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

**7 October 2021**
**173-21**

# Supporting document 3

## Compilation of regulatory approaches and definitions

## P1055 – Definitions for gene technology and new breeding techniques

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As part of work on Proposal P1055, FSANZ has compiled information on international regulatory approaches and relevant definitions in other legislative and regulatory instruments. The findings of this work are presented in this document 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 or guidelines

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

| Country | Regulatory approach | Comments |
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| Argentina | Resolution 173/2015 was introduced by Argentina in 2015. It establishes a process whereby a pre-market consultation is used to determine whether an organism modified using a NBT is a GMO. Decisions are made on a case by case basis.<br><br>Approach is based on whether the NBT results in a "novel combination of genetic material" in the final organism. This approach is based on the Cartagena Protocol on Biosafety definition of a 'Living Modified Organism'.<br><br>https://agroavances.com/img/publicacion_documentos/Lema2019_Article_RegulatoryAspectsOfGeneEditing.pdf | This is a product-based approach that applies to organisms and their products.<br><br>Applies to plants, animals and microorganisms. |
| Brazil | Normative Resolution No. 16 was introduced in 2018. It sets out the technical requirements for submitting an enquiry to the National Technical Commission on Biosafety (CTNBio) about whether a product is exempt from the regulatory framework for GM organisms. Decisions are made on a case by case basis.<br><br>Approach is based primarily around whether recombinant DNA/foreign DNA is present in the final line but also the risk level classification of the modified organism.<br><br>http://bch.cbd.int/database/attachment/?id=18033 | This is a hybrid approach that applies to organisms and their products.<br><br>Applies to plants, animals and microorganisms. |
| Other Central & South American countries | A number of other countries in Central and South America (Chile, Colombia, Ecuador, Honduras, Paraguay) have also adopted new resolutions that address NBTs. Decisions are made on a case by case basis and are largely based upon whether recombinant DNA/foreign DNA is present in the final organism.<br><br>https://www.frontiersin.org/articles/10.3389/fpls.2021.630396/full | These are product-based approaches that apply to organisms and their products. Applies to plants. |
| Canada | Health Canada recently held a consultation (25 March – 26 May 2021) on proposed changes to their interpretation of the novel food regulations specifically in relation to foods derived from the products of plant breeding. The proposed guidance is intended to clarify when such foods would be considered novel and therefore subject to pre-market notification and assessment, and takes into account recent developments in genome editing.<br><br>Food from plants with genetic modifications that: are not the result of foreign DNA insertion; do not change food use; do not have an impact on key nutritional composition and/or metabolism; do not increase levels of an endogenous allergen, toxin or anti-nutrient beyond the document range; or do | The proposed approach is a clarification of the existing product-based approach to novel foods.<br><br>Applies to plants only at this stage. Additional guidance being considered for animals and microorganisms. |

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| | not alter an endogenous protein so that it demonstrates significant homology to a known allergen or toxin relevant to human health would be considered not novel.<br><br>https://www.canada.ca/en/health-canada/programs/consultation-guidance-novel-foods-regulation-plant-breeding.html | |
| European Union | Organisms modified using genome editing techniques are considered GMOs under European Union (EU) Directive 2001/18/EC. This is as a result of the 2018 decision of the Court of Justice of the European Union (CJEU). Information regarding the regulatory status of organisms modified using other NBTs is not currently available.<br><br>Following the CJEU decision, the Council of the EU requested the European Commission (EC) undertake a study on the status of new genomic techniques (NGTs[1]) under EU law.<br><br>One of the main findings of the EC study is that there are strong indications the current 2001 GMO legislation is not fit for purpose for some NGTs. The study also confirmed the current regulatory approach has implementation and enforcement challenges, relating in particular to the detection of products that contain no foreign genetic material and the difficulty in distinguishing them from conventional products.<br><br>https://ec.europa.eu/food/plant/gmo/modern_biotech/new-genomic-techniques_en<br><br>The EC has indicated it will commence a process to explore policy options concerning the regulation of plants derived from certain new genomic techniques. | The current EU approach is process-based. |
| India | At this stage it appears the current regulations for GMOs will be applied on a case by case basis to genome edited organisms and their products.<br><br>Draft guidelines for the tiered assessment of genome edited organisms have been developed. The level of assessment applied depends on the extent of genome changes introduced and the risk category of the organism.<br><br>Organisms in the lowest tier would be indistinguishable from organisms modified using classical mutagenesis techniques. A simplified assessment would be applied to these organisms, mainly to confirm the edit and the absence of off-target genomic changes. The assessment may also consider phenotypic equivalence to existing organisms obtained through conventional breeding.<br><br>http://dbtindia.gov.in/sites/default/files/Draft_Regulatory_Framework_Genome_Editing_9jan2020a.pdf | The regulatory approach applied to GMOs is process-based.<br><br>The proposed tiered assessment approach is product-based. |

[1] 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.

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| Indonesia | Indonesia has a well-established regulatory approach to GM foods. In 2018, a review was initiated to examine the regulatory approach to genome editing, resulting in a policy recommendation being put forward to government in 2021.<br><br>The proposal is to exclude products from existing GM regulations, when foreign DNA has not been introduced or is no longer present (null segregants). A submission is still required proving absence of foreign DNA.<br><br>https://publikasikr.lipi.go.id/index.php/satreps/article/download/640/594<br><br>https://www.isaaa.org/webinars/2021/nbtaustralia/ppts/Dr.%20Bambang%20Prasetya%20-%20NBT%20Australia.pdf | The policy approach is product-based. |
| Israel | A policy for genome editing of plants was adopted in 2017 by the National Committee for Transgenic Plants, in the Ministry of Agriculture. The policy stipulates genome edited plants involving deletion of nucleotides and with no insertion of foreign genetic material, are exempt from seed regulations applied to GM plants. A submission to the Ministry of Agriculture is still required to prove the plant meets the exemption criteria.<br><br>Food regulation is administered by the Ministry of Health and it is unclear if the policy for genome editing of plants applies to food. Currently, transgenic foods, foods with altered nutrient content, foods expressing new polypeptides and foods with no safe history of use, require a pre-market safety assessment under Novel Food regulations. If two OECD countries have already approved a GM food, Israel does not require a pre-market safety assessment.<br><br>While it is unclear if the genome editing policy applies to food, a virus-resistant cucumber developed by CRISPR-Cas9 technology was classified as non-transgenic by the Ministry of Agriculture and may be in commercial use.<br><br>https://bsppjournals.onlinelibrary.wiley.com/doi/10.1111/mpp.12375<br><br>https://apps.fas.usda.gov/newgainapi/api/Report/DownloadReportByFileName?fileName=Agricultural%20Biotechnology%20Annual_Tel%20Aviv_Israel_10-20-2020 | The policy approach is product-based. |
| Kenya | Kenya's National Biosafety Authority has recently prepared a draft guideline to clarify the regulation of genome editing under current GMO regulations.<br><br>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. Null segregant organisms are also proposed to be excluded. | The proposed approach to genome editing and other NBTs is product-based.<br><br>The approach relies on the Cartagena Protocol on Biosafety definition of a 'Living Modified Organism' to define what is a |

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| | An early consultation framework, applying a case by case determination of whether a product is a GMO, is being proposed.<br><br>https://journalajb2t.com/index.php/AJB2T/article/view/30083/56460 | GMO. |
| Nigeria | In 2020, the National Biosafety Management Agency released National Guidelines for the Regulation of Gene Editing.<br><br>Under this regulation, a non-GM regulatory classification is applied to a gene editing product if:<br>• no foreign genetic material is introduced; or<br>• the editing event does not result in a new combination of genetic material; or<br>• the introduced foreign genetic material has been removed from the final product;<br><br>https://nbma.gov.ng/wp-content/uploads/2021/04/NBMA-GENE-EDITING-GUIDELINE.pdf | The policy approach is product-based. |
| Other African countries | Specific regulations for genome editing have not yet been introduced by any African country.<br><br>The Academy of Science of South Africa released a report in 2017 on the regulatory implications of NBTs. It found the current regulatory approach to GMOs could be applied to NBTs, with genetic variation beyond that which may also occur naturally being used as the threshold for regulation. These recommendations have not been taken up by the South African government.<br><br>https://research.assaf.org.za/bitstream/handle/20.500.11911/29/2017_%20assaf_new_breeding_techniques.pdf?sequence=5&isAllowed=y | Many African countries have GMO regulations in place.<br><br>Approach to NBTs still evolving.<br><br>Discussions occurring at a regional level. |
| Japan | A new regulatory policy for the food products of genome editing technology was adopted in 2019.<br><br>Under the new policy, food from genome editing that contains foreign DNA are considered equivalent to existing GM foods and will be subject to the same regulatory requirements.<br><br>In the absence of foreign DNA, food from genome editing is not considered GM food provided the edit consists of: a single base pair deletion; a substitution; a naturally occurring gene deletion; or a concomitant insertion of one to several base pairs. Such modifications are considered to be equivalent to mutations that can occur naturally or through traditional breeding practices and the resulting food products are indistinguishable from conventional foods.<br><br>The new policy includes procedures for an initial consultation with the Ministry for Health Labour and Welfare to determine the regulatory status of the product and, if excluded, to voluntarily notify the intent to commercialise. | The policy approach is product-based.<br><br>Applies to both foods and food additives. |
| Philippines | Philippines has an established regulatory approach to GMOs. A new resolution was issued in 2020 to exclude from GMO regulation, plant products derived by new breeding techniques that do not contain | The policy approach is product- |

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| | foreign DNA or a novel combination of genetic material.<br><br>While the guidelines for this policy are currently being formalised, it is likely a submission to the Department of Agriculture will still be required. If the product meets the non-GM requirements, it will be listed in the Registry of Non-GM Plant Breeding Innovation Products and issued a biosafety permit.<br><br>http://www.ncbp.dost.gov.ph/download/the-regulation-of-plant-and-plant-products-derived-from-the-use-of-plant-breeding-innovations-pbis-or-new-plant-breeding-techniques-nbts | based.<br><br>Applies to food, feed and processed products. |
| United Kingdom | Currently, GMOs in the UK are regulated under retained EU law, which means that genome edited organisms are considered GMOs.<br><br>The Department for Environment, Food and Rural Affairs (DEFRA) released a consultation paper on the regulation of genetic technologies in January 2021. The main focus of the consultation was on genome edited organisms with genetic changes that could have been introduced by traditional breeding.<br><br>It is proposed that genome edited organisms and organisms produced using other genetic technologies should not be regulated as GMOs if they could have been produced by traditional breeding methods. The proposed approach would not apply to organisms with foreign DNA.<br><br>Depending on the outcome of the consultation, DEFRA may seek to amend the GMO definition.<br><br>https://consult.defra.gov.uk/agri-food-chain-directorate/the-regulation-of-genetic-technologies/supporting_documents/20210106%20Gene%20editing%20consultation%20document%20FINAL.pdf | Proposed approach would allow for product-based exclusions from the GMO definition.<br><br>If amended, the definition would apply in England only.<br><br>Proposed approach would apply to organisms, as well as derived food and feed. |
| 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.<br><br>All three agencies have been in the process of updating their approach/regulations to address recent biotechnology innovations. The USDA has finalised this process for plants.<br><br>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 May 2020. The revised rule regulates the importation, interstate movement, and environmental release of genetically engineered organisms that are or may be plant pests. It includes new exemptions for genetically engineered plants that have: a single change resulting from the cell's own repair of a targeted DNA break; a targeted single base pair substitution; been modified to incorporate a gene from the plant's natural gene pool; other | The regulatory approach in the US is product-based.<br><br>Plants are regulated separately to animals, and some approaches may differ. |

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| | modifications that APHIS may propose could have been achieved through conventional breeding.<br><br>Procedures are also in place to enable developers to propose additional exemptions.<br><br>https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/biotech-rule-revision/secure-rule/secure-about/340_2017_perdue_biotechreg<br><br>Guidance from the FDA in relation to plant food is in progress.<br><br>The USDA has also given advanced notice of a proposed rulemaking in relation to animals modified or developed using genetic engineering. Under this notice it is proposed that an expedited safety review be applied to animals with modifications known to occur in the gene pool. If the assessment confirms the modification is equivalent to conventional breeding outcomes no further regulation will be required.<br><br>https://www.aphis.usda.gov/brs/pdf/aphis-2020-0079.pdf | |

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

| Regulations | Definitions |
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| **Australia**<br>*Gene Technology Act 2000*<br>*Gene Technology Regulations 2001* | **Gene technology** means any technique for the modification of genes or other genetic material, but does not include:<br>(a) sexual reproduction; or<br>(b) homologous recombination; or<br>(c) any other technique specified in the regulations of the purposes of this paragraph<br>Techniques that are not gene technology<br>1. Somatic cell nuclear transfer, if the transfer does not involve genetically modified material.<br>2. Electromagnetic radiation-induced mutagenesis.<br>3. Particle radiation-induced mutagenesis.<br>4. Chemical-induced mutagenesis.<br>5. Fusion of animal cells, or human cells, if the fused cells are unable to form a viable whole animal or human.<br>6. Protoplast fusion, including fusion of plant protoplasts.<br>7. Embryo rescue.<br>8. *In vitro* fertilisation.<br>9. Zygote implantation.<br>10. A natural process, if the process does not involve genetically modified material. Examples: Examples of natural processes include conjugation, transduction, transformation and transposon mutagenesis.<br>11. Introduction of RNA into an organism, if:<br>(a) the RNA cannot be translated into a polypeptide; and<br>(b) the introduction of the RNA cannot result in an alteration of the organism's genome sequence; and<br>(c) the introduction of the RNA cannot give rise to an infectious agent. |

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| **New Zealand**<br><br>*Hazardous Substances and New Organisms (HSNO) Act 1996*[2]<br>*HSNO (Organisms not genetically modified) Regulations 1998* | The *HSNO Act 1996* does not explicitly define 'genetic modification' but defines genetically modified organisms[3].<br>In the regulations, the following organisms are not to be regarded as genetically modified:<br>(a) organisms that result solely from selection or natural regeneration, hand pollination, or other managed, controlled pollination:<br>(b) organisms that are regenerated from organs, tissues, or cell culture, including those produced through selection and propagation of somaclonal variants, embryo rescue, and cell fusion (including protoplast fusion):<br>(ba) organisms that result from mutagenesis that uses chemical or radiation treatments that were in use on or before 29 July 1998:<br>(c) organisms that result solely from artificial insemination, superovulation, embryo transfer, or embryo splitting:<br>(d) organisms modified solely by—<br>(i) the movement of nucleic acids using physiological processes, including conjugation, transduction, and transformation; and<br>(ii) plasmid loss or spontaneous deletion:<br>(e) organisms resulting from spontaneous deletions, rearrangements, and amplifications within a single genome, including its extrachromosomal elements.<br><br>Despite anything in subclause (d), if nucleic acid molecules produced using *in vitro* manipulation are transferred using any of the techniques referred to in subparagraph (i) or subparagraph (ii) of subclause (d), the resulting organism is a genetically modified organism. |
| *Cartagena Protocol on Biosafety*[4]<br>(International agreement) | Modern biotechnology means the application of:<br>a. *In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or<br>b. Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection. |
| *Codex Guideline*[5]<br>(International guideline) | Same as Cartagena Protocol on Biosafety |

[2] https://www.legislation.govt.nz/act/public/1996/0030/latest/whole.html#DLM381222

[3] Genetically modified organism means, unless expressly provided otherwise by regulations, any organism in which any of the genes or other genetic material—

(a) have been modified by *in vitro* techniques; or

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| **European Union**<br>*EU Directive 2001/18/EC*[6] | **Genetic modification** occurs at least through the use of<br>(1) 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;<br>(2) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;<br>(3) 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.<br><br>Annex I A, Part 2 – Techniques which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms made by techniques/methods other than those excluded by Annex I B:<br>(1) *in vitro* fertilisation,<br>(2) natural processes such as: conjugation, transduction, transformation,<br>(3) polyploidy induction.<br><br>Annex I B – Techniques/methods of genetic modification yielding organisms to be excluded from the Directive, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are:<br>(1) mutagenesis, cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods. |
| **United States**<br>*SECURE Rule*<br>*(7 CFR Parts 330, 340, and 372)*[7,8] | Genetic engineering – techniques that use recombinant, synthesized, or amplified nucleic acids to modify or create a genome. |

(b) are inherited or otherwise derived, through any number of replications, from any genes or other genetic material which has been modified by *in vitro* techniques

[4] https://bch.cbd.int/protocol/text/
[5] http://www.fao.org/fileadmin/user_upload/gmfp/resources/CXG_044e.pdf
[6] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02001L0018-20210327
[7] https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/biotech-rule-revision/secure-rule/secure-text/sr-text
[8] https://www.aphis.usda.gov/brs/fedregister/BRS_2020518.pdf

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| | 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).<br>(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<br>(2) The genetic modification is a targeted single base pair substitution; or<br>(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.<br>(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[9].<br><br>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[10].<br><br>The SECURE Rule does not explicitly define 'conventional breeding' (§ 340.3)[11]. |

[9] Procedures are in place to enable APHIS-initiated proposals or other parties' requests for exemptions (§ 340.1).
[10] Please see SECURE Rule (footnote 9) for exact wording.
[11] In the final SECURE Rule (footnote 10), 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.