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COLLATION OF THE ANSWERS FOR QUESTIONNAIRE Enhanced Information Exchange on New Breeding Techniques: 2025 Results

Series on the Harmonisation of Regulatory Oversight in Biotechnology No. 78
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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)

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[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)]

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No. 40, Developments in Delegations on the Safety Assessment of Novel Foods and Feeds, March 2024 – March 2025 (2025)

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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.

The Environment, Health and Safety Division publishes free-of-charge documents in twelve different series: **Testing and Assessment**; **Good Laboratory Practice and Compliance Monitoring**; **Pesticides**; **Biocides**; **Risk Management**; **Harmonisation of Regulatory Oversight in Biotechnology**; **Safety of Novel Foods and Feeds; Chemical Accidents; Pollutant Release and Transfer Registers; Emission Scenario Documents; Safety of Manufactured Nanomaterials;** and **Adverse Outcome Pathways.** More information about the Environment, Health and Safety Programme and EHS publications is available on the OECD's World Wide Web site (https://www.oecd.org/en/topics/chemical-safety-and-biosafety.html).

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 second publication from the project, collating responses to the questionnaire distributed to the WP-HROB and the WP-SNFF from December 2024 to March 2025. This was the first time that the WP-SNFF responded to the questionnaire. The document offers valuable insights into the regulatory landscape surrounding NBT approvals and registrations across jurisdictions.

The report is updated annually. 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 endorsed this document, which is published under the responsibility of the Chemicals and Biotechnology Committee of the OECD.

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Argentina

Date of report: 26/02/2025

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them

Agreement between Argentina and Brazil on biosafety:

Memorandum of understanding between the regulatory agencies of Argentina (CONABIA) and Brazil (CTNBIO) for cooperation in biosafety of products derived from modern biotechnology. Signed on 20th October of 2022 by the Ministry of Science and Technology of Brazil and the Ministry of Economy of Argentina. Under this agreement Argentina and Brazil are committed to start working together and to build the necessary mechanisms and procedures for the joint evaluation and authorisations of products of agricultural biotechnology. The analysis and status determination of NBTs products are included in this Agreement.

Agreement between Argentina, Brazil, Paraguay and Uruguay on biosafety:

On June 12, 2024, Argentina, Brazil, Paraguay and Uruguay signed a memorandum for the creation of the International Biosafety Network (ABRE-Bio, Biosafety Agencies Network for Biotechnology).

The main objective of the memorandum is to promote the exchange of scientific information and cooperation in the risk assessment and regulation of genetically modified organisms (GMOs) as well as products derived from new breeding techniques (NBT).

In addition, the countries are committed to working on common procedures for biosafety assessment, seeking to reduce costs and time, as well as harmonize regulations with the specific legislation of each country.The agreement also aims to promote innovation in the agriculture, livestock, fishing and agroindustry sectors through collaboration between public and private institutions.

Each country has designated institutions responsible for carrying out the activities derived from the agreement. In Argentina, the Coordination of Innovation and Biotechnology and the National Advisory Commission on Agricultural Biotechnology (CONABIA) will be in charge of these tasks.

The agreement has an initial validity of five years and can be automatically renewed for additional periods, which ensures a long-term commitment from the parties involved. In addition, the possibility of incorporating new institutions and countries is foreseen, which would further expand the scope and effectiveness of this collaboration.

Item 1-1. General overview on regulatory framework

Since 2015, Argentina has had robust normatives 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 NBTs. The characteristics of NBT normatives 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 normatives 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.

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 analyzed by the National Advisory Commission on Agricultural Biotechnology (CONABIA) in a procedure called Prior Consultation Instance (PCI), as indicated in the normative/resolution N°21/2021, of the former Ministry of Agriculture, Livestock and Fisheries of Argentina.

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

It is analyzed if the product contains a New Combination of Genetic Material (2). If it does, it is considered GMO 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 normative 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

For more information, follow the link below

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

Item 1-1-1. Environmental release

Covered by Argentinian normatives 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

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.

Total PCIs evaluated: 169

Types of PCIs submitted:

1. According to organism:
- plant: 125
- animal: 21
- microorganisms: 23

2. Type of product:
- Final: 114
- In design stage: 44
- En evaluación: 11

3. Type of applicant entity:
- Public: 33
- Private: 133
- Mixed: 3

4. Type of development:
- National: 69
- Foreign: 100

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

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
“Biotecnología y CRISPR en el Ámbito Agropecuario, avances en la Edición Génica y la Propiedad Intelectual”	https://issuu.com/universidadsancarlosusc/docs/boletin_informativo_2024_-_diciembr_12b3a5efc807f3?fr=sM2YwZjgxNTEyODE

Australia

Date of report: 7 March 2025

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them

Item 1-1. General overview on regulatory framework

Genetically modified organisms (GMOs) are regulated under the *Gene Technology Act 2000* (GT Act). Regulatory scope is set by definitions in the GT Act of 'gene technology' and 'GMO'. The GT Act is administered by the Gene Technology Regulator, supported by the Office of the Gene Technology Regulator (OGTR). Some exclusions and inclusions of regulatory scope are provided in the Gene Technology Regulations 2001 (GT Regulations), specifically: Schedule 1A Techniques that are not gene technology; Schedule 1B Organisms that are GMOs; and Schedule 1 Organisms that are not GMOs .

Genetically modified (GM) foods are regulated under Standard 1.5.2 – Food produced using Gene Technology of the *Australia New Zealand Food Standards* Code (the Code), which is a joint standard with New Zealand. Food Standards Australia New Zealand (FSANZ) is an Australian Government agency responsible for administering the Code. This includes undertaking pre-market safety assessment of GM foods and listing approved GM foods in Schedule 26 of the Code.

Item 1-1-1. Environmental release (GMOs)

A description of exclusions from regulation is on the OGTR website – An Overview – status of organisms modified using gene editing and other new technologies (updated February 2025). Note that the regulation of GMOs in Australia also includes work undertaken in physical containment.

The regulatory status of organisms modified by 'new breeding techniques' is determined by the definitions in the GT Act and GT Regulations. The categorization of techniques of Lusser et al. 2011 and Broothaerts et al. 2021 are not adopted in legislation.

The regulatory status of organisms generated through **site directed nuclease techniques** (SDN) is dealt with in Schedules 1 and 1B. Organisms developed through SDN-1 techniques (no template added to guide repair) are not GMOs (Schedule 1, Item 4, see Table 1).

Organisms developed with SDN-2 and SDN-3 techniques (where a template for guided repair is added) and oligo-directed mutagenesis are GMOs (Schedule 1B). Under the current definitions organisms developed with base editing or prime editing methods are regulated as GMOs.

Table 1 **Regulatory status** of organisms with **SDN-1** modifications, by method of SDN application

	SDN protein applied (with or without guide RNA)	SDN expressed from a transgene that is only transiently present in the organism	SDN expressed from transgene integrated in the genome
Status of the initial organisms modified by **SDN-1**	**Not a GMO** (Schedule 1 item 4)	**GMO** while transgene or its expressed products are present **Not a GMO** when transgene and expressed products have degraded (Schedule 1 items 4 & 10)	**GMO**
Status of the offspring inheriting the **SDN-1** modification	**Not a GMO** (Schedule 1 item 9(a))	**Not a GMO** (Schedule 1 item 9(b))	**GMO** if SDN transgene also inherited **Not a GMO** if no SDN transgene inherited (Schedule 1 item 9(b))
In each example the status depends on: • no template being supplied to guide genome repair through homology directed recombination • the organism having no other modifications as a result of gene technology			

Changes to the GT Regulations were made in February 2025 through the Gene Technology Amendment (Minor Measures) Regulations 2025, including to Schedules 1 an 1A. Rationale for these changes is provided in the Explanatory Statement.

Amendment of Schedule 1 item 10 clarifies that organisms that were modified by gene technology but which only have epigenetic changes remaining are not GMOs. (Epigenetic modifications are discussed in the papers of Lusser and Broothaerts.)

Schedule 1A item 1 was expanded to specify that transfer of nuclei (whether or not from somatic cells), plastids and mitochondria are not gene technology if they do not involve genetically modified material. This applies to transfer between cells of the same species and of different species.

Schedule 1A item 11 was amended to address a broader set of techniques involving introduction of nucleic acids to an organism. Amended item 11 provides that introduction of nucleic acid or nucleic acid analogue into an organism is not gene technology if all of the following apply:

- it does not result in an alteration of the organism's genome sequence, and
- it cannot give rise to an infectious agent, and
- in the case of introduced DNA, the DNA cannot be transcribed.

Amended item 11 provides that introducing antisense oligonucleotides to an organism to modulate endogenous gene expression is not gene technology, provided the criteria above are met.

Item 1-1-2. Food and feed

Proposal P1055 – definitions for gene technology and new breeding techniques

Proposal P1055 intends to change the definitions for GM food in the Code. These definitions determine what foods require pre-market safety assessment and approval as GM foods. Such changes are necessary to clarify what foods are GM foods for Code purposes given the emergence of new breeding techniques (NBTs).

FSANZ commenced work on proposal P1055 in 2020. Between July-September 2024, FSANZ undertook final round of public consultation on proposed changes. It was proposed to redefine GM food to mean food from an organism (or cells) that contains novel DNA as an outcome of the genetic modification process. This differs from the current process-based definition which is based on the use of gene technology irrespective of the outcome.

Under the new definition certain NBT foods will be excluded from pre-market safety assessment and approval as GM food under the Code. For example, food from genome editing will only be GM food for Code purposes if the editing process results in the insertion of novel DNA into the genome of the organism from which the food is derived. Such exclusions were informed by an extensive scientific assessment by FSANZ. It concluded that certain NBT food has the same low risk as conventional food because many of the genetic changes introduced using NBTs are indistinguishable from conventional breeding.

Under the proposed new definition, GM foods will continue to require pre-market safety assessment and approval as GM foods, and be subject to GM labelling requirements in the Code. FSANZ has not proposed any changes to GM labelling under P1055.

The proposal is flagged for completion by Q3 2025.

The full set of publicly available documents are available from the FSANZ website at:

https://www.foodstandards.gov.au/food-standards-code/proposals/p1055-definitions-for-gene-technology-and-new-breeding-techniques

Item 1-2. Other regulatory aspects

NA

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

Item 2-1. For environmental release

N/A – Please see response to Item 1-1-1. Note also that there is no requirement for notification to OGTR of work with organisms not regulated as GMOs.

Item 2-2. For food and feed

N/A – Please see response to Item 1-1-2.

Item 2-3. Other products

Item 3: Other information

N/A – Please see response to Item 1.

Austria

Date of report: 11.4.2025

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them

Item 1-1. General overview on regulatory framework

For the general background see the response of the European Commission to this item.

As regards the Austrian position to the proposal of the European Commission the following can be reported:

Subsequent to the Austrian general elections (Nationalratswahlen 2024) held in September 2024 the newly elected government, which is based on a coalition of three parties (Österreichische Volkspartei, Sozialdemokratische Partei Österreich, NEOS), published their joint strategy for the years 2025-2029 (in German language, Regierungsprogramm.Österreich 2025-2029).

Regarding the proposal of the European Commission on a new regulation of NGT plants which is being discussed since July 2023 the government programme states the following:
The Austrian Federal government is working at the European level to ensure that products developed with new genomic techniques (NGTs) undergo a risk assessment and an authorisation procedure and that labelling and traceability are guaranteed, in particular to ensure coexistence (e.g. with organic production).

Based upon the outcome of the further discussions between the Council of the European Union, the EU Parliament and the European Commission and pending an adoption of a NGT-Regulation at the EU-level Austria may amend her current national regulatory framework accordingly. In the meantime, NGT plants and -products continue to be regulated under the current legislation on GMOs, i.e., the Austrian Gene Technology Law (RIS - Gentechnikgesetz - Bundesrecht konsolidiert, Fassung vom 18.04.2023) and its supplementary regulations.

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

Austrian delegates are participating in the work of a recently established subgroup of the EFSA scientific network on GMOs. This NGT subgroup will hold its 2nd meeting in May 2025, ahead of the 19th meeting EFSA Scientific Network for Risk Assessment of GMOs scheduled to be held in June 2025.

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

Item 2-1. For environmental release

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

Item 2-2. For food and feed

See response of the European Commission regarding notifications for foot and feed products regulated at the EU level.

Item 2-3. Other products

None.

Item 3: Other information

Title/Summary of the contents	Source (URL, doi, date accessed etc.,)
Eckerstorfer, M.F.; Dolezel, M.; Miklau, M.; Greiter, A.; Heissenberger, A.; Kastenhofer, K.; Schulz, F.; Hagen, K.; Otto, M.; Engelhard, M. Environmental Applications of GM Microorganisms: Tiny Critters Posing Huge Challenges for Risk Assessment and Governance. Int. J. Mol. Sci. 2025, 26, 3174.	https://doi.org/10.3390/ijms26073174
Miklau, M.; Burn S.-J.; Eckerstorfer, M.; Dolezel, M.; Greiter, A.; Heissenberger, A.; Hörtenhuber S.; Zollitsch, W.; Hagen, K. Horizon scanning of potential environmental applications of terrestrial animals, fish, algae and microorganisms produced by genetic modification, including the use of new genomic techniques. Frontiers in Genome Editing 2024.	https://doi.org/10.3389/fgeed.2024.1376927
Dolezel, M.; Lang, A.; Greiter, A.; Miklau, M.; Eckerstorfer, M.; Heissenberger, A. (2024). Genome Editing — Neue Anforderungen an das Monitoring von Umweltwirkungen. BfN-Schriften 711.	https://doi.org/10.19217/skr711
Dolezel, M.; Lang, A.; Greiter, A.; Miklau, M.; Eckerstorfer, M.; Heissenberger, A.; Willée, E.; Züghart, W. Challenges for the Post-Market Environmental Monitoring in the European Union Imposed by Novel Applications of Genetically Modified and Genome-Edited Organisms. BioTech 2024, 13(2), 14.	https://doi.org/10.3390/biotech13020014

Campa, M., Miranda, S., Licciardello, C., Lashbrooke, J. G., Dalla Costa, L., Guan, Q., et al. (2023). Application of new breeding techniques in fruit trees. Plant Physiol, kiad374.	https://doi.org/10.1093/plphys/kiad374

Belgium

Date of report: 3 March 2025

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them

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

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

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

Item 3: Other information

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

Brazil

Date of report: March 2025

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them

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

The CTNBio (National Biosafety Technical Commission) Normative Resolution No 16, of January 15th, 2018 (http://ctnbio.mctic.gov.br/resolucoes-normativas) is applicable to all types of organisms and establishes a consultation system, on a case-by-case basis, for products obtained from Innovative Precision Breeding Techniques (in portuguese, TIMP - "Técnicas Inovadoras de Melhoramento de Precisão") defined as a set of new methodologies and approaches that differ from the genetic engineering strategy by transgenics, as they result in the absence of recombinant DNA/RNA in the final product. According with the Normative, the product will not be considered a GMO if it meets one of the criteria:

i) Product with proven absence of recombinant DNA/RNA, obtained by a technique that uses GMO as parental;

ii) Product obtained by a technique that uses DNA/RNA that will not multiply in a living cell;

iii) Product obtained by a technique that introduces site-directed mutations, generating gain or loss of gene function, with the proven absence of recombinant DNA/RNA in the product;

iv) Product obtained by a technique where there is expression, temporarily or permanently, of recombinant DNA/RNA molecules, without the presence or introgression of these molecules in the product; and

v) Product where techniques are used that employ DNA/RNA molecules that, whether absorbed or not in a systemic way, do not cause permanent modification of the genome.

Developers must submit detailed information about the original organism, the characteristics of the trait, methods used to generate it, and molecular analysis to CTNBio. If a product is classified as conventional under the established criteria, it can be registered using existing procedures without undergoing full biosafety assessments required for GMOs, according with he biosafety Law No. 11.105/2005 (http://www.planalto.gov.br/cciviL_03////_Ato2004-2006/2005/Lei/L11105.htm).

Item 1-1-1. Environmental release

CTNBio Normative Resolution No. 16 published on January 15th, 2018.

Item 1-1-2. Food and feed

CTNBio Normative Resolution No. 16 published on January 15th, 2018.

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

Item 2-1. For environmental release

Link to the complete list of organisms notified to the CTNBio (National Biosafety Technical Commission):

http://ctnbio.mctic.gov.br/tecnologias-inovadoras-de-melhoramento-genetico-rn16-

Item 2-2. For food and feed

Link to the complete list of organisms notified to the CTNBio (National Biosafety Technical Commission):

http://ctnbio.mctic.gov.br/tecnologias-inovadoras-de-melhoramento-genetico-rn16-

Item 2-3. Other products

Link to the complete list of organisms notified to the CTNBio (National Biosafety Technical Commission):

http://ctnbio.mctic.gov.br/tecnologias-inovadoras-de-melhoramento-genetico-rn16-

Canada

Date of report: January 23, 2025

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them

Item 1-1. General overview on regulatory framework

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.

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.

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 measurable 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.

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. 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.

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.

Guidance related to the regulation of NBTs for feed use

On May 3, 2024, the Canadian Food Inspection Agency (CFIA) introduced updated guidance to clarify when plant-derived feed ingredients require pre-market evaluation under the Feeds Act and Feeds Regulations. This guidance focuses on determining the novelty of ingredients derived through plant breeding techniques, including gene editing, and supplements existing guidance on assessing novel feeds from plant sources.

The guidance specifies that plant-derived feed ingredients are considered novel if they meet the regulatory definitions of a novel feed or contain a novel trait. Novelty is assessed based on the following criteria:

- Whether the ingredient is listed in Schedules IV or V of the Feeds Regulations.
- Whether the ingredient has been modified in a way that significantly alters its composition, purpose, manufacturing process, or usage rate compared to conventional ingredients.

Feed ingredients with novel traits; such as those containing foreign DNA, altered nutrient levels, or new secondary metabolites require a pre-market evaluation to determine their safety and efficacy. This evaluation ensures that the feed is safe for livestock, humans (via the potential transfer of residues to meat, milk, and eggs), and the environment.

CFIA expects proponents of feed ingredients, whether novel or non-novel, to engage in mechanisms promoting transparency, such as industry-led databases or government initiatives like Health Canada's Transparency Initiative. This approach helps ensure producers and consumers benefit from innovative feed products while maintaining the safety and integrity of Canada's feed regulatory framework.

The guidance on determining when a plant-derived ingredient requires a feed pre-market evaluation, including the novelty interpretation of products of plant breeding, is available on the CFIA website.

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.

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.

Notices of Submission

When a submission is made for pre-market assessment of a novel plant product, developers may voluntarily agree to the publication of a notice of submission before a pre-market assessment is concluded. This notice provides summary information about novel plant products they have submitted to the CFIA for assessment for:

- unconfined environmental release
- use as livestock feed

Regardless of if a developer participates in the notices of submission process, following a pre-market assessment, the CFIA updates a database of authorized plant products of biotechnology and related decision documents.

CFIA Decision Documents

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.

Health Canada Decision Documents

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

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

Item 2-1. For environmental release

In May 2023, 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.

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

Item 2-2. For food and feed

Food

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.

Health Canada maintains a list of Completed safety assessments of novel foods including genetically modified (GM) foods. This list includes novel gene-edited plant products that have undergone mandatory pre-market safety assessment and determined to be safe for food use.

Feed

While the CFIA does not publish a feed-specific list, it expects proponents of feed ingredients, whether novel or non-novel, to engage in mechanisms that promote transparency. These mechanisms may include participation in government-led initiatives such as Health Canada's Transparency Initiative or industry-led databases, and the Canadian Variety Transparency Database. Transparency efforts ensure producers and consumers benefit from innovative feed products while upholding the safety and integrity of Canada’s regulatory framework for feed.

Item 2-3. Other products

N/A

Croatia

Date of report: 3rd June 2025

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them

As a member state of the European Union (EU), the Republic of Croatia (Croatia) 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 Croatia. For this item, additionaly we refer to the answer of the European Commission and the following link: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en

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

There has been no change since the previous reporting period as no field trials with NBT plants were authorised in the Republic of Croatia. And for this item, additionally we refer to the answer of the European Commission.

Item 3: Other information

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

Czechia

Date of report: 7 March 2025

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them

Item 1-1. General overview on regulatory framework

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

There has been no change since the previous reporting period as no field trials with NBT plants were authorised in the Czech Republic. However, in January 2025, the Ministry of the Environment received an application submitted by the Institute of Experimental Botany of the Czech Academy of Science for the authorisation of deliberate release into the environment of spring barley lines with edited PIL1 gene using CRISPR/Cas9. The PIL1 gene, which regulates the expression of several genes involved in cell wall expansion, such as expansins, thereby participating in the regulation of plant growth, was the focus of this application. The objective of the small-scale field trial is to evaluate the consistency of the mutant phenotype under field conditions. The application for the field trial is currently under review and is being administered in accordance with Act 78/2004 Coll. on the Use of Genetically Modified Organisms and Genetic Products, as amended. The anticipated approval is expected to be issued in time for the forthcoming growing season.

Item 1-1-2. Food and feed

There has been no alteration in the circumstances since the preceding reporting period. For further information, please refer to the response to this questionnaire submitted by the European Commission.

Item 1-2. Other regulatory aspects

There has been no alteration in the circumstances since the preceding reporting period. For further information, please refer to the response to this questionnaire submitted by the European Commission.

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

Item 2-1. For environmental release

There has been no alteration in the circumstances since the preceding reporting period. For further information, please refer to the response to this questionnaire submitted by the European Commission.

Item 2-2. For food and feed

There has been no alteration in the circumstances since the preceding reporting period. For further information, please refer to the response to this questionnaire submitted by the European Commission.

Item 2-3. Other products

There has been no alteration in the circumstances since the preceding reporting period. For further information, please

Denmark

Date of report: 26 February 2024

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them

Item 1-1. General overview on regulatory framework

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 and one in 2024. 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 CRISPR. The aim was to modify starch composition or increase resistance to late blight, respectively.

In 2025, the competent authority for environmental release of GMOs (The Danish Agricultural and Fisheries Agency) has received two applications for additional experimental releases 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.

Item 2-3. Other products

No other products are approved.

Item 3: Other information

Please refer to the reply from the European Commission.

France

Date of report: 20 March 2025

[English version follows]

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them

Item 1-1. General overview on regulatory framework

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

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

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 version]

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them

Item 1-1. General overview on regulatory framework

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

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

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

Date of report: 11 March 2025

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them

Item 1-1. General overview on regulatory framework

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

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.

Italy

Date of report: 04/03/2025

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them

Item 1-1. General overview on regulatory framework

Item 1-1-1. Environmental release

In the European Union (EU) the regulation of NBTs and their products is still under discussion and Italy as member state of the EU is actively involved in this discussion. For further information see the contribution of the European Commission and the link.

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

Item 2-1. For environmental release

No environmental releases of organisms developed through NBTs, as defined by Lusser et al., 2011 and Broothaerts et al. 2021, have been approved or registered in Italy for commercial purposes.

Field trials of plants obtained by using CRISPR-Cas9 technique have been authorized under legislative decree N° 224 of 8th July 2003 implementing directive 2001/18 (EC) and Decree No. 39 of April 14, 2023, converted with amendments by Law No. 68 of June 13, 2023 and Law No. 101 of July 12, 2024 (Article 9bis).

Link to the National Competent Authority for the environmental release of GMOs website https://bch.mase.gov.it/index.php/it/?view=article&id=435&catid=15

Some information on field trials:

Notification Number B/IT/24/04

Grapevine (*Vitis vinifera* L.) plants modified, through DNA free CRISPR/Cas9 system, to improve the resistance to the etiological agent of downy mildew: the oomycete *Plasmopara viticola* (Peronospora). Inactivation of two genes (DMR6-1 and DMR6-2) by site-directed and specific point-mutations.

Notification Number B/IT/24/03

Grapevine (*Vitis vinifera* L.) plants modified, through DNA free CRISPR/Cas9 system, to improve the resistance to the etiological agent of downy mildew: the oomycete *Plasmopara viticola* (Peronospora). Inactivation of DMR6-1 gene by site-directed and specific point-mutations.

Notification Number B/IT/24/02

Tomato (*Solanum lycopersicum* L.) plants modified, through CRISPR/Cas9 system, to improve resistance to broomrape (*Orobanche* spp.). Inactivation of D27 and CCD7 genes encoding for the first two genes of the strigolactones (SLs) biosynthesis pathway.

Notification Number B/IT/24/01

Rice (*Oryza sativa*) plants modified, through CRISPR/Cas9 system, to improve resistance to blast (*Pyricularia oryzae).* Inactivation of Pi21 and HMA1, HMA2 genes that are involved in susceptibility to blast.

Item 2-2. For food and feed

No food and feed developed through NBTs, as defined by Lusser et al., 2011 and Broothaerts et al. 2021, have been approved or registered in Italy for commercial purposes.

Item 2-3. Other products

Several organisms obtained by NBTs, as defined by Lusser et al., 2011 and Broothaerts et al. 2021, have been authorized for contained use for research purposes, clinical trials and few for commercial purposes.

Japan

Date of report: 15 January 2025

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them

Item 1-1. General overview on regulatory framework

In February 2019, the Ministry of Environment (MOE), the lead ministry among the six relevant authorities[1] 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.

[1] 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 procedures are available at:

https://www.maff.go.jp/j/syouan/nouan/carta/tetuduki/attach/pdf/nbt_tetuzuki-22.pdf

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

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).

http://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
National Agriculture and Food Research Organization	Tomato with extended shelf life, modified with a ripening-related transcription factor	23 Oct. 2024
National Agriculture and Food Research Organization	Barley modified with the seed storage protein produced by genome editing technology	23 Oct. 2024

The University of Tokyo	A group of rice mutants in the genes regulating flowering time, circadian rhythm and stress resistance by genome editing technology	21 Jun. 2024
National Agriculture and Food Research Organization	Rice mutants in the genes regulating sink capacity, source ability, and metabolism of sugar and starch by genome editing	9 May. 2024
Osaka University	Potatoes with low contents of steroidal glycoalkaloids	23 Apr. 2024
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 and high tuber set potato (JA36) notified in Oct 2024 by J.R. Simplot Company.

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.	Fast growth flounder	Dec. 2023	Dec. 2023

Item 3: Other 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 January 2025*

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 January 2025*

- 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://doi.org/10.1038/s41477-021-00954-6 Date accessed, 31 January 2025*
Nakazato I. et al. (2021) Targeted base editing in the mitochondrial genome of Arabidopsis thaliana, PNAS, 119 (20) e2121177119	*https://doi.org/10.1073/pnas.2121177119 Date accessed, 31 January 2025*
Kuwabara C. et al. (2024) A DNA-free and genotype-independent CRISPR/Cas9 system in soybean, Plant Physiology, Volume 196, Issue 4, 2320–2329	*https://doi.org/10.1093/plphys/kiae491 Date accessed, 31 January 2025*
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://doi.org/10.1371/journal.pone.0281767 Date accessed, 31 January 2025*

- 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

Date of report: 2025.3.21

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them

Item 1-2. Other regulatory aspects

A bill was proposed in September 2024, centered on distinguishing organisms developed through genome editing from conventional LMOs and exempting them from related regulations, provided that they demonstrate a level of safety equivalent to that of traditional breeding or naturally occurring mutations.

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.

Lithuania

Date of report: 07-03-2025

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them

Item 1-1. General overview on regulatory framework

No new or amended legislation related to NBTs was introduced or implemented at national level during this reporting period. As a Member State of the European Union, Lithuania's legislation governing the NBTs is in line with EU regulations in this respect. Please see the contribution of the European Commission.

Item 1-1-1. Environmental release

No environmental release of NBTs in the Republic of Lithuania. Please see the contribution of the European Commission.

Item 1-1-2. Food and feed

Please see the contribution of the European Commission.

Item 1-2. Other regulatory aspects

Please see the contribution of the European Commission.

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

Item 2-1. For environmental release

Please see the contribution of the European Commission.

Item 2-2. For food and feed

Please see the contribution of the European Commission.

Item 2-3. Other products

Please see the contribution of the European Commission.

Item 3: Other information

Please see the contribution of the European Commission.

Netherlands

Date of report: 7 March 2025

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them

Item 1-1. General overview on regulatory framework

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 and The Netherlands is actively involved in this process with the aim to achieve agreement between EU Member States and Commission on the new proposal. For more details on this see also the contribution of the European Commission.

Occasionally, the Dutch authorities still receive questions from developers related to the regulatory status of gene edited organisms. In such cases we refer them to current legislative process in the EU.

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

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

Date of report: 13 February 2025

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them

Item 1-1. General overview on regulatory framework

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

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

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

Title/Summary of the contents	Source (URL, doi, date accessed etc.,)
Megan Ceris Matthews, Jos van der Linden, Isabelle Robène, Samuel Rozsasi, Beatrix Coetzee, Manuela Campa, Johan Burger, Uzoma Nobel Akwuruoha, Ndubuisi Johnkennedy Madufor, Willem Perold, Umezuruike Linus Opara, Altus Viljoen and Diane Mostert (2025). A combined recombinase polymerase amplification CRISPR/ Cas12a assay for detection of *Fusarium oxysporum* f. sp. *cubense* tropical race 4. *Scientific Reports* **15**: 2436	https://doi.org/10.1038/s41598-025-85633-8
Abkallo, H.M., Arbuthnot, P., Auer, T.O. et al. Making genome editing a success story in Africa. *Nat Biotechnol* **42**, 551–554 (2024)	https://doi.org/10.1038/s41587-024-02187-2

Spain

Date of report: 07_03_2025

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them

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

In the EU, NBT 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, Regulation (EC) No 1946/2003). 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 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 sustainable use of the EU's natural resources, resilient EU food systems and farming as well as long-term economic, social, health and environmental benefits.

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'). Transgenic plants are not included in the scope of the proposal. More detail on the content of the proposal can be found following the above link to the legislative proposal or in the European Commission's contribution to the 2024 questionnaire

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. The legislative procedure is on-going. 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.

In Spain, a specific section has been created on the website of the Ministry of Agriculture, Fisheries and Food that contains information on NGTs, the current regulation framework and about the ongoing review process of the European legal framework mentioned above. The page is available through the following link: https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/mejora-genetica/

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

Currently, in Spain there is no product developed through NBT approved or registered. These techniques are only used in basic research activities, which are subject to the European and national regulatory framework relating to activities with genetically modified organisms.

United States of America

Date of report: 05/01/2025

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them

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

U.S. Department of Agriculture

Not subject to regulations under 7 CFR 340 (2019)

If an organism does not meet the regulatory definition of "regulated article," it is not subject to APHIS' biotechnology regulations. For example, a genome edited organism (e.g., plant, microbe, insect) that is not a plant pest or likely to be a plant pest is not subject to 7 CFR part 340 (2019), unless the organism retains DNA sourced from a plant pest. Similarly, a transgenic organism that is not a plant pest and not likely to be a plant pest, and does not contain DNA sourced from a plant pest is not subject to 7 CFR part 340 (2019). Developers may voluntarily seek a letter confirming that an organism is not subject to regulation by submitting an Am I Regulated inquiry.

Exemptions under 7 CFR 340 (2020)

Prior to December 2, 2024 USDA-APHIS biotechnology regulations exempted 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 did not apply to plants that had been modified such that they contain either a single modification of a type listed below:

(b)(1): A change resulting from cellular repair of a targeted DNA break in the absence of an externally provided repair template

(b)(2): A targeted single base pair substitution

(b)(3): A gene known to occur in the plant's gene pool, or a change 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

(AM1): An indel or contiguous deletion of any size, made at a targeted location, with or without

insertion of DNA if generated without using a repair template, or without insertion of DNA if generated using a repair template

(AM2): A plant with up to twelve (12) modifications, made simultaneously or sequentially, if each modification individually qualifies for exemption and occurs in a different gene

(c): A plant-trait-mechanism of action combination that has been previously reviewed for risks to plant health and determined by APHIS not to be regulated under this part, either via the Regulatory Status Review process or a petition submitted pursuant to the legacy part 340 regulations.

Additionally, USDA-APHIS biotechnology regulations did not apply to plants with plant-trait-mechanism of action combinations that USDA-APHIS previously reviewed and found not subject to the regulations.

Regulatory Status Review (RSR) under 7 CFR 340 (2020)

Prior to Dec 2, 2024, USDA-APHIS biotechnology regulations provided developers with the option of requesting an RSR for plants developed using genetic engineering that were not otherwise exempt from regulation. We evaluated whether a plant was subject to regulation based on the characteristics of the plant itself and not on the method used to modify the plant.

Environmental Protection Agency

In May 2023, the U.S. Environmental Protection Agency (EPA) released a final rule exempting two categories of plant-incorporated protectants (PIPs) created using genetic engineering from registration requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and from the food or feed residue tolerance requirements under the Federal Food, Drug, and Cosmetic Act (FFDCA).

The final rule reflects the biotechnological advances made since 2001, when the Agency first exempted PIPs derived through conventional breeding from FIFRA registration and FFDCA tolerance requirements, but did not at that time exempt PIPs created through biotechnology.

Specifically, the final rule exempts PIPs derived through genetic engineering from FIFRA pesticide registration and FFDCA pesticide tolerance requirements in cases in which the PIPs are essentially equivalent to those exempted by the 2001 rule.

The rule contains conditions for exempting:

1) PIPs in which genetic engineering has been used to insert a gene from a sexually compatible plant or to modify a gene to match a gene found in a sexually compatible plant. This category of PIPs requires EPA confirmation of eligibility for the exemption.; and
2) Loss-of-function (LoF) PIPs, in which a gene is modified through genetic engineering to reduce or eliminate the activity of that gene. The loss of the activity of that gene then results in the pesticidal effect. For this category of PIP, biotechnology developers can make a self-determination that their PIP meets the exemption criteria, which requires notification but no EPA review, or request EPA confirmation of eligibility for the exemption.

EPA also indicated in the preamble to the rule that EPA would consider exempting additional categories of PIPs from both FIFRA registration and FFDCA tolerance requirements and expanding the categories of PIPs that are allowed the option to self determine and do not require EPA confirmation of eligibility for the exemption.

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

Item 1-1-2. Food and feed

Environmental Protection Agency

See description under Item 1-1-1. Environmental release. EPA is responsible for both environmental release and the food and feed safety of PIPs.

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

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

Item 2-1. For environmental release

U.S. Department of Agriculture

Not subject to regulations under 7 CFR 340 (2019)

Since the re-initiation of the AIR process in 2025, APHIS has confirmed that 32 genome edited organisms are not regulated out of 35 responses as of May 1.

Weblink for table of Am I Regulated inquiries:
https://www.aphis.usda.gov/biotechnology/regulated-article-inquiry

Exemptions under 7 CFR 340 (2020)

APHIS confirmed that 90 genome edited plants were exempt from regulation from 2020-2024 out of 99 responses issued.

Weblink for guidance for requesting a confirmation or exemption from regulation under 7 CFR part 340:
https://www.aphis.usda.gov/brs/pdf/requesting-confirmation-of-exemption.pdf

Regulatory Status Review (RSR) under 7 CFR 340 (2020)

Prior to December 2024, USDA-APHIS issued responses for 38 genome edited plants out of 84 RSR letters issued.

Weblink for table of approved RSRs:
https://www.aphis.usda.gov/biotech-regulatory-status/regulatory-status-review-table

Environmental Protection Agency

- EPA had finalized a rule exempting Plant-Incorporated Protectants Created via Biotechnology that Could have Otherwise Been Created through Conventional Breeding in May 2023, https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/pesticides-exemptions-certain-plant-incorporated-0
    - EPA has since exempted 6 PIPs under this rule. 3 in citrus and 3 in potato.
- The EPA regulates pesticides to protect human health and the environment, including setting tolerances for pesticide residues in food and feed. Over the past calendar year, EPA registered 9 new plant-incorporated protectant active ingredients in corn. EPA also issued experimental use

permits (i.e., field trails) for 3 plant-incorporated protectant active ingredients in corn and 1 plant-incorporated protectant active ingredient in potato.

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

Item 2-2. For food and feed

Environmental Protection Agency

- See description under Item 2-1. For environmental release. EPA is responsible for both environmental release and the food and feed safety of PIPs.

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

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

European Union

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

Date of report: 1 March 2025

Item 1. Development/amendment of regional/national/local regulations on NBTs and products derived from them

Item 1-1. General overview on regulatory framework

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, Regulation (EC) No 1946/2003). 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 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 sustainable use of the EU's natural resources, resilient EU food systems and farming as well as long-term economic, social, health and environmental benefits.

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'). Transgenic plants are not included in the scope of the proposal. More detail on the content of the proposal can be found following the above link to the legislative proposal or in the European Commission’s contribution to the 2024 questionnaire

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. The legislative procedure is on-going. 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

Item 2-1. For environmental release

None.

Item 2-2. For food and feed

On 17 January 2024, the European Food Safety Authority (EFSA) 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). 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 (therefore not falling under the scope of the legislative proposal on plants obtained by certain NGTs). More info on GM maize DP-915635. An authorisation decision was adopted on 2 July 2024.

On 1 August 2024, EFSA issued a favourable scientific opinion for placing on the market of genetically modified maize DP910521 produced by NBT for food and feed uses (Application GMFF-2021-2473). 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 a CRISPR-Cas9-mediated targeted insertion process of a “landing pad” sequence followed by microprojectile co-bombardment. It is a transgenic plant (therefore not falling under the scope of the legislative proposal on plants obtained by certain NGTs). The regulatory approval procedure is ongoing for this product. More info on GM maize DP910521.

Item 2-3. Other products

None.

Item 3: Other information

Title/Summary of the contents	Source (URL, doi, date accessed etc.,)
Scientific Opinion "New developments in biotechnology applied to microorganisms"	Mandate info on OpenEFSA portal First output – Horizon scanning Scientific Opinion "New developments in biotechnology applied to microorganisms"
Mandate to EFSA on new developments in biotechnology applied to animals (including synthetic biology and new genomic techniques)	Mandate info on OpenEFSA portal First output – Knowledge gathering Draft scientific opinion published for public consultation (open until 19/03/2025)
Mandate to EFSA for a regular horizon scanning to	Mandate info on OpenEFSA portal

assess new scientific data on plants, animals, microorganisms and products thereof obtained by new genomic techniques.	

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

Annex. 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.

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[1] and Broothaerts et al., 2021[2] 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:

[1] 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

[2] 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.,)