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[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)

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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)

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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)

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

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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)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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)

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

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

FOREWORD

The 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 39th WP-HROB meeting (24-26 March 2025). It aims at summarising relevant information on activities related to biosafety issues since the previous meeting (March 2024) at the international level, by collating individual contributions from OECD Members, partner countries and observer organisations participating in the work.

The WP-HROB endorsed this document, which is published under the responsibility of the Chemicals and Biotechnology Committee of the OECD.

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1 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 31/24:

The new resolution extends the public consultations including GM microorganisms and animals. The former normative applied only for plants. All consultations will remain open for a period of 30 days for all GM organisms to be approved.

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.

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.

Events for confined field trials

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

During 2023, 50 authorisations were granted for different crops:

	FIELD TRAILS	PRODUCTION	GREENHOUSE
QUANTITY	39	4	7
CROP			
Wheat			1
Corn	8	2	1
Soy	20	2	1
Tobacco	1		
Beet	1		
Ryegrass	1		
Cameline	1		1
Lettuce	1		
Alfalfa	4		2
Sorghum			1
Sugar cane	2		

During 2024 51 authorisations were granted for different crops:

	FIELD TRAILS	PRODUCTION	GREENHOUSE
QUANTITY	43	4	4
CROP			
Wheat	1		
Corn	15	2	2
Soy	19	2	1
cotton	1		
rice	1		
barley	1		
safflawer	1		
lotus			1
potato	2		
Sugar cane	2		

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
Bovine	Expression in milk of human lysozyme and lactoferrin	INTA	field trials since 2011

Events for Commercial Approvals

Since last Meeting, genetically modified events were approved for commercial release in Argentina in 2024:

Unique Identifier	Applicant	Organism Common Names	Traits	Type of use	Date of approval	Decision name
BCS-GM151-6	BASF Argentina S.A.	Soybean	Tolerance to HPPD-inhibiting herbicides and protection against cyst nematode attack	Cultivation, Food and Feed	04/03/2024	DI-2024-8-APN-SSABDR#MEC
DP2Ø2216-6	CORTEVA SEEDS ARGENTINA S.R.L.	Maize	Higher yield potential and tolerance to ammonium glufosinate	Cultivation, Food and Feed	24/06/24	Disposición 9/2024
DP-2Ø2216-6 x MON-ØØ6Ø3-6 x DAS-4Ø278-9, and their intermediate combinations	CORTEVA SEEDS ARGENTINA S.R.L	Maize	Higher yield potential, tolerance to glyphosate-based herbicides, glufosinate-ammonium herbicides, 2,4-dichlorophenoxyacetic acid (2,4-D) and aryloxyphenoxypropionate-based herbicides	Cultivation, Food and Feed	24/06/24	Disposición 9/2024
DP-91Ø521-2	CORTEVA SEEDS ARGENTINA S.R.L	Maize	Protection against certain lepidopteran insects and tolerance to the herbicide glufosinate ammonium	Cultivation, Food and Feed	09/10/24	DI-2024-25-APN-SSPAYF#MEC
DAS-Ø1131-3	CORTEVA SEEDS ARGENTINA S.R.L	Maize	Protection against certain lepidopteran insects and tolerance to glyphosate	Cultivation, Food and Feed	18/10/24	Disposición 31/2024

Microorganisms

Organism	Product	Identifier	Applicant	Date of approval	Decision name
Mycoplasma hyopneumoniae	Vaccine against Mycoplasma hyopneumoniae and porcine circovirus	Nexhyon Strain	HIPRA ARGENTINA S.A	31/01/24	https://www.argentina.gob.ar/microorganismos-gm-con-autorizacion-comercial#:~:text=Disposici%C3%B3n%202/2024-,31/01/2024,-

					Parvovirus%20canino
Canine parvovirus	Nobivac Puppy DP PLUS Vaccine	Strain 630a	INTERVET ARGENTINA S.A	06/05/24	https://www.argentina.gob.ar/microorganismos-gm-con-autorizacion-comercial#:~:text=APN%2DSSBBEI%23MEC-,06/05/2024,-Herpesvirus%20gen%C3%A9ticamente%20modificado
Genetically modified herpesvirus	Poultry vaccine (Marek's disease, infectious bursal disease and laryngotracheitis)	Vaxxitek HVT-IBD-ILT	Boehringer Ingelheim S.A.	21/11/24	https://www.argentina.gob.ar/microorganismos-gm-con-autorizacion-comercial#:~:text=Disposici%C3%B3n%2037/2024-,21/11/2024,-Virus%20gen%C3%A9ticamente%20modificado
Genetically modified virus cPCV-2b	Porcine circovirus type 2a and type 2b (PCV2) and Mycoplasma hyopneumoniae respiratory disease vaccines	FOSTERA GOLD PCV-MH	ZOETIS ARGENTINA S.R.L	05/12/24	https://www.argentina.gob.ar/microorganismos-gm-con-autorizacion-comercial#:~:text=Disposici%C3%B3n%2039/2024-,05/12/2024,-Virus%20recombinante%20cPCV1
cPCV1-2b recombinant virus	Porcine circovirus type 2a and type 2b vaccine (PCV2)	FOSTERA GOLD PCV	ZOETIS ARGENTINA S.R.L	05/12/24	https://www.argentina.gob.ar/sites/default/files/aviso_317819.pdf
vHVT310 virus	Poultry Vaccine (Marek's Disease, Newcastle Disease and Infectious Bursal Disease)	Vaxxitek HVT + IBD + ND	BOEHRINGER INGELHEIM ANIMAL HEALTH ARGENTINA S.A	06/12/24	https://www.argentina.gob.ar/sites/default/files/aviso_317876.pdf
Herpesvirus of Turkey (HVT)	Poultry vaccine (Marek's diseases, infectious laryngitis and infectious bursa disease (IBD)	Innovax ILT-IBD	Intervet Argentina S.A.	09/12/24	https://www.argentina.gob.ar/sites/default/files/aviso_317954.pdf
HVT-IBD recombinant virus	Poultry vaccine (Marek's diseases and infectious bursitis)	Poulvac Procerta HVT-IBD	ZOETIS ARGENTINA S.R.L	09/12/24	https://www.argentina.gob.ar/sites/default/files/aviso_318014.pdf
HVT-ND recombinant virus	Poultry Vaccine (Marek's and	Poulvac Procerta	ZOETIS ARGENTINA S.R.L	09/12/24	https://www.argentina.gob.ar/sites/default/files/

	Newcastle Diseases)	HVT-ND			aviso_318014.pdf
HVT-IBD-ND recombinant virus	Poultry vaccine (Marek's disease, Newcastle disease and infectious bursal disease)	Poulvac Procerta HVT-IBD-ND	ZOETIS ARGENTINA S.R.L	09/12/24	https://www.argentina.gob.ar/sites/default/files/aviso_318014.pdf
Saccharomyces cerevisiae	Genetically modified yeast for bioethanol production	SCY015 Strain	NOVOZIMES	10/12/24	https://www.argentina.gob.ar/sites/default/files/aviso_317953.pdf
Saccharomyces cerevisiae	Genetically modified yeast for bioethanol production and use of burlanda as livestock feed	GICC03671 (GPY010279)	DANISCO ARGENTINA S.A.	20/12/24	https://www.argentina.gob.ar/sites/default/files/microorganismosgm-aviso_318654.pdf
Saccharomyces cerevisiae	Genetically modified yeast for bioethanol production and use of burlanda as livestock feed	GICC03636 (GPY010240)	DANISCO ARGENTINA S.A.	20/12/24	https://www.argentina.gob.ar/sites/default/files/microorganismosgm-aviso_318654.pdf

New Breeding Techniques

A total of 28 Prior Consultation Instance (PCI) forms were submitted for the period April 2024 - March 2025. Thereof 2 (two) PCI forms were submitted for products in development stage, 18 (eighteen) for real products and the rest is under evaluation.

According to organisms, it can be said that out of the 28 PCI forms recieved, 17 PCI was submitted for a microorganism, 1 for animals and the rest for plants.

CONABIA considered that these products complied with characteristics established in the Policy Approach for NTBs (Resolution No. 21/21) and did not fall within the scope of the Regulatory Framework of Genetically Modified Organisms.

Since 2015 to date, 169 PCIs have been analysed for different organisms (plants, animals, and microorganisms).

Participation in International Activities

2024-25:

Bilateral, regional and multilateral high-level meetings:

a. Meeting GT5 “Public policies in biotechnology” of the Southern Agricultural Council (CAS) held on April 25-26 in Asunción, Paraguay.
b. Like-Minded countries meeting (Like Minded Group) held on August 11 and 12 in Lima, Peru. Argentina was the co-organiser of the event. Argentina participation in the 5th International Workshop on Regulatory Approaches for Agricultural Applications of Animals.

c. Meeting of the Commission for Agricultural Biotechnology of SGT No. 08 of MERCOSUR, under the pro tempore presidency of Paraguay, held on April 24 and 25 in Asunción, Paraguay..
d. Meeting of the Commission for Agricultural Biotechnology of SGT No. 08 of MERCOSUR, under the pro tempore presidency of Uruguay, held on October September 10 and 11 in Montevideo, Uruguay.
e. Argentina participation in the CONVENTION ON BIOLOGICAL DIVERSITY AND CARTAGENA PROTOCOL meetings, held from October 21 to November 3 in Cali, Colombia.
f. 11th meeting of our ARG-EU Bilateral Biotechnology Dialogue held virtually on January 8 of 2025.

Other international activities:

- Virtual Workshop on Microbial Biotechnology for South America, held virtually on June 5 and 6. Argentina co-organizer of the event.
- 5th International Workshop on Regulatory Approaches for Agricultural Applications of Animal Biotechnologies" virtual Workshop, August 19-29.

Communication and education

2024-25:

- Training to Kenyan and Ethiopian regulators on September 29 in Buenos Aires, Argentina.
- Training to Vietnam regulators on December 18 in Buenos Aires, Argentina.
- Training to Guatemala regulators from February 10 to 14 in Buenos Aires, Argentina.
- Argentina presented the "Institutional construction of porcine xenotransplantation in Argentina" at the Permanent Veterinary Committee of the Southern Cone (CVP) on November 5, 2024

2 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 2024

Licences for environmental release (at 26 June 2025):

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 2024, the Regulator has authorised one licence for commercial release and 6 limited and controlled release licences (see Table 1 for details).

Table 1. Licences authorising environmental release of GMOs - since April 2024

Type of GMO	Commercial release approvals	Limited and controlled release approvals
GM plants	None	**GM cotton** – herbicide tolerance and insect resistance (DIR 203) **GM wheat** – increased tolerance to environmental stress (DIR 204) **GM canola** – increased abiotic stress tolerance (DIR 205) **GM sorghum** – altered reproduction from sexual to asexual (DIR 209) **Field trial of GM safflower** – dairy protein production and altered fat composition (DIR 211) **Field trial of GM canola** – increased photosynthesis and photorespiration (DIR 212) Field trial of GM canola – dairy protein production (DIR 215)

GMO therapeutics (human)	None	**Clinical trial** for the treatment of mycobacterial infections using **GM bacteriophages** (DIR 206) **Clinical trial** of **GM vaccinia virus** for the treatment of solid tumours (DIR 208) **Clinical trial** of controlled infection with **seasonal Influenza viruses** (DIR 210) **Clinical trial** of GM human adenovirus for the treatment of melanoma (human CD40L expression) (DIR 213)
GMO therapeutics (veterinary)	**Live attenuated vaccine for dogs** containing canine distemper virus and a **GM canine parvovirus** (Nobivac Puppy DP Plus) (DIR 202)	**Trial** of a **GM vaccine for horses** for the prevention of respiratory disease (replication incompetent attenuated human adenovirus vector expressing Virulence-associated protein A (VapA) from *Rhodococcus equi*) (DIR 214)
GMOs used for large scale protein production	None	None

GMO Register authorisations

In August 2024, **GM canola** (MON-ØØØ73-7, glyphosate tolerance) was placed on the GMO Register, following preparation and consultation on a Risk Assessment & Risk Management Plan – Register 003. This GM canola was authorised for commercial release in 2003 under licence DIR 020. Anyone can now undertake dealings with this GM canola.

1.2. Environmental release – licence applications under assessment

At 19 March 2025, there are currently 2 commercial release applications and 5 limited and controlled release applications under assessment – details in Table 2.

Of note is the current application DIR 207 for **commercial scale release** of a **GM (*Aedes aegypti*) mosquito** for the control of dengue fever transmission. This application has generated considerable public interest and OGTR has published additional information to explain the broader regulatory context for the proposed release, including other regulators and agencies that would be involved. (This is only the second DIR application for a GM animal in Australia. An application (DIR 072) for authorisation of GM GloFish for aquarium use was submitted in 2007 but subsequently withdrawn.)

Table 2. Applications for environmental release of GMOs currently under assessment – at 19 March 2025

Type of GMO	Commercial release licence applications currently under assessment	Limited and controlled release licence applications currently under assessment
GM plants	**GM cotton** – insect resistance & herbicide tolerance (Bollgard® 3 ThryvOn™, XtendFlex® Technology,	

	DIR 216) GM tomato – purple fruit colour (DIR 218)	
GMO therapeutics (human)	Nadofaragene firadenovec (**GM adenovirus** expressing interferon gene) for bladder cancer treatment (DIR 217)	
GMO therapeutics (veterinary)	None	
GM Animals	**GM mosquito** (*Aedes aegypti*) strain to help prevent dengue outbreaks (self-limiting gene to prevent female mosquito larvae surviving to adulthood, red fluorescent marker for identification) (DIR 207)	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 2023-2024 Annual Report.

1.4. Risk assessment guidance documents

Two revised biology documents have been published since April 2024:

- The Biology of Brassica napus L. (canola) and Brassica juncea (L.) Czern. & Coss. (Indian mustard) (July 2024)
- The Biology of Sorghum bicolor (L.) Moench subsp. bicolor (Sorghum) (November 2024)

OGTR Biology documents are modelled on the OECD concept and are available at: https://www.ogtr.gov.au/resources

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. A registration guide was published in March 2025 to assist 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 from the OGTR website: https://www.ogtr.gov.au/about-ogtr/legislative-documents

Gene Technology Act 2000

In September 2024, an Exposure draft Gene Technology Amendment Bill 2024 (just proposed amendments) and a 'consultation paper (which explains the proposed changes) and a 'future law compilation' (how amended Act would appear) were released for public consultation (September - November 2024). A public webinar outlining the proposed changes was also held to provide information to the public and stakeholders. Amendments to the GT Regulations would also be required to support the changes to the GT Act.

The draft Bill would implement recommendations of the Third Review of the National Gene Technology Regulatory Scheme. This legislative reform work is being undertaken by the Department of Health, Disability & Ageing on behalf of the Gene Technology Ministers' Meeting (GTMM, comprised of ministers from all Australian jurisdictions). OGTR continues to provide technical and operational information to assist the Department of Health & Aged Care team leading the implementation of review recommendations.

Key features of the proposed changes include:

- amending key definitions that establish the scope of regulation
- new authorisation categories for an enhanced risk tiering framework
- enabling some technical issues to be dealt with in delegated legislation to provide more flexibility to respond to changes in technology and understanding of risk
- enabling certain technical and procedural matters to be delegated to the Regulator
- introducing additional regulatory powers and offences.

The proposed new authorisation categories include: licences, permits, notifiable dealings and non-notifiable dealings (see Figure 1). 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.

Amendments to the GT Regulations would also be required to support the changes to the GT Act. The next steps involve refining the draft Bill in light of feedback from stakeholders, and agreement of the GTMM before introduction of an Amendment Bill to the Federal Parliament.

Figure 1 Proposed new authorisation pathways

Gene Technology Regulations 2001

In February 2025, the GT Regulations were amended by the Gene Technology Amendment (Minor Measures) Regulations 2025, following public consultation in November-December 2024. The rationale for the changes is provided in the Explanatory Statement. The amendments enable OGTR inspectors to undertake audits of Australia's designated Poliovirus Essential Facility to support international obligations under the Global Action Plan for Poliovirus Containment.

Minor technical amendments were also made to adjust and clarify the exclusions in:

Schedule 1A Techniques that are not gene technology

- schedule 1A item 1 was expanded to specify that transfer of nuclei (whether or not from somatic cells), plastids and mitochondria are not gene technology if they do not involve genetically modified material. This applies to transfer between cells of the same species and of different species.
- schedule 1A item 11 was amended to address a broader set of techniques involving introduction of nucleic acids to an organism. Amended item 11 provides that introduction of nucleic acid or nucleic acid analogue into an organism is not gene technology if all of the following apply:
    - it does not result in an alteration of the organism's genome sequence, and
    - it cannot give rise to an infectious agent, and
    - in the case of introduced DNA, the DNA cannot be transcribed.

  revised Schedule 1A item 11 provides that introducing antisense oligonucleotides to an organism to modulate endogenous gene expression is not gene technology, provided the criteria above are

met.

Schedule 1 Organisms that are not GMOs

- revised Schedule 1 item 10 clarifies that organisms that were modified by gene technology but which only have epigenetic changes remaining are not GMOs.

Following commencement of the amendments OGTR published an updated Overview of the status of organisms modified using gene editing and other new technologies. This overview is to assist regulated organisations to understand which gene editing and RNA interference techniques result in GMOs.

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. An information webinar outlining the proposed changes was made available to stakeholders.

2.3 New application forms and guidance

Since April 2024, the OGTR has published a number of new and revised forms for applicants including:

- application for a licence for importation and processing of bulk grain

OGTR forms are available at: https://www.ogtr.gov.au/resources

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 Additional information on GM mosquito application and GM tomato application

In May 2025, OGTR published additional information for the public on the GM mosquito application DIR 207:

- Infographics outlining the timeline and role of Australian regulators in the assessment of GM mosquito release
- Summary of Application
- General mosquito information – lifecycle, how dengue is spread, current control measure
- Risk assessment considerations

OGTR published additional information for the public on the GM tomato application DIR 218:

- Infographic outlining GM Purple Tomato regulatory remits (May 2025)

4.2 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 operation and requirements of the regulatory scheme. A number of documents have been published on the OGTR website since April 2024, including:

- **Current GMO Register & licence for GM plant commercial releases** – with OECD unique identifiers

- **Genetically modified (GM) crops in Australia** – updated Fact Sheet on the types of GM crops authorised to be grown in Australia **June 2024**.
- **Snapshot of Genetically Modified (GM) Canola in Australia** **June 2024**
- **Community attitudes to gene technology** – latest longitudinal survey report **July 2024**.
- **OGTR Regulatory Culture & Posture** – sets out three principles of regulator best practice performance OGTR follows in undertaking its regulatory functions: continuous improvement and building trust; risk based and data-driven; and collaboration and engagement. **September 2024**.
- **mRNA COVID-19 vaccines are not gene therapies** – statement addressing misinformation **June 2024**.
- **Snapshot of genetically modified (GM) wheat trials** in **August 2024**

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

4.3 Gene Technology Ethics & Community Consultative Committee (GTECCC)

GTECCC provides advice to the Regulator on ethical and community matters. The committee has developed a draft document **Guidance for Communicating on Gene Technology** and sought feedback from stakeholders and the public in October-November 2024. It is anticipated that a finalised document will be published in 2025.

4.4 National Institutional Biosafety Committee (IBC) Forum

The OGTR hosted the 10th National Institutional Biosafety Committee (IBC) Forum in Canberra on 16-18 September 2024 with the theme 'Emerging Technology and Horizon Scanning'. The forum included a workshop on the proposed changes to the legislation from the Third Review of the Scheme. IBC forums provide an opportunity for regulated stakeholders (accredited organisations and IBCs) to engage with the OGTR and share experiences about GMO regulation in Australia.

4.5 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 May 2024 OGTR newsletter included information about revision of certification guidelines and OGTR Portal and smart forms. The November 2024 OGTR newsletter included the call for input to the WP-HROB survey on an OECD unique identifier for animals and highlights from the IBC Forum.

2. Updates regarding international activities

Participation in/hosting international symposia/fora relating to biosafety

The OGTR participated in several international forums and conferences since April 2024, including:

- APEC and Agriculture & Food Systems Institute, Agricultural Biotechnology Seminar Series 2024, May-June 2024
- 5th International Workshop on Regulatory Approaches for Agricultural Applications of Animal Biotechnologies, August 2024
- Association of Biosafety for Australia & New Zealand, 7-8 November 2024
- Life Sciences Summit 2025, Wellington, New Zealand, 18-19 March 2025
- Open ended online experts forum on risk assessment and risk management, Cartagena Protocol, April-May 2025

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.

In February 2025, amendments to the GT Regulations commenced and OGTR updated its guidance for stakeholders – An Overview – status of organisms modified using gene editing and other new technologies. Note that the regulation of GMOs in Australia also includes work undertaken in physical containment. Researchers and developers are encouraged to contact OGTR to clarify regulatory requirements for work involving genome editing.

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.

See Section 2 above regarding other technical amendments made to the Schedules of the GT Regulations.

Food Standards Australia New Zealand and New Breeding Techniques and food

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

FSANZ is continuing work on Proposal *P1055 – Definitions for gene technology and new breeding techniques* to update the definitions in the Code for 'food produced using gene technology' and 'gene technology'. Between July-September 2024, FSANZ undertook a final round of public consultation on proposed changes: to redefine GM food to mean food from an organism (or cells) that contains novel DNA as an outcome of the genetic modification process. This differs from the current process-based definition which is based on the use of gene technology irrespective of the outcome.

The full set of publicly available documents on P1055 are available from the FSANZ website

4. Additional Information

In December 2024, an OGTR officer published a paper on the regulation of genome editing: Thygesen (2024) **Regulation of genome edited organisms in Australia** https://doi.org/10.1007/s11248-024-00411-y

3 Austria

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions:

During the current reporting period (April 2024 – March 2025) 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

6. Research projects on biosafety; relevant publications:

The following reports, scientific papers or other documents addressing issues related to biosafety of different GMOs were published since April 2024:

Eckerstorfer, M.F.; Dolezel, M.; Miklau, M.; Greiter, A.; Heissenberger, A.; Kastenhofer, K.; Schulz, F.; Hagen, K.; Otto, M.; Engelhard, M. Environmental Applications of GM Microorganisms: Tiny Critters Posing Huge Challenges for Risk Assessment and Governance. Int. J. Mol. Sci. 2025, 26, 3174. https://doi.org/10.3390/ijms26073174

Miklau, M.; Burn S.-J.; Eckerstorfer, M.; Dolezel, M.; Greiter, A.; Heissenberger, A.; Hörtenhuber S.; Zollitsch, W.; Hagen, K. Horizon scanning of potential environmental applications of terrestrial animals, fish, algae and microorganisms produced by genetic modification, including the use of new genomic techniques. Frontiers in Genome Editing 2024, https://doi.org/10.3389/fgeed.2024.1376927

Dolezel, M.; Lang, A.; Greiter, A.; Miklau, M.; Eckerstorfer, M.; Heissenberger, A.; Willée, E.; Züghart, W. Challenges for the Post-Market Environmental Monitoring in the European Union Imposed by Novel

Applications of Genetically Modified and Genome-Edited Organisms. *BioTech* 2024, *13*(2), 14; https://doi.org/10.3390/biotech13020014

Dolezel M, Miklau M, Heissenberger A, Otto M (2024). Agronomic and phenotypic plant traits as indicators for environmental risks of genetically modified plants. Environ Sci Eur 36:3. https://doi.org/10.1186/s12302-023-00828-y

Spök, A. (2024) Gesellschaftliche Vorbehalte. In: Hartung, Frank; Krause, Dörthe; Sprink, Thorben; Wilhelm, Ralf (2024) : Anwendungen der Grünen Gentechnik in der Landwirtschaft: Potenziale und Risiken, Studien zum deutschen Innovationssystem, No. 5-2024, Expertenkommission Forschung und Innovation (EFI), Berlin; Anwendungen der Grünen Gentechnik in der Landwirtschaft: Potenziale und Risiken

Frieß, J. L., Giese, B., Verma, P., Reeves, R. G., Gokhale, C. S., Seiberl, M., et al. (2024). GDRA – Gene Drive Risk Assessment. Bundesamt für Naturschutz. BfN-Schriften 711; https://doi.org/10.19217/skr711

Rabitz, F., Giese, B., Kelz, R., Otto, M., Potthast, T., Quilodrán, C. S., et al. (2023). Putting gene drives into context: Risks, depth of intervention, and regulatory challenges. GAIA - Ecological Perspectives for Science and Society 33, 165. https://doi.org/10.14512/gaia.33.1.9

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:

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

Regarding the proposal of the European Commission on a new regulation of NGT plants which is being discussed since July 2023 the government programme states the following:

The Austrian Federal government is working at the European level to ensure that products developed with new genomic techniques (NGTs) undergo a risk assessment and an authorisation procedure and that labelling and traceability are guaranteed, in particular to ensure coexistence (e.g. with organic production).

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.Other national activities:

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

4. Research projects on biosafety of NBT products; relevant publications:

The following reports, scientific papers or other documents addressing issues related to NGTs are available (since April 2024):

Eckerstorfer, M.F.; Dolezel, M.; Miklau, M.; Greiter, A.; Heissenberger, A.; Kastenhofer, K.; Schulz, F.; Hagen, K.; Otto, M.; Engelhard, M. Environmental Applications of GM Microorganisms: Tiny Critters Posing Huge Challenges for Risk Assessment and Governance. Int. J. Mol. Sci. 2025, 26, 3174. https://doi.org/10.3390/ijms26073174

Miklau, M.; Burn S.-J.; Eckerstorfer, M.; Dolezel, M.; Greiter, A.; Heissenberger, A.; Hörtenhuber S.; Zollitsch, W.; Hagen, K. Horizon scanning of potential environmental applications of terrestrial animals, fish, algae and microorganisms produced by genetic modification, including the use of new genomic techniques. Frontiers in Genome Editing 2024, https://doi.org/10.3389/fgeed.2024.1376927

Dolezel, M.; Lang, A.; Greiter, A.; Miklau, M.; Eckerstorfer, M.; Heissenberger, A. (2024). Genome Editing — Neue Anforderungen an das Monitoring von Umweltwirkungen. BfN-Schriften 711, https://doi.org/10.19217/skr711

Dolezel, M.; Lang, A.; Greiter, A.; Miklau, M.; Eckerstorfer, M.; Heissenberger, A.; Willée, E.; Züghart, W. Challenges for the Post-Market Environmental Monitoring in the European Union Imposed by Novel Applications of Genetically Modified and Genome-Edited Organisms. *BioTech* 2024, *13*(2), 14; https://doi.org/10.3390/biotech13020014

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

4 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 at 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). Since the last WP meeting, two new field trials have been handed in.

Field trials (2) notified since March 2024

- Field trial with three CRISPR-Cas9 maize concepts (B/BE/24/V7)
- Field trial with a gene-edited maize with improved yield (B/BE/25/V1)

Notifications for clinical trials

One clinical trial with investigational medicinal products containing or consisting of GMOs has been notified and four 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 (1) notified since March 2024

- Phase 1 Hepatitis B vaccine trial (B/BE/25/BVW2)

Clinical trials (4) approved since March 2024

- Phase 1 Yellow Fever & Rabies candidate vaccine trial (B/BE/23/BVW3)
- Phase 3 Limb Muscular Dystrophy gene therapy trial (B/BE/24/BVW4)
- Phase 3 Hemophilia B gene therapy trial (B/BE/24/BVW5)
- Phase 1 Hepatitis B vaccine trial (B/BE/24/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 and of the COP-16 and associated COP-MOPs.
- Belgium hosted the 1st EFSA meeting of the subgroup on New Genomic Techniques on May 29, 2024.
- Belgium hosted the 17th EFSA Scientific Network on Risk Assessment of Genetically Modified Organisms on May 30-31, 2024.

Announcement: 17th symposium of the International Society for Biosafety Research, exploring the theme of Cultivating Bio-Innovation for a Sustainable Future, Ghent, Belgium, 2-6 November 2025

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. Belgium, presided the Council of the EU during the first semester 2024, but did not succeed in obtaining a qualified majority on the legislative proposal on new genomic techniques (for more information on the initiative, we refer to the following link).

Specific cases of application, assessment and decision

One field trial with gene-edited poplars (generated via CRISPR-Cas technology), authorised in 2024, will continue in the coming years. Since March 2024, two new field trials with maize plants (generated via CRISPR-Cas technology), have been handed in and are under evaluation (for more information see link).

5 Brazil

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

Plant	Trait	Notifier	Technical Decision
Soybean	Nematode resistance and herbicide tolerance	BASF S.A.	8870-2024
Soybean	Herbicide tolerance	BASF S.A.	9317-2024
Maize	Herbicide tolerance	Corteva	8949-2024
Maize	Herbicide tolerance and yield	Corteva	9356-2024
Eucalyptus	Herbicide tolerance, insect resistance and yield	Suzano S.A.	8960-2024
Eucalyptus	Herbicide tolerance, insect resistance and yield	Suzano S.A.	9117-2024

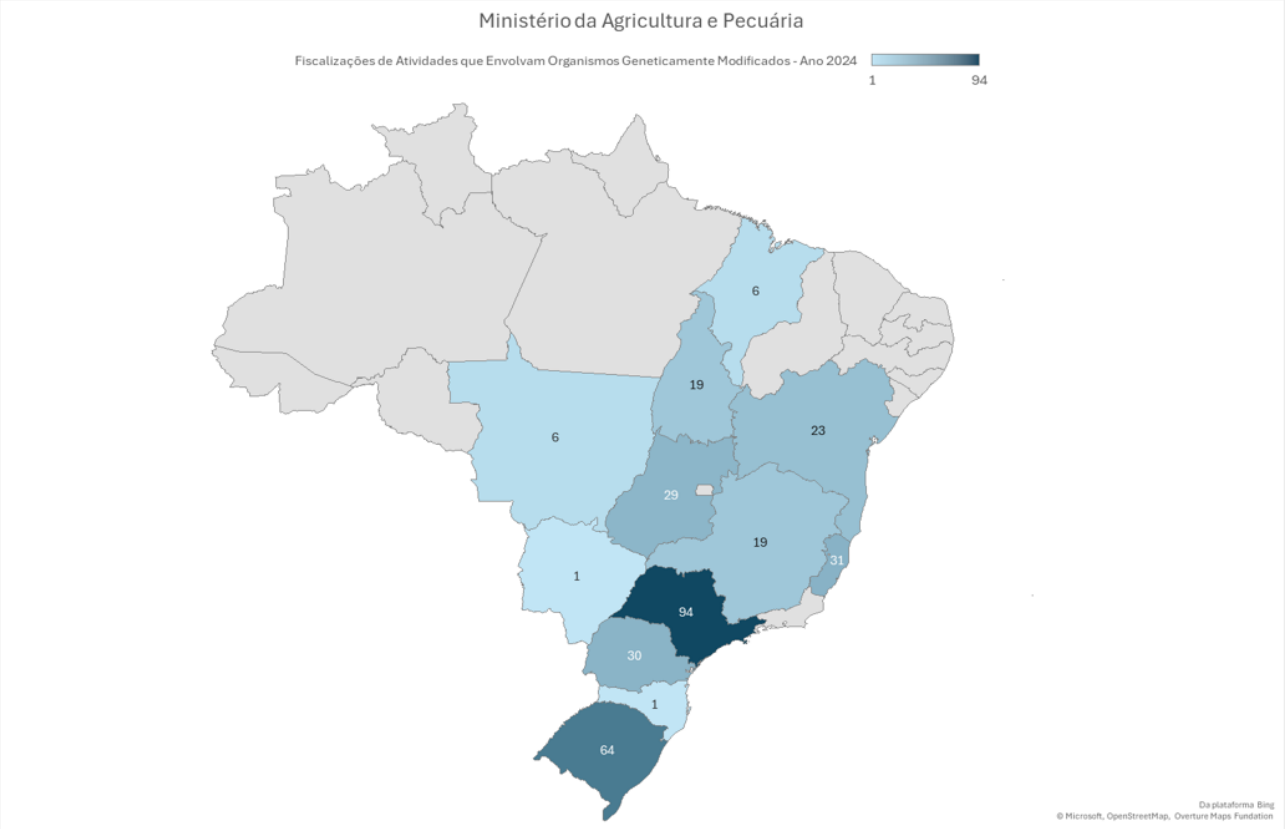
2. Development/review/amendment of national strategies, regulations and guidance

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

3. Risk management measures

Risk management adopting biosafety measures according with CTNBio normative resolutions (http://ctnbio.mctic.gov.br/resolucoes-normativas) are obligatory for field trials. In 2024, the CTNBio approved 72 field trials with different plant species, including maize, soybean, cotton, citrus, sugarcane, eucalyptus etc. The characteristics of the biotech crops includes insect resistance, herbicide tolerance, disease resistance, drought tolerance, increased yield.

The Ministry of Agriculture and Livestock (MAPA) is one of the institutions responsible for inspections in the activities related with GMO use and manipulation to check the compliance with biosafety normative requirements. The MAPA carried out 323 inspections in field trials all over the country in 2024. Furthermore, an additional 47 inspections were conducted in the market to verify compliance with labeling requirements.



2. Updates regarding international activities

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

- The 11th meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP MOP-11)

- Twenty-sixth meeting of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA - 26)

- Meetings of the Comission of the Agricultural Biotechnology (SGT8 - MERCOSUL)

- OECD Working Party on the Harmonisation of Regulatory Oversight in Biotechnology, OECD Meeting of the Working Party for the Safety of Novel Foods and Feeds

3. Specific cases of use of OECD tools and information

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

3. Developments related to new breeding techniques (NBTs)

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

The CTNBio (National Biosafety Technical Commission) Normative Resolution No 16, of January 15th, 2018 (http://ctnbio.mctic.gov.br/resolucoes-normativas) is applicable to all types of organisms and

establishes a consultation system, on a case-by-case basis, for products obtained from Innovative Precision Breeding Techniques (in portuguese, TIMP - “Técnicas Inovadoras de Melhoramento de Precisão”) defined as a set of new methodologies and approaches that differ from the genetic engineering strategy by transgenics, as they result in the absence of recombinant DNA/RNA in the final product.

2. Specific cases of application, assessment and decision

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

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

4. Additional Information

- Platform for gene editing patents:

https://app.powerbi.com/view?r=eyJrIjoiZDJjMzlmZTUtMTEwNC00OGIxLWEzZTctNTdkZWE2OWUwZTI3IiwidCI6IjU4MTVmODA4LTYwOTEtNDdiZC1hY2FiLTMwYzA4ZmU3YjlmMiJ9

6 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 261 confined field trials of plants with novel traits in the 2024 growing season. Trials were conducted at 29 locations across Canada. Crop species tested included barley, canola, corn, lentil, poplar, poppy, soybean, potato, and wheat. There were no notable trends in the 2024 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 2025 growing season and expects to receive a similar number of applications and range of crop types as in the 2024 trials. A detailed list of confined field trials is posted on the CFIA's website:

https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/approved-under-review/field-trials/eng/1313872595333/1313873672306

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:

http://inspection.gc.ca/active/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/plant-varieties/plants-with-novel-traits/approved-under-review/decision-documents/eng/1303704378026/1303704484236

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 April 2024, 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 designation	Trait	Developer	Development method	Authorization dates		
				Unconfined environmental release	Livestock feed use	Human food use
Soybean MON 94637	Lepidopteran resistance	Bayer CropScience	Agrobacterium-mediated transformation	2024/10/03	2024/10/03	2024/10/02
Corn DAS-01131-3	Lepidopteran resistance; glyphosate tolerance	Pioneer Hi-Bred Production Company	Agrobacterium-mediated transformation	2024/09/04	2024/09/04	2024/08/23
Corn MON 95275	Corn rootworm and lepidopteran resistance	Bayer CropScience	Agrobacterium-mediated transformation	2024/08/24	2024/08/24	2024/08/14
Corn DP-051291-2	Resistance to corn rootworm; glufosinate tolerance	Pioneer Hi-Bred Production Company	Agrobacterium-mediated transformation	2024/07/12	2024/07/12	2024/07/18
Corn DP-910521-2	Lepidopteran resistance	Pioneer Hi-Bred Production Company	Agrobacterium-mediated transformation	2024/07/12	2024/07/12	2024/06/19
Corn EH913	Lepidopteran resistance; glufosinate tolerance	Helix Sementes e Mudas Ltda	Agrobacterium-mediated transformation	2024/06/11	2024/06/11	2024/06/10
AXigen Wheat	Herbicide tolerance	Albaugh, LLC	mutagenesis	2024/04/26	N/A*	N/A**

*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:

Biotechnology notices of submission - inspection.canada.ca.

Since April 2024, Canada has posted three new Notices of Submission. Four 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 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

The CFIA is currently drafting tomato and barley biology documents.

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 2009-9: Plants with Novel Traits Regulated under Part V of the Seeds Regulations: Guidelines for Determining When to Notify the CFIA: https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/applicants/directive-2009-09/eng/1304466419931/1304466812439

- CFIA Rationale for Updated Guidance Determining Whether a Plant Is Subject to Part V of the Seeds Regulations: https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/applicants/directive-2009-09/rationale-for-updated-guidelines/eng/1682425597052/1682425597973

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

- Guidance on How to Determine When a Plant-derived Ingredient Requires a Feed Pre-market Evaluation: https://inspection.canada.ca/en/animal-health/livestock-feeds/regulatory-guidance/rg-1/chapter-2#s29c6
    - 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

Canada has published updated feeds regulations. The *Feeds Regulations, 2024* were published in the *Canada Gazette*, Part 2 on July 3, 2024. The regulations have a staggered coming into force period over 18 months to provide stakeholders with time to bring their practices into compliance.

Regulations respecting approval and registration of feeds, labelling, standards and record keeping came into effect right away. Requirements related to labelling and standards have a one-year transition period to allow product to move through the marketplace. This transition period will end on June 17, 2025 at which time all feeds will need to follow the new regulations. At the same time, on June 17, 2025, new requirements respecting hazard analysis, preventive controls and preventive control plans, complaints, recalls, packaging and traceability will come into effect. And finally on December 17, 2025 the expanded scope of livestock species, licencing requirements, authority for issuing export certificates will come into effect.

The regulations include 9 documents that are incorporate by reference which allow standards to be set in a way that 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.

We have published a suite of guidance materials that are available on our website, and we continue to work to update existing guidance. Additional guidance and stakeholder information sessions are planned in support of the June and December coming into force dates this year.

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

New Substances Notifications

Between March 2024 and February 2025, Environment and Climate Change Canada (ECCC)/Health Canada (HC) (New Substances (NS) program) completed 44 new living organism assessments under the *Canadian Environmental Protection Act, 1999* (CEPA). Of this number, 24 were for various environmental or industrial uses, of which 9 were for higher organisms and 15 were for microorganisms. The remaining 20 notifications were for the environmental assessment of organisms used in products regulated under the *Food and Drugs Act* (including genetic therapies and vaccines), of which 15 were for cell and gene therapies, 3 for vaccines, and 2 for other products including 1 phage therapy. Of the 24 organisms notified for environmental and industrial uses, 11 were genetically modified organisms. Of the 20 organisms

notified for food and drugs uses, 12 were genetically modified. The types of organisms that were assessed ranged from bacteria to viruses, virus-like particles, animal cells, fungi and higher organisms (GM *Drosophila*).

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)* (NSNR (O)). On October 17th, 2023 the NS program published a "What We Heard" report (found here) summarising the feedback received from various stakeholders as part of a pre-consultation on a Discussion Paper outlining the various issues to be addressed by proposed regulatory amendments on the online platform PlaceSpeak. In June 2024, the NS program held information seminars to discuss the proposed amendments to the NSNR (Organisms) with interested stakeholders. Following this public engagement, comments and feedback from stakeholders have been incorporated into the proposed regulatory amendments. A summary of feedback along with responses will be published on the New Substances webpage. The NS program is now aiming to publish the amended regulations in the *Canada Gazette Part 1* in 2025.

Consultations on Certain Living Organisms New to Canada

The Government of Canada is promoting public engagement in the risk assessment of 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 that are vertebrate animals, or a prescribed living organism or group of living organisms, 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 consultation 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 during the public consultation period are considered in the risk assessment and made public after the prescribed assessment period. Since 2018, the NS program has held public comment periods for twenty-four lines of genetically modified fish and two lines of genetically modified Drosophila. Information on current and past consultations can be accessed through the New Substances Website.

Revised Microbial Risk Assessment Framework

The Microbial Risk Assessment Framework (MRAF), originally developed in 2010, is used as the basis for the CEPA assessment of micro-organisms. The MRAF has been used for the assessment of micro-organisms on the Domestic Substances List (DSL) but was very qualitative in nature. The work to revise this framework was the result of the need to shift to a semi-quantitative approach for risk assessments (especially given that data is provided when risk assessments on new micro-organisms are conducted). Following consultations with other governmental groups that have an interest/mandate to manage products of biotechnology, the framework was published in April 2024 on the New Substances Website.

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.

7 Croatia

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

Applications for commercialization

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)

Currently, GMOs are authorised for import and use as food/feed products in the European Union at the same time in the Republic of Croatia, only one GMOs (GM maize MON 810) is authorized for cultivation. According to the authorisations, 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.

Notifications for field trials

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.

During the current reporting period April 2024-April 2025 neither cultivation of GMO crops nor deliberate release of GMOs for field trials occurred in the Republic of Croatia.

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

Notifications for clinical trials

During the reporting period March 2024-March 2025 the Republic of Croatia received three request for deliberate release into a living organism of a medicinal product (medical product) consisting of or containing a GMO or a combination of GMOs for the purpose of conducting clinical trial. Two requests have been approved in accordance to EU legislation and third request about live biopharmaceutical products (GM live

microorganisms) is still in the administrative procedure. Currently, live biopharmaceutical products (GM live microorganisms) pose a challenge since their use could involve deliberate release practices and the recommendations in this respect are not available on the EU level.

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.

Risk management measures

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 2024 until 31st December 2024 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 157 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, agriculture inspection of State Inspectorate samples 30 samples of seeds of soybean, rapeseeds, maize, sugar beet and wheat and veterinary inspection of State Inspectorate samples 150 samples of meat products that consisting or containing ingredients on corn, soybean based and 50 samples of feed.

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.

2. Updates regarding international activities

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. At the beginning of the February 2024 the Republic of Croatia was hold pre-accessions meeting with OECD Secretariat.

3. Developments related to new breeding techniques (NBTs)

Since the last WP-HROB meeting, 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) was accepted on the European Council on the 14th March 2025 and now it will begins a trilogue / an informal interinstitutional negotiation between European Commission, European Council and Parliament with the end goal of adopting proposal of NGT Regulation on the European Union level. The Republic of Croatia is actively involved in discussions of that proposals.

8 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 2024, 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 2024 and will be continued in 2025:

- Plum trees with a modification conferring virus resistance (resistance to the plum pox virus), notified by the Crop Research Institute, Prague (640 m^2 without buffer zones);
- Spring barley lines producing peptide LL-37, a research project of the Palacky University in Olomouc, cultivated by the company Usovsko, Olomouc region. In 2024, the trial area was 25 m^2 without buffer zones.

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 seven 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. The number of premises notified for the contained use of GMOs has decreased slightly since 2023, with more than 130 research institutions, universities and companies now using GMOs. Four 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)

According to the legislation of the European Union, organisms produced by NBTs are still considered to be GMOs and thus fall under GMO regulations. However, a new proposal for a Regulation on new genomic techniques (NGT), as part of the 'Food and biodiversity package' is being heavily negotiated at the EU level since 2003. The aim of the regulation proposal is 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.

So far, organisms produced by new genomic techniques (gene editing) have been used under the contained use regime in laboratories, greenhouses, breeding facilities, and industrial premises in the Czech Rrepublic. Most of the activities performed served research purposes.

In January 2025, the Ministry of the Environment received an application submitted by the Institute of Experimental Botany of the Czech Academy of Science for the authorisation of deliberate release into the environment of spring barley lines with edited PIL1 gene using CRISPR/Cas9. The PIL1 gene regulates the expression of several genes involved in cell wall expansion, such as expansins, thereby participating in the regulation of plant growth. The small-scale field trial aims to assess the consistency of the mutant phenotype under field conditions. The application for the field trial is being assessed and administered in accordance with Act 78/2004 Coll. on the Use of Genetically Modified Organisms and Genetic Products, as amended. The authorisation is expected to be issued for the upcoming growing season.

9 Denmark

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

The Danish Agricultural and Fisheries Agency approved two experimental releases of gene edited (GE) potatoes in 2023 and one experimental release in 2024. The GE-potatoes were modified to have increased resistance to potato late blight or a modified starch content. In all cases, the modified traits were introduced through targeted mutations with CRISPR. According to the current EU-regulation such plants are subject to the full GMO-regulation and were handled as experimental releases of GMO's. As described in 3., the EU-regulation of NGT-plants such as the ones mentioned here are currently under review.

In 2025 the Agency has received two application for a new experimental release involving more lines of GE-potato with increased late blight resistance mentioned above.

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

Development of new EU-regulation on NBT (see point 4)

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.

2. Updates regarding international activities

No developments to report.

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 negotiated in the European Council. 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 NBTs (as described in point 1.)

4. Additional Information

The control of conventional seeds for adventitious presence of GMOs has in 2024 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.

10 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 2024 :

OGM	Avis rendus
Betterave sucrière génétiquement modifiée KWS20-1	https://www.anses.fr/fr/system/files/BIOT2023SA0190.pdf
Fleurs coupées d'œillet génétiquement modifié IFD-25958-3	https://www.anses.fr/fr/system/files/PGM2024SA0081.pdf
Fleurs coupées d'œillet génétiquement modifié IFD-26407-2	https://www.anses.fr/fr/system/files/PGM2024SA0082.pdf
Soja génétiquement modifié DBN8002	https://www.anses.fr/fr/system/files/BIOTECHS2023SA0182.pdf
Maïs génétiquement modifié MON94804	https://www.anses.fr/fr/system/files/BIOT2023SA0096.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 2024.

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**
2023	https://www.anses.fr/fr/system/files/PGM2024-AST-0174.pdf

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

L'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (Anses) a adopté le 9 octobre 2024 un avis relatif à l'élaboration de lignes directrices pour l'évaluation des risques environnementaux liés à la dissémination volontaire de médicaments à usage humain ou vétérinaire contenant des organismes génétiquement modifiés ou consistant en de tels organismes.

https://www.anses.fr/fr/system/files/BIOTECHNOLOGIES2022AUTO0167.pdf

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 2024. 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-techniques-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/

Avis et rapports nationaux sur les NBTs

En réponse à une saisine du Gouvernement, l'Anses a adopté en janvier 2024 un avis et un rapport relatifs aux risques sanitaires et environnementaux et aux enjeux socio-économiques associés aux plantes obtenues au moyen de certaines nouvelles techniques génomiques (NTG)

https://www.anses.fr/fr/system/files/BIORISK2021SA0019Ra.pdf

[English version]

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

a) Mise sur le marché

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 2024 :

GMO	Opinion issued
Genetically modified sugar beet KWS20-1	https://www.anses.fr/fr/system/files/BIOT2023SA0190.pdf
Genetically modified carnation cut flowers IFD-25958-3	https://www.anses.fr/fr/system/files/PGM2024SA0081.pdf
Genetically modified carnation cut flowers IFD-26407-2	https://www.anses.fr/fr/system/files/PGM2024SA0082.pdf
Genetically modified soybean DBN8002	https://www.anses.fr/fr/system/files/BIOTECHS2023SA0182.pdf
Genetically modified maize MON94804	https://www.anses.fr/fr/system/files/BIOT2023SA0096.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) Expérimentation en milieu ouvert

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

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

Around 1200 applications for contained use of GMOs were examined in 2024.

d) Culture des OGM

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
2023	https://www.anses.fr/fr/system/files/PGM2024-AST-0174.pdf

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

On 9 October 2024, the French National Agency for Food, Environmental and Occupational Health Safety (Anses) adopted an opinion on the development of guidelines for the assessment of environmental risks associated with the deliberate release of medicinal products for human or veterinary use containing or consisting of genetically modified organisms.

https://www.anses.fr/fr/system/files/BIOTECHNOLOGIES2022AUTO0167.pdf

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-techniques-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/

Avis et rapports nationaux sur les NBTs

In response to a referral from the Government, ANSES adopted in January 2024 an opinion and a report relating to the health and environmental risks and socio-economic issues associated with plants obtained using certain new genomic techniques (NGT).

https://www.anses.fr/fr/system/files/BIORISK2021SA0019Ra.pdf

11 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 have to involve the independent Central Committee on Biological Safety (ZKBS) to advice 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 trails in Germany.

Some examples of research funded by the German government are listed below.

- Vatanparast, M., Merkel, L., Amari, K. (2024): **Exogenous Application of dsRNA in Plant Protection: Efficiency, Safety Concerns and Risk Assessment**. Int. J. Mol. Sci. 2024, 25, 6530. https://www.mdpi.com/1422-0067/25/12/6530
- **AI-supported bioinformatics approach for GMO analysis.** The number of GMOs is steadily increasing. This means that the current (mostly PCR-based) screening methods are becoming increasingly complex, while remaining largely limited to the detection of known GMOs. In order to tackle this growing problem, the BVL is currently working on a generalized, AI-supported bioinformatics approach for the evaluation of next generation sequencing data as a GMO screening tool.
- **Ants as test organisms for GMO risk assessment.** As GMOs could have negative impacts on biodiversity, a research project by the German Federal Agency for Nature Conservation (BfN) investigates the suitability of ants as test organisms for GMO risk assessment.

  Pohl et al. 2024. Ants are not bees – Gaps in the assessment of relevant exposure routes to pesticides and plant incorporated protectants. Environmental Chemistry and Ecotoxicology, 6: 71-80, doi: 10.1016/j.enceco.2024.02.001

2. Updates regarding international activities

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

The German BVL and the Dutch WFSR host and maintain **EUginius**, the **EUropean GMO Initiative for a Unified Database System** (www.euginius.eu) in close cooperation with official GMO detection and identification laboratories of Austria, Italy and Poland. EUginius' 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.

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 are authorized as food/feed or for cultivation in the EU neither have applications been received for food/feed.

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.

- Heinz, S., Neusius, D., Eckermann, K.E., Pietsch, K., Guertler, P. (2025): **Development and in-house validation of two real-time PCR methods for the detection of genome-editing events in soybean FAD2 gene variants.** Journal of Consumer Protection and Food Safety https://doi.org/10.1007/s00003-024-01538-0
- **GeneBEcon** is a Horizon Europe-funded project of the EU that will examine the potential of gene editing in enabling a sustainable bioeconomy in Europe. Through the application of this technology in potato and microalgae, GeneBEcon intends to promote energy-efficient, low-input, and improved agricultural production and industrial processing for a sustainable bioeconomy. BVL is one of the German partners with the responsibility on biosafety data requirements for NGT organisms in the focus of the project. (Further information: www.genebecon.eu)

  Purnhagen, K., Ambrogio Y., Bartsch, D. et al. (2023) Options for regulating new genomic techniques for plants in the European Union. Nature Plants 9, p. 1958–1961; https://doi.org/10.1038/s41477-023-01570-2
- **Analysis of developments in genetic engineering and synthetic biology with regard to environmental aspects and nature conservation.** The BfN investigates the potential impact of technical and regulatory developments in the field of new genomic techniques on nature thereby including both environmental, regulatory and ethical aspects.

  Bohle et al. (2024) Where does the EU-path on new genomic techniques lead us? Frontiers in genome editing, 6, 1377117, doi: 10.3389/fgeed.2024.1377117

  Reichenbecher et al. (2024) For a science-based regulation of plants from new genetic techniques. Federal Agency for Nature Conservation (BfN), Policy Brief. https://www.bfn.de/sites/default/files/2024-02/24_02_07_BfN_policy_brief_NGT-7_0.pdf

  Rabitz et al. (2024) Putting gene drives into context: Risks, depth of intervention, and regulatory challenges. GAIA, 33 (1), 165-169, doi: 10.14512/gaia.33.1.9

Germing et al. (2025) Crop protection by RNA interference: a review of recent approaches, current state of developments and use as of 2013. Environmental Sciences Europe, 37,1. doi: 10.1186/s12302-025-01052-6

- **DERUST**: The DERUST project is developing barley and wheat lines with unprecedented broad-spectrum resistance against all rust diseases relevant to these two plant species. Its aim is to help ensure a sufficient supply of grain under climate conditions that are increasingly conducive to the spread of rust diseases, while significantly reducing the need for fungicides and agricultural land.
- **Beta King**: European sugar beet cultivation is threatened in particular by the green peach aphid Myzus persicae, which transmits the Beet yellows virus (BYV) to sugar beet. The aim of the project is to identify genetic resistance to BYV and make it usable in practice. Precision breeding methods including cross-kingdom RNAi and genome editing will be used to demonstrate feasibility. New varieties will then be created by conventional crossing and selection.
- **TeaM7**: the project seeks to develop high-precision tools for genome editing, particularly for prime and base editing, based on the Cas12a enzyme family. In addition, the efficiency and accuracy of these techniques will be optimized by accompanying work on the 2D structure of the required guide RNAs. The aim is to develop a widely applicable technique for targeted DNA modification with high efficiency in the model organism Arabidopsis and the crop plants barley, rapeseed and potato, providing plant breeding with a practical and precise genome editing system for scientific as well as applied questions.

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). The proposal is discussed among EU Member States and in the European Parliament (EP).

A common position of the Council of EU Member States is still pending. The EP agreed to the proposal with amendments on 7 February 2024. Next, Commission, Parliament and Council will debate the proposal and amendments, and negotiate a common (amended) Regulation text.

This proposal is further discussed among stakeholders, academia, NGOs and the public; numerous statements, opinions, position papers and policy briefs have been published and enrich the debate.

12 Hungary

1. Developments related to implementation of national biosafety

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

Cultivation of GMOs: MON810 GM maize is still the only GM crop authorised for commercial cultivation in the EU. In the course of 2024 no cultivation of GM crops occurred in Hungary because of the Hungarian safeguard clause 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): Two clinical trials were authorised in the course of 2024. 1) The first authorised clinical trial was a multi-center single arm Phase II study in order to evaluate the safety and efficacy of genetically engineered autologous cells expressing anti-CD20 and anti-CD19 specific chimeric antigen receptor in subjects with relapsed and/or refractory diffuse large B cell lymphoma. 2) The second authorised clinical trial was a Randomized, Partially Masked, Controlled, Phase 3 Clinical Study in order to Evaluate the efficacy and safety of RGX-314 Gene Therapy in Participants with nAMD (ASCENT).

Contained use activities: In the course of 2024 one class 1, nineteen class 2, and one class 3 premises were authorised for contained use activities. One contained used activity in class 1 was authorised with GMV. Twenty-seven contained used activities in class 2 were authorised with GMVs and in some cases GMMs, GMAs and GMP too. Two 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 (the Crimean-Congo haemorrhagic fever virus).

2. Updates regarding international activities

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

Hungary is a Party to the Cartagena Protocol on Biosafety. During the Eleventh meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety Hungary held the Presidency of the EU Council and led the negotiations on behalf of the European Union. Hungarian experts are actively engaged in the international activities and participated in the meeting of the Liaison Group on the Cartagena Protocol on Biosafety during the relevant intersessional period.

3. Developments related to new breeding techniques (NBTs)

4. Any other information related to NBTs

On 5 July 2023, the European Commission submitted to the Council and the European Parliament a proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed products. Both the Council and the European Parliament started examining the proposal and the accompanying impact assessment. Hungary has actively participated in the discussions of the Council. In particular in the second half of 2024, Hungary held the Presidency of the EU Council and organised the relevant council meetings to discuss further the proposal of the European Commission.

In the course of 2024 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. Hungary is one of the strongest opponents of agricultural gene technology in the European Union, and this policy has not been changed.

13 Italy

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

Italy is a member of the European Union (EU) and implements EU community-level decisions and regulations on genetically modified (GM) organisms and their products at national level. In the context of the EU legal framework for GMOS (Directive 2001/18/EC and Regulation (EC) No 1829/2003), ISPRA (Italian Institute for Environmental and Research Protection) supports the Italian Competent Authorities (Minister of Environment and Energy Security and Minister of Health) and it is actively involved in the Member State consultation process conducted by the European Food Safety Authority (EFSA) focusing on the risk assessment.

GMOs authorised for the placing on the market under Directive 2001/18/EC can be found: https://ec.europa.eu/food/food-feed-portal/screen/gmoc/search.

Summary notifications of deliberate releases of GMO submitted under part B of Directive 2001/18/EC can be found: https://ec.europa.eu/food/food-feed-portal/screen/gmob/search .

Products that are authorised for placing on the EU market can be found in the EU Register of GM food and feed (https://webgate.ec.europa.eu/dyna2/gm-register/).

About contained use of GM Microorganisms, the responsibility for implementation of the respective Directive (EC) No 2009/41 lies with the Ministry of Health.

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

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

Some information on field trials:

Notification Number B/IT/24/04

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

Notification Number B/IT/24/03

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

Notification Number B/IT/24/02

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

Notification Number B/IT/24/01

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

3. Risk management measures

Currently, in Italy the placing on the market of GMOs is authorised only for import and use as food/feed products. As established by the authorisations, a post-marked environmental monitoring plan (PMEM) must be implemented in accordance with Annex VII of Directive 2001/18/EC. This plan aims to detect both direct and indirect effects identified in the environmental risk assessment. Additionally, when necessary, a post-market monitoring plan (PMM) is required to ensure proper application of usage conditions and to track the consumption of genetically modified (GM) food or feed intended for human and animal consumption.

According to Directive (EU) 2015/412, amending Directive 2001/18/EC, EU Member states have the possibility to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory; Italy has implemented this directive with Legislative decree N°227 of 14th November 2016.

Every year, the Italian Competent Authority responsible for implementing the provisions of directive 2001/18/EC (the Minister for Energy Security) develops a general plan for surveillance activities on the deliberate release into the environment of genetically modified organisms. The plan aims to schedule and to coordinate the inspection activities, to guarantee the flow of information between central, regional and local administrations, and to ensure that the public is adequately informed about the results of the surveillance activities available on the institutional website of the Ministry.

The general plan for surveillance activities is implemented through an annual National Operational Program based on the annual Regional Operational Programs of inspections are developed. More information can be found at: https://bch.mase.gov.it/index.php/en/?view=article&id=456&catid=2

2. Updates regarding international activities

3. Specific cases of use of OECD tools and information

Italian national experts regularly use OECD Consensus documents when evaluating applications for authorisation of GM organisms and their products; and tools and information to be update on the developments on this topic at global level.

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

2. Specific cases of application, assessment and decision

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

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

4. Any other information related to NBTs.

On 5 July 2023, the European Commission introduced a proposal for a Regulation concerning plants developed using certain new genomic techniques (NGT) and their related food and feed products. The proposal suggests the creation of two distinct categories of NGT plants, which would be regulated differently from other genetically modified plants. The proposal is currently under discussion among EU Member States and within the European Parliament (EP). A unified position from the Council of EU Member States has yet to be reached. Italy as member state of the EU is actively involved in this discussion. In the meantime, the plants and products covered by this proposal continue to be regulated under the legislation on GMOs as described in the first paragraph.

For further information see the contribution of the European Commission and the link.

4. Additional Information

New Genomic Techniques in plant science: International Summer School of the Italian Botanical Society (SBI) Summer School 24th-26th September 2024 at Department of Life Sciences and Systems Biology University of Torino

14 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), one oilseed rape, six maize and one mustard greens events have been newly approved for commercial use, and two soybean and one petunia events have been approved for the release for confined field trials (CFTs) since our report at the last WG-HROB meeting held in March 2024 as of the end of March 2025. In addition, the collection of information from domestic CFTs has been judged unnecessary for two maize events and two soybean events.

Table Newly approved LM plants

Unique Identifier	Plant Species	Applicant	Traits	Genes	Date of approval	Type of use
MON-941ØØ-2	Oilseed rape	Bayer CropScience	Tolerance to Dicamba	*dmo*	2024/4/24	food, feed, cultivation
MON-94637-8	Soybean	Bayer CropScience	Resistance to Lepidoptera	*cry1A.2, cry1B.2*	2024/4/24	CFTs
DP-2Ø2216-6×MON-ØØ6Ø3-6×DAS-4Ø278-9	Maize	Corteva Agriscience	Increased yield potential, Tolerance to 2 4-dichlorophenoxyacetic acid (2 4-D), Tolerance to aryloxyphenoxypropionate (AOPP) acetyl coenzyme A carboxylase (ACCase) inhibitor, Tolerance to Glufosinate, Tolerance to Glyphosate	*zmm28, pat,* modified *cp4 epsps,* modified *aad-1*	2024/4/24	food, feed, cultivation
	Petunia	Hakusan, NEC Solution Innovators	Green fluorescence	*eYGFPuv*	2024/4/24	CFTs
ACS-BN ØØ3-6	Mustard greens	BASF	Tolerance to Glufosinate, Fertility restoration	modified *bar, barstar*	2024/7/22	food, feed, cultivation
COR-23134-4	Soybean	Corteva Agriscience	Resistance to Lepidoptera, Tolerance to Acetolactate synthase (ALS) inhibitor	*cry1B.34.1, cry1B.61.1, ipd083Cb, gm-hra_1*	2024/7/22	CFTs
SYN-BTØ11-	Maize	Syngenta Japan K.K.	Resistance to Lepidoptera, Tolerance to Glyphosate,	modified *cry1Ab,*	2024/7/22	food, feed,

1×SYN-IR162-4×DAS-Ø15Ø7-1×MON-ØØ6Ø3-6			Tolerance to Glufosinate	modified *vip3A*, modified *cry1F, pat,* modified *cp4 epsps*		cultivation
SYN-BTØ11-1×SYN-IR162-4×SYN-ØØØ98-3×DP-ØØ4114-3×MON-ØØ6Ø3-6	Maize	Syngenta Japan K.K.	Resistance to Lepidoptera, Resistance to Coleoptera, Tolerance to Glyphosate, Tolerance to Glufosinate	modified *cry1Ab,* modified *vip3A, ecry3.1Ab, mcry3A,* modified *cry1F, cry34Ab1, cry35Ab1, pa*t, modified *cp4 epsps*	2024/7/22	food, feed, cultivation
DAS-Ø1131-3	Maize	Corteva Agriscience	Resistance to Lepidoptera, Tolerance to Glyphosate	modified *cyr1Da2, dgt-28 epsps*	2025/3/21	food, feed, cultivation
DP-91Ø521-2	Maize	Corteva Agriscience	Resistance to Lepidoptera, Tolerance to Glufosinate	*cry1B.34, pat*	2025/3/21	food, feed, cultivation
DP-915635-4	Maize	Corteva Agriscience	Resistance to Coleoptera, Tolerance to Glufosinate	*ipd079Ea, pat*	2025/3/21	food, feed, cultivation

The total number of LM plants ever approved for commercial use as of March 2025 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)	20*[1]	Rose	2
Carnation	8	Soybean	30*[1]
Maize	101*[1]	Sugar Beet	1
Cotton	38*[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.

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

Amended a notice for the approval of LM plants and designated soybean, in addition to maize and cotton, as a host that does not need information collection from domestic CFTs when meeting certain conditions.

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:

- SBSTTA26 in Nairobi, Kenya and CP-MOP11 of the CBD in Cali, Colombia.
- APEC High-level Policy Dialogue on Agricultural Biotechnology (APEC HLPDAB) Plenary meeting and Workshops in Trujillo, Peru.

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 WG-HROB meeting held in March 2024, MAFF did not receive any finalized information form.

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

- Tomato with extended shelf life, modified with a ripening-related transcription factor
- Barley modified with the seed storage protein produced by genome editing technology
- A group of rice mutants in the genes regulating flowering time, circadian rhythm and stress resistance by genome editing technology
- Rice mutants in the genes regulating sink capacity, source ability, and metabolism of sugar and starch by genome editing and
- Potatoes with low contents of steroidal glycoalkaloids

This information is available on the Japan Biosafety Clearing-House website (https://www.biodic.go.jp/bch/bch_8_3.html, in Japanese).

4. Additional Information

Science Communication Activities

MAFF continuously conducts a science communication project focusing biotechnology. In FY 2023, 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 technique were held.

15 Korea

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

In Korea, regulations on Living Modified Organisms (LMOs) are governed by the "Act on Transboundary Movements, etc. of Living Modified Organisms." This law aims to prevent potential risks to public health and the conservation and sustainable use of biodiversity caused by LMOs in advance, thereby enhancing the quality of life for citizens and promoting international cooperation. It establishes safety measures throughout the entire process of LMO development, production, import, export, and distribution. Under this law, relevant central administrative agencies are required to implement necessary policies to prevent risks associated with LMOs.

To date, Korea has approved 192 LMOs for feed use, 213 for food use, 104 for industrial use, and 2 for pharmaceutical use. Notably, there have been no approvals for environmental release or cultivation thus far.

The following new LMO events were approved in the year 2024

Organisms	Event	Type of use	Traits	Company
Maize	DP-202216-6xNK603xDAS-40278-9	Food	Herbicide resistance and yield improvement	Corteva
canola	NS-B50027-4	Feed	Herbicide resistance and altered fatty acid composition	NuSeed
Maize	DP-910521-2	Feed	Insect Resistance & Herbicide Tolerance	Corteva
Maize	Bt11xTC1507xNK603	Food	Insect Resistance & Herbicide Tolerance	Syngenta
Maize	DAS-01131-3	Feed, Food	Insect Resistance & Herbicide Tolerance	Corteva
Maize	DP-202216-6xNK603xDAS-40278-9	Food	Herbicide resistance and yield improvement	Corteva
Maize	DP-023211-2	Feed, Food	Insect Resistance & Herbicide Tolerance	Corteva
Maize	DP-915635-4	Feed, Food	Insect Resistance & Herbicide Tolerance	Corteva
Maize	MON95379	Feed, Food	Herbicide Tolerance	Monsanto
Maize	Bt11xMIR162xMZIR098xDP-004114-3xNK603	Feed, Food	Insect Resistance & Herbicide Tolerance	Syngenta

Canola	MON94100	Food	Herbicide Tolerance	Monsanto
Cotton	T304-40	Food	Insect Resistance & Herbicide Tolerance	BASF
Microbe	LWH001	industrial	3-HP production	LG Chem
canola	LBFLFK	Feed, Food	Herbicide resistance and altered fatty acid composition	BASF
Microbe	APC547	Food	3-fucosyllactose production	AP Technology
Microbe	DS00002	Food	allulose conversion enzyme	Daesang

(Korea Biosafety Clearing House : www.biosafety.or.kr)

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

The 4th LMO (Living Modified Organism) Safety Management Plan (2023–2027): Based on the LMO Act, relevant ministries such as the Ministry of Trade, Industry and Energy; the Ministry of Science and ICT; the Ministry of Agriculture, Food and Rural Affairs; the Ministry of Health and Welfare; the Ministry of Environment; the Ministry of Oceans and Fisheries; and the Ministry of Food and Drug Safety establish a safety management plan for LMOs every five years. These ministries are responsible for overseeing all aspects of LMO safety management, including research and development, experimentation, safety measures, risk assessment and post-monitoring strategies, as well as the distribution of LMOs.

3.Risk management measures

- In Korea, the cultivation of LMOs is not approved, and LMOs are imported for use as food, feed, and other purposes. To prevent the unintended environmental release and naturalization of imported LM crops, regular monitoring is conducted annually, focusing on LMO transportation routes and unauthorized LMO cultivation sites.

- In 2024, follow-up monitoring of the unapproved zucchini squash discovered in 2023 was conducted jointly by the government and the private sector. The investigation is now in its final stages, and the results have been shared with relevant organizations and civil society groups to promote communication and mutual understanding

2. Updates regarding international activities

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

APEC High-Level Policy Dialogue on Agricultural Biotechnology:

As the host economy for APEC in 2025, Korea is preparing to convene the High-Level Policy Dialogue on Agricultural Biotechnology. To support the outcomes of this meeting, Korea submitted a project proposal to the APEC Secretariat under the theme “Digital and Precision Breeding for Sustainable Agriculture and Food Security,” which has been approved. Based on this, Korea plans to host an agri-bio workshop in 2025. Key sessions will include sharing policy trends from relevant government ministries in agricultural biotechnology, as well as presentations on emerging breeding technologies and biotechnology research trends based on big data

3. Developments related to new breeding techniques(NBTs)

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

16 Latvia

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory

In 2024 the State Scientific Institute “Institute of Food Safety, Animal Health and Environment “BIOR”” regularly took part at centralized EU GMO risk assessment procedure. BIOR provided opinion on four applications in respect of GMO placing on the EU market.

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

The amendments to the Law on the Circulation of Genetically Modified Organisms" was adopted in 2024 determining:

1. to improve the legal framework regarding the rights of supervisory and control authorities if protective actions are initiated and the requirements of regulatory enactments regulating the handling of GMOs are violated;
2. to complement the legislation on contained use of GMM with requirements that also apply to contained use of GMOs.

The amendments was adopted in view of the rapid spread of GMOs on the world market, which promotes the unintentional release of GMOs into the environment as well as the admixture of GMOs in conventional seeds.

5. Research projects on biosafety; relevant publications.

In 2024 the project “Monitoring of unintended release of genetically modified plants into environment and evaluation of environmental monitoring programs available in Latvia in connection with general supervision of GMOs” was completed. It was two year project, implemented by the State Scientific Institute “Institute of Food Safety, Animal Health and Environment “BIOR””.

The aim of the project was to assess the possible unintended release of GMOs in Latvia, to provide an analysis of the environmental monitoring programs available in Latvia, as well as to develop recommendations for adapting the existing environmental monitoring programs and seed/plant propagation material monitoring programs for the general monitoring of GMOs in connection with environmental risk assessment and establishing baselines.

3. Developments related to new breeding techniques (NBTs)

Please see information prepared by European Commission.

17 Lithuania

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions:

The situation in Lithuania regarding the deliberate release of genetically modified organisms into the environment remains unchanged. Genetically modified crops are not grown, and genetically modified organisms are not deliberately released into fields for testing.

During the reporting period (March 2024–March 2025), six new notifications concerning the contained use of genetically modified microorganisms (two notifications - class 2, the others - class 1) and seven new notifications concerning genetically modified organisms (level 1) were received.

Lithuania is an EU Member State that implements EU Community-level decisions and regulations on genetically modified food and feed at national level. The EU has a register of genetically modified food and feed: https://ec.europa.eu/food/food-feed-portal/screen/gmo/search.

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

During the reporting period (March 2024 – March 2025) several amendments of GMO's legislation were approved:

2024-04-29 Amendment of Act on "The establishment of the committee of experts on genetically modified organisms and the approval of its rules of procedure" No D1-135
https://www.e-tar.lt/portal/lt/legalAct/dd56e09005e611efbcbfb318996800a8

2024-11-04 A new act on "The approval of the provisions of the Biological diversity information system and the provisions on the security of the Biological diversity information system data"
No D1-372
https://www.e-tar.lt/portal/lt/legalAct/237199709a8511efa605b9842742bf37

2025-01-17 Amendment of Act on "The establishment of the Genetically modified organisms steering committee and approval of its provisions" No D1-48
https://www.e-tar.lt/portal/lt/legalAct/TAR.CFEFA13DF537/asr

3. Public engagement and outreach activities:

Information and data on GMO's legislation, notification/permitting and various guidelines are made available on the new 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 (March 2024 – March 2025) Lithuania took part in 26SBSTTA in Nairobi, Kenya and COPMOP11 in Cali, Colombia.

3. Developments related to new breeding techniques (NBTs)

During the reporting period (March 2024 – March 2025) there was no application received of genetically modified organisms developed by new breeding techniques.

Lithuania participates in the discussion of the European Commission's proposal on plants obtained by certain new genomic techniques and their food and feed and amending Regulation (EU) 2017/625, adopted on 5 July 2023 (NBT's proposal). This proposal is a part of package of legislative proposals to support the EU Farm to Table and Biodiversity strategies.

On June 16, 2025, the Genetically Modified Organisms Steering Committee, composed of representatives from science, agriculture, industry, and government authorities, agreed to continue supporting the position adopted in 2023 on the NBT's proposal.

18 Netherlands

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

Notifications for commercialization

The Netherlands issued two authorizations for renewals for the importation of colour modified carnation lines in the European Union:

- IFD-25958-3 (Moonberry)
- IFD-26407-2 (Moonvelvet)

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 3 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).

Currently the Dutch authorities are evaluating a new application for field trials with genetically modified potatoes. This is the first application for a field trial in years. Although some lines would fall under the scope of the proposed EU regulation on NGT plants, a permit would be needed under the current national GMO Decree and EU regulations.

2. Updates regarding international activities

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

The Netherlands is a party to the CBD and to the Cartagena Protocol, and participated in the SBSTTA26 and COP16/COPMOP11 meetings and preparatory meetings, in particular the agenda items on Risk assessment / Risk management and synthetic biology and Identification & Detection.

The Dutch GMO Office is regularly approached by researchers and developers regarding the regulatory status of specific genetic techniques or the products constructed and/or produced with those techniques. Answering some of these questions proved to be a challenge due to ambiguity of (parts) of the legal definition of a GMO in the European Directive on deliberate release 2001/18/EC. The ministry of Infrastructure and Water Management therefore commissioned a number of studies with the aim to provide clarifications.

Furthermore, in one of these studies (see also below) it was concluded that also European Member States and the Commission may interpret differently the GMO definition, or specific terms within this definition. The Netherlands recognises the divergent views on the interpretation of the GMO definition between Member States. Specific cases and details highlight these national interpretations. The Netherlands supports the conclusion in the report on the need for harmonisation across EU and advocates that discussions on specific cases among Member States and Commission should be facilitated. The Netherlands also concluded that the national policy regarding the interpretation of the GMO definition needs to be reassessed nationally.

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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

Recently two reports were published commissioned by the Dutch ministry Infrastructure and Water management.

The first report is already mentioned above under item 2.2.

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). An accurate definition is essential because it delineates the scope of GMO legislation and ensures that all stakeholders know which organisms are covered by the regulations. The purpose of this report is solely to reflect the possible interpretations as noted by participants and not to provide a definitive interpretation of the GMO definition.

Link to report: https://open.overheid.nl/documenten/15f63566-b13f-4b11-a4cf-570e7d9ed83b/file

Research on Synthetic Genomes

This report explores the state-of-the-art advancements, potential applications, and biosafety considerations of synthetic genomes, an emerging cornerstone of synthetic biology. The field has matured significantly due to scientific breakthroughs.

Link to report: https://www.government.nl/binaries/government/documenten/reports/2024/12/31/research-on-synthetic-genomes/Research+on+Synthetic+Genomes.pdf

19 New Zealand

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

The Environmental Protection Authority (EPA) is the New Zealand 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 approved an application to conduct in containment large-scale fermentation of Risk Group 1 organisms to perform recombinant protein expression (also referred to as precision fermentation) of dairy-identical proteins. More information can be found at the following links.
EPA approves precision fermentation of milk proteins | EPA
https://www.epa.govt.nz/database-search/hsno-application-register/view/APP204652

ii. The EPA has approved the release of genetically modified live Chimeric Antigen Receptor T-cells for use in the treatment of patients with relapsed or refractory large no-Hodgkin B-cell lymphoma in May 2024.
Next step for cancer treatment trial | EPA
https://www.epa.govt.nz/database-search/hsno-application-register/view/APP204765

iii. Numerous approvals for import or development of GMOs in containment. More information can be found at the EPA HSNO 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 Rauhī 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.

Our Māori engagement strategy was updated this last year with details how we would like applicants to engage with Māori.

More information can be found at the following links.

Engaging with Māori | EPA

EPA-Annual-Report-2024.pdf

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

EPA and Wilderlab boost community water testing nationwide

Science at work: Cyclone Gabrielle eDNA programme

Wai Tuwhera o te Taiao – Open Waters Aotearoa | EPA

EPA-Annual-Report-2024.pdf

20 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.

Between 2024-2025, Paraguay approved the use of several GM yeasts for ethanol production. As yeast-derived products and distiller's dried grains with solubles can be used as animal feed, a CONBIO safety assessment was required.

By Resolution 92/2024, MAG granted the first commercial release of the GM insect *Spodoptera frugiperda* OX5382G, which contains a self-limiting gene that produces male-only insects[1]. These modified males mate with wild females and transmit the self-limiting gene to their offspring. The continuous release of GM males in a specific area will decrease the number of wild females and the overall population of these insects.

1. Commercial Approvals

The following GM products were released from 2024 to 2025.

Decision No.	Organism / Product	Event	Proposed commercial use	Characteristics	Regulatory mechanism
18/2025	*Saccharomyces cerevisiae*	GPY012850 (GICC03674)	Ethanol production	Optimization of ethanol production through the expression of glucoamylase enzymes while also providing a parallel route for increased ethanol production and a reduction in glycerol	Commercial release of novel GM (Resolution MAG 18/2015)

[1] MAG, *Resolución Nº 92/2024 Por La Cual Se Autoriza La Liberación Comercial de Organismo Genéticamente Modificado Denominado OX5382G 'Spodoptera Frugiperda', a Favor de La Empresa OXITEC LTD.*, *Resolución MAG*, 2024, 92/2024, 3 <https://doi.org/10.5281/zenodo.10688936> [accessed 10 February 2024].

				production during fermentation	
17/2025	Soybean	MON-94637-8	Insect resistance	Insect-resistant soybean MON 94637 contains the cry1A.2 and cry1B.2 genes from *Bacillus thuringiensis*, which encode the insecticidal proteins Cry1A.2 and Cry1B.2 that provide protection against food damage caused by lepidopteran insects in soybean crops.	Differentiated treatment for the commercial release of GM crops that have been approved in third countries (Resolution MAG 1030/2019 and 1071/2019).
16/2025	Maize	MON-948Ø4-4	Reduced overall plant height compared to conventional non-GM corn.	Reduction of gibberellic acid/gibberellin levels predominantly in the stalk, leading to a reduction of internode length and consequently reduced overall plant height compared to conventional maize comparator	Differentiated treatment for the commercial release of GM crops that have been approved in third countries (Resolution MAG 1030/2019 and 1071/2019).
15/2025	Soybean	MON-94313-8	Soybean line is tolerant to the herbicides dicamba, glufosinate, 2,4-D, and mesotrione	Tolerance to glufosinate is achieved with the expression of the phosphinothricin-N-acetyltransferase (PAT) protein, encoded by the pat gene from the bacterium *Streptomyces viridochromogenes*. Tolerance to dicamba is achieved with the expression of the	Differentiated treatment for the commercial release of GM crops that have been approved in third countries (Resolution MAG 1030/2019 and 1071/2019).

				dicamba mono-oxygenase (DMO) protein, encoded by the dmo gene from the bacterium *Stenotrophomonas maltophilia*. Tolerance to 2,4-D is conferred by the expression of the FT_T.1 protein, encoded by a modified version of the R-2,4-dichlorophenoxy propionate dioxygenase (Rdpa) gene from the bacterium *Sphingobium herbicidovorans*.	
93/2024	*Saccharomyces cerevisiae*	FS0436 (PRCH20080)	Ethanol production	Optimization of ethanol production through the expression of glucoamylase enzymes while also providing a parallel route for increased ethanol production and a reduction in glycerol production during fermentation	Commercial release of novel GM (Resolution MAG 27/2015)
92/2024	*Spodoptera frugiperda*	OX5382G	Self-limiting	The released GM males will seek out and mate with wild females. The self-limiting gene will be transmitted to offspring, preventing female offspring from reaching maturity and reproducing	Commercial release of novel GM (Resolution MAG 27/2015)

2. New Breeding Techniques

A total of 02 (two) Prior Consultations forms (PRY-Form 3) were submitted for the period March 2024 - March 2025.

3. Participation in International Activities

Date	Activities
2024	Argentina, Brazil, Paraguay, and Uruguay signed a memorandum (June 12) for the creation of the **International Biosafety Network (ABRE-Bio, Biosafety Agencies Network for Biotechnology)**. The main goal of the memorandum is to promote the exchange of scientific information and cooperation in the risk assessment and regulation of genetically modified organisms (GMOs) and products derived from new breeding techniques (NBTs). In addition, 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, and agro-industry sectors through collaboration between public and private institutions. Each country has designated institutions responsible for carrying out activities derived from the agreement. In Paraguay, MAG oversees these tasks. The agreement has an initial validity of five years and can be automatically renewed for additional periods, which ensures long-term commitment from the parties involved. Additionally, the possibility of incorporating new institutions and countries is foreseen, which would further expand the scope and effectiveness of this collaboration.
2024	Meeting GT5 “Public policies in biotechnology” of the Southern Agricultural Council (CAS) held on April 25-26 in Asunción, Paraguay.
2024	The Like-Minded countries meeting (Like Minded Group) was held on August 11 and 12 in Lima, Peru.
2024	Meeting of the Commission for Agricultural Biotechnology of SGT No. 08 of MERCOSUR, under the pro-tempore presidency of Paraguay, held on April 24 and 25 in Asunción, Paraguay.
2024	Meeting of the Commission for Agricultural Biotechnology of SGT No. 08 of MERCOSUR, under the pro-tempore presidency of Uruguay, in Montevideo, Uruguay.
2024	Convention on Biological Diversity and Cartagena Protocol meetings held from October 21 to November 3 in Cali, Colombia.

2024	Virtual Workshop on Microbial Biotechnology for South America, held virtually on June 5 and 6.

4. Relevant publications

- 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
- Benitez Candia, N., Ulke, G., Sotelo Torres, P. H., Nara, E. M., Arrúa Alvarenga, A., & Fernández Ríos, 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

21 Philippines

I. Developments related to implementation of the National Biosafety Framework

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

a. Ongoing review and revision of the Philippine Biosafety Guidelines for Contained Use of Genetically Modified Organisms by the National Committee on Biosafety of the Philippines.

b. Conduct of review and enhancing 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).

c. Initial preparation for the conduct of Regulatory Impact Assessment for the draft guidelines for the GM animals.

d. Development of guidance document for the importation of genetically modified (GM)/edited fish and contained use for GM mosquito.

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 GMB151	For food and feed, or for processing	Herbicide Tolerant
2. Corn MON 95275	For food and feed, or for processing	Insect Resistant
3. LBFLFK Canola	For food and feed, or for processing	Herbicide tolerant and modified oil/fatty acid
4. EE-1 eggplant	For commercial propagation	Insect Resistant
5. Bt Cotton - GFM cry1A	For commercial propagation	Insect Resistant
6. Soybean A5547-127	For food and feed, or for processing	Herbicide Tolerant
7. Corn MON 87427	For commercial propagation	Herbicide Tolerant
	For field trial	Herbicide Tolerant
8. High Iron, High Zinc Rice IRS1030-031	For field trial	High Iron, High Zinc
9. High Iron, High Zinc Rice IRS1030-039	For field trial	High Iron, High Zinc

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:
    v. Implementation of temporal or isolation distance
    vi. Ensuring the security of the experimental area (only authorized persons can access the site, free from stray animals, birds, rodents, etc.)
    vii. Disposal of regulated planting materials after harvest
    viii. Monitoring of volunteer plants (fallow period monitoring)
    ix. Implementation of contingency measures when necessary
3. For commercial propagation:
    x. 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
    xi. Indicating in the seed bag label that the product is not intended for propagation in prohibited areas

B. New and emerging regulatory challenge/s

1. Public acceptance and perception gap on GMOs
2. Ongoing Writ of Kalikasan case, which challenges the existing policy on regulating GMOs
3. Limited number of functional laboratories at the ports of entry for testing imported GM commodities
4. Intellectual Property and access to technology
5. Biosecurity concerns (i.e., advances in synthetic biology, unregulated gene drives)
6. Capacity building program for regulators

C. Public Engagement from March 2024 to February 2025

1. Public hearings for field trials;
2. 2024 National Biotechnology Week: A Celebration of Education, Innovation, and Commercialization (November 2024);
3. Series of seminars and webinars on agricultural biotechnology (Biotech advocacy and outreach) (Jan – Dec 2024); and

4. Series of public consultations on the proposed Joint Department Circular (JDC) regarding Genetically Modified (GM) animals (2023)

II. Updates regarding international activities

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

a. ASEAN Workshop on Agricultural Biotechnology (March 4-8, 2024);

b. ASEAN Science and Technology Innovation: Workshop on Gene-Editing Regulations (September 10-11, 2024);

c. APEC Agricultural Biotechnology Seminar and related workshops (November 2024, December 10-11, 2024); and

d. APEC Consultative Meeting on Regulatory Cooperation (January 15, 2025).

2. Bi-/multilateral cooperation with other authorities/organizations

a. The Department of Agriculture – Bureau of Plant Industry (DA-BPI) hosted a bilateral meeting with representatives from South Africa to discuss and deliberate upon the market access and bio-security concerns, specifically on Pest Risk Analysis for apples and pears;

b. Department of Agriculture Secretary Francisco P. Tiu Laurel, Jr. met with Lao PDR's Minister of Agriculture and Forestry, Linkham Douangsavanh, at the World Food Forum in Rome, Italy held on 14 to 18 October 2024. The proposed agreement outlines key initiatives, including establishing a joint genetic bank for rice development to promote innovation in crop cultivation;

c. Asia-Pacific Economic Cooperation (APEC) High Level Policy Dialogue on Agricultural Biotechnology (HLPDAB) - was formed as an ongoing policy dialogue in recognition of biotechnology's potential benefits to agriculture and the complexities of its regulatory framework;

d. ASEAN Genetically Modified Food Testing Network (ASEAN GMFNet) provides a mechanism for the harmonization of the ASEAN GMO regulatory framework for food, feed and the environment, including GMO detection approaches and methods, capacity building on GMO analysis, and information exchange on the development of modern biotechnology in the context of food testing. The Philippines will be hosting the 22nd meeting of the ASEAN GMFNet on June 23-27, 2025;

e. Under the framework of the bilateral agreement between the DA and the Argentine Ministry of Agriculture, Livestock, and Fisheries, Argentina has positively responded to the DA's proposal for joint capacity-building exercises on gene-editing and other emerging breeding technologies.

   The initial meeting was held in February 2024, to set the groundwork for collaboration. The proposed activities focus is on advancing gene-editing applications for both crops and livestock, with targeted training programs for policymakers, researchers, and regulators;

f. PH-Thailand Cooperation: BIOTEC Thailand has expressed its intention to engage in technical cooperation with the Philippines through DA. This potential partnership aims to facilitate knowledge exchange and technical assistance in the development of African Swine Fever vaccine.

3. Specific cases of use of OECD tools and information

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

III. Developments related to New Breeding Techniques (NBTs)

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

a. DA Memorandum Circular No. 8, series of 2022, Rules and Procedure to Evaluate and Determine when Products of Plant Breeding Innovations (PBIs) are Covered under the DOST-DA-DENR-DOH-DILG Joint Memorandum Circular No. 1, series of 2021 (JDC1, s2021) based on the NCBP Resolution No. 1, series of 2020, provides specific guidelines to evaluate and determine when products of plant breeding innovations (PBIs) are covered under GMO regulations.

b. Preparing for the conduct of a comprehensive review of new breeding innovations in animals and their scientific, regulatory, ethical, and socio-economic implications to support the development of science-based, inclusive, and transparent policy.

2. Specific cases of application, assessment, and decision

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

1. High GABA Sicilian Rouge tomato;

2. Reduced Browning Banana; and

3. Black Sigatoka Tolerant Banana.

3. Research projects on biosafety of NBT products and other relevant

Publications

a. Groover, E., Njuguna, E., Bansal, K.C. et al. A technical approach to global plant genome editing regulation. Nat Biotechnol 42, 1773–1780 (2024). https://doi.org/10.1038/s41587-024-02489-5

"The Innovate Genomics Institute brought together regulators from 16 countries to discuss global capacity building for the regulation of genome-edited crops. The workshop provided insights into the suitable use of technical analyses to validate edits and raised future considerations regarding regulation reporting, offering suggestions to help countries meet their objectives in the ever-growing landscape of genome editing techniques."

22 Slovak Republic

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

As part of the information on 'notifications' and 'authorisations' for the year 2024, the Slovak Republic had a total of 167 notifications (including 129 in classes 1 and 2, and 1 in class 3) and authorisations (including 37 in classes 1 and 2). In class 4, we did not register any notifications or authorisations for the year 2024.

In 2023, the Ministry of the Environment of the Slovak Republic extended approval (for a 2-year period) for testing the genetically modified vaccine “FluBHPVE6E7”. The GMO “FluBHPVE6E7” is derived from an influenza B virus (the parental virus) and has been modified at several levels to be used effectively as a viral vector to eliminate human papillomavirus (HPV)-infected cells and cancers induced by HPV by inducing an 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 the activation of an immune response against HPV-infected cells and tumors.

3. Risk management measures

In the year 2023, we had the following: General rules on the coexistence of genetically modified crops with conventional and organic farming are set by Act No. 184/2006. The implementing Decree No. 69/2007 establishes minimum isolation distances for growing genetically modified corn, rapeseed, sugar beet, and potatoes in agricultural production from plants of the same botanical species grown through conventional or organic farming. Minimum requirements for buffer zones are also established; unmodified plants of the same botanical species cannot be grown on the same plot for at least two years, and the surrounding area must be monitored for two years after the harvest of the genetically modified crops.

These same general rules remained unchanged in the year 2024, and we have not implemented any new measures.

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

In 2022, 2023, and also in 2024, we dealt with the same issue: synthetic biology – risk assessment of products under the EU rules applicable to GMMs.

2. Updates regarding international activities

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

In the year 2024, we participated in obligatory meetings.

23 Slovenia

1. Developments related to implementation of national biosafety framework

Slovenia is a member of the EU and is therefore also bound by the common EU legal framework for GMOs. With the change of the government in Slovenia in 2022, the responsibility for overall biosafety related issues was transferred to the newly established Ministry of the Environment, Climate and Energy. Along with that the Inspectorate for Environment and Spatial Planning which was responsible for GMOs was replaced by the Inspectorate for the Environment and Energy.

Other responsibilities and the status of GMO products remain unchanged.

1. Risk assessment/regulatory decisions

- Decisions on contained use of GMOs in 2024

In the field of contained use of GMOs, 108 facilities for the contained use of GMOs had been registered in Slovenia by the end of 2024. Most of these facilities are located in universities (43%), followed by institutes (30%) and industry (26%). Of these, 60% work with biosafety level I GMOs and 40% with biosafety level II GMOs. In addition, 230 decisions for use of GMOs in the contained systems were issued by the end of 2024. The comparison shows that slightly more projects were approved for work with GMOs in contained systems of biosafety level II (55%). During a period of last five years we have observed a shift from work with biosafety level I GMOs to work with biosafety level II GMOs and an increased number of notifications from the commercial sector. We have no class 3 or 4 laboratories.

- Decisions on deliberate release of GMO into the environment in 2024

In the area of the environmental release of GMOs, an authorisation was granted last year in Slovenia for a clinical trial entitled Phase I/II UMCF-LJU anti-CD19 chimeric antigen receptor T-cell study in adults with relapsed/refractory CD19-positive acute lymphoblastic leukaemia. The clinical trial involves anti-CD19 CAR-T treatment of patients in a controlled hospital setting.

3. Risk management measures

- Monitoring of GMOs in seeds in 2024

In the context of ensuring overall safety in the use of products of modern biotechnology, the Ministry of the Environment, Climate and Energy is the competent authority for contained use, deliberate release and placing on the market of GMOs. According to that, it is also responsible for monitoring the presence of GMOs in seeds, which has been carried out in Slovenia for many years. National Institute of Biology (NIB) is the National reference laboratory for GMO testing (NRL) in Slovenia. All samples collected in 2024 were examined for the presence of genetic elements by screening analysis using the five-target method: CaMV 35S promoter, NOS terminator, bar, pat and CTP2-CP4-EPSPS and determination of the reference gene (presence of DNA, maize, soybean, oilseed rape or alfalfa). Maize, DAS40278 and MON95379 are tested separately, as they are not covered by the convenient five-target method. All seed samples of maize,

oilseed rape, soybeans and alfalfa taken and tested in 2024 were negative for the presence of genetically modified elements.

2. Updates regarding international activities

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

- COP 16, COP/MOP 11 and COP/MOP 5 (from 21 October - 1 November 2024, Cali, Columbia);
- Multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology (29 January - 2 February 2024, Montreal, Canada);
- Ad Hoc Technical Expert Group on Risk Assessment (27 February – 1 March 2024, Montreal, Canada);
- Ad Hoc Technical Expert Group on Risk Assessment (29 October – 5 November 2023, Montreal, Canada);
- 18th Meeting of the EFSA GMO Network (online, 27 November 2024)
- Slovenian half day workshop “Increasingly diverse genetically modified organisms” with international participation (19 December 2024, Ljubljana, Slovenia)

3. Developments related to new breeding techniques (NBTs)

On 18 January 2024, the two Slovenian scientific committees (Scientific Committee on the Contained Use of GMOs and Scientific Committee on the Deliberate Release and Placing on the Market of GMOs) issued a positive joint opinion on the draft proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed and amending Regulation (EU) 2017/625. Both committees agreed that this is a first step to update the existing EU GMO legislation from 2001 and 2003 in the light of the remarkable development of biological sciences. The scientific committees also support the introduction of two categories of NGT plants, as this ensures a distinction between plants that have actual equivalence with conventional plants (NGT1 plants) and plants that do not fulfil this criterion (NGT2 plants). They also believe that the proposed regulation will contribute to the innovation and sustainability objectives of the European Green Deal, as well as to the Farm to Fork and Biodiversity strategies, and will increase the competitiveness of the agri-food sector while ensuring a high level of protection of human health and the environment.

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

The National Institute of Biology (NIB), as the National Reference Laboratory of Slovenia [NRL], is a member of the European Network of GMO Laboratories (ENGL) and is:

- a member of the COST Action CA18111 Genome Editing in Plants (https://plantgenomeediting.eu/), which ended in 2023.
- 2024 contribution to a new ENGL report "Sequencing strategies for the traceability of GMOs".
- a member of the European Initiative for Sustainable Agriculture through Genome Editing (EU-SAGE; https://www.eu-sage.eu/), which represents a network of 134 European plant science institutes and societies that have joined forces to provide information on genome editing and to promote the development of strategies at European level and in the EU member states to enable the use of genome editing for sustainable agriculture and food production.

- used one of the new breeding techniques, CRISPR/cas9, to analyse the function of potato genes and miRNAs involved in the response to biotic stress.
- a member of the European project “DETECTIVE – Detection of NGT products to promote innovation in the EU”, which was launched on 1 January 2024. The DETECTIVE consortium is led by the Swedish University of Agricultural Sciences. It comprises a multidisciplinary consortium of 20 partners from eight EU Member States, Switzerland and China as well as the Joint Research Centre of the European Commission. The NIB leads a work package “Protocol development and assay validation” and is involved as a partner in other work packages, playing an important role in the development of multiplex approaches for the detection of NGTs.

24 South Africa

1. South Africa GM Crop Area: 2021/22 Production Season Estimates

(New report released December 2023: Prepared by the Bureau for Food and Agricultural Policy (BFAP) for CropLife South Africa)

CropLife South Africa is a non-profit industry association that serves and represents responsible manufacturers, suppliers and distributors of sustainable crop protection, public health and plant biotechnology solutions in South Africa. They enable their members to be providers of environmentally compatible solutions that ensure sustainable, safe and affordable food production, and therefore food security, in South Africa. CropLife South Africa offers a wealth of resources, training, regulatory assistance and industry updates to its members. In addition, they are the leading industry voice for their members in matters pertaining to crop protection and plant biotechnology in South Africa.

In the field of biotechnology, South Africa is the leader in Africa. No updated figures for 2024/2025 could be found. Thus, it remains as reported in 2024.

GM Cotton

In 2022, 100% of the 18 018 hectares of cotton planted in South Africa were genetically modified. There was no conventional cotton seed available for planting in the 2021/22 production season. 95% of the cotton area was planted to stacked cotton seed with Bollgard II insect resistance and Roundup Ready Flex herbicide tolerance. The remaining 5% was planted to Roundup Ready Flex single trait seed as the mandatory refugia area. Driven by the Southern African Sustainable Cotton Cluster and higher international prices, the cotton industry has seen some revival from 2017, but the industry remains a shadow of its former self largely due to the capital requirements and management difficulties of harvesting (compared to grains and oilseeds), and relatively high prices for competing crops.

GM Soybean

Close to 80% of the total soybean area is planted to farm saved seed, and for this reason the GM adoption (still only glyphosate-resistance) estimate errs on the conservative side at 95%. MON87701 x MON89788 soybean seed (IntactaRR2Pro, which is an insect resistance trait stacked with a new glyphosate-tolerance trait) was first planted in 2022 and should see more substantial plantings in the 2023/24 production season.

GM Maize

The South African commercial GM maize area share has seen a steady increase over the years. After settling around the 70% level between 2008 and 2011, the share increased to closer to the 90% level for 2013-2016, and then declined to closer to an 80% level for 2018-2020. The 2021/22 GM maize area is

estimated at 84.5%, with 65% of the maize area planted to stacked (insect resistance and herbicide tolerant) maize. South Africa's GM maize area percentage is slightly lower than that of other GM maize producing countries. In 2021, 99.6% of Argentina's maize area was planted to GM seed, while Brazil and the US had estimates of 95%.

GM White Maize

The GM white maize area for 2021/22 is estimated at 89%. It is estimated that the conventional white maize area increased slightly from 9% in 2020/21 to 11% in 2021/22 following the sharp drop from 16% in 2019/20. Bt maize (insect resistant) as a single trait (albeit with two Bt events) continued to decrease, dropping from 5% to 3%. The area under herbicide tolerant single trait maize decreased by 144 000 ha, to a relatively similar level as was observed in 2018 and 2019. Despite the total white maize area decline, the stacked maize (insect resistant and herbicide tolerant) area increased with just over 48 000 ha to cover an estimated 74% of total commercial white maize plantings in 2021/22. It would seem as if 'additional' white maize hectares that come in to or go out of maize production per season (due to price or other considerations), are largely planted to herbicide tolerant seed in the Free State or North West Provinces.

GM Yellow Maize

The area planted to stacked yellow maize increased by just over 32 400 ha and the single herbicide tolerant trait area by 16 700 ha. As a result, the GM yellow maize area increased from 72% in 2020/21 to 77.2% in 2021/22. This level is similar to 2019 estimations and lower than the above 85% levels observed in 2012/2016. The yellow maize Bt area decreased with about 5 5000 ha to its second lowest level since the technology's first introduction in 1999. Stacked maize adoption amongst yellow maize farmers are lower compared to white maize, while herbicide tolerant single trait adoption is higher.

2. Genetically Modified Organisms Act [No. 15 of 1997]

To provide for measures to promote the responsible development, production, use and application of genetically modified organisms; to ensure that all activities involving the use of genetically modified organisms (including importation, production, release and distribution) shall be carried out in such a way as to limit possible harmful consequences to the environment; to give attention to the prevention of accidents and the effective management of waste; to establish common measures for the evaluation and reduction of the potential risks arising out of activities involving the use of genetically modified organisms; to lay down the necessary requirements and criteria for risk assessments; to establish a council for genetically modified organisms; to ensure that genetically modified organisms are appropriate and do not present a hazard to the environment; and to establish appropriate procedures for the notification of specific activities involving the use of genetically modified organisms; and to provide for matters connected therewith.

Application of the Act

This Act shall apply to:

a. the genetic modification of organisms;
b. the development, production, release, use and application of genetically modified organisms (including viruses and bacteriophages); and
c. the use of gene therapy.

Executive Council

The Executive Council (EC) advises the Minister for Agriculture on all aspects concerning the development, production use, application and release of genetically modified organisms, and to ensure that all activities with regard to the development, production, use, application and release of genetically modified organisms are performed in accordance with the provisions of the Genetically Modified Organisms Act [No. 15 of 1997].

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Functions of Advisory Committee

(1) The Advisory Committee (AC) shall:

a. act as the national advisory body on all matters concerning or related to the genetic modification of organisms;
b. advise, on request or of its own accord, the Minister of Agriculture, the EC, other Ministries and appropriate bodies, on matters concerning the genetic modification of organisms and, inter alia, advise them:
    i. on all aspects relating to the introduction of genetically modified organisms into the environment;
    ii. on proposals for specific activities or projects concerning the genetic modification of organisms;
    iii. on all aspects concerning the contained use of genetically modified organisms;
    iv. on the importation and exportation of genetically modified organisms; and
    v. on proposed regulations and written guidelines;
c. liaise through the relevant national departments with international groups or organisations concerned with biosafety; and
d. invite written comments from knowledgeable persons on any aspect of the genetic modification of organisms which lies within the Committee's brief.

(2) The AC may appoint subcommittees to deal with specific matters as required.

Appointment of registrar

As soon as possible after the composition of the EC and whenever necessary thereafter the Minister of Agriculture shall, after consultation with the EC, appoint a suitably qualified and experienced person as registrar.

The registrar:

a. is charged with the administration of this Act;
b. may exercise such powers and perform such duties as may be conferred upon or delegated or assigned to him or her by or under this Act or by the EC.

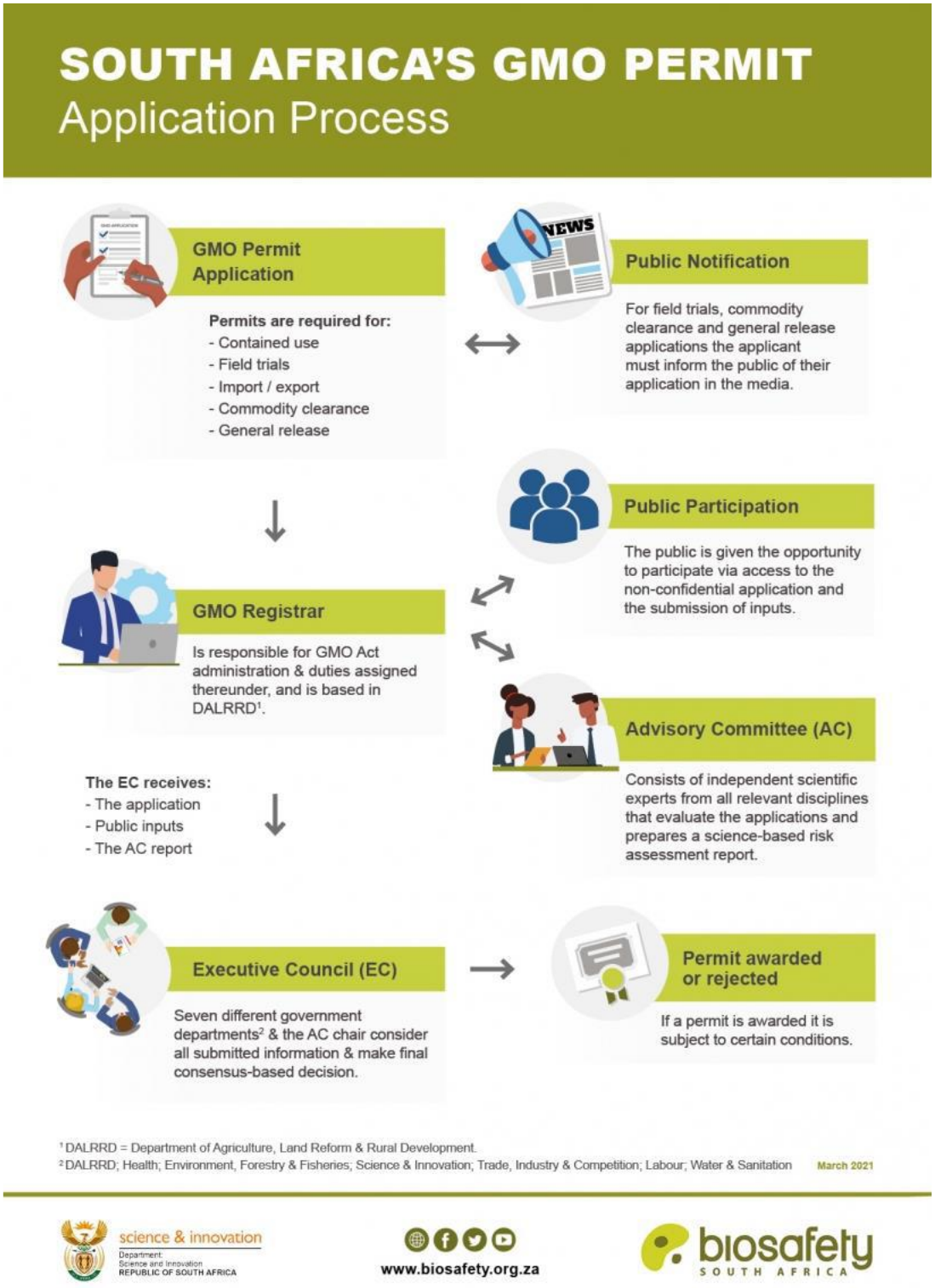
Functions of registrar

The registrar shall subject to the instructions of and the conditions laid down by the EC:

a. issue a permit as required or prescribed under this Act;
b. where he or she has ascertained or suspects on reasonable grounds that genetically modified organisms are being imported or locally produced or used contrary to the provisions of this Act or the conditions of a permit issued thereunder:
    i. serve a notice upon any person by whom or on whose behalf genetically modified organisms are being so imported into, produced or used in the Republic for the removal of such genetically modified organisms to a place or facility and in a manner prescribed by the Council; and
    ii. authorise an inspector to destroy such genetically modified organisms or cause it to be destroyed, subject to procedures and other provisions as set out in this Act.
c. amend or withdraw a permit issued under this Act;
d. furnish an inspector with a certificate of appointment;
e. require the cessation of any genetic modification activity at facilities where the provisions of this Act or the conditions of a permit have not been or are not being complied with; and

f. ensure that appropriate measures are undertaken by all users at all times with a view to the protection of the environment from hazards.

The South African regulatory framework requires amongst others a socio-economic assessment of a new GM crop line before it will be considered and approved for commercial release. In these assessments issues such as international trade, sustainable livelihoods and possible social impacts are considered.


SOUTH AFRICA'S GMO PERMIT
Application Process
GMO Permit Application
Permits are required for:
- Contained use
- Field trials
- Import / export
- Commodity clearance
- General release
NEWS
Public Notification
For field trials, commodity clearance and general release applications the applicant must inform the public of their application in the media.
Public Participation
The public is given the opportunity to participate via access to the non-confidential application and the submission of inputs.
GMO Registrar
Is responsible for GMO Act administration & duties assigned thereunder, and is based in DALRRD[1].
Advisory Committee (AC)
Consists of independent scientific experts from all relevant disciplines that evaluate the applications and prepares a science-based risk assessment report.
The EC receives:
- The application
- Public inputs
- The AC report
Executive Council (EC)
Seven different government departments[2] & the AC chair consider all submitted information & make final consensus-based decision.
Permit awarded or rejected
If a permit is awarded it is subject to certain conditions.
[1] DALRRD = Department of Agriculture, Land Reform & Rural Development.
[2] DALRRD; Health; Environment, Forestry & Fisheries; Science & Innovation; Trade, Industry & Competition; Labour; Water & Sanitation
March 2021
science & innovation
Department:
Science and Innovation
REPUBLIC OF SOUTH AFRICA
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SOUTH AFRICA

3. Department of Agriculture, Land Reform and Rural Development (DALRRD) (Directorate Genetic Resources)

Biosafety:

Mission

To manage a bio-safety regulatory system focused on minimizing potential risks associated with the impact of genetically modified organisms (GMOs) on the environment, human and animal health.

Functions

- Develop and implement policies and strategies to contribute to the safe use, handling and transfer of genetically modified organisms.
- Provide technical advice on matters relating to the application of genetically modified organisms in South Africa, the region and the rest of Africa.
- Facilitate a compliance system for assessing potential risks associated with the application of genetically modified organisms.
- Provide an administrative support system for the bodies established under the Genetically Modified Organisms Act, 1997 (Act No. 15 of 1997) (GMO Act).

Role as the Competent National Authority

The Cartagena Protocol on Biosafety, which is an international agreement that aims to ensure an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology, was established under the Convention of Biological Diversity. South Africa acceded to the Cartagena Protocol on Biosafety on August 14, 2003. In terms of the Protocol the DALRRD (Directorate Genetic Resources) is the recognized Competent National Authority for South Africa and is responsible for ensuring that all provisions and obligations relating to the Protocol are met.

4. New GM approvals in South Africa

The new commodity clearance approvals since the last meeting are presented in Table 1 and are indicated in black bold text. There were no new general release approvals since the last meeting.

Table 1. Commodity clearance imports approved for food and feed in South Africa. Source: http://www.dalrrd.gov.za/

Commodity clearance means that South Africa allows the importation of these events for the use as food and/or feed. Typically, this means seeds that will not be planted, but rather processed in a way that will leave them non-viable. A complete food safety assessment is required, but the environmental assessment is not necessary in line with the limited environmental exposure.

Event	Crop	Trait	Company	Year approved
DAS1131	**Maize**	**Insect resistance Herbicide tolerance**	**Corteva**	**2024**
Bt11 x MIR162 x TC1507 x NK603	**Maize**	**Insect resistance Herbicide**	**Syngenta**	**2024**

		tolerance		
Bt11 x MIR162 x MZIR098 x DP4114 x NK603	**Maize**	**Insect resistance Herbicide tolerance**	**Syngenta**	**2024**
DP202216 x NK603 x DAS-40278-9	Maize	Enhanced grain yield Herbicide tolerance	Corteva	2023
3272 x Bt11 x MIR162 x GA21	Maize	Insect resistance Herbicide tolerance	Syngenta	2023
DP202216	Maize	Enhanced grain yield Herbicide tolerance	Corteva Agriscience RSA	2023
HB4 (IND- ØØ41Ø-5)	Soybean	Abiotic stress tolerant Herbicide tolerant	Bioceres Crop Solutions	2022
HB4 (IND-ØØ412-7)	Wheat	Abiotic stress tolerant Herbicide tolerant	Trigall Genetics SA	2022
3272 x Bt11 x MIR162 x MIR604 x TC1507 x 5307 x GA21	Maize	Insect resistance Herbicide tolerance	Syngenta SA	2022
DAS-44406-6	Soybean	Herbicide tolerance	Corteva Agriscience RSA	2022
DAS-81419-2 x DAS-44406-6	Soybean	Insect resistance Herbicide tolerance	Pioneer Hi-Bred RSA	2022
NK603 x T25 x DAS-40278-9	Maize	Herbicide tolerance	Corteva Agriscience RSA	2022
GMB151	Soybean	Insect resistance Herbicide tolerance	BASF	2021
GHB811	Cotton	Herbicide tolerance	BASF	2021
MON89034 x TC1507 x MIR162 x NK603 x DAS-40278-9	Maize	Insect resistance Herbicide tolerance	Pioneer Hi-Bred RSA (Pty) Ltd	2020
MON87427 x MON89034 x MON810 x MIR162 x MON87411 x MON87419	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2020
MON87427 x MON89034 x MIR162 x MON87419 x NK603	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2020
MON87427 x MON87419 x NK603	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2020
MON87427 x MON89034 x MON87419 x NK603	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2018
MON87427 x MON89034 x TC1507 x MON87411 x DAS 59122-7 x MON87419	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2018
MON87751 x MON87701 x	Soybean	Insect resistance	Monsanto SA	2018

MON87708 x MON89788		Herbicide tolerance		
FG72 x A5547-127	Soybean	Herbicide tolerance	Bayer	2018
MON89034 x TC1507 x MIR162 x NK603	Maize	Insect resistance Herbicide tolerance	DowAgroSciences	2018
BT11 x MIR162 x MIMR604 x MON89034 x 5307 x GA21	Maize	Insect resistance Herbicide tolerance	Syngenta SA	2018
MON87705 x MON87708 x MON89788	Soybean	Herbicide tolerance	Monsanto SA	2018
MON87427 x MON87460 x MON89034 x TC1507 x MON87411 x DAS-59122-7	Maize	Insect resistance Herbicide tolerance Drought or water tolerance	Monsanto SA	2018
MON87427 x MON89034 x MIR162 x MON87411	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2018
MON87427 x MON89034 x TC1507 x MON87411 x DAS-59122-7	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2018
MON87427 x MON87460 x MON89034 x MIR162 x NK603	Maize	Insect resistance Herbicide tolerance Drought or water tolerance	Monsanto SA	2018
MON87708 x MON89788 x A5547-127	Soybean	Herbicide tolerance	Monsanto SA	2018
BT11 x MIR162 x MON89034	Maize	Insect resistance Herbicide tolerance	Syngenta SA	2018
MON87427 x MON89034 x MON88017	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2017
MON89034 x MIR162	Maize	Insect resistance	Monsanto SA	2017
BT11 x MIR162 x MON89034 x GA21	Maize	Insect resistance Herbicide tolerance	Syngenta	2017
DP114 x MON810 x MIR604 x NK603	Maize	Insect resistance Herbicide tolerance	Du Pont Pioneer	2017
TC1507 x MON810 x MIR162 x NK603	Maize	Insect resistant Herbicide tolerant	Du Pont Pioneer	2016
TC1507 x MIR604 x NK603	Maize	Insect resistant Herbicide tolerant	Du Pont Pioneer	2016
TC1507 x MON810 x MIR604 x NK603	Maize	Insect resistant Herbicide tolerant	Du Pont Pioneer	2016
TC1507 x 59122 x MON810 x NK603	Maize	Insect resistant Herbicide tolerant	Du Pont Pioneer	2016
TC1507 X 59122 X MON810 x MIR604 x NK603	Maize	Insect resistant Herbicide tolerant	Du Pont Pioneer	2016
DAS81910-7	Cotton	Herbicide tolerant	DowAgroSciences	2016
DAS-24236-5 x DAS-21023-5	Cotton	Insect resistant	DowAgroSciences	2016

MON89034 x TC1507 x MON88017 x DAS-591227 x DAS-40278-9	Maize	Insect resistant Herbicide tolerant	DowAgroSciences	2016
MON89034 x TC1507 x NK603 x DAS-40278-9	Maize	Insect resistant Herbicide tolerant	DowAgroSciences	2016
DP4114	Maize	Insect resistant Herbicide tolerant	Du Pont Pioneer	2016
NK603 x T25	Maize	Herbicide tolerant	Monsanto	2016
MZHG0JG	Maize	Herbicide tolerant	Syngenta	2016
DP73496	Canola	Herbicide tolerance	Du Pont Pioneer	2016

Table 2. General release approved for importation/exportation, commercial planting, and for food and/or feed in South Africa. Source: http://www.dalrrd.gov.za/ There were no new general release approvals since the last meeting.

Event	Crop	Trait	Company	Year approved
Recombinant Attenuated Salmonella Vaccine -Cp/01	Poultry vaccine	-	Huvepharma South Africa (Pty) Ltd	2023
Nobivac Puppy DP Plus	Canine vaccine	-	Intervet SA (Pty) Ltd	2023
Innovax – ND-ILT	Poultry vaccine	-	Intervet SA (Pty) Ltd	2023
GHB614 x LLCotton25	Cotton	Herbicide tolerance	BASF South Africa (Pty) Ltd	2023
Poulvac Procerta HVT-ND	Poultry vaccine	-	Zoetis South Africa (Pty) Ltd	2023
MON87427	Maize	Herbicide tolerance	Bayer	2023
DP-056113-9	Maize	Pollination control system	Corteva Agriscience RSA	2023
MON89034 x TC1507 x MIR162 x NK603 x DAS-40278-9	Maize	Insect resistance Herbicide tolerance	Corteva Agriscience RSA	2023
DAS-44406-6 x DAS-81419-2	Soybean	Insect resistance Herbicide tolerance	Corteva Agriscience RSA	2022
DAS-44406-6	Soybean	Herbicide tolerance	Corteva Agriscience RSA	2022
MIR162	Maize	Insect resistance	Syngenta	2022
MON87701 x MON89788	Soybean	Insect resistance Herbicide tolerance	Bayer	2021
BT11 x MIR162 x GA21	Maize	Insect resistance Herbicide tolerance	Syngenta	2021
BT11 x MIR162 x MON89034 x GA21	Maize	Insect resistance Herbicide tolerance	Syngenta	2021
MON87427 x MON89034 x MIR162 x NK603	Maize	Insect resistance Herbicide tolerance	Bayer	2020
DAS-40278-9	Maize	Herbicide tolerance	DowAgroSciences	2019
DAS-40278-9 x NK603	Maize	Herbicide	DowAgroSciences	2019

		tolerance		
MON89034 x TC1507 x NK603 x DAS-40278-9	Maize	Insect resistance Herbicide tolerance	DowAgroSciences	2019
Innovax ND - IBD	Poultry vaccine	-	Intervet	2019
VaxSafe TMPM	Poultry vaccine	-	Protectachik	2019
MON89034 x TC1507 x NK603	Maize	Insect resistance Herbicide tolerance	DowAgroSciences	2018
Innovcax-ND	Vaccine	-	Intervet	2015
Vectormune HVT NDT & Ripens	Vaccine	-	Ceva Animal Health	2015
MON87460	Maize	Drought tolerant Antibiotic resistant	Monsanto	2015

5. The regulatory implications of new plant breeding technologies in South Africa

South Africa's Regulatory Approach for New Breeding Techniques
Department of Agriculture, Land Reform and Rural Development (DALRRD)

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

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

6. Genome editing research and activities in South Africa

South Africa realises that CRISPR gene editing technology is advancing rapidly, and that numerous African specific problems can benefit from this technology and biotechnology innovation.

CRISPR/Cas9 research at the Agricultural Research Council (ARC) - Biotechnology Platform

Project Title: Developing virus resistance in a cucurbit species (in collaboration with the University of Pretoria)

Aim: This study aims to develop virus resistance in a cucurbit species using single base pair editing. Virus diversity assessment is still underway. The virus diversity assessment has been completed. They are in the process of finalising the paper and getting the GE work is ongoing.

Project Title: Functional genomics towards development of resistance to the banana bunchy top virus in banana

Banana bunchy top disease (BBTD) is currently the most destructive viral disease of banana and there is

currently no natural resistance to banana bunchy top virus (BBTV), the causal agent, in the crop. It is present in several countries in Africa, Asia and Australia. There are 200 known virus resistance genes in plants and half of these are recessively inherited. This prominence of recessive genes for resistance to plant viruses stems from the specificity of plant-virus protein interactions that confer susceptibility. Disruption of these interactions by mutating the plant susceptibility factors may lead to virus resistance as demonstrated by resistance to potyviruses *via* natural and induced mutations in eIF4E genes in a number of plants. An RNASeq study was conducted to identify genes differentially expressed in response to BBTV.

They have long cloned the CRISPR/Cas9 vectors targeting some candidate virus susceptibility genes and are waiting for the banana suspension cells to be ready in order to do transformations. They are exploring a different transformation method, i.e transforming the apical meristems assisted by developmental regulators babyboom (Bbm) and wuschel (Wus) to enhance transformation events and circumvent formation of chimeras. They are also conducting plant-virus protein-protein interactions assays to determine other target genes.

Project title: Development of translation initiation factor-based potyvirus resistance to sweet potato virus disease in South Africa

Sweet potato (*Ipomoea batatas* Lam) is an important food crop in South Africa and is planted by smallholder and rural communities for household consumption and for income generation. Sweet potato virus disease (SPVD) is one of the most important viruses of sweet potato, associated with reduction in yields by 80% to 100%. The research proposes to identify virus strains associated with the potyvirus *Sweet potato feathery mottle virus* (SPFMV) and the crinivirus *Sweet potato chlorotic stunt virus* (SPCSV). A co-infection of the two viruses results in a condition called SPVD. The study also proposes to investigate the possibility of using CRISPR/Cas9 gene editing technology in attaining resistance to the potyvirus SPFMV, which will ultimately confer resistance to SPVD, due to the synergistic effects of the two viruses, which increases the concentration of SPFMV when the two viruses co-infect the plant. The strategy is to knock out eIF4E and eIF4G and their isoforms, whose knock out is well established in the literature to lead to resistance to potyviruses. eIF4E is a eukaryotic translation initiation factor involved in directing ribosomes to the cap structure of mRNAs. Almost all cellular mRNA require eIF4E in order to be translated into protein. The eIF4E polypeptide is the rate-limiting component of the eukaryotic translation apparatus and is involved in the mRNA-ribosome binding step of eukaryotic protein synthesis. Another subunit is eIF4G. Some viruses cut eIF4G in such a way that the eIF4E binding site is removed and the virus is able to translate its proteins without eIF4E. This is part of the development of integrated disease management strategies to minimize the effects of major viruses of sweet potato.

As indicated in the *Tour de Table* of last year, they conducted some transformations with very low efficiency. They have since been exploring methods to enhance transformation. This includes the use of a ternary vector (instead of binary) for *Agrobacterium*-transformation. The ternary vector expresses additional vir genes that enhance the infection of plant tissue by *Agrobacterium*. They are also finalising cloning of vectors expressing the developmental regulators Bbm and Wus to also assist with enhancing transformation efficiency. They expect to transform the explants towards the end of the year.
CRISPR/Cas9 research at the *Council for Scientific and Industrial Research (*CSIR) and the University of Pretoria

Project title: *N. benthamiana* GEd (subtilases)

In plants (*N. benthamiana*), they are working on transient genome editing of SBTs (subtilases), as well as histone deacetylases for recombinant protein expression improvement.

Project title: Crispr/Cas9 gene regulation in *Rhodococcus*

Nitriles are a potential source of vital acids and amides and serve an important role economically and commercially. Adiponitriles, which serve as starting material to produce polymer nylon and acrylonitrile, which in turn are used to manufacture plastics, are examples of significant nitriles. Due to the stable nature of nitriles, driven by their electronegative nitrogen atom that is attached to the electropositive carbon atom of the cyanide group, they require extreme conditions during their chemical conversion processes. A

greener approach was identified that combats the limitations of the chemical processes and it entailed the use of the enzymes nitrilases, which bioconvert nitriles to form acids and nitrile hydratases which bioconvert nitriles to amides. These enzymes are largely expressed in *Rhodococcus*. A strain of *Rhodococcus* was identified, namely, *Rhodococcus rhodochrous* ATCC BAA-870. This strain was found in soil samples that were collected from Modderfontein, Johannesburg, South Africa by a group of CSIR-Pretoria scientists and it was produced in fed-batch fermentations and several downstream unit operations were tested and optimised to produce active enzymes. However, while the wild-type strain and its partially purified enzyme biocatalyst can convert nitrile raw materials to the desired amide, some of this product is lost due to additional active amidase enzyme activity, which converts the desired product to its cognate acid. The aim of this study is to achieve CRISPR/dCas9-mediated transient downregulation of amidase and to design a nitrile hydratase hyperproducer using the vector pDD143 (Addgene). This will be achieved using site-directed mutagenesis to introduce the sgRNA's specific for amidase into the pDD143 vector, RT-qPCR to assess the downregulation in amidase expression and HPLC to assess the changes in amide/acid production from bioconversion reactions carried out by thec transformed strain. The second step of producing a nitrile hydratase hyper-producer will be achieved by adding the nitrile hydratase gene cluster into the best performing pDD143 vector and replacing the pDD143 arabinose-induced promoter (pBAD) with a constitutive promoter. The intended outcome of this study is to design an overall improved protocol of producing amides using nitrile hydratase, improving the current potential of biocatalysts and vector systems and to provide better understanding of the genetic material of this newfound strain.

Project Title: Investigating the role of sirtuin expression during transient recombinant protein production in *Nicotiana benthamiana*

Nicotiana benthamiana plants are regularly used to express desired recombinant proteins transiently. However, two main drawbacks affect plant expression systems: lower protein yields and degradation. Sirtuins (SRTs) are enzymes that regulate gene expression by modifying DNA packaging through histone deacetylation. In *Arabidopsis*, reducing the expression of these epigenetic regulators leads to a less compact chromatin structure and increases transcription. The effect of SRTs on transient protein production in *N. benthamiana* has not yet been demonstrated.

For this project, cDNA sequences of *NbSRT1* and *NbSRT2* were identified and compared with their homologs from *Arabidopsis thaliana*. Appropriate target sequences were then designed and cloned into two single guide RNA (sgRNA) expressing vectors. The CRISPR/Cas9 and sgRNA-containing constructs were transformed into *Agrobacterium tumefaciens* and co-infiltrated into the leaves of *N. benthamiana* along with a green fluorescent protein (GFP) expression vector. RNA extractions and RT-qPCR are underway to determine the effects of downregulating *NbSRT* genes and if this impacts GFP expression. The transient use of CRISPR/Cas9 to downregulate a gene of interest offers a quick method to evaluate the effect on protein yield before attempting to produce stable transformants.

CRISPR research at the Stellenbosch University

Introduce resistance to potato virus Y by mutating eukaryotic initiation factor 4E (eIF4E) genes. They are just starting to transform potato and they are hoping that this will lead to mutants affecting starch degradation and virus resistance. The project is ongoing.

Repress cold induced sweetening by blocking starch degradation through mutation of the glucan water dikinase 1 (GWD1) gene. The project is ongoing.

They were trying to establish protoplast regeneration so that they have a non-transgenic way of making the mutants, but they have also started a transgenic approach, transforming potatoes with constructs to mutate GWD1. The project is ongoing.

They continue to work on starch phosphorylase also for cold induced sweetening purposes. They will do this in both potato and *Nicotiana tabacum*. The projects are still ongoing.

CRISPR research in the Vitis Lab at Stellenbosch University

They have published a paper titled 'A combined recombinase polymerase amplification CRISPR/ Cas12a assay for detection of *Fusarium oxysporum* f. sp. *cubense* tropical race 4.

Citation

Megan Ceris Matthews, Jos van der Linden, Isabelle Robène, Samuel Rozsasi, Beatrix Coetzee, Manuela Campa, Johan Burger, Uzoma Nobel Akwuruoha, Ndubuisi Johnkennedy Madufor, Willem Perold, Umezuruike Linus Opara, Altus Viljoen and Diane Mostert (2025). A combined recombinase polymerase amplification CRISPR/Cas12a assay for detection of *Fusarium oxysporum* f. sp. *cubense* tropical race 4. Scientific Reports 15: 2436: https://doi.org/10.1038/s41598-025-85633-8

The soilborne pathogen *Fusarium oxysporum* f. sp. *cubense* tropical race 4 (Foc TR4) is currently devastating banana production worldwide. Once introduced, it is not possible to eradicate the pathogen from soils where it can survive for decades. The only management option available then is to replace Foc TR4-susceptible with -resistant varieties. Timely detection of the pathogen, however, is an important strategy to prevent the introduction of Foc TR4 into new areas and prevent its spread from infested sites. In this study, a single-tube detection technique was developed by combining recombinase polymerase amplification (RPA) and clustered regularly interspaced short palindromic repeats (CRISPR)/Cas12a technology (RPA-Cas12a) for detection of Foc TR4. The RPA-Cas12a assay was conducted isothermally, had a sensitivity of up to 10 fg target DNA and did not cross react with any of the 76 non-target isolates included in the specificity testing. The RPA-Cas12a assay detected Foc TR4 from naturally infected banana samples collected in the field and visualization was possible with the naked eye under LED blue light transillumination. The method can be integrated with inexpensive fluorescent or electronic detection devices to accelerate Foc TR4 in-field detection and, thereby, fast-track disease containment strategies.

Grapevine

The negative economic impact of biotic and abiotic stresses in vines are recognised by the international viticulture industry. The rapid developments in genome editing technologies over the last few years, and especially the versatility demonstrated in many applications of CRISPR/Cas9-based technology, may impact radically in the ongoing battle with most of these conditions in vineyards all over the world. As a first step to unlock the immense potential of this technology in the local industry, the project aimed to establish CRISPR technology in grapevine.

They successfully edited grapevine and they are continuing with the characterization of edited grapevine plants for drought and pathogen tolerance. They are also starting with traits more linked to quality.

They are also starting to look into base editors and prime editors in grapevine and to DNA-free genome editing methods in both grapevine and potato.

They are continuing with their work on using viruses as a way to deliver CRISPR components and on the other hand on the use of CRISPR to detect viruses.

Publication: University of Pretoria

Abkallo, H.M., Arbuthnot, P., Auer, T.O. *et al*. Making genome editing a success story in Africa. *Nat Biotechnol* 42, 551–554 (2024). https://doi.org/10.1038/s41587-024-02187-2

OECD *Tour de Table*: Sharing of information on NPBTs in South Africa

When Dr D Oelofse (ARC) requested information from some of the stakeholders on research being performed using NPBTs in South Africa, they all again expressed their continued interest in receiving the information on NPBTs contained in the OECD *Tour de Table*, as submitted by the delegations attending the OECD Working Party on the Harmonisation of Regulatory Oversight in Biotechnology (WP-HROB) and the OECD Working Party on the Safety of Novel Foods and Feeds (WP-SNFF) meetings.

South African database on genome editing

Biosafety South Africa continuously updates the South African database on people who are working on genome editing, as this information is not that easy to obtain, because the plant genome editing community in South Africa is still small. This will continue to assist in the gathering and sharing of information on genome editing research being performed in South Africa at the OECD WP-HROB and the OECD WP-SNFF meetings. This is important because it was previously agreed that delegations will continue with information sharing on NPBTs and other new technologies at these meetings, and that delegations will include in the written *Tour de Table* their experiences in NPBTs and other new technologies.

7. LLP

[Please note that this is not an official statement from the South African Government and that I am not the authorised focal point to speak on the matter, but that this is my understanding of the local situation in South Africa]

South Africa continues to participate in ongoing discussions regarding LLP, and endorses the international statement on LLPs, mindful that we are both importers and, albeit, to a lesser extent, exporters of GMOs. We remain convinced that all risk assessments and management should be based on relevant science and that no arbitrary distinction should be made between food and feed. South Africa has a LLP tolerance of only one percent. However, if the product is milled or otherwise processed, there are usually no importation problems. Rather than testing for unapproved events, import permits are issued for the import of GE consignments, irrespective of the crop and country, provided the exporting country has approved the same or less number and type of events as South Africa.

8. Usefulness of the OECD Biology documents

Biosafety South Africa (https://biosafety.org.za/) is a national technology platform in service of the country's biotech regulators, researchers, technology developers and public.

Their mandate is to enable safe, sustainable and compliant research, development, production, use and application of biotechnology - in particular GMOs. They are an initiative of the Department of Science and Technology (DST) and funded entirely from public sources.

They assist and advise all biosafety stakeholders with regard to regulatory compliance, biosafety and risk analysis best practice and sustainable biotech innovation.

They promote biosafety research and development in support of the national policy and regulatory frameworks and to ensure effective risk management.

They encourage sustainable biotech innovation by creating and enabling environment and investing in the biosafety/sustainability development of biotech products.

They help develop national and regional capacity in sustainability research and development and risk analysis, because they realise that biosafety systems are only as good as the people managing them. They are passionate about communicating the science behind biosafety and biotechnology to all stakeholders; providing answers across the whole spectrum, from the public's general questions to the technical enquiries of biosafety practitioners.

Environmental risk/safety assessments of genetically modified (GM) or genetically engineered (GE) plants are based on a broad body of knowledge and experience with the untransformed species (variety, etc.), i.e. familiarity with the conventional crop plant. The intent of a biology document is to describe portions of this body of knowledge directly relevant to risk/safety assessment in a format readily accessible to regulators.

The biology document is not an environmental risk/safety assessment of the species. Rather, the document provides an overview of pertinent biological information of the untransformed species to help define the baseline and scope (the comparator against which transformed organisms will be compared), in the risk/safety assessment of the transformed organism. Biology documents are not detailed crop handbooks or manuals of agricultural or silvicultural practice or economic botany, but rather focus on the biological information and data that may be clearly relevant to the assessment of newly transformed plants.

Biology documents are categorised into several sections. The sections range from species-specific information to information on the potential effects of the crop species on human health and biosafety. The information contained in the biology document is essentially an assessment of the information pertinent to the environmental risk assessment from collective peer-reviewed sources. In addition, a useful list of references and appendices are usually included at the end of each document.

They indicate that the Organisation of Economic Cooperation and Development's (OECD's) (right click to open the hyperlink to the full list of consensus documents for the WP-HROB) consensus documents for the work on harmonising the regulatory oversight in biotechnology are probably one of the best resources available to risk assessors. The OECD's consensus biology documents relevant to South African GM crops can be accessed directly from their website:

1. Maize
2. Cotton
3. Potato
4. Soybean
5. Sugarcane

25 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 2024, fifty (50) new facilities for different contained use activities have been submitted in Spain to the Competent Authorities (Interministerial Council of GMO or Regional Government, depending on the competent authority procedure) and assessed by the risk assessment competent authority, the National Biosafety Commission (29 of biosafety level (BSL) 1, 20 of BSL 2 and 1 of BSL 3).

141 different activities have been notified to be carried out in these facilities: 29 are classified as risk 1 (BSL 1); 103 as risk 2 (BSL2) and 11 as biological level of risk 3 activities (BSL3).

The GMOs used in these activities are genetically modified viruses or viruses infecting/transfecting human or animal cells lines (42) and animals (including animal cell lines, 43), followed by bacteria (29), virus (19), plants (5), parasites (2) and fungus (1).

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 April 2023, thirty-one (31) 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 Government) and assessed by the National Biosafety Commission:

- Eleven (11) field trials with plants: (one (1) genetically modified rice, three (3) CRISPR/Cas maize and nine (9) genetically modified tobacco as biofactory plants to produce industrially useful substances, some of them produce with genome editing.

- On the other hand, thirty (20) human clinical trials have been notified. Some of them (6) are different genetically modified viruses (Adenovirus, AAV, MVA, VIH, etc.), and others (14) were developed using human cells (T lymphocytes, CAR-T).

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 2023 regarding the placing on the market of GMO´s.

In 2024, the growing surface for Bt maize (MON810) in Spain was 69.411,32 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

2.1 Legal framework applicable to GMOs

There are no new regulations and guidance since April 2023. The legislative framework and other related information are regularly updated in the following official webpage:

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

2.2 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

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 24 years of growing in the main northeast maize cropping area in Spain.

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.

5. 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)

6. Research projects on biosafety; relevant publications

In Spain there is a State Plan of scientific and technical research and Innovation (PEICTI).

The PEICTI 2024-2027 comprises different state programs and include the state aid for R&D&I implemented by the State Administration in different fields, including biotechnology.

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

2. Updates regarding international activities

Spain is a Part to Cartagena Protocol on Biosafety. Therefore, national experts usually had participated in different activities derived from COP and COP-MOP meetings, and in on-line forums and other events, as well.

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

The Ministry of Agriculture, Fisheries and Food regularly updates the information related to GMO in the Information Exchange Center 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 through the following link:

https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/omg/protocolo-cartagena/

In addition, the Ministry of Agriculture, Fisheries and Food attends the meetings of the Working Group of the International Environmental Affairs Council on Biosafety of the European Council.

Delegates from the Ministry of Agriculture, Fisheries and Food, and from the Ministry for Ecological Transition and de Demographic Challenge have attended and actively participated at the meetings of the Convention on Biological Diversity (CBD) (Cali, Colombia, 21 October-1 November 2024) – COP 16 to the CBD – COP-MOP 11 serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety – COP-MOP 4 serving as the Meeting of the Parties to the Nagoya Protocol on Access and Benefit Sharing.

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). This initiative applies to plants produced through directed mutagenesis and cisgenesis, to food and feed and other products derived from these plants.

Negotiation of this proposal began during the Spanish Presidency of the Council of the European Union, in the Working Group on Genetic Resources and Innovation in Agriculture. The dossier is still on discussion in the Council. Representatives of the Ministry of Agriculture, Food and Fisheries attend Council´s meetings.

In the context of these negotiations, in Spain, a working group of scientific experts on this matter was created, within the framework of the National Biosafety Commission. This *Ad-hoc* group of experts provide scientific advice to the Interministerial Council of GMOs as regards certain parts of the NGT proposal, but mainly those aspects related to the Annex I on equivalence criteria between plants obtained by NGT and those conventional ones.

The National Commission of Biosafety and the Interministerial Council of GMO continue to evaluate/process applications for contained use and deliberate release of organisms obtained by new genomic techniques (such as genetic editing techniques) under national GMO regulation, based on the European Court of Justice ruling of 25th July 2018.

4. Any other information related to NBTs.

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 an 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

26 United Kingdom

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

Full 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 2024.

23/R08/01:

A field trial by Rothamsted Research of a genetically modified Camelina sativa. The Camelina has been modified to accumulate non-native lipids in their seeds (such as Omega-3, long chain polyunsaturated fatty acids and ketocarotenoids), or for variations in the accumulation of native fatty acids. The trial aims to determine the performance of the GM Camelina in the field, with respect to oil composition and quality, and other aspects of seed composition.

162 public representations were received for this trial.

Consent granted on 25th March 2024.

24/R56/01:

A multi-site Phase III clinical trial by Sanofi Pasteur, Inc. of a genetically modified Respiratory Syncytial Virus (RSV) vaccine. This is an international, large-scale trial in 0-24 month old infants of a RSV vaccine strain containing three separate, attenuating genetic modifications.

No public representations were received for this trial.

Granted consent 15th April 2024

Variation to consent requested to change and add release sites.

Variation granted in September 2024.

24/R57/01:

A field trial by the University of Oxford of 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. It is a 1-year trial at 4 sites across England: Harpenden (Hertfordshire), Bury St Edmunds (Suffolk), Norwich (Norfolk), and Cambridge (Cambridgeshire)

No public representations were received for this trial.

Granted consent: 23rd January 2025

Variations to previous Deliberate Release Applications

17/R29/01:

Consent held by The Sainsbury Laboratory to release GM potatoes modified using resistance genes from wild potato relatives with the aim to improve late blight (*Phytophthora infestans*) resistance.

Variation requested for the early termination of the post-trial monitoring and disposal via deep burial of the topsoil of the trial sites. This is to allow for building developments on the trial sites.

Variation granted: 23rd May 2024

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 add two additional trial sites and to increase the maximum area of GMOs that may be grown per year up to 6000m^2.

Variation granted: 22nd May 2024

Deliberate release for Marketing purposes

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.

- A vaccine against a mosquito-borne virus. Defra/HSE have provided a considered opinion on this and were content with the risk associated with its intended use.
- A gene therapy treatment which utilises a recombinant Adeno-Associated Virus vector. The sponsor has provided the environmental risk assessment and clinical trial results data to Defra/HSE.
- A medicinal product to treat Leukaemia. The review of this product has not begun.

Contained Use

The Health and Safety Executive (HSE) received 138 notifications for contained use activities. This consisted of 123 new notifications and 15 significant changes to existing notifications, as outlined below.

Notifier Types	Class 1	Class 2	Class 3	Class 4
Academia (inc. Research Institutes)	1	44	11	0
Commercial	34	42	0	0
Healthcare	2	1	0	0
Other (e.g. Government)	0	1	2	0
Total	**37**	**88**	**13**	**0**
Significant changes to existing notifications	0	10	5	0

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

WHO SARS-CoV2 Revised Guidance

World Health Organization (WHO) issued updated guidance relating to laboratory activities using SARS-CoV2. The changes mean certain activities which were previously at Biosafety Level (BSL)-3 can now be undertaken at BSL-2. HSE was asked if GB are to follow the WHO approach, so sought expert scientific opinions from the Advisory Committee on Dangerous Pathogens (ACDP).

ACDP supported the view that current circulating SARS-CoV-2 variants could be handled at Containment Level (CL) 2, but had concerns that new variants might present a different risk. A strain dependent classification of SARS-CoV2 will require a framework detailing what determines a Hazard Group (HG)2 or HG3 strain. A working group is being set up to establish this framework, and HSE intends to include expert representatives from the Scientific Advisory Committee on Genetic Modification (SACGM) to consider the effects on GM Contained Use Regulations.

WHO Global Action Plan for Poliovirus Containment

To minimise the risk of a release from a facility where polioviruses (PV) are handled the WHO launched the Global Action Plan for Poliovirus Containment (GAPIV). The UK Government have committed to the implementation of GAPIV; facilities wishing to retain polioviruses post-eradication are encouraged to be certified by WHO in a process involving HSE. Currently only one facility in GB has entered into the GAPIV certification programme, although polioviruses are currently held in 5 others.

In July 2024 WHO declared that facilities holding wild or vaccine-derived PV1 or PV3 must enter into the GAPIV certification scheme immediately. Because of this ACDP decided the hazard categorisation of PV1 and PV3 should be increased from HG2 to HG3. As such, work with PV1 and PV3 will need to be undertaken at CL3.

3. Public engagement and outreach activities

Engineering Biology Regulatory Networks

Defra and the HSE are members of the cross-Whitehall Group for Engineering Biology and the Engineering Biology Regulators Network (EBRN) and continue to support the development of government initiatives and guidance on Engineering Biology and related technologies.

Engineering Biology is currently one of the four key areas of focus for the Regulatory Innovation Office (RIO). RIO was established in October 2024, with the remit of cutting red tape to speed up access to new technologies. RIO commissioned the Regulatory Horizons Council (RHC) to produce a report on the regulation of Engineering Biology which was published in January 2025.

2. Developments related to new breeding techniques (NBTs)

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

Precision Breeding Act Secondary Legislation (Laid before UK parliament on 25th February 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.

Reference	Project Title
24/Q03	Field assessment of dwarfed diploid potato lines.
24/Q04	Tomatoes optimized for indoor growth.
24/Q05	Demonstration of low asparagine, low acrylamide, genome edited wheat (*Triticum aestivum*) and high lipid genome edited barley (*Hordeum vulgare*) at an agricultural show
24/Q06	Precision-bred cisgenic Camelina with improved agronomic performance
24/Q07	Precision-bred high α-linolenic acid Camelina
25/Q01	Tomatoes optimized for indoor growth.
25/Q02	Improved tomato harvesting.
25/Q03	Eliminating tuber browning.
25/Q04 (awaiting publishing)	Field scale trials of CADENZA low asparagine PBO lines 23 (ACRYLOW Cadenza (PBO) 23) and 59 (ACRYLOW Cadenza (PBO) 59).

3. Any other information related to NBTs.

Following requests for guidance and further information from developers, Defra has produced technical guidance setting out best practices for those notifying under QHP notifications: Notifying under qualifying higher plant notifications: guidance for developers.

The guidance is based off the findings and feedback from early adopters of NBT technologies in England and covers:

- preparation, handling and storage of QHP material
- advice on diagnostic tests to check for transgenic material
- best practice for field trials to ensure QHP material is not marketed such as isolation distances, pollen barriers and post-harvest monitoring periods

It is intended that the regulations covering QHP notifications will be revoked and replaced by the Precision Breeding regulations, if passed by Parliament. The QHP guidance will therefore be replaced and expanded on by the following guidance (currently published in draft form):

- Producing precision bred organisms
- Release notices for precision bred organisms
- Marketing notices for precision bred organisms
- Releasing precision bred plants into the environment in research and development trials
- Technical guidance to applicants for the authorisation of Precision Bred Organisms for food and feed

27 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.*** Effective on December 2, 2024, the United States District Court for the Northern District of California, prospectively vacated the U.S. Department of Agriculture (USDA) final rule (7 CFR part 340) issued in May 2020 for organisms developed using genetic engineering. Regulatory Status Review responses, Confirmation Request responses, and active permits that USDA issued prior to December 2, 2024, remain valid.

  APHIS now regulates modified organisms under the prior 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 is not subject to regulation by submitting an Am I Regulated inquiry.

  On December 19, 2024, APHIS restarted the *Am I Regulated* Process. On January 10, 2025, APHIS began issuing permits. On February 7, 2025, APHIS restarted the notification procedure. Notifications are a streamlined alternative to permits for regulated articles meeting specified eligibility criteria and pre-defined performance standards under 7 CFR § 340.3. On March 3, 2025, APHIS announced it would begin to accept petitions for nonregulated status.

  Weblink for more information on USDA-APHIS biotechnology regulations:
  https://www.aphis.usda.gov/biotechnology/regulations

- ***Modified Organisms Not Subject to Regulation.***

  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 is currently accepting *Am I Regulated* inquiries and since re-initiating the process, has published 35 responses as of May 1, 2025.

  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 May 1, 2025 there are 3 pending petition reviews:1) SUNY ESF Blight Tolerant Chestnut, 2) Bayer Stacked 5 Herbicide Resistant Corn, and 3) Bayer Insect 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.

Developers could voluntarily request USDA-APHIS confirm whether a modified plant qualified for an exemption and was not subject to the regulations under the vacated 7 CFR part 340. USDA-APHIS provided a written response ("confirmation letter") within 120 days of receiving a sufficiently detailed confirmation request. USDA-APHIS posted both the confirmation requests and the issued confirmation letters on its website, with redactions to protect Confidential Business Information and Personal Identifying Information, as appropriate. In total, USDA-APHIS issued 99 responses to confirmation request letters.

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.

The RSR process involved two distinct review steps: an initial review step and a plant pest risk assessment (PPRA) step. USDA-APHIS conducted an initial review of the plant within 180 days of receiving a request for the RSR, except in circumstances that could not reasonably have been anticipated. If USDA-APHIS did not identify a plausible pathway by which the plant or its sexually compatible relatives would pose an increased plant pest risk relative to the comparator(s) in the initial review, USDA-APHIS concluded that the modified plant is unlikely to pose an increased plant pest risk, and the modified plant is not subject to the regulations in 7 CFR part 340. In this case, USDA-APHIS posted the RSR request and the plant, trait, and the general description of the Mechanism of Action (MOA) on the USDA-APHIS website.

If USDA-APHIS did identify a plausible pathway by which the plant or its sexually compatible relatives would pose an increased plant pest risk relative to the comparator(s) in the initial review, the requestor could ask that USDA-APHIS conduct a Plant Pest Risk Assessment (PPRA) to evaluate the factor(s) of concern identified in the initial review to determine the likelihood and consequence of the plausible increased plant pest risk. For those plants for which a PPRA was conducted, and USDA-APHIS did not reach a preliminary finding that the plant is unlikely to pose an increased plant pest risk, the plant

would remain subject to the revised regulations. Alternatively, if USDA-APHIS reached a preliminary finding that the plant is unlikely to pose an increased plant pest risk, USDA-APHIS published the RSR request and the preliminary PPRA in the *Federal Register* and solicited and reviewed comments from the public. If, after reviewing the comments and other information it received related to the preliminary PPRA, USDA-APHIS determined the plant and its sexually compatible relatives are unlikely to pose an increased plant pest risk relative to their comparator(s), the plant was not subject to 7 CFR part 340. USDA-APHIS announced such a finding in a second *Federal Register* notice and posted it on its website along with the original request and the final PPRA.

APHIS began accepting RSR requests in 2021 and published the first RSR response in September 2022. 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) 2024 (10/1/2023 through 09/30/2024), APHIS received 986 permit applications for import, interstate movement, and environmental release through eFile, an automated system for submitting requests. Of those, APHIS issued 845 permits. In addition, 3 applications are pending and 138 were withdrawn. During the portion of FY 2025 that has currently elapsed (10/1/2024 through 05/01/2025), APHIS has received 691 authorizations. Of those, APHIS issued 546 permits and acknowledged 27 notifications. In addition, 20 authorizations are pending, and 98 were withdrawn.

- ***Compliance and oversight.*** From October 1, 2023 through September 30, 2024, USDA-APHIS BRS and Plant Protection and Quarantine (PPQ), along with state partners completed 542 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.

❖ ***2024 USDA-APHIS Stakeholder Meeting.*** On November 14, 2024, 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 provided updates on the Regulatory Status Review and Confirmation Request processes and shared updates on other activities, including permitting, modified microorganisms, international efforts, and priorities for FY 2025. 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 over past calendar year

	Product/Event name	Active ingredient	Plant	Purpose
Registrations	MON95379	Cry1B.868 Cry1Da_7	Corn	Seed increase
	DP915635	IPD079Ea	Corn	Seed increase
	DP23211	DvSSJ1 dsRNA, IPD072Aa	Corn	Seed increase
	DAS1131	Cry1Da2	Corn	Seed increase
	DP910521	Cry1B.34	Corn	Seed increase
	MON 95275	Mpp75Aa1.1, Vpb4Da2, DvSnf7.1 dsRNA	Corn	Seed increase
Experimental Use Permits	MON 95275	Mpp75Aa1.1, Vpb4Da2, DvSnf7.1 dsRNA	Corn	Generate data for registration
	Simplot – BG25 “Gen 3 potato”	PVY dsRNA	Potato	Generate data for registration (extension)

❖ **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
    - EPA has since exempted 6 PIPs under this rule. 3 in citrus and 3 in potato.

Office of Pollution Prevention and Toxics (OPPT)

❖ **Reviewed Biotechnology Submissions**

In the last fiscal year, FY24 (Oct. 1, 2023 to Sept. 30, 2024), the U.S. EPA/OPPT, under the authority of the Toxic Substances Control Act (TSCA), reviewed the closed-system manufacture/import of 18 genetically engineered microbial strains submitted in Microbial Commercial Activity Notices (MCANs). The identity of some of these microorganisms was claimed as confidential. The non-confidential microorganism names of 11 of those strains was *Saccharomyces cerevisiae.* The non-confidential uses of several strains whose identity was claimed as confidential were chemical production, production of a chemical substance, or biopolymer production. A determination of “not likely to present an unreasonable risk to health or the environment” was made for all these 18 genetically engineered strains. OPPT also reviewed one TSCA Experimental Release Application (TERA) which is the submission needed for environmental introduction of genetically engineered microorganisms for research and development purposes. The TERA was for open pond testing of a strain of the yellow-green microalga, *Nannochloropisis oceanica* with an introduced bicarbonate transporter – green fluorescent protein fusion gene. The purpose of this open pond testing was to compare the

productivity and carbon utilization efficiency of the engineered strain with the recipient microorganism outdoors in real-world cultivation conditions. This TERA was approved based on the determination that the proposed activity did not present an unreasonable risk to health or the environment.

❖ **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. Canada will present a report on the document's status and revision issues at the 39th WP-HROB Meeting (Mar. 24-26, 2025). After the meeting further discussions with the delegates will occur prior to finalization of the document and then declassification.

2. International Activities

Updates for the United States Department of Agriculture (USDA)

1. USDA participated in 30 international meetings in 2024 to discuss technical topics related to the regulation of the products of biotechnology, meeting with regulators, reviewers, students, and scientists from more than 40 countries.
2. USDA hosted meetings with foreign regulators to discuss updates of regulations and confer on technical issues that we have encountered. In 2024, regulators from Japan, South Korea, Thailand, Georgia, and Pakistan 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 24-25, 2024. 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, APHIS has confirmed that 32 genome edited organisms are not regulated out of 35 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

28 European Union

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

i. Risk assessment

Since 1st March 2024, the European Food Safety Authority (EFSA GMO Panel) has adopted and published 9 new scientific opinions, of which 2 concern renewal of authorisations:

- AP 159 EFSA-Q-2019-00419 (maize DP-202216-6)
- AP 182 EFSA-Q-2023-00106 (maize MON 94804)
- AP 173 EFSA-Q-2022-00330 (maize MON95275)
- AP 174 GMFF-2021-2473 (maize DP910521)
- AP 162 EFSA-Q-2022-00031 (soy leghemoglobin)
- AP 126 EFSA-Q-2015-00548 (GM soybean MON 87705 × MON 87708 × MON 89788)
- AP 179 GMFF-2021-0071 (GM maize DP51291)

- RX-27 EFSA-Q-2022-00845 (maize MON 89034 x 1507 x MON 88017 x 59122)
- RX-29 EFSA-Q-2022-00868 (maize MON89034×1507xNK603)

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 2024, the European Commission has authorised 4 GM food and feed and has renewed 3 authorisations (including 8 sub-combinations).

New authorisations:

- Maize DP23211
- Maize DP915635
- Maize DP202216
- Cotton COT102

Renewals:

- Maize MON 810

- Maize MON 89034 × 1507 x NK603
- Maize MON 89034 × 1507 × MON 88017 × 59122 and eight of its sub-combinations

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

Since previous meeting, EFSA has adopted a *Technical Note on the quality of DNA sequencing for the molecular characterisation of genetically modified plants* https://open.efsa.europa.eu/questions/EFSA-Q-2023-00886. All EFSA guidance documents applicable to GMOs can be accessed online.

5. Public engagement and outreach activities

EFSA public outreach:

- EFSA is in close contact with its industry stakeholders in the GMO area. In 2024 EFSA organised two Stakeholder's meetings: 8th of April (online) and 7-8th October (in presence) to address concerns and explain in detail the following scientific topics: Protein Safety, Bioinformatics, RNA Interference, Human Dietary Exposure, Toxicology).
- Webinar on new developments in biotechnology, including SynBio and NGTs, applied to animals for food, feed and other agricultural uses [18th February 2025]
- Webinar on draft opinion: Protein safety assessment in genetically modified plants, under public consultation [4th February 2025]
- Webinar: Draft guidance on the characterisation and risk assessment of microorganisms used in the food chain [17th December 2024]
- 18th Meeting of the GMO Network [27th November 2024] Covered Topics: NGT, EFSA OMICS roadmap, Protein Safety
- 17th Meeting of the GMO Network [30-31st May 2024] Covered Topics: NGT animals, NGT micro-organisms,
- Public Consultation with deadline 12th of March 2025 was launched on the 15th of January 2025 on the "Draft scientific opinion on current practice, challenges, and future opportunities in the safety assessment of newly expressed proteins in genetically modified plants"
- Public Consultation with deadline 12th of March 2025 was launched on the 15th of January 2025 on the "Draft scientific opinion on new developments in biotechnology applied to animals: an assessment of the adequacy and sufficiency of current EFSA guidance for animal risk assessment"

European Commission public outreach:

- Each Scientific opinion on GM products 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
- For further public engagement and outreach activities related to new genomic techniques, see section 3 and the Commission's contribution to the Enhanced Information Exchange on New Breeding Techniques (NGTs).

3. Developments related to new breeding techniques (NBTs)

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

In the European Union, products of NBTs (usually referred to as new genomic techniques, NGTs, in the EU) are subject to the legislation on genetically modified organisms (GMOs) which is contained in several main legislative acts (Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No 1830/2003, Directive 2009/41/EC). 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.

On 5 July 2023, the European Commission adopted a legislative proposal for a regulation on plants produced by certain new genomic techniques (NGTs) and their food and feed. The proposal is part of a package of proposals to ensure sustainable use of the EU's natural resources, resilient EU food systems and farming as well as long-term economic, social, health and environmental benefits.

The proposal sets out specific rules for the deliberate release into the environment for any other purpose than placing on the market of plants obtained by targeted mutagenesis and cisgenesis (including intragenesis) and for the placing on the market of food and feed containing, consisting of or produced from such plants, and of products, other than food or feed, containing or consisting of such plants ('NGT plants and products'). Transgenic plants are not included in the scope of the proposal. More detail on the content of the proposal can be found following the above link to the legislative proposal or in the European Commission’s contribution to the 2024 questionnaire.

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

2. Specific cases of application, assessment and decision

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

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)”

29 Business at OECD (BIAC)

1. Developments related to biosafety activities

Reports and technical resources:

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

AgbioInvestor GM Monitor

In 2024, the AgbioInvestor GM Monitor, supported by CropLife International, continues to be updated with new approvals. 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. This new database complements other resources supported by CropLife International such asBioTradeStatus which provides market status information on commercialized GM crops developed by CropLife International member companies.

Updates to Other Databases

CropLife International and its member companies continue to maintain the Detection Methods Database and the Celiac Peptide Database, a list of peptides that have been implicated in triggering celiac disease.

Position Papers

A new position paper on the importance of high covers low policies in the assessment of stacked trait products was published on the CropLife International website in May 2024.

Global Communications Resources

In 2024 CropLife International launched a 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 periodically updating content with new data.

2. Updates regarding international activities

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

CropLife International continues to lead engagement in ongoing negotiations impacting the plant science industry under the UN Convention on Biological Diversity, Cartagena Protocol on Biosafety and Nagoya Protocol on Access and Benefit-sharing (ABS). To that end, CropLife International, represented by its member companies and its global network of partner organizations were pleased to participate in the meetings of the Convention on Biological Diversity (COP-16) and its Protocols in October 2024 and February 2025 where they encouraged the adoption of decisions firmly grounded in science, allowing for the use of modern agricultural practices and tools in ways that support biodiversity conservation and sustainability.

A notable recent outcome of a long-running project of the WP-HROB was the publication of a *Consensus Document on Environmental Considerations for the Release of Transgenic Plants* (OECD 2023). This builds upon the foundational principles established in the early OECD biosafety work to describe an approach to planning and structuring an environmental risk/safety assessment termed "problem formulation" (OECD 2023). This document was critical to inform the development of additional voluntary guidance materials under the Cartagena Protocol to support the case-by-case risk assessment of living modified organisms containing engineered gene drives. Notably this is the first such guidance to utilize a problem formulation approach and the first developed under the Cartagena Protocol to be "welcomed" by the Parties at their 11th meeting (COP/MOP-11).

Additionally, CropLife International engaged in negotiations at COP/MOP-11 and COP-16 on a number of other technical and policy issues relevant to the work of the WP-HROB, including negotiations on: indicators for the monitoring framework of Target 17 on focused on strengthening biosafety and distributing the benefits of biotechnology; detection and identification of living modified organisms; and the future of work under the Convention related to products of synthetic biology.

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 methods[2]. 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.

[2] https://worldseed.org/document/plant-breeding-innovation-consistent-criteria-for-the-scope-of-regulatory-oversight/

We note the establishment of genome editing regulatory processes in 27 jurisdictions worldwide (see ISF PBI Policy map in the ISF statement "A Call for Policy Actions to Foster Plant Breeding Innovation") as well as the ongoing policy developments in a number of other countries, including the EU, Burkina Faso, Indonesia, Malaysia, Pakistan, South Korea, Switzerland and New Zealand. The adoption of clear and future-proofed regulations will support all players in the seed and agri-food sectors. Such regulatory frameworks will enable improved access of growers to high-quality seed, will drive innovation, and foster sustainability in agriculture.

It's imperative to maintain a focus on practical implementation of regulatory policy and guidance such that investment and development of new varieties using these technologies is fully enabled. In this context, the International Seed Federation (ISF) has published a statement emphasizing global experiences with Plant Breeding Innovation policies. The statement highlights key insights from developers and provides a comprehensive overview of **pre-market, post-market, and trade incentive** experiences worldwide. By showcasing practical examples from various regulatory frameworks, the ISF aims to foster a more harmonized and supportive policy environment for innovation in plant breeding. For a deeper dive into these findings, you can access the full statement here: A Call for Policy Actions to Foster Plant Breeding Innovation

The global seed sector recognizes the importance of timely information sharing around plant breeding tools, both at the international and national levels. We support initiatives that provide relevant information to governments, the value chain, and consumers, provided such efforts are both achievable by all users of genome editing in all jurisdictions and that information is not arbitrarily discriminatory toward certain plant breeding approaches versus others. We further note that the content and appropriate systems to share such information are driven, in part, by local context (e.g. national laws) and believe that there is no "one size fits all" solution but rather a collection of reliable information sources. CropLife International further explains its position on transparency in plant breeding in a position paper available on its website.

Global Communications Resources on Genome Editing

The International Seed Federation continues to update 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.

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

30 Secretariat of the Convention on Biological Diversity (UNEP-CBD)

Developments related to biosafety activities

The eleventh meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 11) was held in three parts. The first part was held from 21 October to 1 November 2024 in Cali, Colombia, the second part was held from 3 to 6 December 2024 online and the third part was held from 25 to 27 February 2025 in Rome, Italy, in parallel with the sixteenth meeting of the Conference of the Parties to the Convention on Biodiversity and the fifth meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization.

The eleventh meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety adopted several key decisions for the enhanced implementation of the Cartagena Protocol on Biosafety.

- Compliance Mechanisms: Strengthening compliance by encouraging Parties to submit their national reports and adhere to Protocol obligations. Decision CP-11/1 addresses compliance issues, urging Parties to fulfill their reporting duties. The COP-MOP encouraged Parties to submit information regarding national legislation, regulations and guidelines on new developments in modern biotechnology that are relevant to the Cartagena Protocol. It requested the Secretariat to compile the information and submit it to the COP-MOP, for consideration at its twelfth meeting.
- Financial Mechanisms and Resource Mobilization: Enhancing financial support for developing countries to implement biosafety measures. Decision CP-11/2 focuses on matters related to the financial mechanism and resources and requests the GEF to further explore modalities to reform its operations, including through the consideration of ways to increase funds dedicated to the implementation of the Cartagena Protocol and the use of global and regional projects, and to report on those matters to COP-MOP 12.
- Biosafety Clearing-House (BCH) Operations: Improving the functionality and accessibility of the BCH to facilitate information exchange on living modified organisms (LMOs). Decision CP-11/3 pertains to the operation and activities of the BCH.
- Risk Assessment and Risk Management: Advancing guidance on risk assessment and management of LMOs. Decision CP-11/7 welcomed with appreciation the outcomes of the AHTEG and also welcomed the additional voluntary guidance materials to support the case-by-case risk assessment of living modified organisms containing engineered gene drives.
- Detection and Identification of LMOs: Enhancing methodologies for detecting and identifying LMOs to ensure biosafety. Decision CP-11/8 addresses the compilation of technical reference documents and other materials to complement and update future editions of the *Training Manual on the Detection and Identification of Living Modified Organisms in the Context of the Cartagena*

Protocol on Biosafety as well as experience with new detection techniques, such as those for detecting newly developed living modified organisms and unauthorized living modified organisms, including those that contain stacked events, and with developing, using and maintaining reference materials;.

- Socioeconomic Considerations: Integrating socioeconomic considerations into decision-making processes regarding LMOs. Decision CP-11/9 explores these impacts and invites Parties to use the voluntary guidance on the Assessment of Socio-Economic Considerations in the Context of Article 26 of the Cartagena Protocol on Biosafety and share their experiences.
- Nagoya-Kuala Lumpur Supplementary Protocol: Promoting the ratification and implementation of the Supplementary Protocol on Liability and Redress. Decision CP-11/10 discusses reminds Parties to designate a competent authority to perform the functions set out in its Article 5 and to publish information on the competent authorities in the Biosafety Clearing-House, using the common format available for that purpose.

These decisions reflect the ongoing commitment of the Parties to strengthen the implementation of the Cartagena Protocol on Biosafety and address emerging challenges in the field of biosafety.

Biosafety Clearing-House (BCH) Operations

Article 20 of the Cartagena protocol establishes the Biosafety Clearing-House (BCH) as a mechanism to facilitate the exchange of information on Living Modified Organisms (LMOs) and assist the Parties to better comply with their obligations under the Protocol. Global access to a variety of scientific, technical, environmental, legal and capacity building information is provided in all 6 of the UN languages.

Status of information in the Biosafety Clearing-House

The table below provides the total number of records published and updated in the BCH as **at 6 March 2025**. **Number of records published and updated in the BCH** *(excluding national reports)*

Record type	**As at 6 March 2025**
National records	
National focal points (CPB, BCH, emergency measures contacts (Article 17))	340
Competent national authorities (CNA)	407
Supplementary Protocol competent authority (SPCA)	18
Biosafety laws, regulations, guidelines and agreements (LAW**)**	1180
Countries' decisions or any other communications (DEC)	2853
Risk assessments generated by a regulatory process (RA)	2713
National biosafety websites or databases (NDB)	149
Biosafety experts (EXP)	358
Reference records	
Biosafety virtual library resources (VLR)	1594
Biosafety organizations (ORG)	396
Laboratories for detection and identification of living modified organisms (LAB)	79
Living modified organisms (LMO)	1012
Genetic elements (GENE)	904
Organisms (ORGA)	279
Risk assessment generated by an independent or non-regulatory process (IRA)	32
Capacity development initiatives (CDI)	430
BCH news (BCHN)	566
Submissions (SUB)[3]	645
Contacts[4]	2490
Total	**16445**

[3] Submissions of information in response to notifications issued by the Secretariat.

[4] These are contacts of a person or organization. These types of records are visible in the BCH only when they are referenced in other record types.

31 African Union Development Agency (AUDA-NEPAD)

In the year 2024/25, the African Biosafety Network of Expertise programme of the AUDA-NEPAD has provided technical support and training in several African Union member states that included Burkina Faso, Cameroon, Eswatini, Ethiopia, Ghana, Kenya, Malawi, Mozambique, Namibia, Nigeria, Rwanda, Senegal, Zambia, and Zimbabwe. AUDA-NEPAD's work to create a favourable policy environment for genome edited products in several AU member states is on course, with significant progress evident in the approval of forward-looking guidelines in countries such as Burkina Faso, Ethiopia, Ghana, Kenya, Malawi, Nigeria, and Zambia, while working with additional countries including Eswatini, Mozambique, Namibia, Senegal, and Zimbabwe, on the development of their guidelines. A few of the country summaries and participation in regional and international undertakings are given hereunder.

Mozambique

AUDA-NEPAD provided technical support to the national competent authority for biosafety – GIIBS, which enhanced the in-country capacity that resulted in the successful review and approval of the TELA maize with Events MON87460 × MON810 application for environmental release.

Rwanda

Following the official gazette of the law governing biosafety - Law no. 025/2024 of 16/02/2024 on 21 February 2024, AUDA-NEPAD has sustained its technical support to the national competent authority for biosafety – Rwanda Environment Management Authority (REMA) to enable an effective and efficient implementation of the law in line with best practices. This effort has resulted in the recent approvals of the Ministerial Order no 001/MoE/25 of 13/01/2025 on the application for a permit for living modified organism related activities and the Prime Minister's Order No 006/03 of 18/02/2025 governing the National Biosafety Committee. Sustained support on capacity building and policy development is crucial to ensure a functional biosafety regulatory system. This support is currently being delivered jointly by the AUDA-NEPAD and AFSI in collaboration with REMA.

Nigeria

Nigeria has made significant progress in advancing her regulatory system with risk-proportionate policies with several approvals for biosafety activities. The NBMA Act 2015, mandates the National Biosafety Management Agency (NBMA) to set forth guidelines as required to ensure effective regulation, as appropriate. There are instances where existing regulatory policies governing biotech in a receiving country do not yet have specific policies addressing low level presence (LLP) in seeds and grains yet may need to make a regulatory decision. This is the case of Nigeria and many AU member states. To address this, the NBMA requested for support from AUDA-NEPAD to develop guidance on the management of LLP of

GMOs in seeds and grains in Nigeria. The support was provided and it resulted in the validation of the guidelines on LLP of GMOs on 22 January 2025.

Ghana

The National Biosafety Authority received 14 applications for GMOs intended for use as food, feed, or for processing (FFPs). This is part of efforts to boost familiarity with the technology and better acceptance of environmental release applications. Technical support provided by AUDA-NEPAD resulted in the successful review and decision-making on these applications. Also, the support resulted in the successful validation and adoption of the national genome editing guidelines and guidelines for stacked traits.

Regarding lawsuits by some civil society groups that could potentially stall biosafety processes, support provided by AUDA-NEPAD enabled two (2) court rulings in favour of the National Biosafety Authority (NBA) on 30th April 2024 and 24th May 2024 upholding NBA's diligence and science-based approach in regulating biosafety. The legal proceedings affirmed the NBA's statutory role in regulating GMOs and reinforced the need for continued dialogue and public education to balance innovation with societal concerns. The outcomes marked a significant step toward integrating modern biotechnology into Ghana's agricultural framework responsibly.

Ethiopia

Technical support provided to Ethiopia resulted in the successful validation and adoption of the guidelines for the regulation of stacked traits GM events and guidelines for genome editing. The national Variety Release Committee has approved the registration and release for cultivation of TELA maize. A broad application for testing, cultivation, import and export of genome edited teff (*Eragrostis tef*) for the control of lodging in the crop has been submitted to the Biosafety Directorate by the national institution in collaboration with Donald Danforth Plant Science Centre.

Malawi

Technical support provided to Malawi's competent authority for biosafety resulted in the successful review and approval of the application to conduct confined field trial of Trecepta maize. The trial is now ongoing with a first harvest made successfully. Also, capacity strengthening support addressed empirical stewardship issues along the biosafety life cycle that covered quality control at the containment, confinement, and post-release stages, to ensure compliance with regulatory provisions of the country.

Kenya

AUDA-NEPAD along with other biosafety service providers sustained the technical backstopping support in Kenya. This resulted in both court cases against introduction into the country or development within of genetically modified crops for food and feed uses being dismissed through their final rulings.

Zambia

AUDA-NEPAD provided technical support to the national competent authority for biosafety in Zambia, which resulted in the successful validation and adoption of the national guidelines on stacked genes in 2024. Also, the Compliance and Enforcement on Biosafety Regulation was validated and approved by the Board.

International Activities

- Convention on Biological Diversity (CBD): Technical and coordination support provided to the African Group of Negotiators (AGN) during the meetings of CBD and its Protocols and related intersessional engagements contributed to the declaration of COP/MOPs decisions that are supportive of Research & Development, technology transfer, capacity building and technical cooperation, and ultimately an enabling environment for the safe harnessing of modern biotech and emerging technologies.
- African Seed and Biotechnology Partnership (ASBP): AUDA-NEPAD is collaborating with AUC, member states, Regional Economic Communities (RECs), and key partners in advancing the work on domesticating guidelines that are risk-proportionate and can enhance the uptake of Biotechnology by taking the lead in implementing the Component Ten of ASBP---"Enhance biotechnology uptake for an efficient seed system in Africa". This provides opportunity for AUDA-NEPAD to develop continental guidelines for modern biotechnology and emerging technologies that would inform adoption of common technical standards by member states and RECs.

Short Courses Organized in Partnership with MSU

- Facilitated the participation of experts from Africa in the Food Safety Short Course at Michigan State University, USA in July 2024. The 2024 course was the 25th edition, which was marked with the organization of a Global Food Safety Symposium.

  The key recommendation from the Symposium was to continue strengthening food safety capacity-building programs worldwide through global collaboration and cooperation. With this goal in mind, symposium participants strongly recommended the establishment of a "Global Food Safety Knowledge Hub" to serve as a repository and a clearinghouse for the sharing and exchange of food safety related information, training tools and resources, networking opportunities, funding opportunities, and a roster of food safety professionals. An international steering committee has been formed to coordinate this initiative.
- Facilitated the participation of experts from Africa in the Agricultural Biotechnology and Biosafety Short Course at Michigan State University, USA in August 2024.

Training Workshops Organized in Collaboration with UC Davis and IITA

AUDA-NEPAD played a key role in a series of biotechnology and genome editing training workshops held in Kenya, Zambia, and Mozambique in May and June 2024, in collaboration with the University of California (UC) Davis, the International Institute of Tropical Agriculture (IITA), and with financial support from the USDA. These workshops brought together researchers, academics, and regulatory professionals to discuss biotech advancements, regulatory frameworks, and seed systems, with a focus on genome editing. AUDA-NEPAD contributed regional and continental perspectives on biotech regulation, while experts from various institutions provided insights on intellectual property rights, biotech communication, and global seed trade. The workshops also included laboratory tours and panel discussions that identified priority areas such as biosafety regulation, intellectual property rights, funding, and capacity building to support biotech innovation and commercialization across Africa.

Communication

- Current ABNE Map on Biosafety Landscape in Africa published
- News articles and newsletters on programme activities published

- The Africa Biosafety Regulatory Information Database is being developed to be published on the AUDA-NEPAD website for public access
- Capacity Building Webinar Series on Biosafety Communication (safety and non-safety matters) was launched with the kick-off webinar held on 4 December 2024

E-learning Platform

AUDA-NEPAD is implementing the ICGEB/ABNE e-learning biosafety modules with a total of three hundred and sixty-two (362) stakeholders from fourteen (14) African countries including regulators, lawyers, and media specialists enrolled on the platform. Participating countries include Burkina Faso, Cameroon, Eswatini, Ethiopia, Kenya, Malawi, Mozambique, Namibia, Nigeria, Rwanda, Senegal, Sudan, Zambia, and Zimbabwe.

32 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

Bangladesh Stakeholder Consultation on Agricultural Biotechnology

The United States Department of Agriculture (USDA), with support from AFSI's South Asia Biosafety Program (SABP), convened a day-long stakeholder consultation on agricultural biotechnology on December 4, 2024 to solicit feedback from researchers at the National Agricultural Research System (NARS), private sector developers in the seed industry, and other stakeholders in Bangladesh. The aim of this consultation was to identify operational needs for the development of biotechnology in the country. The consultation enabled participants to better understand the ongoing research and development of agricultural biotechnology in Bangladesh and to encourage discussion between participants to provide feedback for Government of Bangladesh regarding the needs and interests of Bangladeshi stakeholders. The event was attended by 52 participants engaged in research on crop improvement at research organizations and universities in Bangladesh.

Workshop on Non-target Organism Testing for Environmental Risk Assessment

AFSI, in cooperation with the USDA Agricultural Research Service (ARS), Iowa State University, and Corteva Agriscience™, organized technical training on non-target organism testing of transgenic crops on June 24-28, 2024. Supported by a grant from the USDA Foreign Agricultural Service (FAS) Emerging Markets Program (EMP), 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. Eight participants from Indonesia, Kenya, Nigeria, and the US attended the workshop. During the five-day technical training program, participants learned about concepts in environmental risk assessment of genetically engineered plants in the context of non-target organisms 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.

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 2024' for the APEC HLPDAB as part of the U.S.'s self-funded projects. This seminar series has been implemented for three years in a row and plans for 2025 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 2024 seminar series was cosponsored by Canada, Indonesia, Peru, and Viet Nam. As part of this series, the following virtual seminars were facilitated by AFSI:

'Genome Editing - Opportunities for Adoption in Addressing Climate Change and Food Security' led by Peru was held on June 4, 2024. This event attracted 139 participants from 21 economies featuring presentations on issues related to the use of genome editing technology to address food security challenges resulting from climate change. Regulatory aspects that help facilitate the commercialization of products derived from genome editing and the use of genome editing to improve drought tolerance, nitrogen-use efficiency, photosynthesis efficiency, and carbon utilization were the major points of discussion.

The second seminar in the series, 'The Role of Plant Breeding Innovations in Crop Improvement – Status and Prospects' took place on June 25, 2024. With Viet Nam as the lead economy, this activity focused on updates on the development and application of plant breeding innovation, followed by a facilitated discussion on policy development for agricultural biotechnology. It attracted 111 participants from 19 economies and included talks on the potential application of biotech crops in plant breeding, Viet Nam's national program on biotechnology development, the global status of plant breeding innovation to advance crop productivity and climate tolerance, and perspectives on the development of policies and strategies for genome edited plants around the world.

The third seminar in the 2024 series, 'The Role of Agricultural Biotechnologies in Increasing Productivity and Reducing Food Loss and Waste' led by Indonesia was attended by 122 participants from 19 economies. The online event began with presentations by Indonesian experts who provided an overview of the regulatory framework for the approval of genetically modified crops and genome editing products in the country, along with a discussion of biotechnology research for potato, sugarcane, and rice. International speakers then delivered presentations on global developments in agricultural biotechnology and the potential of genome editing to reduce post-harvest waste, followed by a panel discussion.

In addition to the 2024 Agricultural Biotechnology Seminar Series, AFSI implemented a full-day in-person workshop on August 14, 2024, in Trujillo, Peru, prior to the APEC HLPDAB plenary meeting. The 'Workshop on Moving Forward on Agricultural Biotechnology through Continuing Efforts on Regulatory Cooperation in APEC' welcomed over 40 participants, representing Canada, Chinese Taipei, Indonesia, Japan, the Republic of Korea, Malaysia, Mexico, Peru, the Philippines, Russia, Thailand, Viet Nam, and the USA. Discussions at the workshop revolved around examples of different types of regulatory cooperation in agricultural biotechnology, and breakout sessions encouraged participants to contribute their expertise and opinions through the use of case studies. This workshop built upon previous discussions at the 2023 HLPDAB 'Workshop on Reducing Redundancies and Facilitating Efficiencies – Regulatory and Policy Solutions for Oversight of Agricultural Biotechnologies' that happened in Seattle, United States.

At the 2024 workshop, AFSI introduced a draft of the Policy Approaches Document (PAD) for Regulatory Cooperation on Agricultural Biotechnology, a whitepaper for advancing regional cooperation on agricultural biotechnology regulation inspired by the ongoing collaborative environment developed over many years within the APEC HLPDAB. The PAD has been developed by AFSI in consultation with the APEC member economies through a series of consultative meetings with the aim of ensuring the document is fit for purpose and represents policy approaches that have real opportunities for practical uptake. The consultative meetings focused on information sharing, aligning data requirements, standardizing application and dossier templates, harmonizing risk assessment methodologies, and mutual recognition of risk assessments.

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. With this online portal, AFSI aims to foster discussion between stakeholders on practical next steps that can be made to address the shared need for efficient and effective policies for facilitating the safe development, deployment, and trade of products of agricultural biotechnology. On the online portal, the different mechanisms of cooperation described in the white paper are clarified through the use of case studies. Drawing from past regulatory cooperation successes, these write-ups illustrate varying degrees of cooperation via information sharing, policy alignment, and collaboration on risk or safety assessments. Case studies available on the portal include the Global Low Level Presence Initiative, Codex Alimentarius, safety assessment sharing between Health Canada and Food Standards Australia/New Zealand (FSANZ), and more.

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. Examples of these resources include the "Update of the APEC Baseline Study: Regulations of Products Derived from Innovative Agricultural Technologies" and the FAO GM Foods Platform. AFSI is committed to expanding both the white paper and website over time, in an effort to maintain a current and easily accessible public resource to facilitate regulatory cooperation on agricultural biotechnology.

Microbial biotechnology

AFSI has been organizing outreach events on microbial biotechnology since 2020, beginning with a general webinar series for a global audience. This was followed by virtual workshops for stakeholders in the European Union, India, and Southeast Asia. On June 5-6, 2024, AFSI and the Secretariat of Bioeconomy, Ministry of Economy of Argentina, co-hosted a two-day virtual workshop on microbial biotechnology. Simultaneously translated into Spanish, the webinar featured talks on regulatory frameworks for genetically engineered microbes in several countries in the region. With 351 participants from 28 countries, the event included lectures on the history and use of fermented foods and microorganisms for agricultural and ecological use in South America and the regulatory policy outlook in the microbial biotechnology space, as well as panel discussions on the changing landscape of products derived from microbial biotechnology. Recordings of the event, which were shared only with registrants, have accumulated 142 views.

Biologicals in Agriculture

AFSI organized an online discussion session titled 'Innovative Crop Management: Biological Inputs for a Sustainable Future' at the Dupont Summit on Science, Technology, and Environmental Policy 2024 virtual conference on December 6, 2024, in collaboration with the Biotechnology Innovation Organization (BIO) and Biological Products Industry Alliance (BPIA), with the objective of fostering a comprehensive understanding of how biological products can be effectively integrated into modern agricultural practices among policymakers, industry experts, producers, and market participants. During the online event, a

panel of experts examined the pathways to regulatory approval and market adoption, with an eye toward ensuring that innovative solutions provided by biologicals can contribute to a sustainable and resilient agricultural future. The session was attended by 65 participants from 17 countries.

This online session primed a diverse group of stakeholders for a biologicals conference titled 'Understanding the Impacts and Needs in Biologicals Regulation' held on January 23, 2025 in Washington DC, United States. This hybrid event brought together 42 stakeholders with an aim to foster discussions on the emerging biologicals landscape through the examination of recent research and product development, enhance regulatory insight by producing an overview of current regulatory pathways for biological products and identify the potential impacts of these policies, and facilitate stakeholder dialogue to identify unintended impacts, definitional challenges, and need for future regulatory design aligned with the potential of biologicals.

3. Developments related to new breeding techniques (NBTs)

Workshops on Standard Operating Procedures for Research and Release of Genome Edited Plants in Bangladesh

Continuing with outreach and educational events on the topic of genome editing, AFSI, under the auspices of the South Asia Biosafety Program (SABP), in collaboration with the Bangladesh Agricultural Research Council (BARC), Ministry of Agriculture and the Bangladesh Academy of Sciences (BAS), organized the Workshop on Standard Operating Procedures for Research and Release of Genome Edited Plants in Bangladeshon April 22 and 23, 2024, with a different audience attending each day. Similar to a previous workshop organized on February 13, 2024, the program focused on the Ministry of Agriculture's 'Standard Operating Procedures (SOPs) for Research and Release of Genome Edited Plants of Categories SDN-1 and SDN-2 in Bangladesh' and covered the science of genome editing, SOPs for handling genome edited plants during research, and techniques used to demonstrate the absence of the transgene from the final genome edited plant.

Workshop series for South Korea - Gene Edited Plants: Context and Communication for Plant Breeding Innovation

AFSI organized the fourth workshop in the series on Gene Edited Plants: Context and Communication for Plant Breeding Innovation on December 10-11, 2024 in Daejeon, South Korea. 'Enabling Regulatory Environment for Genome Editing in Agriculture in South Korea: Opportunities & Possibilities' aimed to improve dialogue between South Korean government officials, scientists, and other stakeholders, and enable effective communication on issues related to new plant breeding technologies. Supported by a grant from CropLife International, this event brought together a diverse set of stakeholders in agricultural biotechnology. The workshop was attended by 52 participants including scientists and experts from the government, private sector, academia, Korea Biosafety Clearinghouse, public sector institutions, law firms, and scientific organizations involved in policy discussions in the country. Building on the success of previous trainings, this in-person activity fostered a science-based and transparent exchange of ideas around the regulation of genome edited agricultural products in South Korea.

The three preceding technical events under this series were funded by USDA Foreign Agricultural Service's New Technologies and Production Methods Division. Held virtually, the first workshop on April 22, 2021, introduced gene editing and featured presentations on the science, regulatory landscape, and communication, while the second workshop on July 19-23, 2021, allowed discussions among South Korean stakeholders to continue over the course of one week, focusing on improving their understanding of the technology and varying approaches to regulating the products of gene editing. The third workshop took place in person on July 25-26, 2022, in Seoul and covered key concepts in problem formulation,

Codex principles, the basics of food and feed safety assessment for whole foods, and the application of safety assessment concepts to products of gene editing.

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.

33 Public Research and Regulation Initiative (PRRI)

The Public Research and Regulation Initiative (PRRI) offers a forum for public researchers to be informed about and involved in international regulations pertaining to modern biotechnology, such as the Biodiversity Convention and the Cartagena Protocol on Biosafety (CPB).

With regard to environmental risk assessment, PRRI has contributed in various ways to the negotiations in the Meeting of the Parties to the CPB about guidance documents to support environmental risk assessment under the CPB.

PRRI is currently discussing the possibility of developing guidance to identify categories of LMOs that are not likely to have adverse effects and could therefore be subject to simplified procedures or exemptions such as those referred to in articles 7.4, 13 and 14 of the CPB.