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CHEMICALS AND BIOTECHNOLOGY COMMITTEE**

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April 2025 – March 2026**

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- [No. 1, Consensus Document on Key Nutrients and Key Toxicants in Low Erucic Acid Rapeseed (Canola) (2001) – REPLACED with revised consensus document No. 24 (2011)]
- [No. 2, Consensus Document on Compositional Considerations for New Varieties of Soybean: Key Food and Feed Nutrients and Anti-nutrients (2001) – REPLACED with revised consensus doc. No. 25 (2012)]
- No. 3, Consensus Document on Compositional Considerations for New Varieties of Sugar Beet: Key Food and Feed Nutrients and Anti-nutrients (2002)
- [No. 4, Consensus Document on Compositional Considerations for New Varieties of Potatoes: Key Food and Feed Nutrients, Anti-nutrients and Toxicants (2002) – REPLACED with revised consensus document No. 33 (2020)]
- No. 5, Report of the OECD Workshop on the Nutritional Assessment of Novel Foods and Feeds, Ottawa, Canada, February 2001 (2002)
- No. 6, Consensus Document on Compositional Considerations for New Varieties of Maize (*Zea mays*): Key Food and Feed Nutrients, Anti-nutrients and Secondary Plant Metabolites (2002)
- No. 7, Consensus Document on Compositional Considerations for New Varieties of Bread Wheat (*Triticum aestivum*): Key Food and Feed Nutrients, Anti-nutrients and Toxicants (2003)
- No. 8, Report on the Questionnaire on Biomarkers, Research on the Safety of Novel Foods and Feasibility of Post-Market Monitoring (2003)
- No. 9, Considerations for the Safety Assessment of Animal Feedstuffs Derived from Genetically Modified Plants (2003)
- [No. 10, [Consensus Document on Compositional Considerations for New Varieties of Rice (*Oryza sativa*): Key Food and Feed Nutrients and Anti-nutrients (2004) REPLACED with revised consensus document No. 28 (2016)]
- No. 11, Consensus Document on Compositional Considerations for New Varieties of Cotton (*Gossypium hirsutum* and *Gossypium barbadense*): Key Food and Feed Nutrients and Anti-nutrients (2004)
- No. 12, Consensus Document on Compositional Considerations for New Varieties of Barley (*Hordeum vulgare* L.): Key Food and Feed Nutrients and Anti-nutrients (2004)
- No. 13, Consensus Document on Compositional Considerations for New Varieties of Alfalfa and Other Temperate Forage Legumes: Key Feed Nutrients, Anti-nutrients and Secondary Plant Metabolites (2005)
- No. 14, An Introduction to the Food/Feed Safety Consensus Documents of the Task Force for the Safety of Novel Foods and Feeds (2006)
- No. 15, Consensus Document on Compositional Considerations for New Varieties of the Cultivated Mushroom *Agaricus bisporus*: Key Food and Feed Nutrients, Anti-nutrients and Toxicants (2007)
- No. 16, Consensus Document on Compositional Considerations for New Varieties of Sunflower: Key Food and Feed Nutrients, Anti-nutrients and Toxicants (2007)
- No. 17, Consensus Document on Compositional Considerations for New Varieties of Tomato: Key Food and Feed Nutrients, Anti-nutrients, Toxicants and Allergens (2008)
- No. 18, Consensus Document on Compositional Considerations for New Varieties of Cassava (*Manihot esculenta* Crantz): Key Food and Feed Nutrients, Anti-nutrients, Toxicants and Allergens (2009)
- No. 19, Consensus Document on Compositional Considerations for New Varieties of Grain Sorghum [*Sorghum bicolor* (L.) Moench]: Key Food and Feed Nutrients and Anti-nutrients (2010)
- No. 20, Consensus Document on Compositional Considerations for New Varieties of Sweet Potato [*Ipomoea batatas* (L.) Lam.]: Key Food and Feed Nutrients, Anti-nutrients, Toxicants and Allergens (2010)
- No. 21, Consensus Document on Compositional Considerations for New Varieties of Papaya (*Carica papaya* L.): Key Food and Feed Nutrients, Anti-nutrients, Toxicants and Allergens (2010)
- No. 22, Consensus Document on Molecular Characterisation of Plants Derived from Modern Biotechnology (2010)
- No. 23, Consensus Document on Compositional Considerations for New Varieties of Sugarcane (*Saccharum* spp. hybrids.): Key Food and Feed Nutrients, Anti-nutrients and Toxicants (2011)

- No. 24, Revised Consensus Document on Compositional Considerations for New Varieties of Low Erucic Acid Rapeseed (Canola): Key Food and Feed Nutrients, Anti-nutrients and Toxicants (2011)
- No. 25, Revised Consensus Document on Compositional Considerations for New Varieties of Soybean [*Glycine max* (L.) Merr.]: Key Food and Feed Nutrients, Anti-nutrients, Toxicants and Allergens (2012)
- No. 26, Consensus Document on Compositional Considerations for New Varieties of Oyster Mushroom (*Pleurotus ostreatus*): Key Food and Feed Nutrients, Anti-nutrients and Toxicants (2013)
- No. 27, Consensus Document on Compositional Considerations for New Varieties of Common Bean (*Phaseolus vulgaris* L.): Key Food and Feed Nutrients, Anti-nutrients and Other Constituents (2015)
- No. 28, Revised Consensus Document on Compositional Considerations for New Varieties of Rice (*Oryza sativa*): Key Food and Feed Nutrients, Anti-nutrients and Other Constituents (2016)
- No. 29, High-throughput DNA Sequencing in the Safety Assessment of Genetically Engineered Plants: Proceedings of the OECD Workshop held in April 2016 (2016)
- No. 30, Consensus Document on Compositional Considerations for New Varieties of Cowpea (*Vigna unguiculata*): Key Food and Feed Nutrients, Anti-nutrients and Other Constituents (2018)
- No. 31, Consensus Document on Compositional Considerations for New Cultivars of Apple (*Malus × domestica* Borkh.): Key Food and Feed Nutrients, Allergens, Toxicants and Other Metabolites (2019)
- No. 32, Developments in Delegations on the Safety Assessment of Novel Foods and Feeds, April 2019 - March 2020 (2020)
- No. 33, Revised Consensus Document on Compositional Considerations for New Varieties of Potato (*Solanum tuberosum*): Key Food and Feed Nutrients, Toxicants, Allergens, Anti-nutrients and Other Plant Metabolites (2020)
- No. 34, Developments in Delegations on the Safety Assessment of Novel Foods and Feeds, April 2020 - March 2021 (2021)
- No. 35, Developments in Delegations on the Safety Assessment of Novel Foods and Feeds, April 2021 - May 2022 (2022)
- No. 36, Developments in Delegations on the Safety Assessment of Novel Foods and Feeds, June 2022 - April 2023 (2023)
- No. 37, Considerations for Collaborative Work on the Safety Assessments of Foods and Feeds Derived from rDNA Plants (2023)
- No. 38, Developments in Delegations on the Safety Assessment of Novel Foods and Feeds, May 2023 – February 2024 (2024)
- No. 39, COLLATION OF THE ANSWERS FOR QUESTIONNAIRE Enhanced Information Exchange on New Breeding Techniques: 2024 Results (2024)
- No. 40, Developments in Delegations on the Safety Assessment of Novel Foods and Feeds, March 2024 – March 2025 (2025)
- No. 41, COLLATION OF THE ANSWERS FOR QUESTIONNAIRE Enhanced Information Exchange on New Breeding Techniques: 2025 Results (2025)

About the OECD

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

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>).

This publication was developed in the IOMC context. The contents do not necessarily reflect the views or stated policies of individual IOMC Participating Organizations.

The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) was established in 1995 following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. The Participating Organisations are FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank, Basel, Rotterdam and Stockholm Conventions and OECD. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organisations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

FOREWORD

The Working Party for the Safety of Novel Foods and Feeds (WP-SNFF) is a subsidiary body of the Chemicals and Biotechnology Committee of the OECD.

The WP-SNFF aims to assist countries in evaluating the potential risks of novel foods and feeds derived from genetically-engineered organisms, foster communication and mutual understanding of relevant regulations in countries, and facilitate harmonisation in risk/safety assessment of products from modern biotechnology. This programme encourages information sharing, promotes harmonised practices and contributes to prevent duplication of efforts among countries, while consolidating high food and feed safety standards. The WP-SNFF's activities and outputs are complementary to those of the Working Party on the Harmonisation of Regulatory Oversight in Biotechnology, which deals with environmental safety (biosafety) of genetically-engineered organisms.

The WP-SNFF main outputs are the science-based consensus documents on compositional considerations, which are mutually acceptable among member countries and partners. These practical tools contain information for use during the regulatory safety assessment of a particular food/feed product. Already covering 22 different crop species, the consensus documents provide key elements on the nutrients, anti-nutrients or toxicants of the considered product, information of its use as a food/feed and other relevant information. Additional guidance documents are also published by the WP-SNFF, available together with the consensus documents at <https://www.oecd.org/en/topics/biosafety-novel-food-and-feed-safety.html>.

Of different content, this information document compiles elements provided by delegations on the 33rd WP-SNFF meeting (20-22 April 2026). It aims at summarising relevant information on activities related to the safety assessment of novel foods and feeds since the previous meeting (March 2025) at the international level, by collating individual contributions from OECD Members, partner countries and observer organisations participating in the work.

The WP-SNFF has endorsed this document.

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Argentina

New legislations in the regulatory framework

There were some reviews or updates related to GMO Biosafety regulations by the National Advisory Commission on Agricultural Biotechnology.

Resolution 255/2026:

New framework regulations concerning Genetically Modified Organisms (GMOs) for agricultural, agri-food and agro-industrial use, both for experimental and commercial purposes.

The framework regulations concerning Genetically Modified Organisms for agricultural use were updated and modernized to strengthen a clear regulatory framework that improves the predictability of investments, keeping pace with the scientific and technological advances in the sector.

The new resolution replaces the previous regime of Resolution 763/11 and shortens the processes, incorporating more precise technical criteria, reducing evaluation times, costs and eliminating unnecessary administrative burdens.

The field of GMOs in the agricultural sector has expanded over time into the agri-food and agro-industrial fields, giving rise to new activities and proposed uses, including their derived products and by-products. In this sense, the objective of the new regulation is to organize the applicable procedures and evaluations, based on the type of organism and the proposed use, without prejudice to compliance and control of safety in the agroecosystem, human and animal food suitability and the guarantee of export markets.

Link: <https://www.boletinoficial.gob.ar/detalleAviso/primera/339308/20260311?busqueda=1>

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.

Having authorised the necessary internal procedures, both countries commit to begin joint evaluations and authorisations of modern biotechnology products. In 2024, the first 4 applications were submitted for joint evaluation and during 2025-2026 first applications were finalized.

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

In terms of regional cooperation, 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. First notifications were realised and conducted by this Agreement.

Events for confined field trials

Since last Meeting, the following genetically modified events for confined field trials were approved:

During 2025, 50 authorisations were granted for different crops:

	FIELD TRAILS	SEED PRODUCTION	GREENHOUSE
QUANTITY	32	5	13
CROP			
Wheat	1		
Corn	10	3	2
Soy	15	2	3
Cotton	2		2
Rice			1
Barley	1		
Alfalfa			4
Colza	1		
Potato	1		
Sugar cane	1		1

During January, February and March 2026, 6 authorisations were granted for different crops:

	FIELD TRAILS	PRODUCTION	GREENHOUSE
QUANTITY	1	5	
CROP			
Colza		1	
Corn		1	
Soybean	1		
Cotton		1	
Sugar cane		1	
Camelina		1	

Animals:

Animal	Phenotype	Institution	Activity
Bovine	Expression in milk of Human Growth Hormone	Biomill	field trials since 2005
Bovine	Expression in milk of Antibodies against rotavirus	Biomill	field trials since 2011

Events for Commercial Approvals

Since last Meeting, genetically modified events were approved for commercial release in Argentina in 2025:

Vegetables

Unique Identifier	Applicant	Organism Common Names	Traits	Type of use	Date of approval	Decision name
BCS-GM151-6 x DAS-44406-6	BASF ARGENTINA S.A.	Soybean	Protection against attack by <i>Heterodera glycines</i> and tolerance to HPPD-inhibiting herbicides, ammonium glufosinate, glyphosate, and 2,4-D	Cultivation, Food and Feed	31/03/2025	Disposición 9/2025
MON-94804-4	MONSANTO ARGENTINA S.R.L	Maize	Short stature	Cultivation, Food and Feed	10/06/2025	Disposición 91/2025
MON-95379-3	MONSANTO ARGENTINA S.R.L	Maize	Protection against certain lepidopteran insects	Cultivation, Food and Feed	10/06/2025	Disposición 91/2025
MON-87427-7 x MON-94804-4 x MON-95379-3 x SYNIR162-4 x MON-88017-3	MONSANTO ARGENTINA S.R.L	Maize	Short stature, with tolerance to glyphosate and providing protection against certain lepidopteran and coleopteran insects	Cultivation, Food and Feed	10/06/2025	Disposición 91/2025
MON-87427-7 x MON-95379-3 x SYN-IR162-4 x MON-88017-3	MONSANTO ARGENTINA S.R.L	Maize	Tolerance to glyphosate and protection against certain lepidopteran and coleopteran insects	Cultivation, Food and Feed	10/06/2025	Disposición 91/2025

MON-87427-7 x MON-94804-4 x MON-00603-6	MONSANTO ARGENTINA S.R.L	Maize	Short stature and tolerance to glyphosate-based herbicides	Cultivation, Food and Feed	10/06/2025	Disposición 92/2025
DAS-01131-3 x DP-910521-2 x DP-202216-6 x DAS-40278-9	CORTEVA SEEDS SRL	Maize	Potential yield increase. Protection against certain lepidopteran insects and tolerance to herbicides based on glyphosate, ammonium glufosinate, 2,4-dichlorophenoxyacetic acid (2,4-D), and haloxyfop	Cultivation, Food and Feed	30/06/2025	Resolución 113/2025
COR-23134-4	CORTEVA SEEDS SRL	Soybean	Protection against certain lepidopteran insects. Tolerance to acetolactate synthase (ALS)-inhibiting herbicides	Cultivation, Food and Feed	30/06/2025	Resolución 115/2025
MON-00531-6 x MON-01445-2 x ACS-GH001-3	GENSUS S.A	Cotton	Tolerance to glyphosate- and ammonium glufosinate-based herbicides and protection against certain lepidopteran insects	Cultivation, Food and Feed	08/08/2025	Resolución 132/2025
DBN-08205-8	DBNBC Argentina S.R.L.	Soybean	Protection against certain lepidopteran insects and tolerance to the herbicide ammonium glufosinate	Cultivation, Food and Feed	05/09/2025	Resolución 169/2025
SYN-00260-3	SYNGENTA AGRO	Maize	Protection against certain lepidopteran insects	Cultivation, Food and Feed	08/09/2025	Resolución 172/2025

Microorganisms

Organism	Product	Identifier	Applicant	Date of approval	Decision name
<i>Saccharomyces cerevisiae</i>	Genetically modified yeast for bioethanol production	SCY018 Strain	NOVOZYMES BIOAG S.A.	07/03/2025	https://www.boletinoficial.gob.ar/detalleAviso/primera/322355/20250311
<i>Baculovirus ProPCV2bOrf2T131P</i>	Porcilis PCV MHyo ID vaccine (PCV2 antigen production)	<i>Baculovirus ProPCV2bOrf2 T131P</i>	INTERVET ARGENTINA S.A.	07/03/2025	https://www.boletinoficial.gob.ar/detalleAviso/primera/322356/20250311

New Breeding Techniques

A total of 50 Prior Consultation Instance (PCI) submissions were received between March 2025 and March 2026. Of these, 5 corresponded to products at the development stage and 45 to final products.

Regarding organism type, 42 submissions involved plants, 3 animals, and 5 microorganisms.

Based on the information provided, CONABIA concluded that these products met the criteria established under the policy approach for NBTs (Resolution No. 21/2021) and therefore did not fall within the scope of the regulatory framework for genetically modified organisms.

Since the implementation of this policy in 2015, a total of 213 PCIs have been analysed covering plants, animals, and microorganisms.

In March 2026, Argentina updated its normative approach through Resolution No. 24/2026. The update maintains the existing product-based approach while improving procedural clarity and efficiency. The new regulation introduces an instructive annex with definitions and guidance for submissions, clarifies the analytical criteria used to determine the presence of a novel combination of genetic material, and allows the submission of multiple lines derived from the same genomic intervention within a single consultation.

Further information on Argentina's normative approach for NBTs is available at:

https://www.magyp.gob.ar/sitio/areas/biotecnologia/conabia/marco_regulatorio_nbt.php

Participation in International Activities

2025-26:

Bilateral, regional and multilateral high-level meetings:

- Meeting of the Commission for Agricultural Biotechnology of SGT No. 08 of MERCOSUR, under the pro tempore presidency of Argentina, held on April 22 and 23 of 2025 in Buenos Aires, Argentina.
- Meeting of the Commission for Bioinput for Agricultural Use of SGT No. 08 of MERCOSUR, under the pro tempore presidency of Argentina, held on April 24 and 25 of 2025 in Buenos Aires, Argentina.
- Official Mission of the Secretariat of Agriculture, Livestock and Fisheries to the People's Republic of China. IX Meeting of Working Group ARG-China on biotechnology and VII Working Group ARG-China on Seeds. Beijing, China. 3–10 September 2025.
- Meeting of the Commission for Bioinput for Agricultural Use of SGT No. 08 of MERCOSUR, under the pro tempore presidency of Brasil, held on September 16 and 17 of 2025 in Brasília, Brazil.
- Meeting of the Commission for Biotechnology of SGT No. 08 of MERCOSUR, under the pro tempore presidency of Brasil, held on September 29 and 30 of 2025 in Foz do Iguaçu, Brazil.
- Meeting GT5 "Public policies in biotechnology" of the Southern Agricultural Council (CAS) held on September 30 of 2025 in Foz do Iguaçu, Brazil.
- Participation in the 10th Seed Congress of the Americas. Foz do Iguaçu, Brazil. 29 September–3 October of 2025.

- XII Bilateral Dialogue on Aspects Related to the Application of Biotechnology to Agriculture between Argentina and the European Union. 15 December 2025.

Other international activities:

- Participation in the Seed Symposium “Seed Quality for Global Food Security and Biodiversity”. 5–9 May 2025. Christchurch, New Zealand.
- Participation in the 10th Brazilian Biennial Congress on Biosafety. Vitoria, Brazil. 5–6 May 2025
- Study Visit of the Argentine Delegation to the Kingdom of the Netherlands. 19–23 May 2025. The Netherlands
- Participation in Second Capacity Building Workshop on Food Safety Assessment of Genetically Engineered Plants – Agriculture & Food Systems Institute (AFSI) held on 3-4 June, New Delhi, India.
- Official Mission to the Asia-Pacific Economic Cooperation (APEC). 4–8 August 2025. Republic of Korea.
- Participation in the First Capacity-Building Workshop on Synthetic Biology. Vilm Island, Germany, 3–7 November 2025.
- International Society for Biosafety Research (ISBR) Meeting. Sixth International Workshop on Regulatory Approaches for Agricultural Applications of Animal Biotechnology. IICA Workshop for Regulators of the Americas. Ghent, Belgium. 2–8 November 2025.
- International Seed Federation Plant Breeding Innovation (PBI) Global Roundtable. Ghent, Belgium. 2 November 2025.

Australia

1. GM food regulation in Australia

Food Standards Australia New Zealand (FSANZ; <https://www.foodstandards.gov.au/>) is an Australian Government agency responsible for developing food standards for Australia and New Zealand.

GM foods are regulated under Standard 1.5.2 – Genetically modified food of the *Australia New Zealand Food Standards Code* (the Code), which is a joint standard with New Zealand. Approved GM foods are listed in Schedule 26 of the Code. The approvals listed in Schedule 26 apply in both Australia and New Zealand. To obtain a GM food approval, an application must be lodged with FSANZ seeking an amendment to Schedule 26 of Code to include a new food.

- Standard 1.5.2 is available here: <https://www.legislation.gov.au/F2015L00404/latest/text>
- Schedule 26 is available here: <https://www.legislation.gov.au/F2015L00450/latest/text>

2. GM food assessments and approvals in Australia

A full list of the GM foods that have been assessed by FSANZ, as well as links to relevant assessment reports, are available from the FSANZ website at:

<https://www.foodstandards.gov.au/consumer-information/consumer/current-status-genetically-modified-foods-applications>

Approvals since the 32nd Meeting and applications currently under assessment by FSANZ include:

Food derived from:	Current Status:
Food derived from insect-protected corn line MZIR260	Approved March 2025
Food derived from insect-protected soybean line MON94637	Approved May 2025
Food derived from insect-protected soybean line COR23134	Approved June 2025
Food derived from purple tomato lines containing event Del/Ros1-N	Approved November 2025
Food derived from insect-protected corn line COR121	Under assessment

3. Shared Assessment Process between FSANZ and Health Canada

FSANZ and Health Canada have been collaborating on GM safety assessment sharing since 2013. Under the arrangement, where approval for a GM food is being sought from both FSANZ and Health Canada, companies may request to have their product assessed under a safety assessment sharing arrangement.

Under this arrangement, and in line with agreed protocols, an application is submitted to both agencies, but only one food safety assessment is prepared (either by FSANZ or Health Canada). The assessment is then referred to the other agency for review and input to ensure it meets the requirements of both agencies. The joint food safety assessment is then used by both FSANZ and Health Canada for their own

separate and independent decision-making process.

Two pilots were carried out in 2020-21 and 2023-2024. Information about these pilots can be found on the FSANZ website:

<https://www.foodstandards.gov.au/consumer/gmfood/health-canada-fsanz-shared-assessment-process/pilot>

Update

In total, 6 shared safety assessments have been successfully completed by FSANZ and Health Canada. An additional shared safety assessment is in progress in 2026.

FSANZ and Health Canada have developed a range of materials on the shared assessment process including guidance for applicants and updated website content.

Information about the safety assessment process and materials can be accessed on the FSANZ website:

<https://www.foodstandards.gov.au/consumer/gmfood/health-canada-fsanz-shared-assessment-process>

4. New breeding techniques

Between 2020-2025, FSANZ worked on a proposal to amend the definitions in the Code for '*food produced using gene technology*' and '*gene technology*' (Proposal P1055 – Definitions for gene technology and new breeding techniques). These definitions determine what foods require pre-market safety assessment and approval as GM foods. The purpose of the work was to revise and update the GM food definitions in the Code to make it clear what foods, particularly those derived using some of the new and emerging genetic technologies, are GM foods for regulatory purposes.

Update – P1055

On 2 September 2025, changes to the Code were gazetted to update definitions for GM food.

The primary change introduced new definitions for '*genetically modified food*' and '*novel DNA*' to replace the old process-based definitions. Unlike the old definitions, the new definitions focus on the outcome of the genetic modification process which is more relevant to risk.

A food will be a GM food under the Code if it is from an organism or cells containing novel DNA as an outcome of the genetic modification. Novel DNA is defined to exclude the types of genetic modifications introduced through conventional breeding or are naturally occurring. Foods made using new breeding techniques, like genome editing, are not classified as GM food if the genetic change does not introduce novel DNA.

Under the new definitions, GM foods will continue to require pre-market safety assessment and approval and be subject to GM labelling requirements in the Code.

The full set of publicly available documents for Proposal P1055 are available from the FSANZ website:

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

Update – guidance

Following gazettal, FSANZ has been preparing guidance to support the implementation of the Code changes, specifically focusing on the new definitions.

A technical sub-group comprising industry experts was established to provide feedback on the clarity and practical application of the guidance. The group completed its review in early February 2026.

FSANZ is currently seeking input and endorsement from Australian State and Territory food agencies and New Zealand Ministry of Primary Industries (the jurisdictions) through the Implementation Subcommittee for Food Regulation (ISFR). These agencies are responsible for enforcement of the Code in Australia and New Zealand.

5. Cell-based foods

Approvals since the 32nd Meeting and applications currently under assessment by FSANZ include:

Food derived from:	Current Status:
Cultured quail as a novel food	Approved June 2025
Cell-cultured duck (<i>Anas platyrhynchos domesticus</i>) biomass as a food ingredient	Under assessment

Regulatory approach

In June 2025, FSANZ adopted a risk-based approach to regulate the production, sale, and labelling of cell-cultured food in Australia and New Zealand. This approach includes two new standards and one new schedule in the Code:

- Standard 1.5.4 – Cell-cultured foods
Sets the general requirements for cell-cultured foods and mandatory labelling requirements such as the use of the statement “*cell-cultured*” or “*cell-cultivated*” for food identification purposes.
- Standard 3.4.1 – Food safety requirements for processing of cell-cultured food
Sets out food safety requirements for Australian cell-cultured food businesses and cell line suppliers.
- Schedule 25A – Permitted cell-cultured foods.
Lists approved cell-cultured foods and any specific conditions for sale and labelling.

The regulatory approach:

- enables FSANZ to better assess and manage the risks associated with these new types of foods
- ensure consumers are provided with clear and meaningful information, and
- provide regulatory clarity and certainty for the cell-cultured food sector.

Data requirements and guidance

To provide clarity for the cell-cultured food sector when making an application to FSANZ to permit a new cell-cultured food, FSANZ is developing cell-cultured food data requirements and an associated user

guide. The user guide will provide practical information for applicants including the sourcing and establishment of the cell line, the cell proliferation process (including media components) for cell biomass production, the harvest of the resulting biomass, and factors related to the final cell-cultured food product.

FSANZ will be consulting on the cell-cultured food data requirements and user guide as part of a larger piece of work to update the FSANZ Application Handbook. Consultation is anticipated to occur in April 2026.

6. Safety assessment of newly expressed proteins in Australia

Newly expressed proteins are considered as part of FSANZ's GM food safety assessment. This assessment is undertaken in accordance with internationally established scientific principles and guidelines developed through the work of the Organisation for Economic Cooperation and Development (OECD), Food and Agriculture Organization (FAO) of the United Nations, World Health Organization (WHO) and the codex Alimentarius Commission.

Important principles that are applied to newly expressed proteins:

- Case-by-case

The assessment and the issues considered will depend on the specific food, modification and newly expressed protein in question.

Data requirements are adjusted to suit the case being assessed i.e. a flexible hypothesis-led approach (not data driven)

- New scientific information

The assessment approach takes into account new methodologies and scientific information.

- Totality of evidence

Conclusion about safety is based on the totality of evidence.

Newly expressed proteins that are intractable or do not have a history of safe use have been assessed as part of a GM food application. FSANZ has applied the principles above in those cases and the foods have been approved and listed in the Code.

Belgium

1. Safety assessment of newly expressed proteins in food and feed

In Belgium, the safety assessment of newly expressed proteins in genetically modified (GM) food and feed is conducted within a science-based biosafety advisory system that supports the implementation of the European Union regulatory framework for GMOs. This system was established through the Belgian Cooperation Agreement on biosafety and is composed of the Biosafety Advisory Council (BAC) and the Service Biosafety and Biotechnology (SBB) of Sciensano (the Belgian institute for health), which ensures the secretariat of the BAC. The BAC is actively involved in the European Food Safety Authority (EFSA) consultation for placing on the market of GM food and feed.

The safety assessment of newly expressed proteins follows internationally recognised principles and guidances developed by Codex Alimentarius and EFSA, and uses a weight-of-evidence approach. The OECD consensus documents on compositional considerations for new varieties of crops (the series on the safety of Novel Foods and Feeds) are used as reference documents during the evaluations. In addition to food and feed safety, the BAC also evaluates environmental impacts of GMOs. Assessment reports and relevant documents can be consulted on <https://www.bio-council.be> and <https://www.biosafety.be>.

2. GMO detection in Belgium

Detection, identification and quantification of GMOs present in food and feed is conducted by the service "Transversal activities in Applied Genomics" (TAG) of Sciensano. TAG coordinates the Belgian "National Reference Laboratory for Genetically Modified Organisms" (NRL-GMO) established in the frame of Regulation (EC) 1829/2003 on GM Food and Feed and Regulation (EC) 1830/2003 on labelling and traceability of GMO. The NRL-GMO is involved in all the enforcement actions implemented by the Belgian Federal Agency for the Safety of the Food/Feed Chain and the Federal Public Service Public Health, Food Chain Safety and Environment.

The GMOLab of TAG has ISO17025 flexible scope of accreditation for detection of GMOs (plant, microorganisms, etc.) by means of real-time PCR and ddPCR. It also characterizes genetically modified micro-organisms (GMM) isolates using whole genome sequencing and bioinformatic analyses, with sequencing currently covered by accreditation.

Follow-up of the activities in the different Belgian and European research projects:

The ENSURED project (since 2023) develops an open, universal strategy to detect any type of biological impurities at genomic and proteomic levels in fermentation-derived food products, with potential extension to broader food/feed matrices. TAG specifically applies metagenomic approaches, with emphasis on detecting the genetically modified microorganisms (GMM) used for the fermentation.

TAG also leads the ARGUMENT project (since 01/06/2025), which assesses antimicrobial resistance genes (ARG) in fermentation-derived food/feed products, such as vitamins, and their potential transfer risks. The project evaluates which ARG are of concern, their presence in products on the Belgian market, and whether current safety thresholds (e.g. DNA levels) are scientifically justified.

In addition, TAG coordinates the METAMORPHOSE project (Sciensano-funded), which advances shotgun metagenomics methods and demonstrates their application to public health questions, including GMM detection and identification in fermentation products or products used as a bioweapon, vaccine quality control, and microbiome characterization, alongside a risk assessment of ARG and GMM presence in fermentation products.

TAG is also involved in detecting organisms derived from new genomic techniques (NGT). As a WP leader in the EU-funded DARWIN project, TAG develops and validates targeted and untargeted sequencing approaches, including machine learning tools for genetic fingerprinting. In addition, criteria and guidelines for validation of novel methods for detection of genome edited plants are developed. For this work, Sciensano was recognised by the European Commission as a “key innovator” in 2025.

Peer-reviewed publications:

- Orval, R., D'aes, J., De Keersmaecker, S.C.J., Vanneste, K., Deforce, D., Roosens, N.H.C., Fraiture, M.A. Development of a shotgun metagenomics workflow for the comprehensive surveillance of biological impurities in vitamin-containing food products. LWT 231, 118371 (2025). <https://doi.org/10.1016/j.lwt.2025.118371>.
- Fraiture, M.A., D'aes, J., Gobbo, A., Delvoye, M., Meunier, A.C., Frouin, J., Guiderdoni, E., Deforce, D., De Vogelaere, C., De Keersmaecker, S.C.J., Vanneste, K., Roosens, N.H.C.. Genetic fingerprints derived from genome database mining allow accurate identification of genome-edited rice in the food chain via targeted high-throughput sequencing. Food Research International 221, 117218 (2025). <https://doi.org/10.1016/j.foodres.2025.117218>.

3. New Techniques

Belgium is actively involved in the ongoing discussions at EU level on the proposal for regulation on plants obtained with new genomic techniques.

Since the last WP meeting, one new request for authorization for a field trial with CRISPR-Cas-edited maize has been submitted: Field trial with of field-specific genes in maize (B/BE/26/V1).

General information about genetically modified plants that have been approved in Belgium for deliberate release into the environment (R&D) is available on <https://www.biosafety.be/search-gm-plants>.

4. Domestic policies and regulations related to animal cell cultured foods and feeds

In the EU, foods derived from animal cell culture (e.g. cultivated meat or other cellular agriculture products) fall under the Novel Food Regulation, which requires pre-market authorisation. Applications are evaluated through a centralised risk assessment process coordinated by EFSA, followed by a decision by the European Commission and the Member States.

The development and handling of animal cell cultures fall under the Belgian legislation on activities of contained use when the cells are genetically modified. Nevertheless an appropriate risk assessment is recommended also for non-GM cell cultures, as cells may harbour adventitious biological agents.

Brazil

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions (e.g. organisms assessed, type of use, introduced traits/genes);

Plant	Trait	Notifier	Technical Decision
Soybean	Herbicide tolerance and insect resistance	Monsanto	9471-2025
Soybean	Herbicide tolerance and insect resistance	DBNBC	9565-2025
Soybean	Herbicide tolerance and insect resistance	Corteva	9798-2025
Soybean	Herbicide tolerance	Syngenta	10.019-2025
Maize	Herbicide tolerance and insect resistance	Corteva	9635-2025
Maize	Herbicide tolerance	Corteva	9911-2025

Regarding industrial use, 12 genetically modified microorganisms for contained use were approved, particularly yeasts of the genus *Saccharomyces cerevisiae* and bacteria of the genus *Corynebacterium*, as well as their respective derivatives. These products are intended for the industrial production of inputs, amino acids, enzymes, and other compounds of economic interest.

In the field of human health, five GMOs and derivatives intended for the diagnosis and prevention of diseases were approved, including molecular kits for the diagnosis of respiratory viruses, Mayaro virus and Oropouche virus, as well as attenuated vaccines against dengue and chikungunya, developed by national public institutions.

In the area of animal health, CTNBio has approved five recombinant vaccines and live attenuated vaccines intended for the prevention of diseases relevant to animal production and veterinary health, including vaccines for poultry, dogs, and other animals.

2. Development/review/amendment of national strategies, regulations and guidance;

No new regulations have been issued since the previous Tour de Table. All regulations of the CTNBio (National Biosafety Technical Commission) are available at <http://ctnbio.mctic.gov.br/normas-e-leis>.

Since 2023, Brazil has been a member of ABRE-Bio (the Biosafety Agencies Network for Biotechnology). ABRE-Bio is a joint initiative of Brazil, Argentina, Paraguay, and Uruguay aimed at sharing information related to the risk assessment of GMOs and the determination of the regulatory status of products derived

from New Breeding Techniques (NBTs). The main purpose of this network is to foster innovation in the region and, to this end, its operational mechanisms are currently being established.

3. Risk management measures (e.g. limitation of cultivation areas, specific isolation measures, post-release monitoring);

Risk management, including the adoption of biosafety measures in accordance with CTNBio Normative Resolutions (<http://ctnbio.mctic.gov.br/resolucoes-normativas>), is mandatory for field trials. In 2025, 124 field trials involving different plant species were approved, including maize, soybean, cotton, citrus, sugarcane, eucalyptus etc. The traits of these biotech crops include insect resistance, herbicide tolerance, disease resistance, drought tolerance, and increased yield.

The Ministry of Agriculture and Livestock (MAPA) is one of the institutions responsible for inspecting activities related to the use and handling of GMOs to verify compliance with biosafety regulatory requirements. Approved field trials are inspected to ensure compliance with biosafety requirements and a regulatory inspection report is presented with the final field trial report upon their conclusion.

2. Updates regarding international activities

1. Participation in/hosting international symposia/fora relating to biosafety;

- Cartagena Protocol: The 12th meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP MOP-12)
- Convention of Biological Diversity: The 17th meeting of the Conference of the Parties (COP-17)
- Mercosul: SGT-8 Commission of the Agricultural Biotechnology
- CAS (Conselho Agropecuário do Sul): GT-5 Working Group for Agricultural Biotechnology
- OECD: Working Party on the Harmonisation of Regulatory Oversight in Biotechnology and Working Party for the Safety of Novel Foods and Feeds

3. Specific cases of use of OECD tools and information

Relevant information on GMOs approved in Brazil has been registered in the BCH, the FAO GM Foods Platform and the Biotrack.

3. Developments related to new breeding techniques (NBTs)

1. Development/review/amendment of national strategies, regulations and guidance;

Brazil has not had any regulatory updates in the past year.

CTNBio (National Biosafety Technical Commission) Normative Resolution No 16, dated January 15, 2018 (<http://ctnbio.mctic.gov.br/resolucoes-normativas>) applies to all types of organisms and establishes a case-by-case consultation system for products obtained through Innovative Precision Breeding Techniques (in Portuguese, TIMP - “Técnicas Inovadoras de Melhoramento de Precisão”). These techniques are defined as a set of new methodologies and approaches that differ from traditional genetic engineering strategies, as they result in the absence of recombinant DNA/RNA in the final product.

Developers must submit detailed information to CTNBio regarding the original organism, the characteristics of the trait, the methods used to generate it, and the corresponding molecular analysis. If a product is classified as conventional under the established criteria, it may be registered through existing procedures

without undergoing the full biosafety assessments required for GMOs, according with the Biosafety Law No. 11.105/2005 (http://www.planalto.gov.br/ccivil_03/ato2004-2006/2005/Lei/L11105.htm).

2. Specific cases of application, assessment and decision;

The complete list of organisms submitted to CTNBio through consultation procedures under Normative Resolution No. 16 can be accessed at the following link:

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

3. Research projects on biosafety of NBT products; relevant publications;

Article - Updates on the Regulatory Framework of Edited Organisms in Brazil: A Molecular Revolution in Brazilian Agribusiness (DOI: 10.3390/genes16050553)

4. Additional Information - WG-SNFF

There are no specific regulations or guidelines for foods derived from precision fermentation; however, CTNBio Normative Resolution No. 21/2018 (which provides standards for the commercial use of genetically modified microorganisms and their derivatives) may be applicable. <http://ctnbio.mctic.gov.br/resolucoes-normativas>.

Also regarding cell-based products, there is no specific legislation. However, if a product falls under the jurisdiction of the MAPA, the Decree No. 12,709 of 2025—which addresses “whole plants or any of their parts”—would apply to the plant-based component (https://www.planalto.gov.br/ccivil_03/ato2023-2026/2025/decreto/D12709.htm).

In addition, ANVISA (Brazilian Health Regulatory Agency) RDC (Collegiate Board Resolution) No. 839 of 2023 establishes the requirements for the safety assessment of new foods and food ingredients and applies to products derived from cells or tissue cultures or produced using these technologies (<https://www.in.gov.br/en/web/dou/-/resolucao-rdc-n-839-de-14-de-dezembro-de-2023-533593214>).

Canada

Novel Food Approvals

Since 1999, Health Canada (HC) has permitted 271 novel foods to be sold in the Canadian marketplace. Since March 2025, the following novel foods have been authorized:

- Structured medium- and long-chain triacylglycerol (MLCT oil)
- Insect-resistant soybean – COR23134
- Purple Tomato – Del/Ros1-N event
- BG25 potato (SPS-ØBG25-7)
- Insect-resistant MZIR260 corn
- Porcine Reproductive and Respiratory Syndrome Virus-Resistant Pigs

A list of authorized novel foods, each summarized by a decision document, can be found at <https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products.html>

Novel Feed Approvals

The Canadian Food Inspection Agency (CFIA) is responsible for the pre-market assessment of novel feeds, in accordance with the *Feeds Act and Regulations*. To date, the CFIA has approved over 150 novel feeds derived from plant sources and over 40 novel feeds from microbial sources.

Since the last Task Force meeting in March 2025, four novel feeds from a plant source have been authorized.

- Insect-resistant soybean – COR23134
- BG25 potato (SPS-ØBG25-7)
- Insect-resistant MZIR260 corn
- Porcine Reproductive and Respiratory Syndrome Virus-Resistant Pigs

A complete list of approved novel feeds from plants sources is available at: <http://www.inspection.gc.ca/english/plaveg/bio/dde.shtml>

Important resources related to genome editing techniques

CFIA and Health Canada joint webpage regarding the regulation of genome-edited products within the Canadian regulatory framework

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

Health Canada Guidance on the Novelty Interpretation of Products of Plant Breeding

<https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance->

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

Health Canada Guidance on the Pre-Market Assessment of Foods Derived from Retransformants
<https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/guidelines-safety-assessment-novel-foods-derived-plants-microorganisms/guidelines-safety-assessment-novel-foods-2006.html#a6>

Health Canada Transparency Initiative
<https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/transparency-initiative.html>

CFIA Directive 2009-9: Plants with novel traits regulated under Part V of the Seeds Regulations: Guidelines for determining when to notify the CFIA
<https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/applicants/directive-2009-09/eng/1304466419931/1304466812439>

CFIA rationale for updated guidance determining whether a plant is subject to Part V of the Seeds Regulations
<https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/applicants/directive-2009-09/rationale-for-updated-guidelines/eng/1682425597052/1682425597973>

Minister of Agriculture and Agri-Food News Release: Transparency measures for products of plant breeding innovation
<https://www.canada.ca/en/agriculture-agri-food/news/2023/05/the-government-of-canada-moves-forward-with-plant-breeding-innovation-while-upholding-the-integrity-of-the-organic-sector.html>

Guidance on how to determine when a plant-derived ingredient requires a feed pre-market evaluation
<https://inspection.canada.ca/en/animal-health/livestock-feeds/regulatory-guidance/rg-1/chapter-2#s29c6>

Important resources related to Low Level Presence (LLP)

Global Low Level Presence Initiative (GLI) website
<https://llp-gli.org>

The Global Low Level Presence Initiative (GLI) is a group of 15 importing and exporting countries committed to working collaboratively to develop practical approaches to facilitate the management of Low-Level Presence (LLP). The GLI website is a public interface that features useful resources and tools to inform practices to minimize asynchronous approvals and practically manage LLP. The GLI Secretariat is led by Agriculture and Agri-Food Canada and can be contacted at GLI-IMP@canada.ca.

Canadian Feeds Regulations and policy updates

Canada has fully implemented the *Feeds Regulations, 2024*. Following a staggered coming into force period over 18 months to provide stakeholders with time to bring their practices into compliance Canada has now fully implemented the new regulations.

The regulations include approval and registration of feeds, labelling, standards and record keeping hazard analysis, preventive controls and preventive control plans, complaints, recalls, packaging and traceability, an expanded scope of livestock species, licencing requirements, and authority for issuing export certificates.

The regulations include 9 documents that are incorporated by reference (IBR) which allow standards to be set in a way that that can be easily updated following appropriate review and consultation. The Canadian Food Inspection Agency (CFIA) has been regularly updating these IBR documents following consultations.

The CFIA has also transitioned to a standardized inspection process for feed inspections conducted as part of preventive control plan inspections. These involve reviewing the hazards that the companies have identified in their feed businesses and ensuring that preventive control plans are being implemented.

The CFIA has published a suite of guidance materials that are available on its' website, and the CFIA continues to work to provide new guidance and update existing guidance.

The CFIA's Animal Feed Program published their final guidance in June 2025 on [Feed approval or registration requirements for the acceptance of a foreign approval/authorization](#). This policy identifies the pre-market evaluation requirements for the approval or registration of livestock feeds based on the acceptance of foreign approvals or authorizations.

Cellular Agriculture

In December 2023, Health Canada posted a new [website](#) to engage industry stakeholders, partners, and the public on the regulatory oversight of cellular agriculture, a general term for the production of food that is usually derived from animals (e.g., meat, seafood, egg, milk products) using cell culture methods instead of live animals. The website explains that under Canada's *Novel Food Regulations*, these products will be considered 'novel foods' and thus require pre-market safety assessment prior to their sale or advertisement in Canada for food. Other established pre-market frameworks could apply, depending on the intended uses of a given product (i.e., for use as livestock feed, environmental safety). Canada's existing laws pertaining to licensing, manufacturing, and trade of products, as well as the legislative framework for labelling that would apply are explained as well.

Health Canada is currently conducting an analysis of this emerging industry to understand the type of products intended for commercialization and how the safety of these products will be assessed. This analysis will be used to develop additional guidance or materials to support clarity and predictability for cellular agriculture manufacturers, in particular guidance on the information required for the pre-market assessment of these products.

Health Canada has authorized a number of nutrient substances from animal sources produced in genetically modified microorganisms (GMMs), including β -lactoglobulin protein and sugars (e.g., 2'-fucosyllactose, a mixture of human milk oligosaccharides). Products that are the same but produced in different proprietary GMM strains are assessed case by case. To date, Health Canada has not authorized any novel foods made from cultivated animal cells, nor received any requests for novel food authorization for this type of product.

Croatia

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

The Republic of Croatia as a member of the European Union (EU) implements EU community-level decisions and regulations on genetically modified (GM) food and feed at the national level. Regulation (EC) No 1829/2003 regulates the placing on the market of GM food and feed. The Republic of Croatia is actively involved in the Member State consultation process conducted by European Food Safety for placing on the market of genetically modified organisms (GMOs). Input in the risk assessment is provided through Competent Authorities, Council of GMOs, Committee for the assessment of the effects of the deliberate release of GMOS into the environment and Committee for contained use of GMOs.

All products that are authorised for placing on the EU market can be found in the EU Register of GM food and feed (<https://ec.europa.eu/food/food-feed-portal/screen/gmo/search>)

2. Development/review/amendment of national strategies, regulations and guidance

No legislative amendments were introduced or implemented at the Republic of the Croatia during this reporting period.

3. Risk management measures

During the current reporting period April 2025-April 2026 neither cultivation of GMO crops nor deliberate release of GMOs for field trials occurred in the Republic of Croatia.

In accordance to the Commission Implementing Decision (EU) 2016/321 of 3 March 2016 adjusting the geographical scope of the authorisation for cultivation of genetically modified maize (*Zea mays* L.) MON 810 (MON-ØØ81Ø-6) in the Republic of Croatia is not permitted cultivation of GM crops.

Accordingly, no new risk assessment/regulatory decisions were taken by Croatian Competent authorities.

Currently, GMOs are only authorized for import and use as food/feed products in the European Union at the same time in the Republic of Croatia. According to the authorizations, these require a post-marked environmental monitoring plan (PMEM) as per Annex VII of Directive 2001/18/EC e.g. to detect direct and indirect effects which have been identified in the environmental risk assessment.

In addition, a post-market monitoring plan (PMM) regarding the use of the GM food/feed for human/animal consumption is requested in cases where it is appropriate to verify that the conditions of use are properly applied and to monitor the consumption of the product.

State Inspectorate of the Republic of Croatia is responsible body for conducting official controls on GMOs and products that consisting of or containing of or combination GMOs and for deliberate release of GMOs into the environment in line with the rules of the Act on genetically modified organisms (Official Gazette,

126/19). During the period from 1st January 2025 until 31st December 2025 sanitary inspection of State Inspectorate conduct official controls in/on foods on the Croatian market, in production and on the border with third countries. Sanitary inspection was taken 140 samples of different type of foods and ingredients, from origin as soybean, maize, sugar beet, oil rape and cotton and sunflower, papayas, flax seeds to test the presence of GMOs in the Croatian market, 10 samples were taken on the border crossing, agriculture inspection of State Inspectorate was taken 25 samples on the green plant of soybean, and maize at the primary production and 30 samples of seeds of soybean, and maize and veterinary inspection of State Inspectorate samples 50 samples of feed that consisting or containing ingredients on soybean based. . For non-compliant products, measures were taken in accordance with provisions in accordance to the Act on conducting official controls (Official Gazette, 52/21).

4. New and emerging regulatory challenge(s) for products of modern biotechnology (other than NBTs)

On 5 July 2023, the European Commission proposed legislative framework 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. Draft Regulation of the European parliament and of the Council on plants obtained by certain new genomic techniques and their products, and amending Regulation (EU) 2017/625 (first reading) – is in the process of the adoption of the Council's position at first reading. The Republic of Croatia as a member of the European Union (EU) is very activate in the preparation of final proposal. Currently, in the Republic of Croatia, the plants and products covered by this proposal continue to be regulated under the legislation on GMOs as described in the paragraph about NBT under (in Section 3).

Currently in the Republic of Croatia as in the EU, live biopharmaceutical products (genetically modified live microorganisms) pose a challenge, as their use may involve deliberate release practices, for which recommendations are not available at the EU level. For some products, both contained-use and deliberate-release EU legislation apply, which creates additional challenges in the evaluation process and in providing final feedback.

Because of that on 16 December 2025, the European Commission proposed a legislative framework to amend Directives 2001/18/EC and 2010/53/EU regarding the placing on the market of genetically modified micro-organisms (GMMs) and the processing of organs, as part of the new European Biotech Act.

Directive 2001/18/EC was originally designed to regulate genetically modified plants obtained through certain established genomic techniques, in particular those that introduce genetic material from non-crossable species (transgenesis). Taking into account the conclusions of the European Food Safety Authority (EFSA) on GMMs, as well as the biological properties, capabilities, and potential applications of GMMs—which differ significantly from those of plants—Directive 2001/18/EC should be adapted to address the specificities of GMMs. Such adaptation would enable innovative products to reach the market before becoming obsolete and without disproportionate authorisation costs, while maintaining a high level of safety. For this reasons, European Commission decided to amend Directive 2001/18/EC and to introduce specific provisions applicable to the placing on the market of GMMs, with the aim of creating a tailored, more efficient, and streamlined legislative framework that ensures a high level of protection for human health and the environment. The Republic of Croatia is actively participating in the preparation of this proposal.

At the same time on the 22 December 2025 as part of Omnibus European Commission published Proposal for a Regulation for amending Regulations (EC) No 999/2001, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 852/2004, (EC) No 853/2004, (EC) No 396/2005, (EC) No 1099/2009, (EC) No

1107/2009, (EU) No 528/2012, (EU) 2017/625 as regards the simplification and strengthening of food and feed safety requirements. The Republic of Croatia is actively participating in the preparation of this proposal.

5. Public engagement and outreach activities

Conclusion of meetings of Croatian Council of GMOs (Croatian scientific advisory body in relation on GMOs) is published on the web page of the Ministry of Health.

2. Updates regarding international activities

1. Participation in/hosting international symposia/fora relating to biosafety

The Republic of Croatia is a party to the Convention on Biological Diversity, the Cartagena and the Nagoya Protocol, and has actively participated in the meetings of the Subsidiary Bodies.

2. Bi-/multi-lateral cooperation with other authorities/organisations

The Republic of Croatia is a member of the European Enforcement Project on Contained Use and Deliberate Release of GMOs (EEP), which forms a Europe-wide network for inspectors and competent authorities in the field of GMOs.

Representatives of national GMO laboratories are also members of the European Network of GMO Laboratories (ENGL–GMFF).

3. Developments related to new breeding techniques (NBTs)

1. Development/review/amendment of national strategies, regulations and guidance

Republic of Croatia is a member of the European union. In the Republic of Croatia as in the European Union (EU), 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*). In the Republic of Croatia, the main EU acts (*Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No 1830/2003, Directive 2009/41/EC, Regulation (EC) No 1946/2003*) is transposed in the Act on genetically modified organisms (Official Gazette, 126/19) and the Act on the Implementation of European Union Regulations on the Traceability and Labelling of Genetically Modified Organisms in Food and Feed (Official Gazette, No. 81/13, 47/14, 114/18, 83/22) and Act on the implementation of the Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (Official Gazette, No. 81/13). Furthermore, the Act on the implementation of the Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organism (Official Gazette, No. 81/13), defines the competent national authorities for implementation and surveillance, as well as fines for legal and physical persons in cases of breaching the provisions of the Regulation.

2. Specific cases of application, assessment and decision

In The Republic of Croatia, currently the deliberate release of genetically modified organisms and NBT is regulated with the Act on genetically modified organisms (Official Gazette, 126/2019). In the European Union is allowed cultivation of genetically modified maize (*Zea mays* L.) MON 810. The cultivation of genetically modified maize (*Zea mays* L.) MON 810 is prohibited in the territories of the Republic of Croatia regards to the Commission Implementing Decision (EU) 2016/321 of 3 March 2016 adjusting the geographical scope of the authorization for cultivation of genetically modified maize (*Zea mays* L.) MON 810 (MON-ØØ81Ø-6).

Denmark

Developments/Activities in the Safety of Novel Foods and Feeds in Denmark

Denmark as a member of the European Union, follows EU legislation on GM food, novel foods, food and feed additives, enzymes, flavourings etc., which require pre-marketing approval in the EU.

Due to low consumer acceptance, almost no GM food products are marketed in Denmark, whereas the use of GM feed is very common. In organic farming the use of GM feed is not allowed in the EU. Although GM crops are not cultivated in Denmark, our animal sector rely to a large extend on imported feed consisting of or containing of mainly GM soy from cultivation outside EU. A proposal from the European Commission for a new regulation on plants obtained with certain new genomic techniques and their food and feed is awaiting final adoption.

Biotech industry plays a significant role in Danish economy. Especially, Danish companies have a strong position in production of enzymes and microbial cultures for use as food and feed ingredients. A large part of the production uses GMMs in contained use. This production type has been used traditionally for many years for production of enzymes and today the technique is increasingly used also for so-called precision fermentation of a broader variety of ingredients. The final ingredients need pre-marketing approval in the EU under the specific sectoral legislation (novel foods, food and feed additives etc.). Safety assessment of newly expressed proteins is carried out by the European Food Safety Authority (EFSA) as part of the authorization procedure for the specific products. So far, no animal cell cultured foods and feeds are authorized for marketing in the EU including Denmark.

Estonia

Estonia, as a member of the European Union (EU), follows EU regulations on GM food and feed (including new breeding techniques), and novel food.

In Estonia, GMOs are mainly used in animal feed, while GM foods are rarely available on the market.

Maize MON810 is the only GM crop which can be cultivated in EU and it's have not been cultivated in Estonia. The reason is that the maize pest that MON 810 maize is designed to resist, is not common in Estonian climate.

The Gene Technology Committee advises government agencies on gene technology and assesses the environmental risks of GMOs.

The Environmental Board is responsible for supervising the release of GMOs into the environment in Estonia. The Agricultural and Food Board is the competent authority to control the production and marketing of GM food and feed in Estonia. Every year, the Agricultural and Food Board checks the compliance of GMOs in food and feed.

Estonia does not have its own reference laboratory for GMO analysis, therefore monitoring samples are analysed at the BIOR laboratory in Latvia.

No new national developments occurred in this area over the past year. Information on EU-wide topics applicable in Estonia can be found under the EU section.

Finland

Legislation

As a Member State of the European Union (EU), Finland implements EU legislation concerning novel foods (Regulation (EU) 2015/2283) and genetically modified organisms (GMOs) (Directive 2001/18/EC; Regulations (EC) No 1829/2003 and 1830/2003; Directive 2009/41/EC). Finland also participates in the EU-level safety assessment and decision-making procedures.

The EU aims to strengthen the role of biotechnology and bioeconomy in enhancing competitiveness, supporting the green transition, and improving strategic autonomy. These initiatives fall under the EU's Competitiveness Compass. Key current initiatives include:

- **NGT (New Genomic Techniques) Regulation Proposal**
Aims to promote innovative plant breeding and agricultural biotechnology. A preliminary political agreement in the trilogue negotiations was reached in December 2025, but final adoption is still pending.
- **Biotech Act I**
Seeks to develop a leading health biotechnology ecosystem and reinforce EU competitiveness. It also includes initiatives relevant to the food sector. Published in December 2025 and currently under discussion at EU level.
- **Biotech Act II**
A forthcoming regulatory framework covering energy, agriculture, industrial bioprocessing, and defence biotechnology. Publication is expected in late 2026.
- **Biotechnology Directive**
Intended to update the GMO environmental release directive as well as the tissues and cells directive. The goal is to accelerate market access for safe genetically modified microbes (excluding food and feed uses). Council deliberations began in March 2026.

GM Food and Feed

The market situation in Finland regarding GM products remains largely unchanged. Only very limited or sporadic quantities of GM foods are available. Some “GM-free” labelled products are on the market. No unauthorised use of GMOs has been detected in Finland since the previous meeting. GM soybean continues to be used as a protein source in animal feed.

Cultivation and Field Trials

GM plant cultivation is not relevant in Finland, as maize MON810 is the only GM crop approved for cultivation in the EU. The Nordic climate restricts maize cultivation, and the trait in MON810 (protection against the corn borer moth) is not relevant for Finland, where the pest occurs only sporadically. No field trials involving GMOs intended for food or feed use are currently ongoing.

Non-GM Novel Foods

Active discussions on the novel food status of various products have continued at EU level. Finland follows interpretations that have been commonly agreed upon among Member States. Monitoring of novel foods by Customs and municipal authorities is regular and increasingly systematic.

Government-funded research projects on new genomic techniques

Finland currently has a few ministry-funded research projects focusing on new genomic techniques.

KaVEdiT project

The project gathered extensive information through discussions and surveys on consumer and crop producer attitudes toward genome editing, as well as their potential willingness to adopt varieties developed using these methods. The findings support national policymaking and increase the food chain's understanding of short-term impacts should regulatory requirements be relaxed.

GENOVA project

Integrates genomic selection, gene editing, and societal engagement to advance plant breeding. The project focuses on timothy, barley, and turnip rape, aiming to develop new breeding methods to address challenges related to climate change, pests, and more efficient use of production inputs.

Germany

1. Genetically modified food and feed / novel food legislative framework

Germany as a member of the European Union (EU) implements EU community-level decisions and regulations on genetically modified (GM) food and feed at the national level. Regulation (EC) No 1829/2003 regulates the placing on the market of GM food and feed. In this context, Germany is actively involved in the Member State consultation process conducted by the European Food Safety Authority (EFSA) and provides input in the risk assessment through its national Competent Authority, the German Federal Office of Consumer Protection and Food Safety (BVL), which besides food and feed aspects also evaluates environmental impacts of GMOs.

All products that are authorised for placing on the EU market can be found in the EU Register of GM food and feed (<https://ec.europa.eu/food/food-feed-portal/screen/gmo/search>). Currently, GMOs are only authorised for import and use as food/feed products in Germany. If appropriate, a post-market monitoring plan (PMM) regarding the use of the GM food/feed for human/animal consumption is requested in the authorisation to verify that the conditions of use are properly applied and to monitor the consumption of the product.

In the EU, GM food is not considered as 'novel food'. According to regulation (EU) 2015/2283, 'Novel food' means any food that was not used for human consumption within the EU before 15 May 1997. It can be newly developed, innovative food, food produced using new technologies and production processes, as well as food, which is or has been traditionally eaten outside of the EU. The EU Novel Food Catalogue (https://food.ec.europa.eu/safety/novel-food/novel-food-catalogue_en) provides an overview (non-exhaustive list) of products of animal and plant origin and other substances subject to the Novel Food Regulation. Novel foods that have been authorized so far are listed in the Annex to Regulation (EU) No 2017/2470. The Annex represents the Union list of novel foods and is constantly updated with new entries. The products in the list may be placed on the market, if the conditions of use, specific labelling requirements, specifications, and other requirements indicated are met.

In the feed sector, neither a corresponding legal definition of the term 'novel feed' nor an independent regulation is currently in force in the EU.

2. GM food and feed detection

Food and feed safety inspections are organized on the level of Federal States in Germany. Authorised GMO laboratories in the Federal States conduct detection, identification and quantification of GMOs present in food and feed. A "National Reference Laboratory for Genetically Modified Organisms (NRL-GMO)", located at the BVL, supports and coordinates their work. The NRL-GMO together with 19 German enforcement laboratories is part of the European Network of GMO Laboratories (ENGL), which works to harmonise methods for detection and identification of GMOs on EU level. Information on validated DNA-based detection methods can be found in the "GMOMETHODS application" provided by the EU Joint Research Centre (<https://gmo-crl.jrc.ec.europa.eu/gmomethods/>).

In case risks to public health are detected in the food chain, including for example detection of unauthorized GMOs or GM components, information is EU-widely shared by the "RASFF – Rapid Alert Systems for Food

and Feed” (https://ec.europa.eu/food/safety/rasff-food-and-feed-safety-alerts_de), enabling swift reaction in all European countries as appropriate.

The German government funds research related to GM food and feed detection; e.g.:

- **AI-supported bioinformatics approach for GMO analysis.** As the number of GMOs is steadily increasing, the current (mostly PCR based) screening methods are becoming more and more complex, while remaining largely limited to the detection of known GMOs. In order to tackle this growing problem, BVL is currently working on a generalized, AI-supported bioinformatics approach for the evaluation of next generation sequencing data as a GMO screening tool.

3. New breeding techniques

NBT products in the EU are GMOs according to the ruling of the Court of Justice (ECJ) of 25 July 2018, thus fall under the scope of Directive 2001/18/EC and are subject to the obligations laid down therein. Currently, no NBT products that do not contain transgenes are authorized as food/feed or for cultivation in the EU neither have such applications been received.

The German government funds research projects related to NBT products. Funding is furthermore provided for fundamental research in this area and projects on analytical aspects, e.g.:

- The **ALIGN project** (“Advancing Legal, Innovative, and Governance Networks for NGTs in Plants”) examines the ethical, legal and social aspects (ELSA) of new genomic techniques (NGTs) in plant breeding and develops concepts for a responsible governance. As a sub-project, JKI-SB will carry out a systematic literature search of NGT applications on plants and their regulation worldwide. The CADIMA database tool developed and maintained by JKI-SB will be used for this purpose. The scientific literature data obtained will be evaluated with regard to origin and type of NGT application, market relevance, safety and regulation.

4. International activities

- The German BVL and the Dutch WFSR host and maintain EUginus, the “**European GMO Initiative for a Unified Database System**” (<http://www.euginus.eu>) in close cooperation with official GMO detection and identification laboratories in Austria, Italy and Poland. EUginus’ intention is to support competent authorities and private users who seek accurate information on GMOs. It provides detailed information of major and relevant issues regarding the presence, detection and identification of GMOs worldwide, with a focus on the situation in the EU.

Dagand, E., Prins, T.W., Adamse, P. et al. EUginus: a comprehensive database facilitating GMO detection and identification. *J Consum Prot Food Saf* 20, 423–428 (2025). <https://doi.org/10.1007/s00003-025-01568-2>

- The **Expert Forum “Modern Molecular Methods in Biotechnology – Perspectives for Research and Applications” (24–25 February 2026)** was organized by the BVL and served as a platform for professional exchange on new developments and current research approaches in the field of biotechnology. The event focused on the opportunities, as well as the challenges and the legal framework, associated with the use of genetic engineering techniques in various fields of application. In four panels, international experts presented and discussed current applications of new genomic technologies (NGT), gene drives and synthetic biology, as well as the analytical detection of genetic modifications.
- In 2023 the German Federal Institute for Risk Assessment (BfR) in cooperation with the BMLEH, the BVL, the BCH and the JRC organised an International Conference on GMO Analysis and New Genomic Techniques. The results of the discussion of almost 500 participants from more than 50 countries are published.

Hermann Broll, Joachim Bendiek, Albert Braeuning, Kolja Neil Eckermann, Anuscha Gebhardt, Lutz Grohmann, Nina Keiss, Jörn Lämke, Joachim Mankertz, Werner Schenkel, Ursula Vincent, Christopher Weidner, Maddalena Querci (2025). Current status and trends in the analysis of GMO and new genomic techniques. *Journal of Consumer Protection and Food Safety*. *J Consum Prot Food Saf* 20, 89–92 (2025). <https://doi.org/10.1007/s00003-025-01542-y>.

- The BfR is currently coordinating an international research project “BioInsectonomy” dealing with safety aspects of insects as feed. Beside the development of detection methods for insect species, feeding trials are ongoing using different insect species as substrate to feed fish (<https://www.bfr.bund.de/en/project/a-circular-economic-system-based-on-organic-side-streams-using-insects-as-feed-for-sustainable-aquaculture/>). The project ends in 2026.
- The BfR participated in the SFA Roundtable on Novel Foods Regulations organised by the Singapore Food Agency (SFA) and in The Asia-Pacific Agri-Food Innovation Summit 2025 in Singapore in November 2025. The Roundtable discussion among governmental representatives from countries from all continents strived through different aspects of Novel Food safety including precision fermentation and cell-cultured meat. In the Asia-Pacific Agri-Food Innovation Summit 2025 more than 800 senior decision-makers from agribusinesses, food and ingredients brands, governments, funds, philanthropic organisations discussed technologies, policies, finance models, and partnerships that catalysed innovation in farming, food manufacturing, and retail across Asia-Pacific.
- In 2025, the BMLEH officially launched the ‘Forum: Proteins of the Future on Our Plates’, with the aim of promoting the cultivation and use of alternative protein sources such as pulses, nuts, seaweed and mushrooms. It should be a support for start-ups in the novel food sector, as well as the implementation of policy measures. Beside start-ups and governmental institutions, the BfR is also represented for the consideration of food and feed safety aspects. The ‘Forum: Proteins of the Future on Our Plates’ is organising bi-annual meetings with the stakeholders.

Italy

GM food and feed

As a member State of the European Union, EU regulations on biotech products also apply to Italy. Accordingly, Italy participates in the safety assessment and decision-making processes under Regulation (EU) 2015/2283 on novel foods, Regulation (EC) No 1829/2003 on genetically modified foods and feeds and Directive 2001/18/EC on deliberate release into the environment of GMOs.

NTG and field trials

In Italy, field trials of plants obtained by using site-directed mutagenesis or cisgenesis 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 N°. 68 of June 13, 2023 and Law N°. 101 of July 12, 2024.

Further, the 2026 Budget Law (Law N° 199 of 30th december 2025) amending the previous laws allows the deliberate release of crop plants obtained by site-directed mutagenesis or cisgenesis techniques until 31th December 2026. In Italy only deliberate release for experimental purposes have been authorized, the approved field trials consisted of plants obtained by using site-directed mutagenesis or cisgenesis. References and information can be found at the National Competent Authority website.

From March 2025 to March 2026 the following field trials have been authorized:

Notification Number B/IT/25/01

A trial evaluating rice blast tolerance during open-field cultivation without fungicides in rice plants—Telemaco and Vialone Nano varieties, and Tommaso and Pacifico lines—modified using genome editing techniques

Notification Number B/IT/25/02

Open-field trials with apple (*Malus x domestica*) with the insertion of the Rvi12_Cd5 (Vb) gene via cisgenesis into the Gala variety to evaluate the reduction in pesticide use and tolerance to apple scab.

Notification Number B/IT/25/03

Open field experimentation with tomato plants (*Solanum lycopersicum* L.), San Marzano variety, genetically modified with functional deactivation through genome editing techniques of the DMR6_1 gene to induce tolerance to biotic and abiotic stresses

Risk assessment for GMMs

Competent Authorities (CA) under Directive 2009/41/EC, regarding the contained use of Genetically Modified Microorganisms (GMMs) is the Ministry of Health (MoH). In compliance with the Italian Legislative Decree 206/2001, the CA authorizes GMMs installations and activities in accordance with the opinions of the Biotechnology Health Technical Committee (BHTC) of the MoH. The Italian Legislative Decree 206/2001 does not regulate the contained use of GMOs other than GMMs, i.e. GM plants and GM animals. The Contained use of GMMs evaluated for authorization, hold all areas Biotech Sectors (red white and green) and belong mostly to containment classes 1 and 2, except for a small number that belong to containment class 3, often used for research. Most of those GMMs authorized have been obtained by editing techniques (CRIPR Cas 9 and also other techniques), short interfering RNA, microRNA, etc. In some cases, editing techniques have also been used and authorized for advanced therapy drug development (ATMP).

Novel Food

In 2025 The Italian Institute of Health (ISS) started contributing to the Novel Foods risk assessment activities at the EU level carried out by EFSA via a newly established Framework Partnership Agreement (FPA). ISS is part of the first ranked consortium awarded under the FPA, led by DTU (Denmark). Towards the end of 2025 the first dossiers have been assigned and are currently under assessment.

Environmental Risk Assessment

ISPRA, Italian Institute for Environmental Protection and Research, in the last year assessed (with a focus on environmental risk assessment):

3 notifications for experimental environmental release of plants in Italy,

6 notifications for the placing on the market genetically modified organisms as or in products within the European Union and 2 renewal requests for the placing on the market genetically modified organisms as or in products within the European Union,

77 Summary Notification Format for the experimental release of GMOs within the European Union.

The Institute actively follows the Risk assessment and management item of the Cartagena Protocol. ISPRA works within an interest group of the EPA and ENCA networks on GMOs dealing with ERA and monitoring: <https://www.encanetwork.eu/interestgroups/gmo>

Project activity

1. The TEA4IT project (October 2025). Assisted Evolution Technologies (TEA) for Italian agri-food supply chains, a project funded with €9 million by the Ministry of Agriculture, Food Sovereignty and Forestry and coordinated by CREA. The aim is to develop resilient, high-quality varieties that best express the distinctive qualitative and nutritional characteristics of the main Italian crops through Assisted Evolution Technologies (TEA), in particular genome editing and cisgenes. The project will involve several universities (Turin, Bologna, Milan, Tuscany, Verona, Catania, Ferrara), public research bodies such as CNR, Fondazione Edmund Mach, and private entities such as IGA Technology Services - together with the CREA Centres for Genomics and Bioinformatics, Horticulture and Floriculture, Cereal Crops and Industrial Crops, Viticulture and Oenology, Olive Growing, Fruit Growing and Citrus Growing, and Forestry and Wood. The plants developed using TEA4IT will undergo rigorous genetic and phenotypic analyses for field trials, authorised by the Ministry of the Environment, in order to verify the consistency between laboratory results and real-world environmental conditions.

2. COLEMUS is a project run by the University of Turin (April 2025-March 2026) that aims to demonstrate the effectiveness and scalability of a method based on genome editing techniques for growing meat without the use of growth factors. This objective can be achieved using a platform developed at the University of Turin called GERALT ('Genetically Enhanced Renewal and Autonomous Lineage Transdifferentiation'), which allows the expansion of pluripotent stem cells and their subsequent differentiation without the use of expensive growth factors or FBS. GERALT is based on the genetic engineering of safe genomic regions to express two transcription factors capable of dictating stem cell or muscle cell identity; these are reciprocally controlled by a single, inexpensive molecule, doxycycline, to allow alternation between genetic programmes of rapid expansion and rapid differentiation. The aim of COLEMUS is: (1) to validate the scalability of this first prototype and; (2) to demonstrate the applicability of GERALT in a pig cell line already used in the cultured meat production chain.
3. OSF - Development of Fruit Tree Varieties with Novel Traits of Commercial Value by Use of Gene Editing and Related Technologies. Collaborative project between Okanagan Specialty Fruits Inc. (OSF, Canada) and the Edmund Mach Foundation. 2023-2025
4. PRIN 2022: (MUR and Next Generation EU) Development of a transgene-free genome editing tool for clonally propagated fruit crop. University of Bologna and University of Turin (2024-2026).
5. PRIN 2022 PNRR (MUR and Next Generation EU) TOLERANT - ModulaTing hOrmone signaLLing for waTer productivity and dRought resistANce in Tomato National Research Council Institute of Agricultural Biology and Biotechnology, Milano (2023-2026).

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Japan

1. Update information of safety assessment for GM Foods and Food Additives

Safety assessment of GM foods and food additives is mandatory under the Food Sanitation Act. Consumer Affairs Agency (CAA) receives applications for GM foods and food additives, and the Food Safety Commission (FSC) evaluates the safety of GM foods and food additives in terms of human health.

As of February 2026, 345 GM foods (12 potato; 32 soybean; 4 sugar beet; 216 maize; 25 oilseed rape (canola); 49 cotton; 5 alfalfa; 1 papaya; and 1 mustard) and 91 GM food additives have undergone safety assessment and been announced in the Official Gazette; out of these foods and food additives, 8 foods and 5 food additives have undergone safety assessment and been announced in the Official Gazette since the last meeting in March 2025.

2. Update information of safety assessment for GM Feeds and Feed Additives

Safety assessment of GM feeds and feed additives is mandatory under the Law Concerning Safety Assurance and Quality Improvement of Feeds. The Ministry of Agriculture, Forestry and Fisheries (MAFF) receives applications for GM feeds and feed additives. The Agricultural Materials Council of MAFF evaluates risks of feeding them to livestock and the FSC evaluates food safety risks of animal products derived from livestock fed with them.

As of February 2026, 113 GM feeds (21 oilseed rape (canola); 39 maize; 21 soybean; 21 cotton; 4 sugar beet; 3 alfalfa; and 4 potato) and 19 feed additives have undergone safety assessment and been announced in the Official Gazette; out of these feeds and feed additives, 7 feeds and 3 feed additive have undergone safety assessment and been announced in the Official Gazette since the last meeting in March 2025.

Korea

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

In Korea, the regulation of Living Modified Organisms (LMOs) is governed by the "Trans-boundary Movement, etc., of Living Modified Organisms Act". The legislation aims to improve people's lives and promote international cooperation by preventing harmful effects of LMOs on people's health and the sustainable use and conservation of biodiversity. It establishes a framework for ensuring safety on the development, production, import, export, and distribution, etc of LMOs. Under this Act, the state and local governments shall implement policies necessary to prevent risk that may be posed by LMOs.

To the present, Korea has granted approval for 204 LMO events for feed purposes, 222 events for food applications, 104 events for industrial uses, and 2 events for health-related applications. It is noteworthy that there have been no approvals for cultivation to date.

In the year 2025, the following new LMO approval events were recorded:

For food use, 8 new events were approved, including 3 events for maize, 3 events for soybean, 1 event for canola and 1 event for microbes

For feed use, 12 new events were approved, encompassing 5 events for microbes, 4 events for maize, 3 events for soybean.

Table. List of LMO approved for commercial use in Korea during 2025

Organisms	Event	Type of use	Traits
Maize	DP-051291-2	Feed	Insect Resistance & Herbicide Tolerance
	MON95275	Feed	Insect Resistance
	Bt11xMIR162xNK603	Food	Insect Resistance & Herbicide Tolerance
	Bt11xMZIR098xDP-004114-3xNK603	Food	Insect Resistance & Herbicide Tolerance
	DP-910521-2	Food	Insect Resistance & Herbicide Tolerance
	DP-202216-6xNK603xDAS-40278-9	Feed	Yield Improvement & Herbicide Tolerance
	Bt11xMIR162xMZIR098xDP-004114-3xNK603	Feed	Insect Resistance & Herbicide Tolerance

Soybean	MON94313	Feed, Food	Herbicide Tolerance
	DP-305423-1xDAS-44406-6	Feed, Food	Altered Fatty Acid Composition & Herbicide Tolerance
	GMB151xDAS-44406-6	Feed, Food	Insect Resistance & Herbicide Tolerance
Canola	NS-B50027-4	Food	Altered Fatty Acid Composition & Herbicide Tolerance
Microbe	DS003	Food	Enzyme Production For Allulose Conversion
	GC005	Feed	Enzyme Production for 6'-Sialyllactose Process
	GC004	Feed	Enzyme Production for 3'-Sialyllactose Process
	GC003	Feed	Enzyme Production for 3'-Sialyllactose Process
	GC002	Feed	Enzyme Production for 3'-Sialyllactose Process
	GC001	Feed	Enzyme Production for 3'-Sialyllactose Process

2. Development/review/amendment of national strategies, regulations and guidance

Korea is advancing a reform of its GMO labeling system through amendments to Food Sanitation ACT adopted in late 2025. The reform is generally understood as a move toward full GMO labeling. A key feature of the amendment is the shift in labeling criteria from the detectability of genetically modified DNA or protein in the final product to the use of genetically modified raw materials in production. This is expected to broaden the scope of products subject to GMO labeling. The reform also includes changes to the criteria for non-GMO labeling, with further details to be determined through subsequent regulatory measures.

2. Updates regarding international activities

Participation in/hosting international symposia/fora relating to biosafety

In 2025, Korea carried out a range of domestic and international communication activities related to agricultural biotechnology.

At the international level, as Chair of the APEC High-Level Policy Dialogue on Agricultural Biotechnology (HLPDAB), Korea organized a workshop on digital and precision breeding for food security and sustainable agriculture. In addition, a webinar was held to share information on the research and development status and future directions of the Korean agricultural biotechnology sector. These activities provided an opportunity not only to exchange information on domestic R&D, but also to share regulatory trends on agricultural biotechnology products across Asia, the Americas, and Europe, thereby supporting a broader understanding of the global regulatory landscape.

3. Developments related to new breeding techniques (NBTs)

Development/review/amendment of national strategies, regulations and guidance

Korea has continued policy discussions on genome editing technologies through multi-stakeholder forums and seminars.

In late 2025, related events were held to discuss regulatory approaches to gene-edited organisms (GEOs), including international policy trends and possible directions for the domestic regulatory framework.

These discussions also addressed potential legislative and institutional considerations under the existing biosafety system, reflecting continued efforts to explore a science-based approach to the governance of genome editing technologies.

Latvia

Developments/Activities in the Safety of Novel Foods and Feeds

As an EU Member State, Latvia implements EU community-level decisions and regulations on genetically modified (GM) food and feed at the national level. Latvia actively participates in the safety assessment and decision-making processes under Regulation (EU) No 1829/2003 on genetically modified foods and feeds.

GM food is not considered as novel food in the EU. According to regulation (EU) No 2015/2283, 'Novel food' means any food that was not used for human consumption within the EU before 15 May 1997. It can be newly developed, innovative food, food produced using new technologies and production processes, as well as food, which is or has been traditionally eaten outside of the EU. Novel foods that have been authorised so far are listed in the Annex to Regulation (EU) No 2017/2470. The Annex represents the Union list of novel foods and is constantly updated with new entries. The products in the list may be placed on the market, if the conditions of use, specific labelling requirements, specifications, and other requirements indicated are met.

Latvia is involved in the Member State consultation process conducted by the European Food Safety Authority (EFSA) and provides input in the risk assessment through its national Competent Authority - State Scientific Institute "Institute of Food Safety, Animal Health and Environment "BIOR"". In 2025 "BIOR" regularly took part at centralized EU GMO risk assessment procedure and provided opinion on four applications in respect of GMO placing on the EU market.

Authorised GMO laboratory - the State Scientific Institute "Institute of Food Safety, Animal Health and Environment "BIOR"" conduct detection, identification and quantification of GMOs present in food and feed.

There is a special program adopted every year for supervision and control of GMO in food/feed and as well as to control GMO on the border in imported products from third countries. Control is performed by the Food and Veterinary Service on the presence of GMO in approved and non-approved GMO foods, and feeds in accordance with Regulation (EU) No 2017/625.

Due to low consumer acceptance, almost no GM food products are marketed in Latvia, whereas the use of GM feed is very common, our animal breeding sector relies to a large extend on imported feed consisting of or containing of mainly GM soy from cultivation outside EU.

New genomic techniques

On 28 January 2026, the European Parliament's ENVI Committee voted in favour of the final compromise text of the Regulation on plants obtained by certain new genomic techniques and their products (NGT). The proposal, which is supported by Latvia, is still subject to legal-linguistic revision.

Since the adoption of the current EU legislation on genetically modified organisms (GMOs) in 2001, there has been substantial progress in the development of NGTs that enable more targeted, precise and faster changes in the genetic characteristics of plants, as compared to conventional breeding techniques.

The proposal aims to enable the EU agri-food sector to contribute to the innovation and sustainability objectives of the European Green Deal and Farm to Fork and Biodiversity strategies, and to enhance the sector's competitiveness, while maintaining a high level of protection of health and of the environment.

Paraguay

Activities pertaining to agricultural biotechnology are subject to regulations in Paraguay, which established a set of regulations in 1997 and subsequently supplemented them with additional legal instruments. The most recent of these measures, a decree issued in 2012, established the National Agricultural and Forestry Biosafety Commission (CONBIO), which is overseen by the Ministry of Agriculture and Livestock (MAG). This commission is responsible for evaluating, analyzing, and making recommendations on all matters related to the introduction, field trials, pre-commercial and commercial release, and other intended uses of genetically modified products related to the agri-food system.

1. Commercial Approvals

The following GM products were released from 2025 to 2026:

1.1. Genetically modified plants

Decision No.	Organism / Product	Event	Proposed commercial use	Characteristics	Regulatory mechanism
Res. MAG 43/2026	Soybean	BCS-GM151-6 x DAS-44406-6	Resistance to Nematode, Tolerance to Isoxaflutole	cry14Ab-1.b, hppdPf-4Pa	Differentiated treatment for the commercial release of GM crops that have been approved in third countries (Resolution MAG 1030/2019 and 1071/2019)
Res. MAG N° 1853/2025	Maize	DP-2Ø2216-6	Increased yield potential, Tolerance to Glufosinate	mo-pat, zmm28	Differentiated treatment for the commercial release of GM crops that have been approved in third countries (Resolution MAG 1030/2019 and 1071/2019)
Res. MAG N° 1388/2025	Maize	EH-BRS913-2	Resistance to Lepidoptera, Tolerance to Glufosinate	cry1Da, phosphinothricin acetyltransferase (bar)	Differentiated treatment for the commercial release of GM crops that have been approved in third countries (Resolution MAG 1030/2019 and 1071/2019)
Res. MAG	Maize	DAS-	Resistance to	cry1Da2,	Differentiated

N° 1034/25		Ø1131-3	Lepidoptera, Tolerance to Glyphosate	dgt-28 epsps	treatment for the commercial release of GM crops that have been approved in third countries (Resolution MAG 1030/2019 and 1071/2019)
Res. MAG 17/2025	Soybean	MON- 94637-8	Resistance to insect	cry1A.2, cry1B.2	Differentiated treatment for the commercial release of GM crops that have been approved in third countries (Resolution MAG 1030/2019 and 1071/2019).
Res. MAG 16/2025	Maize	MON- 948Ø4-4	Short stature	GA20ox_SUP	Differentiated treatment for the commercial release of GM crops that have been approved in third countries (Resolution MAG 1030/2019 and 1071/2019).
Res. MAG 15/2025	Soybean	MON- 94313-8	Tolerance to 2 4- dichlorophenox yacetic acid (2 4-D), Tolerance to Dicamba, Tolerance to Glufosinate, Tolerance to Mesotrione	dmo, ft_t, pat, tdo	Differentiated treatment for the commercial release of GM crops that have been approved in third countries (Resolution MAG 1030/2019 and 1071/2019).

1.2. Genetically modified microorganisms (MGMs)

Decision No.	Organism	Product	Proposed commercial use	Characteristics	Regulatory mechanism
Res. MAG N° 686/2025	<i>Saccharomyces cerevisiae</i>	SCY021	Ethanol production	Glucoamylase enzyme expression, Reduced glycerol production	Commercial release of novel GM (Resolution MAG 18/2015)
Res. MAG N° 687/2025	<i>Saccharomyces cerevisiae</i>	SCY022	Ethanol production	The strain contains genes encoding alpha-amylase and glucoamylase, which enable the conversion of starch into fermentable	Commercial release of novel GM (Resolution MAG 18/2015)

				sugars during the industrial fermentation process	
Res. MAG N° 1857/2025	<i>Saccharomyces cerevisiae</i>	SCY023	Ethanol production	Glucoamylase enzyme expression, Reduced glycerol production	Commercial release of novel GM (Resolution MAG 18/2015)
Res. MAG N° 1856/2025	<i>Saccharomyces cerevisiae</i>	SCY024	Ethanol production	Glucoamylase enzyme expression, Reduced glycerol production	Commercial release of novel GM (Resolution MAG 18/2015)
Res. MAG N° 1855/2025	<i>Saccharomyces cerevisiae</i>	SCY025	Ethanol production	Glucoamylase enzyme expression, Alpha-amylase enzyme expression, Reduced glycerol production	Commercial release of novel GM (Resolution MAG 18/2015)
Res. MAG N° 18/2025	<i>Saccharomyces cerevisiae</i>	GICC03674 (GPY010285)	Ethanol production	Glucoamylase enzyme expression, Reduced glycerol production	Commercial release of novel GM (Resolution MAG 18/2015)
Res. MAG 18/2025	<i>Saccharomyces cerevisiae</i>	GPY012850 (GICC03674)	Ethanol production	Glucoamylase enzyme expression, Reduced glycerol production	Commercial release of novel GM (Resolution MAG 18/2015)

1.3. Vaccines

Decision No.	Product	Proposed commercial use
Res. MAG N° 1854/2025	VECTORMUNE FP-LT	Developed using a genetically engineered avian poxvirus for use in birds. The avian poxvirus has been genetically modified to express key protective antigens of the avian laryngotracheitis (LT) virus.
Res. MAG N° 1456/2025	Vaxxitek HVT+IBD+ND	Infectious bursal and Newcastle and Marek's disease.
Res. MAG N° 1455/2025	VECTORMUNE FP-MG+AE	Live vector freeze-dried vaccine. For the active immunization of chickens against <i>Mycoplasma gallisepticum</i> , Fowl Pox and Avian Encephalomyelitis.

2. New Breeding Techniques (NBTs)

A total of three (03) prior consultation forms (PRY-Form 3) were submitted for the period March 2025 to March 2026.

In November 2025, under the Multilateral Memorandum of Understanding, a virtual bilateral technical meeting was held between Paraguay and Argentina to jointly analyze the regulatory status of two products derived from NBTs that had been submitted for prior consultation in both countries. Both delegations reviewed the technical information and compared the criteria applied in each country, confirming that the characterization was consistent between the two countries, there were no differences in the scientific and regulatory interpretation of the case, and both countries fully agreed on the determination of the regulatory status of the two products analyzed.

3. Participation in International Activities

Date	Place	Activities
28/11/2025	Asunción, Paraguay Buenos Aires, Argentina	ABRE-Bio: A virtual bilateral technical meeting was held between Paraguay and Argentina to jointly analyze the regulatory status of two products derived from New Breeding Techniques, which were submitted for prior consultation in both countries.
02-08/11/2025	Ghent, Belgium	International Seed Federation (ISF) Meeting, International Society for Biosafety Research (ISBR), Sixth International Workshop on Regulatory Approaches to Agricultural Applications of Animal Biotechnologies, Inter-American Institute for Cooperation on Agriculture (by its Spanish acronym, IICA) Workshop of Regulators of the Americas.
01/10/2025	Foz de Iguazu, Brazil	Meeting of the Commission for Agricultural Biotechnology of SGT No. 08 of MERCOSUR (MERCOSUR-SGT8).
29/09/2025	Foz de Iguazu, Brazil	GT5 meeting "Public policies in biotechnology" of the Southern Agricultural Council (CAS-GT5).
05-06/05/2025	Vitoria, Brazil	10th Biennial Brazilian Biosafety Congress.

4. Relevant publications

Benítez, N., Ulke, G., Sotelo, P., Nara, E., Arrúa, A., & Fernández, D. (2024). Paraguay's approach to Biotechnology Governance: A comprehensive guide. *Frontiers in Bioengineering and Biotechnology*, 12. <https://doi.org/10.3389/fbioe.2024.1373473>

Cardozo Ruíz Díaz, E. B., Quintana, S. A., Rojas, C., & Fernández Ríos, D. (2024). Building bio-innovation systems through advanced biotechnology education. *Frontiers in Bioengineering and Biotechnology*, 12. <https://doi.org/10.3389/fbioe.2024.1415103>

Fernández Ríos, D., Benítez Candia, N., Quintana, S. A., Goberna, M. F., Nara, E. M., Arrúa, A., & Castro Alegría, A. (2025). Naturally transgenic plants and the need to rethink regulatory triggers in biotechnology. *Frontiers in Bioengineering and Biotechnology*, 13. <https://doi.org/10.3389/fbioe.2025.1600610>

Fernández Ríos, D., Benítez Candia, N., Soerensen, M. C., Goberna, M. F., & Arrúa, A. A. (2024). Regulatory landscape for new breeding techniques (NBTs): Insights from Paraguay. *Frontiers in Bioengineering and Biotechnology*, 12, 1332851. <https://doi.org/10.3389/fbioe.2024.1332851>

Fernández Ríos, D., Quintana, S. A., Gómez Paniagua, P., Arrúa, A. A., Brozón, G. R., Bertoni Hicar, M. S., Castro Alegría, A., & Goberna, M. F. (2025). Regulatory Challenges and Global Trade Implications of Genome Editing in Agriculture. *Frontiers in Bioengineering and Biotechnology*, 13. <https://doi.org/10.3389/fbioe.2025.1609110>

Singapore

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

2. Development/review/amendment of national strategies, regulations and guidance

GM food regulations in Singapore

The Singapore Food Agency (SFA; www.sfa.gov.sg) is Singapore's statutory agency that oversees food safety and food security from farm-to-fork.

In 2025, the Food Safety and Security Act (FSSA; <https://sso.agc.gov.sg/Act/FSSA2025>) was passed by Parliament (8 Jan 2025) to consolidate and refresh existing food-related legislation to strengthen Singapore's food safety regime to better protect consumers, and to keep pace with emerging challenges in safeguarding food security. A key provision in FSSA is the formalisation of SFA's existing pre-market approval process for GM food and novel food.

New GM food approval process in Singapore

Under the new approval process, GMO developers who wish to supply GM food or food ingredients must first submit a proposal to SFA. SFA will forward the proposal to Singapore's Genetic Modification Advisory Committee (GMAC). GMAC is a non-regulatory advisory committee that provides scientific advice on the production, research, use and release of GMOs to statutory agencies in Singapore. GMAC conducts a holistic biosafety assessment based on Singapore's guidelines on the release of agriculture-related GMOs, looking at the impact of the GMO on humans, animals, plants, and the environment.

SFA will conduct food safety assessment on the GMO according to Codex guidelines, such as "CAC/GL 45-2003 Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA Plants" and will take into account GMAC's biosafety evaluation to determine the outcome of the GM food/feed application.

As of April 2026, SFA has approved:

- 134 GM crops for use as food. Full list can be found here: sfa.gov.sg/docs/default-source/regulatory-standards-frameworks-and-guidelines/list-of-approved-gm-crops-for-use-as-food-or-as-food-ingredients.pdf
- 137 GM crops for use as feed. Full list can be found here: sfa.gov.sg/docs/default-source/food-import-and-export/list-of-approved-gm-crops-for-animal-feed.pdf

6. Research projects on biosafety; relevant publications.

With inputs from GM crop developers, SFA has incorporated OECD Unique Identifiers into Singapore's latest GMO approval lists (last update on 17 April 2026).

3. Developments related to new breeding techniques (NBTs)

1. Development/review/amendment of national strategies, regulations and guidance

Updates on implementation of a regulatory framework for the use of genome edited crops in food and/or animal feed

SFA's regulatory framework for GEd (Genome Edited) crops (<https://www.sfa.gov.sg/regulatory-standards-frameworks-guidelines/genetically-engineered-food-and-feed/regulatory-framework-for-the-use-of-genome-edited-crops-in-food-and-or-animal-feed>), implemented in August 2024, consists of two regulatory pathways:

- a. **Pathway A** is for GEd crops that are equivalent to crops derived from conventional breeding techniques. Examples of such crops include, but are not limited to:
 - A crop with a non-functional gene arising from cellular repair of a targeted DNA strand break (i.e., gene knock-out).
 - A crop containing a targeted single base pair substitution in any part of the genome.
 - A crop (host) where an endogenous gene has been substituted with a homologous gene variant originating from another crop that can reproduce with said host via conventional breeding (e.g., breeding between two tomato varieties).
- b. **Pathway B** is for GEd crops that contain genetic elements that could not have been introduced using conventional breeding techniques. Examples of such crops include, but are not limited to:
 - A crop containing DNA from a bacterial, animal, viral sources, or containing DNA sequences not found in nature.
 - A crop containing DNA from another crop that cannot undergo conventional breeding with the GEd crop (e.g., insertion of corn DNA into tomato).

Crops that fall under Pathway A can be notified to SFA on a voluntary basis by submitting an Information Checklist ([sfa.gov.sg/docs/default-source/regulatory-standards-frameworks-and-guidelines/guidance-on-regulatory-framework-for-genome-edited-crops-for-use-as-food-and-feed.pdf](https://www.sfa.gov.sg/docs/default-source/regulatory-standards-frameworks-and-guidelines/guidance-on-regulatory-framework-for-genome-edited-crops-for-use-as-food-and-feed.pdf)) to support the developer's claim that the GEd crops are equivalent to crops derived from conventional breeding techniques. Crops that fall under Pathway B will be subject to the prevailing GMO pre-market assessment and approval process.

2. Specific cases of application, assessment and decision

As of April 2026, one GEd crop has completed Pathway A notification ([sfa.gov.sg/docs/default-source/regulatory-standards-frameworks-and-guidelines/list-of-notified-ged-crops.pdf](https://www.sfa.gov.sg/docs/default-source/regulatory-standards-frameworks-and-guidelines/list-of-notified-ged-crops.pdf)) under SFA's regulatory framework for GEd crops.

Slovak Republic

1. National legislation, and the EU legislation

According to the Article 291 of the Treaty on the functioning of the EU, the Slovak Republic implements EU-harmonised food and feed legislation.

Regulations (EC) No 2015/2283 on novel foods, No 1829/2003 on genetically modified foods and feed and No 1831/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms are directly applicable in the Slovak Republic. Their implementation is ensured by the national Act No 152/1995 on food (Food Act), Act No 355/2007 on Protection, Promotion and Development of Public Health and Act No 271/2005 on the production, placing on the market and use of feed (Feed Act). National Act No 151/2002 on the use of genetic technologies and genetically modified organisms (GMO Act) and Implementing Decree No 399/2005 regulate the contained use of GMOs including the field trials. This Act transposes Directive 2001/18/EC and 2009/41/EC. General rules on the coexistence of genetically modified crops with conventional and organic crops have been established by national Act No 184/2006 on the cultivation of genetically modified plants in agricultural production and Decree No 69/2007. The Regulation (EC) 1946/2003 on the transboundary movements of GMOs implements the related provisions of the Cartagena Protocol on Biosafety.

In the EU, products produced by new genomic techniques (NGT) are subject to GMO legislation. On 5 July 2023, the Commission adopted a legislative proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain NGT and their food and feed products. To enter into force adopted, the draft Regulation must be adopted by the Member States in the Council of the European Union and by the European Parliament, following the ordinary legislative procedure. The legislative procedure is still on-going.

2. Domestic policies and regulations related to animal cell cultured foods and feeds

In the European Union animal cell cultured foods are currently captured by the Novel Food Regulation (EU) 2015/2283. In practice, market access is therefore dependent on authorisation as a novel food, following a scientific safety assessment by the European Food Safety Authority (EFSA) and a subsequent approval at the Union level. At the national level, the Slovak Republic does not have specific legislation on animal cell-cultured food and feed in place, and directly applies the relevant EU regulation.

3. Competences and official controls

The Ministry of Agriculture and Rural Development (MoARD) is the central competent authority (CA) for GM food and feed. Under the MoARD, the State Veterinary and Food Administration (SVFA) is the CA for GMO controls of food throughout the food chain except for catering premises and food for infants. The

Central Control and Testing Institute in Agriculture (CCTIA) is the CA for GMO controls of feed of non-animal origin, seed and cultivation of the authorised GM crops. The samples from the official samples are analysed by the State Veterinary and Food Institute, Veterinary and Food Institute in Dolný Kubín and the CCTIA, that are designated as the National Reference Laboratories pursuant to Regulation (EU) 2017/625 on official controls and other official activities.

Novel foods are in the responsibility of the Ministry of Health. Public Health Authority (PHA) carries out the official control in catering premises, including fast food, food supplements, and food for infants.

The Ministry of Environment (MoE) is the CA for the contained use of GMOs and their deliberate release into the environment for experimental purposes and the National Focal Point for the Cartagena Protocol on Biosafety.

The Slovak Environmental Inspectorate (SEI) is the CA for controls of the contained use of GMOs and of their deliberate release into the environment for experimental purposes.

4. GM Crop Cultivation

Maize MON810 is the only GM crop authorised for cultivation in the European Union, and it has not been cultivated in Slovakia since 2016.

5. Safety assessment of newly expressed proteins

The safety assessment of newly expressed proteins in GM food and feed within the European Union is conducted under the framework of Regulation (EC) No 1829/2003. The detailed requirements for applications are further specified in Commission Implementing Regulation (EU) No 503/2013, which establishes data requirements and procedures for the authorisation of GM food and feed, and amends earlier implementing measures.

The scientific risk assessment is carried out by the European Food Safety Authority (EFSA), specifically its GMO Panel. The evaluation of newly expressed proteins follows internationally recognised principles, combining chemical risk assessment approaches with the guidelines of the Codex Alimentarius for foods derived from modern biotechnology. This includes the assessment of potential toxicity, allergenicity, and dietary exposure, as well as the physicochemical and functional properties of the proteins.

At the national level, Slovakia does not perform an independent safety assessment of newly expressed proteins. As an EU Member State, it relies on the centralised scientific evaluation conducted by EFSA.

6. Research Activities and others

In the field of food and feed derived from cultivated animal cells, in 2025 the National Agricultural and Food Centre (NAFC), in cooperation with Mendel University in Brno, prepared and submitted a Horizon Europe project proposal entitled Cultivated Meat: Opportunities for Pathways to Agricultural Sustainability (COMPAS), which is currently under evaluation. Several European partners contributed to the proposal, with the NAFC's share amounting to approximately 15%.

There are ongoing research initiatives in the field of NGT, including the project NextGeneBEcon_SK (No. 09I01-03-V04-00049), coordinated by prof. Ján Pokrivčák at the Slovak University of Agriculture in Nitra. This project is a national complementary initiative funded under the Slovak Recovery and Resilience Plan. It is linked to the GeneBEcon project under Horizon Europe and aims to support and extend its research activities at the national level, particularly in the areas of socio-economic assessment and stakeholder

engagement related to new genomic techniques. The project focuses on assessing the economic impacts of the application of NGT in agriculture at the level of the Slovak republic, the European Union, and globally. In addition, it seeks to identify barriers, challenges, and potential risks associated with the development and deployment of new biotechnologies in both the EU and Slovakia. Current research outputs address topics such as:

POKRIVČÁK, J. and MARČANOVÁ, M. Status and Development of NGT at the Global and European Level [online]. Nitra: FEM SUA in Nitra, NextGeneBEcon_SK project, 2025. (https://www.rcab.sk/nextgenebecon_sk/)

POKRIVČÁK, J. The Political Economy of Decision-Making on NGT in the EU [online]. Nitra: FEM SUA in Nitra, NextGeneBEcon_SK project, 2025. (https://www.rcab.sk/nextgenebecon_sk/)

Specialised conference dedicated to NGT, 25 September 2025

(<https://www.sppk.sk/clanok/5691>):

Conference organised by the Slovak Chamber of Agriculture and Food, together with the Slovak University of Agriculture in Nitra and the Slovak Breeders and Seed Association. The aim was to bring together policymakers, scientific experts, research organisations, and other stakeholders to discuss recent developments in NGT, their practical implications of NGT for agriculture, the food industry, and consumers. The event sought to promote a better understanding of NGT, support evidence-based policymaking, and encourage an open dialogue on opportunities and regulatory aspects associated with these technologies.

Slovenia

CURRENT DEVELOPMENT IN SLOVENIA

Slovenia, as a member State of the European Union, applies EU legislation. Slovenia participates in the decision-making processes under relevant legislation such as Regulation (EU) 2015/2283 on novel foods, Regulation (EC) No 1829/2003 on genetically modified foods and feeds, and Directive 2001/18/EC on deliberate release into the environment of GMOs.

The competences and the status of GM products in Slovenia remains unchanged.

GMOs in food and feed

The Competent Authority for GMOs in food and in feed is The Administration of the Republic of Slovenia for Food Safety, Veterinary Sector and Plant Protection, which is the body within the Ministry of Agriculture, Forestry and Food. On an annual monitoring basis on GMOs in food and feed, we are establishing that feed consisting of or containing GMO is often on the Slovenian market, but we can rarely find the food consisting of or containing GMOs. In 2025, we tested samples of food, feed and seeds. Slovenia is also monitoring the presence of genetically modified microorganisms (GMM) with antibiotic resistance marker genes in food/feed enzymes and additives. In 2026, Slovenia is continuing the testing of the presence of GMOs in food, feed, seeds, plants and GMM in food and feed.

Monitoring of GMOs in seed

In the framework to ensure safety in the use of products of modern biotechnology the Competent Authority for contained use, deliberate release and placing GMOs on the market is in Ministry of the Environment, Climate and Energy. In that respect, it is also responsible for monitoring of GMOs presence in seeds, which is taking place in Slovenia for many years. All seed samples tested in 2025 were negative for the presence of GM elements. In 2026, 27 samples of seeds of maize, rapeseed, soybean and alfalfa are planned for GMO analysis: 15 samples of maize seed, 5 samples of rapeseed, 5 samples of soybean seeds and 2 samples of alfalfa seeds. All samples will be first analysed by screening analysis with the five-target method for the presence of genetic elements: CaMV 35S promoter, NOS terminator, bar, pat and CTP2-CP4-EPSPS and determination of the reference gene (presence of DNA, maize, soybean, rapeseed or alfalfa). In case of maize and soybean, we additionally perform the testing using pre-spotted plates to identify possible presence of GM lines without screening elements covered by five-target method. Until the date of this report, 5 maize samples were tested in 2026. All the 5 maize samples were negative for the presence of GM elements.

GMOs in cultivation

Slovenia has no commercial cultivation of GMOs, neither field trials. The Competent Authority for coexistence of crops is the Ministry of Agriculture, Forestry and Food. In 2025, six samples of maize grains and two samples of oilseed rape from the field were tested for the presence of GMOs under the law on the coexistence of crops with genetically modified plants. All of them were negative on presence of GMO.

Laboratory's Capacity for GMOs detection

National Institute of Biology (NIB) is nominated as National Reference Laboratory for detection of genetically modified organisms in food, feed and seed, for development of methods and other tasks related to GM control by Ministry of Agriculture, Forestry and Food and Ministry of Environment, Climate and Energy of the Republic of Slovenia. NIB is testing samples of food, feed, plants and seeds for official control. NIB is a holder of the national measurement standard in the category of amount of substances/bioanalysis of nucleic acids, especially in the field of GMOs and microorganisms. Department of Biotechnology and Systems biology at NIB has several qPCR-accredited methods for qualitative and quantitative testing of genetically modified organisms in foodstuffs and agricultural products of plant origin. Further methods are yearly in the process of verification: 3 methods for quantification by dPCR and 8 methods for detection of genetically modified microorganisms (3 methods for the screening of antibiotic resistance marker genes (AMR genes), 1 method for *Bacillus subtilis* reference gene, and 4 methods for specific gene detection (Protease 1 (L and R border), Protease 2 and α -amylase)). In 2025, NIB accredited 6 new methods for detection of genetically modified organisms.

Digital PCR is the latest PCR-based approach that enables absolute quantification of nucleic acids. From 2013 on, NIB greatly contributed to the research of digital PCR (dPCR) for GMO analyses and received three 2021 Positive Droplet Awards from Bio-Rad Laboratories, for contributions to digital PCR in the fields of Metrology, Advanced Multiplexing and Food Testing. Digital PCR is used also during routine analyses especially during verification of methods. In 2025, we have finished developing a new multiplex dPCR approach for quantification of all approved GM soybean lines. The work was published in a scientific paper (Jelenčič et. al (2026) Simple, fast, reliable: multiplex digital PCR quantification of 19 genetically modified soybean events; [DOI:10.1080/21645698.2026.2635816](https://doi.org/10.1080/21645698.2026.2635816)) and the protocol is available as a book chapter (Jelenčič et. al (2025) Multiplex Quantification of 19 GM Soybean Lines Using Digital PCR; DOI: [10.1007/978-1-0716-4767-7_2](https://doi.org/10.1007/978-1-0716-4767-7_2)).

NIB cooperates intensively within European network of GMO laboratories (ENGL) and their working groups and additionally with Directorate F of JRC on studies of reference materials. The Institute is also providing scientific and technical support to authorities. NIB is also a member of the Network of Laboratories for the Detection and Identification of GMOs operating under the Cartagena Protocol on Biosafety and plays an active role in preparing documents for the network.

In 2025 NIB hosted a workshop on the detection and identification of living modified organisms and the role of customs officials in implementing the Cartagena Protocol on Biosafety, organized by Secretariat of the Convention on Biological Diversity from United Nations Environment Programme. Moreover, dr. David Dobnik acted as moderator for the Online discussions of the Network of Laboratories for the Detection and Identification of Living Modified Organisms organized by Biosafety Clearing-House.

New Genomic/Breeding techniques

As part of the European Union, Slovenia participates in the process of adopting new legislation on NGT.

The proposal for an EU Regulation on NGT is still in the final stages of negotiations between the EU Council, the European Parliament and the European Commission.

NIB is following the developments in Genome editing in Plants. NIB was a member of COST Action CA18111 Genome Editing in Plants (<https://plantgenomeediting.eu/>), which ended in 2023. Moreover, as a member of European Network of GMO Laboratories (ENGL), NIB is following and contributing to discussions at this level. NIB is also a member of European Initiative for Sustainable Agriculture through Genome Editing (EU-SAGE, <https://www.eu-sage.eu/>). EU-SAGE is a network representing 134 European plant science institutes and societies that have joined forces to provide information about genome editing and promote the development of European and EU member state policies that enable the use of genome editing for sustainable agriculture and food production.

NIB has also been using one of the new breeding techniques, CRISPR/cas9, for functional analysis of potato genes and miRNAs involved in biotic stress response.

On 1.1.2024 the European project "DETECTIVE – Detection of NGT products to promote innovation in the European Union" was started. The consortium of DETECTIVE is led by the Swedish University of Agricultural Sciences. It includes a multi-disciplinary consortium of 20 partners from eight EU Member States, Switzerland, and China as well as the Joint Research Centre from the European Commission. NIB acts as leader of work package "Protocol development and assay validation" and as a partner in other work packages with significant role as developer of multiplex approaches for detection of NGTs.

A researcher from the Biotechnical Faculty of the University of Ljubljana published a review article in Slovenian language:

Berne, S. (2026). New genomic techniques for precision plant breeding. *Acta Agriculturae Slovenica*, 121(2), 1–15. <https://doi.org/10.14720/aas.2025.121.2.21981>

Cellular agriculture – cultivated meat

Cellular agriculture has faced intense public scrutiny across the EU, including Slovenia, as the regulatory status of such products has not yet been established at the EU level. In 2024, the start-up Tech4Meat, which aims to produce and commercialise cultivated meat for international markets, was founded in Slovenia. Recently, an applied, industry co-funded project titled "Development of Animal-Free Growth Conditions for Enhanced Skeletal Muscle Cell Proliferation, Differentiation, and Myosin Production" received funding from the Slovenian Research and Innovation Agency (ARIS). Led by the Centre of Excellence for Biosensors, Instrumentation and Process Control (COBIK), with the Biotechnical Faculty at the University of Ljubljana as a partner, the project aims to optimise muscle cell culture proliferation using animal component-free (ACF) media (excluding fetal bovine serum - FBS). In addition, the project seeks to develop a suspension-adapted platform for the growth and differentiation of otherwise adherent cells, a critical step towards enabling large-scale production.

Non-GM Novel foods

Common European legislation also applies to novel foods in the EU.

Several novel foods were approved in 2025, for example, *Tenebrio molitor* powder, the plants *Lemna minor* and *Lemna gibba*, and extended the use of isomalto-oligosaccharide (IMO) to new food categories.

Nano

Slovenia follows EU rules.

The National Institute of Public Health (NIJZ) attended the EFSA scientific network meeting on nanotechnologies in food and feed. We follow developments in the field of micro- and nanoplastic pollution, as well as advancements in the analysis of micro- and nanoplastics in the environment and in food.

Researchers at the Jozef Stefan Institute (JSI) are measuring indoor air pollution with nanoparticles released by use of sparkler fountains (SFs), along with the temporal decay of particle number concentration under various conditions. Sparkler candles, also known as cake sparkler fountains (SF) are widely used to create light and sparkling effects for entertainment at birthday parties and other celebrations, delighting both children and adults. They can be considered as a type of miniaturized fireworks, but unlike conventional fireworks, SFs are freely available to the general public and do not require the safety restrictions or permits associated with larger pyrotechnic products. The sparkler fountains are typically used indoors, often in crowded spaces with limited ventilation, which can lead to substantial local exposure of people to airborne pollutants. The sparklering of a single SF causes increase in particle number concentration of up to 960,000 NPs/cm³, i.e. around 200 times the background level, and remains high for hours in an unventilated room. Most of the released particles have a diameter of 60 nm to 200 nm. The colour of the SF' frame reveals the presence of the colour-specific marker elements (Cu in blue, Na in gold, Ba in green, and Sr in red), which are partially released as nanoparticles in the air and partially deposited as slag on the substrate underneath the SF, which is often a birthday cake.

Spain

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

General information about activities with genetically modified organisms (GMOs) which have been approved/notified in Spain, as contained use or deliberate release into the environment, and other relevant reports are available from the Ministry of Agriculture, Food and Fisheries and the Ministry for the Ecological Transition and the Demographic Challenge. Web pages:

<https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/omg/registro-publico-omg/>

<https://www.miteco.gob.es/es/calidad-y-evaluacion-ambiental/temas/biotecnologia/organismos-modificados-geneticamente-omg/>

a) Contained use activities in research facilities

Since the last meeting in March 2025, fifty (51) new facilities for different contained use activities have been submitted in Spain to the Competent Authorities (either Interministerial Council of GMO or the relevant Regional Government, depending on the procedure) and assessed by the risk assessment competent authority, the National Biosafety Commission (26 of biosafety level 1 (BSL1), and 25 of BSL2).

167 different activities have been notified to be carried out in these facilities: 27 are classified as risk 1 (BSL1), 130 as risk 2 (BSL2) and 12 as biological level of risk 3 activities (in BSL3 facilities already authorised).

The GMOs used in these activities are genetically modified viruses or viruses infecting/transfecting human or animal cells lines (93), animal cells lines (104), followed by animals (mice, fishes, insects, etc., 17), bacteria (28), plants (6), parasites (2) and fungus (4).

For detailed information:

https://www.miteco.gob.es/es/calidad-y-evaluacion-ambiental/temas/biotecnologia/organismos-modificados-geneticamente-omg/notificaciones-y-autorizaciones/uso_confinado.aspx

<https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/omg/registro-publico-omg/>

b) Experimental deliberate release into the environment

Since March 2025, thirty-three (33) applications for deliberate release trials (including field trials with genetically modified plants and human and animal clinical trials with GMOs) have been notified to the national competent Authorities (Interministerial Council of GMO and Regional Governments) and assessed by the National Biosafety Commission:

- Five (5) field trials with plants: (one (1) genetically modified citrus plants, three (3) CRISPR/Cas

maize and one (1) gene-edited soybean.

- On the other hand, twenty-eight (28) human clinical trials have been notified. Some of them (15) are different genetically modified viruses (Adenovirus, AAV, MVA, VIH, etc.), and others (17) were developed using human cells.

For detailed information:

https://www.miteco.gob.es/es/calidad-y-evaluacion-ambiental/temas/biotecnologia/organismos-modificados-geneticamente-omg-/notificaciones-y-autorizaciones/liberac_voluntaria.aspx

<https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/omg/registro-publico-omg/>

c) Placing on the market

There are no new licenses issued since April 2025 regarding the placing on the market of GMO's **under part C of Directive 2001/18**.

In 2025, the growing surface for Bt maize (MON810) in Spain was 70.006,37 ha

- https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/omg/registro-publico-omg/superficie_cultivada.aspx
- <http://www.mapa.gob.es/es/estadistica/temas/estadisticas-agrarias/agricultura/esyrce/>

2. Development/review/amendment of national strategies, regulations and guidance

EU LEVEL

In the context of the European Commission's simplification agenda, a Food and Feed Safety "Omnibus" package was presented on 16 December 2025, including proposals affecting Regulation (EC) No 1829/2003 on genetically modified food and feed.

In parallel, the European Commission has also launched work under the Biotech Act initiative, which includes a review of Directive 2001/18/EC on the deliberate release of genetically modified organisms.

Spain is actively participating in the relevant EU committees and working groups in both processes, with the objective of contributing to a more flexible, clearer and future-proof GMO regulatory framework in the European Union.

NATIONAL LEVEL

1 Legal framework applicable to GMOs

The legislative framework and other related information are regularly updated on the following official webpage:

<https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/>

2 National control plan on deliberate release of GMOs for food and feed production:

The National Plan for Official Control of the Food Chain describes the official control systems throughout the food chain in Spain, from primary production to points of sale to the final consumer. In this context, since 2020, it is applicable the National control plan on deliberate release of GMOs for food and feed production, according to the Regulation 2017/625/UE (OCR). The strategic objective of this program is to guarantee that the deliberate release of GMOs complies with the requirements established in the current regulations. Official controls will be carried out in three areas:

- 1) cultivation of GMOs to produce food and feed.

2) GMO field trials to produce GM food and feed.

3) seeds for cultivation with the purpose of producing food and feed.

The Ministry of Agriculture, Food and Fisheries publishes a report annually with the results of the official controls in our country. This information is also shared with the European Commission.

Further information is available at:

<https://www.mapa.gob.es/en/agricultura/temas/biotecnologia/omg/PNCOCA%202021-2025.aspx>
[Informes anuales](#)

3. Risk management measures

The monitoring plan for the commercial cultivation of MON810 Bt maize continues ongoing and remains without appearing insect resistant populations in farmlands after more than 25 years of growing in the main northeast maize cropping area in Spain.

Additionally, as it was mentioned in previous questions, since 2020 there is in force a national control plan on deliberate release of GMOs for food and feed production, which includes commercial cultivation of MON 810.

In this context, reference can be made to national coexistence measures established in Spain, such as *Orden APA/1083/2018, de 8 de octubre, por la que se dictan medidas para evitar la contaminación transfronteriza derivada del cultivo de maíz modificado genéticamente* (Order APA/1083/2018 of 8 October laying down measures to prevent cross-border contamination arising from the cultivation of genetically modified maize), which requires a minimum isolation distance of 20 metres in border areas (France) in order to minimise cross-border gene flow.

4. Public engagement and outreach activities

In accordance with Royal Decree 178/2004, which approves the General Regulations for the development of the Law 9/2003, the competent authority must submit to public information all notifications of deliberate release with genetically modified organisms and the activities of contained use with genetically modified organisms of biological level of risk 3 and 4 activities for a period of 30 days.

For detailed information on the public consultation of the notifications:

[Consulta e información al público \(miteco.gob.es\)](#)

5. Research projects on biosafety; relevant publications

In Spain, among other measures/programs, there is a State Plan of scientific and technical research and Innovation (PEICTI).

The PEICTI 2024-2027 comprises different programs, including biotechnology programs in different fields

<https://www.ciencia.gob.es/InfoGeneralPortal/documento/6e566243-bcb5-45d8-ab77-5cfe533060f2>

2. Updates regarding international activities

Spain actively participates in the relevant committees of the European Commission. For example, Committee of the Directive 2009/41/EC on the contained use of genetically modified micro-organisms and the committee of the Directive 2001/18/CE on the deliberate release of genetically modified organisms, as well as in the Standing Committee on Plants, Animals, Food and Feed-Section genetically modified food

and feed. Spain also participates in different working groups of the Council of the EU. For example, the Working Party on Genetic Resources and Innovation in Agriculture.

Furthermore, Spain is a Party to the Cartagena Protocol on Biosafety. Therefore, national experts have regularly participated in activities derived from Conference of the Parties (COP) and Conference of the Parties serving as the Meeting of the Parties (COP-MOP) meetings, as well as in online forums and other related events.

The Ministry of Agriculture, Fisheries and Food and the Ministry for Ecological Transition and the Demographic Challenge closely follow the evolution of the different components of the Cartagena Protocol.

The Ministry of Agriculture, Fisheries and Food regularly updates information related to GMOs in THE Biosafety Clearing-House of the Convention on Biological Diversity: <https://bch.cbd.int/en/countries/ES>

The national website related to the Cartagena Protocol and the Nagoya–Kuala Lumpur Supplementary Protocol is available at: <https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/omg/protocolo-cartagena/>

Furthermore, the Ministry of Agriculture, Food and Fisheries participates in meetings of the Working Group on International Environmental Issues (Biosafety) of the Council of the European Union.

Delegates from the Ministry of Agriculture, Fisheries and Food and from the Ministry for Ecological Transition and the Demographic Challenge have attended and actively participated in meetings under the Convention on Biological Diversity (CBD), including COP 16 (Cali, Colombia, 21 October–1 November 2024), COP-MOP 11 to the Cartagena Protocol on Biosafety, and COP-MOP 4 to the Nagoya Protocol on Access and Benefit-sharing. They are also expected to participate in the forthcoming COP-MOP meeting to be held in Armenia in October 2026.

3. Developments related to new breeding techniques (NBTs)

1. Development/review/amendment of national strategies, regulations and guidance

On 5 July 2023, the College of Commissioners of the European Union adopted a legislative proposal on plants obtained by certain genomic techniques (NGT proposal).

Spain actively participated in the initial discussions of the proposal during its Presidency of the Council of the European Union and continues to be actively involved in ongoing negotiations.

The proposal reached a provisional political agreement between the European Parliament and the Council in December 2025.

The Regulation has not yet been formally adopted. Final adoption by both co-legislators is expected in 2026, followed by publication in the Official Journal of the European Union and entry into force.

Subsequently, a period will be required for the development and adoption of implementing and delegated acts, which will specify the operational aspects of the new framework. Spain will continue to actively contribute to these upcoming steps

To date, no products developed using NBTs have been authorised for commercial use in Spain.

However, applications involving organisms obtained through gene editing techniques (e.g. CRISPR/Cas) are being assessed in the context of contained use and experimental deliberate release.

2. Any other information related to NBTs.

Spain supports several initiatives aimed at improving knowledge on NBTs, including scientific advisory activities, stakeholder engagement and policy-oriented research. In particular, the nGENIA project, coordinated by the Centre for Research in Agrigenomics (CRAAG) in collaboration with the Ministry of Agriculture, Fisheries and Food, provides scientific advice on NGTs and contributes to evidence-based policymaking.

<https://ngenia.cragenomica.es/eng/>

The website of the Ministry of Agriculture, Fisheries and Food includes a specific section on NBTs, which contains general information about these technologies, about the regulatory framework related to NBT in third countries, reports on the role of NBTs in different EU policies, detection and identification issues, amongst other relevant issues related to this topic.

<https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/mejora-genetica/>

The webpage also contains up-to-date information about the regulatory process in the EU to regulate these techniques:

<https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/mejora-genetica/iniciativa.aspx>

Türkiye

1. National regulatory framework and risk assessment related to GMOs.

Türkiye, as a Party to the Cartagena Protocol on Biosafety, conducts the safety assessment of genetically modified organisms (GMOs) and products derived from GMOs within the framework of the Biosafety Law, which entered into force in 2010, and its implementing secondary legislation.

Under the Biosafety Law, decisions on the import, export, experimental release, placing on the market of GMOs or their products, as well as the contained use of genetically modified microorganisms, are taken based on scientific risk assessment.

For this purpose, an Experts List has been established, composed of academic staff and specialists working at universities and at the Scientific and Technological Research Council of Türkiye (TÜBİTAK).

For each GMO application, two scientific committees are established from among the Experts List: a Risk Assessment Committee and a Socio-economic Assessment Committee, each consisting of 11 experts from different disciplines relevant to the application.

The Ministry of Agriculture and Forestry takes the final decision by considering the evaluation reports with favourable opinions issued by the scientific committees, together with national priorities and needs. Where the decision is positive, it is published in the Official Gazette.

2. GMO approvals

During the period 2024–2025, seven genetically modified maize events for feed use and enzymes produced by five genetically modified microorganisms for industrial use were authorised in Türkiye.

3. Novel foods

There is currently no regulation in force in Türkiye regarding novel foods. However, the Turkish Food Codex Novel Foods Regulation Draft has been prepared and is in the process of being published. The aforementioned draft Regulation covers the necessary application and evaluation processes for the use of components that are not significantly used for human consumption in our country as food.

With regard to feed and novel foods that do not fall within the scope of GMOs, no risk/safety assessment study has been conducted to date in Türkiye by the competent authority, the Ministry of Agriculture and Forestry.

Genetically modified organisms fall outside the scope of the novel food regulation preparations in Türkiye.

Written contribution of the European Commission

EUROPEAN UNION

Highlight of developments since the last meeting of the WP-SNFF

1. Developments related to implementation of national biosafety framework (for countries) / or Developments related to biosafety activities (for BIAC and observer organisations)

1. Risk assessment/regulatory decisions (e.g. organisms assessed, type of use, introduced traits/genes)

Risk assessment

Since 1st March 2025, the European Food Safety Authority (EFSA GMO Panel) has adopted and published 24 new scientific opinions, of which 12 are renewal of authorisations:

New applications for market authorisation

- Re-publication AP 162 [EFSA-Q-2022-00031](#) (soy leghemoglobin) after confidentiality decision
- [Maize DAS1131](#) ([EFSA-Q-2022-00410](#))
- [Maize DP202216 × NK603 × DAS-40278-9](#) ([EFSA-Q-2023-00197](#))
- [Soybean DBN9004](#) ([EFSA-Q-2024-00326](#))
- [Soybean MON 94637](#) ([EFSA-Q-2024-00054](#))
- [Soybean MON 94313](#) ([EFSA-Q-2022-00575](#))
- [Soybean GMB151 × DAS-44406-6](#) ([EFSA-Q-2024-00330](#))
- [Oilseed rape LBFLFK](#) ([EFSA-Q-2019-00394](#))
- [Cotton T304-40 × GHB119 × COT102](#) ([EFSA-Q-2018-00809](#))
- [Cotton GHB614 × T304-40 × GHB119 × COT102](#) ([EFSA-Q-2017-00505](#))
- [Sugar beet KWS20-1](#) ([EFSA-Q-2023-00378](#))
- [Oilseed rape MS11](#) ([EFSA-Q-2024-00691](#)) (mandate for assessing additional information)

Renewal applications

- [Maize MON 87427](#)
- [Maize NK603](#)
- [Maize MON 87460](#)
- [T25 maize](#)
- [Maize NK603 × T25](#)
- [Soybean MON 87708](#)
- [Soybean MON 87705](#)
- [Soybean MON 87769](#)
- [Cotton MON 88913](#)
- [Cotton T304-40](#)
- [Cotton GHB614 × LLCotton25](#)
- [Oilseed rape MON 88302](#)

Regulatory decisions

Regulation (EU) 1829/2003 on genetically modified food and feed regulates the placing on the market of GM food and feed in the EU. All EU authorised products are listed in two online registers accessible through [GMO register - European Commission](#).

Since 1 March 2025, the European Commission has authorised 8 GM food and feed and has renewed 7 authorisations.

New authorisations:

- Maize [MON 95275](#)

United States of America

Food and Drug Administration

Voluntary Premarket Consultations completed since the 32nd WP-SNFF meeting

BNF No	Food	Designation	Trait(s)	Developer+	Unique Identifier	Date Completed (sorted Z-A)
204	Cotton	MON 96012	Herbicide tolerance (glyphosate, glufosinate ammonium, dicamba, mesotrione, PPO-inhibiting herbicides)	Bayer CropScience LP	MON-96Ø12-6	Feb 18, 2026
203	soybean	MON 94115	Herbicide tolerance (PPO-inhibiting herbicides)	Bayer CropScience LP	MON-94115-8	Jan 27, 2026
202	Cotton	MON 89151	Insect resistance	Bayer CropScience LP	MON-89151-3	Jun 6, 2025
184	Alfalfa	Altered lignin alfalfa	Altered lignin profile	Cibus, Inc.		May 19, 2025
198	Sugar beet	KWS20-1	Herbicide tolerance (dicamba, glufosinate ammonium, glyphosate)	Bayer CropScience LP	KB-KWS2Ø1-6	Apr 10, 2025
201	Corn	MZIR260	Insect resistance	Syngenta Seeds, LLC.	SYN-ØØ26Ø-3	Apr 1, 2025
195	Corn	MON 94804	Altered plant architecture (short stature)	Bayer CropScience LP	MON-948Ø4-4	Mar 31, 2025

Voluntary Premarket Meetings conducted under 2024 Guidance for Industry: Foods Derived from Plants Produced Using Genome Editing

<u>VPM No.</u>	<u>Date of meeting</u>	<u>Plant</u>	<u>Trait(s)</u>	<u>Designation(s)</u>	<u>Developer</u>	<u>Intended use</u>
0010	Feb 27, 2026	Romaine Lettuce (<i>Lactuca sativa</i>)	Reduced Browning	Browning enzyme edited romaine lettuce (GreenVenus Romaine)	Kendred LLC.	Human Food
0009	Feb 17, 2026	Potato (<i>Solanum tuberosum</i>)	High tuber set	Potatoes with loss-of-function edits in confidential gene "Gn2", e.g., CD6	J.R. Simplot Company	Human and animal food
0008	Feb 2, 2026	Corn (<i>Zea mays</i>)	Improved resistance to four fungal diseases: northern corn leaf blight, gray leaf spot, anthracnose stalk rot, and southern corn rust	DSL maize	Pioneer Hi-Bred International, Inc.	Human and animal food
0007	Dec 18, 2025	Soybean (<i>Glycine max</i>)	Increased yield through changes in plant architecture	Deletions in coding or non-coding regions, in one or more native genes resulting in 1. altered reproductive transition timing, 2. increased seed number, 3. increased seed size, and 4. increased growth	Inari	Human and animal food
0006	Sep 8, 2025	Corn (<i>Zea mays</i>)	Waxy (high amylopectin) starch	CRISPR-Cas Waxy Corn Deletion of endogenous x-1 gene	Pioneer Hi-Bred International, Inc.	Human and animal food
0005-B	May 29, 2025	Rice (<i>Oryza sativa</i>)	Herbicide tolerant rice 3	Mutations in certain genes involved in herbicide tolerance	Cibus, Inc	Human and animal food
0005-A	May 29, 2025	Rice (<i>Oryza sativa</i>)	Herbicide tolerant rice 1	Mutations in certain genes involved in herbicide tolerance	Cibus, Inc	Human and animal food

<u>VPM No.</u>	<u>Date of meeting</u>	<u>Plant</u>	<u>Trait(s)</u>	<u>Designation(s)</u>	<u>Developer</u>	<u>Intended use</u>
<u>0004</u>	Mar 14, 2025	Potato (<i>Solanum tuberosum</i>)	Reduced browning Reduced black spot	Potatoes with loss-of-function edits in certain <i>Ppo</i> genes, e.g., AP695 potato	J.R. Simplot Company	Human and animal food
<u>0003</u>	Dec 6, 2024	Canola (<i>Brassica napus</i>)	Pod shatter reduction	Mutations in certain genes involved in pod shatter reduction (PSR Canola)	Cibus, Inc	Human and animal Food
<u>0002</u>	Dec 4, 2024	Strawberry (<i>Fragaria x ananassa</i>)	Altered flowering for remontancy	Strawberries with loss-of-function edits in confidential gene "Gn1"	J.R. Simplot Company	Human food
<u>0001</u>	Aug 1, 2024	Mustard Greens (<i>Brassica juncea</i>)	Reduced pungency Reduced trichome number	GT225 GT226 GT241 GT267 GT252 GT254 GT269 GT270 GT280 GT286 GT288 GT290 GT291 GT292 GT302 GT303 GT304 GT313 GT314 GT351 GT352	Pairwise Plant Services, Inc.	Human food

FDA Cell Culture Consultations conducted since the 32nd WP-SNFF meeting

File No.	Food	Submission	FDA Response	Scientific Memo
000039	Cultured <i>Gallus gallus domesticus</i> (chicken) cell material	Part 1 - 5/21/2024 (PDF 8.1 MB) Part 2 - 5/21/2024 (PDF 13.4 MB) Part 3 - 5/21/2024 (PDF 11.4 MB) Part 4 - 5/21/2024 (PDF 17.4 MB) Part 5 - 5/21/2024 (PDF 2.5 MB) Disclosable Amendments of Supplement (PDF 992 kB)	7/24/2025 (PDF 169 kB) 9/24/2025 (PDF 156 kB)	7/24/2025 (PDF 1.0 MB)

File No.	Food	Submission	FDA Response	Scientific Memo
000008	Cultured <i>Sus scrofa domestica</i> (pork) fat cell material	Part 1 - 5/25/2022 (PDF 19.5 MB) Part 2 - 5/25/2022 (PDF 17.6 MB)	3/7/2025 (PDF 194 kB)	3/7/2025 (PDF 564 kB)
000005	Cultured <i>Oncorhynchus kisutch</i> (salmon) cell material	Part 1 - 6/2022 (PDF 14.0 MB) Part 2 - 6/2022 (PDF 15.2 MB) Part 3 - 6/2022 (PDF 14.2 MB) Part 4 - 6/2022 (PDF 5.6 MB)	5/28/2025 (PDF 194 kB)	5/29/2025

Intentional genomic alterations (IGAs) in animals

❖ Regulatory Guidance Updates

FDA's Center for Veterinary Medicine has recently released two updated guidance documents. FDA first issued its guidance for industry (GFI) on regulation of genetic modifications in animals in 2009. That GFI discussed heritable modifications made with rDNA technology. In 2017 FDA issued a draft GFI to update the 2009 document. The 2017 draft clarified that the scope of the GFI includes intentional genomic alterations (IGAs) in animals that are made using modern biotechnology including both the rDNA technology and genome editing, such as CRISPR. FDA split the GFI into two parts: [Part A](#) covers FDA's overarching policy for regulating IGAs in animals and describes the agency's risk-based approach to regulation and [Part B](#) covers FDA's approval process for IGAs in animals. Part A was published in May 2024 and Part B was published in January 2025. Part A expanded the types of products appropriate for a risk review process to include IGAs in food-producing animals where they have been altered to be equivalent to animals of the same species that already exist and have a history of safe use. In addition, FDA entered into a [memorandum of understanding](#) with USDA in May 2024 that clarifies the two agencies' roles and responsibilities in regulation of IGAs in animals to enable an efficient regulatory process.

❖ Regulatory Decisions

On April 29, 2025, FDA/CVM approved Genus plc's IGA generated using CRISPR-Cas9 genome editing to confer resistance to porcine reproductive and respiratory syndrome virus in swine (for more information, see the [Freedom of Information Summary](#)).

On September 25, 2025, FDA/CVM expanded the scope of the previous risk review determination for Acceligen's PRLR-SLICK cattle such that the developer may use CRISPR-Cas9 genome editing to introduce the IGA into *Bos taurus* cattle of any breed or genetic background. Additionally, FDA/CVM has made a risk review determination for Acceligen's introduction of the Celtic polled allele using genome editing. For more information, see FDA's [website on Risk-Reviewed IGAs](#).

**Environmental Protection Agency
Office of Pesticide Programs (OPP)**

❖ **Biotechnology Submission Decisions**

Table 1. Plant-incorporated protectant (PIP) actions completed since 2025 Tour de Table

	Product/Event name	Active ingredient	Plant	Purpose
	MON 94637	Cry1A.2 and Cry1B.2	Soybean	Seed increase
	DP 51291	IPD072Aa	Corn	Seed increase
	Gen 3 Potato	PVY dsRNA	Potato	Commercial Use
Experimental Use Permits	MON 95275	Mpp75Aa1.1, Vpb4Da2, DvSnf7.1 ds RNA	Corn	Amendment
	MON 89151	Cry1Da7, Cry1B.3, and Vip3Cb1.1	Cotton	Generate data for registration
	Gen 3 Potato	PVY dsRNA	Potato	Generate data for additional registration actions

- 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>
 - Since the 2025 Tour de Table and NBT Questionnaire, EPA has exempted 47 PIPs under this rule; 6 in corn and 41 in citrus.

Business at OECD (BIAC)

1. Developments related to biosafety

Reports and technical resources:

CropLife International develops and maintains a number of technical resources and databases to provide accurate information about plant biotechnology including safety assessments, as well as to support trade.

AgbioInvestor GM Monitor

In 2025, [the AgbioInvestor GM Monitor](#), supported by CropLife International, continues to be updated with new approvals as well as annual figures for area under production of GM crops. The AgbioInvestor GM Monitor provides information about GM Crop approvals and production in a comprehensive and searchable database. Users can easily find details such as which traits have been approved in which countries. The database also includes links to the relevant regulatory authorities. In addition, the entire database can be downloaded as an excel sheet for more advanced analysis.

BioTradeStatus

The CropLife International supported [BioTradeStatus](#) continues to be updated, which provides market status information on commercialized GM crops developed by CropLife International member companies as a complement to other resources that focus on regulatory status

Updates to Other Databases

CropLife International and its member companies continue to maintain [the Detection Methods Database](#), which provides descriptions of validated DNA methods based on PCR, and lists providers for protein-based detection methods for GM crops produced by CropLife members. It also maintains the [Celiac Peptide Database](#), a list of peptides that have been implicated in triggering celiac disease.

Global Communications Resources

In 2025, CropLife continued its campaign - "[Side with Food Security](#)" – which provides insights into the intersection of innovation, science, and policy in ensuring global food security. The campaign highlights the role of science, technology, and sustainability in securing our food supply, including plant science, crop protection, plant biotechnology, innovation, sustainability, and biodiversity.

CropLife International continues to support the [GMO Answers online platform](#) by updating content with the latest data available.

2. Updates regarding international activities

Continued engagement in the discussions under the Convention on Biological Diversity and its Subsidiary Protocols

CropLife International and the Global Industry Coalition (GIC) continue to participate in the UN Convention on Biological Diversity's biotechnology programs, including on risk assessment and management for Living Modified Organisms and on synthetic biology. In 2025-2026, GIC submitted information and took part in peer review processes relating to synthetic biology, such as the draft thematic action plan ([Thematic Action Plan](#)), independent scientific study ([Scientific Study](#)), and took part in the open ended online forum on synthetic biology ([Open-ended Online Forum 2026](#)). GIC will also contribute as an observer expert at the upcoming Ad Hoc Technical Expert Group meeting ([SYN-AHTEG-2026-01 - Documents](#)). This involvement enables GIC members to offer expertise and promote comprehensive biotechnology governance in alignment with our view of synthetic biology being a continuation of existing biotechnologies. Through Business at OECD, the CLI network also provides expert input to WP BNCT through the Biofutures expert group. Business at OECD supports the work of the WP BNCT and its Secretariat for agile and adaptive regulatory and governance approaches that enable the successful adoption of biotechnological innovation and the development of safe products and applications. We will continue to engage and contribute to these fora and would appreciate including Business at OECD in future discussions.

3. Developments related to new breeding techniques (NBTs)

Recognition of Progress Related to Plant Breeding Innovation

The global seed industry represented by the International Seed Federation (ISF) and CropLife International maintains its science-based position that plant varieties developed through the latest plant breeding methods, such as genome editing, should not be differentially regulated if they are similar or indistinguishable from varieties that could have been produced through conventional plant breeding methods¹. Further, we recommend that the processes used to determine whether products fall in or out of scope of genetically modified organism (GMO) regulations are transparent, predictable, time-efficient, and consider existing regulatory mechanisms for new plant varieties (such as, for example, plant variety registration, national seed laws, or general food safety laws). The adoption of common approaches across countries can be facilitated through alignment of definitions, standardization of information requirements in support of a regulatory status determination, adoption of predictable and efficient assessment timelines, and recognition of other countries' determinations on regulatory status. These common approaches are essential to maintain a functional trading system that facilitates food security enabled by innovative products including those derived from genome editing.

Both organizations welcome the recent regulatory progress across Europe and other countries around the world. We welcome the EU Member States' formal adoption of the Council's first reading position on the Regulation on New Genomic Techniques, confirming the trilogue compromise agreed with the European Parliament last December. This marks an important milestone toward final adoption, pending confirmation by the European Parliament. With hopeful final adoption and publication in the official journal by end of 2026, the seed industry is hopeful implementing regulations will bring the EU closer to the consensus approach being followed in many other countries who have issued guidance around genome editing policy. In parallel, we welcome the entry into force of England's precision breeding regulations in November 2025,

¹ <https://worldseed.org/document/plant-breeding-innovation-consistent-criteria-for-the-scope-of-regulatory-oversight/>

with applications now open for registration of precision-bred plants. We also note Switzerland's introduction of draft legislation, signalling encouraging momentum toward regulatory modernisation.

Furthermore, we acknowledge the development of policies outside Europe regarding genome edited products in various countries including Peru, Vietnam, Indonesia, Panama and Zambia. We recognize that there are on-going determinations for exemption/exclusion from GMO regulatory oversight in more than a dozen countries with the total number of decisions now exceeding 600².

As these frameworks evolve, it is essential to strive for coherent regulation at both regional and international levels to ensure legal certainty, facilitate innovation, and avoid unnecessary disruptions to trade. The seed industry continues to emphasize focus the importance of practical and proportionate implementation of regulatory policy and guidance, particularly in the context of the growing volume and diversity of products currently in the development pipeline.

In this context, the International Seed Federation (ISF) in collaboration with Crop Life International have organized two key events at the recent International Society Biosafety Research (ISBR) in Ghent. These include a Topic Specific Parallel Session and a dedicated Policy workshop on gene editing entitled "Plant Breeding Innovation: Enabling applications and regulatory frameworks" and "Government perspective on implementation of genome edited plant regulatory policies: Challenges and Solutions", respectively. Together, these sessions convened global scientific, regulatory, and industry leaders to advance the policy dialogue on genome editing and other plant breeding innovations (see link to sessions: <https://worldseed.org/2025/11/04/plant-breeding-innovation-isbr-symposium/>).

In addition, ISF has also organized a side event on at the recent WTO Ministerial Conference 14 in Yaoundé, Cameroon entitled "Advancing Global Food Security through Seed Trade and Innovation". The event highlighted the critical role of international seed trade and innovation - including gene editing technologies – in supporting food security objectives. The session also marked the launch of the ISF statement on international seed trade which provides a comprehensive overview of how and why the global seed sector operates within interconnected international markets... For further information, you can access the full statement here

<https://worldseed.org/document/mc14/>

Reports and technical resources:

CropLife International has published a new paper in Nature Biotechnology entitled [Re-evaluating the site-directed nuclease classification as a regulatory trigger for genome-edited plant products that notes the inability of this classification system to handle the evolving applications of genome editing tools in plant breeding](#).

Global Communications Resources on Genome Editing

The International Seed Federation has several resources available on its website, including a [Frequently Asked Questions \(FAQ\) section](#) which addressed Plant Breeding, Intellectual Property and Sustainable Agriculture. The website also includes [position papers](#) (e.g. [Future Proofing Policies for Products of Plant Breeding](#)) and statements including "[A call for Policy Actions to Foster Plant Breeding Innovation](#)" and "[Navigating the Evolution of Plant Breeding Innovation](#)" which celebrates a century of advancements in plant breeding. The ISF global policy map for plant breeding innovation can be found in the following statement "[A call for Policy Actions to Foster Plant Breeding Innovation](#)". This map is updated regularly to accommodate new policy developments.

² Based on publicly available records of decisions and/or government presentations of number of decisions.

Through resources and initiatives like these, ISF continues its commitment to fostering awareness and understanding of plant breeding innovation across various stakeholders.

African Union Development Agency (AUDA-NEPAD)

In 2025/26, AUDA-NEPAD's flagship biosafety programme, the African Biosafety Network of Expertise, provided technical support and training across several African Union member states and Regional Economic Communities (RECs). These efforts aimed at creating enabling policy and legal environments for biotechnology products, strengthening implementation capacity, and fostering networking and partnerships.

1. Developments related to implementation of national biosafety framework / Developments related to biosafety activities

Rwanda

Risk assessment / regulatory decisions	Approval for environmental release for cultivation and direct use as food, feed and for processing of: 1. LM Cassava event 4046 (Unique identifier: DPS-Ø4Ø46-8), containing Cassava brown streak virus (CBSV) and Uganda Cassava brown streak virus (UCBSV) coat protein (CP) genes which confers resistance to Cassava brown streak disease. 2. LM Potato events CIP820050.105 (Unique Identifier: CIP-SHA105-8) and CIP820046.185 (Unique Identifier: CIP-VIC185-13), both containing <i>RB</i>, <i>Rpi-blb2</i>, and <i>Rpi-vnt1</i> genes, which confers resistance to the potato late blight disease. 3. LM Maize with stacked events MON 87460, containing <i>cspB</i> gene that encodes the Cold Shock Protein B (CspB), which confers drought stress tolerance and MON 89034 containing <i>cry1A.105</i> and <i>cry2Ab2</i> genes that encodes Cry1A.105 and Cry2Ab2 proteins, which confer resistance to stem borer and fall armyworm.
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Mozambique

Development / review / amendment of national strategies, regulations and guidance	Validation of national guidelines on Low-Level Presence (LLP) of GMOs in seeds and grains
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East African Community (EAC)

Development / review / amendment of national	Advanced regional coordination in biotechnology through the development and validation of the EAC Biotechnology Strategy (2026–
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strategies, regulations and guidance	2036), led by the East African Science and Technology Commission (EASTECO)
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Common Market for Eastern and Southern Africa (COMESA)

Development / review / amendment of national strategies, regulations and guidance	Building on the adoption of the COMESA Biotechnology and Biosafety Policy (2015) and its Implementation Plan (COMBIP), hosted by ACTESA, a Panel of Experts (PoE) was constituted in 2025 to institutionalize regional risk assessment and provide technical guidance.
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2. Updates on international and continental activities

2.1 Participation in/hosting international symposia/fora relating to biosafety

- Convention on Biological Diversity (CBD): Participation focused on strengthening Africa's coordinated engagement in matters of global biosafety and biodiversity. AUDA-NEPAD, in collaboration with AFSI, supported experts from Burkina Faso, Ghana, Kenya, Malawi, Namibia, Nigeria, Senegal, and Zambia to participate effectively in SBSTTA-27 and SB8J-1 meetings in Panama. This support contributed to a coherent common African position aligned with continental priorities.
- 20th session of the African Ministerial Conference on the Environment (AMCEN 20): AUDA-NEPAD provided coordination support to the African Group of Negotiators, contributing to key decisions that advanced the coherent implementation of Multilateral Environmental Agreements (MEAs) and related treaties, thereby strengthening regional environmental governance.
- African Seed and Biotechnology Partnership (ASBP): Under the ASBP, AUDA-NEPAD presented progress updates to the 6th STC-ARDWE and the 43rd HSGOC, resulting in key policy decisions that were subsequently endorsed by the AU Executive Council in February 2026. These include the adoption of the Continental Framework for Genome Editing Landscape Analysis, approval of the revision of the AU Model Law on Biosafety and AU Guidelines on Biotechnology for Food and Agriculture, and support for the domestication of risk-proportionate regulatory approaches, including for genome editing and low-level presence (LLP). Member States, RECs, and partners were urged to accelerate guideline development and implementation, with momentum building toward a summit-level engagement on seed systems and biotechnology.
- Eleventh Session of the Governing Body (GB-11) of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA): The African Union Commission (AUC) and AUDA-NEPAD provided technical backstopping to the African Group of Negotiators at ITPGRFA GB-11 (Lima, November 2025). This support contributed to enhancing Africa's unified voice in negotiations on access and benefit-sharing, Farmers' Rights, and conservation. This reinforced equity, capacity-building priorities, and the role of ASBPP as a continental coordination platform.
- First Africa Biodiversity Summit and Technical Session on the Maputo Convention: Convened by the AUC under the theme "Leveraging Biodiversity for Africa's Prosperity. AUDA – NEPAD provided technical support to position biodiversity at the centre of Africa's development planning, strengthen the Maputo Convention and align Africa's positions with the Kunming–Montreal Global Biodiversity Framework (KMBGF) and Agenda 2063. The Maputo Convention is scheduled for structured review, with AUDA-NEPAD expected to provide technical and capacity support.
- ISBR Symposium (Ghent, November 2025): AUDA-NEPAD presented progress on data transportability (DT) in Africa, highlighting reliance on external CFT data for regulatory decision-making

while maintaining safety standards. The presentation also underscored the need for harmonized DT guidelines at national and continental levels.

2.2 Bi-/multi-lateral cooperation with other authorities/organisations

- AUDA-NEPAD, in partnership with the Agriculture and Food Systems Institute (AFSI) and Rwanda Environment Management Authority (REMA), supported targeted capacity building, regulatory guideline development, and technical backstopping to strengthen institutional readiness and science-based decision-making in Rwanda.
- AUDA-NEPAD, in partnership with Michigan State University (MSU), facilitated the participation of 10 experts from 9 African countries (Rwanda, Nigeria, Zambia, Kenya, Namibia, Ethiopia, Ghana, Burkina Faso, and Zimbabwe) in a short course on agricultural biotechnology and biosafety at MSU, USA in August 2025. The course enhanced technical capacity in biosafety regulation, risk assessment, and emerging biotechnology applications, while fostering peer learning on global best practices in agricultural biotechnology governance.
- AUDA-NEPAD facilitated the participation of 10 experts in the Non-Target Organism Training Workshop organized by AFSI, by nominating relevant representatives from Nigeria, Namibia, Ghana, Mozambique, and AUDA-NEPAD.

2.3 Specific cases of use of OECD tools and information

OECD tools and resources (including Consensus Documents and the BioTrack Product Database) are actively applied in AUDA-NEPAD–supported countries. They informed risk assessment reviews in Rwanda leading to regulatory decisions and are routinely used in capacity-building trainings. In addition, references to the BioTrack Product Database have been incorporated into FFP import application forms in countries that have developed such forms enabling access to risk assessment summaries and decisions from countries of export, thereby supporting evidence-based and efficient regulatory reliance for informed decisions.

3. Developments related to new breeding techniques (NBTs)

Kenya

Specific cases of application, assessment and decision	Decision to categorize and regulate “SLICK Edited Holstein animals for heat tolerance” as non-GMO
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Zimbabwe

Development / review / amendment of national strategies, regulations and guidance	Validation of national guidelines on genome editing in line with the case-by-case approach recommended by the Policy Framework on the Application of Genome Editing in African Agriculture (2022)
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Africa

Any other information related to NBTs	Adoption of the Continental Framework for Genome Editing Landscape Analysis by the STC-ARDWE (6th Session) to provide strategic direction for analysing the status of genome editing ecosystem across Africa The African Union High-level Panel on Emerging Technologies (APET) has recommended scope expansion of the Policy Framework on the Application of Genome Editing in African Agriculture (2022) beyond plants to include livestock, fisheries, and microorganisms, ensuring a more comprehensive, future-oriented, and anticipatory regulatory approach aligned with evolving biotechnology applications.
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4. Additional Information

AUDA-NEPAD delivered targeted capacity strengthening activities in a number of countries during the period of review, some of which are listed below:

- **Mozambique:** Sensitization workshop to clarify mandates of biosafety and varietal approval committees, improving understanding of post-biosafety approval commercialization requirements
- **Nigeria:** National stakeholder engagement on Seed Production Technology (SPT) to enhance technical understanding and support regulatory guideline development
- **Namibia:** National training on biosafety communication and reporting for regulators, media practitioners, and policymakers

Agriculture & Food Systems Institute (AFSI)

About the Agriculture & Food Systems Institute

The [Agriculture & Food Systems Institute](#) (AFSI) is an independent nonprofit, scientific organization based in Washington DC, United States, that advances science for public benefit. Our mission is to achieve safe and sustainable agri-food, health, and environmental systems that improve the world. We do this through applied research, capacity-building, education, information dissemination, and outreach. Our work is being used to advance understanding and inform policy on agricultural systems, products of biotechnology, sustainable nutrition security, food safety, and related issues.

1. Developments related to biosafety activities

Harmonisation of Genetically Engineered Food and Feed Safety Assessment in South Asia

AFSI implemented a project from 2020 – 2025 to develop a regionally harmonised approach to safety assessment of food and feed derived from genetically engineered (GE) plants in South Asia. This was done by convening an Expert Working Group (EWG) with members from Bangladesh, Bhutan, India, and Sri Lanka, that recognized the similarities among the respective national guidelines based on Codex and agreed to develop a mechanism to harmonise the process for safety assessment. To this end, a guidance document titled '[Towards a harmonised approach to Food Safety Assessment of Genetically Engineered plants in South Asia](#)' that describes a consensus approach to the safety assessment of foods derived from GE crops for application across the participating countries was finalized after multiple rounds of discussion. The report of the EWG includes an application form for developers and a risk assessment summary template for use by regulators, that can be used across the region. Eight capacity building technical workshops were organized for regulators and other stakeholders from the four participating countries, [Bangladesh](#), [Bhutan](#), [India](#), and [Sri Lanka](#), for operationalizing this regional guidance during the course of this work. About 190 people received technical training across these workshops. The Food Safety and Standards Authority of India (FSSAI) adopted a form developed by the EWG in their official draft GM regulations. This form is designated as Form 1A by FSSAI and can be accessed on their website using this link:

https://www.fssai.gov.in/upload/uploadfiles/files/Form1A_Notice_GM_Foods_04_01_2023.pdf.

Bhutan Food and Drug Authority (BFDA) revised their GM food and feed safety guidelines in line with the harmonised guidance document. The revised guideline is available on their government's website and can be accessed using this link: <https://bfda.gov.bt/wp-content/uploads/2026/03/Guidelines-on-Safety-Assessment-of-Food-and-Feed-Derived-from-Genetically-Modified-GM-Plants.pdf>.

The work done as part of this project has been included as an example in OECD's consensus document on Considerations for Collaborative Work on the Safety Assessments of Foods and Feeds Derived from rDNA Plants (2023) ENV/CBC/MONO(2023)37.

2. Updates regarding international activities

APEC High-level Policy Dialogue on Agricultural Biotechnology (APEC HLPDAB)

AFSI worked with the U.S. government to implement the 'Agricultural Biotechnology Seminar Series 2025' for the APEC HLPDAB as part of the U.S.'s self-funded projects. This seminar series has been implemented for four years in a row and plans for 2026 are underway. AFSI organized three seminars, each of which was led by an APEC economy. These seminars brought together policymakers, risk assessors, and scientists, with an objective to foster greater participation and enhance engagement in the APEC HLPDAB outside of the annual meeting. The 2025 seminar series was cosponsored by Canada and the Republic of South Korea. As part of this series, the following virtual seminars were facilitated by AFSI:

['Plant Breeding Innovation in Canada – Regulatory Approach and Opportunities'](#) led by Canada was held on May 27, 2025. This event attracted 123 participants from 17 APEC economies, 5 other countries, and the European Union. The presentations featured Canada's new guidance on the regulation of plant breeding innovations for food, seeds and their environmental release, and animal feed, with a focus on the principles behind their approach. Canadian regulators presented an overview of the final set of guidance that was developed and shared insights into the development of regulatory guidance, recommended best practices, reflections on navigating challenges encountered, and opportunities for complementary initiatives. Perspectives from both regulators and plant breeders were shared, with a focus on opportunities to strengthen innovation, trade, and food security through practical solutions to policy alignment for precision breeding.

The second seminar in the series, ['Products of Modern Biotechnology – A Discussion on Development, Plant Variety Protection, and Intellectual Property'](#) took place on September 8, 2025. With United States as the lead economy, this seminar was structured to discuss the development of products of modern biotechnology using GE and genome editing. Developers talked about recent innovations in the field of agricultural biotechnology, the developmental process, and the steps that are taken to protect intellectual property. Legal experts delivered presentations on the patenting process, legal landscape for genome editing, plant variety protection, and international treaties governing plant breeders' rights. It attracted 185 participants from 18 APEC economies and 8 other countries.

The third seminar in the 2025 series, ['Current Status and Future Strategies for the Development of Agricultural Biotechnology Crops in Korea'](#) led by the Republic of South Korea was attended by 95 participants from 18 APEC economies, and 5 other countries. This virtual seminar focused on the development of products of modern biotechnology to tackle present-day challenges presented by climate change. Developers from the Republic of Korea delivered presentations on innovations in the field of agricultural biotechnology that potentially offer solutions to support a sustainable food system, including the development of resilient plant varieties and oilseeds for biofuels.

In addition to the 2025 Agricultural Biotechnology Seminar Series, AFSI implemented an in-person workshop on August 8, 2025, in Incheon, Republic of Korea, prior to the APEC HLPDAB plenary meeting. The workshop titled ['Successful, Efficient, and Effective Regulatory Cooperation on Agricultural Biotechnology in APEC'](#) welcomed 50 participants, representing ASEAN, Argentina, Australia, Canada, Costa Rica, People's Republic of China, Chinese Taipei, Indonesia, Japan, the Republic of Korea, New Zealand, Malaysia, Peru, the Philippines, Thailand, United States of America, Uruguay, and Viet Nam. Discussions at the workshop focused on furthering regulatory alignment to reduce resource costs, increase efficiency, and facilitate development, adoption, use, and trade of products derived from agricultural

biotechnology. This workshop provided APEC economies with an opportunity to review the complete [Policy Approaches Document](#) (PAD), and share information on collaborative approaches to regulation of biotechnology products aligned with it. The PAD is a whitepaper for advancing regional cooperation on agricultural biotechnology regulation inspired by the ongoing collaborative environment developed over many years within the APEC HLPDAB.

As a companion to the PAD, a website has been built by AFSI – www.biotechpolicyportal.org, to serve as a “living” representation of the document. This website provides an easily accessible resource for APEC economies and other stakeholders interested in regulatory cooperation in agricultural biotechnology. On the online portal, the different mechanisms of cooperation described in the white paper are clarified through the use of case studies. The portal also hosts a compilation of links to useful websites, databases, policy documents, courses, and other materials, which are organized into a database that can be searched and filtered.

AFSI’s Technical Sessions at the International Society for Biosafety Research (ISBR) Symposium

Organized by the International Society for Biosafety Research (ISBR), the 17th ISBR Symposium (ISBR 2025) took place on November 2-6, 2025, in the city of Ghent, Belgium. This in-person symposium featured scientific exchanges between the world’s leading experts on diverse sustainable bio-innovation, biotechnology, and biosafety topics. The ISBR aims to promote scientifically sound research that supports biosafety assessment by improving communication among scientists who study plants, animals, and microbes with new characteristics due to altered DNA and produced using modern biotechnology. AFSI organized four parallel sessions on the following topics: Safe(r) Innovation Approaches – Non-Regulatory Approaches Fostering Safety in Innovation; Safety Considerations for Agricultural Microbial Products Derived from New Genomic Techniques (NGTs); Hands-on Experience with the Crop Composition Database – A Tool Used in Food and Feed Safety Assessment; and Developments in Gene Drive – Advances in Risk Assessment, Regulatory Frameworks, and Field Trial Design. Two plenary talks were provided by AFSI board members. The program for all sessions including speaker details is available on AFSI’s website at: <https://foodsystems.org/event/isbr-2025/>.

4. Additional Information – AFSI Resources

Crop Composition Database

Publication

Bajaj, B., Brune, P.,.....Edwards, A., *et al.* Report on Agriculture & Food Systems Institute’s Crop Composition Database Version 10.1: An open-access resource for high-quality composition data. *Journal of Food Composition and Analysis* 151, 108981 (2026). <https://doi.org/10.1016/j.jfca.2026.108981>.

Composition studies that assess similarities and differences in levels of nutrients, anti-nutrients, and secondary metabolites are an essential part of the safety assessment of new crop varieties that are used as food and feed. It is important to understand the purpose of the data and its context in the safety assessment. The [Crop Composition Database](#) (CCDB) is a publicly available resource of composition data with application in comparative compositional assessment of genetically modified crops, informing healthy diets for livestock, and improving knowledge of global datasets related to food security and overall nutrition. Version 10.1 of the CCDB provides comprehensive composition data for 18 conventionally bred food, feed, fiber, and tree crops. The CCDB contains a little over 1.5 million data points across 232 analytes collected from field trials in 19 countries over a span of 27 years. The aim of this report is to provide information on operation and features of the CCDB, improvements to the database platform, data providers, data users,

and the workflow to include data into CCDB. It also elucidates the analysis of selected datasets from the CCDB to gain an insight into the factors that contribute to the variability that is observed in crop composition.

[Version 10.1 of the CCDB](#) was released in July 2025 with data for a new crop, cowpea.

eLearning courses

Self-paced, interactive [eLearning courses](#) developed by AFSI serve as a complementary resource to in-person and virtual training workshops and are being used to support capacity building programs we conduct in collaboration with our partners. All courses are peer-reviewed and are available in English. Additionally, some courses are available in Chinese, French, Korean, Portuguese, and Spanish.

The eLearning courses are free, and access can be requested to these by filling an [online form](#).

The following eLearning courses offered by AFSI are related to food and feed safety assessments:

- [Concepts in the Safety Assessment of Novel Food and Feed](#): This course discusses how people use information about foods to make basic decisions regarding food safety and how government regulators use similar information to address the safety of novel foods that may be introduced into their country's food supply.
- [Food Safety of Genetically Engineered Animal Products](#): This course covers the safety measures employed to evaluate the risk of genetically engineered animal products and how these animal products are evaluated against non-genetically engineered products.
- [Application of Problem Formulation to Food and Feed Safety Assessments](#): This course teaches how to apply problem formulation to the food and feed safety assessment of GE crops.