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Supporting document 5

Updated compilation of regulatory approaches and definitions

P1055 – Definitions for gene technology and new breeding techniques

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

- **Table 1.** Approaches in other countries to the regulation of NBTs and derived food products
- **Table 2.** Examples of definitions used in other legislation, regulations, guidelines or proposals
- **Table 3.** Summary of international approaches to NBT regulation

Last updated in May 2025.

Table 1. Approaches in other countries to the regulation of NBTs and derived food products

Countries for which there have been updates since the release of the 2nd CFS in July 2024 are shaded in light green

Country/Union	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 during 2025.	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.

[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

China	In **January 2022**, the Chinese Ministry of Agriculture and Rural Affairs (MARA) published 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] In **March 2025**, member states agreed in the European Council to advance negotiations with the European Parliament on NGT regulations. While supporting the main elements of the European Commission proposal, the Council has proposed a number of amendments, largely around patentability aspects of NGT plants.[11] 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. The Council negotiating mandate was amended such that plants containing herbicide tolerance traits as a result of the genetic modification cannot be considered Category 1 NGT plants. 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. The proposed approach would allow product-based exclusions from GMO regulation for selected NBTs.

[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] Council of the EU – negotiating mandate on NGT regulations, 7 March 2025 https://data.consilium.europa.eu/doc/document/ST-6426-2025-INIT/en/pdf

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.[12]	The approach described in the guidelines is product-based.
Kenya	Kenya's National Biosafety Authority released a guideline in **February 2022** to clarify the regulation of genome editing under current GMO regulations.[13] 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.[14] As of 2025, 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.[15] 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	All these approaches apply a product-based approach to genome edited products on a case-by-case basis.

[12] Indian guidelines for the safety assessment of genome edited plants – https://dbtindia.gov.in/latest-announcement/guidelines-safety-assessment-genome-edited-plants2022
[13] 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
[14] 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
[15] Nigerian guidelines for regulation of gene editing – https://nbma.gov.ng/wp-content/uploads/2022/03/NATIONAL-GENE-EDITING-GUIDELINE.pdf

	containing a novel combination of DNA will be regulated as GMOs.[16] In **2023**, Ghana's National Biosafety Authority released its Guidelines for Genome Editing Applications.[17] Under these guidelines, products derived from genome editing techniques are 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[18] clarifying that null segregants (see Table 2 for definition) are not considered to be new organisms for the purpose of the HSNO Act.[19] The New Zealand government is currently also considering additional changes to biotechnology under the Gene Technology Bill (2024) [20] including the creation of a dedicated biotechnology regulator and less restrictive rules for GM and gene edited products.	
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.[21] 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.[22]	The policy approach is product-based. Applies to food, feed and processed products.

[16] Summary of Malawi's genome editing guidelines – https://africenter.isaaa.org/malawis-genome-editing-guidelines-key-promoting-supportive-environment-new-breeding-technologies/
[17] 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
[18] NZ EPA Determination on null segregants – https://www.epa.govt.nz/database-search/hsno-application-register/view/APP204173
[19] Hazardous substances and New Organisms Act Hazardous substances and New Organisms Act – https://www.legislation.govt.nz/act/public/1996/0030/latest/DLM381222.html
[20] NZ Gene Technology Bill – https://www.parliament.nz/en/pb/sc/make-a-submission/document/54SCHEA_SCF_22059628-B0CC-4931-5E07-08DD18A12BFB/gene-technology-bill
[21] Philippines' rules for evaluating NBTs – https://www.da.gov.ph/wp-content/uploads/2022/06/mc08_s2022_Revised.pdf
[22] Policy Brief on the Philippine policy for NBTs – https://www.isaaa.org/resources/publications/policybriefs/2022/pb2/default.asp

Singapore	In **August 2024**, Singapore Food Agency (SFA) implemented a 'Regulatory Framework for the use of Genome Edited Crops for Food and Animal Feed'.[23] Under the framework, genome edited crops that do not contain foreign DNA do not require pre-market assessment as GMOs. Developers of these crops are encouraged to notify SFA of the crop, and submit information to demonstrate their crop does not contain foreign DNA. SFA will then verify the developer's determination and intends to maintain a publicly available list of genome edited crops that have been notified. Genome edited crops that contain foreign DNA require pre-market assessment as GMOs.	The framework allows for product-based exclusions from GMO assessment.
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. In **September 2024**, a draft revision to the LMO Act[24] was submitted to the Korean National Assembly. Under the draft bill, genome edited organisms that do not use or contain any foreign genes would be considered in a new category distinct from LMOs, and would not be subject to the full risk assessment required by the LMO Act.	The proposed revision is a product-based approach.
United Kingdom	In **2023**, the Genetic Technology (Precision Breeding) Act passed into law in England.[25] 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 will be regulated more like their conventionally bred counterparts, rather than as GMOs. Under the Act, the Food Standards Agency (FSA) has been authorised to create a regulatory framework for food and feed derived from PBOs. As of **2025**, the Department for Environment, Food & Rural Affairs (Defra) and the FSA are proceeding with the implementation of secondary legislation[26] which sets out the requirements for food and feed produced from precision bred plants to be placed on the market. Under this framework, the PBO status of organisms will first need to be confirmed by Defra. Following Defra's decision, an application for food or feed authorisation can be submitted to the FSA.	The Act allows for product-based exclusions from the GMO definition. The Act applies in England only.

[23] SFA framework – https://www.sfa.gov.sg/regulatory-standards-frameworks-guidelines/genetically-engineered-food-and-feed/regulatory-framework-for-the-use-of-genome-edited-crops-in-food-and-or-animal-feed

[24] South Korea: Agricultural Biotechnology Annual 2024 (USDA) – https://www.fas.usda.gov/data/south-korea-agricultural-biotechnology-annual-8

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

[26] The Genetic Technology (Precision Breeding) Regulations 2025 (Draft) - https://www.legislation.gov.uk/ukdsi/2025/9780348269123

	The FSA will implement a two-tiered approach to the authorisation of PBOs as food or feed[27] (see table 2 for more detail): • All applicants must complete a 'Tier 1' assessment, which involves an applicant-led safety assessment. In cases where developers can demonstrate that Tier 1 safety assessment is sufficient, marketing authorisation will be granted without the need for a fuller assessment. • Where the Tier 1 assessment identifies potential concerns or where there is uncertainty, a 'Tier 2' application will be required, which involves a fuller assessment by the FSA before marketing authorisation is granted. Unlike GMOs, for both assessments, developers of precision bred plants will not be required to provide scientific detection methods as part of the authorisation process. Both Tier 1 and Tier 2 PBOs for use in food and feed will also be required to be listed on a public register before they can be placed on the market.	
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 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 included new exemptions for genetically engineered plants. In **2024**, a court ruling vacated the final rule, meaning that genome edited organisms that are not plant pests or do not contain DNA sourced from plant pests are no longer subject to APHIS' biotechnology regulations. 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 **2024**, the FDA issued new guidance for developers of foods derived from genome edited plants[29], outlining two voluntary processes (voluntary pre-market consultation or voluntary pre-	The regulatory approach in the US is product-based. Plants are regulated separately to animals, and some approaches may differ.

[27] FSA draft technical guidance to applicants for the authorisation of PBOs for food and feed – https://www.food.gov.uk/document/draft-technical-guidance-to-applicants-for-the-authorisation-of-precision-bred-organisms-for-food-and-feed
[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

	market meetings) that developers may use to inform the FDA of steps they have taken to ensure the safety of their product: • A pre-market consultation is recommended when genome editing results in changes that may raise safety questions or regulatory considerations that put the legal status of the food in question. • Where the genome editing does not raise safety questions according to the FDA guidance, they strongly recommend that developers schedule a pre-market meeting to inform the FDA about the type of food that will be entering the market and the steps they have taken to ensure safety. In **2024**, the FDA also issued guidance for developers on their regulatory approach 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, including in food animals where the alteration is equivalent to what could be theoretically achieved through conventional breeding.	

[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

Table 2. Examples of definitions used in other legislation, regulations, guidelines or proposals

Highlighted in light green – regulations or guidance for which there have been updates since the release of the 2nd CFS in July 2024;

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).

[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

	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.
The Genetic Technology (Precision Breeding) Regulations 2025 (Draft)[34] (England)	**Application for a food and feed marketing authorisation (Tier 1)** **20.**—(1) A person may apply for a food and feed marketing authorisation under this regulation if— (a) the precision bred organism is an organism in respect of which a precision bred confirmation is in force; (b) the person is able to demonstrate that the relevant precision bred organism belongs to a species that has a history of safe food use in accordance with paragraph (2); (c) the person is able to demonstrate that the application of modern biotechnology to the precision bred organism does not introduce genetic changes that are expected to— (i) significantly alter the nutritional quality of the organism as it is being consumed as food or feed at the date of the application in a way that is likely to be disadvantageous to the consumer; (ii) significantly elevate the toxicity of any food or feed produced from the precision bred organism; (iii) alter the allergenicity of any food or feed produced from the precision bred organism; (iv) introduce any additional features that may affect the safety of any food or feed produced from the precision bred organism. **Application for a food and feed marketing authorisation - where a Food Standards Agency assessment is required (Tier 2)** **22.**—(1) A person may apply for a food and feed marketing authorisation under this regulation if— (a) the precision bred organism is an organism in respect of which a precision bred confirmation is in force; (b) the person reasonably concludes that— (i) the precision bred organism does not belong to a species that has a history of safe food use as defined in regulation 20(2);

[34] The Genetic Technology (Precision Breeding) Regulations 2025 (Draft) – https://www.legislation.gov.uk/ukdsi/2025/9780348269123/introduction

	(ii) the application of modern biotechnology to the precision bred organism may introduce genetic changes such that any of paragraphs (i) to (iv) of regulation 20(1)(c) apply or might apply to the precision bred organism.
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[35][36] (Mandate for negotiations with the European Parliament, as at 7 March 2025)	"NGT plant" means a 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 breeders' gene pool 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 targeted 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. The genetic material may be incorporated as a continuous (exact) copy (cisgenesis in the strict sense) or a re-arranged copy of sequences already present in the breeders' gene pool (intragenesis, also considered a subset of cisgenesis in the broader sense). "breeders' gene pool" means the total genetic information available in one species and other taxonomic species with which it can be cross-bred, including by 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), and does not include tolerance to herbicides among the intended traits conveyed by the genetic modification, or (b) is progeny of the NGT plant(s) referred to in point (a), including progeny obtained by crossing of such plants, on the condition that there are no further modifications that would make it subject to Directive 2001/18/EC or Regulation 1829/2003 "Category 2 NGT plant" means a NGT plant other than a category 1 NGT plant. A NGT plant is considered equivalent to conventional plants when it differs from the recipient/parent plant by no more than 20 genetic modifications per monoploid genome of the types referred to in points 1 to 4, in any DNA sequence sharing sequence similarity with the targeted site that can be predicted by bioinformatic tools. Criteria specific to the use of targeted mutagenesis:

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

[36] 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

	(1) substitution or insertion of no more than 20 nucleotides; (2) deletion of any number of nucleotides; <u>Criteria specific to the use of cisgenesis:</u> (3) on the condition that the genetic modification does not interrupt an endogenous gene or that the resulting combination of DNA sequences in the recipient plant already occurs in a species from the breeders' gene pool: (a) targeted insertion of a contiguous continuous DNA sequence existing in the breeders' gene pool; (b) targeted substitution of an endogenous DNA sequence with a contiguous continuous DNA sequence existing in the breeders' gene pool; (4) targeted inversion of a sequence of any number of nucleotides.
Health Canada Guidance on the Novelty Interpretation of Products of Plant Breeding[37] (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).

[37] 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

Environmental Protection Agency (EPA) Final Rule: Exemptions of Certain Plant-Incorporated Protectants (PIPs) Derived from Newer Technologies *(40 CFR Part 174)*[38] (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[39] (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

[38] 40 CFR Part 174 – https://www.ecfr.gov/current/title-40/part-174
[39] NZ EPA Determination on null segregants – https://www.epa.govt.nz/database-search/hsno-application-register/view/APP204173

	3. is descended or otherwise derived, whether sexually or asexually, through any number of replications, from a null segregant progenitor(s), and 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

New approaches since the release of the 2nd CFS in July 2024 are shaded in light green

Proposed approaches, not yet in force are in grey italics.

	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; vacated in 2024. FDA guidance issued in 2024.	Plants and Animals
Canada	Yes[40]	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, European Council negotiating mandate endorsed 2025.*	*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

[40] 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
UK (England only)	Yes	Specific criteria (refer to Table 2)	Yes	Genetic Technology (Precision Breeding) Regulations expected to come into force in 2025	Plants
Israel	Yes	Absence of foreign DNA	Yes *	2017	Plants
South and Central America					
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

	Some NBTs excluded from GMO regulation/pre-market assessment?	Criteria for exclusion	Notification/ Confirmation Required?	Year approach adopted/updated	Applies to
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
Republic of Korea	*Proposed exemption from risk assessment*	*Absence of foreign DNA*	*Yes **	*Draft revision to LMO 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	Yes	Absence of foreign DNA	Yes *	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

	Some NBTs excluded from GMO regulation/pre-market assessment?	Criteria for exclusion	Notification/ Confirmation Required?	Year approach adopted/updated	Applies to
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