FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

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Supporting document 1

Updated compilation of regulatory approaches and definitions

P1055 – Definitions for gene technology and new breeding techniques

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At the 1st Call for Submissions (CFS), FSANZ compiled information in supporting document 3 on international regulatory approaches and relevant definitions in other legislative and regulatory instruments. As part of this 2nd CFS, FSANZ has updated this information, which is presented as follows:

- **Table 1.** Approaches in other countries to the regulation of NBTs and derived food products that have changed since the release of the 1st CFS in October 2021.
- **Table 2.** Examples of definitions used in other legislation, regulations, guidelines or proposals – updates since the release of the 1st CFS in October 2021.
- **Table 3.** Summary of international approaches to NBT regulation

Table 1. Approaches in other countries to the regulation of NBTs and derived food products that have changed since the release of the 1st CFS in October 2021.

Country	Regulatory approach	Comments
Costa Rica	In **November 2023**, Costa Rica updated its agricultural biotechnology regulations to distinguish between "organisms containing a novel combination of genetic material", and "organisms equivalent to those obtained through conventional improvement techniques". A novel combination of genetic material is described as being a stable genomic insertion of DNA that could not have been obtained by conventional breeding.[1] Products derived from organisms modified using NBTs that do not contain a new combination of genetic material will be treated as conventional products, in an approach which is comparable to those taken by other Central and South American countries.[2] Following this update, a disease-resistant genome edited banana is anticipated to be commercialised in Costa Rica later in 2024.	This is a product-based approach that applies to organisms and their products.
Canada	In **May 2022**, Health Canada published a new appendix to their Guidelines to the Safety Assessment of Novel Foods: *Guidance on the novelty interpretation of products of plant breeding.*[3] The intent of this new guidance is to provide greater clarity on when products derived from new tools of genetic modification would be considered novel, and therefore be subject to pre-market notification and assessment. The effect of this guidance is to exclude many genome edited foods from being considered novel foods (see Table 2 for detail). As part of the new guidance, Health Canada also introduced a voluntary transparency initiative for gene edited plants developed for food use that are not novel foods.[4] Developers have the option to submit information about their products to Health Canada for publication on their website.	The new guidance is a clarification of the existing product-based approach to novel foods. Applies to plants only at this stage. Additional guidance being considered for animals and microorganisms.
China	In **January 2022**, the Chinese Ministry of Agriculture and Rural Affairs (MARA) published	

[1] USDA summary/translation of Costa Rican regulatory updates – https://fas.usda.gov/data/costa-rica-costa-rica-opens-door-innovative-biotechnologies
[2] Regulatory landscape for new breeding techniques (NBTs): insights from Paraguay – https://www.frontiersin.org/journals/bioengineering-and-biotechnology/articles/10.3389/fbioe.2024.1332851/full
[3] Health Canada guidance on the novelty interpretation of products of plant breeding – https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/guidelines-safety-assessment-novel-foods-derived-plants-microorganisms/guidelines-safety-assessment-novel-foods-2006.html#a5
[4] Health Canada transparency initiative for gene edited foods – https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/transparency-initiative.html

	preliminary guidelines for a safety evaluation of genome edited plants that do not contain introduced exogenous DNA.[5] In **May 2023**, MARA issued updated *Rules for Review of Gene-Edited Plants for Agricultural Use*, which expand upon and clarify the requirements set out in the preliminary guidelines. The rules categorise gene edited crops into several risk categories, with corresponding data requirements for each category.[6] It remains unclear how the risk categories will be applied, and the corresponding level of assessment required for each one.[7]	
European Union	In **July 2023**, the European Commission (EC) adopted a proposal[8] to remove qualifying NGTs[9] from the European Union GMO regulatory requirements (EU Directive 2001/18/EC) and to introduce a simpler and less onerous regulatory process. In February **2024**, the European Parliament voted in favour of the proposal.[10] The proposal outlines two tiers of NGT plants (see Table 2 for more detail): 1. Category 1 NGT plants are those that could also occur naturally or by conventional breeding. Verified Category 1 NGTs are treated like conventional plants and therefore exempted from the requirements of the GMO legislation. 2. For all other NGT plants (Category 2 NGTs), the requirements of the current GMO legislation apply.	This proposal marks a departure from the current EU approach, which is entirely process-based, to an approach which allows product-based exclusions from GMO regulation for selected NBTs.
India	In **May 2022**, the Department of Biotechnology, in the Ministry of Science and Technology, released final guidelines for the safety assessment of genome edited plants. The guidelines specify that gene edited plants categorised as SDN-1 or SDN-2 (which do not contain exogenous DNA) are exempt from biosafety assessment as transgenic plants. Developers must provide evidence for the absence of exogenous DNA in order for products to be exempt.[11]	The approach described in the guidelines is product-based.

[5] Unofficial translation of MARA's guidelines – https://fas.usda.gov/data/china-mara-issues-first-ever-gene-editing-guidelines
[6] Unofficial translation of the update to MARA's rules – https://fas.usda.gov/data/china-mara-updates-rules-review-gene-edited-plants-agricultural-use
[7] The evolution of China's regulation of agricultural biotechnology – https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9755788/
[8] European Commission proposal for a new regulation on plants produced by certain new genomic techniques – https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology_en
[9] This is a term adopted by the EU to refer to techniques that are capable of altering the genetic material of an organism and which have emerged or been developed since 2001, when the EU GMO legislation was first adopted.
[10] Amendments to the EC proposal adopted by European Parliament, 7 February 2024 – https://www.europarl.europa.eu/doceo/document/TA-9-2024-0067_EN.html
[11] Indian guidelines for the safety assessment of genome edited plants – https://dbtindia.gov.in/latest-announcement/guidelines-safety-assessment-genome-edited-plants2022

Kenya	Kenya's National Biosafety Authority released a guideline in **February 2022** to clarify the regulation of genome editing under current GMO regulations.[12] Not considered to come within the scope of the GMO regulations are modifications using genes and regulatory elements from sexually compatible species, all deletions/knockouts provided the regulatory elements are from the same species; and processed products where foreign DNA cannot be detected. The guideline includes an early consultation framework and applies a case-by-case determination of whether a product is a GMO.	The approach to genome editing and other NBTs is product-based. The guideline applies to plants, animals, and microorganisms.
South Africa	In **2021**, the South African government announced its decision to apply its existing risk assessment framework for GMOs to NBTs.[13] As of 2024, industry attempts to appeal the decision to regulate NBT products as GMOs have been unsuccessful.	The existing approach to GMOs is process-based.
Other African countries	To date (in addition to Kenya), Nigeria, Ghana and Malawi have established genome editing guidelines. In **2021**, the Nigerian National Biosafety Management Agency released National Guidelines for the Regulation of Gene Editing.[14] Under this regulation, a non-GM regulatory classification is applied to a gene editing product if: • no foreign genetic material is introduced; or • the editing event does not result in a new combination of genetic material; or • the introduced foreign genetic material has been removed from the final product. In **2022**, Malawi released its Genome Editing Guidelines, which specify that only products containing a novel combination of DNA will be regulated as GMOs.[15] In **2023**, Ghana's National Biosafety Authority released its Guidelines for Genome Editing Applications.[16] Under these guidelines, products derived from genome editing techniques are	All these approaches apply a product-based approach to genome edited products on a case-by-case basis.

[12] Guidelines for determining the regulatory process of genome edited organisms and products in Kenya – https://healthtechafrica.org/publication/guidelines-for-determining-the-regulatory-process-of-genome-edited-organisms-and-products-in-kenya
[13] South African Department of Agriculture, Land Reform and Rural Development: decisions and results of appeals on NBTs – https://www.dalrrd.gov.za/index.php/publication/413-gmo-publications
[14] Nigerian guidelines for regulation of gene editing – https://nbma.gov.ng/wp-content/uploads/2022/03/NATIONAL-GENE-EDITING-GUIDELINE.pdf
[15] Summary of Malawi's genome editing guidelines – https://africenter.isaaa.org/malawis-genome-editing-guidelines-key-promoting-supportive-environment-new-breeding-technologies/
[16] Guidelines for genome editing applications in Ghana – https://bch.cbd.int/api/v2013/documents/77583F99-8C50-2E71-8410-A8EEC56B8433/attachments/614261/Guidelines%20for%20Genome%20Editing%20Applications%20in%20Ghana.pdf

	exempt from regulation if no foreign DNA is detectable in the final product.	
New Zealand	In **February 2024**, the New Zealand Environmental Protection Authority (EPA) published a decision[17] clarifying that null segregants (see Table 2 for definition) are not considered to be new organisms for the purpose of the HSNO Act.[18] The New Zealand government is currently also considering additional changes to biotechnology regulation in New Zealand, including the creation of a dedicated biotechnology regulator and less restrictive rules for GM and gene edited products.[19]	
Philippines	A new resolution was issued in **2021** excluding plant products derived by new breeding techniques that do not contain a novel combination of genetic material in the final product from regulation as GMOs. In **2022**, the Philippine Department of Agriculture finalised the rules and procedures for evaluating new plant breeding techniques.[20] A request to introduce a NBT product into the Philippines is required and the Philippine Department of Agriculture determines if the product is in fact a non-GM NBT product. These products receive a 'certificate of non-coverage' from the GMO regulation and the determination is made public.[21]	The policy approach is product-based. Applies to food, feed and processed products.
Singapore	In **February 2024**, Singapore Food Agency (SFA) completed a consultation on a proposed regulatory framework for the use of genome edited crops in food and feed.[22] Currently, genome edited crops intended to be used as food or feed are regulated as GMOs and are subject to pre-market safety assessment and approval by SFA. In the proposed approach, genome edited crops containing foreign DNA would require pre-market assessment as per the current approach for GMOs. If a developer determined that their genome edited crop did not contain foreign DNA, the crop would not require pre-market assessment. However, SFA would encourage developers to notify SFA of the crop, and would maintain a publicly available list of genome edited crops that are considered equivalent to conventionally bred crops.	Proposed framework would allow for product-based exclusions from GMO assessment.

[17] NZ EPA Determination on null segregants – https://www.epa.govt.nz/database-search/hsno-application-register/view/APP204173
[18] Hazardous substances and New Organisms Act Hazardous substances and New Organisms Act – https://www.legislation.govt.nz/act/public/1996/0030/latest/DLM381222.html
[19] NZ Harnessing Biotech plan – https://www.national.org.nz/harnessingbiotech
[20] Philippines' rules for evaluating NBTs – https://www.da.gov.ph/wp-content/uploads/2022/06/mc08_s2022_Revised.pdf
[21] Policy Brief on the Philippine policy for NBTs – https://www.isaaa.org/resources/publications/policybriefs/2022/pb2/default.asp
[22] SFA Consultation – https://www.sfa.gov.sg/food-information/public-consultation/others

South Korea	Korea is in the process of revising its Living Modified Organism (LMO) Act, which defines LMOs as possessing a novel combination of genetic material obtained through the application of modern technology, including gene editing. The draft revision to the LMO Act[23] currently being considered by the Korean National Assembly includes a preliminary review system that will consider exemption from risk assessment for certain genome edited products, if: • there is no introduction of foreign DNA, or; • no foreign DNA is present in the final product.	The proposed revision is a product-based approach.
United Kingdom	In **2023**, the Genetic Technology (Precision Breeding) Act passed into law in England.[24] The Act defines a precision bred organism (PBO) as a plant or vertebrate animal (excluding humans) that has been produced by precision breeding techniques such as gene editing, but could have been produced by traditional breeding processes (see Table 2 for details). The main outcome of the Act is that PBOs are no longer subject to regulation as GMOs. The Act also authorises the Food Standards Agency (FSA) to create a regulatory framework in England for food and feed derived from PBOs, as well as to create and maintain and register for approved PBOs for food and feed. In **January 2024**, FSA completed public consultation[25] on a proposed framework, including: a pre-market authorisation system designed around the classification of PBOs into two risk tiers, based on independent scientific advice; and a public register of PBOs for food/feed which have received marketing authorisations. Based on stakeholder feedback, FSA intends to proceed with implementing this approach.[26]	The Act allows for product-based exclusions from the GMO definition. The Act applies in England only.
United States	The products of biotechnology and their use are regulated in the United States (US) under the Coordinated Framework for the Regulation of Biotechnology Products, which involves three primary agencies – the US Environmental Protection Agency (EPA), the US Food and Drug Administration (FDA) and the US Department of Agriculture (USDA), with each having their own separate statutory responsibilities in relation to biotechnology products.	The regulatory approach in the US is product-based. Plants are regulated separately to animals, and some approaches

[23] South Korea: Agricultural Biotechnology Annual 2023 (USDA) – https://fas.usda.gov/data/south-korea-agricultural-biotechnology-annual-7

[24] Genetic Technology (Precision Breeding) Act 2023 – https://www.legislation.gov.uk/ukpga/2023/6/contents/enacted

[25] FSA consultation on a framework for PBOs – https://www.food.gov.uk/news-alerts/consultations/consultation-on-proposals-for-a-new-framework-in-england-for-the-regulation-of-precision-bred-organisms-used-for-food-and-animal

[26] FSA summary of stakeholder responses and next steps – https://www.food.gov.uk/our-work/summary-of-stakeholder-responses-consultation-on-proposals-for-a-new-framework-in-england-for-the-regulation-of-precision-bred

	The USDA Animal and Plant Health Inspection Service (USDA-APHIS) published a final rule revising the 7 C.F.R. Part 340 regulations (85 Fed. Reg. 29790) in **2020**. The revised rule includes new exemptions for genetically engineered plants (see Table 2). In **November 2023**, APHIS issued a public proposal[27] for five additional exemptions: • loss-of-function modifications; • modifications that are a single contiguous deletion; • expanding current modifications to include certain polyploid plants; • allowing up for four edits at a single time; • providing for successive edits. Procedures are also in place to enable developers to propose additional exemptions. In **May 2023**, the EPA published a final rule[28] exempting plant-incorporated protectants (PIPs) created through genetic engineering from certain registration requirements if they could have been created through conventional breeding or if the modification involves a loss-of-function (See Table 2). In **February 2024**, the FDA issued new guidance for developers of foods derived from genome edited plants[29], outlining two voluntary processes (voluntary premarket consultation or voluntary premarket meetings) that developers may use to inform the FDA of steps they have taken to ensure the safety of their product. The FDA's recommendation is that the process chosen is related to the objective characteristics of the food, especially those related to food safety. In **May 2024**, the FDA issued two pieces of guidance for developers on their regulatory approach and approval process for oversight of intentional genomic alterations (IGAs) in animals.[30, 31] The guidance includes a description of situations in which applications for approval may not be required, e.g. in food animals where (1) the alteration is equivalent to what could be theoretically achieved through conventional breeding; (2) based on the genomic sequence, the alteration is not expected to result in changes to food composition; (3) the intended use of the alteration does not include any effect on animal disease, human disease, or other health outcome; and (4) the alteration has no	may differ.

[27] APHIS notice of proposed exemptions – https://www.federalregister.gov/documents/2023/11/15/2023-25122/movement-of-organisms-modified-or-produced-through-genetic-engineering-notice-of-proposed-exemptions
[28] EPA Exemptions of certain plant-incorporated protectants derived from newer technologies – https://www.regulations.gov/document/EPA-HQ-OPP-2019-0508-0122
[29] FDA Guidance for industry: foods derived from plants produced using genome editing – https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-foods-derived-plants-produced-using-genome-editing
[30] FDA Guidance for industry: heritable intentional genomic alterations in animals (approach) – https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-187a-heritable-intentional-genomic-alterations-animals-risk-based-approach
[31] FDA Guidance for industry: heritable intentional genomic alterations in animals (approval process) – https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-187b-heritable-intentional-genomic-alterations-animals-approval-process

	identified risks of concern to humans, animals, or the environment for the intended use. Alterations that “could be achieved through conventional breeding” are considered to exclude insertion of transgenes, but could potentially include deletions, small insertions in coding regions, and possibly deletions, small insertions, and changes to non-coding regions.	

Table 2. Examples of definitions used in other legislation, regulations, guidelines or proposals – updates since the release of the 1st CFS in October 2021.

Regulations/Guidance	Definitions
Genetic Technology (Precision Breeding) Act[32] (England)	An organism is "precision bred" if (a) any feature of its genome results from the application of modern biotechnology, (b) every feature of its genome that results from the application of modern biotechnology is stable, (c) every feature of its genome that results from the application of modern biotechnology could have resulted from traditional processes, whether or not in conjunction with selection techniques, alone, and (d) its genome does not contain any feature that results from the application of any artificial modification technique other than modern biotechnology. "modern biotechnology"[33] means any of the following techniques: (a) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules, produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation; (b) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation; (c) cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally. For plants "traditional processes" means sexual fertilisation, spontaneous mutation, *in vitro* fertilisation, polyploidy induction, embryo rescue, grafting, induced mutagenesis, or somatic hybridisation or cell fusion of plant cells of organisms (with conditions). For animals "traditional processes" means sexual fertilisation, spontaneous mutation, artificial insemination, *in vitro* fertilisation, embryo transfer, polyploidy induction, or recovery and transfer of primordial germ cells.

[32] Genetic Technology (Precision Breeding) Act 2023 – https://www.legislation.gov.uk/ukpga/2023/6/contents
[33] As mentioned in regulation 5(1)(a) or (b) of the Genetically Modified Organisms (Deliberate Release) Regulations 2002 (S.I. 2002/2443) – https://www.legislation.gov.uk/uksi/2002/2443/regulation/5/made

Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625 and Directive 98/44/EC[34][35] (European Commission Proposal including amendments adopted by the European Parliament on 7 February 2024)	"NGT plant" means a genetically modified plant obtained by targeted mutagenesis or cisgenesis, or a combination thereof, on the condition that it does not contain any genetic material originating from outside the gene pool for conventional breeding purposes that temporarily may have been inserted during the development of the NGT plant. "targeted mutagenesis" means mutagenesis techniques resulting in modification(s) of the DNA sequence at precise locations in the genome of an organism; "cisgenesis" means techniques of genetic modification resulting in the insertion, in the genome of an organism, of genetic material already present in the breeders' gene pool; "gene pool for conventional breeding purposes" means the total genetic information available in one species and other taxonomic species with which it can be cross-bred, using advanced techniques such as embryo rescue, induced polyploidy and bridge crosses. "Category 1 NGT plant" means a NGT plant that: (a) fulfils the criteria of equivalence to conventional plants (see below), or (b) is progeny of the NGT plant(s) referred to in point (a), including progeny derived by crossing of such plants, on the condition that there are no further modifications that would make it subject to Directive 2001/18/EC "Category 2 NGT plant" means a NGT plant other than a category 1 NGT plant. A NGT plant is considered equivalent to conventional plants if the following conditions referred to in points 1 and 1a are met: (1) The number of the following genetic modifications, which can be combined with each other, does not exceed 3 per any protein-coding sequence taking into account that mutations in introns and regulatory sequences are excluded from this limit: (a) substitution or insertion of no more than 20 nucleotides; (b) deletion of any number of nucleotides;

[34] European Commission proposal – https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52023PC0411

[35] Amendments to the EC proposal adopted by European Parliament, 7 February 2024 – https://www.europarl.europa.eu/doceo/document/TA-9-2024-0067_EN.html

	(1a) The following genetic modifications, which can be combined with each other, do not create a chimeric protein that is not present in specie from the gene pool for breeding purposes or does not interrupt an endogenous gene; (a) insertion of continuous DNA sequences existing in the gene pool for breeding purposes; (b) substitution of endogenous DNA sequences with continuous DNA sequences existing in the gene pool for breeding purposes; (c) inversion or translocation of continuous endogenous DNA sequences existing in the gene pool for breeding purposes.
Health Canada Guidance on the Novelty Interpretation of Products of Plant Breeding[36] (Canada)	Categories of foods that are **not** considered novel foods under this guidance are: 1. Foods derived from plants with genetic modifications that do not alter an endogenous protein in a way that introduces or increases similarity with a known allergen or toxin relevant to human health; 2. Foods derived from plants with genetic modifications that do not increase levels of a known endogenous allergen, a known endogenous toxin, or a known endogenous anti-nutrient beyond the documented ranges observed for these analytes in the plant species; 3. Foods derived from plants with genetic modifications that do not have an impact on key nutritional composition and/or metabolism; 4. Foods derived from plants with genetic modifications that do not intentionally change the food use of the plant; and 5. Foods derived from plants with genetic modifications that do not result in the presence of foreign DNA in the final plant product. For the purposes of this guidance, the “foreign DNA” means DNA that is originally sourced from genetic sources outside the plant species and cannot be introduced into that plant species using conventional methods of plant breeding (as defined in a list of conventional methods in the guidance).

[36] Health Canada guidance – https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/guidelines-safety-assessment-novel-foods-derived-plants-microorganisms/guidelines-safety-assessment-novel-foods-2006.html#a5

Revised Biotechnology Regulations *(7 CFR Parts 330, 340, and 372)*[37] (United States)	Genetic engineering – techniques that use recombinant, synthesized, or amplified nucleic acids to modify or create a genome. Plants are exempted from the regulations if they have been modified such that they contain either a single modification of a type listed in paragraphs (1) through (3), or additional modifications as determined by the Administrator, and described in paragraph (4). (1) The genetic modification is a change resulting from cellular repair of a targeted DNA break in the absence of an externally provided repair template; or (2) The genetic modification is a targeted single base pair substitution; or (3) The genetic modification introduces a gene known to occur in the plant's gene pool, or makes changes in a targeted sequence to correspond to a known allele of such a gene or to a known structural variation present in the gene pool. (4) The Administrator may propose to exempt plants with additional modifications, based on what could be achieved through conventional breeding. Such proposals may be Agency-initiated or in response to a request.[38] Other exemptions are provided in paragraph (c) and (d) of § 340.1, including plants and plant-trait-mechanism of action combinations that have previously been determined by the Animal and Plant Health Inspection Service (APHIS) not to be regulated. In the final regulations, the APHIS describes conventional breeding as techniques generally involving the deliberate selection of plants with desirable traits from existing population genetic variation or from new genetic variation created through artificial hybridization or induced mutagenesis. Such techniques include marker-assisted breeding, tissue culture, protoplast, cell, or embryo fusion, and chemical or radiation-based mutagenesis.

[37] 7 CFR Parts 330, 340, and 372 – https://www.federalregister.gov/documents/2020/05/18/2020-10638/movement-of-certain-genetically-engineered-organisms
[38] Procedures are in place to enable APHIS-initiated proposals or other parties' requests for exemptions (§ 340.1).

Environmental Protection Agency (EPA) Final Rule: Exemptions of Certain Plant-Incorporated Protectants (PIPs) Derived from Newer Technologies *(40 CFR Part 174)*[39] (United States)	Plant-incorporated protectants (PIPs) which meet the following exemption criteria are exempt from regulatory requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug and Cosmetic Act (FFDCA), provided that the developer complies with specified eligibility determination procedures. **§ 174.26** Active ingredient of a plant-incorporated protectant created through genetic engineering from a sexually compatible plant. The active ingredient is exempt if: (a) The active ingredient is characteristic of the population of plants sexually compatible with the recipient plant and is created through genetic engineering from either an insertion of a native gene into the recipient plant as specified in paragraph (a)(1) of this section or a modification of an existing native gene in the recipient plant as specified in paragraph (a)(2) of this section. (1) ***Insertion.*** A native gene is inserted into the genome of the recipient plant and produces a pesticidal substance identical in sequence to the pesticidal substance identified in the source plant. The regulatory regions inserted as part of the native gene must be identical in nucleic acid sequence to those regulatory regions of the native gene identified in the source plant. (2) ***Modification.*** The existing native gene is modified to match corresponding polymorphic sequence(s) in a native allele of that gene using a single source plant as a template **§ 174.27** Active ingredient of a loss-of-function plant-incorporated protectant. The active ingredient is exempt if: (a) The genetic material of a native gene is modified using genetic engineering to result in a pesticidal effect through the reduction or elimination of the activity of that gene.
Environmental Protection Authority (EPA) 2024 determination of whether or not null segregants are new organisms for the purpose of the Hazardous Substances and New Organisms (HSNO) Act 1996[40] (New Zealand)	A null segregant, defined for the purpose of this statutory determination as– any living eukaryotic organism (other than a human being) that: 1. is descended from one or more genetically modified organisms (GMOs) that are new organisms solely by virtue of being GMOs as defined in the Act, and 2. is descended via sexual reproduction from its GMO parent(s) and allelic segregation from its GMO sibling(s), or 3. is descended or otherwise derived, whether sexually or asexually, through any number of replications, from a null segregant progenitor(s), and

[39] 40 CFR Part 174 – https://www.ecfr.gov/current/title-40/part-174
[40] NZ EPA Determination on null segregants – https://www.epa.govt.nz/database-search/hsno-application-register/view/APP204173

	4. does not contain *in vitro*-modified genes or other genetic material that is not exempted in regulation and that defined its ancestor(s) as a GMO(s) does not meet the definition of a genetically modified organism in the Act, and thus cannot be considered to be a new organism for the purpose of the Act solely by virtue of the criteria of section 2A(1)(d) of the Act.

Table 3: Summary of international approaches to NBT regulation

Highlighted in light green – New approaches since the release of the 1st CFS in 2021;

Grey italics – Proposed approaches, not yet in force.

	Some NBTs excluded from GMO regulation/pre-market assessment?	Criteria for exclusion	Notification/ Confirmation Required?	Year approach adopted/updated	Applies to
North America					
US	Yes	Specific criteria (refer to Table 2)	In some cases	Revised Biotechnology Regulations finalised 2020; updates ongoing	Plants and Animals
Canada	Yes[41]	Absence of foreign DNA in final plant product; no new or increase in toxins, allergens, and antinutrients; no compositional changes; no new food use	Voluntary	Updated guidance published July 2022	Plants
Europe and Middle East					
European Union (proposed)	*Yes*	*Specified maximum number of genetic modifications compared to parent plant (still under consideration)*	*Yes - proposed database*	*European Commission proposal adopted 2024, negotiations with European Council ongoing*	*Plants*
European Union (current)	No	N/A	GMO assessment framework applies	2018 decision of the Court of Justice of the European Union (CJEU)	Plants
UK (England only)	Yes	Could have been produced by traditional breeding	Yes	Genetic Technology (Precision Breeding) Act passed in 2023	Plants and vertebrate animals
Israel	Yes	Absence of foreign DNA	Yes *	2017	Plants
South and Central America					

[41] Exclusion from regulation as “novel foods”, not GMOs

	Some NBTs excluded from GMO regulation/pre-market assessment?	Criteria for exclusion	Notification/ Confirmation Required?	Year approach adopted/updated	Applies to
Argentina	Yes	Absence of new combination of genetic material in NBT organism/final product free of transgenes	Yes *	2015	Plants, Animals, Microorganisms
Brazil	Yes	Absence of recombinant DNA/RNA in final organism	Yes *	2018	Plants, Animals, Microorganisms
Paraguay	Yes	Absence of new combination of genetic material in NBT organism/final product free of transgenes; prior approval in other countries with established regulatory processes	Yes *	2019	Plants, Animals, Microorganisms
Columbia	Yes	Absence of foreign DNA sequences in final organism	Yes *	2018	Plants, Animals, Microorganisms
Chile	Yes	Absence of new combination of genetic material in NBT organism	Yes *	2017	Plants, Animals, Microorganisms
Ecuador	Yes	Absence of recombinant/foreign DNA in final organism	Yes *	2019	Plants, Animals, Microorganisms
Guatemala	Yes	Absence of new combination of genetic material in NBT organism	Yes *	2019	Plants, Animals, Microorganisms
Honduras	Yes	Absence of new combination of genetic material in NBT organism	Yes *	2019	Plants, Animals, Microorganisms
Costa Rica	Yes	Absence of new combination of genetic material in NBT organism	Yes	2023	Plants, Animals, Microorganisms
Asia-Pacific					
Japan	Yes	Absence of foreign DNA	Yes *	Approach adopted in 2019, updated 2020	Plants, Animals, Microorganisms
China	Unclear how rules will apply	NBTs classified into risk categories	Yes *	Rules issued in 2023	Plants

	Some NBTs excluded from GMO regulation/pre-market assessment?	Criteria for exclusion	Notification/ Confirmation Required?	Year approach adopted/updated	Applies to
Republic of Korea	*Proposed exemption from risk assessment*	*Absence of foreign DNA*	*Yes **	*Draft revision to regulations under consideration*	*Plants*
India	Yes	Absence of foreign DNA	Yes *	2022	Plants
Philippines	Yes	Absence of a new combination of genetic material	Yes *	2022	Plants
Singapore	*Proposed exemption from pre-market assessment*	*Absence of foreign DNA*	*Yes **	*Consultation on proposed framework completed in 2024*	*Plants*
Africa					
Nigeria	Yes	Absence of a new combination of genetic material in final product	Yes *	2021	Plants, Animals, Microorganisms
Kenya	Yes	Absence of foreign DNA	Yes *	2022	Plants, Animals, Microorganisms
Malawi	Yes	Absence of novel combination of DNA	Yes *	2022	Plants, Animals, Microorganisms
Ghana	Yes	Absence of foreign genes in final product	Yes *	2023	Plants, Animals, Microorganisms
South Africa	No	N/A	GMO assessment framework applies	2021	Plants, Animals, Microorganisms

* Exclusion is on a case-by-case basis