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

- No. 1, Commercialisation of Agricultural Products Derived through Modern Biotechnology: Survey Results (1995)
- No. 2, Analysis of Information Elements Used in the Assessment of Certain Products of Modern Biotechnology (1995)
- No. 3, Report of the OECD Workshop on the Commercialisation of Agricultural Products Derived through Modern Biotechnology (1995)
- No. 4, Industrial Products of Modern Biotechnology Intended for Release to the Environment: The Proceedings of the Fribourg Workshop (1996)
- No. 5, Consensus Document on General Information concerning the Biosafety of Crop Plants Made Virus Resistant through Coat Protein Gene-Mediated Protection (1996)
- No. 6, Consensus Document on Information Used in the Assessment of Environmental Applications Involving *Pseudomonas* (1997)
- [No. 7, Consensus Document on the Biology of *Brassica napus* L. (Oilseed Rape) (1997) – **REPLACED** with *Consensus Document on Brassica crops (Brassica spp). No. 54 (2012)*]
- No. 8, Consensus Document on the Biology of *Solanum tuberosum* subsp. *tuberosum* (Potato) (1997)
- [No. 9, Consensus Document on the Biology of *Triticum aestivum* (Bread Wheat) (1999) – **REPLACED** with *Revised Consensus Document on the Biology of Wheat (Triticum aestivum L.). No. 76 (2024)*]
- No. 10, Consensus Document on General Information Concerning the Genes and Their Enzymes that Confer Tolerance to Glyphosate Herbicide (1999)
- No. 11, Consensus Document on General Information Concerning the Genes and Their Enzymes that Confer Tolerance to Phosphinothricin Herbicide (1999)
- No. 12, Consensus Document on the Biology of *Picea abies* (L.) Karst (Norway Spruce) (1999)
- No. 13, Consensus Document on the Biology of *Picea glauca* (Moench) Voss (White Spruce) (1999)
- [No. 14, Consensus Document on the Biology of *Oryza sativa* (Rice) (1999) – **REPLACED** with *Revised Consensus Document on the Biology of Rice (Oryza sativa L.) No. 70 (2021)*]
- No. 15, Consensus Document on the Biology of *Glycine max* (L.) Merr. (Soybean) (2000)
- No. 16, Consensus Document on the Biology of *Populus* L. (Poplars) (2000)
- No. 17, Report of the OECD Workshop on Unique Identification Systems for Transgenic Plants, Charmey, Switzerland, 2-4 Oct. 2000 (2001)
- No. 18, Consensus Document on the Biology of *Beta vulgaris* L. (Sugar Beet) (2001)
- No. 19, Report of the Workshop on the Environmental Considerations of Genetically Modified Trees, Norway, September 1999 (2001)
- No. 20, Consensus Document on Information Used in the Assessment of Environmental Applications Involving Baculoviruses (2002)
- No. 21, Consensus Document on the Biology of *Picea sitchensis* (Bong.) Carr. (Sitka Spruce) (2002)
- No. 22, Consensus Document on the Biology of *Pinus strobus* L. (Eastern White Pine) (2002)
- No. 23, Revised 2006: OECD Guidance for the Designation of a Unique Identifier for Transgenic Plants (2006)
- No. 24, Consensus Document on the Biology of *Prunus* spp. (Stone Fruits) (2002)

- No. 25, Module II: Herbicide Biochemistry, Herbicide Metabolism and the Residues in Glufosinate-Ammonium (Phosphinothricin)-Tolerant Transgenic Plants (2002)
- No. 26, Output on the Questionnaire on National Approaches to Monitoring/Detection/Identification of Transgenic Products (2003)
- No. 27, Consensus Document on the Biology of *Zea mays* subsp. *mays* (Maize) (2003)
- No. 28, Consensus Document on the Biology of European White Birch (*Betula pendula* Roth) (2003)
- No. 29, Guidance Document on the Use of Taxonomy in Risk Assessment of Micro-organisms: Bacteria (2003)
- No. 30, Guidance Document on Methods for Detection of Micro-organisms Introduced into the Environment: Bacteria (2004)
- No. 31, Consensus Document on the Biology of *Helianthus annuus* L. (Sunflower) (2004)
- No. 32, An Introduction to the Biosafety Consensus Documents of OECD's Working Group for Harmonisation in Biotechnology (2005)
- No. 33, Consensus Document on the Biology of Papaya (*Carica papaya*) (2005)
- No. 34, Consensus Document on the Biology of *Pleurotus* spp. (Oyster Mushroom) (2005)
- [No. 35, Points to Consider for Consensus Documents on the Biology of Cultivated Plants (2006) – **REPLACED** with Revised Points to Consider document No. 67 (2020)]
- No. 36, Consensus Document on the Biology of *Capsicum annuum* Complex (Chili, Hot and Sweet peppers) (2006)
- No. 37, Consensus Document on Information Used in the Assessment of Environmental Application involving *Acidithiobacillus* (2006)
- No. 38, Consensus Document on the Biology of Western White Pine (*Pinus monticola* Dougl. ex D. Don) (2008)
- No. 39, Abstracts of the OECD Expert Workshop on the Biology of Atlantic Salmon (2006)
- No. 40, Consensus Document on the Biology of *Pinus banksiana* (Jack Pine) (2006)
- No. 41, Consensus Document on the Biology of the Native North American Larches: Subalpine Larch (*Larix lyallii*), Western Larch (*Larix occidentalis*), and Tamarack (*Larix laricina*) (2007)
- No. 42, Consensus Document on the Safety Information on Transgenic Plants Expressing *Bacillus thuringiensis* – Derived Insect Control Protein (2007)
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- No. 44, Consensus Document on the Biology of Lodgepole Pine (*Pinus contorta* Dougl. ex. Loud.) (2008)
- No. 45, Consensus Document on the Biology of Cotton (*Gossypium* spp.) (2008)
- No. 46, Consensus Document on Information Used in the Assessment of Environmental Applications Involving *Acinetobacter* (2008)
- No. 47, Guide for Preparation of Biology Consensus Documents (2008)
- No. 48, Consensus Document on the Biology of Bananas and Plantains (*Musa* spp.) (2009)
- No. 49, Consensus Document on the Biology of *Picea mariana* [Mill.] B.S.P. (Black spruce) (2010)
- No. 50, Guidance Document on Horizontal Gene Transfer between Bacteria (2010)
- No. 51, Consensus Document on Molecular Characterisation of Plants Derived from Modern Biotechnology (2010)
- No. 52, Guidance Document on the Use of Information on Pathogenicity Factors in Assessing the Potential Adverse Health Effects of Micro Organisms: Bacteria (2011)

- No. 53, Consensus Document on the Biology of *Cucurbita* L. (Squashes, Pumpkins, Zucchini and Gourds) (2012)
- No. 54, Consensus Document on the Biology of the Brassica Crops (*Brassica* spp.) (2012)
- No. 55, Low Level Presence of Transgenic Plants in Seed and Grain Commodities: Environmental Risk/Safety Assessment, and Availability and Use of Information (2013)
- No. 56, Consensus Document on the Biology of Sugarcane (*Saccharum* spp.) (2013)
- No. 57, Consensus Document on the Biology of Cassava (*Manihot esculenta* Crantz) (2014)
- No. 58, Consensus Document on the Biology of *Eucalyptus* spp. (2014)
- No. 59, Consensus Document on the Biology of Common bean (*Phaseolus vulgaris* L.) (2015)
- No. 60, Consensus Document on the Biology of Cowpea (*Vigna unguiculata* (L.) Walp.) (2015)
- No. 61, Report of the OECD Workshop on Environmental Risk Assessment of Products derived from New Plant Breeding Techniques (2016)
- No. 62, Consensus Document on the Biology of Sorghum (*Sorghum bicolor* (L.) Moench) (2016)
- No. 63, Consensus Document on the Biology of Tomato (*Solanum lycopersicum* L.) (2016)
- No. 64, Consensus Document on the Biology of Atlantic salmon (*Salmo salar*) (2017)
- No. 65, Consensus Document on the Biology of Mosquito *Aedes aegypti* (2018)
- No. 66, Consensus Document on the Biology of Apple (*Malus domestica* Borkh.) (2019)
- No. 67, Revised Points to Consider for Consensus Documents on the Biology of Cultivated Plants (2020)
- No. 68, Consensus Document on the Biology of Safflower (*Carthamus tinctorius* L.) (2020)
- No. 69, Developments in Delegations on Biosafety Issues, April 2020 – March 2021 (2021)
- No. 70, Revised Consensus Document on the Biology of Rice (*Oryza sativa* L.) (2021)
- No. 71, Developments in Delegations on Biosafety Issues, April 2021 – May 2022 (2022)
- No. 72, Developments in Delegations on Biosafety Issues, June 2022 – April 2023 (2023)
- No. 73, Consensus Document on Environmental Considerations for Risk/safety Assessment for the Release of Transgenic Plants (2023)
- No. 74, Developments in Delegations on Biosafety Issues, May 2023 – February 2024 (2024)
- No. 75, COLLATION OF THE ANSWERS FOR QUESTIONNAIRE Enhanced Information Exchange on New Breeding Techniques: 2024 Results (2024)
- No. 76, Revised Consensus Document on the Biology of Wheat (*Triticum aestivum* L.) (2024)
- No. 77, Developments in Delegations on Biosafety Issues, March 2024 – March 2025 (2025)
- No. 78, COLLATION OF THE ANSWERS FOR QUESTIONNAIRE Enhanced Information Exchange on New Breeding Techniques: 2025 Results (2025)

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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 on the Harmonisation of Regulatory Oversight in Biotechnology (WP HROB) is a subsidiary body of the Chemicals and Biotechnology Committee of the OECD.

The WP-HROB aims to assist countries in evaluating the potential risks of genetically-engineered organisms, foster communication and mutual understanding of relevant regulations in countries, and facilitate harmonisation in environmental risk/safety assessment of organisms produced through modern biotechnology. This programme encourages information sharing, promotes harmonised practices and contributes to prevent duplication of efforts among countries, while consolidating high biosafety standards. The WP-HROB's activities and outputs are complementary to those of the Working Party for the Safety of Novel Foods and Feeds, which deals with risk/safety of novel foods and feeds derived from genetically-engineered organisms.

The WP-HROB main outputs are the science-based consensus documents. Dealing with the biology of certain plant (crops, trees) and animal species, selected traits introduced into transformed plants, information on micro-organisms, the consensus documents are mutually acceptable among member countries and partners. These practical tools contain information for use during the regulatory assessment of the environmental safety (or 'biosafety') of a particular product of biotechnology. They are available 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 occasion of the 40th WP-HROB meeting (22-24 April 2026). It aims at summarising relevant information on activities related to biosafety issues 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-HROB 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-444Ø6-6	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-948Ø4-4	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-948Ø4-4 x MON-95379-3 x SYNIR162-4 x MON-88Ø17-3	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-88Ø17-3	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 Brasilia, 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. Developments related to implementation of national biosafety framework

Australia's legislation regulating genetically modified organisms (GMOs), the *Gene Technology Act 2000* (GT Act) and its supporting Gene Technology Regulations 2001 (GT Regulations), is administered by the Gene Technology Regulator (the Regulator) and the Office of the Gene Technology Regulator (OGTR).

1. Risk assessment/regulatory decisions

1.1 Environmental release - approvals, since April 2025

Licences for environmental release (at 12 May 2026):

Environmental release of GMOs requires authorisation under a licence for GMO dealings involving intentional release to the environment (DIR licence). Details of all environmental release applications, Risk Assessment and Risk Management Plans (RARMPs) and approvals are available on the OGTR website: <https://www.ogtr.gov.au/what-weve-approved/dealings-involving-intentional-release>

Since April 2025, the Regulator has authorised three licences for commercial release and nine limited and controlled release licences (see Table 1 for details).

Table 1. Licences authorising environmental release of GMOs - since April 2025

Type of GMO	Commercial release approvals	Limited and controlled release approvals
GM plants	GM cotton – herbicide tolerance & insect resistance (DIR 216) GM tomato – purple fruit colour (DIR 218)	GM canola – dairy protein production (DIR 215) GM canola – increased photosynthesis & photorespiration (DIR 212) GM safflower – dairy protein production & altered fat composition (DIR 211)
GMO therapeutics (human)	Commercial supply of nadofaragene firadenovec – bladder cancer treatment (DIR 217) (GM human adenovirus)	Clinical trial GM adenovirus for treatment of bladder cancer (DIR 223) Clinical trial GM adenovirus for treatment of rectal cancer (DIR 222) Clinical trial GM <i>Escherichia coli</i> for treatment of ulcerative colitis (DIR 221) Clinical trial GM adenovirus for treatment of melanoma (DIR 213)

		Clinical trial GM influenza viruses – controlled infection studies (DIR 210)
GMO therapeutics (veterinary)	None	Trial of GMO vaccine for prevention of respiratory disease in horses (DIR 214)

The OGTR evaluation of the application for authorisation of the purple GM tomato was undertaken in parallel with a food safety assessment and subsequent approval of the GM tomato ([A1333](#)) by Food Standards Australia New Zealand.

GMO Register authorisations

No GMO dealings were entered on the GMO Register between April 2025 and March 2026.

1.2 Environmental release – licence applications under assessment

At 12 May 2026, there is currently 1 commercial release application and 2 limited and controlled release applications under assessment – details in Table 2.

Table 2. Applications under assessment for environmental release of GMOs – at 12 May 2026

Type of GMO	Commercial release licence applications currently under assessment	<u>Limited and controlled release licence applications currently under assessment</u>
GM plants	None	None
GMO therapeutics (human)	None	None
GMO therapeutics (veterinary)	GMO vaccine (Venezuelan equine encephalitis virus) against feline leukemia virus (DIR 220) GMO vaccine (Turkey herpesvirus) multivalent vaccine for chickens (DIR 224)	None

1.3 Trends in application types

The trend of increased numbers of applications for GMOs for human and veterinary therapy has continued. Some trend analysis of applications is presented in OGTR's [2024-2025 Annual Report](#).

1.4 Risk assessment guidance documents

OGTR produces Biology documents (modelled on the OECD concept) and these are available at: <https://www.ogtr.gov.au/resources> OGTR staff occasionally publish academic papers, these are available at: <https://www.ogtr.gov.au/about-ogtr/academic-publications>

1.5. Modernisation of application processes – OGTR Online Services Portal

The OGTR is continuing to modernise its information management systems and enhance digital service delivery. The [OGTR Online Services Portal](#) streamlines application creation and submission, and enables access to information holdings for authenticated users.

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

2.1 Amendments to legislation and ongoing Policy Review activities

Versions of the *Gene Technology Act 2000* (GT Act) and the *Gene Technology Regulations 2001* (GT Regulations) currently in force can be accessed via the OGTR website: <https://www.ogtr.gov.au/about-ogtr/legislative-documents> that links to the [Federal Register of Legislation](#).

Proposed amendments to Gene Technology legislation

The September 2024 [Consultation on Exposure draft Gene Technology Amendment Bill 2024](#) introduced the [new authorisation categories](#) (see Figure 1) proposed in the recommendations of the [Third Review of the National Gene Technology Regulatory Scheme](#).

A public [Consultation on the proposed amendments to the Gene Technology Regulations 2001](#) was undertaken from January to March 2026. Changes to the GT Regulations will also be needed to give effect to the proposed changes to the scheme. The proposed changes would enable the Gene Technology Regulator to make rules for prescribed matters that are required or permitted by the GT Act or the GT Regulations. In addition to rules for risk-tiering, the Regulator would have the ability to make rules for accreditation, certification, and the transport, storage and disposal of GMOs. These rules would replace the current guidelines.

OGTR continues to provide technical and operational information to assist the policy team in the Department of Health, Disability & Ageing leading the implementation of review recommendations.

Figure 1 Proposed new authorisation pathways

*Note that some dealings covered by a GMO licence currently may fall into lower authorisation pathways under the new regulatory approach (e.g. GMO permit or notifiable dealing).

2.2 Review of guidelines for certification of Physical Containment (PC) facilities

The OGTR has an ongoing program to revise the Regulator's guidelines for certification of Physical Containment (PC) facilities. A review of the PC2 guidelines is ongoing.

2.3 Application forms and guidance

In October 2025, a number of OGTR application forms for GMO licences had minor updates in relation to Confidential Commercial Information. OGTR forms are available at: <https://www.ogtr.gov.au/resources>

Guidance material is available on the [OGTR website](#).

3. Risk management and compliance activities

OGTR inspectors have a program of monitoring of GMO dealings (DIR and DNIR licences) and certified facilities to ensure compliance with the legislation and licence conditions. [OGTR adopts a cooperative compliance approach](#) and focuses on the prevention of adverse outcomes before they can arise. Details of OGTR monitoring activities are published in [OGTR Annual Reports](#) and are available on the OGTR website. OGTR also publishes [quarterly summaries of monitoring and compliance activities](#).

4. Regulated stakeholder and public engagement and outreach activities

4.1 Fact sheets and other documents

The OGTR publishes Fact Sheets, Policies and Guidance Notes to provide information to the public and to regulated stakeholders on the operation and requirements of the regulatory scheme.

In March 2026, OGTR published a revised fact sheet [Overview of the status of organisms modified using gene editing and other new technologies](#). This document is to assist regulated organisations to understand which gene editing (SDN-1, SDN-2 or SDN-3) and RNA interference (RNAi) techniques result in GMOs.

Guidance documents (new and revised) published on the OGTR website since April 2025, include:

[Infographic outlining GM Purple Tomato regulatory remits](#) – May 2025

[Financial suitability requirements for applicants](#) – September 2025

[Fire Ant baits are not GMOs](#) – September 2025

[Current GM plants authorised for release into the environment \(GMO Register and licences for commercial releases\)](#) – November 2025

OGTR Fact Sheets and other publications are available at: <https://www.ogtr.gov.au/resources>

4.2 Gene Technology Advisory Committees

The Gene Technology Technical Advisory Committee (GTTAC) provides advice to the Regulator on licence applications and RARMPs. [GTTAC communiques](#) are published on the OGTR website. A [new GTTAC membership](#) was recently announced.

The [Gene Technology Ethics & Community Consultative Committee](#) (GTECCC) provides advice to the Regulator on ethical and community matters. In 2025, GTECCC published [Guidance for Communicating on Gene Technology 2025](#) and the aim of the document is to improve gene technology communication outcomes and to foster and support responsible communication about gene technology and the regulatory scheme. It is accompanied by: [Working with GTECCC's guiding questions - GTECCC's story-telling case studies for communicating on gene technology](#). The new membership of GTECCC is expected to be notified soon.

4.4 OGTR newsletter

OGTR has continued its periodic Newsletter to communicate with regulated organisations about key updates, clarification of application processes and compliance requirements and current issues. The [November 2025 OGTR newsletter](#) noted minor updates to application forms and included a feature on the 50th anniversary of the 1975 Asilomar conference on recombinant DNA.

2. Updates regarding international activities

Participation in/hosting international symposia/fora relating to biosafety

An OGTR officer contributed to the program planning for the 2025 symposium of the International Society for Biosafety Research.

Other updates may be included in the final version for WP-HROB publication.

3. Developments related to new breeding techniques (NBTs)

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

OGTR and GMO regulation

The regulatory status of organisms modified by 'new breeding techniques' (aka genome editing) is determined by the definitions of 'GMO' and 'gene technology' in the GT Act. Some exclusions and inclusions are provided in the GT Regulations, specifically: Schedule 1A Techniques that are not gene technology; Schedule 1B Organisms that are GMOs; and Schedule 1 Organisms that are not GMOs .

Gene edited organisms excluded from regulation as GMOs are those resulting from site directed nuclease-1 (SDN-1) type modifications and without any introduced nucleic acid template to guide genome repair from regulation (see Table 1).

Table 3 Regulatory status of organisms with SDN-1 modifications, by method of SDN application

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

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

Food Standards Australia New Zealand and New Breeding Techniques and food

In September 2025, changes to the *Australia New Zealand Food Standards Code* (the Code) were gazetted to update definitions for genetically modified (GM) food. Genetically modified (GM) foods are regulated under Standard 1.5.2 of the Code – [Genetically Modified Food](#) (formerly Food produced using

Gene Technology). [Food Standards Australia New Zealand](#) (FSANZ) is the Australian Government agency responsible for administering the Code. This includes undertaking pre-market safety assessment of GM foods and listing approved GM foods in [Schedule 26 of the Code](#)

The changes were the result of the *Proposal P1055 – Definitions for gene technology and new breeding techniques* and introduce a more outcome-based approach than the former process-based definitions. The full set of [publicly available documents on P1055](#) is available from the FSANZ website.

Austria

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

During the current reporting period (April 2025 – March 2026) neither cultivation of GM crops nor deliberate release of GMOs for field trials occurred in Austria.

Accordingly, no new risk assessment/regulatory decisions were taken by Austrian competent authorities. Austria, however, participated actively in the targeted consultations involving member states authorities/institutions which are conducted by EFSA for the risk assessment for notifications of GM-products for EU-wide authorisation for import and processing as well as food and feed use.

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

No legislative amendments were introduced or implemented at the Austrian Federal level during this reporting period.

3. Risk management measures

No new developments can be reported for the implementation of Directive 2015/412/EU in Austria: All prior decisions regarding the restrictions of geographical scope of GMO applications/authorisations for cultivation in Austria of several GM maize events (MON810, 1507, 59122, 1507x59122, Bt11, GA21, MIR604 and Bt11xMIR604xGA21) are still in place. Respective information is available at: https://ec.europa.eu/food/plant/gmo/authorisation/cultivation/geographical_scope_en#at

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

At the level of the committee of competent authorities according to EU directive 2001/18/EC a discussion about the interpretation of the definition of GMOs provided in the Directive is ongoing. A working group was established to draft a proposal to identify criteria for the interpretation of the GMO definition in EU Dir. 2001/18/EC. The Austrian Ministry of Health is participating in the drafting group led by The Netherlands.

6. Research projects on biosafety; relevant publications

June 2025

Dolezel, M.; Miklau, M.; Heissenberger, A.; Kroeger, I.; Otto, M. Complexity Meets Risk—The Next Generation of Genome-Edited Plants Challenges Established Concepts for Environmental Risk Assessment in the EU. *Plants* 2025, 14, 1723. <https://doi.org/10.3390/plants14111723>

Sept. 2025

Dolezel, M.; Eckerstorfer, M.F.; Miklau, M.; Greiter, A.; Heissenberger, A.; Hörtenhuber, S.; Burn, S.-J.; Zollitsch, W.; Kastenhofer, K.; Hagen, K.; et al. Governance Perspectives on Genetically

Modified Animals for Agriculture and Aquaculture: Challenges for the Assessment of Environmental Risks and Broader Societal Concerns. *Animals* 2025,15, 2731. <https://doi.org/10.3390/ani15182731>

2026

Sabra D. A., Frieß J. L., Giese B., Jeremias G. Improving Governance in the Age of Synthetic Biology, Artificial Intelligence, and Diverging Threats. *Front. Bioeng. Biotechnol.* 14:1705143. <https://doi.org/10.3389/fbioe.2026.1705143>

2. Updates regarding international activities

- Environment Agency Austria participates in the Liaison Group of the Cartagena Protocol and serves as representative of the WEOG in the Compliance Committee of the Protocol.
- Austria participated in informal and formal meetings of SBSTTA and SBI of the CBD (relevant topics: synthetic biology, risk assessment and management of LMOs, compliance, implementation plan post 2020 for the Cartagena Protocol).
- Austria is participating in the discussions of the EFSA GMO Network and the recently established subgroup on New Genomic Techniques (NGTs) of the GMO Network.

3. Developments related to new breeding techniques (NBTs)

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

In 2023 the European Commission introduced a [legislative proposal for a regulation on plants produced by certain new genomic techniques \(NGTs\) and their food and feed](#). For details see the submission of the European Commission. To become law, the Regulation must be adopted by the Member States in the Council of the European Union and the European Parliament, following the standard legislative procedure. A decision on the proposal may be reached in the near future. If the proposal is adopted implementation into the Austrian national legislation will be initiated and led by the Austrian Ministry of Health.

2. Specific cases of application, assessment and decision

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

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

Research projects:

The Austrian Agency for Health and Food Safety is conducting a research project on New Genomic Techniques (NGTs) in Agriculture and Food Production: Relevance of the EU-NGT-Regulation for Austria, led by Alexandra Ribarits. The project started in late 2025 and will continue until the end of 2027. The regulation proposal concerning plants produced using new genomic techniques (NGTs) and the food and feed derived from them could enter into force in the first half of 2026 and would then have to be implemented in the first half of 2028 at a latest. This will have implications for agriculture, the economy, consumers, and public administration in Austria. In the project opportunities and challenges are identified from the perspective of agricultural holdings as well as of selected upstream and downstream sectors, such as seed production, feed production, and food processing. In addition to possible solution approaches, the practical application of NGT 1 also presents challenges for organic and GMO-free production and food manufacturing. These include questions of coexistence, necessary measures, and traceability from the perspective of agricultural holdings, as well as options for marketing products without

NGT 1 (according to the classification in the legislative proposal of the European Commission for a regulation on plants produced by certain new genomic techniques (NGTs) and their food and feed).

For further details, an english abstract of the project can be found here: [NGT-AT: Neue genomische Techniken \(NGT\) in der Agrar- und Lebensmittelwirtschaft: Bedeutung der EU-NGT-Verordnung für Österreich - BMLUK DaFNE](#)

The Austrian Agency for Health and Food Safety is furthermore a partner in the Horizon Europe project DETECTIVE (Detection of NGT products to promote innovation in the European Union, 2024–2027). The project is coordinated by Prof. Dennis Eriksson of the Swedish University of Agricultural Sciences (Sveriges lantbruksuniversitet, SLU) and aims to develop, validate and promote innovative approaches for the detection, traceability and authenticity of products derived from new genomic techniques (NGTs) in plants and animals. AGES under the lead of Rupert Hochegger (Head of the National Reference Laboratory for Genetically Modified Organisms) contributes to all work packages, including activities on technical detection and identification methods, validation, and data spaces. Alexandra Ribarits leads Task 2.4: “Co-design and execute the empowerment programme.” This task focuses on structured stakeholder engagement through surveys and participatory workshops, as well as on the development of an empowerment and capability-building programme. The programme is designed to support competent authorities, laboratories and agri-food chain actors in preparing for and implementing upcoming EU regulatory requirements on NGTs, thereby strengthening regulatory preparedness and enforcement capacity. Furthermore, an Austrian case study examines the feasibility of NGT-free production systems, using soybean and maize as representative crops. The case study focuses on technical and organisational requirements along the production and supply chain in Austria.

More information is available at: <https://detective-ngt.eu/>

Publications:

June 2025

Dolezel, M.; Miklau, M.; Heissenberger, A.; Kroeger, I.; Otto, M. Complexity Meets Risk—The Next Generation of Genome-Edited Plants Challenges Established Concepts for Environmental Risk Assessment in the EU. *Plants* 2025, 14, 1723. <https://doi.org/10.3390/plants14111723>

Sept. 2025

Dolezel, M.; Eckerstorfer, M.F.; Miklau, M.; Greiter, A.; Heissenberger, A.; Hörtenhuber, S.; Burn, S.-J.; Zollitsch, W.; Kastenhofer, K.; Hagen, K.; et al. Governance Perspectives on Genetically Modified Animals for Agriculture and Aquaculture: Challenges for the Assessment of Environmental Risks and Broader Societal Concerns. *Animals* 2025, 15, 2731. <https://doi.org/10.3390/ani15182731>

4. Any other information related to NBTs

Austrian delegates are participating in the work of a recently established subgroup of the EFSA scientific network on GMOs. This NGT subgroup held its 2nd meeting in May 2025, the next meeting is planned in spring/summer 2026, ahead of the 21st meeting of the EFSA Scientific Network for Risk Assessment of GMOs scheduled to be held in June 2026.

Belgium

1. Developments related to implementation of national biosafety framework

Risk assessment/regulatory decisions

Applications for commercialisation

Belgium is actively involved in the European Food Safety Authority (EFSA) and European Medicine Agency (EMA) consultation for placing on the market of genetically modified organisms (GMOs). Input in the risk assessment is provided through the Biosafety Advisory Council, which besides food and feed aspects also evaluates environmental impacts of GMOs. The Service Biosafety and Biotechnology (SBB) of Sciensano (<https://www.sciensano.be/en>) ensures the secretariat of the Biosafety Advisory Council and provides permanent scientific support to its activities. Assessment reports and relevant documents can be consulted on <http://www.bio-council.be> and <http://www.biosafety.be>. The OECD consensus documents on the biology of plants are consulted during the evaluations.

Notifications for field trials

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

Currently, two field trials with poplar are ongoing (*B/BE/24/V1 - gene-edited poplars with a decreased lignin content*; and *B/BE/24/V2 - GM poplars with a modified wood composition*), and two with maize (*B/BE/24/V7 - field trial with three CRISPR-Cas9 maize concepts*; and *B/BE/25/V1 - gene-edited maize with improved yield*). Since the last WP-HROB meeting, one new field trial has been handed in.

Field trial (1) notified since March 2025:

- Scientific field evaluation of field-specific genes in maize (*B/BE/26/V1*)

Notifications for clinical trials

Five clinical trials with investigational medicinal products containing or consisting of GMOs have been notified and five of such clinical trials have been approved under the framework of deliberate release since the last WP-HROB meeting (for more information, see: <https://www.biosafety.be/content/clinical-trials-gmos-database>).

Clinical trials (5) notified since March 2025:

- Phase 3 Eye degenerative disease gene therapy trial (*B/BE/25/BVW7*)
- Phase 3 Duchenne muscular dystrophy gene therapy trial (*B/BE/25/BVW8*)
- Phase 1/2 Neurodegenerative disease gene therapy trial (*B/BE/25/BVW9*)
- Phase 1/ 2 Eye degenerative disease gene therapy trial (*B/BE/26/BVW2*)
- Phase 1/ 2/ 3 Duchenne muscular dystrophy gene therapy trial (*B/BE/26/BVW3*)

Clinical trials (5) approved since March 2025:

- Phase 1 Hepatitis B vaccine trial (B/BE/25/BVW2)
- Phase 3 Hemophilia B gene therapy trial (B/BE/25/BVW3)
- Phase 1 Eye degenerative disease gene therapy trial (B/BE/25/BVW4)
- Phase 2 Congestive heart failure gene therapy trial (B/BE/25/BVW5)
- Phase 1 Nipah and measles virus vaccination trial (B/BE/25/BVW6)

2. Updates regarding international activities

Participation in/hosting international symposia/fora relating to biosafety

Belgium 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.

3. Developments related to new breeding techniques (NBTs)

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

A first legislative proposal on new genomic techniques was published by the European Commission on July 5th, 2023 and is under discussion at EU level (for more information on the initiative, we refer to the following [link](#)).

Specific cases of application, assessment and decision

Since 2018, several field trials with gene-edited plants (maize and poplar) generated via CRISPR-Cas technology have been conducted (for more information see [link](#)).

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

CANADIAN FOOD INSPECTION AGENCY (PLANTS WITH NOVEL TRAITS, NOVEL FEEDS) AND HEALTH CANADA (NOVEL FOODS)

Regulatory Decisions: Confined Field Trials of Plants with Novel Traits

The Canadian Food Inspection Agency (CFIA) authorized 224 confined field trials of plants with novel traits in the 2025 growing season. Trials were conducted at 40 locations across Canada. Crop species tested included canola, wheat, corn, barley, potato, soybean, pea, camelina, lentil, poplar and poppy. Notably, 18 corn trials were conducted in New Brunswick, which were the first in the province since 2015. Otherwise, there were no notable trends in the 2025 growing season as compared with recent years in terms of crop kinds or number or location of trials. The CFIA is still receiving applications for confined field trials for the 2026 growing season and expects to receive a similar number of applications and range of crop types as in the 2025 trials. A detailed list of confined field trials is posted on the CFIA's website:

<https://inspection.canada.ca/en/plant-health/plant-varieties/novel-traits/approved-under-review/field-trials>

Regulatory Decisions: Authorizations of Novel Plant Products

The CFIA maintains a database on the regulatory status of novel plant products in Canada. This table includes information on when the products have been authorized for unconfined environmental release (e.g. cultivation), livestock feed use, use as food, whether the plant is an LMO, and whether varieties containing the trait have received variety registration. The database is available at:

<https://active.inspection.gc.ca/netapp/plantnoveltraitpnt-vegecarnouvcn/pntvcne.aspx>

The CFIA prepares "Decision Documents" whenever regulatory decisions are made about novel plant products intended for unconfined environmental release and/or livestock feed use. Decision Documents describe the introduced traits, explain what information was reviewed to reach a decision, and why certain conclusions were reached. Decision Documents are available in hard copy and on the CFIA's website at:

<https://inspection.canada.ca/en/plant-health/plant-varieties/novel-traits/approved-under-review/decision-documents>

Health Canada publishes similar summaries for novel foods on their website at:

<http://www.hc-sc.gc.ca/fn-an/gmf-agm/appro/index-eng.php>

Although not a Party to the Cartagena Protocol on Biosafety, Canada is responsible for submitting summaries of its decisions with respect to living modified organisms to the Biosafety Clearing-House.

Since our last update in March 2025, Canada has authorized the following plants for release into the environment and/or for use in food and/or for use as livestock feed:

Product	Trait	Developer	Development	Authorization dates
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designati on			method	Unconfined environment al release	Livestock feed use	Human food use
Insect- resistant MZIR260 corn	Lepidoptera n resistance including fall armyworm	Syngenta Canada Inc.	Agrobacterium- mediated transformation	2026/01/07	2026/01/07	2026/01/0 7
Potato event BG25	Resistance to late blight fungus; lower reducing sugar levels; reduced browning	J.R. Simplot Company	Agrobacterium- mediated transformation	2026/01/07	2026/01/07	2026/01/0 7
Purple Tomato – Del/Ros1- N event	Elevated anthocyanin levels and purple colour in fruit	Norfolk Healthy Produce	Agrobacterium- mediated transformation	2025/08/12	*	2025/08/1 2
Herbicide tolerant sorghum – ADV-HT2	Tolerance to herbicides that inhibit HPPD	Advanta Seeds	Mutagenesis (non-LMO)	2025/07/22	*	**
Insect- resistant soybean – COR2313 4	Lepidoptera n resistance; Acetolactate synthase (ALS)- inhibiting herbicide resistance	Pioneer Hi- Bred Canada Company	Agrobacterium- mediated transformation	2025/06/10	2025/06/10	2025/06/1 0

*Not assessed for livestock feed in Canada

**Not considered to be a novel product of plant breeding for food use as indicated in <https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/transparency-initiative/list-non-novel-products-plant-breeding-food-use.html>

Regulatory Decisions: Applications Currently Under Review

The CFIA, together with Health Canada, coordinates a voluntary “Notices of Submission” process. This process allows product developers to provide a public-facing summary of the product and the types of data submitted (e.g. description of the inserted genes, agronomic data from field trials, etc.). Members of the public are invited to submit scientific questions to CFIA and Health Canada evaluators for consideration in the assessment. Notices of Submission are available at:

<https://inspection.canada.ca/en/plant-health/plant-varieties/novel-traits/notices-submission>

Since March 2025, Canada has posted three new Notices of Submission. Three plant products are currently undergoing feed, food, and/or environmental release assessments. Since the Notices of Submission process is voluntary, and since the assessment can begin before the notices are posted, not all products currently being assessed are listed.

CFIA-Led Novelty Determination and Transparency of Non-Novel Status

The CFIA offers an optional service if proponents want support interpreting the *Seeds Regulations* to

determine whether their product is a plant with novel trait(s). A summary of this process is available at the new webpage:

<https://inspection.canada.ca/en/plant-health/plant-varieties/novel-traits/approved-under-review/request-determination>

The CFIA also published a related webpage listing non-novel products of plant breeding for environmental release. If, through the novelty determination process, the product is not considered a plant with novel traits, the CFIA encourages proponents to add their product to a list of non-novel products. This list of non-novel plants helps to support a consistent understanding of the CFIA's novelty guidance using real examples, increases transparency about non-novel product of plant breeding that may be used in Canada, and allows interested parties to verify what types of traits are considered non-novel.

<https://inspection.canada.ca/en/plant-health/plant-varieties/novel-traits/approved-under-review/non-novel-products>

To date, 7 lines are listed on this webpage as non-novel following CFIA's novelty determinations from 2020 to 2026.

CFIA Biology Documents

All available biology documents are available on the CFIA website:

<https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/applicants/directive-94-08/biology-documents/eng/1330723572623/1330723704097>

Since meeting in March 2025, the CFIA published a [tomato biology document](#).

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>
- 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 2009-09: 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](https://www.inspection.canada.ca/en/plant-health/plant-varieties/novel-traits/approved-under-review/request-determination)

- Agriculture and Agri-Food: Transparency for Products of Plant Breeding Innovation
<https://agriculture.canada.ca/en/sector/crops/transparency-plant-breeding-innovations>
- List of Non-Novel Products of Plant Breeding for Environmental Release
<https://inspection.canada.ca/en/plant-health/plant-varieties/novel-traits/approved-under-review/request-determination>
- 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>
 - On May 3, 2024, the CFIA introduced updated guidance to clarify when plant-derived feed ingredients require pre-market evaluation under the *Feeds Act* and *Feeds Regulations*. This guidance supplements existing policies on the assessment of novel feeds from plant sources by providing specific criteria to help plant developers determine when a plant product is considered novel and requires a pre-market assessment.
 - The new guidance focuses on product characteristics that may impact feed safety or feed use compared to ingredients already listed and approved. Given the close policy alignment between food and feed, the policy direction for feed incorporates elements that align, where possible, with Health Canada's approach to food regulation. The updated guidance remains science-based and consistent with Canada's product-based regulatory framework for feeds.
 - To develop this guidance, the Animal Feed Program conducted extensive stakeholder consultations, ensuring it reflects industry needs while maintaining regulatory integrity. By clarifying the interpretation of the novel feed definition, this guidance will help product developers make informed decisions early in the development process. Importantly, it does not change the current regulatory approach to novel feeds under either the existing or new Feeds Regulations.

Canadian Feeds Regulations

Following the publication of the updated *Feeds Regulations, 2024* in the *Canada Gazette*, Part 2 on July 3, 2024, the staggered coming into force period continued over the next 18 months to provide stakeholders with time to bring their practices into compliance.

The transition period for requirements related to labelling and standards ended on June 17, 2025. At the same time, on June 17, 2025, new requirements respecting hazard analysis, preventive controls and preventive control plans, complaints, recalls, packaging and traceability came into effect. And finally on December 17, 2025 the expanded scope of livestock species, licencing requirements, authority for issuing export certificates came into effect.

The regulations include 9 documents that are incorporated by reference, which allow standards to be set in a way that can be easily updated following appropriate review and consultation.

The new regulations are less prescriptive, and more focused on the overall health and safety outcomes of the system. The amendments increase responsiveness to industry changes, and provide more clarity, flexibility and transparency to affected regulated parties. They also reflect the latest science, technological advancements, industry best practices, and introduce a modern approach to risk management and oversight. In addition, the feed ingredient approval process has been updated to provide better transparency and clarity to stakeholders. Lastly, the new preventive control plan approach better aligns Canadian feed requirements with those of international trading partners.

A suite of guidance materials has been published and are available online, and work is ongoing to update

existing guidance. Additional guidance was published in support of the June and December coming into force of regulatory requirements. More information can be found on the Feed regulatory modernization page at:

<https://inspection.canada.ca/en/animal-health/livestock-feeds/regulatory-modernization>

ENVIRONMENT AND CLIMATE CHANGE CANADA AND HEALTH CANADA (NEW SUBSTANCES PROGRAM)

New Substances Notifications

Between March 2025 and March 2026, Environment and Climate Change Canada (ECCC)/Health Canada (HC) (New Substances (NS) program) completed 60 new living organism assessments under the *Canadian Environmental Protection Act, 1999* (CEPA). Of this number, 23 were for various environmental or industrial uses, of which 9 were for higher organisms and 14 were for microorganisms. The remaining 37 notifications were for the environmental assessment of organisms used in regulated under the Canada's *Food and Drugs Act* (including biologic drugs and novel foods), of which 13 were for cell and gene therapies, 5 for vaccines, 14 for phage therapies, 1 consortium, and 4 for higher organisms. Of the 23 organisms notified for environmental and industrial uses, 20 were genetically modified organisms. Of the 37 organisms notified for food and drugs uses, 17 were genetically modified. The types of organisms that were assessed included bacteria, archaea, viruses, human cell cultures, fungi, and higher organisms (GM *Drosophila*, GloFish®, and gene-edited pigs).

Risk Assessment Summaries

Summaries of selected risk assessments for new living organisms assessed under CEPA can be accessed through the “list or group” function of [Substance Search](#).

Regulatory Review

The NS Program is continuing to undertake a comprehensive review and modernization of the *New Substances Notification Regulations (Organisms)*. On October 17, 2023 the NS program published a “What We Heard” report (found [here](#)) summarizing the feedback from partners and stakeholders as part of a pre-consultation on the online platform [PlaceSpeak](#). In June 2024, the NS program held information sessions on proposed amendments to the NSNR (Organisms) with interested partners and stakeholders. A summary of that, as well as responses to questions, was published on the [New Substances webpage](#) in Fall 2025. Publication of the proposed amendments to the regulations are anticipated in 2026/27 in the *Canada Gazette Part 1*.

Consultations on Certain Living Organisms New to Canada

The Government of Canada is promoting public engagement in the risk assessment of new higher organisms (such as genetically modified fish, insects and livestock animals) conducted by the NS program. [Amendments to CEPA introduced in June 2023](#) now require that all notifications of new living organisms including vertebrate animals undergo a mandatory public consultation process. When these consultation requirements do not apply, the NS program continues to encourage notifiers of other higher organisms to participate voluntarily in a public engagement process. As such, the NS program publishes non-confidential summaries of notifications for certain organisms that are notified under the NSNR (O) to allow for public comments during the risk assessment process. Comments received are considered in the risk assessment and also made public. Since 2018, the NS program has held public comment periods for twenty-seven lines of genetically modified fish, two lines of genetically modified *Drosophila*, and four lines of gene-edited

pigs. As part of the public engagement process, the NS program continues to prioritize meaningful engagement with Indigenous groups. Information on current and past consultations can be accessed through the [New Substances Website](#).

DRAFT Whole Genome Sequencing Guidance for the purpose of microbial risk assessment under NSNR (O) of CEPA

The New Substances program is developing a Whole Genome Sequence (WGS) guidance document to provide advice to the notifiers on the nature, type and breadth of WGS data that can be submitted to meet specific information requirements of the NSNR (O) of CEPA. Two case studies to illustrate WGS and metagenome sequence data analyses for risk assessment purpose are also planned to be included. This guidance is intended to expand upon the [Microbial Identification Framework for Risk Assessment \(MIFRA, 2010\)](#). It envisaged that WGS and metagenome sequence analyses could be used as new approach methods to predict adverse effects of micro-organisms used in biotechnology products with less reliance on animal testing.

International Initiatives

Canada submitted its 7th National Report to the Convention on Biological Diversity, covering the 2020 to the 2025 period. The report focused on progress made toward implementing the Kunming-Montreal Global Biodiversity Framework, such as Target 17: Strengthen Biosafety and Distribute the Benefits of Biotechnology.

Canada also reviewed the draft thematic action plan to support capacity-building and development, access to and transfer of technology and knowledge-sharing in the context of synthetic biology, and participated in the Discussions of the Open-Ended Online Forum on Synthetic Biology.

At the IUCN World Conservation Congress in 2025, ECCC collaborated with Parks Canada to develop Canada's position on the motions of synthetic biology and the moratorium on genetically engineered wild species in ecosystems and led discussions in the virtual contact groups. At the Congress, participants voted to pass the motion on synthetic biology and to fail the moratorium.

GLOBAL LOW LEVEL PRESENCE INITIATIVE

<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.

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).

Czechia

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

The Czech Republic as a member of the European Union (EU) shall implement EU community-level decisions and regulations on genetically modified (GM) food and feed at the national level, in accordance to Regulation (EC) No 1829/2003 on the placing on the market of GM food and feed. All the products authorised for placing on the EU market are listed in the EU Register of GM food and feed (<https://webgate.ec.europa.eu/dyna2/gm-register/>).

The only GM crop authorised for cultivation in the EU is MON 810 maize, which is resistant to the European corn borer. Although it has never been banned at national level, MON 810 has not been cultivated in the Czech Republic since 2017.

Furthermore, field trials and clinical trials with medical products containing GMOs were authorised / carried out in 2025, according to EU Directive 2001/18/EC, on deliberate release of GMOs into the environment.

Concerning field trials, only two small-scale field trials were carried out in 2025 and will be continued in 2025:

- 2x Spring barley, a research project of the Palacký University in Olomouc, Olomouc region.

The number of clinical trials of medicines containing genetically modified cells or viruses (adeno-associated virus or human cells genetically modified with retroviral or lentiviral vectors, e.g. CAR-T) follows the same trend. Last year, the Ministry of the Environment issued five approvals for the deliberate release of GMOs or a combination of GMOs for the purpose of clinical trials.

Most of the activities were carried out under the contained use regime according to EU Directive 2009/41/EC on contained use of genetically modified micro-organisms. More than 130 research institutions, universities and companies now using GMOs. Five laboratories are now classified at BSL level 3, the others at BSL level 1 or 2.

2. Public engagement and outreach activities

Information on legislation, issued authorisations, registers of authorised users and GMOs, and various guidelines are made available on the website of the Ministry of the Environment at https://www.mzp.cz/cz/navigace_temata in Czech and <http://www.mzp.cz/biosafety> in English (the Czech node of the Biosafety Clearing House).

Public consultations are part of the authorisation process of deliberate release of GMOs into the environment (field trials and clinical trials).

2. Developments related to new breeding techniques (NBTs)

At the EU level, a significant regulatory development is the proposal submitted by the European Commission on 5 July 2023 for a new regulation on plants obtained by certain NGTs (targeted mutagenesis and cisgenesis). This proposal aims to establish specific rules for these plants and their products, while excluding transgenic organisms. The proposal is still under negotiation and has not yet entered into force.

In addition, the European Food Safety Authority issued a favourable opinion in 2024 on a genetically modified maize (DP910521) developed using a new breeding technique, which was subsequently authorised for food and feed use in 2025. This reflects ongoing scientific and regulatory progress at the EU level.

Overall, NBT development in the Czech Republic is currently limited to research activities, while broader regulatory and market developments are driven at the EU level.

Denmark

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

In 2025 the Competent Authority (The Danish Veterinary, Food, Agricultural and Fisheries Agency) approved two applications for experimental releases involving lines of GE-potato with increased late blight resistance.

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

Development of new EU-regulation on new genomic techniques (NGT) (NGT is the term used in EU-legislation for NBT) (see point 3).

Proposal for new EU-legislation on genetically modified microorganisms (GMMs) has been tabled by the European Commission and is currently dealt with according to the ordinary legislative procedure.

3. Risk management measures

The sites of the abovementioned experimental releases are monitored for at least four years after the last GE potato has been grown in the field.

3. Developments related to new breeding techniques (NBTs)

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

On July 5, 2023, the European Commission tabled a proposal for a new regulation of plants obtained by certain new genomic techniques and their food and feed. This proposal is currently under adoption following the ordinary legislative procedure. Please refer to the reply from the European Commission for more details on this proposal.

2. Specific cases of application, assessment and decision;

Decisions on experimental releases of potatoes obtained with NGT (as described in point 1.)

4. Additional Information

The control of conventional seeds for adventitious presence of GMOs has in 2025 focused on imports of Alfalfa (*Medicago sativa*), Danish production of Oilseed rape (*Brassica napus*) certified seed and Maize (*Zea mays*) seed.

No GMO's have been found.

Estonia

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

The situation in Estonia regarding deliberate release of GMOs into the environment remains unchanged. There is no cultivation of GMO crops and there has been no deliberate release of GMOs for field trial.

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

No legislative amendments were introduced or implemented in Estonia during this reporting period.

3. Risk management measures

Not applicable, as there is no cultivation of GMOs and no field trials with GMOs.

2. Updates regarding international activities

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

Estonia is participating in the discussions under the Cartagena protocol and synthetic biology discussions under the convention of biological diversity.

3. Developments related to new breeding techniques (NBTs)

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

A legislative proposal on the Regulation of the European parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Directives 68/193/EEC, 1999/105/EC, 2002/53/EC, 2002/55/EC, and Regulation (EU) 2017/625 (NGT Regulation) is under negotiation between European Commission, European Council and Parliament with the end goal of adopting proposal of NGT Regulation on the European Union level. Estonia is involved in discussions of that proposal.

4. Any other information related to NBTs.

There has been no applications for field trials for organisms made with new breeding techniques.

France

[English version follows]

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

a) Mise sur le marché

Des évaluations de risque sont réalisées au niveau national par l'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (Anses) sur les dossiers de demandes d'autorisation de mise sur le marché d'OGM déposés au titre du règlement européen (CE) n°1829/2003 concernant les denrées alimentaires et les aliments pour animaux génétiquement modifiés ou au titre de la directive 2001/18/CE relative à la dissémination volontaire d'OGM dans l'environnement.

Les évaluations suivantes ont été publiées depuis mars 2025 :

OGM	Avis rendus
Soja génétiquement modifié COR23134	https://www.anses.fr/system/files/PGM2024-SA-0181.pdf
Soja génétiquement modifié GMB151 x DAS-44406-6	https://www.anses.fr/system/files/PGM2024-SA-0141.pdf
Soja génétiquement modifié MON 94 637	https://www.anses.fr/system/files/PGM2024-SA-0065.pdf
Maïs génétiquement modifié DP51291	https://www.anses.fr/system/files/PGM2023-SA-0112.pdf

Ces évaluations de risque sont utilisées par les autorités compétentes françaises pour définir les positions de vote de la France sur les projets de décision d'autorisation soumis par la Commission européenne aux États membres.

S'agissant des denrées alimentaires et des aliments pour animaux (règlement 1829/2003), les autorités françaises transmettent par ailleurs des commentaires de l'Anses à l'Autorité européenne de sécurité des aliments (EFSA), en charge de l'évaluation des dossiers au niveau européen, dans le cadre des consultations des États membres organisées par celle-ci. Les décisions d'autorisation de mise sur le marché des OGM sont adoptées par la Commission européenne après le vote des États membres.

S'agissant des usages non alimentaires (directive 2001/18/CE), les autorités françaises transmettent des commentaires à la Commission européenne dans le cadre des consultations des États membres sur les dossiers. La décision d'autorisation de mise sur le marché de l'OGM est adoptée par l'Etat membre qui a reçu le dossier. Dans le cas où un Etat membre a maintenu une objection lors des consultations, la décision finale est adoptée après un vote des Etats membres et une décision de la Commission européenne.

b) Expérimentation en milieu ouvert

Aucune demande d'autorisation pour l'expérimentation d'OGM en milieu ouvert n'a été déposée en France depuis la dernière réunion du Groupe de travail.

c) Utilisations d'OGM en milieu confiné (en laboratoire)

Environ 1200 dossiers de demandes d'utilisations confinées d'OGM ont été examinés en 2025.

d) Culture des OGM

Il n'y a pas de cultures commerciales d'OGM ni d'essais au champ d'OGM autorisés en France.

La culture commerciale des OGM est interdite en France depuis 2008. La culture du maïs MON810, seul OGM autorisé à la mise en culture au niveau européen, est interdite en France en application de la Décision d'exécution (UE) 2016/321 de la Commission du 3 mars 2016 modifiant la portée géographique de l'autorisation de cultiver le maïs génétiquement modifié (*Zea mays* L.) MON 810.

Même en l'absence de culture sur le territoire français, les autorités françaises transmettent à la Commission européenne leurs commentaires sur la surveillance environnementale du maïs MON810, sur la base d'avis rendus par l'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (Anses).

Année de surveillance	Avis rendus par l'Anses
2024	https://www.anses.fr/system/files/PGM2025-SA-0132.pdf

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

Le Gouvernement a adopté le [décret n° 2025-345 du 14 avril 2025](#) pour préciser la liste des techniques de mutagenèse produisant des organismes exemptés de la réglementation relative aux OGM.

Ce décret fait suite à un recours initié en 2015 sur la mutagenèse auprès du Conseil d'Etat. Dans le cadre de ce recours, le Conseil d'Etat a interrogé à deux reprises la Cour de justice de l'Union européenne (CJUE) afin de clarifier l'interprétation du droit européen concernant le statut juridique des techniques de mutagenèse vis-à-vis de la réglementation OGM.

Le 1er arrêt de la CJUE, rendu le 25 juillet 2018, concluait que tous les organismes obtenus par mutagenèse sont des OGM et que seuls sont exclus du champ d'application de la directive 2001/18 ceux qui sont issus de techniques de mutagenèse qui ont été traditionnellement utilisées pour diverses applications et dont la sécurité est avérée depuis longtemps. Il en découle que les nouvelles techniques de mutagenèse, développées après l'adoption de la directive en 2001, et les organismes qui en sont issus, sont soumis aux obligations de la réglementation OGM. Il ressort du 2ème arrêt de la CJUE, rendu le 7 février 2023, que les organismes issus de mutagenèse aléatoire in vitro sont exemptés de la réglementation OGM, au même titre que ceux issus de mutagenèse aléatoire in vivo.

Dans sa décision du 23 octobre 2024, le Conseil d'Etat a enjoint au Gouvernement d'adopter un décret pour préciser la liste limitative des techniques ou méthodes de mutagenèse traditionnellement utilisées pour diverses applications et dont la sécurité est avérée depuis longtemps.

Le décret n° 2025-345 restreint la liste des techniques de mutagenèse considérées comme ayant fait l'objet d'une utilisation traditionnelle et dont la sécurité pour la santé publique ou l'environnement est avérée depuis longtemps à la mutagenèse aléatoire.

2. Developments related to new breeding techniques (NBTs)

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

En tant qu'Etat membre de l'Union européenne, la France participe aux négociations sur le projet de règlement européen sur les végétaux obtenus par certaines nouvelles techniques génomiques, qui se sont poursuivies en 2025. Le projet de règlement a été présenté par la Commission européenne le 5 juillet 2023 (https://food.ec.europa.eu/plants/genetically-modified-organisms/new-developments-biotechnology_en).

2. Any other information related to NBTs

Programme de recherche sur la sélection végétale avancée pour faire face au défi climatique et assurer la transition agro-écologique.

Dans le cadre du plan de relance et du 4ème programme d'investissements d'avenir, le Gouvernement a décidé en 2021 la mise en place d'un Programme et équipement prioritaire de recherche (PEPR) sur la sélection végétale avancée pour faire face au défi climatique et assurer la transition agro-écologique. Le programme est doté de 30 millions d'euros, pour 8 ans, et son pilotage est confié à l'Institut national de recherche pour l'agriculture, l'alimentation et l'environnement (INRAE). Le programme a démarré en 2023.

Le programme a pour mission d'accompagner des transitions agroécologiques en rendant accessible rapidement une plus large gamme de variétés de plantes répondant aux conditions actuelles et futures pour pallier l'urgence des défis qui se posent à l'agriculture (réduction de l'usage des pesticides, accès limité aux ressources naturelles, dérèglement climatique). Le programme se focalise sur l'évaluation de la contribution potentielle de l'édition des génomes comme outil de sélection en excluant la transgénèse.

Les axes du programme de recherche sont les suivants :

- Développement de l'édition des génomes pour l'application à un large panel d'espèces ;
- Edition des génomes pour accompagner la transition agroécologique ;
- Intégration de l'édition des génomes dans les schémas de sélection ;
- Etude des dynamiques de régulation de l'édition des génomes et aide à la conception de régime de sélection légitimes.

Les informations actualisées relatives à ce programme de recherche sont publiées sur le site : <https://www.pepr-selection-vegetale.fr/>

Participation au projet de recherche européen DARWIN

Le projet de recherche DARWIN vise à mettre au point conjointement une stratégie de détection novatrice en combinant des méthodes d'analyse ciblées basées sur la PCR, des méthodes de séquençage non ciblées et des solutions numériques. <https://darwin-ngt.eu/>

L'Agence nationale de la sécurité sanitaire, de l'alimentation, de l'environnement et du travail participe au consortium du projet DARWIN.

[English version]

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory

a) Placing on the market

Risk assessments are carried out at the national level by the National Agency for Food, Environmental and Occupational Health and Safety (Anses) on applications for marketing authorisation for GMOs submitted under European Regulation (EC) No. 1829/2003 on genetically modified food and feed or under Directive 2001/18/EC on the deliberate release into the environment of GMOs.

The following evaluations have been published since March 2025 :

GMO	Opinion issued
Genetically modified soybean COR23134	https://www.anses.fr/system/files/PGM2024-SA-0181.pdf
Genetically modified soybean GMB151 x DAS-44406-6	https://www.anses.fr/system/files/PGM2024-SA-0141.pdf
Genetically modified soybean MON 94 637	https://www.anses.fr/system/files/PGM2024-SA-0065.pdf
Genetically modified maize DP51291	https://www.anses.fr/system/files/PGM2023-SA-0112.pdf

These risk assessments are used by the French competent authorities to define France's voting positions on the draft authorisation decisions submitted by the European Commission to the Member States.

In the case of food and feed (Regulation 1829/2003), the French authorities also send comments to the European Food Safety Authority (EFSA), in charge of evaluating the dossiers at European level, as part of the consultations of the Member States organized by the latter. Decisions to authorize the placing on the market of GMOs are adopted by the European Commission after the vote of Member states.

In the case of non-food uses (Directive 2001/18/EC), the French authorities send comments to the European Commission as part of the Member States consultation on the dossiers. The decision to authorise the placing on the market of the GMO is taken by the Member State that received the dossier. If a Member State maintains an objection during the consultations, the final decision is adopted after a vote by the Member States and a decision by the European Commission.

b) Field trials

No authorisation application for experimentation of GMOs in the environment has been filed in France since the last meeting of the WG-HROB.

c) Use of GMOs in contained environments (in the laboratory)

Around 1200 applications for contained use of GMOs were examined in 2025.

d) Cultivation of GMOs

There are no commercial GMO crops or GMO field trials authorised in France. The commercial cultivation of GMOs has been prohibited in France since 2008. The cultivation of MON810 maize, the only GMO authorized for cultivation at European level, is prohibited in France in application of 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.

Even in the absence of cultivation on French territory, the French authorities are sending the European

Commission their comments on the environmental monitoring of MON810 maize, based on opinions issued by the National Agency for Food, Environmental and Occupational Health and Safety (Anses).

Monitoring year	Anses opinion
2024	https://www.anses.fr/system/files/PGM2025-SA-0132.pdf

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

The Government has adopted Decree No. 2025-345 of 14 April 2025 to specify the list of mutagenesis techniques that produce organisms exempt from the regulations on GMOs.

This decree follows an appeal lodged in 2015 concerning mutagenesis with the Conseil d'Etat. In the context of this appeal, the Conseil d'Etat twice referred the matter to the Court of Justice of the European Union (CJEU) to clarify the interpretation of European law regarding the legal status of mutagenesis techniques in relation to GMO regulations.

The CJEU's first judgment, delivered on 25 July 2018, concluded that all organisms obtained by mutagenesis are GMOs and that only those resulting from mutagenesis techniques which have conventionally been used in a number of applications and have a long safety record are excluded from the scope of Directive 2001/18. It follows that new mutagenesis techniques, developed after the adoption of the Directive in 2001, and the organisms derived from them, are subject to the obligations of the GMO regulations. It follows from the second judgment of the CJEU, delivered on 7 February 2023, that organisms resulting from in vitro random mutagenesis are exempt from the GMO regulations, in the same way as those resulting from in vivo random mutagenesis.

In its decision of 23 October 2024, the Conseil d'Etat ordered the Government to adopt a decree specifying the list of mutagenesis techniques or methods which have conventionally been used in a number of applications and have a long safety record.

Decree No. 2025-345 restricts the list of mutagenesis techniques considered to have conventionally been used in a number of applications and having a long safety record to random mutagenesis.

2. Developments related to new breeding techniques (NBTs)

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

As a member state of the European Union, France is participating in the negotiations on the draft European regulation on plants obtained by certain new genomic techniques, which continued in 2024. The draft regulation was presented by the European Commission on July 5, 2023.

(https://food.ec.europa.eu/plants/genetically-modified-organisms/new-developments-biotechnology_en).

2. Any other information related to NBTs.

Research programme on advanced plant breeding to meet the climate challenge and ensure agro-ecological transition.

As part of the recovery plan and the 4th future investment programme, the government has decided in 2021 to set up a Priority Research Programme and Equipment (PEPR) on advanced plant breeding to meet the climate challenge and ensure the agro-ecological transition. The programme has been allocated €30 million for 8 years, and will be managed by the French National Research Institute for Agriculture, Food and the Environment (INRAE). The programme started in 2023.

The programme's mission is to support agro-ecological transitions by rapidly making available a wider range of plant varieties that meet current and future conditions, in order to address the urgent challenges

facing agriculture (reduced use of pesticides, limited access to natural resources, climate change). The programme focuses on assessing the potential contribution of genome editing as a selection tool, excluding transgenesis.

The research programme focuses on the following areas:

- Development of genome editing for application to a wide range of species;
- Genome editing to support the agro-ecological transition;
- Integrating genome editing into selection schemes;
- Studying the regulatory dynamics of genome editing and helping to design legitimate selection regimes.

Updated information on this research programme is published on the website: <https://www.pepr-selection-vegetale.fr/>

Participation in the European DARWIN research project

The DARWIN research project aims to co-develop a pioneering detection strategy by integrating targeted analytical PCR-based methods, untargeted sequencing methods, and digital solutions. <https://darwin-ngt.eu/>

The French Agency for Food, Environmental and Occupational Health and Safety is a member of the DARWIN project consortium.

Germany

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

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>).

In context of the contained use of GMOs, the responsibility for implementation of the respective Directive No 2009/41/EC lies with the German Federal States. These are advised by the independent Central Committee on Biological Safety (ZKBS) e.g. on biosafety levels. The ZKBS publishes annual overviews about nationwide activities; see https://www.zkbs-online.de/ZKBS/EN/Home/home_node.html.

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

In Germany, the GMO legal framework of the EU applies. It ensures that the development of modern biotechnology takes place under safe conditions and aims to protect human and animal health and the environment. It includes i.a. a safety assessment before any GMO is placed on the market, harmonized procedures for risk assessment and authorisation, labelling requirements and ensures traceability of GMOs placed on the market.

Essential elements of the legal framework are Directive (EC) No 2001/18 on the deliberate release of GMOs into the environment, Regulation (EC) No 1829/2003 on GM food and feed as well as the implementing Regulation (EU) No 503/2013 on applications for authorisation of GM food and feed in accordance with Regulation (EC) No 1829/2003, Directive 2015/412/EC on the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, Regulation (EC) No 1830/2003 concerning traceability and labelling, Directive 2009/41/EC on contained use of GMOs, and Directive (EC) 1946/2003 on transboundary movements of GMOs.

Additionally, guidance is provided in EFSA scientific opinions, and EFSA guidance documents detail e.g. what type of scientific data and other information need to be included in GMO applications (<https://www.efsa.europa.eu/en>).

3. Risk management measures

There is currently no authorisation for the cultivation of GMOs in Germany, only for import and use as food/feed. According to the authorisations, these require a post-market 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.

6. Research projects on biosafety; relevant publications.

Research on products of modern biotechnology is conducted under contained use conditions only, as there are currently no authorized field trials in Germany.

An example of research funded by the German government is listed below.

- Vatanparast, M., Amari, K., 2025. Development and efficacy of dsRNA pesticides targeting the Colorado potato beetle with enhanced stability via chitosan formulations. *Pesticide Biochemistry and Physiology* 214. <https://doi.org/10.1016/j.pestbp.2025.106606>

2. Updates regarding international activities

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

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.

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

The German BVL and the Dutch WFSR host and maintain **EUginus**, the **EUropean GMO Initiative for a Unified Database System** (www.euginus.eu) in close cooperation with official GMO detection and identification laboratories of 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 German Federal Agency for Nature Conservation (BfN), together with the Secretariat of the Convention on Biological Diversity (CBD), hosted the first **CBD Capacity-building Workshop on Synthetic Biology** (<https://www.cbd.int/meetings/SYNBIO-WS-2025-01>) in **November 2025**, with 20 participants from all five CBD regions. The workshop focused on the history of the assessment of Synthetic

Biology at the CBD, on current challenges in capacity-building for synthetic biology and its assessment, and on recent research results.

3. Specific cases of use of OECD tools and information

German national authorities regularly use OECD tools and information e.g. when evaluating applications for authorisation of GM products. Guidance documents by the EFSA refer to OECD Consensus Documents concerning compositional aspects of GMOs.

Furthermore, German national authorities frequently consult the OECD Verification digit checker that verifies suggested GMO Unique Identifiers and information available in the OECD BioTrack Product Database when enforcing their legal tasks.

3. Developments related to new breeding techniques (NBTs)

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

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.

2. Specific cases of application, assessment and decision

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.

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

The German government funds several research projects related to NBT products. Funding is furthermore provided for fundamental research in this area and projects on analytical aspects. Some examples are listed below.

- Diaz, C., Ayobahan, S., Simon, S., Zühl, L., Schiermeyer, A., Eilebrecht, E., Eilebrecht, S. (2025): Classification of and detection techniques for RNAi-induced effects in GM plants, *Front. Plant Sci.* (Frontiers in Plant Science), 16, doi: 10.3389/fpls.2025.1535384
- Dolezel, M., Miklau, M., Heissenberger, A., Kroeger, I., Otto, M. (2025): Complexity Meets Risk—The Next Generation of Genome-Edited Plants Challenges Established Concepts for Environmental Risk Assessment in the EU, *Plants* (Basel, Switzerland), 14, doi: 10.3390/plants14111723
- HOFFIE, R. et al.: PROGRESS- Precision and Optimisation of Genome Editing for Resilient Crops (funding: 031B1555). Genome editing allows for the targeted modification of plant genes. To do this, a specific site within a gene is targeted using molecular scissors, the DNA strand is cut at that site, and the break is then repaired by the cell's own repair mechanisms. However, while this method allows for precise targeting of the location of the genetic modification, the outcome—that is, the resulting genetic sequence—is to some extent left to chance. In simpler applications of genome editing, small deletions or insertions typically occur; in other words, individual letters are lost or added during the repair of the DNA cut. This allows genes to be switched off very efficiently, but not precisely altered in their function. PROGRESS aims to make genome editing even more precise based on a DNA repair mechanism that has been little used to date, and to make existing advancements more efficient by improving the gRNA.

- Kardung, M., Ambrogio, Y., Cingiz, K., Consmüller, N., Unkel, K., Purnhagen, K., & Wesseler, J. (2026). Comparing the Effects of Regulating New Genomic Techniques on Investment Decisions in the European Union. *European Review of Agricultural Economics*.
- Kempe, K. et al: BeetAdapt - Breeding of climate-adapted sugar beets (funding: 031B1551A-E). The project aims to accelerate the breeding of climate-adapted sugar beet varieties in Germany and Europe in order to keep agriculture competitive and sustainable. To this end, an interdisciplinary consortium is collaborating to combine modern technologies such as genome editing, high-throughput phenotyping, AI-supported image analysis, and new transformation methods. Notable innovations include novel endonucleases and a DNA-free laser method. The goal is to develop more efficient breeding processes, improve yield prediction, and detect diseases early. The findings are to be directly applied in practice to strengthen competitiveness and ensure food security.
- Mundorf, J., Simon, S., Engelhard, M. (2025): The European Commission's regulatory proposal on new genomic techniques in plants: a focus on equivalence, complexity, and artificial intelligence, *Environ Sci Eur (Environmental Sciences Europe)*, 37, doi: 10.1186/s12302-025-01199-2
- Rönspies, M., Khosravi, S., Helia, O., Valisi, A., Fajkus, J., Fojtova, M., Houben, A. and Puchta, H. (2025): CRISPR-Cas-mediated heritable chromosome fusions in Arabidopsis. *Science* (Vol 390, Issue 6775), <https://doi.org/10.1126/science.adz8505>. "Rönspies et al. used the model plant Arabidopsis thaliana as a testbed to implement CRISPR-Cas technology to fuse chromosomes together...The researchers generated plants with eight chromosomes instead of 10, which appeared to be phenotypically normal and were self-fertile. Altered recombination patterns illustrated the changes to genetic inheritance rules. This work opens avenues for large-scale chromosomal changes in plants and provides insights into the plasticity of plant genomes." (Madeleine Seale, editor) (funding: i.a. 031B1220B)
- Research project: "Monitoring of environmental impacts of microorganisms and viruses developed using new genomic techniques (NGTs)" (funding: 35 23 84 0400). Rapid advances in new genomic techniques, combined with automation and artificial intelligence, are expanding the use of genetically modified microorganisms and viruses across various applications. However, their diversity and the limited knowledge of microbial ecosystems pose major challenges for environmental monitoring. This project aims to develop basic requirements for monitoring, including detection, tracking spread, and assessing environmental impacts.
- Schulman, A.H., Hartung, F., Smulders, M.J.M., Sundström, J.F., Wilhelm, R., Rognli, O.A. and Metzlauff, K. (2025), Proposed EU NGT legislation in light of plant genetic variation. *Plant Biotechnol. J.*, 23: 4261-4270. <https://doi.org/10.1111/pbi.70228>
- Tissier, A. et al: INNO-TOM - Utilization of pangenomes and gene-targeting approaches for the breeding of disease-resistant and nutrient-enriched cis- and intragenic INNOvative tomato varieties (funding: 031B1538A-C). INNO-TOM aims to develop new cis- and intragenic tomato varieties that benefit both farmers and consumers. The focus is on disease resistance to bacteria and viruses, as well as improving nutrient content (biofortification). To achieve this, the precise and rapid genome-editing technology Cas-Exo is being used, which can specifically swap genes and avoid traditional breeding problems. Specifically, the goal is to make tomatoes resistant to bacterial spot disease and certain viruses that cause significant crop losses. In addition, varieties with purple, anthocyanin-rich fruits are being developed that are healthier, have a longer shelf life, and are less susceptible to mold. The project is being carried out by a consortium of research institutions, a bioinformatics company, and breeding firms, which are jointly responsible for the development, analysis, and practical application of the new tomato lines.

- Yasar, S., Gehrke, F., Capdeville, N., and Puchta, H. (2026): Recent progress in plant genome engineering: from large insertions to chromosome number changes. *Current Opinion in Biotechnology* <https://doi.org/10.1016/j.copbio.2025.103426>. The adaptation of the CRISPR/Cas system as a biotechnological tool has enabled a wide spectrum of targeted genome modifications. Whereas earlier approaches focused on small sequence changes, recent years have seen a shift toward larger-scale alterations. Advances in homology-directed gene targeting now enable efficient, scar-free kilobase insertions, while combining nuclease-deficient Cas effectors with recombinases or transposases allows the integration of much larger sequences. Prime editing further expands this scope, enabling inversions, replacements, and deletions spanning hundreds of kilobases to several megabases. More recently, genome engineering has reached a new stage with chromosome fission and fusion, demonstrating the feasibility of controlled karyotype restructuring. Together, these advances open new opportunities for crop improvement, from establishing reproductive barriers and mimicking evolutionary processes to trait stacking on Plant Artificial Chromosomes.

4. Any other information related to NBTs

On 5 July 2023, the European Commission published a proposal for a Regulation on plants obtained by certain new genomic techniques (NGT) and their food and feed. According to the proposal, two categories of NGT plants should be established and regulated differently compared to other genetically modified plants (compare section 1.2. above).

In December 2025 the EU Member States and the European Parliament (EP) came to a provisional agreement about the final text of the NGT regulation. This agreement is awaiting final confirmation in Council and Parliament, probably before the summer break.

Hungary

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

Cultivation of GMOs: No changes have occurred since the last reporting period. In the course of 2025 no cultivation of GM crops occurred in Hungary because of the Hungarian safeguard clause for MON810 GM maize and also the relevant national application of Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory.

Deliberate release of GMOs for any other purposes than for placing on the market (field trials, and clinical trials): The number of clinical trials authorised were significantly increased in the course of 2025. The scopes of the clinical trials were the followings:

- 1) A Phase 2 clinical trial to evaluate the efficacy and safety of rapcabtagene autoleucel versus standard of care in patients suffering from systemic lupus erythematosus (SLE) with active, refractory lupus nephritis (LN).
- 2) A Phase 2 clinical trial to evaluate the efficacy and safety of rapcabtagene autoleucel versus rituximab treatment in participants with severe refractory diffuse cutaneous systemic sclerosis.
- 3) A Phase 2 clinical trial to evaluate the efficacy and safety of rapcabtagene autoleucel versus comparator in participants with severe refractory idiopathic inflammatory myopathies (IIM).
- 4) A Phase 3 clinical trial of a single intravitreal injection of 4D 150 in adults with macular neovascularization secondary to age-related macular degeneration.
- 5) A Phase 3b clinical trial to assess the injection burden, efficacy, safety, and long-term preservation of visual acuity of surabgene lomparvovec (ABBV-RGX-314) in a real-world context in subjects with neovascular age-related macular degeneration (nAMD).
- 6) A phase 2 clinical trial (EXACT 2) to evaluate the safety, feasibility and efficacy of a single dose level of XC001 (Encoberminogene rezmadenovec), a recombinant virus-based gene therapy product, administered by percutaneous endovascular catheter-facilitated intramyocardial delivery of XC001 in patients with refractory angina (RA) due to obstructive coronary artery disease (CAD).
- 7) A phase 2 clinical trial (EXACT-CABG) to evaluate the effects of XC001 versus placebo on residual ischemic burden in patients with coronary artery disease.

Contained use activities: In the course of 2025 three class 1 and twelve class 2 premises were authorised for contained use activities. One contained used activity in class 1 was authorised with GMV. Twenty-five

contained used activities in class 2 were authorised mainly with GMVs, GMMs and GMAs in some cases with GMPs too. One contained used activities in class 3 were authorised with GMVs (African swine fever virus). One contained used activity in class 4 was authorised with GMVs (Nipah virus, Zaire ebolavirus and Hendra virus).

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

In order to meet Hungary's international obligations, the Hungarian Government adopted the National Biodiversity Strategy for 2030 (NBS) in 2023. The NBS was developed in parallel with the Kunming-Montreal Global Biodiversity Framework (K-M GBF) and it also reflects on the EU Biodiversity Strategy for 2030. In order to support the preparation of the CBD seventh national report (CBD NR7), the interim evaluation of the NBS's implementation was carried out during 2025. The development of both the interim evaluation of the NBS and the CBD NR7 were coordinated by the Ministry of Agriculture. Specific target (target 7) relates to the release of genetically modified organisms (GMO) into the environment including three sub-targets. Concrete implementation measures and monitoring indicators are given for each sub-target.

According to the report relating to the details of the specific GMO target, among others Hungary strengthened the risk assessment and also the controls of gene technology activities in contained uses by organising specific trainings for the controlling authorities.

2. Updates regarding international activities

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

Since Hungary is a party to the Cartagena Protocol on Biosafety, the Hungarian Ministry of Agriculture actively participated in the discussion of risk assessment and management of LMOs during the 27th meeting of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) of the Convention on Biological Diversity (CBD) which took place in October 2025 in Panama City, Panama. Hungary submitted its fifth national report on the implementation to the CBD Secretariat in February 2026. Hungary was also participating in the discussions of the EFSA GMO Network and the subgroup on New Genomic Techniques (NGTs) of the GMO Network. Expert from the Ministry of Agriculture became a member of the steering committee of the European Enforcement Project on GMOs.

3. Developments related to new breeding techniques (NBTs)

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

In the course of 2025 neither cultivation of GM crops produced by new genomic techniques nor deliberate release of GMOs produced by new genomic techniques for field trials and for clinical trials occurred in Hungary.

4. Additional Information

Keeping agriculture free from genetically modified organisms (GMOs) is a key objective of the Hungarian Government, laid down in the Fundamental law of Hungary. This policy has not been changed.

Italy

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

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.

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).

6. Research projects on biosafety; relevant publications

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>

3. Developments related to new breeding techniques (NBTs)

2. Specific cases of application, assessment and decision

NGT 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

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

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, Tuscia, 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) 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
- 3) 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).
- 4) 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).

Some Publications

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- Shahbaz, U.; Videau, P.; Coulonnier, E.; Papon, C.; Navarro-payá, D.; Vidal, A.; Matus, J.T.; Malnoy, M.; Zekri, O.; Fiorani, F.; Faralli, M.; Dalla Costa, L. (2025). Reduced stomatal density improves water-use efficiency in grapevine under climate scenarios of decreased water availability. PLANT CELL REPORTS, 44: 195. doi: 10.1007/s00299-025-03577-9
- Spinella, K.; Dalla Costa, L.; La Rocca, D.; Ciuffa, S.; Verginelli, D.; Shahbaz, U.; Videau, P.; Zekri, O.; Marchesi, U. (2025). High-Resolution Melting (HRM) analysis for screening edited lines: a case study in Vitis spp.. INTERNATIONAL JOURNAL OF PLANT BIOLOGY, 16 (4): 126. doi: 10.3390/ijpb16040126 handle: <https://hdl.handle.net/10449/93135>
- Yousaf, A.; Baldi, P.; Piazza, S.; Gualandri, V.; Komjanc, M.; Dalla Costa, L.; Patocchi, A.; Malnoy, M. (2025). The Hansen's baccata #2 gene Rvi12_Cd5 confers scab resistance to the susceptible apple cultivar "Gala Galaxy". PLANT JOURNAL, 121 (2): e17214. doi: 10.1111/tpj.17214 handle: <https://hdl.handle.net/10449/88056>
- Salvagnin, U.; Pupi, E.; Di Gaspero, G.; Vezzulli, S.; Dalla Costa, L.; Giacomelli, L. (2025). Transgene-free CRISPR-Cas and cisgenesis approaches for resistance to powdery and downy mildew in grapevine. In: 68th Annual Congress of the Italian Society of Agricultural Genetics: Leveraging genetic innovation for future-proofing crops: from conventional breeding to multi-omics and AI in sustainable agriculture, Viterbo, 9-12 September 2025. handle: <https://hdl.handle.net/10449/92236>
- Tamburino, R., D'Agostino, N., Aufiero, G., Nicolia, A., Facchiano, A., Giordano, D., Sannino, L., Paparo, R., Arimura, S.I., Scotti, N. and Cardi, T. Mitochondrial gene editing and allotopic expression unveil the role of orf125 in the induction of male fertility in some Solanum spp. hybrids and in the evolution of the common potato Plant Biotechnology Journal (2025) 23, pp. 1862–1875 doi: 10.1111/pbi.70012.

- Amoroso, C.G., Ercolano, M.R. Key issues in editing elite-tomato lines by CRISPR-Cas9 system. *Euphytica* 221, 198 (2025). <https://doi.org/10.1007/s10681-025-03648-8>
- Dellino, M., de Giovanni, C., Miazzi, M.M., Montemurro, C. and Nigro, D. (2025), Genome Editing Technologies to Improve Health-Related Phytochemicals in Crops. *Food Frontiers.*, 6: 1271-1286. <https://doi.org/10.1002/fft2.70005>

Japan

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

Latest Situation of Approval for Releasing of LMOs

In accordance with the Cartagena Act (Japanese national law to implement the Cartagena Protocol on the Biosafety to Convention on Biological Diversity), four maize, two soybean, one cotton, one oilseed rape and one sugar beet events have been newly approved for commercial use, and one soybean event has been approved for the release for confined field trials (CFTs) since our report at the last WP-HROB meeting held in March 2025 as of February 2026.

Table Newly approved LM plants

Unique Identifier	Plant Species	Applicant	Traits	Genes	Date of approval	Type of use
MON-948Ø4-4	Maize	Bayer CropScience	Short statue	<i>GA20ox_SUP</i>	2025/7/9	food, feed, cultivation
COR-Ø1921-4	Soybean	Corteva Agriscience	Resistance to Lepidoptera	<i>cry1B.61.1, cry1Ca.03, vip3Ab1.740</i>	2025/7/18	CFTs
DP-Ø51291-2	Maize	Corteva Agriscience	Resistance to Coleoptera, Tolerance to Glufosinate	<i>ipd072Aa, pat</i>	2025/7/18	food, feed, cultivation
MON-95275-7	Maize	Bayer CropScience	Resistance to Coleoptera	<i>mpp75Aa1.1, vpb4Da2, DvSnf7.1</i>	2025/10/27	food, feed, cultivation
MON-87427-7 × MON-89Ø34-3 × SYN-IR162-4 × MON-95275-7 × MON-88Ø17-3	Maize	Bayer CropScience	Tolerance to Glyphosate, Tolerance to Glufosinate, Resistance to Lepidoptera, Resistance to Coleoptera	modified <i>cp4 epsps, cry1A.105, modified cry2Ab2, modified vip3A, mpp75Aa1.1, vpb4Da2, DvSnf7.1, modified cry3Bb1</i>	2025/10/27	food, feed, cultivation
NS-B5ØØ27-4	Oilseed rape	Nufarm Limited	Production of omega-3 fatty acid, Tolerance to Glufosinate	<i>Lackl-Δ12D, Picpa-ω3D, Micpu-Δ6D, Pyrco-Δ6E, Pavsa-Δ5D,</i>	2026/1/13	food, feed, cultivation

				<i>Pyrco-Δ5E, Pavsa-Δ4D, pat</i>		
KB-KWS2Ø1-6	Sugar beet	Bayer CropScience	Tolerance to Glyphosate, Tolerance to Glufosinate, Tolerance to Dicamba	modified <i>cp4 epsps, pat</i> , modified <i>dmo</i>	2026/1/13	food, feed, cultivation
MON15947-5	Cotton	Bayer CropScience	Resistance to Lepidoptera	modified <i>cry2Ab2</i>	2026/2/24	food, feed
DP-3Ø5423-1 × DAS-444Ø6-6	Soybean	Corteva Agriscience	High-oleic acid content, Tolerance to Acetolactate synthase (ALS)–inhibiting herbicide, Tolerance to Aryloxyalkanoate herbicides, Tolerance to Glyphosate herbicide, Tolerance to Glufosinate herbicide	<i>gm-fad2-1, gm-hra</i> , modified <i>aad-12, 2mepsps, pat</i>	2026/2/24	food, feed, cultivation

The total number of LM plants ever approved for commercial use as of February 2026 are described in the Table. Decision documents and summary reports of environmental risk/safety assessments are available at Japan Biosafety Clearing House (J-BCH) (URL; <https://www.biodic.go.jp/bch/lmo.html>, in Japanese).

Table LM plants approved for commercial use

Plant Species	Event Number	Plant Species	Event Number
Alfalfa	5	Papaya	1
Oilseed rape (Canola)	21 ^{*1}	Rose	2
Carnation	8	Soybean	31 ^{*1}
Maize	105 ^{*1}	Sugar beet	2
Cotton	39 ^{*1}	Phalaenopsis	1
Mustard greens	1		

^{*1}Some of the events counted in the table are not approved for cultivation because the scope of their use does not include cultivation.

3. Risk management measures

Ministry of Agriculture, Forestry and Fisheries of Japan (MAFF) conducts sampling and analysis of plant seeds at the border to prevent cross-border entry of unauthorized GMOs. MAFF also requires importers of designated seeds and seedlings to make notification of import and test them to check the presence of unauthorized GMOs.

2. Updates regarding international activities

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

Participated in the following meetings:

- SBSTTA27 in Panama City, Panama.
- APEC High-level Policy Dialogue on Agricultural Biotechnology (APEC HLPDAB) Plenary meeting and Workshops in Incheon, Republic of Korea.

3. Specific cases of use of OECD tools and information

Consensus Documents are often referred to in risk assessment reports.

3. Developments related to new breeding techniques (NBTs)

2. Specific cases of application, assessment and decision

Since the last WP-HROB meeting held in March 2025, MAFF received the finalized information forms of

- Nile tilapia (*Oreochromis niloticus*) with increased edible part which had been produced using genome editing techniques
- Tomato with increased GABA which had been produced using genome editing techniques and
- Tomato with enhanced fruit quality which had been produced using genome editing techniques.

The information submission forms were released on the MAFF website (https://www.maff.go.jp/j/syouan/nouan/carta/tetuduki/nbt_tetuzuki.html, in Japanese).

For research use, the information forms were submitted to the Ministry of Education, Culture, Sports, Science and Technology (MEXT) for

- Potatoes with disease resistance
- A group of rice mutants in the genes regulating flowering time, circadian rhythm and metabolism of sugars and starches by genome editing technology
- A group of rice mutants in the genes regulating flowering time, circadian rhythm and stress resistance by genome editing technology and
- A group of rice mutants in the genes regulating flowering time, circadian rhythm, stress resistance, fertilization, metabolism of sugars and starches, general transcription regulation, strigolactone biosynthesis, nitrogen use efficiency by genome editing technology.

This information is available on the MEXT website

(https://www.mext.go.jp/a_menu/lifescience/bioethics/mext_02730.html, in Japanese).

4. Additional Information

Science Communication Activities

MAFF continuously conducts a science communication project focusing biotechnology. In FY 2025, approximately 30 science communication events such as public lectures aimed at consumers, college students, high school students and so on, were held in the project. Additionally, tours for research institutes developing products using genome editing technology were held.

Since genome editing technology is highly advanced and the term itself is still unfamiliar to many people, some consumers may feel vague concerns. To help address this, efforts are being made to improve consumer understanding and acceptance of genome editing technology. These efforts include presenting

the term '*Breeding Acceleration Technology*' alongside 'genome editing technology' and encouraging its use in communication activities, as the term clearly and simply conveys the characteristics of the technology.

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

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

In the year 2025 the State Scientific Institute “Institute of Food Safety, Animal Health and Environment “BIOR”” participated in the targeted consultations involving member states authorities/institutions which are conducted by EFSA for the risk assessment for notifications of GM-products for EU-wide authorisation for import and processing as well as food and feed use. “BIOR” provided opinion on four applications in respect of GMO placing on the EU market.

During the current reporting period (March 2025 – April 2026) neither cultivation of GM crops nor new deliberate release of GMOs for field trials occurred in Latvia. Accordingly no new risk assessment/regulatory decisions were taken by Latvian competent authorities.

According to the Directive (EU) No 2001/18/EC and amendment the Directive (EU) No 2015/412, an EU Member State may decide to restrict the cultivation of an authorized GMO, based on grounds related to environmental or agricultural policy objectives, or other compelling grounds including socioeconomic impacts, which might arise from the cultivation of the GMO on the territory of the Member State concerned. Latvia implements the requirements of the directive through national regulatory enactments. Latvia has no GMO cultivation.

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

As a member state of the European Union, Latvia is participating in the negotiations on the draft European regulation on plants obtained by certain new genomic techniques, which continued in 2025 and 2026.

2. Updates regarding international activities

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

In the year 2025, we participated in obligatory meetings.

3. Developments related to new breeding techniques (NBTs)

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.

Lithuania

1. Developments related to implementation of national biosafety framework

During the reporting period, Lithuania continued to implement its national biosafety framework in line with European Union legislation on genetically modified organisms (GMOs) and new breeding techniques (NBTs).

1. Risk assessment/regulatory decisions:

Lithuania continued to implement GMO risk assessment and regulatory decision-making in line with the European Union legal framework, including Directive 2001/18/EC, Directive 2009/41/EC, Regulation (EC) No 1829/2003, and Regulation (EC) No 1830/2003.

Risk assessments were conducted at European Union level by the European Food Safety Authority (EFSA). Regulatory decisions on GMO authorization continued to be taken within the European Union comitology framework, with Lithuania participating in voting processes. European Union Register of authorized genetically modified food and feed – covers GMO authorizations under Regulation (EC) No 1829/2003 and Directive 2001/18/EC (including products authorized or withdrawn). Available here:

<https://ec.europa.eu/food/food-feed-portal/screen/gmo/search>

https://food.ec.europa.eu/plants/genetically-modified-organisms/gmo-register_en

During the reporting period, a total of 14 new notifications were submitted for the contained use of genetically modified microorganisms (7 notifications for class 2 and 2 notifications for class 1), along with 5 new notifications concerning genetically modified organisms at level 1.

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

No new regulations since the previous Tour de Table.

3. Public engagement and outreach activities:

Information and data on GMO's legislation, notification/permitting and various guidelines are made available on the Genetically Modified Organisms Database website of the Ministry of the Environment of the Republic of Lithuania via link: <https://gmo.biip.lt/>.

2. Updates regarding international activities

Lithuania is a party to the Convention of Biological Diversity and a party to the Cartagena Protocol. During the reporting period Lithuania took part in 27SBSTTA in Panama City, Panama, Thirteenth meeting of Informal Advisory Committee on the Biosafety Clearing-House,

3. Developments related to new breeding techniques (NBTs)

As a Member State of the European Union, Lithuania's legislation on NBTs aligns with the EU regulations. Please refer to the reply from the European Commission for more details.

During the reporting period, neither cultivation of GM crops produced by new genomic techniques nor deliberate release of GMOs produced by NBTs for field trials in Lithuania.

Netherlands

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

Notifications for commercialization

- No updates for the reporting period.

Notifications for field trials and clinical trials in the Netherlands

The Dutch authorities received several new applications for deliberate release into the environment under directive 2001/18/EC partB. General information about genetically modified organisms that have been approved in the Netherlands for deliberate release into the environment is made available from the website of the Ministry for the Environment / GMO Office (<http://www.ggo-vergunningverlening.nl>).

Over the last period Netherlands issued 19 new permits and 11 amendments on existing permits for clinical or veterinary trials. The majority of those permits concern clinical trials with adeno-associated virus (AAV) or human cells genetically modified by means of retroviral or lentiviral vectors (e.g. CAR-T). One trial worth mentioning in particular is a clinical study on the implementation of a controlled human infection model for Influenza A to test vaccines and antiviral therapies using a genetically modified infectious Influenza virus [Dossier IM-MV 24-004_001 public](#) (mostly in Dutch, only partly in English).

During this reporting period the Dutch authorities authorized a small scale field trial with genetically modified potatoes with resistance or tolerance against *Phytophthora* (potato late blight). This is the first authorised a field trial in the Netherlands in years. Although some lines concern NGT potatoes and the field trial as a whole still requires a permit under the current national GMO Decree and existing EU regulations.

2. Updates regarding international activities

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

Interpretation of the GMO definition in the EU

In the written contribution of last year we mentioned the report commissioned by the Dutch ministry for Infrastructure and Water management on the interpretation of the GMO definition in EU Member States. This report provides an inventory of the different experiences within European member states with the definition of a genetically modified organism (GMO).

As a follow-up Dutch national experts, jointly with national experts from some other Member States, started discussions with the aim to address some key elements of the GMO definition and how these key elements can be assessed in a structured approach while considering how to interpret the GMO definition in specific

cases of biotechnological applications. The aim of the activity is to develop common guidance material for Member States that reflects the interpretation by the national competent authorities responsible for the application and execution of the GMO framework. It is therefore expected that this document will contribute to increase transparency and predictability for stakeholders (amongst others developers of biotechnological products) regarding the scope of the GMO definition across the EU. This activity is ongoing.

Proposal European Biotech Act

On 16 December 2025, the European Commission (EC) presented the Biotech Act part I proposal. The proposal proposes a comprehensive framework to increase competitiveness by creating the necessary conditions for the health biotechnology sector to thrive and to strengthen and streamline the regulatory environment in areas such as clinical trials and cell and gene therapies and the placing on the market of certain genetically modified micro-organisms. As this proposal will effect the Dutch national GMO framework as well, The Netherlands is actively involved at the European level concerning this proposal. More details on this proposal may be available in the written contribution of the European Union. The proposal itself is also available online [Biotech Act proposal - European Commission](#)

3. Developments related to new breeding techniques (NBTs)

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

For details see our contribution to the NBT project and questionnaire.

4. Additional Information

Since the 39th meeting of WPHROB a number of reports were published that were commissioned by the Dutch Ministry of Infrastructure and Water Management or the Dutch scientific advisory committee COGEM. These reports are listed below, including a summary and link to the corresponding report.

Research Report ‘Can new gene therapies result in unintended germline modification? Unveiling the frontiers: current insights and limits of testing’

The Central Committee on Research Involving Human Subjects (CCMO) and the Netherlands Commission on Genetic Modification (COGEM) commissioned a study into the risk of unintended germline modification, with a particular focus on new forms of gene therapy. The study was conducted by Sciensano and Perseus BV.

Germline modification involves changes to germ cells, which can lead to (adverse) consequences for offspring. Modifying germ cells is not permitted. Therefore, it is of great importance to know whether unintended germline modification can occur as a “side effect” of gene therapy, and what consequences this could have for treated individuals who wish to have children in the future.

The report discusses the various forms of gene therapy currently under development and provides an update on the available data regarding the distribution of gene therapy throughout the body (biodistribution) and the likelihood that unintended germline modification may occur. It also lists the relevant gene therapy guidelines from, among others, the FDA and the EMA.

The main conclusions of the report are that the occurrence of unintended germline modification has very rarely been the subject of research in the past. However, the limited available information does not indicate

that gene therapy leads to changes in germ cells and that the genetic modifications are passed on to offspring.

The report is available online: [Research Report Can new gene therapies result in unintended germline modification?](#)

Research report Grey areas in the regulation of green and red biotechnology. Towards robust legislation for rapid technological change

The Netherlands Commission on Genetic Modification (COGEM) commissioned earlier concerning the grey areas in the regulation of green a study The English translation of the COGEM report on 'grey areas' in the regulation of green and red biotechnology (CGM/2025-01) is now available. The report provides building blocks for more resilient legislation in the field of GMOs.

COGEM is of the opinion that the research report 'Grey areas in the regulation of green and red biotechnology' offers valuable input on several points for government policy in the field of biotechnology. The table with an overview of building blocks with advantages and disadvantages in the development of new regulations for specific issues at hand can help to make a more balanced choice for a particular type of regulation.

In response to the report, COGEM notes that regulation of GMOs primarily takes place at EU level, so that new EU regulations should be developed in a resilient manner in order to overcome the problem of regulations constantly lagging behind technological developments. This will ensure that new legislation can better and longer keep pace with future innovations.

The report is available online: [Research report on robust legislation for grey areas](#)

Research report 'Introgression from cultivated plants into their wild relatives'

The outcrossing of genetically modified (GM) plants to wild relatives (introgression), and the subsequent spread of transgenes in nature, are key elements in the environmental risk assessment of experiments involving GM plants and crops. The National Institute for Sustainable Development (IRD) in Montpellier conducted a literature review on behalf of COGEM to gain insight into whether introgression between cultivated plants and wild relatives occurs, how it can be detected, the factors that contribute to it, the scale of its occurrence and its potential impact on wild populations.

The report is available online: [Research report Introgression from cultivated plants into their wild relatives](#)

Research report Biological entity – A legal, philosophical and biological analysis

This report is commissioned by the Ministry of Infrastructure and Water Management and concerns a study into the definition of the concept of 'biological entity', which is part of the legal definition of a genetically modified organism. For ensuring the environmental safety of products of modern biotechnology, it is important to gain an understanding of what can be understood by a biological entity, in order to determine whether applications involving biotechnological uses fall under the regulations for genetically modified organisms.

The report is available online: [Biological Entity - A Legal, Philosophical and Biological Analysis](#)

New Zealand

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

The New Zealand Environmental Protection Authority (Te Mana Rauhi Taiao) is Aotearoa New Zealand's government agency that regulates the assessment and approval of 'new organisms' that also includes any organism that has been genetically modified' under the Hazardous Substances and New Organisms Act 1996 (HSNO).

- i. The EPA has decided that a non-viral gene editing investigational drug does not meet the definition of an organism and therefore is not a new organism under the HSNO Act 1996. To determine if the gene therapy TSRA-196 and similar treatments that use reverse transcriptase to prime genetic repair in somatic cells are new organisms for the purpose of the Hazardous Substances and New Organisms Act 1996. More information can be found at the following link <https://www.epa.govt.nz/database-search/hsno-application-register/view/APP205031/>
- ii. The EPA has approved an application to develop in containment genetically modified invertebrates for research and teaching, that will be used to investigate 'gene drive' and other approaches in containment for the potential biocontrol of several invertebrate species. More information can be found at the following link <https://www.epa.govt.nz/database-search/hsno-application-register/view/APP204994/>
- iii. Numerous approvals for either the importation or development of GMOs in containment. More information can be found at the EPA link. <https://www.epa.govt.nz/database-search/hsno-application-register/>

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

Regulatory Framework

The New Zealand Environmental Protection Authority (Te Mana Rauhi Taiao) is Aotearoa New Zealand's national environmental regulator. Our work is about protecting the environment to enhance a safe and sustainable way of life, and future, for all New Zealanders. We regulate human activities that impact the environment and people of Aotearoa New Zealand.

We are a Crown Agent under the Crown entities Act 2004 and established under the Environmental Protection Authority Act 2011 that sets out our role, and we have specific functions under certain environmental Acts.

One of the legislative functions of the EPA is as the government agency that regulates the assessment and approval of new organisms. This includes the regulation of any organism new to Aotearoa New Zealand and any organism that has been genetically modified as defined under the Hazardous Substances and New Organisms Act 1996 (HSNO) and associated regulations.

As noted in last year's summary, the Aotearoa New Zealand regulatory framework for the regulation of genetically modified organisms is undergoing change. The current government announced the modernisation of New Zealand's gene technology laws in August 2024.

[New Zealand to benefit from end to gene tech ban | Beehive.govt.nz](#)

The new legislation will be based upon Australia's Gene Technology Act 2000 and modified to work in a New Zealand context with a regulator to be established to manage potential risks to human health and the environment.

The Gene Technology Bill has passed the first reading in Parliament and further information on the legislative process and the timeline for the bill becoming law can be found at the following links.

[Gene technology regulation | Ministry of Business, Innovation & Employment](#)

[Gene Technology Bill](#)

He Whetū Mārama the Mātauranga Framework

At the EPA we recognise the unique relationship of Māori with the environment in Aotearoa New Zealand, their place as tāngata whenua – the people of the land – and the important role they play in New Zealand's economic, environmental, social, and cultural wellbeing. As land managers, owners, guardians, and governors of significant natural resources, Māori can contribute a range of knowledge, skills and experience invaluable to environmental decision-making.

More information can be found at the following links.

[Engaging with Māori | EPA](#)

[Our annual reports | EPA](#)

5. Public engagement and outreach activities

Since 2020, the EPA has funded 200 groups in its Wai Tuwhera o te Taiao – Open Waters Aotearoa science programme, which helps local groups, iwi and hapū collect environmental DNA (eDNA) samples to learn more about their waterways.

More information can be found at the following links

[Wai Tuwhera o te Taiao – Open Waters Aotearoa | EPA](#)

[Our annual reports | EPA](#)

2. Updates regarding international activities

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

The Life Sciences Summit (March 2026 – Wellington, New Zealand); 17th symposium of the International Society for Biosafety Research, Ghent (November 2025 – Ghent, Belgium).

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>

Philippines

1. Developments related to implementation of the National Biosafety Framework

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

- a. Reviewed and enhanced the risk assessment instrument used in the evaluation of the safety of GM applications for plants under the Joint Department Circular No. 1, Series of 2021 of the Department of Science and Technology (DOST), Department of Agriculture (DA), Department of Environment and Natural Resources (DENR), Department of Health (DOH), and Department of the Interior and Local Government (DILG);
- b. Initial preparation for the conduct of Regulatory Impact Assessment for the draft guidelines on GM animals;
- c. Development of guidelines for the joint conduct of field trials of GM plants with insect resistance traits by the Bureau of Plant Industry and Fertilizer and Pesticide Authority; and
- d. Development of Insect Resistance Management Guidelines for Bt corn with traits targeting Fall Army Worm.

2. Risk assessment/regulatory decisions

The following transformation events were applied under the new biosafety regulations and issued with corresponding biosafety permits:

Transformation event	Type of Use	Trait
1. Soybean MON94313	For direct use	Herbicide Tolerant
2. Corn MON94804	For direct use	Short Stature

Regulatory decisions are uploaded to the BPI Biotech Website: <http://biotech.buplant.da.gov.ph>

3. Risk management measures

- a. The BPI issued the following measures as indicated in the permit issued:
 1. For food and feed, or for processing:
 - i. The regulated article shall be imported solely and exclusively for direct use as food and feed or for processing and not to be used for field trial or commercial propagation
 - ii. In the case of imported regulated articles, importers are required to present GMO declarations to ensure that only approved transformation events will enter the country

- iii. In the case of accidental release (e.g., road spillage) of seeds not approved for commercial propagation, the permit holder shall assist the importers in the management of spillage and report to BPI immediately
- iv. The permit holder shall provide reference materials (positive and negative controls) of the regulated article

2. For field trial:

- i. Implementation of temporal or isolation distance
- ii. Ensuring the security of the experimental area (only authorized persons can access the site, free from stray animals, birds, rodents, etc.)
- iii. Disposal of regulated planting materials after harvest
- iv. Monitoring of volunteer plants (fallow period monitoring)
- v. Implementation of contingency measures when necessary

3. For commercial propagation:

- i. Prohibition of planting GM crops in areas that are not identified as agricultural lands and in areas with known ordinances prohibiting the propagation of GM crops
- ii. Indicating in the seed bag label that the product is not intended for propagation in prohibited areas

B. Emerging policy and regulatory considerations in Agricultural Biotechnology

- 1. Public acceptance and perception gap on GMOs;
- 2. Legal uncertainty due to ongoing Writ of Kalikasan proceedings;
- 3. Laboratory and inspection capacity constraints at ports of entry for testing imported GM commodities;
- 4. Intellectual property considerations and access to technology;
- 5. Preparedness for emerging biotechnology applications (i.e., synthetic biology, gene drives); and
- 6. Capacity building program for regulators.

C. Public Engagement from March 2025 to February 2026

- 1. 2025 National Biotechnology Week: A Celebration of Education, Innovation, and Commercialization (October 2025);
- 2. Series of seminars and webinars on agricultural biotechnology (Biotech advocacy and outreach) (Jan – Dec 2025);
- 3. Stakeholder consultations conducted to strengthen science-based local decision-making on agricultural biotechnology; and
- 4. Series of public consultations on the proposed Joint Department Circular (JDC) regarding Genetically Modified (GM) animals (2023).

2. Updates regarding international activities

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

- a. Hosted the ASEAN Genetically Modified Food Testing Network Meeting (June 23-27, 2025)

2. Bi-/multilateral cooperation with other authorities/organizations (e.g., capacity building, outreach activities, policy advocacy)

- a. Asia-Pacific Economic Cooperation (APEC) High Level Policy Dialogue on Agricultural Biotechnology (HLPDAB) - continued representation in APEC High Level Policy Dialogue on Agricultural Biotechnology discussions on regulatory approaches and trade-related cooperation in agricultural biotechnology;
- b. ASEAN Genetically Modified Food Testing Network (ASEAN GMFNet) Sustained engagement in ASEAN Genetically Modified Food Testing Network activities to strengthen regional collaboration on laboratory testing, regulatory coordination, and food safety oversight related to biotechnology products;

3. Specific cases of use of OECD tools and information (e.g., Consensus Documents, other guidance materials, BioTrack product database, etc)

The assessors referred to OECD consensus documents during the assessment of GM applications.

3. Developments related to New Breeding Techniques (NBTs)

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

Ongoing development of guidelines for the evaluation of the regulatory status of gene-edited animals, following the completion of the comprehensive review of gene editing in animals and its scientific, regulatory, ethical, and socio-economic implications to support policy development, which was submitted to the National Committee on Biosafety of the Philippines

2. Specific cases of application, assessment, and decision

DA-BPI received requests for the technical determination of whether the following PBI products will be covered by GMO regulations in the Philippines:

1. Panama disease (TR4)- resistant Bananas: TRB041001, TRB041002, TRB041003, TRB041005, and TRB041006
2. Panama disease (TR4)- resistant Bananas: TRB041007 and TRB041008

Certificates of Non-Coverage have been issued to the products above.

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. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

In 2025, the Ministry of the Environment of the Slovak Republic extended the approval for a two-year period for the testing of the genetically modified vaccine FluBHPVE6E7. The GMO FluBHPVE6E7 is derived from an influenza B virus (parental virus) and has been modified on several levels to be used effectively as a viral vector to eliminate human papillomavirus (HPV) infected cells and cancers induced by HPV by inducing a HPV E6 and E7 antigen-specific cellular immune response. No plasmid vector sequences are present in the genome of FluBHPVE6E7.

The intended outcome of the genetic modification is to activate an immune response against cells infected with HPV and against tumour cells.

Most activities were carried out under contained use conditions in accordance with Directive 2009/41/EC on the contained use of genetically modified microorganisms. During the current reporting period (March 2025 – March 2026), 39 notifications were submitted, of which six were classified as Class 2 and the remainder as Class 1. Two laboratories are classified at Biosafety Level 3 (BSL-3), while the remaining laboratories are classified at Biosafety Level 2 (BSL-2) and Biosafety Level 1 (BSL-1).

3. Risk management measures

General rules regarding the coexistence of genetically modified crops with conventional and organic farming are established by Act No. 184/2006. The implementing Decree No. 69/2007 specifies minimum isolation distances when cultivating genetically modified corn, rapeseed, sugar beet, and potatoes. These distances apply to the separation between genetically modified crops and non-modified plants of the same botanical species grown by conventional or organic methods. The decree also sets minimum requirements for buffer zones. Additionally, non-modified plants of the same botanical species cannot be cultivated on the same plot for at least two years, and the area surrounding the cultivation site must be monitored for two years after the harvest of the genetically modified crops.

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

Synthetic biology – risk assessment of products under the EU rules valid for GMMs.

2. Updates regarding international activities

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

In 2025, we participated in mandatory meetings.

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>

United Kingdom

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

New Deliberate Release Applications

The Department for Environment Food and Rural Affairs (Defra) is the competent authority for deliberate release of GMOs to the environment in England. Defra has received the following applications since March 2025.

[25/R50/01:](#)

A clinical study by the University of Southampton of a genetically modified *Neisseria lactamica*. The *N. lactamica* has been modified to express Factor H binding protein and *Neisseria* adhesion A. The aim of the experiment is to increase the degree to which *N. lactamica* “looks like” *Neisseria meningitidis* to the immune system, as a potential method for future vaccine development.

No public representations were received for this trial.

Granted consent: 23rd September 2025

[25/R58/01:](#)

A veterinary vaccine trial by Defra and the Animal and Plant Health Agency (APHA) of a high pathogenicity avian influenza vaccine. The vaccine consists of a Herpesvirus of Turkeys backbone which expresses both the VP2 gene of the Infectious Bursal Disease Virus and a synthetic haemagglutinin A gene based on a consensus of highly pathogenic avian influenza virus H5N1 strains.

No public representations were received for this trial.

Granted consent: 17th February 2026

Variations to previous Deliberate Release Applications

[24/R57/01:](#)

Consent held by the University of Oxford to release a genetically modified wheat var. Fielder. The trial aims to examine agronomic performance of wheat that has been gene edited with respect to chloroplast-associated protein degradation (CHLORAD); parts of the transformation construct remained in some of the plant lines.

Variation requested to extend the release period by 3 years.

Variation granted: 10th November 2025

[22/R55/01:](#)

Consent held by Wild Bioscience Ltd to release GM wheat var. Cadenza, to investigate altered agronomic performance through the expression of plant photosynthetic regulators.

Variation requested to extend the release period, adjust the 4-figure grid references of the release, and increase the maximum distance between the trial plots and pollen barrier.

Variation granted: 14th November 2025

Deliberate release for Marketing purposes

GM/26/01:

Defra have received a deliberate release marketing application for a genetically modified yeast, '[Sourvisiae](#)', from Lallemand. The yeast is a strain of *Saccharomyces cerevisiae* modified to contain a lactate dehydrogenase gene. Sourvisiae is capable of producing lactic acid in addition to alcohol during fermentation, this allows the brewer to ferment and sour the beer in one step.

Defra are currently reviewing the application and will be going out to public consultation once we have completed our assessment.

Medical & Veterinary:

Defra and the Health and Safety Executive (HSE) work with the Medicines & Healthcare products Regulatory Agency (MHRA) to assess marketing applications for Great Britain for medical products/ vaccines containing GMOs. Defra also works with the Veterinary Medicines Directorate (VMD) to assess marketing applications for veterinary medicines. Since the last meeting we have assessed:

- A gene therapy treatment which utilises a recombinant Adeno-Associated Virus vector. Defra/HSE have provided a considered opinion on this and were content with the risk associated with its intended use.
- A medicinal product to treat Leukaemia. Defra/HSE have provided a considered opinion on this and were content with the risk associated with its intended use.
- A veterinary vaccine against Marek's Disease, Infectious Bursal Disease and Newcastle Disease in chickens. Defra have provided a considered opinion on this and were content with the risk associated with its intended use.

Contained Use

The Health and Safety Executive (HSE) received 260 notifications for contained use activities. This consisted of 247 new notifications and 13 significant changes to existing notifications, as outlined below.

Notifier Types	Class 1	Class 2	Class 3	Class 4
Academia (inc. Research Institutes)	2	109	10	1
Commercial	59	65	2	0
Healthcare	3	0	0	0
Government	0	5	3	1
Total	64	179	15	2
Significant changes to existing notifications	0	11	1	1

2. Research projects on biosafety; relevant publications.

Funding has recently been received for a cross-sector One Health regulatory sandbox to address critical gaps in the regulation of engineered bacteriophage (phage) products. This sandbox will coordinate efforts across five regulatory agencies (MHRA, UK Health Security Agency (UKHSA), Food Standards Agency

(FSA), VMD, Defra) to develop harmonised, evidence-based frameworks, tools, and guidance. Using phages as an exemplar, the work will support broader application to engineering biology. Outputs will include regulatory guidance, reference materials, and Safe(r) Innovation Approach (SIA)-like toolboxes tailored to developer needs. This initiative also supports UK Government priorities, including the AMR National Action Plan and PATH-SAFE.

2. Updates regarding international activities

The UK submitted the 5th National Report on the implementation of the Cartagena Protocol on Biosafety in February 2026. In March 2026, the UK submitted the 7th National Report to the Convention of Biological Diversity. The report assesses the UK's progress against 23 national biodiversity targets which are aligned with the 23 targets in the Kunming-Montreal Global Biodiversity Framework (GBF). The report states that the UK is currently on track to achieve Target 17.

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

The UK remains active in attending international fora. UK regulators presented on our regulatory experiences around GM microorganisms at a workshop on the Emerging applications of SynBio Microorganisms and their risk assessment, co-hosted by the Austrian and German governments in Bonn, Bad Godesburg in September 2025. The UK also attended a workshop on viral replicons and self-amplifying RNA vaccines, organised by COGEM (GM regulatory committee advising the Netherlands Government) in Amsterdam in December 2025.

UK regulators presented on the Precision Breeding Regulations 2025 at the 17th International Society for Biosafety Research Symposium in Ghent, Belgium and attended the BVL expert forum on modern molecular methods in Biotechnology in February 2026.

3. Developments related to new breeding techniques (NBTs)

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

Precision Breeding Act Secondary Legislation (Came into force November 2025)

THE GENETIC TECHNOLOGY (PRECISION BREEDING) REGULATIONS 2025 implements the Genetic Technology (Precision Breeding) Act 2023 (the Act) for precision bred plants. The instrument contains the detailed regulations for meeting the requirements provided for in the Act, these include:

- Provisions for notifying the Secretary of State for Defra of the deliberate release of precision bred plants into the environment for non-marketing purposes, such as for field trials.
- The application process for a precision bred assessment and confirmation to enable precision bred plants to be marketed, such as for commercial cultivation.
- Provisions for applying to the Secretary of State, through the Food Standards Agency, for a food and feed marketing authorisation to allow food and feed produced from confirmed precision bred plants to be placed on the market.
- Provisions for two public registers: one of prescribed information associated with the release and marketing of precision bred plants kept by Defra and one of precision bred plants that have been authorised for food and feed marketing authorisations kept by the Food Standards Agency.

2. Specific cases of application, assessment and decision;

Qualifying Higher Plant Notifications

Defra have received 9 notifications for the release of Qualifying Higher Plants (QHP) since the last meeting.

Precision Bred marketing notices

Reference	Project Title
25/Q06	Field assessment of wheat GSK1 knockout lines
25/Q07	Short Vegetative Phase (SVP) cis-regulation in bread wheat
25/Q08	Improving photosynthesis capabilities in Gene-Edited Wheat 2025/10
25/Q09	Short Vegetative Phase (SVP) cis-regulation in bread wheat
25/Q10	Increasing dormancy time in potato tubers
25/Q11	Reducing cold-induced sweetening in potato tubers
25/Q12	Improved flavour of tomato fruit
25/Q13	Strengthening the stem of tomato plants
25/Q14	Increasing sweetness of tomato fruits

Since the Precision Breeding (PB) Regulations came into force Defra has received 5 PB marketing notices. So far one of these has been granted precision bred status by Defra ([Link](#)). The other 4 are still being assessed.

Precision Bred release notices

Defra have received 2 notifications for the release of precision bred plants since the PB Regulations came into force. Any further release notices and marketing notices will be published on the [Precision Breeding Register](#).

Reference	Species & purpose of changes
PBR/26/001	<i>Camelina sativa</i> with increased seed size
PBR/26/002	The group is investigating gynoeceum development in <i>Pisum sativum</i> L. (garden pea) and will test the effect of this line on gynoeceum growth and development in the field.

3. Any other information related to NBTs.

Since the Precision Breeding regulations came into force our guidance (shared last year as drafts) has been finalised, following feedback from stakeholders:

- [ACRE guidance on producing precision bred organisms](#)
- [Submitting a release notice for a precision bred plant](#)
- [Submitting a marketing notices for a precision bred plant](#)
- [Releasing precision bred plants into the environment](#)
- [Technical guidance to applicants for the authorisation of Precision Bred Organisms for food and feed](#)

United States of America

1. Developments related to revision and implementation of national biosafety framework

Updates for the United States Department of Agriculture (USDA)

❖ **USDA Animal and Plant Health Inspection Service's (USDA-APHIS) Biotechnology Regulations in 7 CFR part 340.**

APHIS regulates modified organisms under the 7 CFR part 340 (2019) regulations. Under these regulations, a modified organism is regulated if it meets the definition of a “regulated article”. If an organism does not meet the regulatory definition of “regulated article,” it is not subject to APHIS’ biotechnology regulations (i.e., such organisms do not require a permit or notification prior to introduction). For example, a genome edited organism (e.g., plant, microbe, insect) that is not a plant pest or likely to be a plant pest is not subject to 7 CFR part 340 (2019), unless the organism retains DNA sourced from a plant pest. Similarly, a transgenic organism that is not a plant pest and not likely to be a plant pest, and does not contain DNA sourced from a plant pest is not subject to 7 CFR part 340 (2019). Developers may voluntarily seek a letter confirming that an organism does not meet our definition of a regulated article by submitting an Am I Regulated inquiry.

Weblink for more information on USDA-APHIS biotechnology regulations:

<https://www.aphis.usda.gov/biotechnology/regulations>

❖ **Modified Organisms that are not regulated articles**

If a developer is unsure whether their modified organism meets the definition of a regulated article as described in 7 CFR part 340, they may seek a confirmation of regulatory status of the modified organism from APHIS through an *Am I Regulated* inquiry. APHIS published 69 responses in FY25 and has published 12 responses in FY26 as of responses as of February 2, 2026. Of the responses, 67 were for genome edited products. In FY25, responses took an average of 31 days to complete.

Weblink for information on the Am I Regulated process:

<https://www.aphis.usda.gov/biotechnology/am-i-regulated>

Weblink for table of Am I Regulated inquiries:

<https://www.aphis.usda.gov/biotechnology/regulated-article-inquiry>

❖ **Petitions for non-regulated status.**

Plants that meet the definition of a regulated article may qualify for non-regulated status under the petition process. In the petition process, BRS evaluates interactions between the modified plant and plant pests, potential effects on non-target organisms, changes to weediness, and effects on other organisms which may acquire the modification from the modified plant. BRS may conclude that the

modified plant does not pose greater plant pest risk than the non-modified plant, thereby granting nonregulated status. Currently as of February 2, 2026 there are 3 pending petition reviews: 1) SUNY ESF Blight Tolerant Chestnut, 2) Bayer Stacked 5 Herbicide Resistant Corn, 3) Bayer Insect (coleopteran) Resistant Corn. In FY25, 2 petitions were completed: Ishihara Sangyo Kaisha Blue Orchid and Bayer Insect (lepidopteran) Resistant Corn

Weblink for petition documents:

<https://www.aphis.usda.gov/biotechnology/legacy-petition-process/petitions>

❖ **Previous Exemptions from Regulation**

Prior to Dec 2, 2024, USDA-APHIS biotechnology regulations exempted certain modified plants that (1) are achievable through conventional breeding techniques and thus are unlikely to pose an increased plant pest risk compared to conventionally bred plants, or (2) have a plant-trait-mechanism of action combination that is the same as a plant that USDA-APHIS previously reviewed and determined to be unlikely to pose plant pest risk.

In total, USDA-APHIS issued 99 responses to confirmation request letters, which can be viewed at the link below.

Weblink for table of confirmation letters:

<https://www.aphis.usda.gov/biotech-exemptions/confirmation-letters>

❖ **Regulatory Status Review (RSR)**

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

USDA-APHIS published a total of 84 RSR response letters.

Weblink for table of approved RSRs:

<https://www.aphis.usda.gov/biotech-regulatory-status/regulatory-status-review-table>

❖ **Applications for import, interstate movement, and environmental release**

In Fiscal Year (FY) 2025 (10/1/2024 through 09/30/2025), APHIS received 1023 permit applications for import, interstate movement, and environmental release and acknowledged 44 notifications through eFile, an automated system for submitting requests. Of those, APHIS issued 862 permits. In addition, 0 applications are pending and 161 were withdrawn. During the portion of FY 2026 that has currently elapsed (10/1/2025 through 02/02/2026), APHIS has received 355 authorizations. Of those, APHIS issued 201 permits and acknowledged 11 notifications. In addition, 102 authorizations are pending, and 39 were withdrawn.

❖ **Compliance and oversight**

From October 1, 2024, through September 30, 2025, USDA-APHIS BRS and Plant Protection and Quarantine (PPQ) completed 505 inspections of regulated release locations. The inspections serve to assess compliance to 7 CFR 340 and to meet oversight goals for the regulation of environmental releases involving organisms developed using genetic engineering. USDA-APHIS relies mostly on in-person inspections to assess compliance, though virtual inspections are utilized as an available compliance evaluation tool if weather, for example, precludes an on-site inspection.

❖ **2026 USDA-APHIS Stakeholder Meeting.**

On February 26, 2026, USDA-APHIS held its annual stakeholder meeting. Stakeholder meetings are open to the public to foster engagement and transparency in USDA-APHIS regulatory activities. USDA-APHIS described how it reinstated its regulatory operations after the court vacatur of SECURE regulations in December 2024. USDA-APHIS described its phased implementation of different regulatory processes, revision of Guides and staff reorientation. USDA-APHIS provided updates on its accomplishments and developments on petitions, Am I Regulated letters, permitting, compliance inspections, modified microorganisms, international efforts, and priorities for FY 2026. The agenda, presentation, transcript, and video of the meeting can be found on the USDA-APHIS-BRS websites along with the question and answer in the “News and Announcements” section under “Meetings.”

Weblink for USDA-APHIS-BRS activities:

<https://www.aphis.usda.gov/aphis/ourfocus/biotechnology>

Weblink for USDA-APHIS-BRS news and announcements:

<https://www.aphis.usda.gov/news/program-updates?page=1&search=>

EPA Office of Pesticide Programs (OPP)

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

❖ **Biotechnology Submission Decisions**

- 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 Questionare, EPA has exempted 47 PIPs under this rule; 6 in corn and 41 in citrus.

Office of Pollution Prevention and Toxics (OPPT)

❖ Reviewed Biotechnology Submissions

In the last fiscal year, FY25 (Oct. 1, 2024 to Sept. 30, 2025), the U.S. EPA/OPPT, under the authority of the Toxic Substances Control Act (TSCA), reviewed the closed-system manufacture/import of 10 genetically engineered microbial strains submitted in Microbial Commercial Activity Notices (MCANs). The identity of some of these microorganisms was claimed as confidential. Of the non-confidential microorganisms, many were *Saccharomyces cerevisiae* for production of chemical substances or biofuel. Two genetically engineered strains of *Escherichia coli* were reviewed. These were modified with genetically stable plasmid-borne DNA for production of enzymes or DNA for internal manufacturing. A determination of “not likely to present an unreasonable risk to health or the environment” was made for all these genetically engineered strains.

❖ Microalgae Consensus Document

U.S. EPA/OPPT and Canadian members of the Working Party on Harmonization of Regulatory Oversight in Biotechnology (WP-HROB) continued to work as co-leads on the OECD microalgae consensus document entitled “Consensus Document on Information used in the Assessment of Environmental Applications Involving Photoautotrophic Microalgae for Biomass Production”. Canada first presented the progress on a draft of this document at the 36th WP-HROB Meeting (May 18-20, 2022). A revised document was sent to all delegates in mid-September 2022, and comments received by the end of 2022 from several member countries and the Public Research & Regulation Initiative (PRRI) were addressed by the co-leads in early 2023. The First Full Draft was posted on the O.N.E. site prior to the 37th Meeting of the WP-HROB (April 17-19, 2023). Canada again provided a presentation on the document during the 37th meeting. Comments on this First Full Draft were received by five countries and PRRI. A new revision of the document addressing all the comments was completed in late summer of 2023. Australia then provided comments on this new version. The co-leads worked to address Australia’s comments resulting in the Second Full Draft, that was distributed to delegates for discussion at the 38th WP-HROB Meeting (March 20-22, 2024). Canada again made a presentation at that meeting. Several delegates suggested that the document could be improved by incorporating the concepts and terminology used in the recently declassified OECD Consensus Document on Environmental Considerations for the Release of Transgenic Plants. The WP Chair, several Bureau members, and the Secretariat volunteered to revise the document accordingly. Their revision provided to the co-leads in Dec. 2024 were discussed. At the 39th WP-HROB Meeting (Mar. 24-26, 2025) Canada reported on the progress made, and delegates discussed the next steps. Following the meeting, Canada and the United States met with Bureau members to plan and agree on steps for finalisation. It was then decided that a revised draft will be circulated to the WP-HROB by the end of 2025/early 2026 for final remarks. Pending no adverse comments, the document will be finalised by the ad hoc expert group and forwarded to the Chemicals and Biotechnology Committee (CBC) for declassification by written procedure.

US Food & Drug Administration

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 Recombinetics' 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 (for more information, see the [Risk Assessment Summary](#)).

2. International Activities

Updates for the United States Department of Agriculture (USDA)

1. USDA participated in 8 international meetings in 2025 to discuss technical topics related to the regulation of the products of biotechnology, meeting with regulators, reviewers, students, and scientists from more than 30 countries.
2. USDA hosted meetings with foreign regulators to discuss updates of regulations and confer on technical issues that we have encountered. In 2025, regulators from Japan, South Korea, and Taiwan visited USDA.
3. **Technical Trilateral Working Group (TTWG).** The TTWG is a technical working group for biotechnology among the United States, Canada, and Mexico. The TTWG annual meeting was held on September 24, 2025. The TTWG also conducts quarterly calls throughout the year.

3. Developments in New Breeding Techniques (NBT)

Updates for the United States Department of Agriculture

Not subject to regulations under 7 CFR 340 (2019)

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

Since the re-initiation of the AIR process in 2025 until February 2, 2026, APHIS has confirmed that 67 genome edited organisms are not regulated out of 81 responses.

Weblink for table of Am I Regulated inquiries:

<https://www.aphis.usda.gov/biotechnology/regulated-article-inquiry>

Exemptions under 7 CFR 340 (2020)

Prior to December 2, 2024 USDA-APHIS biotechnology regulations exempted certain modified plants that (1) are achievable through conventional breeding techniques and thus are unlikely to pose an increased plant pest risk compared to conventionally bred plants, or (2) have a plant-trait-mechanism of action combination that is the same as a plant that USDA-APHIS previously reviewed and determined to be unlikely to pose plant pest risk.

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

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

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

(b)(3): A gene known to occur in the plant’s gene pool, or a change in a targeted sequence to correspond to a known allele of such a gene or to a known structural variation present in the gene pool

(AM1): An indel or contiguous deletion of any size, made at a targeted location, with or without insertion of DNA if generated without using a repair template, or without insertion of DNA if generated using a repair template

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

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

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

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

Weblink for guidance for requesting a confirmation or exemption from regulation under 7 CFR part 340:

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

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

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

Weblink for table of approved RSRs:

<https://www.aphis.usda.gov/biotech-regulatory-status/regulatory-status-review-table>

European Union

OECD 38th Meeting of the WG on the Harmonisation of Regulatory Oversight in Biotechnology

22-24 April 2026

Written contribution of the European Commission

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

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)
 - i. 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](#)

ii. 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 8GM food and feed and has renewed 7 authorisations.

New authorisations:

- Maize [MON 95275](#)
- Maize [DP910521](#)
- Maize [MON 94804](#)
- Soybean [MON 87705 × MON 87708 × MON 89788](#)
- Maize [DP51291](#)
- Maize [DAS1131](#)
- Sugar beet [KWS20-1](#)

Soybean [DBN-09004-6](#)

Renewals:

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

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

Legislative developments:

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

For information related to the new Regulation on plants produced by certain new genomic techniques (NGTs) and their products, see section 3.1 of the current document.

On 16 December 2025, the European Commission adopted a proposal for a [Directive amending Directives 2001/18/EC and 2010/53/EU as regards the placing on the market of genetically modified micro-organisms and the processing of organs](#). The proposal is part of a package of proposals for a Biotech Act to strengthen the competitiveness of the health and other biotechnology sectors.

The amendments to Directive 2001/18/EC are consistent with the overall objectives of that Directive, namely, to ensure a high level of protection of human health and the environment in the deliberate release and placing on the market of GMOs and to ensure the effective functioning of the EU internal market. The adjustments proposed have the aim of creating a tailored, more efficient and streamlined regulatory framework for GMMs. They relate to the information requirements for the risk assessment of GMMs as or in products, to the validity of the consent granted for their placing on the market, and to detection methods applicable to all GMMs. In addition, the concept of low-risk GMMs is introduced, including scientific criteria confirming this status, to define certain GMMs that would be eligible for a more streamlined authorisation procedure and for which post-market environmental monitoring can be waived if justified on a case-by-case basis. These measures to be introduced reflect recent scientific assessments by European scientific and technical bodies and are in line with scientific and technical progress after the adoption of Directive 2001/18/EC.

To become law, the Directive must be adopted by the Member States in the Council of the European Union and by the European Parliament, following the ordinary legislative procedure. Afterwards, Member States will need to transpose the Directive into national law. The legislative procedure is on-going. In the meantime, products containing or consisting of GMMs continue to be regulated under Directive 2001/18/EC.

In addition and as part of the [Food and Feed Safety Simplification Package](#), the European Commission has proposed an amendment to Regulation (EC) No 1829/2003 clarifying that fermentation products obtained using genetically modified micro-organisms but in which the genetically modified micro-organisms are not present in the final product are not in the scope of this Regulation.

Developments in the European Food Safety Authority:

Since the previous meeting, EFSA has adopted a guidance on [Risk assessment considerations for RNAi-based genetically modified plants](#) and a cross cutting [Guidance on the characterisation of microorganisms in support of the risk assessment of products used in the food chain](#), the latter provides a unique guidance for assessment of microorganisms including genetically modified microorganisms used in the food chain.

All EFSA guidance documents applicable to GMOs can be accessed online: <https://www.efsa.europa.eu/en/applications/gmo#getting-started>. EFSA has invested in a new landing page to help applicants on how to prepare and submit a dossier for scientific assessment: <https://www.efsa.europa.eu/en/applications/gmo#getting-started>.

EFSA has recently published a [Catalogue of EFSA Guidance Documents](#). The Catalogue is a comprehensive resource, allowing users to retrieve all EFSA guidance documents. It contains guidance documents that are currently valid, those being phased out (valid only for applications submitted before a certain date), as well as documents that are now considered obsolete.

EFSA has recently published a scientific statement regarding the assessment of GM plants containing stacked transformation events obtained by conventional crossing¹ of genetically modified plants with one or several transformation event(s).

EFSA is also working on updating and maintenance of the preDQ – software tool for peptide binding prediction to HLA-DQ2 and HLA-DQ8 (EFSA-Q-2025-00296 in progress).

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

EFSA is supporting the EC for the assessment on Post Market Environmental Monitoring reports on MON 810 cultivation: For 2023 ([EFSA-Q-2025-00152](#)) for 2024 (EFSA-Q-2026-00114 in progress).

EFSA is supporting the EC on post-market monitoring reports of GM oilseed rape 73496 for 2024 ([EFSA-Q-2025-00197](#)) and for 2025 (EFSA-Q-2026-00143 in progress).

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

5. Public engagement and outreach activities

EFSA public outreach:

EFSA is in close contact with its industry stakeholders in the GMO area. In 2025 EFSA organised two Stakeholder's meetings: [19th March](#) (online) and [30-31st October](#) (in presence). The meetings address scientific topics and risk assessment approaches not individual applications for premarket authorization. An [Ad hoc meeting with EFSA's stakeholders following the public consultation on the draft opinion on protein safety](#) in GMOs was organized the 4th of June 20.

The GMO EFSA scientific network terms of reference include sharing best practices in GMO/GM food & feed risk assessment expertise and experiences. The network met twice in 2025, [5- 6th June](#) and [24 November](#).

European Commission public outreach:

Each Scientific opinion on GM food and feed mentioned under point 1.1.i. is followed by a one-month public consultation. The results of the consultations are available here: https://ec.europa.eu/food/plant/gmo/public_consultations_en

6. Research projects on biosafety; relevant publications

¹ Available at <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2026.10177>

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

2. Updates regarding international activities

1. Participation in/hosting international symposia/fora relating to biosafety
2. Bi-/multi-lateral cooperation with other authorities/organisations (e.g. capacity building, outreach activities)
3. Specific cases of use of OECD tools and information (e.g. Consensus Documents, other guidance materials, BioTrack Product Database...)

3. Developments related to new breeding techniques (NBTs)

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

Shortly after the 38th Meeting of the WG on the Harmonisation of Regulatory Oversight in Biotechnology, new EU rules for plants obtained by certain new genomic techniques were adopted in June 2026: [Regulation \(EU\) 2026/1388](#) on plants obtained by certain new genomic techniques and their products. They will apply to plants obtained by targeted mutagenesis and cisgenesis and their food and feed. The new rules will apply from 17 July 2028.

The legislation establishes two categories of NGT plants:

Category 1: Plants that are comparable to natural or conventionally bred plants require verification and are not subject to the requirements of the GMO legislation.

Category 2: Plants with more complex modifications and plants altered to be tolerant to herbicides or to produce known insecticidal substances remain subject to the requirements of the GMO legislation, with certain adaptations to risk assessment and other requirements.

The legislation also contains specific provisions to steer the development of NGT plants in support of sustainability goals; provisions to ensure transparency about NGT plants; and rules on licensing, transparency and guidance on patents and assessment of their impact on the EU market.

2. Specific cases of application, assessment and decision
3. Research projects on biosafety of NBT products; relevant publications

At the request of the European Commission, EFSA performs a regular horizon scanning to assess new scientific data on plants, animals, microorganisms and products thereof obtained by new genomic techniques. The [first report](#) covering new scientific data on plants and their products obtained by new genomic techniques (January 2022 to May 2025) was followed by a [second report](#) covering new scientific data on plants, microorganisms and animals, and their products obtained by new genomic techniques (October 2025). Further reports will follow.

4. Any other information related to NBTs

For ongoing mandates and research projects related to NBTs, please see our contribution to the questionnaire “Enhanced Information Exchange on New Breeding Techniques (NBTs)”

4. Additional Information

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 methods². 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,

² <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 600³.

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.

³ 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

Workshop on Non-target Organism Testing for Environmental Risk Assessment

AFSI, in cooperation with the Donald Danforth Plant Science Center, St. Louis, Missouri, USA, Corteva Agriscience™, and Bayer Crop Science, organized a 5-day technical training workshop titled [Environmental Risk Assessment Workshop: Non-Target Organism Testing](#) on June 23-27, 2025. This capacity building workshop provided regulatory scientists and environmental risk assessors with an experiential learning opportunity in laboratory and field testing of non-target organisms (NTOs). 16 participants from eight countries attended the workshop: Ghana, India, Mozambique, Nigeria, Namibia, Philippines, South Africa, and Viet Nam. During the five-day technical training program, participants learned about concepts in environmental risk assessment of genetically engineered plants in the context of NTOs including tiered testing, test organisms, laboratory bioassays, field assays, insect resistance management, and data transportability. Through group work, presentations, and facilitated exchanges, they gained an understanding of the limits of NTO testing in environmental risk assessment. Using laboratory facilities provided by the Donald Danforth Plant Science Center, workshop participants had the opportunity to set up bioassays to assess the impacts of insect-resistant corn on corn earworm, the target pest, and on ladybird beetles, a beneficial non-target species. They also had the opportunity to review and critique data generated by commercial laboratories, which are typically provided to government regulators in support of applications to authorize commercial planting of insect-resistant crops, and peer-reviewed publications on NTO studies.

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

Global Environmental Zones Explorer

AFSI’s [Global Environmental Zones \(GEnZ\) Explorer](#) is a simple-to-use online tool that allows users to visualize agroclimatic zonations and their relationships to the locations of Confined Field Trials (CFTs). For any of the 21 included crops, the tool can identify environments at the country, regional, or global level that are important for cultivation to help determine where to best locate CFTs and maximize data utility.

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 biosafety and biotechnology:

- [Genetic Variability in Crops](#): This course discusses genetic variability in crops, providing a basic review of genetics and plant breeding, an overview of modern breeding technologies, and a discussion of how new plant cultivars are released.
- [Environmental Risk Assessment of Non-Target Organisms for GE Crops](#): This course discusses when, why, and how environmental risk assessments for GE crops are informed by testing non-target organisms.

- [Understanding Low Level Presence in Agricultural Biotechnology](#): This course teaches what low level presence is and how associated environmental risks can be assessed.
- [Application of Problem Formulation to the Environmental Risk Assessment of Genetically Engineered Crops](#): This course introduces the key concepts of problem formulation for the environmental risk assessment of genetically engineered crops.
- [Confined Field Trials of Genetically Engineered Plants](#): This course provides a comprehensive discussion of risk management methods for confined field trials of genetically engineered plants and how those methods may be incorporated into a regulatory framework.
- [Genetic Engineering in Livestock Production](#): This course covers advancements in genetic engineering in animals that have been demonstrated in laboratory settings and their application in livestock production. The course provides an overview of conventional livestock breeding as well as presents techniques that can be used to delete or alter existing genes or introduce new genetic sequences into livestock. The course also highlights obstacles in genetic improvement in animals and discusses opportunities for improved production for genetically engineered and gene edited livestock.

Public Research and Regulation Initiative (PRRI)

1. Developments related to biosafety activities

6. Research projects on biosafety; relevant publications

PRRI: Survey among interested PRRI members on approaches of national biosafety advisory bodies and national authorities in identifying scientifically plausible pathways to harm, e.g. use of 'checklist' or 'case by case'.

2. Updates regarding international activities

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

PRRI: Participating in intersessional events and activities leading up to the Seventeenth meeting of the Conference of the Parties to the Convention on Biological Diversity, and the Twelfth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, 19 – 30 October 2026, Yerevan, Armenia. Specific focus in the upcoming COP and MOP on: Target 17 of the Global Biodiversity Framework, Risk Assessment, Synthetic Biology, Public Awareness and Communication.

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

Collaboration in the context of COPs and MOPs with like-minded organisations in a so-called 'Biodiversity Innovation Coalition'.

3. Specific cases of use of OECD tools and information

Several PRRI members regularly use OECD consensus documents as a 'checklist for completeness' in notifications to competent authorities.

3. Developments related to new breeding techniques (NBTs)

4. Any other information related to NBTs

Several PRRI members have in their research projects benefitted from the clarification provided by authorities in some countries as to which gene edited crops fall under the regulatory definitions of GMO/LMO and which gene edited crops do not fall under those definitions.

