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COLLATION OF THE ANSWERS FOR QUESTIONNAIRE Enhanced Information Exchange on New Breeding Techniques: 2024 Results

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COLLATION OF THE ANSWERS FOR QUESTIONNAIRE Enhanced Information Exchange on New Breeding Techniques: 2024 Results

Environment Directorate

ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT

Paris 2024

Also published in the Series on Harmonisation of Regulatory Oversight in Biotechnology:

No. 1, Commercialisation of Agricultural Products Derived through Modern Biotechnology: Survey Results (1995)

No. 2, Analysis of Information Elements Used in the Assessment of Certain Products of Modern Biotechnology (1995)

No. 3, Report of the OECD Workshop on the Commercialisation of Agricultural Products Derived through Modern Biotechnology (1995)

No. 4, Industrial Products of Modern Biotechnology Intended for Release to the Environment: The Proceedings of the Fribourg Workshop (1996)

No. 5, Consensus Document on General Information concerning the Biosafety of Crop Plants Made Virus Resistant through Coat Protein Gene-Mediated Protection (1996)

No. 6, Consensus Document on Information Used in the Assessment of Environmental Applications Involving *Pseudomonas* (1997)

[No. 7, Consensus Document on the Biology of *Brassica napus* L. (Oilseed Rape) (1997) – ***REPLACED*** *with Consensus Document on* Brassica *crops* (Brassica *spp*)*. No. 54 (2012)*]

No. 8, Consensus Document on the Biology of *Solanum tuberosum* subsp. *tuberosum* (Potato) (1997)

No. 9, Consensus Document on the Biology of *Triticum aestivum* (Bread Wheat) (1999)

No. 10, Consensus Document on General Information Concerning the Genes and Their Enzymes that Confer Tolerance to Glyphosate Herbicide (1999)

No. 11, Consensus Document on General Information Concerning the Genes and Their Enzymes that Confer Tolerance to Phosphinothricin Herbicide (1999)

No. 12, Consensus Document on the Biology of *Picea abies* (L.) Karst (Norway Spruce) (1999)

No. 13, Consensus Document on the Biology of *Picea glauca* (Moench) Voss (White Spruce) (1999)

[No. 14, Consensus Document on the Biology of *Oryza sativa* (Rice) (1999) – ***REPLACED*** *with Revised Consensus Document on the Biology of Rice* (*Oryza sativa L.*) *No. 70 (2021)*]

No. 15, Consensus Document on the Biology of *Glycine max* (L.) Merr. (Soybean) (2000)

No. 16, Consensus Document on the Biology of *Populus* L. (Poplars) (2000)

No. 17, Report of the OECD Workshop on Unique Identification Systems for Transgenic Plants, Charmey, Switzerland, 2-4 Oct. 2000 (2001)

No. 18, Consensus Document on the Biology of *Beta vulgaris* L. (Sugar Beet) (2001)

No. 19, Report of the Workshop on the Environmental Considerations of Genetically Modified Trees, Norway, September 1999 (2001)

No. 20, Consensus Document on Information Used in the Assessment of Environmental Applications Involving Baculoviruses (2002)

No. 21, Consensus Document on the Biology of *Picea sitchensis* (Bong.) Carr. (Sitka Spruce) (2002)

No. 22, Consensus Document on the Biology of *Pinus strobus* L. (Eastern White Pine) (2002)

No. 23, Revised 2006: OECD Guidance for the Designation of a Unique Identifier for Transgenic Plants (2006)

No. 24, Consensus Document on the Biology of *Prunus* spp. (Stone Fruits) (2002)

No. 25, Module II: Herbicide Biochemistry, Herbicide Metabolism and the Residues in Glufosinate-Ammonium (Phosphinothricin)-Tolerant Transgenic Plants (2002)

No. 26, Output on the Questionnaire on National Approaches to Monitoring/Detection/Identification of Transgenic Products (2003)

No. 27, Consensus Document on the Biology of *Zea mays* subsp. *mays* (Maize) (2003)

No. 28, Consensus Document on the Biology of European White Birch (*Betula pendula* Roth) (2003)

No. 29, Guidance Document on the Use of Taxonomy in Risk Assessment of Micro-organisms: Bacteria (2003)

No. 30, Guidance Document on Methods for Detection of Micro-organisms Introduced into the Environment: Bacteria (2004)

No. 31, Consensus Document on the Biology of *Helianthus annuus* L. (Sunflower) (2004)

No. 32, An Introduction to the Biosafety Consensus Documents of OECD's Working Group for Harmonisation in Biotechnology (2005)

No. 33, Consensus Document on the Biology of Papaya (*Carica papaya*) (2005)

No. 34, Consensus Document on the Biology of *Pleurotus* spp. (Oyster Mushroom) (2005)

[No. 35, Points to Consider for Consensus Documents on the Biology of Cultivated Plants (2006) – ***REPLACED*** *with Revised Points to Consider document No. 67 (2020)*]

No. 36, Consensus Document on the Biology of *Capsicum annuum* Complex (Chili, Hot and Sweet peppers) (2006)

No. 37, Consensus Document on Information Used in the Assessment of Environmental Application involving Acidithiobacillus (2006)

No. 38, Consensus Document on the Biology of Western White Pine (*Pinus monticola* Dougl. ex D. Don) (2008)

No. 39, Abstracts of the OECD Expert Workshop on the Biology of Atlantic Salmon (2006)

No. 40, Consensus Document on the Biology of *Pinus banksiana* (Jack Pine) (2006)

No. 41, Consensus Document on the Biology of the Native North American Larches: Subalpine Larch (*Larix lyallii*), Western Larch (*Larix occidentalis*), and Tamarack (*Larix laricina*) (2007)

No. 42, Consensus Document on the Safety Information on Transgenic Plants Expressing *Bacillus thuringiensis* – Derived Insect Control Protein (2007)

No. 43, Consensus Document on the Biology of Douglas-Fir (*Pseudotsuga menziesii* (Mirb.) Franco (2008)

No. 44, Consensus Document on the Biology of Lodgepole Pine (*Pinus contorta* Dougl. ex. Loud.) (2008)

No. 45, Consensus Document on the Biology of Cotton (*Gossypium* spp.) (2008)

No. 46, Consensus Document on Information Used in the Assessment of Environmental Applications Involving *Acinetobacter* (2008)

No. 47, Guide for Preparation of Biology Consensus Documents (2008)

No. 48, Consensus Document on the Biology of Bananas and Plantains (*Musa* spp.) (2009)

No. 49, Consensus Document on the Biology of *Picea mariana* [Mill.] B.S.P. (Black spruce) (2010)

No. 50, Guidance Document on Horizontal Gene Transfer between Bacteria (2010)

No. 51, Consensus Document on Molecular Characterisation of Plants Derived from Modern Biotechnology (2010)

No. 52, Guidance Document on the Use of Information on Pathogenicity Factors in Assessing the Potential Adverse Health Effects of Micro Organisms: Bacteria (2011)

No. 53, Consensus Document on the Biology of *Cucurbita* L. (Squashes, Pumpkins, Zucchinis and Gourds) (2012)

No. 54, Consensus Document on the Biology of the Brassica Crops (*Brassica* spp.) (2012)

No. 55, Low Level Presence of Transgenic Plants in Seed and Grain Commodities: Environmental Risk/Safety Assessment, and Availability and Use of Information (2013)

No. 56, Consensus Document on the Biology of Sugarcane (*Saccharum* spp.) (2013)

No. 57, Consensus Document on the Biology of Cassava (*Manihot esculenta* Crantz) (2014)

No. 58, Consensus Document on the Biology of *Eucalyptus* spp. (2014)

No. 59, Consensus Document on the Biology of Common bean (*Phaseolus vulgaris* L.) (2015)

No. 60, Consensus Document on the Biology of Cowpea (*Vigna unguiculata* (L.) Walp.) (2015)

No. 61, Report of the OECD Workshop on Environmental Risk Assessment of Products derived from New Plant Breeding Techniques (2016)

No. 62, Consensus Document on the Biology of Sorghum (*Sorghum bicolor* (L.) Moench) (2016)

No. 63, Consensus Document on the Biology of Tomato (*Solanum lycopersicum* L.) (2016)

No. 64, Consensus Document on the Biology of Atlantic salmon (*Salmo salar*) (2017)

No. 65, Consensus Document on the Biology of Mosquito *Aedes aegypti* (2018)

No. 66, Consensus Document on the Biology of Apple (*Malus domestica* Borkh.) (2019)

No. 67, Revised Points to Consider for Consensus Documents on the Biology of Cultivated Plants (2020)

No. 68, Consensus Document on the Biology of Safflower (*Carthamus tinctorius L.*) (2020)

No. 69, Developments in Delegations on Biosafety Issues, April 2020 – March 2021 (2021)

No. 70, Revised Consensus Document on the Biology of Rice (*Oryza sativa* L.) (2021)

No. 71, Developments in Delegations on Biosafety Issues, April 2021 – May 2022 (2022)

No. 72, Developments in Delegations on Biosafety Issues, June 2022 – April 2023 (2023)

No. 73, Consensus Document on Environmental Considerations for Risk/safety Assessment for the Release of Transgenic Plants (2023)

No. 74, Developments in Delegations on Biosafety Issues, May 2023 – February 2024 (2024)

Also published in the Series on the Safety of Novel Foods and Feeds:

[No. 1, Consensus Document on Key Nutrients and Key Toxicants in Low Erucic Acid Rapeseed (Canola) (2001) – REPLACED with revised consensus document No. 24 (2011)]

[No. 2, Consensus Document on Compositional Considerations for New Varieties of Soybean: Key Food and Feed Nutrients and Anti-nutrients (2001) – REPLACED with revised consensus doc. No. 25 (2012)]

No. 3, Consensus Document on Compositional Considerations for New Varieties of Sugar Beet: Key Food and Feed Nutrients and Anti-nutrients (2002)

[No. 4, Consensus Document on Compositional Considerations for New Varieties of Potatoes: Key Food and Feed Nutrients, Anti-nutrients and Toxicants (2002) – REPLACED with revised consensus document No. 33 (2020)]

No. 5, Report of the OECD Workshop on the Nutritional Assessment of Novel Foods and Feeds, Ottawa, Canada, February 2001 (2002)

No. 6, Consensus Document on Compositional Considerations for New Varieties of Maize (*Zea mays*): Key Food and Feed Nutrients, Anti-nutrients and Secondary Plant Metabolites (2002)

No. 7, Consensus Document on Compositional Considerations for New Varieties of Bread Wheat (*Triticum aestivum*): Key Food and Feed Nutrients, Anti-nutrients and Toxicants (2003)

No. 8, Report on the Questionnaire on Biomarkers, Research on the Safety of Novel Foods and Feasibility of Post-Market Monitoring (2003)

No. 9, Considerations for the Safety Assessment of Animal Feedstuffs Derived from Genetically Modified Plants (2003)

[No. 10, [Consensus Document on Compositional Considerations for New Varieties of Rice (*Oryza sativa*): Key Food and Feed Nutrients and Anti-nutrients (2004) REPLACED with revised consensus document No. 28 (2016)]

No. 11, Consensus Document on Compositional Considerations for New Varieties of Cotton (*Gossypium hirsutum* and *Gossypium barbadense*): Key Food and Feed Nutrients and Anti-nutrients (2004)

No. 12, Consensus Document on Compositional Considerations for New Varieties of Barley (*Hordeum vulgare* L.): Key Food and Feed Nutrients and Anti-nutrients (2004)

No. 13, Consensus Document on Compositional Considerations for New Varieties of Alfalfa and Other Temperate Forage Legumes: Key Feed Nutrients, Anti-nutrients and Secondary Plant Metabolites (2005)

No. 14, An Introduction to the Food/Feed Safety Consensus Documents of the Task Force for the Safety of Novel Foods and Feeds (2006)

No. 15, Consensus Document on Compositional Considerations for New Varieties of the Cultivated Mushroom *Agaricus bisporus*: Key Food and Feed Nutrients, Anti-nutrients and Toxicants (2007)

No. 16, Consensus Document on Compositional Considerations for New Varieties of Sunflower: Key Food and Feed Nutrients, Anti-nutrients and Toxicants (2007)

No. 17, Consensus Document on Compositional Considerations for New Varieties of Tomato: Key Food and Feed Nutrients, Anti-nutrients, Toxicants and Allergens (2008)

No. 18, Consensus Document on Compositional Considerations for New Varieties of Cassava (*Manihot esculenta* Crantz): Key Food and Feed Nutrients, Anti-nutrients, Toxicants and Allergens (2009)

No. 19, Consensus Document on Compositional Considerations for New Varieties of Grain Sorghum [*Sorghum bicolor* (L.) Moench]: Key Food and Feed Nutrients and Anti-nutrients (2010)

No. 20, Consensus Document on Compositional Considerations for New Varieties of Sweet Potato [*Ipomoea batatas* (L.) Lam.]: Key Food and Feed Nutrients, Anti-nutrients, Toxicants and Allergens (2010)

No. 21, Consensus Document on Compositional Considerations for New Varieties of Papaya (*Carica papaya* L.): Key Food and Feed Nutrients, Anti-nutrients, Toxicants and Allergens (2010)

No. 22, Consensus Document on Molecular Characterisation of Plants Derived from Modern Biotechnology (2010)

No. 23, Consensus Document on Compositional Considerations for New Varieties of Sugarcane (*Saccharum* spp. hybrids.): Key Food and Feed Nutrients, Anti-nutrients and Toxicants (2011)

No. 24, Revised Consensus Document on Compositional Considerations for New Varieties of Low Erucic Acid Rapeseed (Canola): Key Food and Feed Nutrients, Anti-nutrients and Toxicants (2011)

No. 25, Revised Consensus Document on Compositional Considerations for New Varieties of Soybean [*Glycine max* (L.) Merr.]: Key Food and Feed Nutrients, Anti-nutrients, Toxicants and Allergens (2012)

No. 26, Consensus Document on Compositional Considerations for New Varieties of Oyster Mushroom (*Pleurotus ostreatus*): Key Food and Feed Nutrients, Anti-nutrients and Toxicants (2013)

No. 27, Consensus Document on Compositional Considerations for New Varieties of Common Bean (*Phaseolus vulgaris* L.): Key Food and Feed Nutrients, Anti-nutrients and Other Constituents (2015)

No. 28, Revised Consensus Document on Compositional Considerations for New Varieties of Rice (*Oryza sativa*): Key Food and Feed Nutrients, Anti-nutrients and Other Constituents (2016)

No. 29, High-throughput DNA Sequencing in the Safety Assessment of Genetically Engineered Plants: Proceedings of the OECD Workshop held in April 2016 (2016)

No. 30, Consensus Document on Compositional Considerations for New Varieties of Cowpea (*Vigna unguiculata*): Key Food and Feed Nutrients, Anti-nutrients and Other Constituents (2018)

No. 31, Consensus Document on Compositional Considerations for New Cultivars of Apple (*Malus* × *domestica* Borkh.): Key Food and Feed Nutrients, Allergens, Toxicants and Other Metabolites (2019)

No.32, Developments in Delegations on the Safety Assessment of Novel Foods and Feeds, April 2019 - March 2020 (2020)

No.33, Revised Consensus Document on Compositional Considerations for New Varieties of Potato (*Solanum tuberosum*): Key Food and Feed Nutrients, Toxicants, Allergens, Anti-nutrients and Other Plant Metabolites (2020)

No.34, Developments in Delegations on the Safety Assessment of Novel Foods and Feeds, April 2020 - March 2021 (2021)

No.35, Developments in Delegations on the Safety Assessment of Novel Foods and Feeds, April 2021 - May 2022 (2022)

No.36, Developments in Delegations on the Safety Assessment of Novel Foods and Feeds, June 2022 - April 2023 (2023)

No.37, Considerations for Collaborative Work on the Safety Assessments of Foods and Feeds Derived from rDNA Plants (2023)

No. 38, Developments in Delegations on the Safety Assessment of Novel Foods and Feeds, May 2023 – February 2024 (2024)

ABOUT THE OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 38 countries in North and South America, Europe and the Asia and Pacific region, as well as the European Union, meet to co-ordinate and harmonise policies, discuss issues of mutual concern, and work together to respond to international problems. Most of the OECD's work is carried out by more than 200 specialised committees and working groups composed of member country delegates. Observers from several Partner countries and from interested international organisations attend many of the OECD's workshops and other meetings. Committees and working groups are served by the OECD Secretariat, located in Paris, France, which is organised into directorates and divisions.

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This publication is available electronically, at no charge.

For this and many other Biosafety publications, consult the OECD's World Wide Web site (https://www.oecd.org/env/ehs/biotrack/)

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OECD Environment, Health and Safety Publication

FOREWORD

The OECD Working Party on Harmonisation of Regulatory Oversight in Biotechnology (WP-HROB) and the OECD Working Party for the Safety of Novel Foods and Feeds (WP-SNFF) serve as forums for exchanging approaches and experience in environmental risk/safety assessments of organisms produced through modern biotechnology, aiming to improve mutual understanding and to increase the efficiency of the assessments. They identify and address issues from the development and application of biotechnology, aiming to facilitate harmonisation in risk/safety assessments, while promoting the safe use.

New breeding techniques (NBTs) are a rapidly developing area in biotechnology. The Working Parties have been following recent regulatory developments and exchanging information on the techniques, the organisms derived from them, their applications and regulatory implications since 2022. The information exchanged on products related to NBT applications and regulatory aspects is tailored to meet the current needs of the OECD delegations.

The joint WP project on 'Enhanced Information Exchange on NBTs', led by Japan, aims to collectively present comprehensive and accurate information on regional, national, and local regulations related to NBT through an annual questionnaire. This document is the first publication from the project, collating responses to the questionnaire distributed to WP-HROB from December 2023 to March 2024. It offers valuable insights into the regulatory landscape surrounding NBT approvals and registrations across jurisdictions.

The report is updated annually. Responses from WP-SNFF will be included in the 2025 edition. A system for regular collection and exchange of NBTs information at the OECD level increases trust and publication enhances confidence in the use of these products of modern biotechnology.

The WP-HROB and the WP-SNFF approved this document for publication at the 2024 Working Party meetings and it is published under responsibility of the Chemicals and Biotechnology Committee of the OECD.

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BACKGROUND

In recent years, new breeding techniques (NBTs), including genome editing and related methods, have led to the development of a variety of new products. Some countries have already defined and implemented their regulatory approach for the NBT products, while others are considering their approach to these products. International trade of NBT-produced products is expected to increase, prompting national and regional authorities to closely monitor NBT developments.

In April 2019, Japan presented an initial project proposal on Enhanced Information Exchange on NBTs at the 33rd meeting of the OECD Working Party on Harmonisation of Regulatory Oversight in Biotechnology (WP-HROB) and the 26th meeting of the OECD Working Party for the Safety of Novel Foods and Feeds (WP-SNFF). While the overall concept was supported, delegates sought more clarity on the proposal at that time.

In the following years, the proposal was revised several times in consultation with an ad hoc group of representatives from both Working Parties (WPs). Particular attention was paid to the agreement of the key information to be collected. In October 2022, the project 'Enhanced Information Exchange on NBTs' was finalised and agreed by both WPs.

In December 2022, the first questionnaire was distributed to the WP-HROB and the responses to the questionnaire were collected and collated by the OECD Secretariat and shared at the Joint WP meeting the following year. The WP-SNFF decided to continue to monitor the progress of the project, and therefore the second questionnaire was distributed only to the WP-HROB in December 2023. At the Joint WPs meeting held in March 2024 it was agreed to extend the questionnaire distribution to WP-SNFF members and to declassify the survey results. Based on this agreement, the 2024 results of the questionnaire were prepared for publication.

This publication is a collation of 19 delegations' responses to the WP-HROB questionnaire distributed from December 2023 to March 2024.

Part I By Country

Argentina

Delegation: National Directorate of Bioeconomy

Date of report: 21 February 2024 (received OECD)

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them (laws, rules, policies, and guidelines)

Since 2015, Argentina has had robust regulations for products derived from new breeding techniques (NBTs), including gene editing, whose criteria are updated as consultations are received to determine whether these products are Genetically Modified Organisms (GMOs) or not.

In 2020, Argentina undertook a review and update of its entire regulatory framework for both GMOs and NTBs. The characteristics of NTB regulations require a prior scientific analysis, on a case-by-case basis, of the organisms already obtained or to be obtained (in the design stage), in order to determine whether or not they fall within the scope of the regulations applicable to Genetically Modified Organisms (GMOs).

In other words, the regulation of products derived from NBTs sets out the procedures for determining whether or not any organism obtained through these techniques of modern biotechnology falls within the scope of the GMO regulation.

For more information, see

https://www.argentina.gob.ar/agricultura/alimentos-y-bioeconomia/nuevas-tecnicas-de-mejoramiento-nbt

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

Argentina promotes New Breeding Techniques (NBTs) as tools for adding value to products and processes involved in agricultural practices, in order to help achieve sustainability, respecting biodiversity and addressing the climate crisis.

The products derived from the application of the NBTs are analysed by the National Advisory Commission on Agricultural Biotechnology (CONABIA) in a procedure called Instancia de Consulta Previa (ICP), as indicated in the regulation N°21/2021, of the then Ministry of Agriculture, Livestock and Fisheries of Argentina.

This is a procedure to determine whether a product obtained by NTBs falls under the definition of Genetically Modified Organism of the Cartagena Protocol (1).

It is analysed if the product contains a New Combination of Genetic Material (2). If it does, it is considered GMO (equivalent to transgenic) and must be evaluated as such according to the regulations in force, depending on whether it is a plant, animal or micro-organism.

If it does not have a new combination of genetic material, it is considered non-GMO.

This type of regulation allows developers to submit a PCI form for products in the design stage, providing guidance on the regulatory status of their product until they obtain the final product. For which they must resubmit the form together with studies demonstrating that the product does not contain a novel combination of genetic material.

(1) Definition of GMO in the Cartagena Protocol, which states that a GMO is any living organism that possesses a novel combination of genetic material obtained through the application of modern biotechnology.

2) New combination of genetic material: change produced in the genome of the organism by the incorporation, in a stable and joint form, of ONE (1) or more genes or nucleic acid sequences that form part of a defined genetic construct.

Link to the resolution and annexes of the Argentine regulatory framework for products derived from NTBs: https://www.magyp.gob.ar/sitio/areas/biotecnologia/conabia/marco_regulatorio_nbt.php

Item 1-1-1. Environmental release

Covered by Argentinian regulations for products derived from New Breeding Techniques, Res. 21/21

Item 1-1-2. Food and feed

Covered by Argentinian regulations for products derived from New Breeding Techniques, Res. 21/21

Item 1-2. Other regulatory aspects

Covered by Argentinian regulations for products derived from New Breeding Techniques, Res. 21/21

Item 2: Products developed using NBTs approved/registered by or reported/notified to authorities (if available; limited to public and/or official information basically on relevant plants)

Argentina still has no NBT-derived products on the market. In addition, Argentina does not publish a third list of products derived from NBT.

In this sense, the information that can be provided is the following:

Total PCIs evaluated: 133

Types of PCIs submitted:

1. According to organism:
    - plant: 111 (81 final products and 30 products in development stage)
    - animal: 19 (7 final products and 12 products in development stage)
    - microorganisms: 5 (4 final products and 1 product in design stage).
2. Type of product:
    - Final: 91
    - In design stage: 42
3. Type of applicant entity:
    - Public: 29
    - Private: 101
    - Mixed: 3
4. Type of development:
    - National: 64
    - Foreign: 10
    - Foreign development with national presentation: 59

Item 2-1. For environmental release

not applicable

Item 2-2. For food and feed

not applicable

Item 2-3. Other products

not applicable

Item 3: Other information (if available; limited to public and/or official information)

The analysis of the entire experience generated by the application of these regulations reveals the following conclusions about the PCI cases analysed: i) the developers can predict costs and period of time in the product development, even at the design stage; ii) the developers can put their products into the market sooner; iii) there are a greater phenotype varieties in different crops, animals and microorganisms; and iv) the speed of innovation of products obtained by NBTs is greater in relation to GMOs the innovation speed.

Publications related to Argentine NBT regulation carried out by the National Bioeconomy Directorate:

Title/Summary of the contents	Source (URL, doi, date accessed etc.,)
Whelan, A. I., and Lema, M. A. (2015). Regulatory framework for gene editing and other new breeding techniques (NBTs) in Argentina.*GM Crops & Food*6, 253–265. doi: 10.1080/21645698.2015.1114698.	https://pubmed.ncbi.nlm.nih.gov/26552666/
Goberna, M. F., Whelan, A. I., Godoy, P., and Lewi, D. M. (2022). Genomic Editing: The Evolution in Regulatory Management Accompanying Scientific Progress.*Front. Bioeng. Biotechnol.*10, 835378. doi: 10.3389/fbioe.2022.835378.	https://www.frontiersin.org/articles/10.3389/fbioe.2022.835378/full
Goberna, M.F., Lewi, D. M., Godoy, P and Hopp, E. Capítulo “Gene Editing Regulation in Argentina”. En: Global Regulatory Outlook for CRISPRized Plants 1st Edition - November 1, 2023; Editorial Elsevier; Editores: Kamel A Abd-Elsalam, Aftab Ahmad; Paperback ISBN: 9780443184444; eBook ISBN: 9780443184451. number of pages: 625.	https://shop.elsevier.com/books/global-regulatory-outlook-for-crisprized-plants/a-abd-elsalam/978-0-443-18444-4
Fernández Ríos D, Benítez Candia N, Soerensen MC, Goberna MF and Arrúa AA (2024) Regulatory landscape for new breeding techniques (NBTs): insights from Paraguay. Front. Bioeng. Biotechnol. 12:1332851. doi: 10.3389/fbioe.2024.1332851	https://www.frontiersin.org/articles/10.3389/fbioe.2024.1332851/full

Austria

Delegation: Austria

Date of report: 1 March 2024

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them (laws, rules, policies, and guidelines)

No legislative amendments concerning NBTs and NBT products were introduced or implemented at the Austrian Federal level during this reporting period.

However at the EU level the European Commission (EC) introduced a legislative proposal for a regulation on plants produced by certain new genomic techniques (NGTs) and their food and feed. For details on this proposal pls. refer to the respective contribution of the EC to this survey.

The Austrian competent authorities and national institutions involved in risk assessment and management of GM products submitted comments to the EC proposal on a new regulation of NGT plants to the Ad Hoc Working Group of the EU council and are actively participating in the discussions addressing the proposal of the EC. Austria identified many critical issues related to the proposal and the need for further discussion. These issues include the criteria used to classify NGTs, the lack of labelling requirements, the lowered risk assessment standards, incentives related to claimed sustainability, patents, the possible impact on organic and GM-free production, and subsidiarity issues related to coexistence and the possibility to prohibit cultivation of NGTs.

At the parlamentary level the Committee for EU Affairs of the second chamber of the Austrian parliament discussed the proposal of the EC on a new regulation of NGT plants in November of 2023: The Committee took note of an joint opinion of the Austrian Bundesländer (the Austrian Federal States) on the EC proposal. This unanimous opinion states that the proposed regulation (i) violates the principle of subsidiarity, because it effectively eliminates the Member States' previous freedom of choice to authorise, restrict or prohibit the cultivation of genetically modified organisms (GMOs) on their territory, (ii) curtails the Member States' powers to participate in EU legislation by giving the EU Commission broad permission to adopt delegated and implementing acts and (iii) uses the wrong legal instrument due to the choice of a EU regulation instead of a EU directive. According to the Austrian constitution the Austrian Federal Government shall be bound by such an joint opinion adopted by the Bundesländer regarding negotiations and votes in the EU on legislative proposals within the framework of the EU, which concern matters that are subject to legislation implemented by the Bundesländer.
Based on the mentioned opinion the members of the Committee unanimously rejected the proposal of the EC and required that the Austrian government shall demand compliance with the following principles: The possibility of measures concerning the cultivation of all plants obtained using genetic engineering, including NGTs, in individual EU member states on the basis of national decisions ("opt-out regulation") and mandatory labelling and authorisation procedures for all organisms obtained using genetic engineering, including NGTs, which include a risk assessment in accordance with the precautionary principle.
EU-Ausschuss des Bundesrats spricht sich einstimmig gegen neue genomischen Techniken in der Landwirtschaft aus (PK1147/07.11.2023) | Parlament Österreich

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

Item 1-1-1. Environmental release

Item 1-1-2. Food and feed

Item 1-2. Other regulatory aspects

Item 2: Products developed using NBTs approved/registered by or reported/notified to authorities (if available; limited to public and/or official information basically on relevant plants)

To date, Austria did not receive any applications for authorisation of an NGT-product which is subject to the EU GMO regulations according to the ruling by the European Court of Justice (Case C-528/16).

If any NGT-applications are submitted in the future, the current GMO authorisation procedure and labelling requirements according to the Austrian Gene Technology Act will apply for these products.

Item 2-1. For environmental release

Item 2-2. For food and feed

Item 2-3. Other products

Item 3: Other information (if available; limited to public and/or official information)

Title/Summary of the contents	Source (URL, doi, date accessed etc.,)
A symposium for national and European stakeholders addressing issues related to the proposal of the European Commission (EC) for a regulation of NGT plants was held in Vienna on October 11th 2023. The event consisted of several sessions addressing the regulatory proposal of the EC, the risk assessment of NGT plants, the precautionary principle, consumer protection, and impacts on organic agriculture and the production of GM free agricultural products. The	

participants represented a wide range of different stakeholders, such as the European Commission and authorities from different EU Member States including Hungary, Slovenia, Belgium, France, Poland and the Netherlands, associations for GM-free food production and organic farming, scientists, and NGOs. The discussion addressed the following topics: • The proposal of the EC and issues regarding the Risk Assessment of NGT plants and application of the precautionary principle • Impacts of NGT applications on Organic and GM-free Production and on IPR protection by patents The main results of the symposium include: 1. The entrepreneurial freedom and consumer freedom of choice remain central aspects of the discussion. The use of new genetic engineering products (both NGT1 and NGT2) is not seen as an option for organic farming and the GMO-free sector. Accordingly, labelling and traceability are of great importance in order not to jeopardize these sectors. 2. Questions of liability and coexistence are also central for assessing the impacts of the EC proposal. The proposed reversal of the burden of proof in the event of contamination is viewed critically. Another key point that is particularly important for stakeholders from the GMO-free sector is that the EC's proposal would no longer allow exemptions from GMO cultivation in individual Member States ("opt-out"). 3. The patentability of NGT products is also an important issue in the framework of the discussion. The potential benefits of NGTs must also be available to small breeders, without restricting the accessibility to breeding materials. However, the possibilities for implementation of such policies remain unclear, as patents on NGT products are possible in principle under current legislation and the European Patent Office is not governed by EU institutions. 4. The safety of NGT products for humans and the environment is of great importance. Unlike the proposed EC regulation of NGT plants the implementation of the precautionary principle by the current EU GMO legislation and the Cartagena Protocol on Biosafety mandates a case-by-case risk assessment. The proposed deviation from the current GMO legislation is controversially discussed. 5. The categorisation of NGT1 and NGT2 plants and the assumption of the EC proposal that NGT1 plants are equivalent to conventionally bred plants, was intensively discussed. It was stressed that the actual properties of individual NGT plants as well as unintended changes and risks are not taken into account by the technical criteria proposed by the EC.	
Aspects regarding the policy proposal of the European Commission were also discussed at an information and	A webcast of the event in German language is available at: Klare Kennzeichnung und Sicherheits-

discussion event with Members of the European Parliament, i.e. Thomas Waitz, Greens, and Günther Sidl, Social Democrats, held at the EU representation in Vienna (Haus der EU) on Jan 22nd 2024: The event "New genetic engineering: future technology or greenwashing?" co-organised by Global2000 and the Austrian Chamber of Labour (Arbeiterkammer) addressed the question what a deregulation of new genetic engineering in the EU would mean for the environment, consumer transparency and GMO-free agriculture in Austria. The event featured presentations by Margret Engelhard, (Federal Agency for Nature Conservation, Germany), Katherine Dolan (ARCHE NOAH, Austria) and Andreas Heissenberger (Environment Agency Austria) addressing newly published studies concerning the impacts of the regulations for NGT plants proposed by the EC, the impacts of patents on NGT plants and the lack of an adequate risk assessment of unintended effects of NGT plants according to the regulation proposed by the EC, respectively. The presentations and the activities of the EU parliament were further discussed in a panel with Thomas Waitz and Günther Sidl.	Checks bei Neuer Gentechnik in Lebensmitteln nötig! | GLOBAL 2000
Representatives of Austrian Universities and research institutions published an open letter calling for a non-ideological and science-based approach to regulating green biotechnology and applications of new genomic techniques	Grüne Gentechnik: Offener Brief für eine wissenschaftsbasierte Beurteilung (oeaw.ac.at)
A publication commissioned by the Austrian Chamber of Labor (Arbeiterkammer) and conducted by Environment Agency Austria (Eckerstorfer & Heissenberger 2023) was presented at the event organised by two Austrian Members of the European Parliament indicated above. The study addresses how the current GMO legislation or the proposal of the EC for NGT plants deal with potential unintended risks of GM / NGT products. Although the safety of NGT products is of considerable importance for developers, consumers and legislators, respectively, this aspect is not a focal issue of the current debate on the EC proposal for a new regulation for NGT products. The study examines this topic on the basis of representative examples of NGT plants. The analysis intends to direct the focus of attention on possible unintended effects, which may be associated with individual NGT products.	Eckerstorfer, M. and Heissenberger, A. (2023). "New Genetic Engineering - possible unintended effects." Wien: Verlag Arbeiterkammer Wien. urn:nbn:at:at-akw:g-6550206, DOI: 10.13140/RG.2.2.12482.969694 Available at: (22) (PDF) NEW GENETIC ENGINEERING - POSSIBLE UNINTENDED EFFECTS (researchgate.net)

Belgium

Delegation: Belgium

Date of report: 29 February 2024

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them (laws, rules, policies, and guidelines)

For this item, we refer to the answer of the European Commission and the following link.

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

Item 1-1-1. Environmental release

Item 1-1-2. Food and feed

Item 1-2. Other regulatory aspects

Item 2: Products developed using NBTs approved/registered by or reported/notified to authorities (if available; limited to public and/or official information basically on relevant plants)

For this item, we refer to the answer of the European Commission.

Item 2-1. For environmental release

Item 2-2. For food and feed

Item 2-3. Other products

Item 3: Other information (if available; limited to public and/or official information)

For this item, we refer to the answer of the European Commission.

Brazil

Delegation: Brazil

Date of report: 10 March 2024

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them (laws, rules, policies, and guidelines)

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

In January 2018, the National Technical Commission on Biosafety (CTNBio) established evaluation procedures for products derived from Precision Breeding Innovation techniques.

Item 1-1-1. Environmental release

A) Regarding the original organism (Parentals), the proponent must provide:

1 - Identification of the genetic technology, objective, and intended use of the resulting organism and its derivatives.

2 - Taxonomic classification, from family to the most detailed level of the organism to be released, including, when appropriate, subspecies, cultivar, pathovar, strain, and serotype.

3 - Risk classification of the genetically modified organism according to Normative Resolution nº. 2, dated November 27, 2006.

4 - The gene(s) and/or genetic element(s) manipulated, organism(s) of origin, and their specific functions, when applicable.

5 - The genetic strategy(ies) used to produce the desired modification(s); the genetic map(s) of the construction(s) used in the process indicating all genetic elements present.

6 - Molecular characterization of the manipulation result in the recipient organism (parentals and final product), when applicable, providing information related to: (1) number of manipulated copies (e.g., number of genomic sequences, number of alleles, etc.); (2) location in the genome of the manipulated region, when possible; (3) identification of unintended genetic modifications (off-target), when applicable.

7 - The product of expression of the manipulated genomic region(s), described in detail, when applicable.

B) Regarding the product (offspring, lineage, or final product), the proponent must provide information on:

1 - Confirmation of the absence of recombinant DNA/RNA molecules using molecular methods.

2 - Determination of whether the product containing DNA/RNA molecules for topical/systemic use has recombinant capacity to insert into the target species and/or non-target species.

3 - Confirmation of whether the product subject to the request is commercially approved in other countries.

4 - If the product utilizes the principle of gene targeting (gene drive), which may allow the conferred phenotypic alteration to potentially spread throughout the population of the recipient organism, clarification of measures for monitoring the organism, using at least two different strategies.

5 - Evaluation of the possibility of any unintended effects (off-target) of the technology that may be present in the product.

Item 1-1-2. Food and feed

Same requirements presented above (item 1-1-1. Environmental release)

Item 1-2. Other regulatory aspects

Item 2: Products developed using NBTs approved/registered by or reported/notified to authorities (if available; limited to public and/or official information basically on relevant plants)

Item 2-1. For environmental release

Link to the list of organisms notified to the National Technical Commission on Biosafety (in Portuguese) http://ctnbio.mctic.gov.br/tecnologias-inovadoras-de-melhoramento-genetico-rn16-

Organisms in the list (for commercial use) – English translation from the original information in Portuguese.

Notifier	Organism name	Notification date	Start of use
Ourofino	Vaccine against canine parvovirus	2018	-
Du Pont do Brasil	*Zea mays*	2018	-
AquaBounty Technologies	Tilapia fish	2019	-
Forest	Sterile mosquitoes	2019	-
Evolutta Agro Biotecnologia Ltda	dsRNA insecticide	2020	-
Pivot Bio	*Klebisiela variicola* Kv 137-3933 Nitrogen fixation	2020	-
Pivot Bio	*Klebisiela variicola* Kv137-1034 Nitrogen fixation	2020	-
Evolutta Agro Biotecnologia Ltda	dsRNA insecticide	2021	-
Bioheuris	Soybean, Herbicide resistance	2021	-
BASF S.A	*Bacillus thuringiensis* Solubilization of soil nutrients for plants	2021	-
Bayer S.A	*Bacillus* sp., Soil nematode control	2021	-
GDM Genética do Brasil S.A	Soybean, Low raffinose	2022	-
GDM Genética do Brasil S.A	Soybean, Drought tolerance	2022	-
Evolutta Agro Biotecnologia Ltda.	dsRNA insecticide	2022	-
Mosaic Fertilizantes do Brasil Ltda	*Paenibacillus polymyxa* BEC 176 Nitrogen fixation	2022	-
Mosaic Fertilizantes do Brasil Ltda.	*Paenibacillus polymyxa* BEC 177 Nitrogen fixation	2022	-
Evolutta Agro Biotecnologia Ltda	dsRNA fungicide	2022	-
Tevah Consultoria Regulatória	Bactéria *Kosakonia sacchari* Nitrogen fixation	2022	-
Embrapa Soja - Centro Nacional de Pesquisa de Soja	Sybean, Low lectin	2022	-
Embrapa Agroenergia	Sugar cane, High sugar	2022	-
Evolutta Agro Biotecnologia LTDA	dsRNA fungicide	2022	-
Evolutta Agro Biotecnologia Ltda	dsRNA insecticide	2022	-
Tevah Consultoria Regulatória	*Klebisiela variicola* Nitrogen fixation	2022	-
Evolutta Agro Biotecnologia Ltda	dsRNA insecticide	2022	-
SEMPRE AgTech	dsRNA insecticide	2023	-
Embrapa Soja	Soybean, Drought tolerance	2023	-
KWS SAAT SE & Co. KGaA	*Zea mays,* Insect resistance	2023	-
SEMPRE AgTech	dsRNA insecticide	2023	-

Bioheuris	Cotton, Herbicide tolerance	2023	-
GreenLight Biosciences Inc.	dsRNA insecticide	2023	-
Bioheuris	Sorghum, Herbicide tolerance	2023	-
Tevah Consutoria Regulatória	Soybean, Growth promotion	2023	-
Corteva Agriscience do Brasil Ltda.	*Zea mays,* Fungal resistance	2023	-
Bioheirus	Rice, Herbicide tolerance	2023	-
Bioheirus	Cotton, Herbicide tolerance	2023	-
Tevah Consutoria Regulatória	*Klebsiella* sp., Nitrogen fixation	2023	-
BioConsortia, Inc.	*Bacillus* sp., Nitrogen fixation	2023	-
GDM - Genética do Brasil Ltda	Soybean, Drought tolerance	2024	-
Evolutta Agro Biotecnologia Ltda.	dsRNA fungicide	2024	-
SEMPRE AGRITECH	dsRNA, Soil nematode control	2024	-

Item 2-2. For food and feed

Link to the list of organisms notified to the National Technical Commission on Biosafety (in Portuguese) http://ctnbio.mctic.gov.br/tecnologias-inovadoras-de-melhoramento-genetico-rn16-

Organisms in the list (for commercial use) – English translation from the original information in Portuguese.

Notifier	Organism name	Notification date	Start of use
Tevah Consultoria Regulatória	*Escherichia coli* Additive for feed poultry farming	2020	-
Acceligen do Brasil Biotecnologia e Pesquisa Científica Ltda	Bovine, Myostatin	2021	-
Tevah Consultoria Regulatória	*Escherichia coli* Additive for feed poultry farming	2023	-
Acceligen do Brasil Biotecnologia e Pesquisa Científica Ltda.	Bovine, Thermotolerance	2023	-

Item 2-3. Other products

Link to the list of organisms notified to the National Technical Commission on Biosafety (in Portuguese) http://ctnbio.mctic.gov.br/tecnologias-inovadoras-de-melhoramento-genetico-rn16-

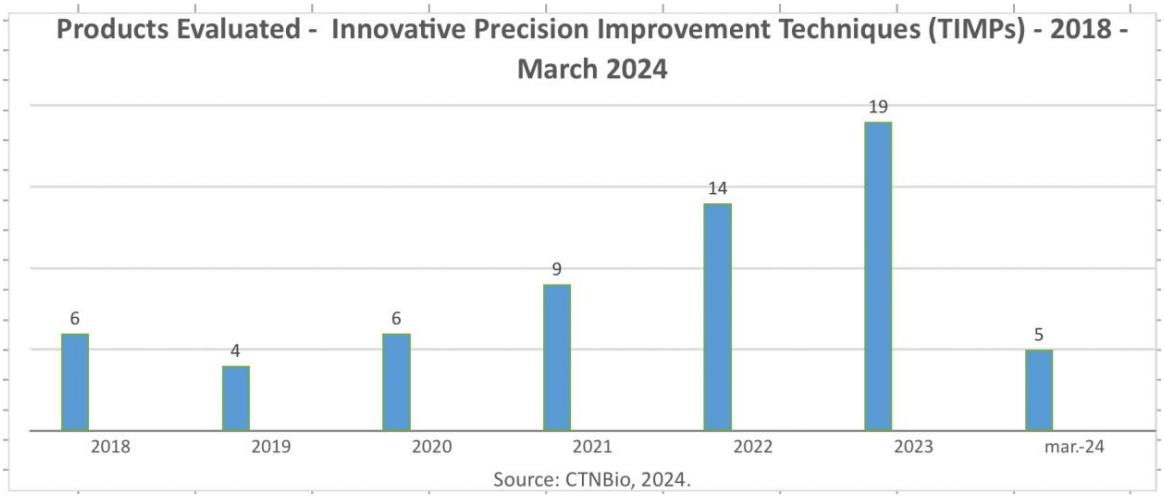
Organisms in the list (for commercial use) – English translation from the original information in Portuguese.

Products approved for biofuel production (ethanol and biodiesel) under a containment system.

Notifier	Organism name	Notification date	Start of use
Globalyeast JV CO Brasil S.A	*Saccharomyces cerevisiae,* Bioethanol	2018	-

Notifier	Organism name	Notification date	Start of use
Globalyeast JV CO Brasil S.A	*Saccharomyces cerevisiae*, Bioethanol	2018	-
Lallemand Brasil Ltda.	*Saccharomyces cerevisiae*, Bioethanol	2018	-
Lallemand Brasil Ltda.	*Saccharomyces cerevisiae*, Bioethanol	2019	-
Lallemand Brasil Ltda.	*Saccharomyces cerevisiae*, Bioethanol	2019	-
Lallemand Brasil Ltda.	*Saccharomyces cerevisiae*, Bioethanol	2020	-
Lallemand Brasil Ltda.	*Saccharomyces cerevisiae*, Bioethanol	2020	-
YesSinergy Agroindustrial Ltda	*Saccharomyces cerevisiae*, Bioethanol	2021	-
Lallemand Brasil LTDA	*Saccharomyces cerevisiae*, Bioethanol	2021	-
Lallemand Brasil LTDA	*Saccharomyces cerevisiae*, Bioethanol	2021	-
Embrapa Agroenergia	*Saccharomyces cerevisiae*, Bioethanol	2021	-
Lallemand Soluções Biológicas Ltda.	*Saccharomyces cerevisiae*, Bioethanol	2022	-
Fermentec Ltda.	*Saccharomyces cerevisiae*, Bioethanol	2023	-
CERLEV – Projetos e Inovação na Biotecnologia da Fermentação LTDA. 01245.012472/2023-08	*Saccharomyces cerevisiae*, Bioethanol	2023	-
CERLEV – Projetos e Inovação na Biotecnologia da Fermentação LTDA. 01245.012456/2023-15	*Saccharomyces cerevisiae*, Bioethanol	2023	-
CERLEV – Projetos e Inovação na Biotecnologia da Fermentação LTDA 01245.012455/2023-62	*Saccharomyces cerevisiae*, Bioethanol	2023	-

Item 3: Other information (if available; limited to public and/or official information)



Canada

Delegation: Canada

Date of report: 29 February 2024

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them (laws, rules, policies, and guidelines)

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

Canada's regulatory approach is based on the characteristics of the product and not the method of development. Novel products subject to the *Seeds Regulations*, the *Feeds Regulations*, and/or the *Food and Drug Regulations* may be the result of mutagenesis, recombinant DNA techniques or other methods of plant breeding such as gene editing techniques.

When a product of plant breeding is novel (i.e., different from what is already available in Canada), the Canadian Food Inspection Agency (CFIA) and Health Canada conduct pre-market assessments to ensure the safety of the plant from a food, livestock feed, and environmental perspective.

- The CFIA assesses the safety of the plant for release into the environment and to be grown as a crop in Canada
- The CFIA assesses the safety and efficacy of the product for use as a livestock feed
- Health Canada assesses the safety of the product for use as human food

Some products of plant breeding developed using gene editing techniques may not meet the regulatory definition of "novel". If a product is not novel, it is considered equivalent to its existing counterparts, and no pre-market assessment is required. In these cases, product developers are still expected to participate in transparency measures about the use of editing (see below).

The CFIA and Health Canada have published a joint webpage describing Canada's regulatory framework for the environmental release of Plants with Novel Traits (PNTs), novel feeds, novel foods, and how products derived from gene editing techniques may or may not be considered novel. This webpage is available on CFIA's website:

https://www.inspection.gc.ca/plant-health/plants-with-novel-traits/gene-editing-techniques/eng/1541800629219/1541800629556

Item 1-1-1. Environmental release

Canada's *Seeds* Regulations do not make distinctions between the various technologies that may be used in the development of a plant. This is a logical and product-based approach that places emphasis on the traits of the plant (that is, its observable or measureable characteristics), and its interactions with the environment.

Plant developers are responsible for understanding their regulatory obligations and notifying the CFIA as required. CFIA provides regulatory guidance to clarify which plants – whether developed via conventional breeding or through new plant breeding innovation methods – are novel and require CFIA approval before being released into the environment: https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/applicants/directive-2009-09/eng/1304466419931/1304466812439

This guidance outlines that a plant is novel when it has a new trait that could impact the 5 environmental safety criteria:

- weediness potential
- impacts of gene flow to related plants
- plant pest potential
- impacts on non-target organisms
- impacts on biodiversity

Plants with DNA from genetic sources outside the plant species (foreign DNA) and plants with new herbicide tolerance traits are always considered to be novel. Outside of these categories, the CFIA does not foresee significant negative impacts on the 5 environmental safety criteria for crop plants that are already grown in Canada, and does not expect to receive requests to authorize such plants, regardless of the methods used in the development of the plant. However, it remains the proponent's responsibility to notify the CFIA if the plant could have significant negative environmental impacts and be considered a PNT. Proponents are also expected to fully participate in mechanisms that provide transparency about non-novel products. The CFIA is available to provide advice to proponents regarding novelty determination.

Item 1-1-2. Food and feed

Guidance related to the regulation of NBTs for food use

In May 2022, Health Canada published new guidance on the Novelty Interpretation of Products of Plant Breeding to further clarify when products of plant breeding (including gene-edited plant products) are considered novel and require pre-market assessment.

Health Canada guidance on the Novelty Interpretation of Products of Plant Breeding is available on the Health Canada website:

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

Transparency Initiative

Along with this guidance, Health Canada is maintaining its Transparency Initiative to provide people in Canada with information on the types of gene-edited plant products that may be used as food in the Canadian market. This initiative helps developers better understand how the novel foods regulatory framework applies to different types of gene-edited plant products and ensures that gene-edited plant products that meet the definition of a novel food are notified to Health Canada for pre-market assessment.

Information on the Transparency Initiative is available on the Health Canada website: https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/transparency-initiative.html

Item 1-2. Other regulatory aspects

Scientific opinion on the regulation of gene-edited plant products within the context of Division 28 of the Food and Drug Regulations (Novel Foods)

In support of its guidance on the Novelty Interpretation of Products of Plant Breeding (including gene-edited plant products), Health Canada has published a scientific opinion on the Regulation of Gene-edited Plant Products within the Context of the *Novel Food Regulations*. The scientific opinion is based on a

comprehensive review of the available scientific literature on gene editing techniques, how they may be used in plant breeding, and how gene-edited plant products should be related under Canada's product-based regulatory framework.

Health Canada's Scientific opinion on the regulation of gene-edited plant products within the context of Division 28 of the Food and Drug Regulations (Novel Foods) is available on the Health Canada website:

https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/scientific-opinion-regulation-gene-edited-plant-products-within-context-division-28-food-drug-regulations.html

Analysis of NBTs

CFIA conducted an analysis of NBTs in the context of plant breeding practices and products of biotechnology that CFIA has assessed in the past. Based on the review of the available information, it is the scientific opinion of the CFIA that gene editing does not present any unique or specifically identifiable environmental or health concerns as compared to other technologies for developing plants. This analysis was used in the development of a policy rationale that is available on the CFIA website:

https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/applicants/directive-2009-09/rationale-for-updated-guidelines/eng/1682425597052/1682425597973

Item 2: Products developed using NBTs approved/registered by or reported/notified to authorities (if available; limited to public and/or official information basically on relevant plants)

Item 2-1. For environmental release

For all plants with novel traits, following a pre-market assessment, the CFIA updates a database of authorized plant products of biotechnology[1] and related decision documents[2].

Decision documents outline the information that was assessed, including information on how the plant was developed. The CFIA posts this information for all plant products that have received a pre-market assessment. As of March 1, 2024, there are no novel products developed using NPBTs authorized for unconfined environmental release.

Transparency about non-novel seed lines developed using NPBTs will be provided through non-regulatory measures. In May 2023, an Industry-Government Technical Committee on Plant Breeding Innovation Transparency released its Chair's Report, which outlined several key recommendations to improve transparency around seed varieties, including establishing a Government-Industry Steering Committee to advance recommended transparency initiatives: https://agriculture.canada.ca/en/department/transparency/chairs-report-minister-industry-government-technical-committee-plant-breeding-innovation

Agriculture and Agri-Food Canada's Government-Industry Steering Committee on Plant Breeding Innovation Transparency, launched in June 2023, provides input and perspectives on the industry-led Canadian Variety Transparency Database.

[1] https://active.inspection.gc.ca/netapp/plantnoveltraitpnt-vegecarnouvcn/pntvcne.aspx

[2] https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/approved-under-review/decision-documents/eng/1303704378026/1303704484236

Item 2-2. For food and feed

When Health Canada authorizes a novel food product, it updates its list of completed safety assessments of novel foods[3] and publishes a summary of each assessment.

Health Canada maintains a list of non-novel products of plant breeding for food use. This list includes non-novel gene-edited plant products that have been notified to the Department voluntarily by the developer.

List of non-novel products of plant breeding for food use: https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/transparency-initiative/list-non-novel-products-plant-breeding-food-use.html

Item 2-3. Other products

N/A

Item 3: Other information (if available; limited to public and/or official information)

N/A

[3] https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products.html

Costa Rica

Delegation: Costa Rica

Date of report: 1 March 2024

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them (laws, rules, policies, and guidelines)

In December 2023, the State Phytosanitary Service (authority for the implementation of the regulation of plants improved with modern biotechnology techniques) published a reform to the biosafety framework for organisms (plants) obtained through the application of modern biotechnology, including New Breeding Techniques (NBTs). This regulatory framework establishes the procedures to define whether a crop obtained using NBTs is or is not a LMO and therefore should be regulated under the current regulation for LMO (No. 7664: Phytosanitary Protection Law).

The regulatory framework, articles 111-13 (Spanish language only), is available on the following Government website:

https://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm_texto_completo.aspx?nValor1=1&nValor2=43150

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

Item 1-1-1. Environmental release

The criteria to discriminate relies on the presence or absence of additional DNA sequences compared to conventional breeding methods and spontaneous mutation. The additional DNA sequence is described as a "novel combination of genetic material" to match the legal definition of LMO of the Cartagena Protocol. If the final product does not contain a "novel combination of genetic material," it is equivalent to an organism obtained by conventional breeding methods and spontaneous mutation. In addition, a new combination of genetic material is defined as a “stable insertion in the genome, of one of more genes or DNA sequences encoding double stranded DNA, RNA, proteins or regulatory sequences that could not be obtained by conventional breeding”.

The analysis will not be restricted to a list of NPBTs, the applicants must submit information regarding the methodology used to modify the crop, the innovative trait introduced, evidence of the genetic changes present in the product, evidence of elimination of the transitory transgene employed to achieve the product (if necessary), and any additional information that Regulators consider necessary.

If it is determined that the organism does not has a novel combination of genetic material, it is not regarded as LMO specified in the Protocol of Cartagena on Biosafety (no subject to the regulations) and is recognized as organism equivalent to those obtained through conventional improvement technique.

Item 1-1-2. Food and feed

Costa Rica's regulatory framework is limited to the release into the environment of plants improved with modern biotechnological techniques, including NBT, for research or export purposes. At the moment, there are no regulations for feed and food derived from these organisms. However, there is an initiative led by

the Ministry of Agriculture and Livestock as well as the Ministry of Health, to prepare a draft on this matter, the first version is expected to be ready by the end of this year.

Item 1-2. Other regulatory aspects

N/A

Item 2: Products developed using NBTs approved/registered by or reported/notified to authorities (if available; limited to public and/or official information basically on relevant plants)

Costa Rica has not yet evaluated any plants improved with NBTs

Public Universities are researching on NBT rice and coffee with potential further use.

- Salinity and drought tolerance rice https://vinv.ucr.ac.cr/sigpro/web/projects/B7294
- Coffee with reduced caffeine https://vinv.ucr.ac.cr/sigpro/web/projects/C0462

Item 2-1. For environmental release

N/A

Item 2-2. For food and feed

N/A

Item 2-3. Other products

N/A

Item 3: Other information (if available; limited to public and/or official information)

N/A

Croatia

Delegation: The Republic of Croatia

Date of report: 1 March 2024

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them (laws, rules, policies, and guidelines)

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

The Republic of Croatia is a Member of the European Union. All EU legislations in the field of GMOs.

have been transposed in the Croatian legislation. Currently new bereding techniques (NBT) and products of NBTs referred to as new genomic techniques, NGTs, in the EU are subject to the legislation on genetically modified organisms (GMOs) which is contained in several main legislative acts (Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No 1830/2003, Directive 2009/41/EC).

They establish procedures requiring an authorisation for the contained use or the deliberate release of GMOs into the environment for experimental purposes as well as for the placing on the market and cultivation of GMOs and GM food and feed. This authorisation system is based on an assessment of the risks to human and animal health and the environment, and includes requirements for post-market monitoring, labelling and traceability.

On 5 July 2023, the European Commission adopted a legislative proposal for a regulation on plants produced by certain new genomic techniques (NGTs) and their food and feed. The proposal is part of a package of proposals to ensure resilient and sustainable use of the EU's natural resources. On 5 July 2023, the European Commission adopted a legislative proposal for a regulation on plants produced by certain new genomic techniques (NGTs) and their food and feed. The proposal is part of a package of proposals to ensure resilient and sustainable use of the EU's natural resources.

The proposal sets out specific rules for the deliberate release into the environment for any other purpose than placing on the market of plants obtained by targeted mutagenesis and cisgenesis (including intragenesis) and for the placing on the market of food and feed containing, consisting of or produced from such plants, and of products, other than food or feed, containing or consisting of such plants ('NGTplants and products').

To become law, the Regulation must be adopted by the Member States in the Council of the European Union and the European Parliament, following the ordinary legislative procedure. In the meantime, the plants and products covered by this proposal continue to be regulated under the legislation on GMOs as described in the first paragraph.

Item 1-1-1. Environmental release

See Item 1-1.

Item 1-1-2. Food and feed

See Item 1-1.

Item 1-2. Other regulatory aspects

In the Republic of Croatia in the field regulated by Directive (EC) 2009/41 of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms 14 closed systems of contained use GMMs use new genetic techniques such as ODM, CRISPER/ Cas9, cisgenesis and intragenesis.

Item 2: Products developed using NBTs approved/registered by or reported/notified to authorities (if available; limited to public and/or official information basically on relevant plants)

Item 2-1. For environmental release

None.

Item 2-2. For food and feed

On 17 January 2024, the European Food Safety Authority issued a favourable scientific opinion for placing on the market of genetically modified maize DP-915635 produced by NBT for food and feed uses (Application EFSA-GMO-NL-2020-172). The regulatory approval procedure is ongoing for this product. This event was created by site-specific integration using two sequential transformation steps to insert an integration site sequence, at a specific location of the maize genome using biolistic and a CRISPR-Cas9-mediated targeted insertion process, and to insert the intended expression cassettes in the maize genome using Agrobacterium-mediated transformation. It is a transgenic plant. More info on GM maize DP-915635 is available at https://bch.cbd.int/en/database/record?documentID=260914

Item 2-3. Other products

None.

Czech Republic

Delegation: Czech Republic

Date of report: 4 March 2024

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them (laws, rules, policies, and guidelines)

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

As a member state of the European Union (EU), the Czech Republic (CZ) follows the EU regulatory framework for NBTs. Therefore, all information provided by the European Commission, Directorate-General for Health & Food Safety (DG SANTE) by completing all the items of this questionnaire is also valid for CZ.

At the moment, we have no additional information on NBTs in CZ.

Item 1-1-1. Environmental release

Please see the answer provided by DG Sante. No environmental release of NBTs in CZ.

Item 1-1-2. Food and feed

Please see the answer provided by DG Sante.

Item 1-2. Other regulatory aspects

Please see the answer provided by DG Sante.

Item 2: Products developed using NBTs approved/registered by or reported/notified to authorities (if available; limited to public and/or official information basically on relevant plants)

Item 2-1. For environmental release

Please see the answer provided by DG Sante. No environmental release of NBTs in CZ.

Item 2-2. For food and feed

Please see the answer provided by DG Sante.

Item 2-3. Other products

Please see the answer provided by DG Sante.

Item 3: Other information (if available; limited to public and/or official information)

Denmark

Delegation: Denmark

Date of report: 26 February 2024

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them (laws, rules, policies, and guidelines)

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

Denmark adheres to the common GMO-regulation of the EU. Currently, plants made with new breeding techniques are subject to the full GMO-regulation of the EU. However, a proposal for new regulation of plants obtained by certain new genomic techniques is currently under discussion. Please refer to the reply from the European Commission for more details on both the legislation in force and on the pending legislative proposal.

Item 1-1-1. Environmental release

See above

Item 1-1-2. Food and feed

See above

Item 1-2. Other regulatory aspects

See above

Item 2: Products developed using NBTs approved/registered by or reported/notified to authorities

Item 2-1. For environmental release

Two experimental trials with potatoes made with NBTs took place in 2023. The experimental trials were approved under the current GMO-regulation in the EU (see 1.1) and involved potato lines with targeted mutations made with CRRISPR. The aim was, respectively, to modify starch composition and increase resistance to late blight.

In 2024, the competent authority for environmental release of GMOs (The Danish Agricultural Agency) has received an application for experimental release of potatoes made with NBT which includes some of the same lines as mentioned above as well as new lines.

Item 2-2. For food and feed

Please refer to the reply from the European Commission concerning a genetically modified maize produced by NBT for food and feed use.

Item 2-3. Other products

No such products are approved.

Item 3: Other information

Please refer to the reply from the European Commission.

France

Delegation: France

Date of report: 15 February 2024

[French]

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them (laws, rules, policies, and guidelines)

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

La France étant membre de Union européenne (UE), le cadre applicable en France aux organismes obtenus par NBT est celui défini au niveau de l'UE : voir la contribution de la Commission européenne.

Item 1-1-1. Environmental release

Item 1-1-2. Food and feed

Item 1-2. Other regulatory aspects

Item 2: Products developed using NBTs approved/registered by or reported/notified to authorities (if available; limited to public and/or official information basically on relevant plants)

Item 2-1. For environmental release

Les autorisations de mise sur le marché des produits obtenus par NBT relèvent du niveau européen : voir la contribution de la Commission européenne.

Aucun essai de dissémination volontaire dans l'environnement de produits obtenus par NBT n'est autorisé en France.

Item 2-2. For food and feed

Les autorisations de mise sur le marché des produits obtenus par NBT relèvent du niveau européen : voir la contribution de la Commission européenne.

Item 2-3. Other products

Les autorisations de mise sur le marché des produits obtenus par NBT relèvent du niveau européen : voir la contribution de la Commission européenne.

Item 3: Other information (if available; limited to public and/or official information)

Title/Summary of the contents	Source (URL, doi, date accessed etc.,)
Information gouvernementale sur les NBT : des informations sur les NBT sont disponibles sur les sites internet des ministères chargés de l'agriculture et de l'environnement	https://agriculture.gouv.fr/les-nouvelles-technologies-de-selection https://www.ecologie.gouv.fr/organismes-genetiquement-modifies-ogm-0
Programme et Equipements Prioritaires de Recherche (PEPR) « Sélection Végétale Avancée pour faire face au défi climatique et assurer la transition agroécologique »	https://www.pepr-selection-vegetale.fr/

[English]

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them (laws, rules, policies, and guidelines)

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

As France is a member of the European Union (EU), the framework applicable in France to organisms obtained by NBT is that defined at EU level : see the contribution of the European Commission

Item 1-1-1. Environmental release

Item 1-1-2. Food and feed

Item 1-2. Other regulatory aspects

Item 2: Products developed using NBTs approved/registered by or reported/notified to authorities (if available; limited to public and/or official information basically on relevant plants)

Item 2-1. For environmental release

Marketing authorisations for products obtained by NBT fall within the European level: see the contribution of the European Commission

No trials for deliberate release into the environment of products obtained by NBT have been authorised in France.

Item 2-2. For food and feed

Marketing authorisations for products obtained by NBT fall within the European level: see the contribution of the European Commission

Item 2-3. Other products

Marketing authorisations for products obtained by NBT fall within the European level: see the contribution of the European Commission

Item 3: Other information (if available; limited to public and/or official information)

Title/Summary of the contents	Source (URL, doi, date accessed etc.,)
Government information on NBTs: information on NBTs is available on the websites of the ministries responsible for agriculture and the environment :	https://agriculture.gouv.fr/les-nouvelles-technologies-de-selection https://www.ecologie.gouv.fr/organismes-genetiquement-modifies-ogm-0
Priority Research Programme and Equipments (PEPR) "Advanced Plant Breeding to meet the climate challenge and ensure the agro-ecological transition"	https://www.pepr-selection-vegetale.fr/

Germany

Delegation: Germany

Date of report: 1 March 2024

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them (laws, rules, policies, and guidelines)

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

Germany as a member of the European Union (EU) implements EU community-level regulations; therefore, we relegate to the information provided by the European Commission.

Item 1-1-1. Environmental release

See above.

Item 1-1-2. Food and feed

See above.

Item 1-2. Other regulatory aspects

See above.

Item 2: Products developed using NBTs approved/registered by or reported/notified to authorities (if available; limited to public and/or official information basically on relevant plants)

Item 2-1. For environmental release

We relegate to the information provided by the European Commission.

Item 2-2. For food and feed

See above.

Item 2-3. Other products

See above.

Japan

Delegation: Japan

Date of report: 1 March 2024

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them (laws, rules, policies, and guidelines)

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

In February 2019, the Ministry of Environment (MOE), the lead ministry among the six relevant authorities[4] for the implementation of the Cartagena Act, published the finalised policy to the general public and requested relevant authorities to consider specific details for the practical implementation of the policy.

The Ministry of Health, Labour and Welfare (MHLW) has established procedures for hygienic handling of Food and Additives derived from Genome Editing Technology. The procedures took effect in October 2019.

In February 2020, the Ministry of Agriculture, Forestry and Fisheries of Japan (MAFF) published the Feed Safety Guidelines for Genome Edited Feeds and Feed Additives.

Item 1-1-1. Environmental release

The key components of the policy are as follows; in the future, they may be reconsidered as necessary after reviewing accumulated scientific information:

- An organism that has no remnants of inserted nucleic acid processed extracellularly is not subject to the Cartagena Act;
- For use of such an organism in the environment, users are requested to submit certain information to the competent authorities prior to the intended use;
- The competent authorities may request the user to provide additional information when a question arises concerning its potential effect on biological diversity through the review of the submitted information;
- The competent authorities may also request the user to take appropriate measures if the use of the organism demonstrates a likelihood of potential effect on biological diversity.

The MOE published a leaflet explaining the policy and introducing competent authorities corresponding to the categories of organisms. The leaflet is available at:

https://www.biodic.go.jp/bch/download/genome/genome_chirashi_english.pdf

[4] six relevant authorities (categories of organisms);
Ministry of Environment (all organisms)
Ministry of Education, Culture, Sports, Science and Technology (organisms used for experiments in research, etc.)
Ministry of Health, Labour and Welfare (organisms used for medical products and gene therapy, etc.)
Ministry of Agriculture, Forestry and Fisheries (organisms used for production in agriculture, forestry and fisheries, including those used for the production of veterinary drug, etc.)
Ministry of Economy, Trade and Industry (organisms used for manufacturing processes of industrial products, etc.)
National Tax Agency (organisms used for the production of alcoholic beverages)

In October 2019, the MAFF published a notification regarding specific procedures for providing information to the MAFF regarding organisms obtained through genome editing technology, which falls under administrative jurisdiction of the MAFF. The key components of the procedure are as follows:

- Any person intending to use organisms obtained through genome editing provides information to the MAFF regarding the characteristics of the organisms and the views of their possible adverse effects on biological diversity, prior to the use of the organisms.
- A first draft of the information form needs to be submitted to the MAFF by the person for "Prior Consultation".
- The MAFF asks opinions, as needed, from academic experts and requests the person to provide additional information if any question arises concerning its potential effects on biological diversity.
- After the completion of the prior consultation with the MAFF, the person finalizes the information form and submits it to the MAFF.
- The information form is published on the MAFF website, except for one that may cause any unfair advantages or disadvantages to specific persons, if it is disclosed.
- The MAFF also requests the person to take appropriate measures if the use of the organism demonstrates a possibility of potential effect on biological diversity.

Item 1-1-2. Food and Feed

The MHLW has established procedures for hygienic handling of Food and Additives derived from Genome Editing Technology. The procedures took effect in October 2019.

The procedures are available at: https://www.mhlw.go.jp/content/000550824.pdf

In February 2020, the MAFF published the Feed Safety Guidelines for Genome Edited Feeds and Feed Additives. The guidelines are available at: https://www.maff.go.jp/j/syouan/tikusui/siryo/attach/pdf/biofeed_22-7.pdf

Item 2: Products developed using NBTs approved/registered by or reported/notified to authorities (if available; limited to public and/or official information basically on relevant plants)

Item 2-1. For environmental release

Link to the list of organisms notified to the MAFF (in Japanese).

https://www.maff.go.jp/j/syouan/nouan/carta/tetuduki/nbt_tetuzuki.html#flow03

Organisms in the list (for commercial use) – English translation from the original information in Japanese.

Notifier	Organism name	Notification date	Start of use
Sanatech Seed Co., Ltd.	Tomato with increased GABA	Dec. 2020	Dec. 2020
Corteva Agriscience Japan Ltd.	Maize with waxy trait	Mar. 2023	-
Sanatech Seed Co., Ltd.	Tomato with increased GABA*	Jul. 2023	-

*different variety of the tomato which was notified in 2020

Link to the list of organisms notified to the MOE (in Japanese).

https://www.biodic.go.jp/bch/bch_8_3.html

Organisms in the list (for research use) – English translation from the original information in Japanese.

Notifier	Organism name	Notification date
The University of Tokyo	A group of rice mutants in the genes regulating flowering time, circadian rhythm and metabolism of sugars and starches by genome editing technology	7 Jul. 2023
OSAKA UNIVERSITY	Potatoes with low contents of steroidal glycoalkaloids	26 Apr. 2023
The University of Tokyo	A group of rice mutants in the genes regulating flowering time or circadian rhythm by genome editing technology	13 Sep. 2022
National Agriculture and Food Research Organization	Pre-harvest sprouting tolerant wheat modified with alanine aminotransferase	22 Sep. 2021
The University of Tokyo	A group of rice mutants in florigen genes produced by genome editing technology	29 Jun. 2021
RIKEN	Potatoes with low contents of steroidal glycoalkaloids	5 Apr. 2021

Item 2-2. For food and feed

Same as the list (for commercial use) above.

Item 2-3. Other products

Link to the list of organisms notified to the MAFF (in Japanese).

https://www.maff.go.jp/j/syouan/nouan/carta/tetuduki/nbt_tetuzuki.html#flow03

Organisms in the list (for commercial use) – English translation from the original information in Japanese.

Notifier	Organism name	Notification date	Start of use
Regional Fish Institute, Ltd.	Increased-filet sea bream	Sep. 2021	Sep. 2021
Regional Fish Institute, Ltd.	Fast growth tiger puffer	Oct. 2021	Oct. 2021
Regional Fish Institute, Ltd.	Flounder with growth enhancement	Dec. 2023	Dec. 2023

Item 3: Other information (if available; limited to public and/or official information)

Commercially cultivated/grown organisms produced by NBTs (For clarification, delegations are invited to provide this information accompanied with the period/season/year when delegations recognised it.)

Title/Summary of the contents	Source (URL, doi, date accessed etc.,)
In May 2021, Sanatech Seed Co., Ltd. first distributed seedlings of "Sicilian Rouge High GABA", the genome-edited tomato strain with increased GABA, for home gardeners free of charge. The company started selling fruits this tomato strain from September 2021, and then seedlings for home gardeners from October 2021. (Information confirmed in October 2021 through press releases by the company)	*https://sanatech-seed.com/en/newslist-en/* *Date accessed,31 August 2023*
In October 2021, Regional Fish Institute, Ltd. started distribution of fillets of the increased-fillet sea bream through a crowdfunding platform. (Information confirmed in October 2021 through a press release by the company)	*https://regional.fish/en/news* *Date accessed, 31 August 2023*

Scientific and technological development expected to be used for products commercialised in coming years, to support and complement the information collection by the OECD policy analyst

Title/Summary of the contents	Source (URL, doi, date accessed etc.,)
Nakazato I. et al. (2021) Targeted base editing in the plastid genome of Arabidopsis thaliana, Nature Plants, Vol. 7, 906-913	*https://www.nature.com/articles/s41477-021-00954-6* *Date accessed,31 August 2023*
Hamada, H. et al. (2017) An in planta biolistic method for stable wheat transformation. Sci Rep 7, 11443.	*https://www.nature.com/articles/s41598-017-11936-0* *Date accessed,31 August 2023*
Yanagawa Y. et al. (2023) Genome editing by introduction of Cas9/sgRNA into plant cells using temperature-controlled atmospheric pressure plasma. PLoS One. 16;18(2):e0281767	*https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0281767* *Date accessed,31 August 2023*

New biotechnology to be possibly added in future to the NBTs list (*other than Lusser et al., 2011 and Broothaerts et al., 2021*), to support and complement the information collection by the OECD policy analyst

Title/Summary of the contents	Source (URL, doi, date accessed etc.,)
Base editing in organelles	

Korea

Delegation: Republic of Korea

Date of report: 12 March 2024

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them (laws, rules, policies, and guidelines)

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

At the initiative of the Ministry of Trade, Industry and Energy, a partial amendment bill to the Transboundary Movement, etc. of Living Modified Organisms Act (LMO Act) has been submitted to the National Assembly in July 2022 to allow the request for exemption from risk assessment if the novel living modified organisms(LMO) using new technologies such as genome editing techniques are confirmed to be safe at a level similar to natural mutation or traditional breeding through the preliminary review system.

Main contents

A. Exemption from risk assessment for new LMOs (new Article 7.3)

(1) A person who has developed a novel LMO may apply to the head of the competent national authority for "exemption from risk assessment" if the novel LMO does not introduce foreign genes during its development process, or if any foreign genes introduced during development are not present in the final product and are at a level similar to traditional breeding or natural mutation.

(2) If the head of the competent national authority receives an application for exemption from risk assessment and recognizes that the novel LMO has ensured safety at the level of natural mutation, the head of the competent national authority may exempt it from risk assessment.

Item 1-2. Other regulatory aspects

Item 2: Products developed using NBTs approved/registered by or reported/notified to authorities

There is no product developed by NBTs approved in the Republic of Korea.

Item 2-1. For environmental release

Item 3: Other information (if available; limited to public and/or official information)

Item 2-2. For food and feed

Item 2-3. Other products

Lithuania

Delegation: The Republic of Lithuania

Date of report: 29 February 2024

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them (laws, rules, policies, and guidelines)

The Republic of Lithuania is a Member of the European Union (EU). The EU framework for NBT's as outlined by the submission of the European Commission also applies for Lithuania.

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

-

Item 1-2. Other regulatory aspects

-

Item 2: Products developed using NBTs approved/registered by or reported/notified to authorities (if available; limited to public and/or official information basically on relevant plants)

The Republic of Lithuania is a Member of the European Union (EU). The EU framework for NBT's as outlined by the submission of the European Commission also applies for Lithuania.

Item 2-1. For environmental release

-

Item 2-2. For food and feed

-

Item 2-3. Other products

-

Item 3: Other information (if available; limited to public and/or official information)

Netherlands

Delegation: The Netherlands

Date of report: 2 February 2024

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them (laws, rules, policies, and guidelines)

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

For a general overview on the regulatory framework we refer to the contribution of the European Commission.

In the years 2005-2007 the Dutch authorities received several questions regarding the regulatory status of plants obtained with NPBTs. We forwarded these questions to the European Commission as to the opinion of the Netherlands is that these matters require harmonization at EU level. During that period the Netherlands did not receive any formal applications regarding fields trials with plants obtained with NPBTs. In the ruling of the European Court of Justice (ECJ) of 25 July 2018 (Case C-528/16), it was considered that gene-edited plants to be released in the field should be considered as GMOs as defined in the EU Directive 2001/18/EC on the deliberate release of GMOs.

As a follow-up of the ECJ ruling, on 5 July 2023 the European Commissions published a proposal for a new Regulation on plants produced by certain new genomic techniques. The proposal covers plants that contain genetic material from the same plant (targeted mutagenesis) or from crossable plants (cisgenesis, including intragenesis); transgenic plants (which contain genetic material from non-crossable species) will remain subject to the GMO legislation as it stands today. (See also contribution of European Commission for more details).

The Netherlands is of the opinion that current legislation, which dates back to 2001, is not fit for purpose with regard to plants derived from new genomic techniques that do not cross species boundaries. The Netherlands strives to adapt the current European legislative framework to make breeding with NGTs simpler, preserving and ensuring safety for human health and the environment while the innovative potentials and opportunities are not left unexploited. We also recognize that such new techniques may bring challenges also, and the Netherlands wants to pay attention to this in the development of the legislation. The ultimate core of the Dutch effort is safe, future-proof, proportional and science-based legislation. In light of this the Dutch government is in general supportive of the proposal.

Currently the legislative process is still going on. For more details on this see also the contribution of the European Commission.

Item 1-1-1. Environmental release

To date, the Netherlands did not receive any applications for authorisation of a NGT-plant product which is subject to the EU GMO regulations according to the ruling by the European Court of Justice (Case C-528/16).

Applications for commercial releases require an EU coordinated procedure. We therefore refer to the contribution of the European Commission.

Item 1-1-2. Food and feed

Applications for commercial releases for food and feed use require an EU coordinated procedure. We therefore refer to the contribution of the European Commission.

Item 1-2. Other regulatory aspects

In relation to the current EU discussions concerning the new proposal of the European Commission on NGT plants, the Dutch advisory committee COGEM has issued an advice to amend and clarify the proposed criteria for NGT plants that could also occur naturally or by conventional breeding (so-called 'category 1 NGT plants' in the proposal). See also Opinion to revise the criteria in Annex I of the EC proposal for new legislation for NGT plants (cogem.net)

Item 2: Products developed using NBTs approved/registered by or reported/notified to authorities (if available; limited to public and/or official information basically on relevant plants)

Item 2-1. For environmental release

None at national level. At EU level see contribution European Commission.

Item 2-2. For food and feed

None at national level. At EU level see contribution European Commission.

Item 2-3. Other products

None at national level. At EU level see contribution European Commission.

Item 3: Other information (if available; limited to public and/or official information)

South Africa

Delegation: South Africa

Date of report: 3 March 2024

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them (laws, rules, policies, and guidelines)

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

PUBLIC NOTICE: 27 October 2021

South Africa's Regulatory Approach for New Breeding Techniques

Department of Agriculture, Land Reform and Rural Development (DALRRD)

New breeding techniques (NBTs) provide new methods for genetic engineering and enable the production of a range of innovative products. These products are differentiated from those generated using early genetic engineering tools. The nature of NBTs led to discussions whether or not these techniques and their products must be subject to the existing regulatory system for GMOs.

In South Africa the Genetically Modified Organisms Act 1997 (Act No. 15 of 1997), as amended by Genetically Modified Organisms Act, 2006 (Act No. 23 of 2006), regulates the development and use of GMOs. The GMO Act defines a Genetically Modified Act (GMO) as an organism the genes or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination or both. Based on the definition of a GMO under the GMO Act, the Executive Council has concluded that the risk assessment framework that exists for GMOs, would apply to NBTs.

In line with the above, the application templates for contained use, trial release, commodity clearance and general release have been revised and the use of the revised application forms will be effective as of 01 December 2021.

Item 1-1-1. Environmental release

N/A

Item 1-1-2. Food and feed

N/A

Item 1-2. Other regulatory aspects

N/A

Item 2: Products developed using NBTs approved/registered by or reported/notified to authorities (if available; limited to public and/or official information basically on relevant plants)

Item 2-1. For environmental release

N/A

Item 2-2. For food and feed

N/A

Item 2-3. Other products

N/A

Item 3: Other information (if available; limited to public and/or official information)

Title/Summary of the contents	Source (URL, doi, date accessed etc.,)
Spencer KP, Burger JT and Campa M (2023) CRISPR-based resistance to grapevine virus A. *Front. Plant Sci.* 14:1296251.	http://doi: 10.3389/fpls.2023.1296251

Spain

Delegation: Spain

Date of report: 8 February 2024

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them (laws, rules, policies, and guidelines)

As a Member State of the European Union, the Spanish legislation regarding NBTs follows the European Union's regulations in this regard.

On 5 July 2023, the European Commission has adopted a proposal for a new Regulation on plants produced by certain new genomic techniques. The proposal was accompanied by an impact assessment, supported by an external study, Joint Research Center's case studies on several applications of NBTs and the scientific work of EFSA in the area of new genomic techniques. All these are available at the following link: https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology_en

To become law, the Regulation must be adopted by the Member States in the Council and the European Parliament. The ordinary legislative procedure in this regard is currently taking place.

In Spain, a specific section on NBT has been created on the website of the Ministry of Agriculture, Fisheries and Food. The webpage is available at the following link: https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/mejora-genetica/

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

Products obtained by NBT´s follow the European and national regulatory frameworks applicable to genetically modified organisms. Spain is contributing actively in the negotiations of the Commission´s proposal since it was presented last 5th of July.

All the information provided by the European Commission in **Item 1-1** of this questionnaire is shared by Spain as a member state of the European Union.

Item 1-1-1. Environmental release

Item 1-1-2. Food and feed

Item 1-2. Other regulatory aspects

Item 2: Products developed using NBTs approved/registered by or reported/notified to authorities (if available; limited to public and/or official information basically on relevant plants)

No products developed through NBTs have been approved or registered in Spain for commercial purposes. Nevertheless, Spain has issued a license to perform some field trials during the last years with NGT plants under the deliberate release legislative framework. Please see some examples below.

In addition, several contained used activities with products obtained by NBT have been carried out for research purposes.

Item 2-1. For environmental release

Consent given for field trials under Part B for GM plants (gene edited plants) in Spain.

B/ES/23/36 - Development of a gene-edited tobacco line with high anatabine content.

The tobacco plants have mutations (deletions and insertions) in endogenous MPO genes. The mutations have been generated using the CRISPR / Cas9 system. The purpose of the proposed release is to determine the optimal field growth conditions of the edited line for use as an anatabine biofactory line.

B/ES/21/28 - Molecular approaches to increase salinity and drought tolerance in broccoli

It is a genome edited broccoli using the CRISPR/Cas9 system. These initial explants (To) will be grown in the greenhouse and self-fertilised to obtain T1 plants. After that plant with a small modification that changes the reading pattern of the target protein without having incorporated foreign genetic material are selected. The main objective of this project is to obtain broccoli lines with greater resistance to salinity and drought and evaluate whether the edited material is more resistant to salinity and drought, without repercussions on other commercial qualities. More specifically, to evaluate its agronomic suitability

Item 2-2. For food and feed

N/A

Item 2-3. Other products

N/A

Item 3: Other information (if available; limited to public and/or official information)

Title/Summary of the contents	Source (URL, doi, date accessed etc.,)
Monograph New Technologies for Plant Genetic Improvement - Producers, Industry, Wholesalers and Distributors The main objective of this monograph was to analyse the importance that the development and application of new technologies to improve plant production had for business agents in relation to the following objectives: Contribute to waste reduction (e.g. foods with a longer shelf life). Increase crop yields. Improve crop adaptation to climate change. Improve the nutritional properties and quality of food and feed (e.g. foods with higher content of vitamins and antioxidants). Reduce crop dependence on certain inputs, such as fertilizers or phytosanitary products.	https://www.mapa.gob.es/es/alimentacion/temas/consumo-tendencias/2022-3-trimestremejorageneticavegetal_tcm30-654219.pdf
Monograph New Technologies for Plant Genetic Improvement – Consumers The interviewees were asked to rate the development and application of new technologies to genetically improve plant production and its derived products in relation to different objectives: Contribute to waste reduction (e.g. foods with a longer shelf life).	https://www.mapa.gob.es/es/alimentacion/temas/consumo-tendencias/2022-3trimestremejorageneticavegetalconsumidores_tcm30-654239.pdf

Title/Summary of the contents	Source (URL, doi, date accessed etc.,)
Increase crop yields. Improve crop adaptation to climate change. Improve the nutritional properties and quality of food and feed (e.g. foods with higher content of vitamins and antioxidants). Reduce crop dependence on certain inputs, such as fertilizers or phytosanitary products. Next, the interviewees were asked to rate how important would be for them to know certain information about these crops and their derived products: Features and properties. Contribution to environmental protection. Data on its safety and harmlessness. Exact name of the innovative technology applied crop breeding.	
Report from the Ad-Hoc expert Group on new genomic techniques. National Commission of Biosafety (scientific advisory body Spain)	https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/notagrupocnbsobrengtfinal_tcm30-675213.pdf

United States

Delegation: USA

Date of report: 05 March 2024

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them (laws, rules, policies, and guidelines)

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

USDA-APHIS has operated under modernized biotechnology regulations since 2020, which account for advances in genetic engineering and our understanding of the plant pest risks posed by modified organisms. USDA-APHIS now focuses on the organism's characteristics, rather than on the method used to produce it. This risk-proportionate approach enables USDA-APHIS to regulate organisms developed using genetic engineering for increased plant pest risk with greater precision, reducing regulatory burden for developers of organisms that are unlikely to pose increased plant pest risk and allowing USDA-APHIS to continue regulating modified organisms that may pose an increased plant pest risk. Based new information and experience over the past three years, USDA-APHIS seeks to updates to its regulations expand to regulatory exemptions for plants with modifications achievable through conventional breeding methods.

https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/revised-rule/revised-regulations

The United States regulates biotechnology through The Coordinated Framework for Biotechnology, finalized in 1986 where the United States uses existing laws to regulate products of biotechnology rather than a special biotechnology law. The primary agencies involved in U.S. biotechnology regulation are the Animal and Plant Health Inspection Service (APHIS) in the U.S. Department of Agriculture (USDA); the Food and Drug Administration (FDA) in the Department of Health and Human Services (HHS); and the Environmental Protection Agency (EPA). For environmental release, EPA regulates pesticidal traits in plants to ensure that these products do not pose unintended or unreasonable risks to humans, animals, or the environment. USDA safeguards plant and animal health, including protecting agriculture and agriculturally important resources.

EPA-OPP's (Office of Pesticide Programs) regulatory framework for pesticidal substances produced and used in plants (plant-incorporated protectants, or PIPs) was established in 2001. Since then, EPA-OPP has been implementing regulations for PIPs and has registered a diverse array of pest resistant (e.g., dsRNA targeting coleopteran pests, proteins derived from non-*Bt* sources targeting coleoptera and lepidopteran pests) and disease resistant PIPs (e.g., viral coat protein genes, R-proteins). In turn, EPA has approved over 30 PIP active ingredients and over 100 PIP products.

Reflecting the advances in new plant breeding techniques, EPA released a final rule in May 2023 exempting two categories of PIPs from registration requirements that could be created using genetic engineering. This rule ensures that human health and the environment are protected while reducing costs for the regulated community. These exemptions may result in increased research and development activities, commercialization of new pest control options for farmers, and reduced use of conventional pesticides.

https://www3.epa.gov/pesticides/chem_search/reg_actions/pip/pip_rule.pdf

https://www.epa.gov/ingredients-used-pesticide-products/current-and-previously-registered-section-3-plant-incorporated

Item 1-1-1. Environmental release

USDA-APHIS biotechnology regulations exempt certain modified plants that (1) are achievable through conventional breeding techniques and thus are unlikely to pose an increased plant pest risk compared to conventionally bred plants, or (2) have a plant-trait-mechanism of action combination that is the same as a plant that USDA-APHIS previously reviewed and determined to be unlikely to pose plant pest risk.

USDA-APHIS biotechnology regulations do not apply to plants that have been modified such that they contain either a single modification of a type listed below:

(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 and follow the process in paragraph (b)(4)(i) of this section, or in response to a request made in accordance with paragraph (b)(4)(ii) of this section.

Additional, USDA-APHIS biotechnology regulations do not apply to plants with plant-trait-mechanism of action combinations that USDA-APHIS previously reviewed and found not subject to the regulations. USDA-APHIS continuously updates this list of exemptions as it completes Regulatory Status Reviews and remaining petitions from the legacy regulations.

Developers may voluntarily request USDA-APHIS confirm a modified plant qualifies for an exemption and is not subject to the regulations in 7 CFR part 340. USDA-APHIS will provide a written response ("confirmation letter") within 120 days of receiving a sufficiently detailed confirmation request. USDA-APHIS posts both the confirmation requests and the issued confirmation letters on its website, with redactions to protect Confidential Business Information and Personal Identifying Information, as appropriate.

https://www.aphis.usda.gov/brs/pdf/requesting-confirmation-of-exemption.pdf

Plants which are not exempt from the regulations may be reviewed via a Regulatory Status Review (RSR) process, which evaluates the characteristics of the plant and if it could pose an increased plant pest risk relative to the comparator plant. Some plants which have been reviewed under RSR were developed using NBTs.

https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulatory-processes/exemptions-confirmations

https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulatory-processes/regulatory-status-reviews/rsr

EPA revised regulations in 2023 to expand exceptions to PIP's edited to achieve results like what can be accomplished through conventional breeding.

In May 2023, EPA finalized a "Rule to Accelerate Use of Plant-Incorporated Biotechnologies to Protect Against Pests." The final rule includes:

- Exemptions from FIFRA registration and FFDCA tolerance requirements for:
  1. PIPs in which genetic engineering has been used to insert or modify a gene to match a gene found in a sexually compatible plant; and,
  2. Loss-of-function PIPs in which the genetically engineered modification reduces or eliminates the activity of a gene, which then helps make the plant resistant to pests.
- A required notification process to increase transparency and public confidence. Developers of PIPs in the first category of exemptions require EPA confirmation that the product is eligible for exemption, but developers of PIPs in the second exempted category can use a self-determination process.

https://www.regulations.gov/docket/EPA-HQ-OPP-2019-0508

https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/pesticides-exemptions-certain-plant-incorporated-0

At EPA, plants that are not exempt from regulations are registered under the Pesticide Registration Improvement Act (PRIA). Using a risk assessment process (hazard x exposure), EPA evaluates the pesticidal trait and if it could pose an environmental or human health risk.

Item 1-1-2. Food and feed

Item 1-2. Other regulatory aspects

APHIS's revised regulations also allow for expanding the exemptions based on scientific evidence of what can be achieved through conventional breeding. In November 2023, APHIS issued a public proposal for five additional exemptions that include the following types of modifications:

Loss of Function modifications and modifications that are a single contiguous deletion;

Expanding current modifications to include certain polyploid plants;

Allowing up for four edits at a single time; and

Providing for successive edits.

USDA-APHIS received 6,500 public comments during the review period, which closed on January 19, 2024. USDA-APHIS is reviewing the comments and considering next steps.

The full text of the proposal is available at:

Federal Register: Movement of Organisms Modified or Produced Through Genetic Engineering; Notice of Proposed Exemptions; Reopening of Comment Period

Item 2: Products developed using NBTs approved/registered by or reported/notified to authorities

Item 2-1. For environmental release

Below are some of the examples of novel plants approved by US agencies for environmental release.

Plant	Trait	Requester	Effective date	Agency
Teff	Reduced height	Donald Danforth Plant Science Center	March 31, 2023	USDA

Plant	Trait	Requester	Effective date	Agency
Banana	1) Altered fruit quality and 2) Marker gene	Tropic Biosciences UK LTD	November 14, 2023	USDA
Pennycress	1) Lowered erucic acid in seeds and 2) Lowered fiber in seeds	Hjelle Advisors	November 14, 2023	USDA
Brown mustard	1) Reduced pungency and 2) Reduced trichome production	Pairwise Plant Services, Inc	November 14, 2023	USDA
Blackberry	Confidential	Pairwise Plant Services, Inc	January 16, 2024	USDA
Black Raspberry	Confidential	Pairwise Plant Services, Inc	January 16, 2024	USDA
Orange	Loss of function, canker resistance	University of Florida	August 21, 2023	EPA
Confidential	Loss of function PIP; trait confidential	Soil Culture Solutions, LLC (d/b/a Soilcea)	October 17, 2023	EPA
Confidential	Loss of function PIP; trait confidential	Soil Culture Solutions, LLC (d/b/a Soilcea)	October 17, 2023	EPA

Effective date indicates date a response was issued by USDA, or date self-determination was submitted to EPA.

Item 2-2. For food and feed

Item 2-3. Other products

Item 3: Other information (if available; limited to public and/or official information)

European Union

Delegation: European Commission, Directorate-General for Health & Food Safety (DG SANTE)

Date of report: 1 March 2024 (received OECD)

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them (laws, rules, policies, and guidelines)

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

In the European Union, products of NBTs (usually referred to as new genomic techniques, NGTs, in the EU) are subject to the legislation on genetically modified organisms (GMOs) which is contained in several main legislative acts (Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No 1830/2003, Directive 2009/41/EC). They establish procedures requiring an authorisation for the contained use or the deliberate release of GMOs into the environment for experimental purposes as well as for the placing on the market and cultivation of GMOs and GM food and feed. This authorisation system is based on an assessment of the risks to human and animal health and the environment, and includes requirements for post-market monitoring, labelling and traceability.

On 5 July 2023, the European Commission adopted a legislative proposal for a regulation on plants produced by certain new genomic techniques (NGTs) and their food and feed. The proposal is part of a package of proposals to ensure resilient and sustainable use of the EU's natural resources.

The proposal sets out specific rules for the deliberate release into the environment for any other purpose than placing on the market of plants obtained by targeted mutagenesis and cisgenesis (including intragenesis) and for the placing on the market of food and feed containing, consisting of or produced from such plants, and of products, other than food or feed, containing or consisting of such plants ('NGT plants and products').

The main measures of the proposal include:

1. The proposal (in Chapter I) makes the deliberate release and placing on the market of NGT plants and products subject to one of two procedures: verification procedure to establish equivalence with conventional plants/products or authorisation in accordance with EU legislation on GMOs:
2. Chapter II of the proposal provides for a verification procedure and criteria to verify whether NGT plants/products obtained by targeted mutagenesis or cisgenesis could also have been obtained naturally or by conventional breeding techniques, based on the criteria laid down in Annex I ('category 1 NGT plants'). Category 1 NGT plants/products are exempted from the requirements of the GMO legislation, and subject to the rules on conventionally bred plants. Transparency is ensured in a public database, through labelling of the seeds and through the relevant registers on plant varieties.
3. Chapter III of the proposal applies to NGT plants/products which do not meet the criteria to consider that they could also be obtained naturally or by conventional breeding ('category 2 NGT plants'). They remain subject to the rules on GMOs with adaptations as regards risk assessment, detection method, monitoring and renewal requirements. They are made subject to traceability and labelling requirements of the GMO legislation, with the possibility of a voluntary label to indicate the purpose of the genetic modification. The proposal includes regulatory incentives for

Category 2 NGT plants/products featuring traits that could contribute to the overall performance of varieties as regards sustainability (Annex III to the proposal).

4. The proposal provides that NGT plants/products are prohibited in organic production.
5. The proposal includes provisions for the monitoring of economic, environmental and social impacts of NGT plants and products, supporting implementation reports and the future evaluation of the legislation. To become law, the Regulation must be adopted by the Member States in the Council of the European Union and the European Parliament, following the ordinary legislative procedure. In the meantime, the plants and products covered by this proposal continue to be regulated under the legislation on GMOs as described in the first paragraph.

Item 1-1-1. Environmental release

See Item 1-1.

Item 1-1-2. Food and feed

See Item 1-1.

Item 1-2. Other regulatory aspects

None.

Item 2: Products developed using NBTs approved/registered by or reported/notified to authorities (if available; limited to public and/or official information basically on relevant plants)

Item 2-1. For environmental release

None.

Item 2-2. For food and feed

On 17 January 2024, the European Food Safety Authority issued a favourable scientific opinion for placing on the market of genetically modified maize DP-915635 produced by NBT for food and feed uses (Application EFSA-GMO-NL-2020-172). The regulatory approval procedure is ongoing for this product. This event was created by site-specific integration using two sequential transformation steps to insert an integration site sequence, at a specific location of the maize genome using biolistic and a CRISPR-Cas9-mediated targeted insertion process, and to insert the intended expression cassettes in the maize genome using Agrobacterium-mediated transformation. It is a transgenic plant. More info on GM maize DP-915635 is available at https://bch.cbd.int/en/database/record?documentID=260914

Item 2-3. Other products

None.

Item 3: Other information (if available; limited to public and/or official information)

Title/Summary of the contents	Source (URL, doi, date accessed etc.,)
Mandate to European Food Safety Authority (EFSA) on new developments in biotechnology applied to microorganisms: this mandate foresees a horizon scanning on microorganisms and their products obtained by new developments in biotechnology, followed by a scientific opinion on potential novel hazards/risks from new developments in biotechnology applied to microorganisms and adequacy of the current EFSA risk assessment guidance	Mandate info on OpenEFSA portal First output – Horizon scanning
Mandate to EFSA on new developments in biotechnology applied to animals (including synthetic biology and new genomic techniques): this mandate foresees a knowledge gathering on known cases of animals (and their food and feed products) obtained by these new developments, followed by a scientific opinion on their potential novel hazards/risks applied to current and near market animals and the adequacy of the current EFSA risk assessment guidance, covering all aspects of molecular characterisation, food feed safety & welfare, and environmental impact.	Mandate info on OpenEFSA portal First output – Knowledge gathering:

Several EU-funded research projects directly concern or address aspects related to new developments in biotechnology (non-exhaustive): GeneBEcon, DETECTIVE, DARWIN, SHIELD4GRAPE, GrapeBreed4IPM.

Part II By Question item

Item 1. Development/amendment of regional/national/local regulations on NBTs related to environmental safety aspects (laws, rules, policies and guidelines)

Argentina

Since 2015, Argentina has had robust regulations for products derived from new breeding techniques (NBTs), including gene editing, whose criteria are updated as consultations are received to determine whether these products are Genetically Modified Organisms (GMOs) or not.

In 2020, Argentina undertook a review and update of its entire regulatory framework for both GMOs and NTBs. The characteristics of NTB regulations require a prior scientific analysis, on a case-by-case basis, of the organisms already obtained or to be obtained (in the design stage), in order to determine whether or not they fall within the scope of the regulations applicable to Genetically Modified Organisms (GMOs).

In other words, the regulation of products derived from NBTs sets out the procedures for determining whether or not any organism obtained through these techniques of modern biotechnology falls within the scope of the GMO regulation.

For more information, see

https://www.argentina.gob.ar/agricultura/alimentos-y-bioeconomia/nuevas-tecnicas-de-mejoramiento-nbt

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

Argentina promotes New Breeding Techniques (NBTs) as tools for adding value to products and processes involved in agricultural practices, in order to help achieve sustainability, respecting biodiversity and addressing the climate crisis.

The products derived from the application of the NBTs are analysed by the National Advisory Commission on Agricultural Biotechnology (CONABIA) in a procedure called Instancia de Consulta Previa (ICP), as indicated in the regulation N°21/2021, of the then Ministry of Agriculture, Livestock and Fisheries of Argentina.

This is a procedure to determine whether a product obtained by NTBs falls under the definition of Genetically Modified Organism of the Cartagena Protocol (1).

It is analysed if the product contains a New Combination of Genetic Material (2). If it does, it is considered GMO (equivalent to transgenic) and must be evaluated as such according to the regulations in force, depending on whether it is a plant, animal or micro-organism.

If it does not have a new combination of genetic material, it is considered non-GMO.

This type of regulation allows developers to submit a PCI form for products in the design stage, providing guidance on the regulatory status of their product until they obtain the final product. For which they must resubmit the form together with studies demonstrating that the product does not contain a novel combination of genetic material.

(1) Definition of GMO in the Cartagena Protocol, which states that a GMO is any living organism that possesses a novel combination of genetic material obtained through the application of modern biotechnology.

(2) New combination of genetic material: change produced in the genome of the organism by the incorporation, in a stable and joint form, of ONE (1) or more genes or nucleic acid sequences that form part of a defined genetic construct.

Link to the resolution and annexes of the Argentine regulatory framework for products derived from NTBs: https://www.magyp.gob.ar/sitio/areas/biotecnologia/conabia/marco_regulatorio_nbt.php

Item 1-1-1. Environmental release

Covered by Argentinian regulations for products derived from New Breeding Techniques, Res. 21/21

Item 1-1-2. Food and feed

Covered by Argentinian regulations for products derived from New Breeding Techniques, Res. 21/21

Item 1-2. Other regulatory aspects

Covered by Argentinian regulations for products derived from New Breeding Techniques, Res. 21/21

Austria

No legislative amendments concerning NBTs and NBT products were introduced or implemented at the Austrian Federal level during this reporting period.

However at the EU level the European Commission (EC) introduced a legislative proposal for a regulation on plants produced by certain new genomic techniques (NGTs) and their food and feed. For details on this proposal pls. refer to the respective contribution of the EC to this survey.

The Austrian competent authorities and national institutions involved in risk assessment and management of GM products submitted comments to the EC proposal on a new regulation of NGT plants to the Ad Hoc Working Group of the EU council and are actively participating in the discussions addressing the proposal of the EC. Austria identified many critical issues related to the proposal and the need for further discussion. These issues include the criteria used to classify NGTs, the lack of labelling requirements, the lowered risk assessment standards, incentives related to claimed sustainability, patents, the possible impact on organic and GM-free production, and subsidiarity issues related to coexistence and the possibility to prohibit cultivation of NGTs.

At the parlamentary level the Committee for EU Affairs of the second chamber of the Austrian parliament discussed the proposal of the EC on a new regulation of NGT plants in November of 2023: The Committee took note of an joint opinion of the Austrian Bundesländer (the Austrian Federal States) on the EC proposal. This unanimous opinion states that the proposed regulation (i) violates the principle of subsidiarity, because it effectively eliminates the Member States' previous freedom of choice to authorise, restrict or prohibit the cultivation of genetically modified organisms (GMOs) on their territory, (ii) curtails the

Member States' powers to participate in EU legislation by giving the EU Commission broad permission to adopt delegated and implementing acts and (iii) uses the wrong legal instrument due to the choice of a EU regulation instead of a EU directive. According to the Austrian constitution the Austrian Federal Government shall be bound by such an joint opinion adopted by the Bundesländer regarding negotiations and votes in the EU on legislative proposals within the framework of the EU, which concern matters that are subject to legislation implemented by the Bundesländer.
Based on the mentioned opinion the members of the Committee unanimously rejected the proposal of the EC and required that the Austrian government shall demand compliance with the following principles: The possibility of measures concerning the cultivation of all plants obtained using genetic engineering, including NGTs, in individual EU member states on the basis of national decisions ("opt-out regulation") and mandatory labelling and authorisation procedures for all organisms obtained using genetic engineering, including NGTs, which include a risk assessment in accordance with the precautionary principle.
EU-Ausschuss des Bundesrats spricht sich einstimmig gegen neue genomischen Techniken in der Landwirtschaft aus (PK1147/07.11.2023) | Parlament Österreich

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

Item 1-1-1. Environmental release

Item 1-1-2. Food and feed

Item 1-2. Other regulatory aspects

Belgium

For this item, we refer to the answer of the European Commission and the following link.

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

Item 1-1-1. Environmental release

Item 1-1-2. Food and feed

Item 1-2. Other regulatory aspects

Brazil

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

In January 2018, the National Technical Commission on Biosafety (CTNBio) established evaluation procedures for products derived from Precision Breeding Innovation techniques.

Item 1-1-1. Environmental release

A) Regarding the original organism (Parentals), the proponent must provide:

1 - Identification of the genetic technology, objective, and intended use of the resulting organism and its derivatives.

2 - Taxonomic classification, from family to the most detailed level of the organism to be released, including, when appropriate, subspecies, cultivar, pathovar, strain, and serotype.

3 - Risk classification of the genetically modified organism according to Normative Resolution nº. 2, dated November 27, 2006.

4 - The gene(s) and/or genetic element(s) manipulated, organism(s) of origin, and their specific functions, when applicable.

5 - The genetic strategy(ies) used to produce the desired modification(s); the genetic map(s) of the construction(s) used in the process indicating all genetic elements present.

6 - Molecular characterization of the manipulation result in the recipient organism (parentals and final product), when applicable, providing information related to: (1) number of manipulated copies (e.g., number of genomic sequences, number of alleles, etc.); (2) location in the genome of the manipulated region, when possible; (3) identification of unintended genetic modifications (off-target), when applicable.

7 - The product of expression of the manipulated genomic region(s), described in detail, when applicable.

B) Regarding the product (offspring, lineage, or final product), the proponent must provide information on:

1 - Confirmation of the absence of recombinant DNA/RNA molecules using molecular methods.

2 - Determination of whether the product containing DNA/RNA molecules for topical/systemic use has recombinant capacity to insert into the target species and/or non-target species.

3 - Confirmation of whether the product subject to the request is commercially approved in other countries.

4 - If the product utilizes the principle of gene targeting (gene drive), which may allow the conferred phenotypic alteration to potentially spread throughout the population of the recipient organism, clarification of measures for monitoring the organism, using at least two different strategies.

5 - Evaluation of the possibility of any unintended effects (off-target) of the technology that may be present in the product.

Item 1-1-2. Food and feed

Same requirements presented above (item 1-1-1. Environmental release)

Item 1-2. Other regulatory aspects

Canada

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

Canada's regulatory approach is based on the characteristics of the product and not the method of development. Novel products subject to the *Seeds Regulations*, the *Feeds Regulations*, and/or the *Food and Drug Regulations* may be the result of mutagenesis, recombinant DNA techniques or other methods of plant breeding such as gene editing techniques.

When a product of plant breeding is novel (i.e., different from what is already available in Canada), the Canadian Food Inspection Agency (CFIA) and Health Canada conduct pre-market assessments to ensure the safety of the plant from a food, livestock feed, and environmental perspective.

- The CFIA assesses the safety of the plant for release into the environment and to be grown as a crop in Canada
- The CFIA assesses the safety and efficacy of the product for use as a livestock feed
- Health Canada assesses the safety of the product for use as human food

Some products of plant breeding developed using gene editing techniques may not meet the regulatory definition of "novel". If a product is not novel, it is considered equivalent to its existing counterparts, and no pre-market assessment is required. In these cases, product developers are still expected to participate in transparency measures about the use of editing (see below).

The CFIA and Health Canada have published a joint webpage describing Canada's regulatory framework for the environmental release of Plants with Novel Traits (PNTs), novel feeds, novel foods, and how products derived from gene editing techniques may or may not be considered novel. This webpage is available on CFIA's website:

https://www.inspection.gc.ca/plant-health/plants-with-novel-traits/gene-editing-techniques/eng/1541800629219/1541800629556

Item 1-1-1. Environmental release

Canada's *Seeds Regulations* do not make distinctions between the various technologies that may be used in the development of a plant. This is a logical and product-based approach that places emphasis on the traits of the plant (that is, its observable or measureable characteristics), and its interactions with the environment.

Plant developers are responsible for understanding their regulatory obligations and notifying the CFIA as required. CFIA provides regulatory guidance to clarify which plants – whether developed via conventional breeding or through new plant breeding innovation methods – are novel and require CFIA approval before being released into the environment: https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/applicants/directive-2009-09/eng/1304466419931/1304466812439

This guidance outlines that a plant is novel when it has a new trait that could impact the 5 environmental safety criteria:

- weediness potential

- impacts of gene flow to related plants
- plant pest potential
- impacts on non-target organisms
- impacts on biodiversity

Plants with DNA from genetic sources outside the plant species (foreign DNA) and plants with new herbicide tolerance traits are always considered to be novel. Outside of these categories, the CFIA does not foresee significant negative impacts on the 5 environmental safety criteria for crop plants that are already grown in Canada, and does not expect to receive requests to authorize such plants, regardless of the methods used in the development of the plant. However, it remains the proponent's responsibility to notify the CFIA if the plant could have significant negative environmental impacts and be considered a PNT. Proponents are also expected to fully participate in mechanisms that provide transparency about non-novel products. The CFIA is available to provide advice to proponents regarding novelty determination.

Item 1-1-2. Food and feed

Guidance related to the regulation of NBTs for food use

In May 2022, Health Canada published new guidance on the Novelty Interpretation of Products of Plant Breeding to further clarify when products of plant breeding (including gene-edited plant products) are considered novel and require pre-market assessment.

Health Canada guidance on the Novelty Interpretation of Products of Plant Breeding is available on the Health Canada website:

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

Transparency Initiative

Along with this guidance, Health Canada is maintaining its Transparency Initiative to provide people in Canada with information on the types of gene-edited plant products that may be used as food in the Canadian market. This initiative helps developers better understand how the novel foods regulatory framework applies to different types of gene-edited plant products and ensures that gene-edited plant products that meet the definition of a novel food are notified to Health Canada for pre-market assessment.

Information on the Transparency Initiative is available on the Health Canada website: https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/transparency-initiative.html

Item 1-2. Other regulatory aspects

Scientific opinion on the regulation of gene-edited plant products within the context of Division 28 of the Food and Drug Regulations (Novel Foods)

In support of its guidance on the Novelty Interpretation of Products of Plant Breeding (including gene-edited plant products), Health Canada has published a scientific opinion on the Regulation of Gene-edited Plant Products within the Context of the *Novel Food Regulations*. The scientific opinion is based on a comprehensive review of the available scientific literature on gene editing techniques, how they may be used in plant breeding, and how gene-edited plant products should be related under Canada's product-based regulatory framework.

Health Canada's Scientific opinion on the regulation of gene-edited plant products within the context of Division 28 of the Food and Drug Regulations (Novel Foods) is available on the Health Canada website:

https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/scientific-opinion-regulation-gene-edited-plant-products-within-context-division-28-food-drug-regulations.html

Analysis of NBTs

CFIA conducted an analysis of NBTs in the context of plant breeding practices and products of biotechnology that CFIA has assessed in the past. Based on the review of the available information, it is the scientific opinion of the CFIA that gene editing does not present any unique or specifically identifiable environmental or health concerns as compared to other technologies for developing plants. This analysis was used in the development of a policy rationale that is available on the CFIA website:

https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/applicants/directive-2009-09/rationale-for-updated-guidelines/eng/1682425597052/1682425597973

Costa Rica

In December 2023, the State Phytosanitary Service (authority for the implementation of the regulation of plants improved with modern biotechnology techniques) published a reform to the biosafety framework for organisms (plants) obtained through the application of modern biotechnology, including New Breeding Techniques (NBTs). This regulatory framework establishes the procedures to define whether a crop obtained using NBTs is or is not a LMO and therefore should be regulated under the current regulation for LMO (No. 7664: Phytosanitary Protection Law).

The regulatory framework, articles 111-13 (Spanish language only), is available on the following Government website:

https://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm_texto_completo.aspx?nValor1=1&nValor2=43150

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

Item 1-1-1. Environmental release

The criteria to discriminate relies on the presence or absence of additional DNA sequences compared to conventional breeding methods and spontaneous mutation. The additional DNA sequence is described as a "novel combination of genetic material" to match the legal definition of LMO of the Cartagena Protocol. If the final product does not contain a "novel combination of genetic material," it is equivalent to an organism obtained by conventional breeding methods and spontaneous mutation. In addition, a new combination of genetic material is defined as a "stable insertion in the genome, of one of more genes or DNA sequences encoding double stranded DNA, RNA, proteins or regulatory sequences that could not be obtained by conventional breeding".

The analysis will not be restricted to a list of NPBTs, the applicants must submit information regarding the methodology used to modify the crop, the innovative trait introduced, evidence of the genetic changes present in the product, evidence of elimination of the transitory transgene employed to achieve the product (if necessary), and any additional information that Regulators consider necessary.

If it is determined that the organism does not has a novel combination of genetic material, it is not regarded as LMO specified in the Protocol of Cartagena on Biosafety (no subject to the regulations) and is recognized as organism equivalent to those obtained through conventional improvement technique.

Item 1-1-2. Food and feed

Costa Rica's regulatory framework is limited to the release into the environment of plants improved with modern biotechnological techniques, including NBT, for research or export purposes. At the moment, there are no regulations for feed and food derived from these organisms. However, there is an initiative led by the Ministry of Agriculture and Livestock as well as the Ministry of Health, to prepare a draft on this matter, the first version is expected to be ready by the end of this year.

Item 1-2. Other regulatory aspects

N/A

Croatia

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

The Republic of Croatia is a Member of the European Union. All EU legislations in the field of GMOs. have been transposed in the Croatian legislation. Currently new breding techniques (NBT) and products of NBTs referred to as new genomic techniques, NGTs, in the EU are subject to the legislation on genetically modified organisms (GMOs) which is contained in several main legislative acts (Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No 1830/2003, Directive 2009/41/EC).

They establish procedures requiring an authorisation for the contained use or the deliberate release of GMOs into the environment for experimental purposes as well as for the placing on the market and cultivation of GMOs and GM food and feed. This authorisation system is based on an assessment of the risks to human and animal health and the environment, and includes requirements for post-market monitoring, labelling and traceability.

On 5 July 2023, the European Commission adopted a legislative proposal for a regulation on plants produced by certain new genomic techniques (NGTs) and their food and feed. The proposal is part of a package of proposals to ensure resilient and sustainable use of the EU's natural resources. On 5 July 2023, the European Commission adopted a legislative proposal for a regulation on plants produced by certain new genomic techniques (NGTs) and their food and feed. The proposal is part of a package of proposals to ensure resilient and sustainable use of the EU's natural resources.

The proposal sets out specific rules for the deliberate release into the environment for any other purpose than placing on the market of plants obtained by targeted mutagenesis and cisgenesis (including intragenesis) and for the placing on the market of food and feed containing, consisting of or produced from such plants, and of products, other than food or feed, containing or consisting of such plants ('NGTplants and products').

To become law, the Regulation must be adopted by the Member States in the Council of the European Union and the European Parliament, following the ordinary legislative procedure. In the meantime, the plants and products covered by this proposal continue to be regulated under the legislation on GMOs as described in the first paragraph.

Item 1-1-1. Environmental release

See Item 1-1.

Item 1-1-2. Food and feed

See Item 1-1.

Item 1-2. Other regulatory aspects

In the Republic of Croatia in the field regulated by Directive (EC) 2009/41 of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms 14 closed systems of contained use GMMs use new genetic techniques such as ODM, CRISPER/ Cas9, cisgenesis and intragenesis.

Czech Republic

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

As a member state of the European Union (EU), the Czech Republic (CZ) follows the EU regulatory framework for NBTs. Therefore, all information provided by the European Commission, Directorate-General for Health & Food Safety (DG SANTE) by completing all the items of this questionnaire is also valid for CZ.

At the moment, we have no additional information on NBTs in CZ.

Item 1-1-1. Environmental release

Please see the answer provided by DG Sante. No environmental release of NBTs in CZ.

Item 1-1-2. Food and feed

Please see the answer provided by DG Sante.

Item 1-2. Other regulatory aspects

Please see the answer provided by DG Sante.

Denmark

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

Denmark adheres to the common GMO-regulation of the EU. Currently, plants made with new breeding techniques are subject to the full GMO-regulation of the EU. However, a proposal for new regulation of plants obtained by certain new genomic techniques is currently under discussion. Please refer to the reply from the European Commission for more details on both the legislation in force and on the pending legislative proposal.

Item 1-1-1. Environmental release

See above

Item 1-1-2. Food and feed

See above

Item 1-2. Other regulatory aspects

See above

France

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

[French]

La France étant membre de Union européenne (UE), le cadre applicable en France aux organismes obtenus par NBT est celui défini au niveau de l'UE : voir la contribution de la Commission européenne.

Item 1-1-1. Environmental release

Item 1-1-2. Food and feed

Item 1-2. Other regulatory aspects

[English]

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

As France is a member of the European Union (EU), the framework applicable in France to organisms obtained by NBT is that defined at EU level : see the contribution of the European Commission

Item 1-1-1. Environmental release

Item 1-1-2. Food and feed

Item 1-2. Other regulatory aspects

Germany

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

Germany as a member of the European Union (EU) implements EU community-level regulations; therefore, we relegate to the information provided by the European Commission.

Item 1-1-1. Environmental release

See above.

Item 1-1-2. Food and feed

See above.

Item 1-2. Other regulatory aspects

See above.

Japan

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

In February 2019, the Ministry of Environment (MOE), the lead ministry among the six relevant authorities[5] for the implementation of the Cartagena Act, published the finalised policy to the general public and requested relevant authorities to consider specific details for the practical implementation of the policy.

The Ministry of Health, Labour and Welfare (MHLW) has established procedures for hygienic handling of Food and Additives derived from Genome Editing Technology. The procedures took effect in October 2019.

In February 2020, the Ministry of Agriculture, Forestry and Fisheries of Japan (MAFF) published the Feed Safety Guidelines for Genome Edited Feeds and Feed Additives.

Item 1-1-1. Environmental release

The key components of the policy are as follows; in the future, they may be reconsidered as necessary after reviewing accumulated scientific information:

- An organism that has no remnants of inserted nucleic acid processed extracellularly is not subject to the Cartagena Act;
- For use of such an organism in the environment, users are requested to submit certain information to the competent authorities prior to the intended use;
- The competent authorities may request the user to provide additional information when a question arises concerning its potential effect on biological diversity through the review of the submitted information;
- The competent authorities may also request the user to take appropriate measures if the use of the organism demonstrates a likelihood of potential effect on biological diversity.

[5] six relevant authorities (categories of organisms);
Ministry of Environment (all organisms)
Ministry of Education, Culture, Sports, Science and Technology (organisms used for experiments in research, etc.)
Ministry of Health, Labour and Welfare (organisms used for medical products and gene therapy, etc.)
Ministry of Agriculture, Forestry and Fisheries (organisms used for production in agriculture, forestry and fisheries, including those used for the production of veterinary drug, etc.)
Ministry of Economy, Trade and Industry (organisms used for manufacturing processes of industrial products, etc.)
National Tax Agency (organisms used for the production of alcoholic beverages)

The MOE published a leaflet explaining the policy and introducing competent authorities corresponding to the categories of organisms. The leaflet is available at:

https://www.biodic.go.jp/bch/download/genome/genome_chirashi_english.pdf

In October 2019, the MAFF published a notification regarding specific procedures for providing information to the MAFF regarding organisms obtained through genome editing technology, which falls under administrative jurisdiction of the MAFF. The key components of the procedure are as follows:

- Any person intending to use organisms obtained through genome editing provides information to the MAFF regarding the characteristics of the organisms and the views of their possible adverse effects on biological diversity, prior to the use of the organisms.
- A first draft of the information form needs to be submitted to the MAFF by the person for “Prior Consultation”.
- The MAFF asks opinions, as needed, from academic experts and requests the person to provide additional information if any question arises concerning its potential effects on biological diversity.
- After the completion of the prior consultation with the MAFF, the person finalizes the information form and submits it to the MAFF.
- The information form is published on the MAFF website, except for one that may cause any unfair advantages or disadvantages to specific persons, if it is disclosed.
- The MAFF also requests the person to take appropriate measures if the use of the organism demonstrates a possibility of potential effect on biological diversity.

Item 1-1-2. Food and Feed

The MHLW has established procedures for hygienic handling of Food and Additives derived from Genome Editing Technology. The procedures took effect in October 2019.

The procedures are available at: https://www.mhlw.go.jp/content/000550824.pdf

In February 2020, the MAFF published the Feed Safety Guidelines for Genome Edited Feeds and Feed Additives. The guidelines are available at: https://www.maff.go.jp/j/syouan/tikusui/siryo/attach/pdf/biofeed_22-7.pdf

Item 1-2. Other regulatory aspects

Korea

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

At the initiative of the Ministry of Trade, Industry and Energy, a partial amendment bill to the Transboundary Movement, etc. of Living Modified Organisms Act (LMO Act) has been submitted to the National Assembly in July 2022 to allow the request for exemption from risk assessment if the novel living modified organisms (LMO) using new technologies such as genome editing techniques are confirmed to be safe at a level similar to natural mutation or traditional breeding through the preliminary review system.

Main contents

A. Exemption from risk assessment for new LMOs (new Article 7.3)

(1) A person who has developed a novel LMO may apply to the head of the competent national authority for "exemption from risk assessment" if the novel LMO does not introduce foreign genes during its development process, or if any foreign genes introduced during development are not present in the final product and are at a level similar to traditional breeding or natural mutation.

(2) If the head of the competent national authority receives an application for exemption from risk assessment and recognizes that the novel LMO has ensured safety at the level of natural mutation, the head of the competent national authority may exempt it from risk assessment.

Item 1-1-1. Environmental release

Item 1-1-2. Food and feed

Item 1-2. Other regulatory aspects

Lithuania

The Republic of Lithuania is a Member of the European Union (EU). The EU framework for NBT's as outlined by the submission of the European Commission also applies for Lithuania.

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

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Item 1-1-1. Environmental release

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Item 1-1-2. Food and feed

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Item 1-2. Other regulatory aspects

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Netherlands

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

For a general overview on the regulatory framework we refer to the contribution of the European Commission.

In the years 2005-2007 the Dutch authorities received several questions regarding the regulatory status of plants obtained with NPBTs. We forwarded these questions to the European Commission as to the opinion of the Netherlands is that these matters require harmonization at EU level. During that period the Netherlands did not receive any formal applications regarding fields trials with plants obtained with NPBTs. In the ruling of the European Court of Justice (ECJ) of 25 July 2018 (Case C-528/16), it was considered

that gene-edited plants to be released in the field should be considered as GMOs as defined in the EU Directive 2001/18/EC on the deliberate release of GMOs.

As a follow-up of the ECJ ruling, on 5 July 2023 the European Commissions published a proposal for a new Regulation on plants produced by certain new genomic techniques. The proposal covers plants that contain genetic material from the same plant (targeted mutagenesis) or from crossable plants (cisgenesis, including intragenesis); transgenic plants (which contain genetic material from non-crossable species) will remain subject to the GMO legislation as it stands today. (See also contribution of European Commission for more details).

The Netherlands is of the opinion that current legislation, which dates back to 2001, is not fit for purpose with regard to plants derived from new genomic techniques that do not cross species boundaries. The Netherlands strives to adapt the current European legislative framework to make breeding with NGTs simpler, preserving and ensuring safety for human health and the environment while the innovative potentials and opportunities are not left unexploited. We also recognize that such new techniques may bring challenges also, and the Netherlands wants to pay attention to this in the development of the legislation. The ultimate core of the Dutch effort is safe, future-proof, proportional and science-based legislation. In light of this the Dutch government is in general supportive of the proposal.

Currently the legislative process is still going on. For more details on this see also the contribution of the European Commission.

Item 1-1-1. Environmental release

To date, the Netherlands did not receive any applications for authorisation of a NGT-plant product which is subject to the EU GMO regulations according to the ruling by the European Court of Justice (Case C-528/16).

Applications for commercial releases require an EU coordinated procedure. We therefore refer to the contribution of the European Commission.

Item 1-1-2. Food and feed

Applications for commercial releases for food and feed use require an EU coordinated procedure. We therefore refer to the contribution of the European Commission.

Item 1-2. Other regulatory aspects

In relation to the current EU discussions concerning the new proposal of the European Commission on NGT plants, the Dutch advisory committee COGEM has issued an advice to amend and clarify the proposed criteria for NGT plants that could also occur naturally or by conventional breeding (so-called 'category 1 NGT plants' in the proposal). See also Opinion to revise the criteria in Annex I of the EC proposal for new legislation for NGT plants (cogem.net)

South Africa

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

PUBLIC NOTICE: 27 October 2021

South Africa's Regulatory Approach for New Breeding Techniques

Department of Agriculture, Land Reform and Rural Development (DALRRD)

New breeding techniques (NBTs) provide new methods for genetic engineering and enable the production of a range of innovative products. These products are differentiated from those generated using early genetic engineering tools. The nature of NBTs led to discussions whether or not these techniques and their products must be subject to the existing regulatory system for GMOs.

In South Africa the Genetically Modified Organisms Act 1997 (Act No. 15 of 1997), as amended by Genetically Modified Organisms Act, 2006 (Act No. 23 of 2006), regulates the development and use of GMOs. The GMO Act defines a Genetically Modified Act (GMO) as an organism the genes or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination or both. Based on the definition of a GMO under the GMO Act, the Executive Council has concluded that the risk assessment framework that exists for GMOs, would apply to NBTs.

In line with the above, the application templates for contained use, trial release, commodity clearance and general release have been revised and the use of the revised application forms will be effective as of 01 December 2021.

Item 1-1-1. Environmental release

N/A

Item 1-1-2. Food and feed

N/A

Item 1-2. Other regulatory aspects

N/A

Spain

As a Member State of the European Union, the Spanish legislation regarding NBTs follows the European Union's regulations in this regard.

On 5 July 2023, the European Commission has adopted a proposal for a new Regulation on plants produced by certain new genomic techniques. The proposal was accompanied by an impact assessment, supported by an external study, Joint Research Center's case studies on several applications of NBTs and the scientific work of EFSA in the area of new genomic techniques. All these are available at the following link: https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology_en

To become law, the Regulation must be adopted by the Member States in the Council and the European Parliament. The ordinary legislative procedure in this regard is currently taking place.

In Spain, a specific section on NBT has been created on the website of the Ministry of Agriculture, Fisheries and Food. The webpage is available at the following link: https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/mejora-genetica/

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

Products obtained by NBT´s follow the European and national regulatory frameworks applicable to genetically modified organisms. Spain is contributing actively in the negotiations of the Commission´s proposal since it was presented last 5th of July.

All the information provided by the European Commission in **Item 1-1** of this questionnaire is shared by Spain as a member state of the European Union.

Item 1-1-1. Environmental release

Item 1-1-2. Food and feed

Item 1-2. Other regulatory aspects

United States

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

USDA-APHIS has operated under modernized biotechnology regulations since 2020, which account for advances in genetic engineering and our understanding of the plant pest risks posed by modified organisms. USDA-APHIS now focuses on the organism's characteristics, rather than on the method used to produce it. This risk-proportionate approach enables USDA-APHIS to regulate organisms developed using genetic engineering for increased plant pest risk with greater precision, reducing regulatory burden for developers of organisms that are unlikely to pose increased plant pest risk and allowing USDA-APHIS to continue regulating modified organisms that may pose an increased plant pest risk. Based new information and experience over the past three years, USDA-APHIS seeks to updates to its regulations expand to regulatory exemptions for plants with modifications achievable through conventional breeding methods.

https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/revised-rule/revised-regulations

The United States regulates biotechnology through The Coordinated Framework for Biotechnology, finalized in 1986 where the United States uses existing laws to regulate products of biotechnology rather than a special biotechnology law. The primary agencies involved in U.S. biotechnology regulation are the Animal and Plant Health Inspection Service (APHIS) in the U.S. Department of Agriculture (USDA); the Food and Drug Administration (FDA) in the Department of Health and Human Services (HHS); and the Environmental Protection Agency (EPA). For environmental release, EPA regulates pesticidal traits in plants to ensure that these products do not pose unintended or unreasonable risks to humans, animals, or the environment. USDA safeguards plant and animal health, including protecting agriculture and agriculturally important resources.

EPA-OPP's (Office of Pesticide Programs) regulatory framework for pesticidal substances produced and used in plants (plant-incorporated protectants, or PIPs) was established in 2001. Since then, EPA-OPP has been implementing regulations for PIPs and has registered a diverse array of pest resistant (e.g., dsRNA targeting coleopteran pests, proteins derived from non-*Bt* sources targeting coleoptera and lepidopteran pests) and disease resistant PIPs (e.g., viral coat protein genes, R-proteins). In turn, EPA has approved over 30 PIP active ingredients and over 100 PIP products.

Reflecting the advances in new plant breeding techniques, EPA released a final rule in May 2023 exempting two categories of PIPs from registration requirements that could be created using genetic engineering. This rule ensures that human health and the environment are protected while reducing costs for the regulated community. These exemptions may result in increased research and development activities, commercialization of new pest control options for farmers, and reduced use of conventional pesticides.

https://www3.epa.gov/pesticides/chem_search/reg_actions/pip/pip_rule.pdf

https://www.epa.gov/ingredients-used-pesticide-products/current-and-previously-registered-section-3-plant-incorporated

Item 1-1-1. Environmental release

USDA-APHIS biotechnology regulations exempt certain modified plants that (1) are achievable through conventional breeding techniques and thus are unlikely to pose an increased plant pest risk compared to conventionally bred plants, or (2) have a plant-trait-mechanism of action combination that is the same as a plant that USDA-APHIS previously reviewed and determined to be unlikely to pose plant pest risk.

USDA-APHIS biotechnology regulations do not apply to plants that have been modified such that they contain either a single modification of a type listed below:

(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 and follow the process in paragraph (b)(4)(i) of this section, or in response to a request made in accordance with paragraph (b)(4)(ii) of this section.

Additional, USDA-APHIS biotechnology regulations do not apply to plants with plant-trait-mechanism of action combinations that USDA-APHIS previously reviewed and found not subject to the regulations. USDA-APHIS continuously updates this list of exemptions as it completes Regulatory Status Reviews and remaining petitions from the legacy regulations.

Developers may voluntarily request USDA-APHIS confirm a modified plant qualifies for an exemption and is not subject to the regulations in 7 CFR part 340. USDA-APHIS will provide a written response ("confirmation letter") within 120 days of receiving a sufficiently detailed confirmation request. USDA-APHIS posts both the confirmation requests and the issued confirmation letters on its website, with redactions to protect Confidential Business Information and Personal Identifying Information, as appropriate.

https://www.aphis.usda.gov/brs/pdf/requesting-confirmation-of-exemption.pdf

Plants which are not exempt from the regulations may be reviewed via a Regulatory Status Review (RSR) process, which evaluates the characteristics of the plant and if it could pose an increased plant pest risk relative to the comparator plant. Some plants which have been reviewed under RSR were developed using NBTs.

https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulatory-processes/exemptions-confirmations

https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulatory-processes/regulatory-status-reviews/rsr

EPA revised regulations in 2023 to expand exceptions to PIP's edited to achieve results like what can be accomplished through conventional breeding.

In May 2023, EPA finalized a "Rule to Accelerate Use of Plant-Incorporated Biotechnologies to Protect Against Pests." The final rule includes:

- Exemptions from FIFRA registration and FFDCA tolerance requirements for:
  1. PIPs in which genetic engineering has been used to insert or modify a gene to match a gene found in a sexually compatible plant; and,
  2. Loss-of-function PIPs in which the genetically engineered modification reduces or eliminates the activity of a gene, which then helps make the plant resistant to pests.
- A required notification process to increase transparency and public confidence. Developers of PIPs in the first category of exemptions require EPA confirmation that the product is eligible for exemption, but developers of PIPs in the second exempted category can use a self-determination process.

https://www.regulations.gov/docket/EPA-HQ-OPP-2019-0508

https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/pesticides-exemptions-certain-plant-incorporated-0

At EPA, plants that are not exempt from regulations are registered under the Pesticide Registration Improvement Act (PRIA). Using a risk assessment process (hazard x exposure), EPA evaluates the pesticidal trait and if it could pose an environmental or human health risk.

Item 1-1-2. Food and feed

Item 1-2. Other regulatory aspects

APHIS's revised regulations also allow for expanding the exemptions based on scientific evidence of what can be achieved through conventional breeding. In November 2023, APHIS issued a public proposal for five additional exemptions that include the following types of modifications:

Loss of Function modifications and modifications that are a single contiguous deletion;

Expanding current modifications to include certain polyploid plants;

Allowing up for four edits at a single time; and

Providing for successive edits.

USDA-APHIS received 6,500 public comments during the review period, which closed on January 19, 2024. USDA-APHIS is reviewing the comments and considering next steps.

The full text of the proposal is available at:

Federal Register: Movement of Organisms Modified or Produced Through Genetic Engineering; Notice of Proposed Exemptions; Reopening of Comment Period

European Union

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

In the European Union, products of NBTs (usually referred to as new genomic techniques, NGTs, in the EU) are subject to the legislation on genetically modified organisms (GMOs) which is contained in several main legislative acts (Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No

1830/2003, Directive 2009/41/EC). They establish procedures requiring an authorisation for the contained use or the deliberate release of GMOs into the environment for experimental purposes as well as for the placing on the market and cultivation of GMOs and GM food and feed. This authorisation system is based on an assessment of the risks to human and animal health and the environment, and includes requirements for post-market monitoring, labelling and traceability.

On 5 July 2023, the European Commission adopted a legislative proposal for a regulation on plants produced by certain new genomic techniques (NGTs) and their food and feed. The proposal is part of a package of proposals to ensure resilient and sustainable use of the EU's natural resources.

The proposal sets out specific rules for the deliberate release into the environment for any other purpose than placing on the market of plants obtained by targeted mutagenesis and cisgenesis (including intragenesis) and for the placing on the market of food and feed containing, consisting of or produced from such plants, and of products, other than food or feed, containing or consisting of such plants ('NGT plants and products').

The main measures of the proposal include:

1. The proposal (in Chapter I) makes the deliberate release and placing on the market of NGT plants and products subject to one of two procedures: verification procedure to establish equivalence with conventional plants/products or authorisation in accordance with EU legislation on GMOs:
2. Chapter II of the proposal provides for a verification procedure and criteria to verify whether NGT plants/products obtained by targeted mutagenesis or cisgenesis could also have been obtained naturally or by conventional breeding techniques, based on the criteria laid down in Annex I ('category 1 NGT plants'). Category 1 NGT plants/products are exempted from the requirements of the GMO legislation, and subject to the rules on conventionally bred plants. Transparency is ensured in a public database, through labelling of the seeds and through the relevant registers on plant varieties.
3. Chapter III of the proposal applies to NGT plants/products which do not meet the criteria to consider that they could also be obtained naturally or by conventional breeding ('category 2 NGT plants'). They remain subject to the rules on GMOs with adaptations as regards risk assessment, detection method, monitoring and renewal requirements. They are made subject to traceability and labelling requirements of the GMO legislation, with the possibility of a voluntary label to indicate the purpose of the genetic modification. The proposal includes regulatory incentives for Category 2 NGT plants/products featuring traits that could contribute to the overall performance of varieties as regards sustainability (Annex III to the proposal).
4. The proposal provides that NGT plants/products are prohibited in organic production.
5. The proposal includes provisions for the monitoring of economic, environmental and social impacts of NGT plants and products, supporting implementation reports and the future evaluation of the legislation. To become law, the Regulation must be adopted by the Member States in the Council of the European Union and the European Parliament, following the ordinary legislative procedure. In the meantime, the plants and products covered by this proposal continue to be regulated under the legislation on GMOs as described in the first paragraph.

Item 1-1-1. Environmental release

See Item 1-1.

Item 1-1-2. Food and feed

See Item 1-1.

Item 1-2. Other regulatory aspects

None.

Item 2: Products developed by NBTs approved/registered by or reported/notified to authorities (if available; public and official information only; basically plants)

Argentina

Argentina still has no NBT-derived products on the market. In addition, Argentina does not publish a third list of products derived from NBT.

In this sense, the information that can be provided is the following:

Total PCIs evaluated: 133

Types of PCIs submitted:

1. According to organism:
    - plant: 111 (81 final products and 30 products in development stage)
    - animal: 19 (7 final products and 12 products in development stage)
    - microorganisms: 5 (4 final products and 1 product in design stage).
2. Type of product:
    - Final: 91
    - In design stage: 42
3. Type of applicant entity:
    - Public: 29
    - Private: 101
    - Mixed: 3
4. Type of development:
    - National: 64
    - Foreign: 10
    - Foreign development with national presentation: 59

Item 2-1. For environmental release

not applicable

Item 2-2. For food and feed

not applicable

Item 2-3. Other products

not applicable

Austria

To date, Austria did not receive any applications for authorisation of an NGT-product which is subject to the EU GMO regulations according to the ruling by the European Court of Justice (Case C-528/16).

If any NGT-applications are submitted in the future, the current GMO authorisation procedure and labelling requirements according to the Austrian Gene Technology Act will apply for these products.

Item 2-1. For environmental release

Item 2-2. For food and feed

Item 2-3. Other products

Belgium

For this item, we refer to the answer of the European Commission.

Item 2-1. For environmental release

Item 2-2. For food and feed

Item 2-3. Other products

Brazil

Item 2-1. For environmental release

Link to the list of organisms notified to the National Technical Commission on Biosafety (in Portuguese) http://ctnbio.mctic.gov.br/tecnologias-inovadoras-de-melhoramento-genetico-rn16-

Organisms in the list (for commercial use) – English translation from the original information in Portuguese.

Notifier	Organism name	Notification date	Start of use
Ourofino	Vaccine against canine parvovirus	2018	-
Du Pont do Brasil	*Zea mays*	2018	-
AquaBounty Technologies	Tilapia fish	2019	-
Forest	Sterile mosquitoes	2019	-
Evolutta Agro Biotecnologia Ltda	dsRNA insecticide	2020	-
Pivot Bio	Klebisiela variicola Kv 137-3933 Nitrogen fixation	2020	-
Pivot Bio	Klebisiela variicola Kv137-1034 Nitrogen fixation	2020	-
Evolutta Agro Biotecnologia Ltda	dsRNA insecticide	2021	-
Bioheuris	Soybean, Herbicide resistance	2021	-
BASF S.A	*Bacillus thuringiensis* Solubilization of soil nutrients for plants	2021	-
Bayer S.A	*Bacillus* sp., Soil nematode control	2021	-
GDM Genética do Brasil S.A	Soybean, Low raffinose	2022	-
GDM Genética do Brasil S.A	Soybean, Drought tolerance	2022	-
Evolutta Agro Biotecnologia Ltda.	dsRNA insecticide	2022	-
Mosaic Fertilizantes do Brasil Ltda	*Paenibacillus polymyxa* BEC 176 Nitrogen fixation	2022	-
Mosaic Fertilizantes do Brasil Ltda.	*Paenibacillus polymyxa* BEC 177 Nitrogen fixation	2022	-
Evolutta Agro Biotecnologia Ltda	dsRNA fungicide	2022	-
Tevah Consultoria Regulatória	Bactéria *Kosakonia sacchari* Nitrogen fixation	2022	-
Embrapa Soja - Centro Nacional de Pesquisa de Soja	Sybean, Low lectin	2022	-
Embrapa Agroenergia	Sugar cane, High sugar	2022	-
Evolutta Agro Biotecnologia LTDA	dsRNA fungicide	2022	-
Evolutta Agro Biotecnologia Ltda	dsRNA insecticide	2022	-
Tevah Consultoria Regulatória	*Klebisiela variicola* Nitrogen fixation	2022	-
Evolutta Agro Biotecnologia Ltda	dsRNA insecticide	2022	-
SEMPRE AgTech	dsRNA insecticide	2023	-
Embrapa Soja	Soybean, Drought tolerance	2023	-
KWS SAAT SE & Co. KGaA	*Zea mays,* Insect resistance	2023	-

Notifier	Organism name	Notification date	Start of use
SEMPRE AgTech	dsRNA insecticide	2023	-
Bioheuris	Cotton, Herbicide tolerance	2023	-
GreenLight Biosciences Inc.	dsRNA insecticide	2023	-
Bioheuris	Sorghum, Herbicide tolerance	2023	-
Tevah Consutoria Regulatória	Soybean Growth promotion	2023	-
Corteva Agriscience do Brasil Ltda.	*Zea mays,* Fungal resistance	2023	-
Bioheirus	Rice, Herbicide tolerance	2023	-
Bioheirus	Cotton, Herbicide tolerance	2023	-
Tevah Consutoria Regulatória	*Klebsiella* sp., Nitrogen fixation	2023	-
BioConsortia, Inc.	*Bacillus* sp., Nitrogen fixation	2023	-
GDM - Genética do Brasil Ltda	Soybean, Drought tolerance	2024	-
Evolutta Agro Biotecnologia Ltda.	dsRNA fungicide	2024	-
SEMPRE AGRITECH	dsRNA, Soil nematode control	2024	-

Item 2-2. For food and feed

Link to the list of organisms notified to the National Technical Commission on Biosafety (in Portuguese) http://ctnbio.mctic.gov.br/tecnologias-inovadoras-de-melhoramento-genetico-rn16-

Organisms in the list (for commercial use) – English translation from the original information in Portuguese.

Notifier	Organism name	Notification date	Start of use
Tevah Consultoria Regulatória	*Escherichia coli* Additive for feed poultry farming	2020	-
Acceligen do Brasil Biotecnologia e Pesquisa Científica Ltda	Bovine, Myostatin	2021	-
Tevah Consultoria Regulatória	*Escherichia coli* Additive for feed poultry farming	2023	-
Acceligen do Brasil Biotecnologia e Pesquisa Científica Ltda.	Bovine, Thermotolerance	2023	-

Item 2-3. Other products

Link to the list of organisms notified to the National Technical Commission on Biosafety (in Portuguese) http://ctnbio.mctic.gov.br/tecnologias-inovadoras-de-melhoramento-genetico-rn16-

Organisms in the list (for commercial use) – English translation from the original information in Portuguese.

Products approved for biofuel production (ethanol and biodiesel) under a containment system.

Notifier	Organism name	Notification date	Start of use
Globalyeast JV CO Brasil S.A	*Saccharomyces cerevisiae,* Bioethanol	2018	-
Globalyeast JV CO Brasil S.A	*Saccharomyces cerevisiae,* Bioethanol	2018	-
Lallemand Brasil Ltda.	*Saccharomyces cerevisiae,* Bioethanol	2018	-
Lallemand Brasil Ltda.	*Saccharomyces cerevisiae,* Bioethanol	2019	-
Lallemand Brasil Ltda.	*Saccharomyces cerevisiae,* Bioethanol	2019	-
Lallemand Brasil Ltda.	*Saccharomyces cerevisiae,* Bioethanol	2020	-
Lallemand Brasil Ltda.	*Saccharomyces cerevisiae,* Bioethanol	2020	-
YesSinergy Agroindustrial Ltda	*Saccharomyces cerevisiae,* Bioethanol	2021	-
Lallemand Brasil LTDA	*Saccharomyces cerevisiae,* Bioethanol	2021	-
Lallemand Brasil LTDA	*Saccharomyces cerevisiae,* Bioethanol	2021	-
Embrapa Agroenergia	*Saccharomyces cerevisiae,* Bioethanol	2021	-
Lallemand Soluções Biológicas Ltda.	*Saccharomyces cerevisiae,* Bioethanol	2022	-
Fermentec Ltda.	*Saccharomyces cerevisiae,* Bioethanol	2023	-
CERLEV – Projetos e Inovação na Biotecnologia da Fermentação LTDA. 01245.012472/2023-08	*Saccharomyces cerevisiae,* Bioethanol	2023	-
CERLEV – Projetos e Inovação na Biotecnologia da Fermentação LTDA. 01245.012456/2023-15	*Saccharomyces cerevisiae,* Bioethanol	2023	-
CERLEV – Projetos e Inovação na Biotecnologia da Fermentação LTDA 01245.012455/2023-62	*Saccharomyces cerevisiae,* Bioethanol	2023	-

Canada

Item 2-1. For environmental release

For all plants with novel traits, following a pre-market assessment, the CFIA updates a database of authorized plant products of biotechnology[6] and related decision documents[7].

Decision documents outline the information that was assessed, including information on how the plant was developed. The CFIA posts this information for all plant products that have received a pre-market assessment. As of March 1, 2024, there are no novel products developed using NPBTs authorized for unconfined environmental release.

[6] https://active.inspection.gc.ca/netapp/plantnoveltraitpnt-vegecarnouvcn/pntvcne.aspx

[7] https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/approved-under-review/decision-documents/eng/1303704378026/1303704484236

Transparency about non-novel seed lines developed using NPBTs will be provided through non-regulatory measures. In May 2023, an Industry-Government Technical Committee on Plant Breeding Innovation Transparency released its Chair's Report, which outlined several key recommendations to improve transparency around seed varieties, including establishing a Government-Industry Steering Committee to advance recommended transparency initiatives:

https://agriculture.canada.ca/en/department/transparency/chairs-report-minister-industry-government-technical-committee-plant-breeding-innovation

Agriculture and Agri-Food Canada's Government-Industry Steering Committee on Plant Breeding Innovation Transparency, launched in June 2023, provides input and perspectives on the industry-led Canadian Variety Transparency Database.

Item 2-2. For food and feed

When Health Canada authorizes a novel food product, it updates its list of completed safety assessments of novel foods[8] and publishes a summary of each assessment.

Health Canada maintains a list of non-novel products of plant breeding for food use. This list includes non-novel gene-edited plant products that have been notified to the Department voluntarily by the developer.

List of non-novel products of plant breeding for food use: https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/transparency-initiative/list-non-novel-products-plant-breeding-food-use.html

Item 2-3. Other products

N/A

Costa Rica

Costa Rica has not yet evaluated any plants improved with NBTs

Public Universities are researching on NBT rice and coffee with potential further use.

- Salinity and drought tolerance rice https://vinv.ucr.ac.cr/sigpro/web/projects/B7294
- Coffee with reduced caffeine https://vinv.ucr.ac.cr/sigpro/web/projects/C0462

Item 2-1. For environmental release

N/A

Item 2-2. For food and feed

N/A

Item 2-3. Other products

N/A

[8] https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products.html

Croatia

Item 2-1. For environmental release

None.

Item 2-2. For food and feed

On 17 January 2024, the European Food Safety Authority issued a favourable scientific opinion for placing on the market of genetically modified maize DP-915635 produced by NBT for food and feed uses (Application EFSA-GMO-NL-2020-172). The regulatory approval procedure is ongoing for this product. This event was created by site-specific integration using two sequential transformation steps to insert an integration site sequence, at a specific location of the maize genome using biolistic and a CRISPR-Cas9-mediated targeted insertion process, and to insert the intended expression cassettes in the maize genome using Agrobacterium-mediated transformation. It is a transgenic plant. More info on GM maize DP-915635 is available at https://bch.cbd.int/en/database/record?documentID=260914

Item 2-3. Other products

None.

Czech Republic

Item 2-1. For environmental release

Please see the answer provided by DG Sante. No environmental release of NBTs in CZ.

Item 2-2. For food and feed

Please see the answer provided by DG Sante.

Item 2-3. Other products

Please see the answer provided by DG Sante.

Denmark

Item 2-1. For environmental release

Two experimental trials with potatoes made with NBTs took place in 2023. The experimental trials were approved under the current GMO-regulation in the EU (see 1.1) and involved potato lines with targeted mutations made with CRRISPR. The aim was, respectively, to modify starch composition and increase resistance to late blight.

In 2024, the competent authority for environmental release of GMOs (The Danish Agricultural Agency) has received an application for experimental release of potatoes made with NBT which includes some of the same lines as mentioned above as well as new lines.

Item 2-2. For food and feed

Please refer to the reply from the European Commission concerning a genetically modified maize produced by NBT for food and feed use.

Item 2-3. Other products

No such products are approved.

France

[French]

Item 2-1. For environmental release

Les autorisations de mise sur le marché des produits obtenus par NBT relèvent du niveau européen : voir la contribution de la Commission européenne.

Aucun essai de dissémination volontaire dans l'environnement de produits obtenus par NBT n'est autorisé en France.

Item 2-2. For food and feed

Les autorisations de mise sur le marché des produits obtenus par NBT relèvent du niveau européen : voir la contribution de la Commission européenne.

Item 2-3. Other products

Les autorisations de mise sur le marché des produits obtenus par NBT relèvent du niveau européen : voir la contribution de la Commission européenne.

[English]

Item 2-1. For environmental release

Marketing authorisations for products obtained by NBT fall within the European level: see the contribution of the European Commission

No trials for deliberate release into the environment of products obtained by NBT have been authorised in France.

Item 2-2. For food and feed

Marketing authorisations for products obtained by NBT fall within the European level: see the contribution of the European Commission

Item 2-3. Other products

Marketing authorisations for products obtained by NBT fall within the European level: see the contribution of the European Commission.

Germany

Item 2-1. For environmental release

We relegate to the information provided by the European Commission.

Item 2-2. For food and feed

See above.

Item 2-3. Other products

See above.

Japan

Item 2-1. For environmental release

Link to the list of organisms notified to the MAFF (in Japanese).

https://www.maff.go.jp/j/syouan/nouan/carta/tetuduki/nbt_tetuzuki.html#flow03

Organisms in the list (for commercial use) – English translation from the original information in Japanese.

Notifier	Organism name	Notification date	Start of use
Sanatech Seed Co., Ltd.	Tomato with increased GABA	Dec. 2020	Dec. 2020
Corteva Agriscience Japan Ltd.	Maize with waxy trait	Mar. 2023	-
Sanatech Seed Co., Ltd.	Tomato with increased GABA*	Jul. 2023	-

*different variety of the tomato which was notified in 2020

Link to the list of organisms notified to the MOE (in Japanese).

https://www.biodic.go.jp/bch/bch_8_3.html

Organisms in the list (for research use) – English translation from the original information in Japanese.

Notifier	Organism name	Notification date
The University of Tokyo	A group of rice mutants in the genes regulating flowering time, circadian rhythm and metabolism of sugars and starches by genome editing technology	7 Jul. 2023
OSAKA UNIVERSITY	Potatoes with low contents of steroidal glycoalkaloids	26 Apr. 2023
The University of Tokyo	A group of rice mutants in the genes regulating flowering time or circadian rhythm by genome editing technology	13 Sep. 2022
National Agriculture and Food Research Organization	Pre-harvest sprouting tolerant wheat modified with alanine aminotransferase	22 Sep. 2021
The University of Tokyo	A group of rice mutants in florigen genes produced by genome editing technology	29 Jun. 2021
RIKEN	Potatoes with low contents of steroidal glycoalkaloids	5 Apr. 2021

Item 2-2. For food and feed

Same as the list (for commercial use) above.

Item 2-3. Other products

Link to the list of organisms notified to the MAFF (in Japanese).

https://www.maff.go.jp/j/syouan/nouan/carta/tetuduki/nbt_tetuzuki.html#flow03

Organisms in the list (for commercial use) – English translation from the original information in Japanese.

Notifier	Organism name	Notification date	Start of use
Regional Fish Institute, Ltd.	Increased-filet sea bream	Sep. 2021	Sep. 2021
Regional Fish Institute, Ltd.	Fast growth tiger puffer	Oct. 2021	Oct. 2021
Regional Fish Institute, Ltd.	Flounder with growth enhancement	Dec. 2023	Dec. 2023

Korea

There is no product developed by NBTs approved in the Republic of Korea.

Item 2-1. For environmental release

Item 2-2. For food and feed

Item 2-3. Other products

Lithuania

The Republic of Lithuania is a Member of the European Union (EU). The EU framework for NBT's as outlined by the submission of the European Commission also applies for Lithuania.

Item 2-1. For environmental release

-

Item 2-2. For food and feed

-

Item 2-3. Other products

-

Netherlands

Item 2-1. For environmental release

None at national level. At EU level see contribution European Commission.

Item 2-2. For food and feed

None at national level. At EU level see contribution European Commission.

Item 2-3. Other products

None at national level. At EU level see contribution European Commission.

South Africa

Item 2-1. For environmental release

N/A

Item 2-2. For food and feed

N/A

Item 2-3. Other products

Spain

No products developed through NBTs have been approved or registered in Spain for commercial purposes. Nevertheless, Spain has issued a license to perform some field trials during the last years with NGT plants under the deliberate release legislative framework. Please see some examples below.

In addition, several contained used activities with products obtained by NBT have been carried out for research purposes.

Item 2-1. For environmental release

Consent given for field trials under Part B for GM plants (gene edited plants) in Spain.

B/ES/23/36 - Development of a gene-edited tobacco line with high anatabine content.

The tobacco plants have mutations (deletions and insertions) in endogenous MPO genes. The mutations have been generated using the CRISPR / Cas9 system. The purpose of the proposed release is to determine the optimal field growth conditions of the edited line for use as an anatabine biofactory line.

B/ES/21/28 - Molecular approaches to increase salinity and drought tolerance in broccoli

It is a genome edited broccoli using the CRISPR/Cas9 system. These initial explants (To) will be grown in the greenhouse and self-fertilised to obtain T1 plants. After that plant with a small modification that changes the reading pattern of the target protein without having incorporated foreign genetic material are selected. The main objective of this project is to obtain broccoli lines with greater resistance to salinity and drought and evaluate whether the edited material is more resistant to salinity and drought, without repercussions on other commercial qualities. More specifically, to evaluate its agronomic suitability

Item 2-2. For food and feed

N/A

Item 2-3. Other products

N/A

United States

Item 2-1. For environmental release

Below are some of the examples of novel plants approved by US agencies for environmental release.

Plant	Trait	Requester	Effective date	Agency
Teff	Reduced height	Donald Danforth Plant Science Center	March 31, 2023	USDA
Banana	1) Altered fruit quality and 2) Marker gene	Tropic Biosciences UK LTD	November 14, 2023	USDA
Pennycress	1) Lowered erucic acid in seeds and 2) Lowered fiber in seeds	Hjelle Advisors	November 14, 2023	USDA
Brown mustard	1) Reduced pungency and 2) Reduced trichome production	Pairwise Plant Services, Inc	November 14, 2023	USDA
Blackberry	Confidential	Pairwise Plant Services, Inc	January 16, 2024	USDA
Black Raspberry	Confidential	Pairwise Plant Services, Inc	January 16, 2024	USDA
Orange	Loss of function, canker resistance	University of Florida	August 21, 2023	EPA
Confidential	Loss of function PIP; trait confidential	Soil Culture Solutions, LLC (d/b/a Soilcea)	October 17, 2023	EPA
Confidential	Loss of function PIP; trait confidential	Soil Culture Solutions, LLC (d/b/a Soilcea)	October 17, 2023	EPA

Effective date indicates date a response was issued by USDA, or date self-determination was submitted to EPA.

Item 2-2. For food and feed

Item 2-3. Other products

European Union

Item 2-1. For environmental release

None.

Item 2-2. For food and feed

On 17 January 2024, the European Food Safety Authority issued a favourable scientific opinion for placing on the market of genetically modified maize DP-915635 produced by NBT for food and feed uses (Application EFSA-GMO-NL-2020-172). The regulatory approval procedure is ongoing for this product. This event was created by site-specific integration using two sequential transformation steps to insert an integration site sequence, at a specific location of the maize genome using biolistic and a CRISPR-Cas9-mediated targeted insertion process, and to insert the intended expression cassettes in the maize genome

using Agrobacterium-mediated transformation. It is a transgenic plant. More info on GM maize DP-915635 is available at https://bch.cbd.int/en/database/record?documentID=260914

Item 2-3. Other products

None.

Item 3: Other information (if available; public and official information only)

Argentina

The analysis of the entire experience generated by the application of these regulations reveals the following conclusions about the PCI cases analysed: i) the developers can predict costs and period of time in the product development, even at the design stage; ii) the developers can put their products into the market sooner; iii) there are a greater phenotype varieties in different crops, animals and microorganisms; and iv) the speed of innovation of products obtained by NBTs is greater in relation to GMOs the innovation speed.

Publications related to Argentine NBT regulation carried out by the National Bioeconomy Directorate:

Title/Summary of the contents	Source (URL, doi, date accessed etc.,)
Whelan, A. I., and Lema, M. A. (2015). Regulatory framework for gene editing and other new breeding techniques (NBTs) in Argentina.*GM Crops & Food*6, 253–265. doi: 10.1080/21645698.2015.1114698.	https://pubmed.ncbi.nlm.nih.gov/26552666/
Goberna, M. F., Whelan, A. I., Godoy, P., and Lewi, D. M. (2022). Genomic Editing: The Evolution in Regulatory Management Accompanying Scientific Progress.*Front. Bioeng. Biotechnol.*10, 835378. doi: 10.3389/fbioe.2022.835378.	https://www.frontiersin.org/articles/10.3389/fbioe.2022.835378/full
Goberna, M.F., Lewi, D. M., Godoy, P and Hopp, E. Capítulo "Gene Editing Regulation in Argentina". En: Global Regulatory Outlook for CRISPRized Plants 1st Edition - November 1, 2023; Editorial Elsevier; Editores: Kamel A Abd-Elsalam, Aftab Ahmad; Paperback ISBN: 9780443184444; eBook ISBN: 9780443184451. number of pages: 625.	https://shop.elsevier.com/books/global-regulatory-outlook-for-crisprized-plants/a-abd-elsalam/978-0-443-18444-4
Fernández Ríos D, Benítez Candia N, Soerensen MC, Goberna MF and Arrúa AA (2024) Regulatory landscape for new breeding techniques (NBTs): insights from Paraguay. Front. Bioeng. Biotechnol. 12:1332851. doi: 10.3389/fbioe.2024.1332851	https://www.frontiersin.org/articles/10.3389/fbioe.2024.1332851/full

Austria

Title/Summary of the contents	Source (URL, doi, date accessed etc.,)
A symposium for national and European stakeholders addressing issues related to the proposal of the European Commission (EC) for a regulation of NGT plants was held in Vienna on October 11th 2023. The event consisted of several sessions addressing the regulatory proposal of the EC, the risk assessment of NGT plants, the precautionary principle, consumer protection, and impacts on organic agriculture and the production of GM free agricultural products. The participants represented a wide range	

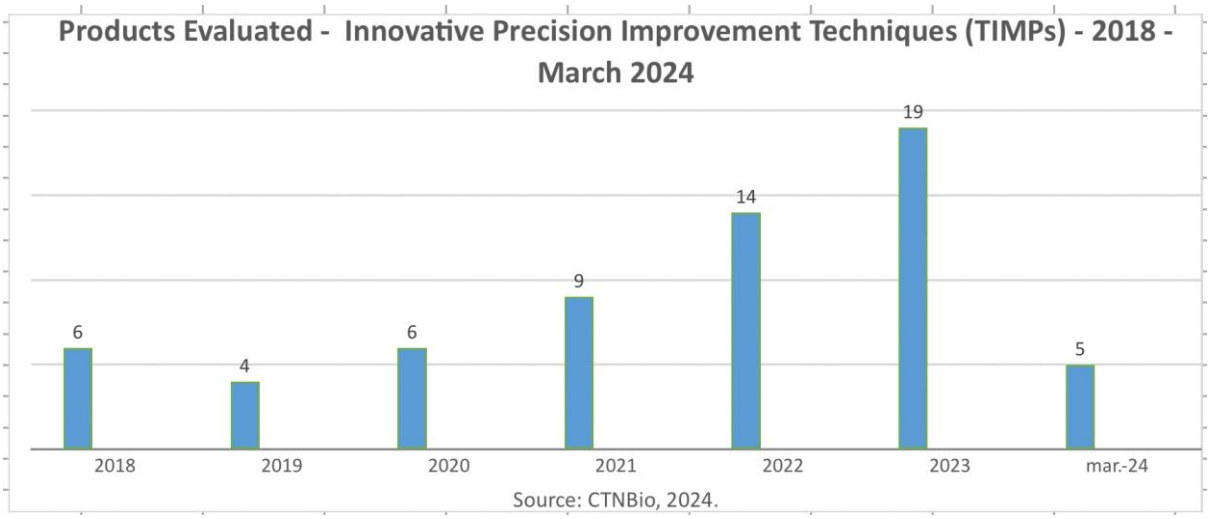
Title/Summary of the contents	Source (URL, doi, date accessed etc.,)
of different stakeholders, such as the European Commission and authorities from different EU Member States including Hungary, Slovenia, Belgium, France, Poland and the Netherlands, associations for GM-free food production and organic farming, scientists, and NGOs. The discussion addressed the following topics: • The proposal of the EC and issues regarding the Risk Assessment of NGT plants and application of the precautionary principle • Impacts of NGT applications on Organic and GM-free Production and on IPR protection by patents The main results of the symposium include: 1. The entrepreneurial freedom and consumer freedom of choice remain central aspects of the discussion. The use of new genetic engineering products (both NGT1 and NGT2) is not seen as an option for organic farming and the GMO-free sector. Accordingly, labelling and traceability are of great importance in order not to jeopardize these sectors. 2. Questions of liability and coexistence are also central for assessing the impacts of the EC proposal. The proposed reversal of the burden of proof in the event of contamination is viewed critically. Another key point that is particularly important for stakeholders from the GMO-free sector is that the EC's proposal would no longer allow exemptions from GMO cultivation in individual Member States ("opt-out"). 3. The patentability of NGT products is also an important issue in the framework of the discussion. The potential benefits of NGTs must also be available to small breeders, without restricting the accessibility to breeding materials. However, the possibilities for implementation of such policies remain unclear, as patents on NGT products are possible in principle under current legislation and the European Patent Office is not governed by EU institutions. 4. The safety of NGT products for humans and the environment is of great importance. Unlike the proposed EC regulation of NGT plants the implementation of the precautionary principle by the current EU GMO legislation and the Cartagena Protocol on Biosafety mandates a case-by-case risk assessment. The proposed deviation from the current GMO legislation is controversially discussed. 5. The categorisation of NGT1 and NGT2 plants and the assumption of the EC proposal that NGT1 plants are equivalent to conventionally bred plants, was intensively discussed. It was stressed that the actual properties of individual NGT plants as well as unintended changes and risks are not taken into account by the technical criteria proposed by the EC.	
Aspects regarding the policy proposal of the European Commission were also discussed at an information and discussion event with Members of the European Parliament, i.e. Thomas Waitz, Greens, and Günther Sidl, Social Democrats, held at the EU representation in Vienna (Haus der EU) on Jan 22nd 2024: The event “New genetic engineering: future technology or greenwashing?” co-organised by Global2000 and the Austrian Chamber of Labour (Arbeiterkammer) addressed the question what a deregulation of new genetic engineering in the EU would mean for the environment, consumer transparency and GMO-free agriculture in Austria.	A webcast of the event in German language is available at: Klare Kennzeichnung und Sicherheits-Checks bei Neuer Gentechnik in Lebensmitteln nötig! | GLOBAL 2000

Title/Summary of the contents	Source (URL, doi, date accessed etc.,)
The event featured presentations by Margret Engelhard, (Federal Agency for Nature Conservation, Germany), Katherine Dolan (ARCHE NOAH, Austria) and Andreas Heissenberger (Environment Agency Austria) addressing newly published studies concerning the impacts of the regulations for NGT plants proposed by the EC, the impacts of patents on NGT plants and the lack of an adequate risk assessment of unintended effects of NGT plants according to the regulation proposed by the EC, respectively. The presentations and the activities of the EU parliament were further discussed in a panel with Thomas Waitz and Günther Sidl.	
Representatives of Austrian Universities and research institutions published an open letter calling for a non-ideological and science-based approach to regulating green biotechnology and applications of new genomic techniques	Grüne Gentechnik: Offener Brief für eine wissenschaftsbasierte Beurteilung (oeaw.ac.at)
A publication commissioned by the Austrian Chamber of Labor (Arbeiterkammer) and conducted by Environment Agency Austria (Eckerstorfer & Heissenberger 2023) was presented at the event organised by two Austrian Members of the European Parliament indicated above. The study addresses how the current GMO legislation or the proposal of the EC for NGT plants deal with potential unintended risks of GM / NGT products. Although the safety of NGT products is of considerable importance for developers, consumers and legislators, respectively, this aspect is not a focal issue of the current debate on the EC proposal for a new regulation for NGT products. The study examines this topic on the basis of representative examples of NGT plants. The analysis intends to direct the focus of attention on possible unintended effects, which may be associated with individual NGT products.	Eckerstorfer, M. and Heissenberger, A. (2023). "New Genetic Engineering - possible unintended effects." Wien: Verlag Arbeiterkammer Wien. urn:nbn:at:at-akw:g-6550206, DOI: 10.13140/RG.2.2.12482.969694 Available at: (22) (PDF) NEW GENETIC ENGINEERING - POSSIBLE UNINTENDED EFFECTS (researchgate.net)

Belgium

For this item, we refer to the answer of the European Commission.

Brazil



Canada

N/A

Costa Rica

N/A

Croatia

N/A

Czech Republic

N/A

Denmark

Please refer to the reply from the European Commission.

France

[French]

Title/Summary of the contents	Source (URL, doi, date accessed etc.,)
Information gouvernementale sur les NBT : des informations sur les NBT sont disponibles sur les sites internet des ministères chargés de l'agriculture et de l'environnement	https://agriculture.gouv.fr/les-nouvelles-technologies-de-selection https://www.ecologie.gouv.fr/organismes-genetiquement-modifies-ogm-0
Programme et Equipements Prioritaires de Recherche (PEPR) « Sélection Végétale Avancée pour faire face au défi climatique et assurer la transition agroécologique »	https://www.pepr-selection-vegetale.fr/

[English]

Title/Summary of the contents	Source (URL, doi, date accessed etc.,)
Government information on NBTs: information on NBTs is available on the websites of the ministries responsible for agriculture and the environment :	https://agriculture.gouv.fr/les-nouvelles-technologies-de-selection https://www.ecologie.gouv.fr/organismes-genetiquement-modifies-ogm-0
Priority Research Programme and Equipments (PEPR) "Advanced Plant Breeding to meet the climate challenge and ensure the agro-ecological transition"	https://www.pepr-selection-vegetale.fr/

Germany

N/A

Japan

- Commercially cultivated/grown organisms produced by NBTs (For clarification, delegations are invited to provide this information accompanied with the period/season/year when delegations recognised it.)

Title/Summary of the contents	Source (URL, doi, date accessed etc.,)
In May 2021, Sanatech Seed Co., Ltd. first distributed seedlings of "Sicilian Rouge High GABA", the genome-edited tomato strain with increased GABA, for home gardeners free of charge. The company started selling fruits this tomato strain from September 2021, and then seedlings for home gardeners from October 2021. (Information confirmed in October 2021 through press releases by the company)	*https://sanatech-seed.com/en/newslist-en/* *Date accessed,31 August 2023*
In October 2021, Regional Fish Institute, Ltd. started distribution of fillets of the increased-fillet sea bream through a crowdfunding platform. (Information confirmed in October 2021 through a press release by the company)	*https://regional.fish/en/news* *Date accessed, 31 August 2023*

- Scientific and technological development expected to be used for products commercialised in coming years, to support and complement the information collection by the OECD policy analyst

Title/Summary of the contents	Source (URL, doi, date accessed etc.,)
Nakazato I. et al. (2021) Targeted base editing in the plastid genome of Arabidopsis thaliana, Nature Plants, Vol. 7, 906-913	*https://www.nature.com/articles/s41477-021-00954-6* *Date accessed,31 August 2023*
Hamada, H. et al. (2017) An in planta biolistic method for stable wheat transformation. Sci Rep 7, 11443.	*https://www.nature.com/articles/s41598-017-11936-0* *Date accessed,31 August 2023*
Yanagawa Y. et al. (2023) Genome editing by introduction of Cas9/sgRNA into plant cells using temperature-controlled atmospheric pressure plasma. PLoS One. 16;18(2):e0281767	*https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0281767* *Date accessed,31 August 2023*

- New biotechnology to be possibly added in future to the NBTs list (*other than Lusser et al., 2011 and Broothaerts et al., 2021*), to support and complement the information collection by the OECD policy analyst

Title/Summary of the contents	Source (URL, doi, date accessed etc.,)
Base editing in organelles	

Korea

N/A

Lithuania

N/A

Netherlands

N/A

South Africa

Title/Summary of the contents	Source (URL, doi, date accessed etc.,)
Spencer KP, Burger JT and Campa M (2023) CRISPR-based resistance to grapevine virus A. *Front. Plant Sci.* 14:1296251.	http://doi: 10.3389/fpls.2023.1296251

Spain

Title/Summary of the contents	Source (URL, doi, date accessed etc.,)
Monograph New Technologies for Plant Genetic Improvement - Producers, Industry, Wholesalers and Distributors The main objective of this monograph was to analyse the importance that the development and application of new technologies to improve plant production had for business agents in relation to the following objectives: Contribute to waste reduction (e.g. foods with a longer shelf life). Increase crop yields. Improve crop adaptation to climate change. Improve the nutritional properties and quality of food and feed (e.g. foods with higher content of vitamins and antioxidants). Reduce crop dependence on certain inputs, such as fertilizers or phytosanitary products.	https://www.mapa.gob.es/es/alimentacion/temas/consumo-tendencias/2022-3-trimestremejorageneticavegetal_tcm30-654219.pdf
Monograph New Technologies for Plant Genetic Improvement – Consumers The interviewees were asked to rate the development and application of new technologies to genetically improve plant production and its derived products in relation to different objectives: Contribute to waste reduction (e.g. foods with a longer shelf life). Increase crop yields. Improve crop adaptation to climate change. Improve the nutritional properties and quality of food and feed (e.g. foods with higher content of vitamins and antioxidants). Reduce crop dependence on certain inputs, such as fertilizers or phytosanitary products. Next, the interviewees were asked to rate how important would be for them to know certain information about these crops and their derived products: Features and properties. Contribution to environmental protection. Data on its safety and harmlessness. Exact name of the innovative technology applied crop breeding.	https://www.mapa.gob.es/es/alimentacion/temas/consumo-tendencias/2022-3trimestremejorageneticavegetalconsumidores_tcm30-654239.pdf
Report from the Ad-Hoc expert Group on new genomic techniques. National Commission of Biosafety (scientific advisory body Spain)	https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/notagrupocnbsobrengtfinal_tcm30-675213.pdf

United States

N/A

European Union

Title/Summary of the contents	Source (URL, doi, date accessed etc.,)
Mandate to European Food Safety Authority (EFSA) on new developments in biotechnology applied to microorganisms: this mandate foresees a horizon scanning on microorganisms and their products obtained by new developments in biotechnology, followed by a scientific opinion on potential novel hazards/risks from new developments in biotechnology applied to microorganisms and adequacy of the current EFSA risk assessment guidance	Mandate info on OpenEFSA portal First output – Horizon scanning
Mandate to EFSA on new developments in biotechnology applied to animals (including synthetic biology and new genomic techniques): this mandate foresees a knowledge gathering on known cases of animals (and their food and feed products) obtained by these new developments, followed by a scientific opinion on their potential novel hazards/risks applied to current and near market animals and the adequacy of the current EFSA risk assessment guidance, covering all aspects of molecular characterisation, food feed safety & welfare, and environmental impact.	Mandate info on OpenEFSA portal First output – Knowledge gathering:

Several EU-funded research projects directly concern or address aspects related to new developments in biotechnology (non-exhaustive): GeneBEcon, DETECTIVE, DARWIN, SHIELD4GRAPE, GrapeBreed4IPM.

Annex A. Questionnaire format circulated

QUESTIONNAIRE
Enhanced Information Exchange on New Breeding Techniques (NBTs)
Instructions

Survey respondents are requested to indicate their affiliation and to respond to the questionnaire within their own jurisdiction. Where possible, survey respondents are encouraged to provide comprehensive responses, following consultation with the relevant authorities. As the format of the questionnaire has been modified, delegations are invited to answer the questionnaire using the updated format.

The following is extracted from the project proposal [ENV/CBC/BIO(2020)4/REV3] approved by written procedure on 10 October 2022:

- *The objective of the project is to collect timely public and official information on regulatory frameworks and approved/registered/reported/notified products of NBTs, and to share the information among the delegates of the WPs.*
- *Delegations are invited to provide an update of information on NBTs* (defined by Lusser et al., 2011[9] and Broothaerts et al., 2021[10] except for synthetic genomics (synthetic biology))*.*
- *Gene drive technology is out of the scope because it is accompanied with insertion of transgenes, which will be covered by existing regulatory frameworks in most countries and regions.*
- *Only public and official information will be collected in the project, such as regulatory frameworks implemented or promulgated by authorities and approved/registered/reported/notified products. Delegations will not be asked to provide any confidential information such as on regulatory frameworks under consideration, products under authorisation process or pre-submission consultation.*
- *Information that regulatory authorities are not yet aware of is out of the scope of this project, and no additional search for information is required.*
- *The project covers plants at the start, aiming to demonstrate its feasibility. Delegations are free to provide information related to other organisms.*
- *Delegations will not be asked to provide information on organisms developed solely for basic research purposes.*

Delegation:
Date of report:

[9] Lusser et al. (2011), "New plant breeding techniques: State-of-the-art and prospects for commercial development", JRC Scientific and Technical Reports, doi:10.2791/54761

[10] Broothaerts et al. (2021) "New Genomic Techniques: State-of-the-Art Review", EUR 30430 EN, Publications Office of the European Union, Luxembourg, 2021, ISBN 978-92-76-24696-1, doi:10.2760/710056, JRC121847

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them (laws, rules, policies, and guidelines)

Delegations are invited to provide an overview of the regulatory framework for NBTs (including links to related websites if available) with relevant regulations on NBTs and derived products for application/registration/report/notification including information on the competent authorities involved and their contact details. If more than one authority is involved, provide their relevant jurisdiction.
Delegations are also invited to provide a brief description on the key elements in the normative for decision-making and any specific criteria for inclusions/exclusions of NBTs in/from regulations and any other regulatory aspects clarifying additional criteria for products reported in Item 2, in particular those on risk/safety assessment (e.g. guidelines).

Item 1-1. General overview on regulatory framework. Key elements, and criteria for inclusion/exclusion of NBTs can be included here.

Item 1-1-1. Environmental release

Item 1-1-2. Food and feed

Item 1-2. Other regulatory aspects

Item 2: Products developed using NBTs approved/registered by or reported/notified to authorities (if available; limited to public and/or official information basically on relevant plants)

Delegations are invited to provide links to public and official websites listing organisms/products developed using NBTs and approved/registered by or reported/notified to authorities, if available.
Delegations are not asked to provide information of products at research stage.
Delegations can also provide voluntarily additional information on such organisms/products (for example, English translation of lists of organisms/products developed using NBTs).
Delegations are free to provide information related to other organisms, for example animals, here or in Item 3.

Item 2-1. For environmental release

Item 2-2. For food and feed

Item 2-3. Other products

Item 3: Other information (if available; limited to public and/or official information)

Title/Summary of the contents	Source (URL, doi, date accessed etc.,)