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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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No. 39, COLLATION OF THE ANSWERS FOR QUESTIONNAIRE Enhanced Information Exchange on New Breeding Techniques: 2024 Results (2024)

About the OECD

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

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

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

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

Of different content, this information document compiles elements provided by delegations on the 32nd WP-SNFF meeting (26-28 March 2025). It aims at summarising relevant information on activities related to the safety assessment of novel foods and feeds 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-SNFF endorsed this document, which is published under the responsibility of the Chemicals and Biotechnology Committee of the OECD.

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Argentina

New legislations in the regulatory framework

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

Resolution 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 received, 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

Australia

1. GM food regulation in Australia

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

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

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

2. GM food assessments and approvals in Australia

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

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

Approvals since the 31st Meeting and applications currently under assessment by FSANZ include:

Food derived from:	**Current Status:**
Herbicide tolerant soybean line MON94313	Approved March 2024
Herbicide tolerant and insect protected corn line DAS1131	Approved April 2024
Herbicide tolerant and insect protected corn line DP910521	Approved June 2024
Short-stature corn line MON94804	Approved July 2024
Disease resistant, low reducing sugars and reduced browning potato line BG25	Approved October 2024
Food derived from herbicide-tolerant sugar beet line KWS20-1	Approved February 2025
Food derived from insect-protected corn line MZIR260	Under assessment
Food derived from insect-protected soybean line MON94637	Under assessment
Food derived from insect-protected soybean line COR23134	Under assessment

3. Shared Assessment Process between FSANZ and Health Canada

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

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

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

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

Update

In total, four shared safety assessments have been successfully completed by FSANZ and Health Canada. A further two shared safety assessments are in progress in 2025.

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

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

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

4. New breeding techniques

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

Update

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

Under the new definition certain NBT foods will be excluded from pre-market safety assessment and approval as GM food under the Code. This exclusion was informed by an extensive scientific assessment by FSANZ. It concluded that certain NBT food has the same low risk as conventional food because many of the genetic changes introduced using NBTs are indistinguishable from conventional breeding.

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

FSANZ has completed its analysis of the 1485 submissions to the second public consultation, as well as additional targeted consultation with key stakeholders and other interested or impacted parties. A decision Regulatory Impact Statement has been prepared.

The proposal is flagged for completion by Q3 2025.

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

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

5. Cell-based food assessment in Australia

FSANZ has assessed its first cell-based food application. The application is from Vow Group Pty Ltd, who are seeking approval for the use of cell-cultured quail, developed using embryonic fibroblasts from Japanese quail (*Coturnix japonica*).

Update

Between December 2024 - January 2025, FSANZ undertook a second and final round of public consultation. In addition to considering cell-cultured quail, FSANZ proposed a new regulatory approach for cell culture foods.

This approach includes two new standards and one new schedule in the Code:

- Standard 1.5.4 – Cell-cultured foods
- Standard 3.4.1 – Food safety requirements for processing of cell-cultured food
- Schedule 25A – Permitted cell-cultured foods.

The regulatory approach:

- requires all cell-cultured foods to undergo a pre-market assessment focussing on food safety including a requirement that processing and production measures are in place for all foods of this type, providing an appropriate level of protection of public health and safety.
- supports transparency and consumer choice by mandating use of either of the terms ‘cell-cultured’ or ‘cell-cultivated’ in relation to the sale of these foods
- provides clarity for enforcement of these foods by regulators in the States and Territories and New Zealand Ministry of Primary Industries (the Jurisdictions)
- supports innovation, and provides guidance and clarity for this sector of the food industry when making applications to FSANZ

FSANZ has continued to engage with the Jurisdictions, particularly with regard to food safety requirements and guidance for auditing purposes.

The application is flagged for completion by mid-2025.

Further information, including relevant assessment reports, can be found on the FSANZ website at:

https://www.foodstandards.gov.au/food-standards-code/applications/A1269-Cultured-Quail-as-a-Novel-Food

Belgium

1. Notifications for commercialisation

Belgium remains actively involved in the European Food Safety Authority (EFSA) 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 (the Belgian institute for health) 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 https://www.bio-council.be and https://www.biosafety.be. The OECD consensus documents on compositional considerations for new varieties of crops (the series on the safety of Novel Foods and Feeds) are used as reference documents during the evaluations.

2. GMO detection in Belgium

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

The GMOlab of TAG has ISO17025 flexible scope of accreditation for detection of GMOs (plant, microorganisms, etc.) by means of real-time PCR and ddPCR.

Follow-up of the activities:

TAG coordinates a Belgian federal project on development of a new open strategy for impurity surveillance of commercial microbial fermentation food products (ENSURED), which started in 2023. This project aims at developing an innovative and universal open strategy, able to monitor any type of impurities of biological origin, both at the genomic and proteomic level, in microbial fermentation products, and, if possible, to be extended to any type of food/feed matrices. TAG focuses on metagenomic approaches to detect this kind of impurities with a special focus on genetically modified micro-organisms (GMM) that are used to produce these products.

TAG will also coordinate another project related to GMM (starting date 01/06/2025) financed by the Belgian competent authorities and named ARGUMENT (Assessment of the presence of Antimicrobial Resistance Genes in food/feed prodUcts obtained by Microbial fErmentatioN and of their risk of Transmission). The research will focus on vitamins and other products obtained via microbial fermentation, some of which with direct intake as a study case: (i) Based on EFSA and WHO information and guidelines, what are the ARG of most concern which should be avoided in the food chain, and how can these be quantified? (ii) To which

extent (quantity, type, genetic context) are products obtained via microbial fermentation with direct and indirect intake, and available on the Belgian market, containing these ARG?; (iii) Is the horizontal transfer of these ARG, as intact free DNA and/or in living bacteria, possible from these products to other bacteria with potential impact for food safety; Is the threshold of 10 ng DNA of the production strain per g or ml product in the context of food safety scientifically justified?; Is there a potential ARG transfer from GMM present in a sample circulating at the BE market of microbial fermentation products?; (iv) Do the results provide new scientific information that calls into question EFSA's conclusions on the risk of the presence of ARG in fermentation products?

TAG also coordinate a transversal project “METAMORPHOSE” (Sciensano funding) : The objective of this research project is to develop the shotgun metagenomics approach generically (at the wet and dry lab levels) and to deliver a proof-of-concept of the potential of the approach to answer public health questions using three case studies: i) detection and characterization of GMMs used in fermentation products or as a bioweapon, ii) quality control of vaccines and medicinal products and iii) characterization of microbiomes. In the frame of this project, a theoretical assessment of the risks associated with the presence of GMMs and antibiotic resistance genes in fermentation products will be conducted.

TAG is actively involved in the development and evaluation of approaches for the detection of organisms derived from new genome editing techniques. TAG participates in the EU project DARWIN (Transition to safe & sustainable food systems through new & innovative detection methods & digital solutions for plant-based products derived from new genomic techniques, under a co-creation approach), call HORIZON-CL6-2023-FARM2FORK-01. DARWIN aims to contribute to a fair, healthy, safe and environmentally friendly food system by co-developing an innovative detection strategy by integrating targeted analytical PCR-based methods, untargeted sequencing methods, and digital solutions.

TAG is WP leader and works on development of untargeted sequencing approaches (including WGS, LCM and metagenomics for pure genome edited plant products and mixtures, as well as on machine learning tools for genetic fingerprints). TAG participates in validation of methods developed within the project, as well as in development of criteria and guidelines for validation of novel methods for detection of genome edited plants.

Peer-reviewed publications:

J. D’aes, M.A. Fraiture, B. Bogaerts, Y. Van Laere, S.C.J. De Keersmaecker, N.H.C. Roosens, K. Vanneste; Metagenomics-based tracing of genetically modified microorganism contaminations in commercial fermentation products. Food Chemistry: Molecular Sciences 2024, 10: 100236. https://doi.org/10.1016/j.fochms.2024.100236.

3. New Techniques

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

Currently, one field trial with gene-edited plants is ongoing (B/BE/24/V1 - gene-edited poplars with a decreased lignin content).

Since the last WP meeting, two new requests for authorization for field trials have been submitted:

- 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)

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

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

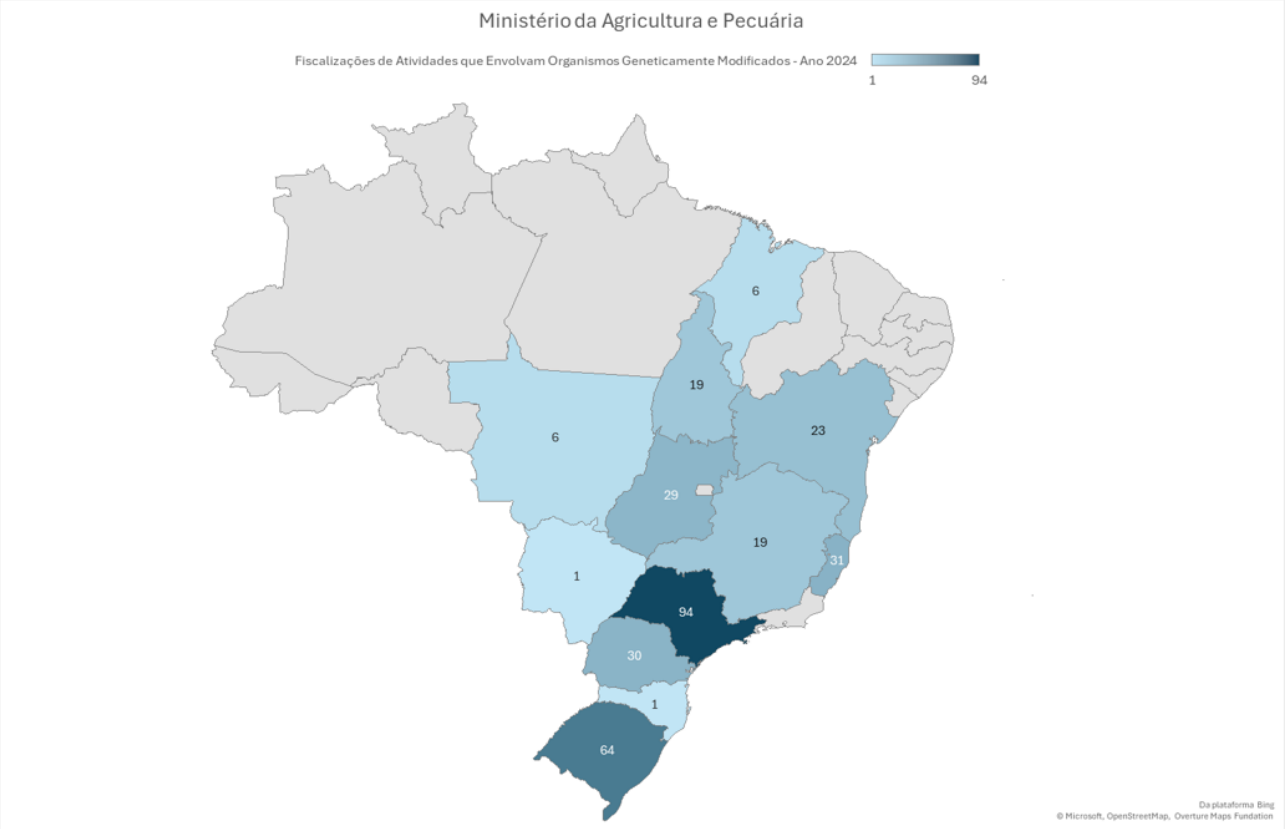
2. Development/review/amendment of national strategies, regulations and guidance

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

Canada

Novel Food Approvals

Since 1999, Health Canada (HC) has permitted 265 novel foods to be sold in the Canadian marketplace. Since March 2024, the following novel foods have been authorized:

- Artic® apple event PG451
- Maize event EH913
- Insect-resistant and herbicide-tolerant DP-910521-2 maize
- Insect-resistant and herbicide-tolerant maize – DP-∅51291-2
- Sourvisae®
- Insect-resistant maize – MON 95275-7
- Insect-resistant and herbicide-tolerant maize – DAS-∅1131-3
- Insect-resistant soybean – MON 94637-8
- Neoagarooligosaccharides (NAO), an enzymatic hydrolysis product of agar-agar
- Mixture of Five Human Milk Oligosaccharides (5HMO-Mix)

A list of authorized novel foods, each summarized by a decision document, can be found at

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

Novel Feed Approvals

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

Since the last Task Force meeting in March 2024, seven novel feeds from a plant source have been authorized.

- LLC's AXigen wheat (*Triticum aestivum* L.) developed through chemical mutagenesis
- Resistance to lepidoptera (fall armyworm) and tolerance to glufosinate corn – EH-BRS913-2
- Insect resistance and glufosinate tolerance – DP-910521-2
- Insect resistance (coleoptera) and glufosinate tolerance – DP-∅51291-2
- Insect resistance to coleoptera – MON-95275-7
- Insect resistance (lepidopteran) and glyphosate tolerance – DAS-∅1131-3
- Insect resistance – MON-94637-8

A complete list of approved novel feeds from plants sources is available at:

http://www.inspection.gc.ca/english/plaveg/bio/dde.shtml

Important resources related to genome editing techniques

CFIA and Health Canada joint webpage regarding the regulation of genome-edited products within the Canadian regulatory framework
https://www.inspection.gc.ca/plant-health/plants-with-novel-traits/gene-editing-techniques/eng/1541800629219/1541800629556

Health Canada Guidance on the Novelty Interpretation of Products of Plant Breeding
https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/guidelines-safety-assessment-novel-foods-derived-plants-microorganisms/guidelines-safety-assessment-novel-foods-2006.html#a5

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

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.

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

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.

Important resources related to Low Level Presence (LLP)

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

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

Canadian Feeds Regulations

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.

Cellular Agriculture

In December 2023, Health Canada posted a new website to engage industry stakeholders, partners, and the public on the regulatory oversight of cellular agriculture, a general term for the production of food that is usually derived from animals (e.g., meat, seafood, egg, milk products) using cell culture methods instead of live animals. The website explains that under Canada's *Novel Food Regulations*, these products will be considered 'novel foods' and thus require pre-market safety assessment prior to their sale or advertisement in Canada for food. Other established pre-market frameworks could apply, depending on the intended uses

of a given product (i.e., for use as livestock feed, environmental safety). Canada's existing laws pertaining to licensing, manufacturing, and trade of products, as well as the legislative framework for labelling that would apply are explained as well.

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

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

Croatia

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

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.

Denmark

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

Denmark as a member of the European Union, follows EU legislation on GM food and feed as well as novel food and feed additives legislations.

Due to low consumer acceptance, almost no GM food products are marketed in Denmark, whereas the use of GM feed is very common. In organic farming the use of GM feed is not allowed in the EU.

Although GM crops are not cultivated in Denmark, our animal sector rely to a large extend on imported feed consisting of or containing of mainly GM soy from cultivation outside EU.

Biotech industry plays a significant role in the Danish economy. Especially, Danish companies have a strong position in production of enzymes and microbial cultures for use as food and feed ingredients. A large part of the production uses GMMs in contained use. This production type has been used traditionally for many years for production of enzymes and today the technique is increasingly used also for so-called precision fermentation of a broader variety of ingredients.

New genomic techniques

The EU-Commission has in July 2023 presented a proposal for a new regulation on plants obtained with certain new genomic techniques and their food and feed. The proposal, which is supported by Denmark, is still under negotiation.

Estonia

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

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

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

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

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

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

In 2024, the Accelerate Estonia (national innovation laboratory) has finished the project with the aim of accelerating the introduction of novel foods to the market in the EU. The project resulted in a roadmap that will support companies in finding information and financing and help the Estonian Business and Innovation Agency start international cooperation.

Finland

Legislation

As a European Union (EU) Member State, Finland applies EU legislation to novel foods (Regulation (EU) 2015/2283) and genetically modified organisms (GMOs) (Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No 1830/2003, Directive 2009/41/EC). Accordingly, Finland participates in the safety assessment and decision-making processes under EU legislation.

In the EU, products produced by new genomic techniques (NGTs) are subject to GMO legislation. On 5 July 2023, the European Commission adopted a legislative proposal for a regulation on plants produced by new genomic techniques and their food and feed. To become law, the regulation must be adopted by the Member States in the Council of the EU and the European Parliament, following the ordinary legislative procedure. The European Parliament reached its position on the proposal in April 2024, and on 13 March 2025 Member States' representatives endorsed the Council's negotiating mandate on the Regulation. Final negotiations with the Commission, Council and Parliament will start at the end of April.

GM Food and Feed

The situation in Finland regarding GM products on the market remains unchanged. There are very few or sporadic GM foods on the market. Some “GM free” labelled foods are available. No unauthorised use of GM has been detected in Finland since the last meeting. GM soy continues to be used as a feed protein.

Cultivation and Field Trials

Cultivation of GM plants is not relevant in Finland because only maize MON810 has been approved for cultivation in the EU. The Nordic climate limits maize cultivation, and the modified trait of MON810 (protection against the corn borer moth) is of no relevance to us since the pest is only sporadically found in Finland. There are currently no ongoing field trials with GMOs intended for food or feed use.

Non-GM Novel Foods

Active discussion on the novel food status of different products has continued at the EU level. Finland follows any interpretations that have been commonly agreed upon in the EU. Novel foods are regularly and increasingly monitored by Customs and municipal control authorities.

Germany

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

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

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

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

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

2. GM food and feed detection

Food and feed safety inspections are organized on the level of Federal States in Germany. Authorised GMO laboratories in the Federal States conduct detection, identification and quantification of GMOs present in food and feed. A "National Reference Laboratory for Genetically Modified Organisms (NRL-GMO)", located at the BVL, supports and coordinates their work. The NRL-GMO together with 19 German enforcement laboratories is part of the European Network of GMO Laboratories (ENGL), which works to harmonise methods for detection and identification of GMOs on EU level. Information on validated DNA-

based detection methods can be found in the "GMOMETHODS application" provided by the EU Joint Research Centre (https://gmo-crl.jrc.ec.europa.eu/gmomethods/).

In case risks to public health are detected in the food chain, including for example detection of unauthorized GMOs or GM components, information is EU-widely shared by the "RASFF – Rapid Alert Systems for Food and Feed" (https://ec.europa.eu/food/safety/rasff-food-and-feed-safety-alerts_de), enabling swift reaction in all European countries as appropriate.

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

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

3. New breeding techniques

NBT products in the EU are GMOs according to the ruling of the Court of Justice (ECJ) of 25 July 2018, thus fall under the scope of Directive 2001/18/EC and are subject to the obligations laid down therein. Currently, no NBT products are authorized as food/feed or for cultivation in the EU, neither have applications been received for food/feed.

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

- 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

4. International activities

- The German BVL and the Dutch WFSR host and maintain EUginius, the **"EUropean GMO Initiative for a Unified Database System"** (http://www.euginius.eu) in close cooperation with official GMO detection and identification laboratories in 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.
- The German Federal Institute for Risk Assessment (BfR) in cooperation with Matís, Iceland, EFSA, Singapore Food Agency and FDA organised the "**International conference on alternative Proteins for Food and Feed**" in December 2024 in Berlin, Germany. The conference comprised topics such as the regulatory landscape of Novel Foods, safety, nutrition, consumer perception and sustainability aspects. More than 300 scientists from all over the world took part in the 3-days event. Presentations are available at https://www.bfr-akademie.de/english/archive/2024/apff-2024.html.

Ireland

As part of the European Union (EU), Ireland implements EU food law including legislation on GM food and feed as well as novel food. Although GM crops are not cultivated in Ireland, the animal feed sector remains very reliant on imported protein sources from GM crops like maize and soya bean. The biopharmaceutical industry plays a significant role in the Irish economy and is very dependent on the contained use of GMMs. Ireland is also engaged in the debate on how the EU should regulate new genomic techniques (NGTs).

Italy

GM food and feed

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

NTG and field trials

Italy's interest in NGT is evidenced by the June 2023 regulatory intervention (art. 9bis Law n° 68) by which Parliament approved the carrying out of research activities at authorized experimental sites, in application of Directive 2001/18/EC, of plants produced by genome editing techniques through site-directed mutagenesis or cisgenesis to support production of new plant varieties capable of responding adequately to water scarcity and to grow in the presence of environmental and biotic stresses of particular intensity. While waiting for the European Union's new Regulation on the topic, a new Law in 2024 (No. 101 of July 12, Article 9bis) has extended the time frame for trials notification in Italy until the end of 2025, and the field of application to plant varieties with improved qualitative and nutritional characteristics.

Four notification of plants obtained through site-directed mutagenesis or cisgenesis has been presented and approved in Italy in 2024 and one presented in January 2025 is under evaluation. More details can be found in the Food and Feed Information Portal Database of the European Commision (https://ec.europa.eu/food/food-feed-portal/screen/gmob/search) and in the website of the Italian National Competent Authority for the environmental release of GMOs

(https://bch.mase.gov.it/index.php/it/?view=article&id=435&catid=15).

Some information on field trials:

Notification Number B/IT/24/01

Proposed period of release: 30/03/2024 to 26/10/2024

Name of the Institute: University of Milan (UNIMI)

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.

Notification Number B/IT/24/02

Proposed period of release: 13/05/2024 to 31/12/2027

Name of the Institute: Council for Agricultural Research and Economics (CREA) - Research centre for Vegetable and Ornamental Crops

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/24/03

Proposed period of release: 31/7/2024 to 31/10/2028

Name of the Institute: EdiVite

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/24/04

Proposed period of release: 15/5/2025 to 31/10/2030

Name of the Institute: Fondazione Edmund Mach

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/25/01 (under approval)

Proposed period of release: 30/03/2025 to 12/10/2027

Name of the Institute: University of Milan (UNIMI)

Rice (Oryza sativa) plants of 4 different varieties modified, through CRISPR/Cas9 system, to improve resistance to blast (Pyricularia oryzae). Two of the lines have already been released following authorization from the Italian Ministry of environment (MASE-notification B/IT/24/01)

Risk assessment for GMMs

Competent Authorities (CA) under Directive 2009/41/EC, regarding the contained use of Genetically Modified Microorganisms (GMMs) is the Ministry of Health (MoH). In compliance with the Italian Legislative Decree 206/2001, the CA authorizes GMMs installations and activities in accordance with the opinions of the Biotechnology Health Technical Committee (BHTC) of the MoH. The Italian Legislative Decree 206/2001 does not regulate the contained use of GMOs other than GMMs, i.e. GM plants and GM animals. in the three-year period 2022-2024, 407 activity notifications, covering the three areas of Research, Development and Production, were evaluated by the BHTC for their approval. The Contained use of GMMs evaluated for authorization, hold all areas Biotech Sectors (red white and green) and belong mostly to containment classes 1 and 2, except for a small number that belong to containment class 3, often used for research. Most of those GMMs authorized have been obtained by editing techniques (CRIPR Cas 9 and also other techniques), short interfering RNA, microRNA, etc. In some cases, editing techniques have also been used and authorized for advanced therapy drug development (ATMP).

Risk assessment research projects

OnFoods, **https://onfoods.it/research-projects?rp-spoke-id=0ac97898-0ca2-4ce3-b381-7711011f8b1f** (Research and innovation network on food and nutrition Sustainability, Safety and Security) is the Italia n research and innovation network for sustainable food and nutrition. Funded under the National Recover y and Resilience Plan (NRRP), € 114.500.00, (2022-2025).

The project, coordinated by University of Parma (UNIPR), is a partnership extended to university, research centres and companies that brings together, coordinates and amplifies the work of 26 public and private organisations, leaders in scientific research and sustainable innovation of food systems.

In particular, Spoke 03 is focused on enhancing food and nutrition quality to better meet the needs and expectations of the modern consumer. The project achieves this through various means, such as food reformulation, innovative and sustainable technologies, and new food design. Research activities under Spoke 03 include evaluating new, emerging, and (re)-emerging risks in the food system. The project develops strategies to ensure the healthiness of food, taking into account new sustainable technologies. Additionally, Spoke 02 aims to understand the applicability and safe use of new foods in the food system.

Novel Food

Within the framework of the 'GP/EFSA/NUTRI/2021/01' call for activities to support the safety evaluation of novel foods and nutrient sources, three Italian research groups support EFSA in its third year, namely University of Parma (UNIPR), Council For Agricultural Research And Economics (CREA – Center for Food and Nutrition, Rome) and National Research Council of Italy (CNR Rome).

Environmental Risk Assessment

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

4 notifications for the environmental release of plants in Italy,

22 notifications for the placing on the market genetically modified organisms as or in products within the Europena Union,

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

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

- *Development of a roadmap for action on the application of Omics and associated Bioinformatics Approaches in Risk Assessment*. Santiago Radio, Marco Di Marsico, Costanza Bersani, Roberto Malinverni, Josep Casacuberta, Chiara Corpetti, Riccardo Aiese Cigliano, Walter Sanseverino. Sequentia Biotech SL; **Centre for Research in Agricultural Genomics CSIC - IRTA - UAB -** UB; Annion Pharma; Network Research Belgium, Trasys International. EFSA Supporting publication 2024:EN-9086, **doi: 10.2903/sp.efsa.2024.EN-9086**
- *Refinement of the Risk Assessment Methodology for Open Reading Frames in GMO Applications* Daniele Urbani, Marianna Penzo, Martina Evangelisti, Marco Daniele Parenti, Alberto Del Rio Innovamol Srl, Alma Mater Studiorum – University of Bologna, Reference: OC/EFSA/GMO/2021/0 **doi: 10.2903/sp.efsa.2024.EN-8561**

- *Development of in silico methodologies to predict the toxicity of novel proteins in the context of food and feed risk assessm*ent L. Palazzolo, T. Laurenzi, O. Ben Mariem, A. Bassan, U. Guerrini, I. Eberini, **Dipartimento di Scienze Farmacologiche e Biomolecolari, Università degli Studi di Milano; INNOVATUNE, Padova, Italia. doi:10.2903/sp.efsa.2024.EN-9063 External Scientific Report**
- *Outsourcing preparatory work based on a systematicliterature review for the development of adverseoutcome pathways (AOPs) relevant for the capacityof proteins to trigger celiac disease***.** Camilla Bebi, Daniele Urbani, Martina Evangelisti, Valentina Grossi,Francesco Russo, Alberto Del Rio Innovamol Srl, Modena, Italy; National Institute of Gastroenterology Research Hospital – IRCCS Castellana Grotte (Bari), Italy. **EFSA Supporting publication 2024:EN-8570 : 10.2903/sp.efsa.2024.EN-8570**
- *Book: A Roadmap for Plant Genome Editing, Publisher Springer Cham, 2024* *https://doi.org/10.1007/978-3-031-46150-7*
  -Chapter 3: Novel Delivery Methods for CRISPR-Based Plant Genome Editing, Barbara Doyle Prestwich, **Teodoro Cardi**, Allah Bakhsh, **Alessandro Nicolia**, and Kaushal Kumar Bhati (**Pages 41-67)**
  -Chapter 6: Methods and Techniques to Select Efficient Guides for CRISPR-Mediated Genome Editing in Plants, **Fabio D'Orso, Valentina Forte, Simona Baima, Marco Possenti, Daniela Palma, Giorgio Morelli (Pages 89-117)**
  Chapter 11: Current Status and Future Prospective of Genome Editing Application in Maize, **Serena Varotto (Pages 165-182)**
  -Chapter 12: Using Gene Editing Strategies for Wheat Improvement, **Domenica Nigro**, Mark A. Smedley, **Francesco Camerlengo**, and Sadiye Hayta (Pages **183-201)**
  -Chapter 22: Engineering Phytonutrient Content in Tomato by Genome Editing Technologies Aurelia Scarano and Angelo Santino **(Pages 385-393)**
  "The distinctive effect of different insect powders as meat extenders in beef burgers subjected to cooking and in vitro gastrointestinal digestion" (June1, 2024)
  Rocchetti, G., Leni, G., Rebecchi, A., Dordoni, R., Giuberti, G., & Lucini, L. Food Chemistry, 2024, 442, 138422, doi.org/10.1016/j.foodchem.2024.138422

Japan

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

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

As of January 2025, 336 GM foods (12 potato; 29 soybean; 3 sugar beet; 213 maize; 24 oilseed rape (canola); 48 cotton; 5 alfalfa; 1 papaya; and 1 mustard) and 85 GM food additives have undergone safety assessment and been announced in the Official Gazette; out of these foods and food additives, 3 foods and 5 food additives have undergone safety assessment and been announced in the Official Gazette since the last meeting in March 2024.

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

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

As of January 2025, 106 GM feeds (20 oilseed rape (canola); 36 maize; 19 soybean; 21 cotton; 3 sugar beet; 3 alfalfa; and 4 potato) and 16 feed additives have undergone safety assessment and been announced in the Official Gazette; out of these feeds and feed additives, 3 feeds and 1 feed additive have undergone safety assessment and been announced in the Official Gazette since the last meeting in March 2024.

3. Feed safety guideline for feeds and feed additives derived from genome editing technology

MAFF has established guidelines for commercializing the feeds and feed additives derived from genome editing technology. The guideline requests developers and/or users to notify them before their commercialization. Feeds or feed additives obtained through recombinant DNA technology are not subject to the notification.

Notification is not required for crossbred progeny that has been obtained by crossbreeding conventional products and others* by a traditional breeding method with respect to the item notified as a genome edited feed (amended in April 2021).

* Conventional breeds as well as new breeds, such as those already notified as genome edited feeds and recombinant DNA feed products which have been judged safe by safety assessment

Detailed information will be available on the MAFF website:

https://www.maff.go.jp/e/policies/ap_health/petfood/

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.

Latvia

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

As an EU Member State, Latvia applies the EU legislation to novel foods, GM food and feed, contained use of GMOs, and the deliberate release of GMOs into the environment. Accordingly, Latvia participates in the safety assessment and decision-making processes under Regulation (EC) No 1829/2003 on genetically modified foods and feeds, Directive 2001/18/EC on deliberate release into the environment of GMOs and Regulation (EU) 2015/2283 on novel foods.

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.

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

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)

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

The proposal is part of a package of proposals to ensure resilient and sustainable use of the EU's natural resources.

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

The legislative procedure is on-going. Latvia participated in the work on the proposal at the level of experts of the EU member states. Considering that the use of news genomic techniques should be properly regulated in the EU level.

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

Slovenia

Slovenia, as a member of the EU is bound by the common European legislation. The competences and the status of GM products in Slovenia remains unchanged.

GMOs in food and feed

The Competent Authority for GMOs in food and in feed is The Administration of the Republic of Slovenia for Food Safety, Veterinary Sector and Plant Protection, which is the body within the Ministry of Agriculture, Forestry and Food. In 2024 we tested samples of food and feed. On an annual monitoring basis, we are establishing that feed consisting of or containing GMO is often on the Slovenian market, but we can rarely find the food consisting of or containing GMOs, same goes for presence of unapproved GMOs. Last year Slovenia continued monitoring the presence of genetically modified microorganisms (GMMs) with antibiotic resistance marker genes in food and feed. Despite the good results of the annual monitoring, Slovenia in the year 2025 is continuing the testing of the presence of GMOs and GMMs in food and feed in our market.

Monitoring of GMOs in seed

In the framework to ensure safety in the use of products of modern biotechnology the Competent Authority for contained use, deliberate release and placing GMOs on the market is in the Ministry of the Environment, Climate and Energy. In that respect it is also responsible for monitoring of GMOs presence in seeds, which is taking place in Slovenia for many years. All seed samples tested in 2024 were negative for the presence of GM elements. In 2025, 27 samples of seeds of maize, rapeseed, soybean and alfalfa are planned for GMO analysis: 15 samples of maize seed, 5 samples of rapeseed, 5 samples of soybean seeds and 2 samples of alfalfa seeds. All samples will be analyzed by screening analysis with the five-target method for the presence of genetic elements: CaMV 35S promoter, NOS terminator, bar, pat and CTP2-CP4-EPSPS and determination of the reference gene (presence of DNA, maize, soybean, rapeseed or alfalfa). In case of maize additionally DAS40278 and MON95379 are tested, because they are not covered by five-target method. Till now we have tested 5 maize samples. All the 5 maize samples tested were negative for the presence of GM elements.

GMOs in cultivation

Slovenia has no commercial cultivation of GMOs, neither field trials. The Competent Authority for coexistence of crops is The Ministry of Agriculture, Forestry and Food. In 2024 cultivation plants were tested for the presence of GMOs under the law on the coexistence of crops with genetically modified plants. All of them were negative on presence of GMO.

Laboratory's Capacity for GMOs detection

National Institute of Biology (NIB) is nominated as National Reference Laboratory for detection of genetically modified organisms in food, feed and seed, for development of methods and other tasks related to GM control by Ministry of Agriculture, Forestry and Food and Ministry of Environment, Climate and

Energy of the Republic of Slovenia. NIB is testing samples of food, feed, plants and seeds for official control. NIB is a holder of the national measurement standard in the category of amount of substances/bioanalysis of nucleic acids, especially in the field of GMOs and microorganisms. Department of Biotechnology and Systems biology at NIB has 80 qPCR accredited methods for qualitative and quantitative testing of genetically modified organisms in foodstuffs and agricultural products of plant origin (further methods are yearly in the process of verification), 3 methods for quantification by dPCR and 6 methods for detection of genetically modified microorganisms (3 methods for the screening of antibiotic resistance marker genes (AMR genes) and 3 methods for specific gene detection (Protease 1, Protease 2 and α–amylase). In 2024 NIB accredited 6 new methods for detection of genetically modified organisms.

Digital PCR is the latest PCR-based approach that enables absolute quantification of nucleic acids. From 2013 on, NIB greatly contributed to the research of digital PCR (dPCR) for GMO analyses and received three 2021 Positive Droplet Awards from Bio-Rad Laboratories, for contributions to digital PCR in the fields of Metrology, Advanced Multiplexing and Food Testing. Digital PCR is used also during routine analyses especially during verification of methods. In 2024 we've developed a new multiplex dPCR approach for quantification of all approved GM soybean lines. We plan to publish the results of the development in 2025. NIB cooperates intensively within European network of GMO laboratories (ENGL) and their working groups and additionally with Directorate F of JRC on studies of reference materials. The Institute is also providing scientific and technical support to authorities. NIB is also a member of the Network of Laboratories for the Detection and Identification of GMOs operating under the Cartagena Protocol on Biosafety and plays an active role in preparing documents for the network.

New Genomic Techniques (NGT)

NGT (New Genomic Techniques) products are, according to the ruling of the Court of Justice (ECJ) of 25July 2018, GMOs. They are under the scope of Directive 2001/18/EC and subject to the requirements of this Directive. For now, no NGT products are authorized as food/feed or for cultivation in the EU. The discussion of the proposal is being discussed at the Council and Parliament level. Slovenia participates in the discussion about NGT.

During this time, the two Slovenian scientific committees for work with GMOs (for release and intended for contained use) also held a debate on the EU proposal on the use of New Genomic Techniques (NGTs) for the breeding of cultivated plants, which was supported by the European Parliament on 07 February 2024. Both committees supported the proposal in a joint expert opinion and thus prepared the basis for the implementation of the EU proposal in our area as well. This is also important because, in the coming months/years, the initiative will most likely extend to the use of these technologies in the selection of farm animals.

National Institute of Biology (NIB) is following the developments in Genome editing in Plants as a member of COST Action CA18111 Genome Editing in Plants (https://plantgenomeediting.eu/), which ended in 2023.

Moreover, as a member of European Network of GMO Laboratories (ENGL), NIB is following and contributing to discussions at this level.

In 2024 NIB contributed to a new ENGL report " Sequencing strategies for the traceability of GMOs"). NIB is also a member of European Initiative for Sustainable Agriculture through Genome Editing (EU-SAGE; https://www.eu-sage.eu/). EU-SAGE is a network representing 134 European plant science institutes and societies that have joined forces to provide information about genome editing and promote the development of European and EU member state policies that enable the use of genome editing for sustainable agriculture and food production.

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

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

Non-GM Novel foods

As in other European countries, also in Slovenia, very current topics are breeding and use of different kinds of insects, and the cultivation and use of hemp and hemp-derived product as a food. Such products are mainly, with a few exceptions, according to the EU novel food catalogue, considered as novel foods and they require a novel food authorization before entering the market in EU.

Nano

We are taking part in preparation of COMMISSION DELEGATED REGULATION amending Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods as regards the definition of ‘engineered nanomaterial’ which is in its final stages.

We follow the work of EFSA scientific network on nanotechnologies in food and feed.

The Jozef Stefan Institute, in cooperation with its spin-off companies, has developed the first sensor with the ability to measure the numerical concentration of respiratory droplets in animal housing and distinguish them from solid aerosol particles. The detection is immediate in real time. Droplet concentrations of up to 6 billion droplets in cubic meter can be detected. The size of the detected droplets is between 100 nanometers and 100 microns. Preliminary tests were carried out in a housing with 16 adult cows and showed relatively high concentrations of animal droplets of up to 80,000 in cubic meter. The device is suitable for alarming of increased concentrations of respiratory droplets released by animals with a respiratory disease. On animal farms with high densities of reared animals, ventilation inside the housing requires a high level of attention to prevent disease transmission. Monitoring aerosols in animal housing can contribute to the control of animal diseases and also to the protection of breeders. Zoonotic pathogens are responsible for 75% of emerging infectious diseases in humans, and outbreaks of zoonotic pathogens can have significant economic consequences worldwide.

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.

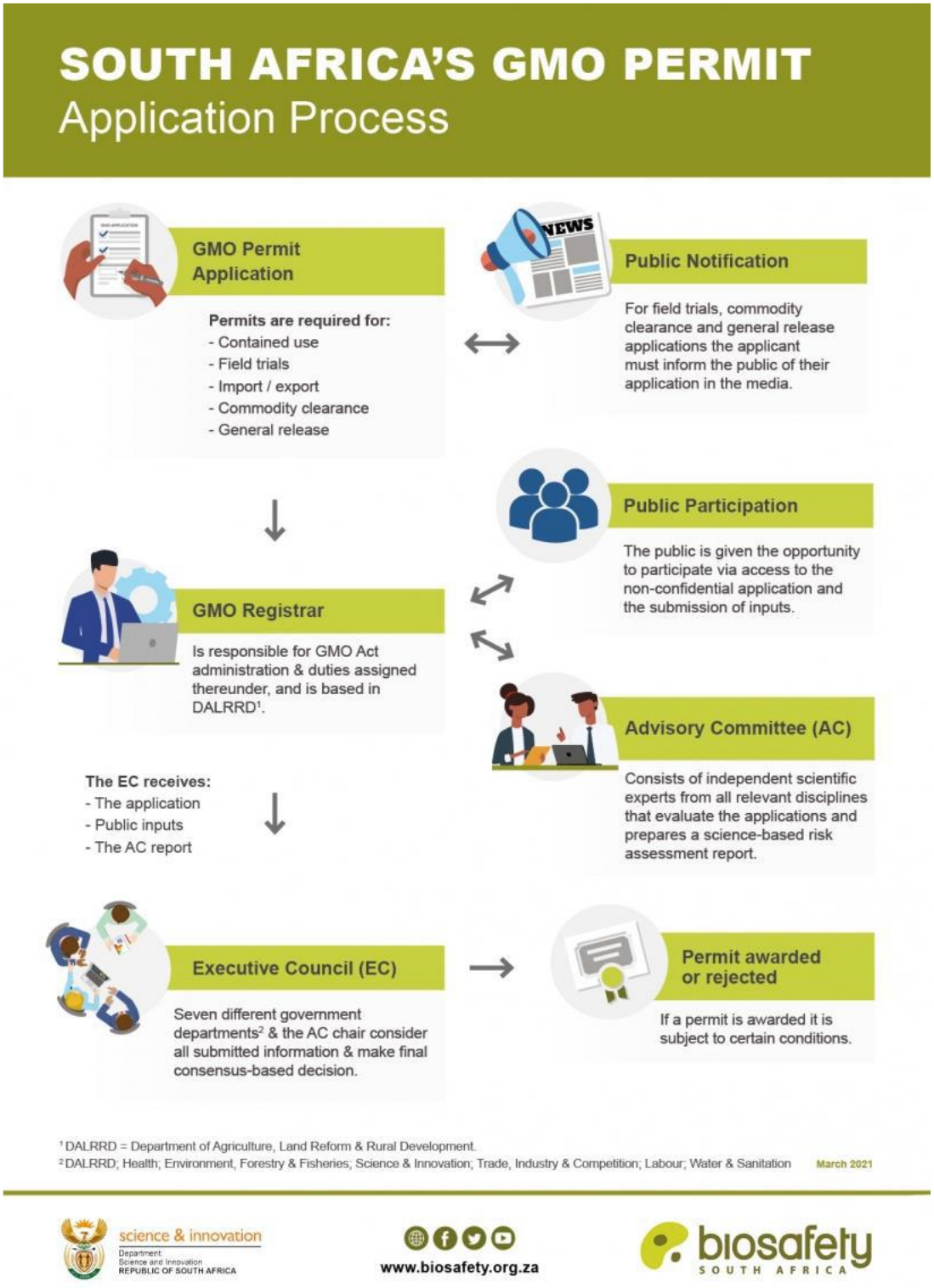
Functions of registrar

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
www.biosafety.org.za
biosafety
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

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

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

United States of America

Food and Drug Administration

Completed Premarket Consultations

BNF No	Food	Designation	Trait(s)	Developer+	Unique Identifier	Date Completed
192	Apple	PG451	Change in composition (reduced polyphenol oxidase activity)	Okanagan Specialty Fruits, Inc.	OKA-PGØØ4-1	Sep 19, 2024
197	Potato	BG25	Blight Resistance Change in composition (reduced levels of reducing sugars) (reduced polyphenol oxidase activity) (reduced black spot bruising)	J.R. Simplot Company	SPS-ØBG25-7	Sep 19, 2024
193	Soybean	MON 94313	Herbcide tolerance (dicamba, glufosinate ammonium, 2,4-D, mesotrione)	Bayer CropScience LP	MON-94313-8	Sep 18, 2024
196	Corn	DP51291	Insect resistance Herbicide tolerance (glufosinate ammonium)	Pioneer Hi-Bred International, Inc.	DP-Ø51291-2	Jul 12, 2024
194	Corn	EH913	Insect resistance Herbicide tolerance (glufosinate ammonium)	Helix Sementes e Biotecnologia Ltda.	EH-BRS913-2	May 22, 2024

Premarket meetings for food from certain genome edited plants:

VPM No.	Date of meeting	Plant	Trait(s)	Designation(s)	Developer	Intended use
00001	Aug 1, 2024	Mustard Greens (*Brassica juncea*)	Reduced pungency Reduced trichome number	GT225 GT226 GT241 GT267 GT252 GT254 GT269 GT270 GT280 GT286 GT288 GT290 GT291 GT292 GT302 GT303 GT304 GT313 GT314 GT351 GT352	Pairwise Plant Services, Inc.	Human food

Completed Pre-market Consultations for Human Food Made with Cultured Animal Cells:

File No.	Food	Submission	FDA Response	Scientific Memo
000008	Cultured *Sus scrofa domesticus* (pork) fat cell material	Part 1 - 5/25/2022 Part 2 - 5/25/2022	3/7/2025	3/7/2025

Intentional genomic alterations (IGAs) in animals

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

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.

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.

3. 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).

2. 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

3. 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)"

3. Developments related to novel foods and feeds

1. Novel foods

Since Regulation (EU) 2015/2283 on novel foods became applicable as of 1 January 2018, an e-submission system was developed to allow the applicants to submit novel foods applications and/or traditional foods notifications from third countries, online. The system has been adapted to the requirements of Regulation (EU) 2019/1381 (transparency regulation), which became applicable as of 27 March 2021.

Overall, the European Commission has received, to date, through the e-submission system 664 (607 by Feb 2024) applications and 121 (114 by Feb 2024) traditional foods from third countries for authorisation since the regulation became applicable. To date, the Union list of novel foods has been amended 156 (129 times by Feb 2024), including the authorisation of twelve traditional foods.

2. Novel feeds

The European Food Safety Authority (EFSA) adopted in 2015 an opinion on the risk profile related to products and consumption of insects as food and feed[2]. This opinion is one of the elements that served as a basis to regulate the use of these products from different angles.

Animal Nutrition regulatory framework

Regulation (EC) No 767/2009[3] on the placing on the market and use of feed regulates some aspects related to the production and placing on the market of insects. It requires, amongst others, that the feed business operator marketing insects or products derived therefrom for feed use must guarantee their safety. It also prohibits certain products to be used as substrates for the feeding of insects.

Commission Regulation (EU) 2017/1017[4] on the Catalogue of Feed Materials has split the former feed material “Terrestrial invertebrates” into two different feed materials: “Terrestrial invertebrates, live” and “Terrestrial invertebrates, dead”. Therefore, live insects are permitted as feed under the national legislation in accordance with Regulation (EC) No 767/2009 and pets. In addition, if a feed material is labelled with a name in the Catalogue (e.g. processed animal protein), the name must be supplemented as appropriate by certain indications. For insects, the life stage (e.g. larvae) is one of these indications.

Directive 2002/32/EC[5] on undesirable substances, as well as Regulation (EC) No 396/2015[6] establishing pesticide residue limits, apply to feed derived from insects.

[2] EFSA Journal 2015;13(10):4257

[3] Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed (OJ L 229, 1.9.2009, p. 1).

[4]Commission Regulation (EU) 2017/1017 of 15 June 2017 amending Regulation (EU) No 68/2013 on the Catalogue of feed materials (OJ L159, 21.6.2017, p. 48).

[5] Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed - Council statement (OJ L 140, 30.5.2002, p. 10).

[6] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1–16)

Animal by-products regulatory framework

Regulation (EC) No 1069/2009[7] on animal by-products (the ABP Regulation) lays down that insects reared in the EU are farmed animals; this has also implications on the substrates for them, as it prohibits feeding insects with category 1 and 2 materials, including catering waste and certain former foodstuffs.

The ABP regulatory framework covers killed insects and processed animal protein (PAP) from insects, but not live insects.

Both killed 'untreated' whole insects and killed whole 'treated' insects (e.g. 'dry or frozen insects') are prohibited for use as feed for farmed animals other than fur animals. The ABP Regulation allows insects not processed in accordance with the specific ABP methods (e.g. simple treatments like freezing or drying) for pet food.

Finally, Regulation (EU) No 142/2011[8] implementing Regulation (EC) No 1069/2009 laid down requirements for the production of processed animal protein (PAP) from insect, including a positive list of eligible insect species (4 as of November 2021), as well as import conditions that reflect these EU internal standards.

TSE regulatory framework

Regulation (EC) No 999/2001 lays down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies (the TSE Regulation). It includes a general prohibition to feed, inter alia, any PAP to farmed animals, other than fur animals.

However, by derogation, Commission Regulation (EU) 2017/893[9] authorised insect PAP in feed for aquaculture animals. The use of insect PAP was further extended to poultry and porcine animals by Commission Regulation (EU) 2021/1372[10]. The analytical methods for the control of these feed ban rules are laid down in Annex VI to Commission Regulation (EC) No 152/2009[11].

The feed ban laid down in the TSE Regulation does not apply to live insects, nor to fats and oils derived from insects.

[7] Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (OJ L 300, 14.11.2009, p. 1).

[8] Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1)

[9] Commission Regulation (EU) 2017/893 of 24 May 2017 amending Annexes I and IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Annexes X, XIV and XV to Commission Regulation (EU) No 142/2011 as regards the provisions on processed animal protein. (OJ L 138, 25.5.2017, p. 92).

[10] Commission Regulation (EU) 2021/1372 of 17 August 2021 amending Annex IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the prohibition to feed non-ruminant farmed animals, other than fur animals, with protein derived from animals (OJ L 295, 18.8.2021, p. 1–17)

[11] Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 054 26.2.2009, p. 1)

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[12]. 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.

[12] 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.

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.

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.

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.

2. 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 Bangladesh on 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

Crop Composition Database

AFSI's Crop Composition Database (CCDB) is a curated, open access resource that provides compositional data on the natural variability in nutrients, anti-nutrients, and secondary metabolites of some conventionally bred crop species that form the world's food and feed supply. The data can be applied to improve overall knowledge of human nutrition, inform the development of diets that promote the healthy growth of livestock, and improve global datasets related to food security and nutrition modelling. The database contains compositional data from 17 crops obtained from controlled field trials done over 26 years across 17 countries.

Version 10.0 of the CCDB was released in May 2024 with data for a new tree crop, eucalyptus and additional data for field corn, canola, cotton, soybeans, and potato.

eLearning courses

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

The eLearning courses are free, and access can be requested to these by filling an online form.

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

- *Concepts in the Safety Assessment of Novel Food and Feed*: This course discusses how people use information about foods to make basic decisions regarding food safety and how government regulators use similar information to address the safety of novel foods that may be introduced into their country's food supply.
- *Food Safety of Genetically Engineered Animal Products*: This course covers the safety measures employed to evaluate the risk of genetically engineered animal products and how these animal products are evaluated against non-genetically engineered products.

- *Application of Problem Formulation to Food and Feed Safety Assessments*: This course teaches how to apply problem formulation to the food and feed safety assessment of GE crops.