canada has created the Global Low Level Presence Initiative (GLI), a group of countries that have endorsed an **International Statement on LLP** and committed to working collaboratively to develop international approaches to manage LLP.

Establishing LLP policies is one of Canada’s commitments under the new trade agreement with the US and Mexico (CUSMA).

After extensive consultations, Agriculture and Agri-Food Canada (AAFC) published a **policy model** for managing LLP of GM crops in imported grain and food or feed products derived from grains to stimulate the discussions. The model proposes a risk-management approach based on two levels:

- a level of 0.2%, which would address situations of LLP resulting from dust, lingering traces of discontinued GM varieties, or foreign GM crops intended for domestic use only; and
- a compliance threshold of 3%, which would address LLP situations resulting from the commercialisation of a GM crop not yet approved in the importing country.

To be considered LLP under this model, an unauthorised GM crop should meet two criteria:

- the GM crop should be approved for food use in at least one country in accordance with Codex Guidelines; and
- test methodologies and reference materials should have been provided to the importing country to facilitate monitoring.

Two additional criteria should be met for the compliance threshold to apply to LLP levels between 0.2% and 3%:

- application for the authorisation of the GM crop should have been provided to the importing country;
- proactive LLP risk assessments completed by importing country.

If over 3%, LLP policy would not apply, and a case-by-case assessment would be needed.

However, **no decision** has yet been taken on how the Government of Canada will address the potential for LLP of unauthorised GM crops. Until a decision is made, Canada's current zero-tolerance approach to the LLP of unauthorised GM crops continues to apply.

In the event of a LLP occurrence, and at the request of the CFIA, Health Canada will conduct a risk assessment of the unauthorised GM crop on a case-by-case basis to inform any risk management action taken by the Agency.

2.5.10 Monitoring/enforcement

Canada does not have a monitoring program for products derived through the use of biotechnology and does not actively test for GM products.

2.5.11 Products on the market

Currently, the **list** of competed novel food safety assessments include GM alfalfa, apple, canola, cotton, corn, flax, papaya, potato, rice, soybean, squash, sugar beet, sugarcane, and tomato. Recently, two varieties of gene edited canola were reviewed as well.

Grown in Canada are canola, corn, soy, sugar beet and alfalfa. The country also produces GM salmon and a trial batch was sold in retail. The rest (apple, papaya, squash, cottonseed oil) are imported into Canada – mostly from the United States but GM cottonseed oil may also come from China or India.

2.5.12 Summary

While most other jurisdictions trigger regulatory oversight for every new rDNA insertion into organism's genome, the Canadian approach triggers regulatory scrutiny only when a new trait is expressed in the product, whether or not it is a product of rDNA. Plants developed using traditional breeding, not rDNA, may equally trigger regulatory review for expressing novel traits (e.g. conventionally bred variety of barley expressing low phytate).

This approach ensures that no changes to legislation are needed to accommodate any new techniques that may be introduced. It also creates a level playing field for all novel products without obstructing unnecessarily the progress and innovation.

On the other hand, it also means that the relevant requirements in the legislation are not only scarce but also scattered throughout different pieces of legislation. The aspects of practical implementation are often only provided in the directives and guidance documents.

All novel trait products, prior to authorisation, depending on the intended use, are thoroughly tested by the CFIA, Health Canada and/or ECCC using scientific approaches. While the authorities rely heavily on data and information provided by the applicant in making its scientific assessment, the requirements for the data to be submitted are quite extensive and tailored to each type of application. The information requirements for each application are addressed in-depth during a series of strongly encouraged pre-submission consultations. The consultation step is aimed to increase the quality of dossiers to be submitted and improve predictability of the overall outcome of the application review.

As the regulatory oversight is primarily based on the novel traits, there is a possibility to reuse information for previously approved products with comparable traits, so that the relevant data would not need to be generated again.

It is important to note that since Canada does not have a mandatory labelling system for genetically modified foods, most products from genetically modified crops enter the food supply system seamlessly. For example, GM salmon was sold as a trial in the Canada and the public was informed only later.

2.6 United States

2.6.1 Competent authorities

Three federal agencies within the U.S. government work together to regulate most GMOs and to ensure that GMOs are safe for human, plant, and animal health. These agencies also monitor the impact of GMOs on the environment.

U.S. Food and Drug Administration (FDA) regulates most human and animal food, including GMO foods. In doing so, FDA makes sure that foods that are GMOs or

have GMO ingredients meet the same strict safety standards as all other foods. FDA sets and enforces food safety standards that those who produce, process, store, ship, or sell food must follow, no matter how the foods are created.

U.S. Environmental Protection Agency (EPA) is responsible for protecting human health and the environment, which includes regulating pesticides. EPA regulates the safety of the substances that protect GMO plants, referred to as **plant-incorporated protectants** (PIPs), that are in some GMO plants to make them resistant to insects and disease. EPA also monitors all other types of pesticides that are used on crops, including on GMO and non-GMO crops.

Animal and Plant Health Inspection Service (APHIS) of the **U.S. Department of Agriculture** (USDA) protects agriculture in the United States against pests and disease. APHIS sets regulations to make sure GMO plants are not harmful to other plants, and USDA's **Biotechnology Regulatory Services** implements these regulations. USDA's **Food Safety and Inspection Service** (FSIS) regulates meat, poultry, egg products, and fish of the order of *Siluriformes*, including those derived using genetic engineering.

USDA's **Agricultural Marketing Service** (AMS) is responsible for overseeing the new National Bioengineered Food Disclosure Standard. It is also responsible for administering plant variety and seed laws, which also cover biotechnology-derived seeds.

2.6.2 Key legislation

The overall regulatory framework is best summarised in the **2017 Update to the Coordinated Framework for the Regulation of Biotechnology**, although it is already partially outdated.

United States do not have any federal legislation that is specific to biotechnology products, except for labelling bioengineered food and the movement of organisms modified or produced through genetic engineering. Instead, the products of biotechnology are regulated under health, safety, and environmental legislation

governing conventional products. FDA, USDA, and EPA, each have developed regulations and guidance documents to implement their statutory authority under existing laws to help ensure the safety and, where applicable, effectiveness of biotechnology products for their intended application.

For instance, APHIS oversees the importation, interstate movement and environmental release of genetically engineered organisms to ensure they do not pose a plant pest risk under the Plant Protection Act (**7 U.S. Code §7701** *et seq.*). Products of biotechnology that may pose risk to animal health are regulated by APHIS under the Animal Health Protection Act (AHPA) (**7 U.S. Code §8301** *et seq.*).

FDA relies on its authorities granted by the Federal Food, Drug, and Cosmetic (FD&C) Act (**21 U.S. Code §301** *et seq.*) and the Public Health Service (PHS) Act (**42 U.S. Code §201** *et seq.*). Under the National Environmental Policy Act (NEPA) (**42 U.S. Code §4321** *et seq.*), FDA also evaluates the environmental impacts of "major actions", such as product approvals.

EPA operates under both FD&C Act and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (**7 U.S. Code §136** *et seq.*), and is also subject to requirements under NEPA. Biotechnology products that are new microorganisms not regulated by other statutes are regulated by EPA under the Toxic Substances Control Act (TSCA) (**15 U.S. Code §2601** *et seq.*).

Depending on its intended use and the characteristics of the product, the end-product may be overseen by more than one agency or might not be regulated at all. For instance, if a GM crop has no pest risk and is not considered a plant-incorporated protectorant, it is likely to be only subject to FDA's "voluntary" consultation for use in food or feed.

The lack of dedicated legislation sometimes means that authorities must resort to being creative when addressing new challenges (e.g. genetic modification of animals regulated under the "new animal drug" provision in **21 U.S. Code §321(v)** of the

FD&C Act). FD&C Act makes in unlawful to introduce unapproved new animal drugs into commerce.

This is because the federal government may only regulate an area if it is assigned to the federal jurisdiction by the constitution or if the congress acts and creates a new mandate for the government. Otherwise, federal government does not have mandate to legislate.

Additionally, there is a trend towards further deregulation of biotechnology products. For instance, the new SECURE **final rule** exempts from APHIS oversight in terms of import or interstate movement licencing any genetically engineered organism that is unlikely to pose plant pest and noxious weed risks.

Equally, EPA has recently published a **proposed rule** to exempt certain plant-incorporated protectorants (PIP) derived from newer technologies from EPA's oversight. The proposed rule would require the interested party to submit a self-determination letter and/or request for EPA confirmation that their PIP meets the criteria for exemption.

The recent **attempt** by USDA to take over the oversight of genetically modified animals from FDA could also be seen as a major step towards deregulation. USDA not only published an **advanced notice** of proposed rulemaking and request for comments, with less than a month left before the change of administration, but also signed, still within the 60 days comment period, a **Memorandum of Understanding** (MoU) with the FDA. Notably, the MoU was signed with the Assistant Secretary for Health and Head of the Public Health Service as the FDA Commissioner refused to sign it.

If the effort succeeds, it would affect "amenable species" (cattle, sheep, swine, goats, horses, mules, or other equines, fish of the order of *Siluriformes*, chickens, turkeys, ducks, geese, guineas, ratites, and squabs) developed using genetic engineering that are intended for agricultural purposes (i.e. human food, fibre, and

labour). FDA would maintain authority over any other animals as well as over animals from amenable species not intended for agricultural purposes.

2.6.3 Definitions/terminology

National Bioengineered Food Disclosure Standard (**7 CFR §66.1**) defines "bioengineered food" to mean a food that contains genetic material that has been modified through *in vitro* rDNA techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature, provided that such food does not contain modified genetic material if the material is not detectable pursuant to **7 CFR §66.9**. Also, an incidental additive present in food at an insignificant level and that does not have any technical or functional effect in the food, as described in **21 CFR §101.100(a)(3)**, is not a bioengineered food.

"Bioengineered substance" is defined to mean substance that contains genetic material that has been modified through *in vitro* recombinant deoxyribonucleic acid (rDNA) techniques and for which the modification could not otherwise be obtained through conventional breeding or found in nature.

The standard does not define what "conventional breeding" or "found in nature" actually means.

APHIS regulations regarding the movement of organisms modified or produced through genetic engineering as amended by SECURE rule **define** "genetic engineering" as techniques that use recombinant, synthesized, or amplified nucleic acids to modify or create a genome. Before the amendment, "genetic engineering" was **defined** as genetic modification of organisms by recombinant DNA techniques.

Other documents and legislation may use a wide range of other terms interchangeably, including "modern technology", "recombinant DNA technology", "bioengineering", "genetic modification", or "genetically modified organism", but most are not clearly defined in the federal legislation.

Genetically engineered animals are currently regulated under the concept of “new animal drug” which is defined in **21 U.S. Code §321(v)** as follows:

The term “new animal drug” means any drug intended for use for animals other than man, including any drug intended for use in animal feed but not including such animal feed, —

(1) the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of animal drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labelling thereof; except that such a drug not so recognized shall not be deemed to be a “new animal drug” if at any time prior to June 25, 1938, it was subject to the Food and Drug Act of June 30, 1906, as amended, and if at such time its labelling contained the same representations concerning the conditions of its use; or

(2) the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

Provided that any drug intended for minor use or use in a minor species that is not the subject of a final regulation published by the Secretary through notice and comment rulemaking finding that the criteria of paragraphs (1) and (2) have not been met (or that the exception to the criterion in paragraph (1) has been met) is a new animal drug.

2.6.4 Scope of regulation

Generally, the regulatory approach is to determine if individual new genetic modification product is regulated – a case-by-case analysis is needed to determine whether the product is regulated, and if so, who would oversee it and to what extent.

As stated in **7 CFR §340.1**, APHIS requirements in terms of GM crop movement control would not apply to plants with:

- a plant-trait-mechanism of action combination that has previously undergone an analysis by APHIS and has been determined by APHIS not to be regulated;
- a plant-trait-mechanism of action combination found in a plant that APHIS determined to be deregulated under the previous petition process.

Under the new **SECURE rule**, APHIS does not regulate plants that could otherwise have been developed through traditional breeding techniques as long as the crop is not a plant pest or developed using plant pests. A person can assess whether a plant developed using genetic engineering meets the criteria for a regulatory exemption and has the option of submitting a request for confirmation. If the plant is exempt under this rule, it will not be subject to APHIS oversight for importation, interstate movement and environmental release but may be subject to oversight by FDA and/or EPA.

FDA's consultation programs on food from new plant varieties also does not distinguish between classic genetic modification and genome editing – each product would be assessed on a case-by-case basis. FDA's official position is that, as a class, foods from genetically engineered or genome-edited plant varieties do not present different or greater safety concerns than foods developed by traditional plant breeding.

For genome-edited animals, FDA intends to use the same "new animal drug" provision as for all animals with "intentional genomic alterations". So, currently, animals developed using new breeding techniques would not be exempt.

This may change if USDA's recent attempt to take over the oversight of genetically modified animals from FDA succeeds. On the other hand, it would only affect "amenable species" (cattle, sheep, swine, goats, horses, mules, or other equines, fish of the order of *Siluriformes*, chickens, turkeys, ducks, geese, guineas, ratites, and squabs) developed using genetic engineering that are intended for agricultural purposes (i.e. human food, fibre, and labour). FDA would maintain authority over any other animals as well as over animals that are not intended for agricultural purposes.

2.6.5 Processes

The current regulatory framework and how all three agencies work together is summarised in the **2017 Update to the Coordinated Framework for the Regulation of Biotechnology**. The document best explains the roles and responsibilities through case studies.

2.6.5.1 APHIS

According to **7 U.S. Code §7712**, APHIS regulates the planting, importation, or transportation of GM plants and may prohibit or restrict the importation, entry, exportation, or movement in interstate commerce of any plant and plant product if it is considered necessary to prevent the introduction of a plant pest or noxious weed within the United States.

Under the new SECURE rule, developers can **request a confirmation** from APHIS that a modified plant qualifies for an exemption and is not subject to APHIS regulations in **7 CFR Part 340** in terms of controlling the movement of organisms modified or produced through genetic engineering. APHIS will provide a written response within 120 days as long as the information submitted is sufficiently detailed. Both the request and the confirmation letter will be posted on its website.

If regulated, a permit from APHIS will be required for the movement of GE organisms as stipulated in **7 CFR §340.5**.

2.6.5.2 FDA

The FDA's primary statutory authority is the FD&C Act, which authorises the agency to regulate, among other things, "**adulterated food**", "**food additives**", and "**new animal drugs**".

Under FD&C Act, substances added to food can be classified either as "food additives" or substances added to food classified as "generally recognised as safe" (GRAS) under the intended conditions of use. While food additives require approval

from the FDA that they are safe before they can be marketed, GRAS uses of substances are not subject to preapproval requirement.

In most cases, FDA treats foods derived from GMOs like those derived from conventional counterparts and therefore presumptively GRAS. However, if a GM product differs significantly in structure, function, or composition from substances found currently in food, premarket approval of the substance as a food additive would be required.

FDA has a “voluntary” **consultation procedure** in place for developers of new plant varieties intended for food use, including GMOs. This procedure is mandatory in practice. During the consultation, the FDA aims to determine if regulatory action is needed with respect to food derived from the new variety regarding “significantly increased levels of plant toxicants or anti-nutrients, reduction of important nutrients, new allergens, or the presence in the food of an unapproved food additive”. The consultation also addresses food safety aspects of **new proteins** produced by new plant varieties, including those developed through genetic engineering. The detailed information regarding completed **consultations of new non-pesticidal proteins** is made public by the FDA.

The FDA **claims** jurisdiction over GE animals using its authority to regulate “new animal drugs”. Under FD&C Act, new animal drugs are automatically deemed unsafe unless the FDA has approved a New Animal Drug Application (NADA) for the particular use of the drug. Except in cases in which the FDA exercises discretion to decline to require compliance, or where the drug is only for investigational use and thus need only conform to specified exemptions, the FDA requires a GE animal to be the subject of an approved NADA based on a demonstration that it is safe and effective for its intended use.

A NADA for a GE animal must include information on the animal’s identification, chemistry, clinical purpose, labelling, components and composition, manufacturing methods, facilities, and controls, safety and effectiveness; environmental impact, and

other information. Currently, **AquAdvantage salmon** and **GalSafe pigs** are the only GE animals approved for human consumption.

2.6.5.3 EPA

Under FIFRA, the EPA regulates the manufacture, sale and use of pesticides. Under FD&C Act, the EPA must establish a tolerance or exempt the pesticide from the requirement to have a tolerance. Pesticides must not cause "unreasonable adverse effects on the environment", which is defined to include both the safety to the environment and safety for human consumption, and all must be registered with the EPA before they can be distributed commercially. Before they can be registered, they must be tested and shown to be safe.

As stated in **40 CFR §174.1**, the above also applies to genetically engineered plant-incorporated protectorants (PIPs) with herbicide tolerance and/or insecticide properties covered by **40 CFR Part 174**. Therefore, standard registration procedure for pesticides apply unless they are made exempt by regulation. For instance, PIPs are **exempt** from registration under FIFRA if the PIP is used in a crop used in food, and its residues are exempt from regulation under FD&C Act, if the PIP is an inert ingredient listed as exempt by the EPA, or if the PIP is from a plant that is sexually compatible with the recipient plant.

Under TSCA, the EPA has **authority** to regulate GE microorganisms that may present an unreasonable risk of injury to health or the environment. Manufacturers of covered substances must submit a pre-manufacture notification (**Microbial Commercial Activity Notice**) to the EPA before these are used for commercial purposes.

2.6.5.4 Assessment of environmental effects (all agencies)

The NEPA requires federal agencies to prepare **Environmental Assessments** (EA) of "major" federal actions, such as adopting a policy or approving a product or a permit, to determine if they are likely to significantly impact the environment. If a federal action is likely to have a significant impact, the agency must prepare a more

detailed evaluation called an **Environmental Impact Statement** (EIS). In theory, federal agency approvals of GMOs may require an EA or an EIS.

Many actions are categorically excluded from the requirements of the NEPA. If not already categorically excluded, the agencies have a lot of freedom to decide whether a more comprehensive EIS is warranted or less comprehensive EA suffices, meaning that the assessment for the effects to the environment may potentially be neglected.

2.6.6 Regional restrictions

The federal pre-emption doctrine bars conflicting State regulation in the areas that Congress intends to regulate on the federal level. Therefore, this precludes many aspects of State regulation of GMOs in the United States.

However, cultivation may be banned in certain areas of the United States, including by municipal governments.

2.6.7 Labelling

National Bioengineered Food Disclosure Standard (**7 CFR §66.3**), which primarily applies to human food derived from plants, requires manufacturers, importers, and certain retailers to disclose the presence of bioengineered foods and bioengineered food ingredients.

The definition of “bioengineered food” stipulates that foods modified through *in vitro* rDNA techniques do not contain modified genetic material if the material is not detectable. However, according to **7 CFR §66.9**, modified genetic material is considered “not detectable” if, pursuant to the recordkeeping requirements of **7 CFR §66.302**, the entity responsible for making a BE food disclosure maintains:

1) Records to verify that the food is sourced from a non-bioengineered crop or source; or
2) Records to verify that the food has been subjected to a refinement process validated to make the modified genetic material in the food undetectable; or

3) Certificates of analysis or other records of testing appropriate to the specific food that confirm the absence of modified genetic material.

Therefore, “not detectable” is a term of art as it includes not only the common sense meaning of the term but also provides for the records from suppliers or the records on the refinement process used to justify the conclusion that the modified genetic material is not detectable.

Incidental additives, such as processing aids, are not considered bioengineered food as long as these are present in food at an insignificant level and do not have any technical or functional effect in the food.

As per **7 CFR §66.5**, the following are exempt from the requirement to be labelled under the National Bioengineered Food Disclosure Act:

- food served in a restaurant or similar retail food establishment;
- very small food manufacturers;
- a food in which no ingredient intentionally contains a bioengineered substance, with an allowance for inadvertent or technically unavoidable BE presence of up to 5% for each ingredient;
- a food derived from an animal that was fed feed produced from, containing, or consisting of a bioengineered substance; and
- food certified under the National Organic Program.

AMS maintains a **List of Bioengineered Foods**, listing the crops or foods that are available in a bioengineered form. Currently, it lists alfalfa, apple (Arctic™ varieties), canola, corn, cotton, eggplant (BARI Bt Begun varieties), papaya (ringspot virus-resistant varieties), pineapple (pink flesh varieties), potato, salmon (AquAdvantage®), soybean, squash (summer), and sugar beet.

For foods on the list, and those derived from the foods on the list, there is a presumption that it is BE food unless the entity has other records to demonstrate that it is not. For foods not on the list, like enzymes, yeasts, and other microorganisms, if

a regulated entity's records demonstrate that they have actual knowledge that they are using a bioengineered version of these foods, then they must make a disclosure.

Special rules apply to foods under USDA jurisdiction (i.e. poultry, meat, egg products, catfish) – such foods would only be subject to BE food labelling requirements if the most predominant ingredient of the food is not meat, poultry, or egg product, or in the case where the most predominant ingredient is broth, stock, water, or a similar solution, then the second-most predominant ingredient.

FDA also has own **guidance for industry** on voluntary labelling indicating whether foods have or have not been derived from genetically engineered plants. It was recently updated to reflect that the FDA no longer has authority over voluntary labelling to indicate the presence of genetically engineered content in human foods including those derived from plants. However, FDA retains jurisdiction over labelling statements to indicate the absence of genetically engineered content in human food. While the FDA uses the term "genetically engineered", the guidance indicates that it is included under the term "bioengineered" as used in the national standard.

Additionally, there are third parties who offer certification for "non GM" claims on food products such as the **Non-GMO Project**. In addition, organic certification would also ensure a "non-GM" claim would be met.

2.6.8 Traceability

There are no legal requirements regarding traceability. Submitting reference samples or testing methods as part of seeking approval in the US is not required.

When it comes to labelling GM foods under the National Bioengineered Food Disclosure Standard, besides actual testing, the records from suppliers or the records on the refinement process may also be used to substantiate the conclusion that the food contains no detectable modified genetic material. USDA AMS provides **guidance** on testing methods and refining process validation.

For foods on the List of Bioengineered Foods, there is an automatic assumption that it is bioengineered unless proven otherwise.

2.6.9 Low level presence policy

United States **endorsed** the International Statement on Low Level Presence and participates in the Global Low-Level Presence Initiative. It also signed an **agreement** with Argentina, Brazil, and Canada on LLP.

Establishing LLP policies is one of Canada's commitments under the new trade agreement with the US and Mexico (CUSMA).

Currently, there is only an outdated **statement** by APHIS regarding USDA's policy on LLP from 2007.

2.6.10 Monitoring/enforcement

There are no legal requirements for the monitoring.

2.6.11 Products on the market

Currently, there are events approved in the United States for alfalfa, apple, canola, chicory, cotton, corn, flax, melon, papaya, pineapple, plum, potato, rice, soybean, squash, sugar beet, sugarcane, tobacco, tomato, and wheat.

GE salmon and GE pork have also received approval for food use.

2.6.12 Summary

United States mostly regulate the products based on the characteristics of the product and its intended use, regardless of the process used to create the product. The important exception to the above would be GE animals as these are currently regulated as "new animal drugs".

For everything other than the GE animals, the risk of the product is compared to products that already exist in the market. If the new GE product is no riskier than conventional counterparts are, then it is deemed scientifically equivalent and considered as generally recognised as safe (GRAS) under the intended conditions of use.

The above does not apply to GM animals as these are regulated under “new animal drugs” provisions of the FD&C Act and as a result very much differently from conventionally bred animals. At the same time, all biotechnology animals are regulated the same way regardless of the particular technique used. FDA’s regulation of animal biotechnology products differs from its regulation of plant products because FDA’s review for animals includes determining whether intentional genetic alterations are safe to the target animal, in addition to a determination of food safety (for food-producing animals), and efficacy. However, the above may substantially change if USDA succeeds in taking control over GE animals from FDA.

Since both GE products and conventional counterparts are deemed to be substantially equivalent, there is no need to have a separate legislation for genetically engineered products. This obviously means that legislation that is specific to genetically engineered products does not exist and various provisions are scattered throughout different pieces of legislation and guidance documents by at least three federal agencies.

The distribution of responsibilities and oversight between the federal agencies in the regulation of products of biotechnology was summarised in a recently an updated Coordinated Framework. However, it is already partially outdated as a result of ongoing efforts to relax the regulations.

It is also important to note that the decision-making process cancan be swayed not only to influence by politics but also by industrial lobbyism.

Under the updated Coordinated Framework, information submitted for previously approved crops with comparable traits can be reused, so that all the relevant data would not need to be generated again.

2.7 Comparison

2.7.1 Regulatory approach

All six markets reviewed here have substantial differences in how GMOs and products derived from GMOs are regulated. A brief comparison of regulatory frameworks in all 6 markets is provided in **Annex 3** to this report. Authorisation procedures for deliberate (commercial) release are compared in **Annex 4** to further illustrate the differences.

The starkest difference is in the fact that the European Union and Australia make significant emphasis on the process used to derive the product while Argentina, Canada, and the United States may not regulate a product as a GMO if the product is substantially equivalent to the product derived by more conventional techniques. In this regard, Canada and the United States do not even have a legislation specifically dedicated to reviewing GMOs – genetically modified products are regulated under exactly the same legal provisions as their conventional counterparts.

In Brazil, the introduction of a separate process for the assessment of products derived using newer techniques on a case-by-case basis has effectively created a hybrid system where anything considered falling within the scope of older GM legislation is subject to a full oversight under the older legislation but products demonstrated to meet one of the conditions in the legislation will not be considered GMOs and as a result will escape further oversight by the authorities. To benefit from less oversight, an assessment first needs to be requested from the authorities and the absence of such request puts the product fully within the scope of GMO legislation.

The focus on the final product rather than on the processes used to derive the product in Argentina, Canada, the United States, and partially in Brazil means that

the approach is flexible enough to accommodate any new techniques. Meanwhile, the Australian approach relies on the Regulator periodically reviewing the lists of techniques that generate or does not generate GMOs, but amending the lists is a lengthy process as it involves consulting various stakeholders. The regulatory system in the European Union in this regard offers little by offers little by way of flexibility since all organisms obtained by new mutagenesis techniques are automatically considered GMOs in so far as the techniques and methods of mutagenesis alter the genetic material of an organism in a way that does not occur naturally.

The lack of dedicated legislation in Canada and the United States has meant that the regulation of GM products is fragmented across multiple pieces of legislations. Products tend to be regulated by different agencies based on the intended use or depending on specific characteristics of the product (presence of pest elements, expressed insecticide or herbicide-resistance properties etc.). By contrast, in Australia, all dealings with GMOs are not only regulated within the same regulatory scheme but also overseen and monitored by a single central authority dedicated to gene technology. Albeit, the intended use may trigger additional layer of oversight by other agencies but that is also true in other markets with the exception of the European Union.

Another area of major differences is the extent of oversight. New plant varieties are subject to a “voluntary” consultation (*de facto* mandatory), GM animals are currently approved as “new animal drugs”, and plant-incorporated protectants are subject to a review by EPA. Other than that, proponents are given a lot of freedom but also responsibility to make the necessary assessments on their own or with outside assistance whether the product and associated activities require any involvement from the authorities.

Similarly, the regulatory frameworks in Australia and Brazil also provide that lower risk activities involving GMOs can be conducted without prior authorisation from the authorities. For example, in Brazil, planned release into the environment of risk class 1 GMOs can be authorised by the company’s own CIBio. In Australia, a wide range

of activities with GMOs undertaken in containment may be undertaken as long as an IBC established by an accredited organisation concludes that the dealing is considered a notifiable low risk dealing. By contrast, in Argentina, all activities, including contained, that involve GMOs to be used in the context of agriculture require prior authorisation.

In theory, deregulation of lower risk activities helps the authorities to save precious resources and focus on riskier activities. Less red tape also benefits the developers. On the other hand, these activities may not receive a consistent level of in-depth scrutiny, as could be noted in the US and Brazil approach. This appeared driven in part by the lack of sufficient resources available to the competent authority.

The Canadian approach is special in a sense that the authorities make a great emphasis on various pre-submission consultations including the assistance in determining whether the authorisation is needed in the first place. This way the authorities gain greater visibility of products currently in the development. Well-defined procedures for in-depth consultations also help with finalising approvals within fairly tight timeframes established by legislation.

It is also important to consider the authorities responsible for the oversight of GMOs in all six markets, especially in their independence and resources. A case in point is the regulatory framework in Brazil where the second level of review before approval by a council of government ministers has effectively diminished, leaving CTNBio that represents mostly the interests of biotechnology industry as solely responsible for the approvals.

By contrast, the system in Argentina has more checks in place as the risk assessments are conducted both by a dedicated department within the relevant ministry and national advisory committee representing various government institutions, universities, and industry associations leaving the final decision with the government.

2.7.2 LLP and traceability

Stark differences between the markets reviewed here could be seen in their efforts to agree a policy for dealing with LLP. It is not surprising to see countries with the highest numbers of GM approvals and countries mostly importing the crops potentially containing GM crops on the opposite sides of the issue. Main exporters of GM crops (United States, Canada, Argentina, and Brazil) have long lists of GM approvals and are interested in the LLP issue so it does not restrict their exports. They are less concerned with the possibility of LLP in their own imports as they are more likely to have the GM crop inadvertently present already approved.

In contrast, the EU applies a zero tolerance policy. The issue in the EU is contributed by the recent ruling of the Court of Justice of the EU confirming the wide reach of GM legislation and the fact that products derived through the use of new breeding techniques may not be even traceable.

Even for GMOs produced using older techniques, non-EU countries reviewed here do not seem to have comparable universal post-market requirements like in the EU, where GMOs, after authorisation, are subject to traceability, labelling, monitoring, and liability obligations defined by law. To assist with the monitoring and enforcement, the EU has a central Reference Laboratory for GM Food and Feed that works together with national enforcement laboratories within the European Network of GMO Laboratories.

Other countries tend to have only some but not all of the elements established in the EU. For example, submitting test methods and reference materials is mandatory in Argentina (unlike in other 4 non-EU countries) but there is no official traceability system in place and tracing is done on the private basis, as needed.

2.7.3 Labelling

Labelling of GM foods is one of the areas where differences between the countries assessed within the scope of this report are the most prominent. Regulatory

approaches to GM labelling in all 6 countries are summarised in **Annex 5** to this report.

The European Union and Australia (and New Zealand by association) have the most comprehensive regulatory frameworks for the labelling of GM foods. However, there are crucial differences in the approach between the two. First of all, the labelling requirements in the EU are based purely on whether a GM food or feed derived from a GM source has been used anywhere in the production process whereas Australian labelling regime focuses primarily on the presence or absence of novel DNA and/or novel protein in the final food. As a result, in Australia, highly refined ingredients, food additives, and even processing aids would be automatically exempt from the requirement to be labelled as GM foods as long as they do not contribute novel DNA or novel protein to the final product. In the EU, ingredients such as highly refined oils and food additives would not be exempt regardless whether they contain any novel DNA or novel protein or not. Processing aids would be exempt but only because these are not considered food or feed for the purposes of GM regulation in the EU.

There are also some additional differences as well. For instance, flavourings are specifically exempt in Australia if present in the final food in a concentration of no more than 0.1%. There is no such exemption in the EU as there is no equivalent exemption for foods for immediate consumption as in Australia.

Also, EU labelling requirements extend to feed as well while in Australia the requirements are limited to food. On the other hand, while in both countries foods derived from animals fed GM feed are not considered genetically modified, the Australian Competition and Consumer Commission **deemed** it is misleading to claim that GM-fed poultry is GM-free as consumers may perceive the claim to mean that everything about this poultry is GM-free.

The GM labelling requirements in Brazil apply to all foods (packaged, in bulk, or sold as such) intended for human or animal consumption containing more than 1% of GM ingredients. The label must provide information regarding their transgenic origin as well as a specific symbol. Also, consumer must be informed about the donor species

of the gene within the list of ingredients. Interestingly, foods derived from animals fed GM feed are also covered by mandatory GM labelling.

Conversely, the legislation specifically addresses the question of negative GM claims as it permits the claims about the ingredient being GM-free (e.g. GM-free corn) only on crops that have a genetically modified counterpart in the Brazilian market. The draft proposal to update the GM labelling requirements appears to be stuck in the Parliament since 2015.

Two countries, Argentina and Canada, have no mandatory requirements for labelling GM content in foods. Both treat GM foods the same as non-GM foods when it comes to labelling requirements. While Argentina has no intention to establish any special labelling rules for GM foods that are substantially equivalent to their conventional counterparts, Canada at least has a national standard for voluntary labelling and advertising of foods that are or are not products of genetic engineering, which helps to model voluntary positive and negative label declarations that are understandable and not misleading.

This standard considers the levels of 5% and 95% for making positive claims:

- if below 5%, cannot claim the presence of genetically engineered ingredient;
- if between 5-95%, then “from a GE/non-GE blend” would be acceptable;
- if more than 95%, permitted to claim that an ingredient is a product of GE.

It also provides for an adventitious (accidental) inclusion of food from a genetically engineered crop of less than 5% when making negative claims. Processing aids, enzymes below 0.01% and other components used in small amounts are not deemed to affect whether a food or ingredient is considered to be or not to be a product of genetic engineering.

Notably, the standard defines genetic engineering to cover any products modified by techniques by which the genetic material of an organism is changed in a way that does not occur naturally by multiplication and/or natural recombination. Hence, this labelling standard is entirely process-based.

Although GM foods in the United States are largely considered to be substantially equivalent to the conventional counterparts, mandatory labelling requirements for bioengineered foods were recently established in the National Bioengineered Food Disclosure Standard. It mainly applies to human food from plants and mandatory labelling requirement is limited to foods modified through *in vitro* rDNA techniques.

Processing aids and other incidental additives are not considered bioengineered food if present at an insignificant amount and have no technical or functional effect in the food. In contrast, enzymes, yeasts, and other microorganisms that do not meet the definition of an incidental additive would be subject to the mandatory labelling if a regulated entity's records show that they have actual knowledge that they are using a bioengineered version of these.

Equally out of the scope would be foods modified through *in vitro* rDNA techniques if the modified genetic material is deemed "not detectable". This "not detectable" status can be demonstrated not only by testing but also by gathering records from suppliers to show that the food is sourced from a non-BE crop or source or by showing records that the food has been subjected to a refinement process that has been validated to reduce the level of modified genetic material below the level of analytical level of detection.

The Standard also includes some broad exceptions from the requirement to label the food as bioengineered for very small food manufacturers, foods served in restaurants and other retail food establishments, and foods certified under the National Organic Program. A food derived from an animal that was fed BE feed is also exempt. The limit for inadvertent or technically unavoidable BE presence is established at up to 5% for each ingredient.

Unlike any other countries assessed, the AMS maintains a list of crops or foods that are available in a bioengineered form worldwide. If the food contains any crop or food on the list, the food is automatically bioengineered unless the records are available to demonstrate the opposite.

The standard does not address negative labelling. So, this must only be truthful and not misleading.

2.7.4 Conclusions

GMO products do not enjoy a wide public support in any of the six markets reviewed, to say the least. Yet, some countries made a political decision to embrace agricultural biotechnology and the potential economic benefits it may offer to a much greater extent compared to the EU. There is no doubt that the way GMOs are regulated and how quickly new products can be brought onto the market has a direct impact on how widespread the adoption of GM crops in the agriculture is in these countries.

Notably, the markets with the most approvals of GM products reviewed here are also the leading exporting countries globally. Of course, it may be rather a coincidence or caused predominantly by other factors as some doubts as to the economic benefits of the use of GM crops, including crop yields, are raised from time to time, for example, by the **Canadian Biotechnology Action Network** (CBAN).

Nonetheless, the European Academies Science Advisory Council (EASAC), representing European national academies and academic bodies, in its **statement**, considers the EU approach ‘cumbersome’ and ‘no longer fit for purpose’, and is calling for a *radical reform*. The quick adoption of new genome editing techniques elsewhere in the world, especially against the backdrop of the CJEU ruling concerning “precision breeding techniques”, could put the EU agricultural sector at a considerable disadvantage.

Slow adoption of agricultural biotechnology, especially newer techniques, may also force plant researcher to seek opportunities **outside of Europe** given these firms will likely prefer to conduct research and trials where they encounter less obstacles in the process and where the final outcome is much more predictable, including in terms of timelines.

On the other hand, even the markets that are more open to the use of agricultural biotechnology are sensitive to how the same product would be regulated by their major export partners. Therefore, a scenario that moved closer towards finding at least a certain level of common ground across the international stage would be most desirable.

3 Novel & GM foods: multinational treaty implications

3.1 Introduction

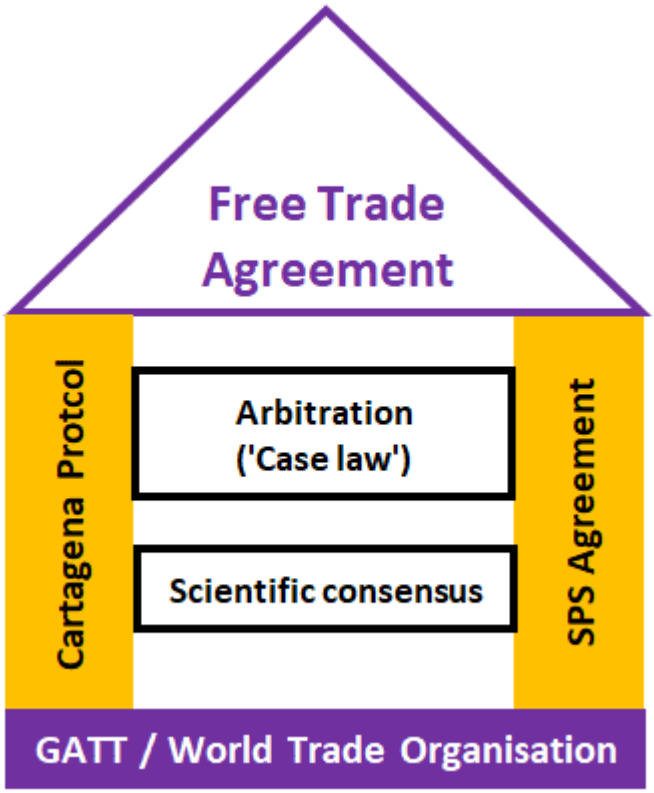
International trade between most jurisdictions is usually subject to the provisions of global agreements and in certain cases free trade agreements, where two or more jurisdictions decide to agree on more liberal agreements in specified aspects in the trade of goods and/or services. This part of the report considers the role of such agreements in establishment and operation of regulations concerning “novel foods” or foods derived from genetically modified organisms.

3.2 International trade agreements

3.2.1 Principles

Figure 5 presents a schema showing the relationship between relevant global treaties and free trade agreements. At a global level and of relevance to this discussion are treaties established under the auspices of the WTO. These include the GATT, SPS Agreement, and TBT Agreement as well as the Cartagena Protocol on Biosafety (see glossary). This relationship is strengthened through the generation of a common scientific consensus (in particular, through the Codex Alimentarius Commission) and ‘case law’ arising from arbitration proceedings in the case of trade disputes or discussions in relevant instances. As will be discussed subsequently, free trade agreements between two or more jurisdictions derive from those established within the WTO.

Figure 5. Overview of relationship between relevant international treaties, free trade agreements and supporting processes (GATT, SPS)



3.2.2 The Cartagena Protocol on Biosafety to the Convention on Biological Diversity

Irrespective of purpose (e.g. research or trade), the movement of live genetically modified organisms is subject to an international agreement in the form of the **Cartagena Protocol** on Biosafety to the Convention on Biological Diversity. The Cartagena Protocol has been described as “an international agreement which aims to ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health”. Its scope covers organisms produced by:

a. *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or

b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection. (Article 3)

Fundamental to the protocol is that Article 1 assigns an important role to the "precautionary principle" (see **glossary**) from the point of view of environmental protection as articulated in Principle 15 of the **Rio Declaration** on Environment and Development 1992. Principle 15 of the Declaration states:

- In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation.

Other salient points of the Cartagena Protocol are that:

- It establishes lines of communication between those exporting genetically modified organisms and those importing them (this includes the Biosafety Clearing House discussed below);
- While the protocol is generally concerned with minimising the effects of genetically modified organisms on biodiversity, there are specific provisions relating to "living modified organisms intended for direct use as food or feed, or for processing", which place similar responsibilities on signatories; (Article 11)
- It sets out the terms of reference for their risk assessment (again, making reference to the precautionary principle) and risk management. (Articles 15 and 16)

The protocol currently has 173 parties including the United Kingdom. It also operates the **Biosafety Clearing House** (BCH), which provides a range of resources for sharing information concerning genetically modified organisms. These include:

- **Living Modified Organism (LMO) Registry** (provides summary information on all living modified organisms registered in the BCH including transformation

events, genetic modifications, and the unique identification code (if available) for each record);

- **Organism Registry** (includes those organisms that have been registered with the BCH as parental, recipient or donor organisms);
- **Gene and DNA Sequence Registry** (provides summary information on gene inserts and characteristics of the genetic modifications of the LMOs registered in the BCH).

3.2.3 General Agreement on Tariffs and Trade (GATT) / WTO

Currently, world trade is regulated under the auspices of the WTO. This is the direct successor of the **General Agreement on Tariffs and Trade** (GATT) which still underpins the WTO. Trade agreements between individual members of the WTO derive from GATT and other instruments developed by the WTO. As will become apparent, trade treaties are economic in nature and, while there are protocols relating to food safety, animal and plant health (sanitary and phytosanitary agreements), little or no detail is provided regarding food derived from genetically modified organisms and “novel foods”. At the WTO level, additional agreements are in place to ensure that any national regulations concerning food safety as well as animal or plant health are proportionate and do not place potential importing nations at a competitive disadvantage.

3.2.4 WTO Agreement on the Application of Sanitary and Phytosanitary Measures

Of relevance to this report is The WTO Agreement on the Application of Sanitary and Phytosanitary Measures **(SPS Agreement)**. Essentially, this agreement recognises the right of WTO Members to establish control measures to protect human, animal and plant health. However, in doing so, Members must ensure that the measures they deploy are scientifically based and do not act as a discriminatory barrier to trade. Furthermore, the SPS Agreement promotes harmonisation of SPS measures through adoption of a scientific consensus (e.g. Codex Alimentarius) and requires Members to advise each other in advance of the introduction of new or altered legislation relevant to the agreement. To date, it has been that the SPS Agreement is both used as the text on which criticisms or disputes relating to legislation

concerning genetically modified organisms or novel foods as barriers to international trade are based and also constitutes the precedent for relevant sections of free trade agreements.

3.2.5 WTO Agreement on Technical Barriers to Trade

The **TBT Agreement** aims to ensure that technical regulations, standards, and conformity assessment procedures are non-discriminatory and do not create unnecessary obstacles to trade. At the same time, it recognises WTO members' right to implement measures to achieve legitimate policy objectives, such as the protection of human health and safety, or protection of the environment. Although the TBT Agreement has been invoked in trade disputes (discussed in **Section 3.2.7**) concerning genetically modified organisms primarily on the basis that control measures introduced by the European Union discriminated against imports, their application was considered to be inapplicable given that there were SPS issues involved. Article 1.5 of the TBT Agreement states that "the provisions of this Agreement do not apply to sanitary and phytosanitary measures as defined in Annex A of the Agreement on the Application of Sanitary and Phytosanitary Measures".

3.2.6 Codex Alimentarius Commission texts concerning risk assessment of foods derived from application of new biotechnology methods

Although the **Codex Alimentarius Commission** does not come under the aegis of the WTO, the organisation makes reference to the Commission as a source of scientific consensus. The Codex Alimentarius Commission has produced a number of documents concerning the risk assessment of foods generated using "modern biotechnology methods" (typically, based on technologies which have been developed since the 1970's). These are listed in **Table 1** below. One document (CXG 44-2003) sets out the basic principles for risk assessing foods produced by novel technological methods; three (CXG 45-2003, CXG 46-2003, and CXG 68-2008) provide guidance for the safety-assessment of foods derived from plants, microorganisms or animals produced by recombinant DNA technology. A further document (CXG 74-2010) provides guidance on performance data and validation methods for laboratory methods to test for the presence of recombinant DNA

sequences. The final document (CXG 76-2011) is a compilation of relevant documents. It should be noted that definitions used by the Codex Alimentarius Commission with respect to what constitutes a modern biotechnology method are similar to those employed in the Cartagena Protocol (discussed in **Section 3.2.2**).

Table 1. Codex Alimentarius Commission documents relating to the risk assessment of foods derived from modern biotechnology

Reference	Title
CXG 44-2003	Principles for the Risk Analysis of Foods Derived from Modern Biotechnology
CXG 45-2003	Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants
CXG 46-2003	Guideline for the Conduct of Food Safety Assessment of Foods Produced Using Recombinant-DNA Microorganisms
CXG 68-2008	Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Animals
CXG 74-2010	Guidelines on Performance Criteria and Validation of Methods for Detection, Identification and Quantification of Specific DNA Sequences and Specific Proteins in Food
CXG 76-2011	Compilation of Codex texts relevant to the labelling of foods derived from modern biotechnology

Source: **Codex Alimentarius Commission**

3.2.7 WTO adjudications relating to GM foods (case law)

Members of the WTO have the duty to use the organisation's offices to settle trade disputes with other members considered to be in breach of GATT or the subsidiary agreements – in this case the SPS and TBT Agreements. Of relevance to this discussion are the complaints raised by **Argentina**, **Canada** and the **United States** in 2003 concerning the European Union's then approach on the approval of genetically modified commodities ("biotech products"). At issue were:

- An alleged general EU **moratorium** on approvals of biotech products;

- EU measures affecting the timely approval of such products;
- Individual EU Member States prohibiting the import/sale of specific biotech products within their respective territories.

In each case, the arbitration board adjudicated in favour of the complainants based on specific provisions of the SPS Agreement and an overview of the relevant sections of the SPS Agreement concerned is provided in **Table 2**. Dealing with each point in turn.

EU moratorium: The arbitration panel concluded that the moratorium was purely procedural in nature and was not designed to achieve a particular level of sanitary and phytosanitary protection and could not be considered to be an SPS control measure as set out in the agreement.

EU measures affecting the timely approval of such products: The Panel found, that in 24 of the 27 product-specific approval procedures it examined, the procedure had not been completed without undue delay.

Individual EU Member States prohibiting the import/sale of specific biotech products within their respective territories: Some Member States had invoked the precautionary principle to prohibit the import or sale of biotech products within their territories. Although the SPS Agreement permits use of the precautionary principle where insufficient scientific data is available (Article 5.7). This arbitration panel considered that there was sufficient scientific evidence available to perform a risk assessment and that the precautionary principle could not be invoked.

This dispute has been to a large degree resolved, however, the positions of individual Member States with regard to genetically modified organisms is ongoing. Part of the dispute resolution process has been the establishment of the Bilateral Dialogue on Biotech Market Access Issues (discussed in **Section 3.3.2** within the context of the Comprehensive and Economic Trade Agreement between the EU and Canada).

Table 2. Overview of WTO adjudication on dispute DS293 (EC — Approval and Marketing of Biotech Products)

Issue	Adjudication	Relevant sections of SPS Agreement cited
Moratorium	Upheld	2.2 Application of provisional measures in the absence of sufficient scientific evidence5.1 Requirement that risk assessment methods be in accordance with international best practice 8 Requirement to observe provisions of Annex C Annex C, 1.3 Control, inspection and approval procedures
Non-timely approval	Upheld	Article 8 Requirement to observe provisions of Annex C, 1.3 Control, inspection and approval procedures
Individual MS bans on import/sale	Upheld	

Source: **World Trade Organization**

3.2.8 WTO discussions relating to EU novel foods regulation

Consideration of WTO and Codex Alimentarius documentation finds no definition of a novel food as currently set out in Article 3(2)(a) of Regulation (EU) 2015/2283. Although not the subject of a dispute, regulation of novel foods is a topic of ongoing discussion between the EU and other members of the WTO. **Specific trade concerns** in relation to the old regulation on novel foods in the EU were first raised at WTO SPS Committee meetings in 2006 and the last entry, regarding the new regulation, was made in 2017.

The discussion was initiated by various South American countries concerned about restrictions introduced by the initial EU novel foods legislation (Regulation (EC) No 258/97) in relation to indigenous plant-based foods with a significant history of consumption in that country and also permitted for sale in other jurisdictions, coupled with proposal to revise the legislation. In the period up to 2015 when the new regulation was promulgated, discussions focussed on the perceived need for the EU to revise its legislation in order to differentiate foods with a prior history of consumption in a third country. One outcome from these discussions was a revised approval process for “traditional foods” as set out in Chapter III (Articles 14-20) of Regulation (EU) 2015/2283. Nevertheless, adoption of this regulation with its provision for “traditional foods” has not fully resolved the issue. South American States in particular have argued that:

- The replacement regulation itself was not to be based on scientific evidence and a risk assessment and therefore to be inconsistent with Articles 2.3 (discrimination and failure to recognise equivalence), 5.1 (requirement to conform with international best practice), and 5.2 (availability of scientific evidence) of the SPS Agreement;
- The 25 year period of demonstrated consumption was not scientifically justified;
- The replacement regulation continues to place an undue burden and cost and therefore goes against Article 10 (requirement to take into account needs of developing countries).

In response, the EU has stated that:

- It was confident that the new regulation was consistent with the SPS Agreement. As it was not possible to anticipate potential risks associated with novel foods or processing methods in one comprehensive risk assessment, the high-level of food safety pursued in the European Union could only be achieved through a pre-market approval scheme, in accordance with Article 8 (requirement to observe provisions of Annex C) and Annex C (Control, inspection and approval procedures) of the SPS Agreement.
- The 25-year period of consumption translated into roughly one generation, which was on the lower end of the spectrum recommended by international best practice.
- The new regulation was in line with special and differential treatment (Article 10), as it provided for a simplified and faster procedure for the products in question.

3.3 Trade agreements between specific jurisdictions

This section considers certain trade agreements to which either the EU or Canada have been parties to. It is divided into three parts:

- EU / international trade in key commodities;
- The relevant provisions of the treaties;
- Some policy or operational implications.

3.3.1 EU / international commodity trade

3.3.1.1 Overview

Table 3 presents an overview of the major GM crops cultivated around the world and the numbers of countries involved (as of 2015). Commodities of interest would include maize, cotton (as cotton seed), soya, and oil seed rape. Although both raw and refined sugar are internationally traded commodities, for technological reasons, the parent crops (sugar cane or sugar beet) are not. Due to the sugar refining process, any DNA that might be carried over into raw or refined sugar is so degraded that it is not possible to differentiate the product from conventional or GM crops (**Oguchi *et al.*, 2009**).

In terms of global production, the Royal Society reported that, in 2015, GM crops accounted for 83% soybean, 75% cotton, 29% maize, and 25% oil seed rape (canola). Among the countries growing GM crops, by area planted the largest users were the USA (70.9 Mha), Brazil (44.2 Mha), Argentina (24.5 Mha), India (11.6 Mha), and Canada (11 Mha).

For 2019, ISAAA deemed the area dedicated to GM crops to be 71.5 Mha in the USA, 52.8 Mha in Brazil, 24 Mha in Argentina, 12.5 Mha in Canada, and 11.9 Mha in India. 79% cotton, 74% soybeans, 31% maize, and 27% canola were biotech crops.

According to USDA Foreign Agricultural Service report, Spain and Portugal were the only two countries within the European Union to grow GM maize in 2020.

Table 3. Overview of significant GM crops grown around the world (2015)

Crop	No. countries	Crop	No. countries
Maize	17	Sugar beet	2 (US & Canada)
Cotton	15	Papaya	2 (US & China)
Soya	11	Potato, squash, alfalfa	1 (US)
Oil seed rape	4	Aubergine	1 (Sri Lanka)

Source: The Royal Society

The key major exporters into the EU of potentially GM crops of interest for the last year for which there are complete data (2019/2020) are shown in Table 4. A breakdown of cotton seed, cotton seed oil or cotton seed cake data is not presented due to the low volumes imported as reported by Index Mundi. The top two exporters of any of the three commodities accounted for approximately 80% of exports into the EU. For soya beans, these were Brazil (45%) and the US (35%); for maize, Ukraine (62%) and Brazil (25%); for oil seed rape, Ukraine (47%) and Canada (32%). Of the major exporters, the US, Brazil, and Canada have substantial areas under GM cultivation (Table 5). According to USDA Foreign Agricultural Service, in Ukraine and Serbia, cultivation of genetically engineered crops is currently not permitted.

Table 4. Import volumes (millions of tonnes) of soya bean, maize, and oil seed rape into the EU (2019/2020) shown by country of origin

Soya bean 14.7 millions of tonnes (total import volume):

Country	**Volume (%)**
Brazil	6.6 (45)
USA	5.2 (35)
Canada	1.5 (10)
Ukraine	0.7 (5)
Serbia	0.1 (0.7)

Source: **European Commission**

Maize 18.5 millions of tonnes (total import volume):

Country	**Volume (%)**
Ukraine	11.4 (62)
Brazil	4.7 (25)
Serbia	1.2 (6)
Canada	0.3 (2)
Russia	0.2 (1)

Source: **European Commission**

Oil seed rape 6.2 millions of tonnes (total import volume):

Country	**Volume (%)**
Ukraine	2.9 (47)
Canada	2.0 (32)
Moldova	0.09 (1.5)
UK	0.08 (1.3)
Serbia	0.05 (0.8)

Source: **European Commission**

Importantly, EU import statistics are based on multiple commodity codes which do not differentiate between GM and non-GM products. Consequently, it is not possible to break down the data further into what proportion might be GM, still less what proportion may contain a particular event (e.g. MON 810). However, some indication can be found by looking at the relative areas under cultivation (**Table 5**) in the major non-European exporters (US, Brazil, and Canada). In each of these countries in excess of 90% of the cultivated area for soya, maize, and oil seed rape is dedicated to GM varieties. The major events concern herbicide tolerance, insect resistance or stacked events relating to both. Irrespective of country of origin or commodity, almost all of the GM varieties grown have herbicide tolerance as either a single or stacked event. Most of the maize crops grown in the US and Brazil as well as soya beans grown in Brazil also have insect resistance, again as either a single or stacked event.

Table 5. Proportion of crop area under GM cultivation of major soya, maize, and oil seed rape exporters

Soya:

Exporter (year)	Herbicide tolerant	Insect Resistant	Herbicide tolerant and Insect Resistant
US (2016)	94%	Not disclosed	Not disclosed
Brazil (2017)	39%	Not disclosed	58%
Canada (2016)	94	Not disclosed	Not disclosed

Source: ISAAA reports for the **US**, **Brazil**, and **Canada**

Maize:

Exporter (year)	Herbicide tolerant	Insect Resistant	Herbicide tolerant and Insect Resistant
US (2016)	13%	3%	76%
Brazil (2017)	4%	21%	75%
Canada (2016)	93	Not disclosed	Not disclosed

Source: ISAAA reports for the **US**, **Brazil**, and **Canada**

Oil Seed Rape:

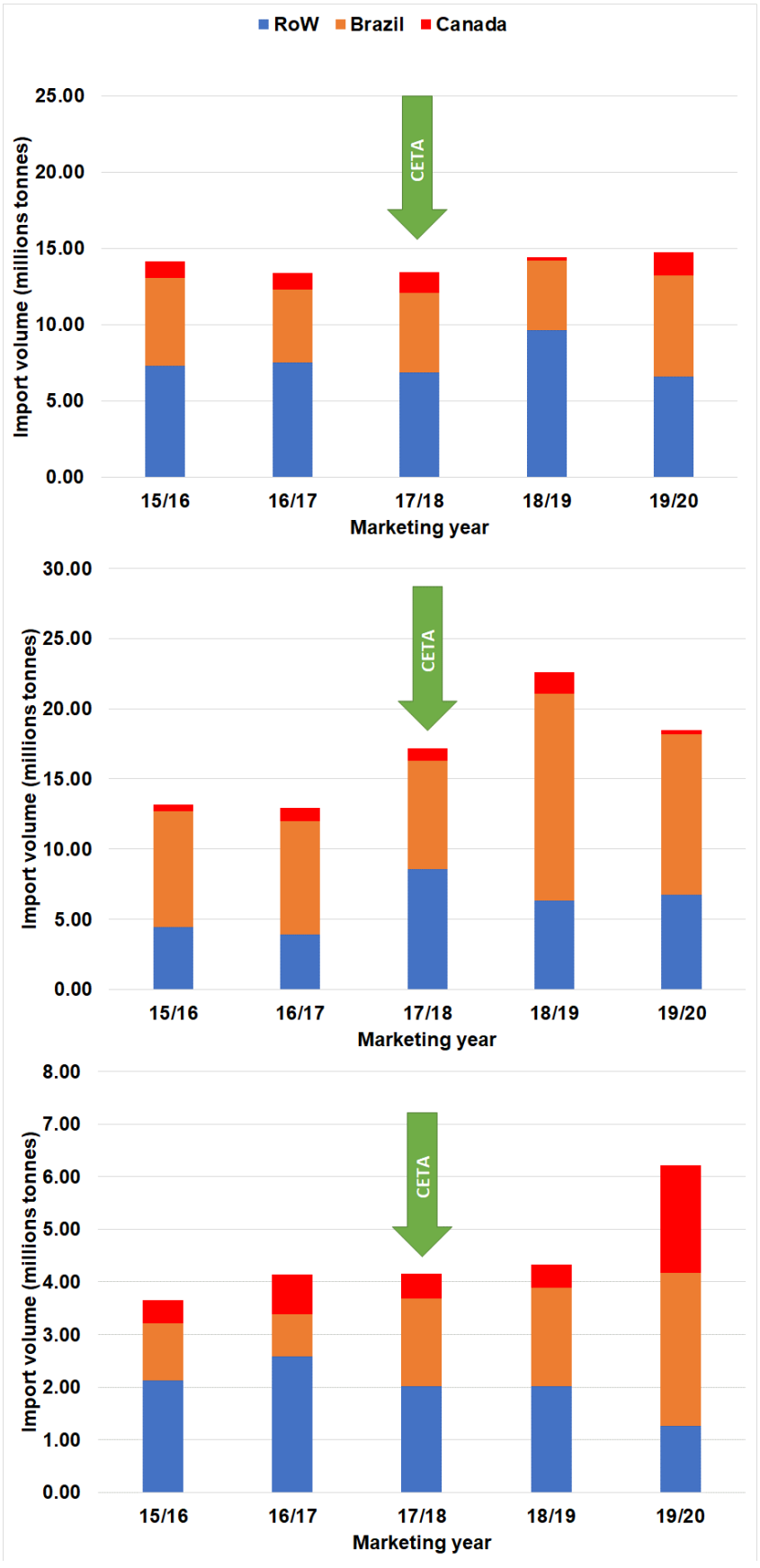
Exporter (year)	Herbicide tolerant	Insect Resistant	Herbicide tolerant and Insect Resistant
US (2016)	90%	Not disclosed	Not disclosed
Brazil (2017)	-	-	-
Canada (2016)	93%	Not disclosed	Not disclosed

Source: ISAAA reports for the **US**, **Brazil**, and **Canada**

3.3.1.2 Effect of trade agreements on commodity trading (CETA)

Imports of commodities into the EU are driven by a number of factors including, but not restricted to, global availability, demand, levels of home production, transport costs and imposition of quotas and tariffs on one or more importing countries. All of these factors vary from year to year. As shown in **Table 4**, one of the top five importers of the three key commodities is Canada which entered into a free trade agreement with the EU in 2017 (CETA, discussed in **Section 3.3.2**). Canada's share of imports relative to the country with the largest share of imports in a five year period before and after entering the agreement are shown in **Figure** . The agreement provisionally came into force on 16th September 2017 – approximately three months into the 'import year' used to calculate import statistics (July-June). Depending on the commodity and year, the Canadian share of annual imports of either soya or maize has fluctuated (sometimes higher sometimes lower) since the agreement came into force. It has only been in the case of oil seed rape that the share of oil seed rape imports has increased (as too has that of Ukraine). It is not possible to determine whether or not the progressive increase in Canadian imports of this commodity reflect the introduction of CETA, productivity issues with the EU and UK crop in general, or a combination of the two.

Figure 6. Share of soya, maize and oil seed rape imports from Canada before and after implementation of the Comprehensive Economic and Trade Agreement (CETA)



3.3.2 EU treaties (considering the Comprehensive and Economic Trade Agreement in particular)

It is important to bear in mind that, like the agreements established under the WTO, trade agreements are essentially economic in nature and, in the case of SPS-related matters, deal with principles rather than specifics. A review of the SPS related provisions of EU treaties with Canada (**Comprehensive and Economic Trade Agreement**, CETA), Japan (**EU-Japan Economic Partnership Agreement**) as well as the **agreement in principle** between the EU and Mercosur is provided in **Annex 6**, which shows that provisions relating to sanitary and phytosanitary measures are similar in all three cases.

Given that treaty with Canada (CETA) is the only one with a specific reference to food from genetically modified organisms, it has been used as the example to be considered further. An overview to the relevant chapters which relate (at least in part) to food safety and thus genetically modified or novel foods is provided in **Annex 7**.

In terms of food safety in general and GM foods in particular, Chapters 3 (Trade remedies), 6 (Customs and trade facilitation), 21 (Regulatory cooperation), and 25 (Bilateral dialogues and cooperation) are concerned with exchanges of information to ensure that relevant stakeholders are aware of the regulatory and enforcement environments of the signatories (Chapters 3 and 6) and structures within which regulators may discuss legislation and enforcement in their respective jurisdictions (Chapters 21 and 25). The treaty also addresses technical barriers to trade (Chapter 4), however, as in the case of the World Trade Organization TBT Agreement discussed above, the provisions of this chapter specifically do not apply to “a sanitary or phytosanitary measure as defined in Annex A of the SPS Agreement” (§4.1(b)).

Operationally, the key chapters of the treaty relating to GM foods are Chapters 5 (Sanitary and phytosanitary measures), Chapter 6 (Customs and trade facilitation), and Chapter 25 (Bilateral dialogues and cooperation) and are considered separately below.

Chapter 5 (Sanitary and phytosanitary measures) essentially reaffirms the signatories' commitment to the World Trade Organization SPS Agreement and emphasises that nothing in CETA undermines it. While most of the provisions of this chapter concern animal and plant health from a regulatory communication point of view (issues which had been raised at WTO level, discussed in **Section 3.2.7**), provision is made such that:

- If a Party has a significant concern with respect to food safety, plant health, or animal health, or an SPS measure that the other Party has proposed or implemented, that Party may request technical consultations with the other Party. The Party that is the subject of the request should respond to the request without undue delay. Each Party shall endeavour to provide the information necessary to avoid a disruption to trade and, as the case may be, to reach a mutually acceptable solution. (§5.12)

Chapter 6 (Customs checks and trade facilitation). For the purposes of CETA a "customs check" would include any sanitary or phytosanitary inspection at port of entry. Critically, these should be based on "risk assessment principles, rather than requiring each shipment offered for entry to be examined in a comprehensive manner for compliance with import requirements".

Chapter 25 (Bilateral dialogues and cooperation). As discussed in **Section 3.2.7**, one of the outcomes from the dispute concerning GM between Canada and the EU that was adjudicated by the WTO was the establishment of the "Bilateral Dialogue on Biotech Market Access Issues". This dialogue was incorporated within the terms of reference established by this part of the treaty. Summaries of the meetings held in **2018** and **2019** have been made available in the public domain. Key issues to arise from the discussions related to:

- Communication between individual applicants and EFSA both before a formal application is made and during the risk assessment process;
- The timeliness of both the EFSA risk assessment process and, when favourable, the comitology process for the enabling legislation to place the material on the market;

- The issue of GM salmon traceability was raised by the EU. The Canadian authorities advised that this salmon was not outgrown in Canada and that Canadian exporters were aware of their responsibilities when exporting to the EU (e.g. both a general level in terms of **guidance** to Canadian food exporters, and the **specific requirements** in securing a licence to export fish to the EU);
- The implications of the ruling of the Court of Justice of the European Union (CJEU) concerning "precision breeding techniques" together with the **International Statement on Agricultural Applications of Precision Biotechnology** tabled at the World Trade Organisation and to which Canada was a signatory;
- The possibility for the Member States to restrict or prohibit the use of GM food and feed in their territory and on changes to the comitology process;
- Low Level Presence (LLP), this is when small amounts of a GM crop that has been assessed as safe following Codex Guidelines by at least one country, but has not been approved in the importing country, is unintentionally present in shipments exported to that country. Canada emphasised the importance for jurisdictions, including the EU, to adopt a pragmatic approach to managing LLP to avoid unnecessary disruptions to trade (discussed in **Section 3.3.4**).

As can been seen from the above, most of the issues discussed related either to aspects of the signatories' legislation or its execution and in particular the approval mechanisms used for GM materials. Consideration of the **agenda** for the October 2020 meeting suggests that the same themes remain under discussion. Canada was again seeking details on the operation of the EFSA risk assessment process (Item 2) and post risk assessment approval processes (Item 3), and both parties were to provide further details of ongoing or proposed legislative changes within their jurisdictions (Items 4 and 5).

3.3.3 Canada-United States-Mexico Agreement (CUSMA)

This **agreement** replaced the North American Free Trade Agreement (NAFTA). It has three sections of direct relevance to this report – Chapter 3 (Agriculture), Chapter 9 (Sanitary and phytosanitary measures), and Chapter 11 (Technical

barriers to trade). Chapter 9 reasserts the signatories' commitment to the World Trade Organization SPS Agreement and states that nothing in CUSMA detracts from it. Chapter 11 reiterates the principal articulated in the corresponding WTO agreement that SPS related legislation and enforcement practices cannot in themselves be considered to be technical barriers to trade. Chapter 3 has specific provisions relating to GM foods and is discussed in more detail below.

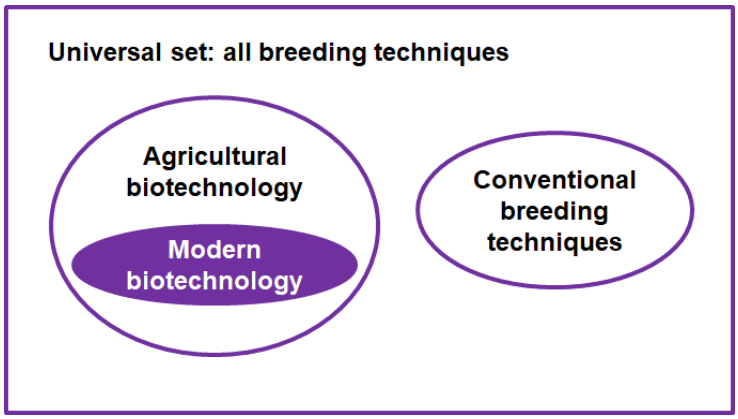
Chapter 3 (Agriculture) is divided into two sections. Section A (General provisions) deals primarily with the economic aspects of agriculture and their impact on cross-border trade. Of relevance to this report is Section B (Agricultural biotechnology) and critically the agreed terminology (Article 3.12) which is detailed in **Annex 8** to this report. Of particular note is the differentiation between different methods used to alter the genetic make-up of a source organism, an overview of which in the form of Venn diagram is provided in **Figure 7**. Breeding techniques essentially fall into two broad subsets:

- Conventional breeding techniques; i.e. those which neither involve the targeted modification of the host DNA nor the direct introduction of DNA from a different species. Examples of conventional breeding techniques would include crossbreeding and mutation breeding;
- Agricultural biotechnology; this term applies to any "deliberate manipulation of an organism to introduce, remove, or modify one or more heritable characteristics of a product … that are not technologies used in traditional breeding and selection". The subset is further divided to establish a further subset, "modern biotechnology", which is restricted to either foods derived from organisms produced by "*in vitro* nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles; or fusion of cells beyond the taxonomic family". For all intents and purposes, this replicates the definitions set out in the Cartagena Protocol discussed in **Section 3.2.2**.

Article 3.14 of the agreement establishes the signatories' recognition of the contribution made by "agricultural biotechnology", recognises the right of signatories to have their own approval processes, but requires that these processes are

transparent, and timely, both regards to any initial application but also where approval needs to be renewed.

Figure 7. Venn diagram showing inter-relationship of different breeding techniques used in food production



LLP occurrence (inadvertent presence of DNA from a genetically modified organism and approved in another signatory country and risk assessed using Codex Alimentarius Commission methodology, **Table 1**) is also addressed within the treaty. Article 3.15 of the treaty places an obligation on signatories to have policies or approaches in place designed to facilitate the management of any LLP occurrences and for the appropriate exchanges of information by both the exporting and importing countries. Control of imports of GM plant material into Canada and its policy on LLP occurrence are discussed in the next section.

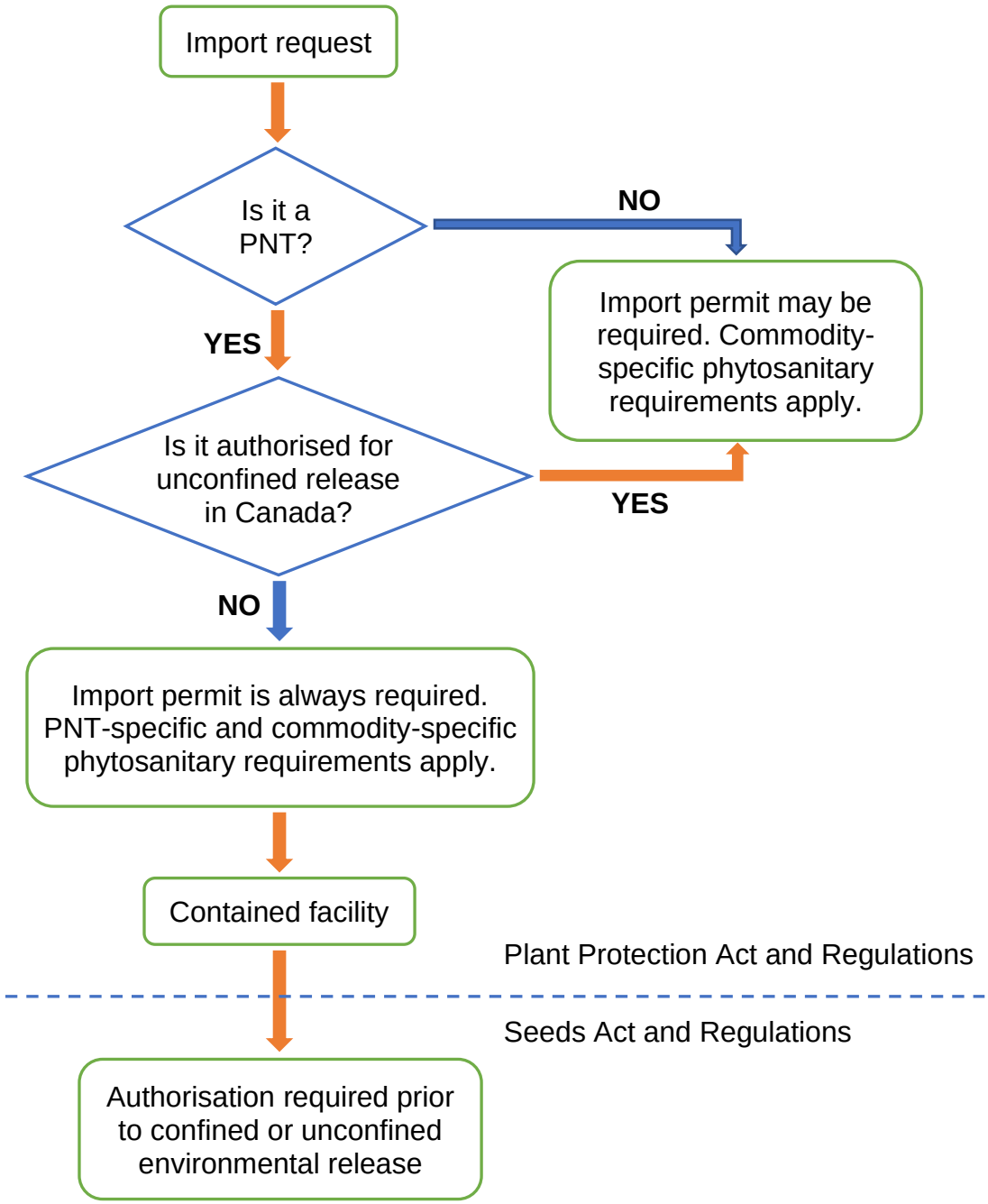
3.3.4 Imports of GM plant material: Canadian perspective

3.3.4.1 Entry of nonapproved GM materials

Imports of GM plants into Canada are addressed as part of its biosecurity and phytosanitary controls where specific provisions are made for the import of '**Plants with Novel Traits' (PNTs)**'. Imports of PNTs are differentiated by whether or not a specific PNT is authorised for unconfined release in Canada. A schema showing the process is provided in **Figure 8**. Essentially, the intention to import plant material must be pre-notified to the enforcement agency (CFIA). For biosecurity reasons and irrespective of whether or not they are a PNT, some materials will always require an import certificate of some kind (e.g. **wheat)**. If the material is derived from an

approved PNT, no further permit is required apart from those required for biosecurity purposes. If the material is not an authorised material, a further permit is required, which is issued subject to appropriate containment controls being in place.

Figure 8. Schema showing Canadian regulatory enforcement of imports of Plants with Novel Traits (PNTs)



Source: CFIA

3.3.4.2 LLP occurrence

As a signatory to the **International Statement on Agricultural Applications of Precision Biotechnology** and in line with its commitments under CUSMA, the Canadian Government has detailed its **policy** on how low level presence of GM material should be addressed. The model policy defines LLP as “the unintentional presence, at low levels, of unauthorised GM crops in imported grain, food or feed; where the GM crop is authorised for food use in one or more foreign jurisdictions but is not authorised in the importing country” (§2.1).

The model policy excludes events involving the following:

- Seed intended for propagation in the environment;
- GM fruits and vegetables;
- Adventitious presence, which is defined, for the purpose of this Policy, as the unintended release of GM crops that have not been authorised for use in any foreign jurisdiction;
- GM animals and microorganisms;
- Other GM crops modified to produce plant-made pharmaceutical or industrial products unless approved for food and feed use. (§5.2)

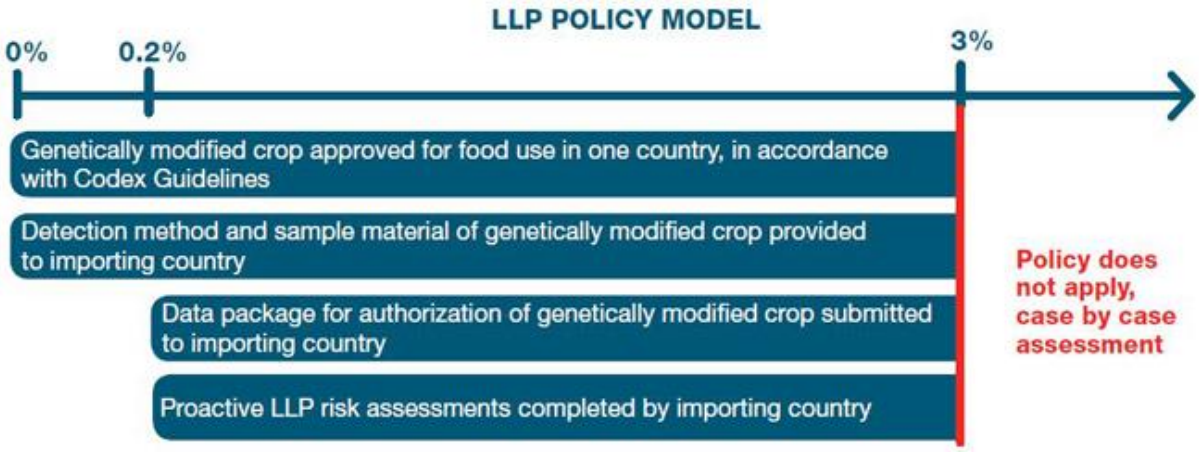
It also establishes two eligibility criteria both of which must be met:

i. The GM crop must be approved for food use in at least one country, in accordance with the Codex Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003);
ii. Appropriate test methodologies and reference materials for the detection and identification of the specific GM crop should be made available to the importing country to support monitoring of LLP in imports. (§6.1)

Providing the contaminating organisms meet the criteria set out above, a risk-based approach is taken to deciding what degree of LLP might be considered acceptable. The model policy currently addresses one of two scenarios (§7.2 & 7.3):

- Presence “resulting from dust, lingering traces of discontinued varieties, or foreign crops intended for domestic use only” (threshold 0.2%);
- Presence of an “asynchronously approved” (GM product approved by the exporter and pending approval by the importer, threshold 3%). This threshold only applies if an application has already been made for the GM crop’s approval in the importing country and that favourable risk assessments have been performed to demonstrate that the “GM event does not pose a risk, should it be present in an import shipment at levels below the compliance threshold”.

This shows an example of a low level presence (LLP) policy model schema.



Source: **Agriculture and Agri-Food Canada**

3.4 Key lessons

3.4.1 Function of international treaties

International trade agreements have been **described** by the National Bureau of Economic Research as “a formal expression of intergovernmental cooperation”, where “governments relinquish their sovereign rights to choose their own trade (and other) policies in exchange for similar concessions by others”. Their aims are therefore to facilitate trade in specified products and services to the mutual advantage of both parties and are therefore fundamentally economic in nature. Such treaties have to balance the duty of governments to protect human, animal and plant health as well as the environment against the potential misuse of necessary control

measures to impair international trade or give an unfair economic advantage to one party.

3.4.2 WTO and the SPS Agreement

The balance between ease of trading and maintaining human, animal and plant health with respect to trade in food is based on a set of principles elaborated in the SPS Agreement. The development of this agreement has meant that food safety legislation and its enforcement are considered independently and not within the context of the agreement relating to technical barriers to trade.

With regards to the rights of signatories, consideration of Articles 2 and 5 of the SPS Agreement **indicates** that the agreement "explicitly recognises the right of governments to take measures to protect human, animal and plant health, as long as these are based on science, are necessary for the protection of health, and do not unjustifiably discriminate among foreign sources of supply. Likewise, governments have the right to determine the levels of food safety and animal and plant health protection in their own jurisdictions. Neither the WTO nor any other international body does this." Furthermore, the agreement allows countries to give food safety, animal and plant health priority over trade, provided they can demonstrate that their food safety and health requirements are based on science (e.g. European Novel Foods legislation). Each country has the right to assess the risks and determine what it considers to be an appropriate level of food safety and animal and plant health.

Signatories to the agreement, therefore, have the right to establish relatively higher standards of safety as long as these are science-based and do not discriminate between home produced and imported food. However, and notwithstanding the above, an ambition of the agreement is to seek harmonisation of approaches (Article 3) and to this end it recognises the role played by relevant international organisations and their subsidiary bodies, in particular, the Codex Alimentarius Commission, the International Office of Epizootics, and the international and regional organisations operating within the framework of the International Plant Protection Convention to establish an internationally agreed consensus (see preamble to agreement and Article 3.4).

Neither novel foods, as defined by Article 3 of Regulation (EU) 2015/2283, nor foods from genetically modified organisms (foods produced using biotechnology) are specifically addressed within the SPS Agreement. Nevertheless, at a Codex Alimentarius Commission level, guidance has been provided concerning risk analysis, food safety assessment, and the performance criteria and validation requirements of relevant testing methods (**Table 1**).

3.4.3 Disputes and discussions regarding GM or novel foods ('case law')

Although neither foods from genetically modified organisms nor "novel foods" are specifically addressed within the SPS Agreement, EU legislation and its application/enforcement have been the subject of WTO activity. Key learnings from these activities are that:

1. Relevant processes regarding risk assessments and **comitology** should be transparent and timely;
2. Although membership of the WTO does not preclude, it does restrict application of the precautionary principle. For instance, the arbitration board considered that once a favourable risk assessment had been performed in accordance with due process, for the purposes of international trade this was sufficient evidence regarding the food's safety;
3. Although the concept of "novel foods" as articulated originally in Regulation (EC) No 258/97 and currently in Regulation (EC) 2015/2283 has been discussed, it has not been challenged within the WTO. Concerns expressed about the approach taken with regards to foods with a history of consumption in third countries have to one degree or another been addressed through the provisions of Chapter III of the current Regulation.

3.4.4 Bi- or multilateral free trade agreements

Using examples of free trade agreements signed by the European Union and/or Canada, food safety matters are generally addressed through the SPS provisions of the agreement which in turn cross-references to the SPS Agreement. Consequently, no special reference is made to the human, animal or plant health implications of these foods. The only reference to foods originating from genetically modified

organisms found related to the Dialogue on Biotech Market Access Issues in the EU's treaty with Canada which had originally been set up in response to a dispute arbitrated by the WTO.

In contrast to its agreement with the EU, the agreement between Canada, Mexico and the United States makes direct provision for commodities and foods produced by "agricultural biotechnology". This recognises the rights of signatories to have risk-assessment based approval systems for such products but requires that such processes are timely and transparent. It also makes provision for the low level presence (LLP) of DNA from organisms which may have been approved, based on a recognised risk assessment system, by one signatory but not permitted by another.

3.4.5 Exporters' obligations

The Cartagena Protocol places obligations on signatories to advise other signatories of what genetically modified organisms are permitted to be grown within their territories. This is effected through the **Biosafety Clearing House** and databases which use its information (e.g. the **ISAAA GM Approval Database**). Although pre-export controls performed by the local enforcement agency (e.g. CFIA in Canada) in the country of origin might be required for some types of food (e.g. the requirements for fish exports discussed in **Section 3.3.2**), these appear to relate to routine sanitary and phytosanitary considerations (chemical and/or microbial safety) and not to issues concerning either GM or "novel foods". Thus, although national governments may provide advice to exporters on the regulatory implications of exporting to a particular jurisdiction, responsibility for ensuring that imports of commodities or other foods of interest are compliant with GM or novel foods legislation rests entirely on the importing country.

3.4.6 Genome editing ('precision biotechnology')

Developments in molecular biology have led to technologies which can modify or delete specific sequences of DNA within the target organism to suppress or increase particular attributes. Adoption of such technologies (e.g. CRISPR) means that changes to DNA sequences of organisms can be achieved both *in vitro* and *in vivo.* Organisms produced in this manner (particularly using *in vivo* technologies) are more

akin to those produced by classical mutagenesis techniques used by plant breeders through the twentieth century. Arguably they therefore differ from genetically modified organisms anticipated by the Cartagena Protocol which discusses organisms produced by *in vitro* DNA manipulation or cell fusion using taxonomically different organisms. The use of such technology has highlighted differences in the regulatory approaches to foods produced from organisms using this technology. This in turn is impacting on the ongoing discussions which support international trade agreements. In 2018, the Court of Justice of the European Union **ruled** that:

- Organisms obtained by mutagenesis are GMOs and are, in principle, subject to the obligations laid down by the GMO Directive;
- However, organisms obtained by mutagenesis techniques which have conventionally been used in a number of applications and have a long safety record are exempt from those obligations, on the understanding that the Member States are free to subject them, in compliance with EU law, to the obligations laid down by the directive or to other obligations.

This view has not been shared by other jurisdictions – a case in point is the decision by the Argentinian competent authority (CONABIA) not to consider a gene-edited variant of tilapia (FLT 01) as being subject to Argentine legislation relating to genetically modified organisms. This was essentially on the grounds that FLT 01 was developed using gene editing techniques and does not contain a foreign DNA or a new combination of genetic material and, consequently, is not considered as a GMO. Other jurisdictions (e.g. US, Brazil, and Australia) have adopted **positions** which, to one degree or another, are compatible with that of Argentina. This position is also finding resonance at the level of international trade agreements with the above countries plus Canada, Guatemala, Honduras, and Paraguay who have issued a previously mentioned common statement on agricultural applications of “precision biotechnology”.

3.5 Glossary

Term	Definition
Cartagena Protocol on Biosafety	An international agreement which aims to ensure the safe handling, transport and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on biological diversity, taking also into account risks to human health
Codex Alimentarius Commission	A United Nations organisation which develops and adopts food standards that serve as a reference for international food trade
Comitology	The process by which EU law is modified or adjusted
CUSMA	Canada-United States-Mexico Agreement
General Agreement on Tariffs and Trade (GATT)	A legal agreement between many countries, whose overall purpose was to promote international trade by reducing or eliminating trade barriers such as tariffs or quotas. Administered by the WTO
Genetically modified organism (GMO)	Organisms (i.e. plants, animals or microorganisms) in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating and/or natural recombination. The technology is often called “modern biotechnology” or “gene technology”, sometimes also “recombinant DNA technology” or “genetic engineering”
Genome editing (“precision biotechnology”)	A type of targeted genetic engineering in which DNA is inserted, deleted, modified or replaced in the genome of a living organism

Mercosur	A South American customs union whose full members are Argentina, Brazil, Paraguay, and Uruguay (Venezuela's membership is currently **suspended**)
Novel food	A food that historically had not been consumed to a significant degree by humans in a particular jurisdiction. Definitions of what constitutes "novel" differ between jurisdictions. In the UK and the EU, the current definition can be found in Regulation (EU) 2015/2283, Article 3.2 (a)
Precautionary principle	As articulated by Wingspread Conference, the principle can be summarised as "when an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically"
World Trade Organisation, WTO	The World Trade Organization (WTO) deals with the global rules of trade between nations. Its main function is to ensure that trade flows as smoothly, predictably and freely as possible
WTO Agreement on Technical Barriers to Trade (TBT)	An agreement managed by the WTO which aims to ensure that technical regulations, standards, and conformity assessment procedures are non-discriminatory and do not create unnecessary obstacles to trade
WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS)	An agreement managed by the WTO on how governments can apply food safety and animal and plant health measures

Annex 1 Comparison of approaches to novel food regulation

Parameter	EU/UK	Australia	Canada	Japan	United States
Concept of novel food in use?	Yes	Yes	Yes	No	No
If no, what else could be relevant?	N/A	N/A	N/A	Products with certain health-related claims may need to be authorised or notified	Must either be approved by a regulation as an additive, considered GRAS for that use, or notified as a new dietary ingredient
What is included under “novel food”?	Any food that was not used for human consumption to a significant degree within the EU before 15 May 1997	Any non-traditional food that requires an assessment of the public health and safety	Substances without a history of safe use as a food; foods made using new processes if it causes a major change; and GM foods	N/A	N/A
What geographical aspects apply for the regulation?	Evidence of human consumption to a significant degree is limited to the EU territory but there are separate rules for traditional foods from third countries	“Non-traditional” means a food or a substance without a history of human consumption in either Australia or New Zealand	Evidence of a history of safe use is not limited to Canada	N/A	Dietary ingredients must have been marketed in the US in a dietary supplement before 15 October 1994. Otherwise, new dietary ingredient. Not applicable to conventional foods

Annex 2 Approval processes for new foods and food ingredients in 5 countries

Parameter	EU/UK	Australia	Canada	Japan	United States
Who reviews the dossier?	European Commission	FSANZ	Health Canada's Food Directorate	MHLW or CAA (for foods with health claims) MHLW (for food additives)	FDA (for food and colour additives and new dietary ingredients) GRAS panel with optional review by FDA (for GRAS uses of substances)
Who conducts a risk assessment?	EFSA	FSANZ	Health Canada's Food Directorate	FSC (for food additives and certain foods with health claims)	FDA (for food and colour additives) Manufacturers (for GRAS uses of substances and new dietary ingredients)
Who makes the final decision on the novel food application?	European Commission after a favourable by SCoPAFF	FSANZ but the Forum and/or the Government of New Zealand may request review	Food Rulings Committee (representatives from HC's Food Directorate and CFIA)	Not applicable	FDA (for food and colour additives) Manufacturers (for GRAS uses of substances and new dietary ingredients)
Is there exclusivity in place?	Possible (up to 5 years)	Possible (up to 15 months)	Each proponent submits own notification	Not applicable	No (for food and colour additives). But theoretically, possible for GRAS and new dietary ingredients

Annex 3 Comparison of regulatory frameworks for GMOs

Parameter	EU/UK	Argentina	Australia	Brazil	Canada	United States
Cartagena Protocol on Biosafety	Approved and ratified by individual MS	Signed but not ratified	Not signed	Accepted and ratified	Signed but not ratified	Not signed
Regulatory approach to GMOs	Process-based	Product-based	Process-based	Hybrid system (product-based for NBTs, process-based for the rest)	Product-based	Product-based
Legislation specifically for GM products?	Yes	Yes	Yes	Yes	No	No (apart from Bio-engineered food labelling)
If no, how are GMOs regulated?	N/A	N/A	N/A	N/A	Covered by the same legislation that covers non-GM products (conventional breeding products can trigger oversight as well)	Covered by existing legislation that deals with non-GM products with a trend for deregulation GM animals regulated as “new animal drugs”
Is there an authority dedicated solely to GMOs?	No	Yes (CONABIA and the Directorate of Biotechnology)	Yes (OGTR)	Yes (CTNBio)	No	No

Annex 4 Authorisation procedures for deliberate release of GMOs

Parameter	EU/UK	Argentina	Australia	Brazil	Canada	United States
Who reviews the dossier?	Member States, European Commission	The Directorate of Biotechnology and CONABIA	The Office of Gene Technology Regulator	CTNBio	CFIA, Health Canada, ECCC	EPA (PIPs) FDA (GE animals, new plant varieties)
Who makes the final decision?	European Commission together with the Member States	SAYBI	The Office of Gene Technology Regulator	CTNBio (decisions are no longer reviewed by CNBS)	CFIA, Health Canada, ECCC	EPA (PIPs) APHIS (crops with plant pest components) FDA (GE animals) Proponent (in other cases)
Who conducts safety assessments for food use?	EFSA	SENASA	FSANZ	ANVISA	Health Canada's Food Directorate	FDA (if warranted by safety concerns) Proponent (in all other cases)
Who conducts environmental assessment?	EFSA	The Directorate of Biotechnology and CONABIA	The Office of Gene Technology Regulator in consultation with other stakeholders	Proponent (CTNBio reviews the information submitted, assessments conducted elsewhere etc.)	CFIA, ECCC	EPA, APHIS, FDA, proponent

Annex 5 Comparison of GM labelling requirements

Parameter	EU/UK	Argentina	Australia	Brazil	Canada	United States
Labelling requirements established?	Yes	No	Yes	Yes	Yes (voluntary standard)	Yes
If yes, what it is based on?	Whether a GM food or food derived from a GM source has been used anywhere in the production process	N/A	Whether novel DNA and/or novel protein is present in the final food	Whether food or food ingredients contain or are produced from GMOs	Whether an ingredient is a product of genetic engineering	Whether it is a BE food or contains a BE ingredient (some foods are presumed to be BE)
Food intended for immediate consumption	Not exempt	N/A	Exempt	Not exempt	N/A	Exempt
Unpackaged foods	Not exempt	N/A	Not exempt	Not exempt	N/A	Not exempt
Very small food manufacturers	Not exempt	N/A	Not exempt	Not exempt	N/A	Exempt
Highly refined	Not exempt	N/A	Exempt if novel DNA or protein is removed	Not exempt	N/A	Exempt (records of validated refinement process required)
Processing aids	Not subject to GM labelling requirements	N/A	Exempt if no novel DNA or protein present in the food	Unlikely to exceed 1%	N/A	Incidental additives (e.g. processing aids) are exempt

Annex 5 cont. Comparison of GM labelling requirements (continued)

Food additives	Not exempt	N/A	Exempt if no novel DNA or protein present in the food	Not exempt	N/A	Not exempt
Flavourings	Not exempt	N/A	GM flavouring substances not exceeding 0.1% of food are exempt	Not exempt	N/A	Not exempt
Unintentional presence	0.9% threshold for adventitious presence of approved GMOs per ingredient	N/A	GM food unintentionally present in the food at no more than 1% of each ingredient is exempt	Labelling requirement universally applies above 1% of GMOs in the product	(5% for adventitious inclusion when making voluntary negative claims)	5% for inadvertent or technically unavoidable BE presence for each ingredient
Food from animals fed GM feed	Exempt	N/A	Not subject to GM labelling requirements	Not exempt	N/A	Exempt
Animal feed	Not exempt	N/A	Not covered	Not exempt	N/A	Not covered
Negative GM claims	Must not mislead the consumer	Permitted but not regulated	Must not be false, misleading, or deceptive (ACCC says GM feed prevents GM-free claims)	Permitted only if the source has a GM counterpart	Subject to voluntary standard	Must be truthful and not misleading

Annex 6 Comparison of SPS-related provisions of free trade agreements between the EU and Canada, Japan, and Mercosur (provisional)

Provision	**Canada**	**Japan**	**Mercosur ***
Trade remedies (Commitment to WTO principles)	Chapters 3 & 12	Chapter 5	Addressed
Differentiation between TBT & SPS measures	Chapter 4	Chapter 7	Addressed
Sanitary and phytosanitary measures	Chapter 5	Chapter 6	Addressed
Regulatory co-operation	Chapter 21	Chapters 4, 17 & 18	Addressed
Bilateral fora	Chapter 25 (Bilateral dialogues and cooperation)	Chapter 19 (Cooperation in the field of agriculture)	Not mentioned

* No Chapter numbers provided

Annex 7 Overview of significant provisions of EU-Canada Comprehensive Economic and Trade Agreement (CETA)

Chapter (Title)	Significance
3 (Trade remedies)	Requires signatories adopting global safeguard measures to "endeavour to impose them in a way that least affects bilateral trade" (§3.6.1) and also that "the importing Party shall offer to hold consultations with the exporting Party in order to review the matter referred to in paragraph 1. The importing Party shall not adopt measures until 30 days have elapsed since the date the offer to hold consultations was made" (§3.6.2). See also Chapters 6 (Customs and trade facilitation) and 12 (Domestic regulation)
4 (Technical barriers to trade)	As in the WTO Technical Barriers to Trade Agreement, the provisions of this chapter specifically do not apply to "a sanitary or phytosanitary measure as defined in Annex A of the SPS Agreement" (§4.2(b))
5 (Sanitary and phytosanitary measures)	The principal chapter addressing human, animal and plant health. As set out in §5.2, the objectives of the chapter are to: a) protect human, animal and plant life or health while facilitating trade; b) ensure that the Parties' sanitary and phytosanitary ("SPS") measures do not create unjustified barriers to trade; c) further the implementation of the SPS Agreement

Annex 7 cont. Overview of significant provisions of EU-Canada Comprehensive Economic and Trade Agreement (CETA) (continued)

6 (Customs and trade facilitation)	Deals with (amongst other things) the principles of border inspections. In particular it requires both parties to: • Make publicly available “legislation, regulations, judicial decisions and administrative policies relating to requirements for the import or export of goods” (§6.2.1) • Provide appropriate notice and details when proposing changed or new “regulations and administrative policies relating to customs matters” (§6.2.2) • Subject to the conditions of Article 6.3.2, “adopt or maintain simplified customs procedures for the efficient release of goods” (§6.3.1) • Base “its examination, release and post-entry verification procedures on risk assessment principles” (§6.7.1)
21 (Regulatory collaboration)	Builds on an existing agreement between the EU and Canada on regulatory cooperation and encourages regulators to exchange experiences and information, as well as identifying areas where they could cooperate. The scope of the chapter includes the SPS Agreement (§21.1) and one of the principles of the chapter is to “contribute to the protection of human life, health or safety, animal or plant life or health” (§21.3(a))
25 (Bilateral dialogues and cooperation)	Incorporates previous agreements on dialogue and cooperation on trade and economic matters between the two parties into the agreement so that all such activity has the same basis

Annex 8 Canada-United States-Mexico Agreement (CUSMA). Definitions of terms relating to foods from genetically modified organisms

Term	Definition (as set out in Article 3.12)
Agricultural biotechnology	Technologies, including modern biotechnology, used for the deliberate manipulation of an organism to introduce, remove, or modify one or more heritable characteristics of a product for agriculture and aquaculture use and that are not technologies used in traditional breeding and selection
Low Level Presence (LLP) Occurrence	Low levels of recombinant deoxyribonucleic acid (DNA) plant materials that have passed a food safety assessment according to the Codex Guideline for the Conduct of a Food Safety Assessment of Foods Derived from Recombinant-DNA Plants (CAC/GL 45-2003) in one or more countries, which may on occasion be inadvertently present in food or feed in importing countries in which the food safety of the relevant recombinant DNA plant has not been determined
Modern biotechnology	The application of: (a) in vitro nucleic acid techniques, including recombinant DNA and direct injection of nucleic acid into cells or organelles; or (b) fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection