Organisation for Economic Co-operation and Development

ENV/CBC/MONO(2024)20

Unclassified

English - Or. English

18 June 2024

ENVIRONMENT DIRECTORATE
CHEMICALS AND BIOTECHNOLOGY COMMITTEE

DEVELOPMENTS IN DELEGATIONS ON THE SAFETY ASSESSMENT OF NOVEL FOODS AND FEEDS, MAY 2023 – FEBRUARY 2024

Series on the Safety of Novel Foods and Feeds
No. 38

JT03546381

OECD Environment, Health and Safety Publications

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Environment Directorate

ORGANISATION FOR ECONOMIC COOPERATION AND DEVELOPMENT

Paris 2024

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)

No.35, Developments in Delegations on the Safety Assessment of Novel Foods and Feeds, April 2021 - May 2022 (2022)

No.36, Developments in Delegations on the Safety Assessment of Novel Foods and Feeds, June 2022 - April 2023 (2023)

No.37, Considerations for Collaborative Work on the Safety Assessments of Foods and Feeds Derived from rDNA Plants (2023)

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

This publication is available electronically, at no charge.

For this and many other publications on the Safety of Novel Foods and Feeds, consult the OECD's World Wide Web site (www.oecd.org/env/ehs/biotrack/)

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OECD Environment, Health and Safety Publication

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 www.oecd.org/env/ehs/biotrack/.

Of different content, this information document compiles elements provided by delegations on the 31st WP-SNFF meeting (18-20 March 2024). It aims at summarising relevant information on activities related to the safety assessment of novel foods and feeds since the previous meeting (April 2023) 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 no reviews or updates related to GMO Biosafety regulations by the National Advisory Commission on Agricultural Biotechnology.

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.

In this sense, in 2023 Argentina approved Resolution 481/23: Approval of the procedure for the submission of applications for commercial authorisation of a Genetically Modified Organism (GMO) for agricultural and/or agroindustrial use, within the framework of the Memorandum of Understanding between the Ministry of Science, Technology and Innovations of the Federative Republic of Brazil and the Ministry of Economy of the Argentine Republic for cooperation in biosafety of modern biotechnology products[1].

Having authorised the necessary internal procedures, in 2024 both countries commit to begin joint evaluations and authorisations of modern biotechnology products.

Biodesarrollar Program

The launch of the Biodesarrollar Program in 2022 under Resolution 63/2022[2]. The objective of BIODESARROLLAR is to promote the development, innovation, adoption and production of bioproducts of the bioeconomy that include the areas of biotechnology, bioinputs, biomaterials and bioenergy, by micro, small and medium-sized companies, as well as cooperatives and public research entities and mixed articulation. Priority will be given to initiatives that focus on promoting regional development and adding value at source, with a circular economy vision. Through a component of (1) Financial assistance and another of (2) Technical support.

During 2023, the Program provided financial assistance to 23 bioeconomy projects (biotechnologies, bioenergies, bioinputs and biomaterials) for a total of 250 million pesos with an average assigned amount of 10.5 million pesos per project. The list of beneficiaries, areas, amounts and objectives were published on the website of the Secretary of Agriculture, Livestock and Fisheries:

[1] https://www.argentina.gob.ar/normativa/nacional/resoluci%C3%B3n-481-2023-394385

[2] https://www.boletinoficial.gob.ar/detalleAviso/primera/273291/20221006?busqueda=2

https://www.argentina.gob.ar/sites/default/files/listado-de-entidades-seleccionadas-de-la-primera-convocatoria-del-programa-biodesarrollar.pdf

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		

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 2023-2024:

Unique Identifier	Applicant	Organism Common Names	Traits	Type of use	Date of approval	Decision name
MON-Ø4Ø32-6 x ACSGMØØ6-4	GDM	Soybean	Tolerant to herbicides based on glyphosate and glufosinate ammonium	Cultivation, Food and Feed	31/05/2023	https://www.boletinoficial.gob.ar/detalleAviso/primera/287682/20230602
SYN-BTØ11-1 x SYN-IR162-4 xMON-ØØ6Ø3-6	Syngenta Agro S.A.	Maize	Resistance to certain Lepidoptera and tolerance to glyphosate and glufosinate ammonium	Cultivation, Food and Feed	29/09/23	https://www.boletinoficial.gob.ar/detalleAviso/primera/295411/20231003
DNB-Ø9ØØ4-3xDNB-Ø8ØØ2-3	INDEAR S.A.	Soybean	Tolerance to glyphosate and glufosinate ammonium and resistance to certain Lepidoptera	Cultivation, Food and Feed	02/10/23	https://www.boletinoficial.gob.ar/detalleAviso/primera/295503/20231004
BCS-GHØØ4-7 x BCS-GHØØ5-8 x BCS-GH811-4 x SYN-IR1Ø2-7	BASF	Cotton	Tolerant to HPPD, glyphosate, glufosinate ammonium and protected against certain lepidopterans	Cultivation, Food and Feed	02/11/23	https://www.magyp.gob.ar/sitio/_pdf/Disposicion-50-2023.pdf
MON-87751-7 x MON-877Ø1-2 x MON- 877Ø8-9 x MON-89788-1	MONSANTO	Soybean	Raw material for agroindustrial processing and for human and animal food use	Only for processing	06/02/24	https://www.argentina.gob.ar/sites/default/files/disposicion-n-3-2024-soja-mon-87751-7-x-mon-877o1-2-x-mon-877o8-9-x-mon-89788-1.pdf

Microorganisms

Organism	Product	Identifier	Applicant	Phenotype	Date of approval	Decision name
Mycoplasma hyopneumoniae	Recombinant HVT + IBD + ILT virus present in Vaxxitek HVT-IBD-ILTvaccine.	Cepa Nexhyon	HIPRA ARGENTINA S.A	Protects against Marek's disease (MD), infectious bursal disease (IBD, Gumboro disease), and infectious laryngotracheitis (ILT).	31/01/24	https://www.argentina.gob.ar/sites/default/files/disposicion-22024-di-2024-2-apn-ssabdr-mec.pdf
Yeast *Saccharomyces cerevisiae*	GICC03506 (GPY10023) Bioethanol production from grain fermentation	GICC03506 (GPY10023	DANISCO ARGENTINA S.A.	Genetically modified yeast (*Saccharomyces cerevisiae*) with enhanced capability for bioethanol production from grain fermentation	29/12/23	https://www.argentina.gob.ar/sites/default/files/rsolu-2023-3-apn-sagypmec_0.pdf
Yeast *Saccharomyces cerevisiae*	GICC03486 (GPY10009) Bioethanol production from grain fermentation	GICC03486 (GPY10009)	DANISCO ARGENTINA S.A.	Genetically modified yeast (*Saccharomyces cerevisiae*) with enhanced capability for bioethanol production from grain fermentation	29/12/23	https://www.argentina.gob.ar/sites/default/files/rsolu-2023-3-apn-sagypmec_0.pdf
Yeast *Saccharomyces cerevisiae*	GICC03578 (GPY10168), Bioethanol production from grain fermentation	GICC03578 (GPY10168)	DANISCO ARGENTINA S.A.	Genetically modified yeast (*Saccharomyces cerevisiae*) with enhanced capability for bioethanol production from starch."	04/01/24	https://www.argentina.gob.ar/sites/default/files/resol-2024-6-apn-sagypmec_0.pdf
Yeast *Saccharomyces cerevisiae*	GICC03588 (GPY00603) Bioethanol production from grain fermentation	GICC03588 (GPY00603)	DANISCO ARGENTINA S.A.	Genetically modified yeast (*Saccharomyces cerevisiae*) with enhanced capability for bioethanol production from starch."	04/01/24	https://www.argentina.gob.ar/sites/default/files/resol-2024-6-apn-sagypmec_0.pdf
Saccharomyces cerevisiae	Yeast Saccharomyces cerevisiae strain Fermboost MR Bioethanol production from grain fermentation	Fermboost MR	LALLFERM S.A.	Genetically modified yeast with improved capacity for bioethanol production from starch fermentation	24/01/24	https://www.argentina.gob.ar/sites/default/files/di-2024-1-apn-ssabdr-mec.pdf

It is important to note that Argentina has authorised 6 (six) genetically modified organisms since the last report. These authorisations of vaccines for animal health and yeasts for bioethanol production constitute the first authorisations of GM microorganisms in Argentina under Resolution 5/18[3] and Resolution 52/19[4], which provided a legal framework for these authorisations.

New Breeding Techniques

A total of 68 Prior Consultation Instance (PCI) forms were submitted for the period April 2023 - March 2024. Thereof 7 forms were submitted for products in development stage and 61 for real products.

According to organisms, it can be said that out of the 64 PCI forms, 1 (one) PCI was submitted for a microorganism, 9 (nine) 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, 135 PCIs have been analysed for different organisms (plants, animals, and microorganisms).

[3] https://magyp.gob.ar/sitio/areas/biotecnologia/conabia/_pdf/RES_005_2018_2%20anexos.pdf
[4] https://magyp.gob.ar/sitio/areas/biotecnologia/conabia/_pdf/RES_052_2019_2%20anexos.pdf

Participation in International Activities

2023:

Three bilateral, regional and multilateral high-level meetings:

a. Meeting GT5 “Public policies in biotechnology” of the Southern Agricultural Council (CAS) held on March 16-17 in Buenos Aires, Argentina.

b. Like-Minded countries meeting (Like Minded Group) April 28 and 29 in Saint Louis, United States. Argentina co-organizer of the event.

c. Participation in the 16th ISBR Symposium (The International Society for Biosafety Research) event from April 30 to May 4 in Saint Louis, United States.

d. International Gene Edition Workshop held on May 18 and 19 in Buenos Aires, Argentina: cooperation with regulators and officials from Latin America and Africa.

e. Bilateral meeting between Argentina and Saudi Arabia: On May 11th Bilateral meeting with the regulatory agency of Saudi Arabia to coordinate positions regarding the regulation of modern biotechnology and advance future cooperation criteria in the matter.

f. Bilateral meeting between Argentina and the representatives of the Paraguayan biosafety commission of Paraguay on June 30.

g. Argentina participation in APEC HLPDAB SOM3 Workshop held on July 30 and 31 in Seattle, United States on Reducing Redundancies and Facilitating Efficiencies: Regulatory and Policy Solutions for Oversight of Agricultural Biotechnologies.

h. Argentina participation in AGRICULTURE BIOTECHNOLOGY REGULATORS RETREAT, Open Forum on Agricultural Biotechnology in Africa (OFAB) in Petroria, South Africa, from August 1 to 4.

i. SOUTH-SOUTH Collaboration Workshop on Innovations, held in Nairobi, Kenya, from August 23 to 25. Co-organized between Kenya and Argentina. Regulators from Latin America, Africa and Southeast Asia participated.

j. Workshop for the Exchange of Experiences in Scientific Communication between Regulators of New Technologies, the Closed Meeting between Government Officials: Regulatory Aspects in Gene Publishing and the REGULATORS AND SAA MEETING, organized by IICA and SAA, on September 28 and 29 in Lima, Peru. Workshop on gene editing, the Agreement between Argentina and Brazil on Biosafety and on the SOUTH SOUTH Cooperation that Argentina is promoting with the countries of Latin America, Africa and Southeast Asia.

k. Meeting of the Commission for Agricultural Biotechnology of SGT No. 08 of MERCOSUR, under the pro tempore presidency of Brazil, held on October 4 and 5 in São Paulo, Brazil.

l. 10th meeting of our ARG-EU Bilateral Biotechnology Dialogue held virtually on October 26.

m. Bilateral meeting between Argentina and the United Kingdom: virtually meeting on November 10 about the experiences of Argentina's regulation on NBT, on the eve of the UK's presentation of its new regulations on NBT.

n. Bilateral meeting between Argentina and Kenia: virtually meeting on November 10.

o. Visit to Argentina by a delegation of Kenya Agricultural and Livestock Research Organization (KALRO) officials from Kenya from October 16 to 20.

p. Participation in the Paraguayan Symposium on Advances in Agricultural Biotechnology, on November 15 and 16 in Asunción, Paraguay.

Other international activities held on 2023-2024

- Global Low Level Presence (GLI) Meeting on June 7 virtually.
- Argentina organized the 27th INTERNATIONAL CONSORTIUM ON APPLIED BIOECONOMY RESEARCH (ICABR) Bioeconomy Congress, in Buenos Aires, Argentina from July 4 to 5.
- On November 30, virtually Argentina, Argentine representation at the Virtual Like Minded Group Meeting.

Communication and education

2023:

- FOAR project "Strengthening of capacities for activities with new breeding techniques (NBT), including gene editing" with Peru for technical assistance and training in gene editing that was carried out during four missions in 2023 and 2023:
    - 1st Mission of 2023: Week in March of training for officials and technicians from Peru: 3rd FOAR Mission in Lima, Peru.
    - 2nd Mission of 2023: training for officials and technicians from Peru: 4th FOAR Mission held in Buenos Aires, Argentina, on October 16 and 17.
- Document publication of GT5 “Policies for Biotechnology” of the Southern Agricultural Council (CAS): “Evolution of the use of biotechnology in the countries of the Southern Agricultural Council[5]”
- On May 6, training for boys in their last year of high school from all over the country, an activity organized together with the Junior Achievement Argentina Program Partners association (https://junior.org.ar/programas/)
- Publication of three editions of the magazine Biodesarrollar[6]. A way to communicate and share all the advances in the bioeconomy.
- Training given to National Public Universities, to provide basic knowledge about agricultural biotechnology, its journey to modern biotechnology in production animals and its regulatory system in Argentina.
    - June 29, 2023 - Faculty of Veterinary Sciences of the National University of Buenos Aires (UBA): "INTRODUCTION TO MODERN BIOTECHNOLOGY IN ANIMALS IN THE AGRICULTURAL FIELD".
    - October 5, 2023 - Veterinary Medicine of the National University of Rio Negro (UNRN): "INTRODUCTION TO MODERN BIOTECHNOLOGY IN ANIMALS IN THE AGRICULTURAL FIELD".
    - October 25, 2023 - Faculty of Veterinary Sciences of the National University of La Pampa (UNLPam): "INTRODUCTION TO MODERN BIOTECHNOLOGY IN ANIMALS IN THE AGRICULTURAL FIELD".

[5] http://consejocas.org/wp-content/uploads/2023/07/Publicaci%C3%B3n-Evoluci%C3%B3n-del-uso-de-la-biotecnolog%C3%ADa-en-los-pa%C3%ADses-del-CAS.pdf
[6] https://www.argentina.gob.ar/agricultura/alimentos-y-bioeconomia/revista-biodesarrollar

AUSTRALIA

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

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 30th Meeting and applications currently under assessment by FSANZ include:

Food derived from:	Current Status:
Insect protected corn line MON95275	Approved August 2023
Drought and herbicide tolerant soybean line IND-00410-5	Approved September 2023
Herbicide tolerant and insect protected corn line DP51291	Approved December 2023
Herbicide tolerant and insect protected corn line DP915635	Approved February 2024
Disease resistant banana line QCAV-4	Approved February 2024
Herbicide tolerant soybean line MON94313	Under assessment
Herbicide tolerant and insect protected corn line DAS1131	Under assessment
Herbicide tolerant and insect protected corn line DP910521	Under assessment
Short-stature corn line MON94804	Under assessment
Disease resistant, low reducing sugars and reduced browning potato line BG25	Under assessment

Disease resistant banana line QCAV-4

FSANZ has approved an application from Queensland University of Technology (QUT) to permit food derived from a banana line genetically modified for resistance to Panama disease. In a separate but parallel regulatory assessment, the Office of the Gene Technology Regulator (OGTR) has approved a licence for the commercial cultivation of banana line QCAV-4 in Australia.

Banana line QCAV-4 is the first whole GM fruit assessed and approved by FSANZ and the first GM banana approved in the world. FSANZ notified Australian and New Zealand food ministers of the decision

on 16 February 2024. Food ministers have 60 days to consider the approval. If they do not request a review, the Code will be amended to permit the sale and use of food derived from the banana.

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

https://www.foodstandards.gov.au/food-standards-code/applications/A1274-Food-derived-from-disease-resistant-banana-line-QCAV-4

GM safety assessment sharing between FSANZ and Health Canada – update

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. See also: https://www.foodstandards.gov.au/consumer/gmfood/GM-food-safety-assessment-sharing

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 joint safety assessments have been successfully completed by FSANZ and Health Canada in 2021 and 2023. In the second pilot, a common template was developed for when applications are being assessed under the sharing arrangement. FSANZ and Health Canada are currently formalising the safety assessment arrangement by developing a range of materials including: guidance for applicants, standard operating procedures and updated website content. Further shared safety assessments are planned for 2024.

New breeding techniques – update

Since 2020, FSANZ has been working on a proposal to amend the definitions in the *Australia New Zealand Food Standards Code* (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.

FSANZ undertook a first round of public consultation at the end of 2021 where it was proposed to exclude certain low risk foods from pre-market assessment and approval as GM foods on the basis of their equivalence to foods derived through conventional breeding. A total of 1736 submissions were received in response.

After analysing the submissions, FSANZ has decided to affirm its conclusion that certain foods and substances added to food will be equivalent to conventional products in terms of risk and should not be GM foods for regulatory purposes. In response to submitter feedback, FSANZ has further simplified the approach to improve clarity and enforceability, and ensure that consistent and scientifically supportable regulatory outcomes would be achieved. This refined approach will be subject to a further round of consultation, anticipated to occur mid-2024. For this second consultation, FSANZ will provide the proposed draft amendments to the Code, including a new definition for genetically modified food.

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

Cell-based food assessment in Australia

FSANZ is currently assessing its first cell-based food application. The application is from Vow Group Pty Ltd who are seeking approval for cultured quail cells as a novel food. The first of two public consultations occurred over December 2023 – February 2024 and sought views on FSANZ's assessment.

As part of the first public consultation, FSANZ made available its hazard and risk assessment which evaluated:

1. hazards associated with the cell line;
2. the production process, including any relevant inputs used to grow and propagate the cells; and
3. the cells at the point of harvest which includes collection, packaging and freezing.

The assessment found the cultured quail cell line to be genetically stable and microbiological risks associated with cell line sourcing and harvest are very low. FSANZ also found no toxicological, nutritional safety or food allergenicity concerns associated with the consumption of the cultured quail cells.

FSANZ also prepared a rapid systematic evidence review on consumers' understanding, preference and acceptance of different terminologies for cell-cultured meats, as well as consumers' perceptions of cell-cultured meat relative to conventional meat. Terms that incorporate the word 'cell' (e.g. 'cell-cultured', 'cell-cultivated' and 'cell-based') best enabled consumers to correctly identify the true nature of the product and were perceived as being the most descriptive by consumers. The first public consultation proposed the term 'cell-cultured' be used in labelling of the product.

FSANZ is currently analysing public consultation submissions and anticipates the second public consultation to occur mid-2024. 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

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.

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 is part of 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:

Development of a Next Generation Sequencing (NGS)-based approach to characterize unauthorised GMOs. This can be applied in isolated GMO or complex matrices using enrichment steps for targeted DNA by DNA walking.

Detection of genetically modified microorganisms (GMM): As a result of the national research project SPECENZYM (RT17/5), TAG has developed the FEDA database (Food Enzyme Database - https://bioit-webapp-prod.sciensano.be/specenzyme/) which is a web application gathering information about food enzyme preparations available on the European market.

TAG coordinates a Belgian federal project on development of new open strategy for impurity surveillance of commercial microbial fermentation food products (ENSURED), which started in 2023.

In parallel, another research project (AMRSEQ) involved in the characterisation of plasmids, financed by Sciensano, is on-going. Plasmids are elements that are often present in GMM and may carry antibiotic resistance genes, and are particularly difficult to characterize. Therefore, in this project, the specific abilities of different NGS platforms are combined, such as aligning high-quality short reads generated by the Illumina® technology to substitutes for reference sequences created by the long reads generated by the Pacific Biosciences® and/or Oxford Nanopore® technologies.

A research project focusing on metagenomics approaches (sequencing the whole sample) was also initiated in order to strengthen the current GMO detection system for unauthorised GMO (UGM) as well the feasibility to integrate the MinION NGS.

“METAMORPHOSE”: The objective of this research project (financed by Sciensano) 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 characterisation of GMMs used in fermentation products or as a bioweapon, ii) quality control of vaccines and medicinal products and iii) characterisation 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.

Development and evaluation of approaches for detection of organisms modified by new genome editing techniques (GenEdit): The Belgian federal project on development of novel approaches and strategies for detection of GE plants in food and feed products started in 2021. TAG has worked on the application of ddPCR for detection of GE plants. Next year, targeted NGS using Illumina technology is foreseen.

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 will focus on development of untargeted sequencing approaches (including WGS, LCM and metagenomics for pure NGT products and mixtures, as well as on machine learning tools for genetic fingerprints and participate in validation of methods developed within the project.

Peer-reviewed publications:

- B. Bogaerts, M.A. Fraiture, A. Huwaert, T. Van Nieuwenhuysen, B. Jacobs, K. Van Hoorde, S.C.J. De Keersmaecker, N.H.C. Roosens*, K. Vanneste*. Retrospective surveillance of viable Bacillus cereus group contaminations in commercial food and feed vitamin B2 products sold on the Belgian market using whole-genome sequencing. Frontiers in Microbiology - Food Microbiology 2023; 14, 1173594. doi: http://doi.org/10.3389/fmicb.2023.1173594.
- M.A. Fraiture, J. D’aes, E. Guiderdoni, A.C. Meunier, T. Delcourt, S. Hoffman, E. Vandermassen, S.C.J. De Keersmaecker, K. Vanneste, N.H.C. Roosens. Targeted High-Throughput Sequencing Enables the Detection of Single Nucleotide Variations in CRISPR/Cas9 Gene-Edited Organisms. Foods 2023; 12 (455), 1-14. doi: https://doi.org/10.3390/foods12030455
- M.A. Fraiture, A. Gobbo, N. Papazova, N.H.C. Roosens. Development of a taxon-specific real-time PCR method to detect Trichoderma reesei contaminations in fermentation products. Fermentation 2023; 926, 1-13. doi: https://doi.org/10.3390/fermentation9110926
- M.A. Fraiture, A. Gobbo, C. Guillitte, U. Marchesi, D. Verginelli, J. De Greve, J. D'aes, K. Vanneste, N. Papazova, N.H.C. Roosens. Pilot market surveillance of GMM contaminations in alpha-amylase food enzyme products: A detection strategy strengthened by a newly developed qPCR method targeting a GM Bacillus licheniformis producing alpha-amylase. Food Chemistry: Molecular Sciences 2023; 8, 100186. doi: https://doi.org/10.1016/j.fochms.2023.100186.

New Techniques

Belgium, as the current holder of the presidency of the Council of the EU, is actively involved in the ongoing discussions on plants produced by New Genomic Techniques.

BRAZIL

Regulatory Framework

For the past couple of years, a quite a few GMO Biosafety regulations have had reviewed by the National Biosafety Technical Commission – CTNBio, and in this way in the last November it was released the Normative Resolution nº38 about international cooperation in biosafety. This Normative establishes procedures for cooperation between the CTNBio and counterpart international institutions.

Commercial Approvals

Commercial approvals for GMO can be found on the link below.

https://ctnbio.mctic.gov.br/liberacao-comercial#/liberacao-comercial/consultar-processo

GMO Research

In 2023, the CTNBio approved 87 field trials with different plant species, including maize, soybean, lettuce, wheat, citrus, eucalyptus etc. The characteristics of the biotech crops depicts insect resistance, herbicide tolerance, disease resistance, drought tolerance, increased yield and folic acid. The main crops under trial included 35 trials with soybeans, 18 with corn, 9 with sugarcane, 4 with eucalyptus, 3 with cotton and 1 with citrus.

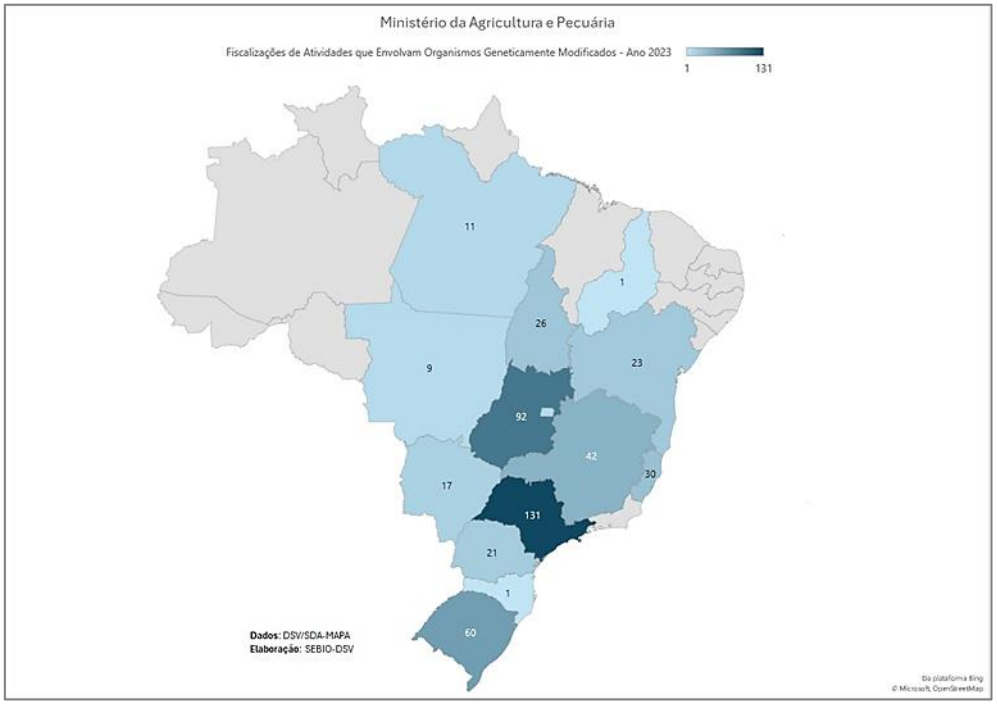
GMO Crops Production

Currently, Brazil is the second-largest producer of biotech crops around the world with 125 events approved for commercial cultivation, of which 62 events are for corn, 24 for cotton, 21 for soybeans, six for sugarcane, eight for eucalyptus, one for a virus resistant variety edible beans and one for drought-tolerant wheat. Therefore, for the 2023/2024 crop season a 56 million hectares planted with GE traits. The widespread adoption of GE events in Brazil has contributed to record soybean (155.3 million metric tons) and corn (117.6 million metric tons) production. The Biotec-Latam reports the following adoption rates in Brazil

- Soybeans: The adoption rate of GE soybean seeds in 2023 was 99 percent;
- Corn: The adoption rate of GE corn seeds in 2023 was 97 percent;
- Cotton: The adoption rate of GE cotton in 2023 was 99 percent;

GMO Inspections

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 464 inspections in field trials all over the country in 2023.



Developments related to new breeding techniques (NBTs)

The CTNBio (National Biosafety Technical Commission) Normative Resolution nº 16 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 (IPB) techniques 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. In practical terms, products obtained either by site-directed random mutation involving the joining of non-homologous ends (SDN1 mutation), or site-directed homologous repair involving one or few nucleotides (SDN2 mutation) meets the conditions established in Normative Resolution nº 16 to be designated as not GM in a case-by-case analysis, but then again, site-directed transgene insertions (SDN3 mutation) are designated GM according to the provisions of the normative and will have to go through all biosafety requirements.

The following IPB products (link below) were considered as conventional in 2023:

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

GM data bank

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

Cell cultured foods

Regulatory aspects

MS National Health Surveillance Agency – ANVISA

BOARD OF DIRECTORS RESOLUTION - RDC No. 839, DATED DECEMBER 14, 2023

(Published at the Official Gazette on December 18, 2023. Available at link)

This resolution addresses the proof of safety and authorisation for the use of new foods and ingredients. It supplements existing standards and also applies to products not covered by these standards.

Key points of the resolution include:

- Definition of terms and concepts
- General requirements for proving safety and authorisation of new foods and ingredients
- Specific requirements for demonstrating safety based on risk assessment, scientific studies, and technical data
- Mandate for a technical-scientific report (TSR) in Portuguese, covering identity, characterisation, specification, analytical methods, production process, consumption history, safety assessment studies, bioavailability, safety value determination, purpose, conditions of use, exposure assessment, and risk characterisation.

The resolution also includes specific guidelines for new foods and ingredients produced from cell cultures or tissues, emphasizing the importance of providing detailed information such as biological origin, laboratory/culture collection, cell identity, substrate used, and culture type.

Furthermore, it outlines requirements for characterisation of new foods and ingredients, including nutritional composition, anti-nutritional factors, impurities, degradation products, and contaminants. For foods and ingredients produced from cell or tissue cultures, additional characterisation details are required, including methods for screening and selection of cells or tissues, modifications made to cell lines, and information on cell line preparation and maintenance.

Regarding production processes, the resolution necessitates detailed descriptions, especially for foods and ingredients derived from cell or tissue cultures, which should include composition of culture media, culture conditions, and information about purity and genetic factors.

This Resolution comes into effect on March 16, 2024.

Research

Research is being carried out mainly by universities, research institutes and private companies. Two major facilities are being built and are expected to be operational by 2025.

CANADA

Novel Food Approvals

Since 1999, Health Canada (HC) has permitted 254 novel foods to be sold in the Canadian marketplace. Since April 2023, the following novel foods have been authorised:

- Herbicide tolerant (HT4) soybean – MON 94313
- β-Lactoglobulin protein from yeast strain *Komagataella phaffii* yRMK-66
- Head-on-Gutted AquAdvantage Salmon
- Herbicide tolerant sugar beet – KWS20-1
- Short stature maize – MON 94804

A list of authorised 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 140 novel feeds derived from plant sources and over 40 novel feeds from microbial sources.

Since the last Task Force meeting in April 2023, three novel feeds from a plant source have been authorised.

- Herbicide tolerant (HT4) soybean – MON 94313
- Herbicide tolerant sugar beet – KWS20-1
- Short stature maize – MON 94804

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

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

Genome Editing Techniques

In Canada, the approach to regulatory oversight of plant products is under review. Canada's regulatory approach is based on the characteristics of the product and not the means of development. Novel products subject to Part V of the *Seeds Regulations*, the *Feed Regulations*, and/or the *Food and Drug Regulations* may be the result of mutagenesis, recombinant DNA (rDNA) techniques or other methods of plant breeding such as gene/genome editing techniques. Canada views gene-editing techniques as additional tools for plant breeders. As with conventional breeding and rDNA techniques, gene editing

techniques have the potential to develop both novel and non-novel products. In Canada, only those gene-edited products that are deemed novel require a pre-market assessment.

By allowing for risk-appropriate decision-making and focusing on outcomes, Canada's regulatory system can accommodate new developments in biotechnology techniques.

The CFIA and Health Canada recognize the need of product developers to accurately determine the regulatory status of gene-edited products in Canada, and for regulatory decisions to be transparent, consistent, and predictable. Canadian regulators are working cooperatively with the industry developers to provide greater clarity regarding our regulatory programs (i.e., environment, feed, and food) as they apply to gene editing and other plant breeding innovations.

Health Canada published its *Guidance on the Novelty Interpretation of Products of Plant Breeding* and *Guidance on the Pre-Market Assessment of Foods Derived from Retransformants* on May 18, 2022. This guidance is available on the Health Canada website:

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

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

Along with this guidance, Health Canada is maintaining its Transparency Initiative to provide people in Canada with information on the types of gene-edited plant products that may be used as food in the Canadian market. This initiative helps developers better understand how the novel foods regulatory framework applies to different types of gene-edited plant products and ensures that gene-edited plant products that meet the definition of a novel food are notified to Health Canada for pre-market assessment. Information on the Transparency Initiative is available on the Health Canada website: https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/transparency-initiative.html

The CFIA held a 120-day public consultation on proposed updated guidance for determining whether a plant is subject to Part V of the Seeds Regulations from May 19, 2021, to September 16, 2021. The guidance provides additional clarity for the agricultural biotechnology sector when it comes to new technologies like gene editing, including when a product may be considered novel and require pre-market assessment under the regulations. The CFIA received and reviewed 508 responses through the consultation. A "What We Heard" report, summarizing the comments received was published on the CFIA website: https://inspection.canada.ca/about-the-cfia/transparency/consultations-and-engagement/completed/guidance-for-part-v-of-the-seeds-regulations/what-we-heard/eng/1682345500276/1682345500947

The CFIA guidance was revised and published accordingly on May 3, 2023, following the consultation process and targeted follow-up conversations with key stakeholder groups. This guidance is available on the CFIA website:

https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/applicants/directive-2009-09/eng/1304466419931/1304466812439

The CFIA also published rationale for the 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

Alongside guidance publication, the Minister of Agriculture and Agri-Food published a news release regarding the updates and the strengthening of transparency measures for products of plant breeding innovation. This news release is available on the Government of Canada's website: 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

The CFIA's Animal Feed Program held a public consultation on their draft "Guidance on how to determine when a plant-derived ingredient requires a feed pre-market assessment." The consultation ended November 27, 2023, and will supplement the existing CFIA "Guidelines for the assessment of novel feeds: Plant sources." The primary focus of this guidance is to help determine when a plant-derived feed ingredient requires a pre-market assessment and aims to assist product developers in making informed business decisions early in the product development process. The CFIA is currently reviewing comments. A What We Heard Report will be published at the same time as the document is finalised. Similarly, to Plants with Novel Traits (PNTs) and novel foods, Canada's regulatory oversight of plant products of biotechnology destined for livestock feeds is based on the traits/characteristics of the product, regardless of how it was developed. Therefore, for feeds with novel traits, it is the presence of the novel trait that triggers a pre-market assessment under the Feeds Regulations and not the method used to introduce the trait. Hence the plant, rather than the process, is subject to regulatory oversight. Novel feeds may be created by such methods as traditional breeding, mutagenesis, cell fusion, genome editing or rDNA techniques.

The CFIA and Health Canada have published a joint webpage describing Canada's regulatory framework for the environmental release of PNTs, novel feeds, novel foods, and how products derived from gene-editing techniques may or may not be considered novel. This webpage is available on CFIA's website:

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

Low Level Presence (No update since last meeting)

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). As more countries consider products of biotechnology as one of the tools to improve or address issues facing the agricultural sector, GLI members participate in international and regional discussions to raise awareness of asynchronous approvals, and best practices to mitigate trade implications. They also engage in discussions on the importance of a predictable and transparent global trading environment to the benefit of food security and agricultural sustainability.

The GLI website: https://llp-gli.org is a public interface that features useful resources and tools to inform practices to minimize asynchronous approvals and practically manage LLP. It includes background information on factors leading to LLP, their impacts, and best management practices; an overview of potential approaches for governments and technology developers to consider minimizing occurrences of asynchronous authorisations; as well as key principles to data sharing and collaboration to facilitate the management of LLP. The GLI Secretariat is led by Agriculture and Agri-Food Canada and can be contacted at GLI-IMP@canada.ca.

Feed Regulatory Renewal Project

The proposed *Feeds Regulations, 2024* were pre-published in the *Canada Gazette*, Part I on June 12, 2021. A public comment period of 126 days was available for Canadians, other interested parties and the World Trade Organization (WTO) to provide feedback on the regulatory proposal. The CFIA has completed its analysis of all comments received during the *Canada Gazette*, Part I public consultation period and is making the appropriate changes to the regulatory package. A "What We Heard" report was published on the CFIA website in December 2022.

The proposed *Feeds Regulations, 2024* would be less prescriptive, and more focused on the overall health and safety outcomes of the system. They would include a range of new or updated requirements for feeds and for regulated parties involved in their production and commerce, including hazard identification, preventive controls, traceability, record-keeping requirements, and licensing. The amendments would increase responsiveness to industry changes, and provide more clarity, flexibility and transparency to affected regulated parties. They would 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 will be updated to provide better transparency and clarity to stakeholders. Lastly, it would better align Canadian feed requirements with those of international trading partners.

It is anticipated the final amendments will be published in the *Canada Gazette*, Part II in Spring 2024. The regulations will include transition time and delayed coming into force, to provide stakeholders with time to bring their practices into compliance. In addition, a suite of guidance materials and stakeholder information sessions are anticipated accompanying the final publication. These will be aimed at helping stakeholders understand the new regulations and how to comply.

Nanotechnology (No update since last meeting)

Currently, Health Canada is using existing legislative frameworks to regulate applications of nanotechnology. However, it recognizes that new approaches may be necessary in the future to keep pace with the advances in this area. Potential risks/benefits of nanotechnology-based products are examined on a case-by-case approach, as it is still a new field of applications and research. In 2011, the Department adopted the Policy Statement on Health Canada's Working Definition for Nanomaterial. This Working Definition provides Health Canada with a consistent approach across its diverse regulatory program areas to identify regulated products and substances that may be or may contain nanomaterials. The definition also helps further the development of policy, guidance and programs applicable to nanomaterials. Given the range of nanomaterial-related regulatory responsibilities at Health Canada, the working definition is intentionally broad and applies more specifically in each regulatory program area.

Health Canada's Food Directorate completed research projects on nanoparticle immunotoxicology and continues to take part in various initiatives to strengthen its analytical and regulatory capacity. For instance, the Food Directorate collaborated with the CFIA in developing the Government of Canada - Nanotechnology Technical Network (NTN). This forum facilitates a Community of Practice across federal departments, allowing discussions, presentations and collaborative activities between federal nanotechnology laboratories.

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 commercialisation 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 recently authorised the sale of β-lactoglobulin protein, the major protein in cow's milk, produced from a genetically modified yeast strain, *Komagataella phaffii* yRMK-66. This is the first novel food authorisation of an animal-derived protein produced by microbial fermentation.

COLOMBIA

Developments related to implementation of national biosafety framework

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

Please note that this is not an official statement from the Colombian Government; this is the information provided from the authorised organisation that regulates cultivation and feed (ICA) and the authorised organisation that regulates food (INVIMA).

Authorisations granted in 2023 by the Instituto Colombiano Agropecuario - ICA:

Unique identifier	Decision	Organism	Trait	Authorised for
MON-Ø4Ø32-6	15257	Soybean	Herbicide tolerance	Field trials
DAS-Ø1131-3	15258	Maize	Insect resistance Herbicide tolerance	Feed
DP-91Ø521-2	15259	Maize	Insect resistance Herbicide tolerance	Feed
Colour-modified Rose	15260	Rose	Changes in quality and/or metabolite content: Pigmentation / Coloration Flavonoids (e.g. anthocyanin)	Cultivation

* Additional information about the ICA decisions can be found at the following link: https://www.ica.gov.co/normatividad/normas-ica/resoluciones-ovm

Authorisations granted in 2023 by the Instituto Nacional de Vigilancia de Medicamentos y Alimentos - INVIMA:

Unique identifier	Decision	Organism	Trait	Authorised for
BCS-GHB811-4 x BCS-GHØØ4-7 x BCS-GHØØ5-8 x SYN-IR1Ø2-7	Resolution 2023024849 June 6, 2024	Cotton	Pest resistance Herbicide Resistance	Food
MON-ØØØ21-9	Resolution 2023024847 June 6, 2024	Maize	Herbicide Resistance	Food
SYN-BTØ11-1 x MON-ØØØ21-9	Resolution 2023024863 June 6, 2024	Maize	Pest resistance Herbicide Resistance	Food
MON-887Ø2-4 X MON-15985-7 X SYN-IR1Ø2-7 X MON 887Ø1-3 X MON-88913-8	Resolution 2023024846 June 6, 2024	Cotton	Pest resistance Herbicide Resistance	Food
BCS-GHB811-4 x BCS-GHØØ4-7 x BCS-GHØØ5-8 x SYN-IR1Ø2-7 X MON-887Ø1-3	Resolution 2023024851 June 6, 2024	Cotton	Pest resistance Herbicide Resistance	Food
SYN-IR6Ø4-5	Resolution 2023044322 September 22, 2023	Maize	Pest resistance	Food
BCS-GHB811-4 x ACS-GHØØ1-3 X MON-887Ø1-3	Resolution 2023053288 November 10,2023	Cotton	Pest resistance Herbicide Resistance	Food
DAS-Ø1131-3	Resolution 2023053292 November 10,2023	Maize	Pest resistance	Food
DP-91Ø521-2	Resolution 2023053290 November 10,2023	Maize	Pest resistance	Food

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

N/A

Risk management measures

INVIMA

Invima had in place in 2023 the National Surveillance and Control Plan for transboundary movement of non-authorised GMO events into Colombia.

ICA

According to the 12257 decisions, the approval for limited field research on genetically modified soybean (*Glycine max*) with tolerance to the application of the herbicide glyphosate (cp4epsps) must be developed according to the following specifications and in compliance with strict biosafety measures:

1. Phenotypic evaluation of the material obtained under laboratory conditions.
2. The duration of this approval corresponds to the duration of the trials according to the crop cycle, approximately two (2) years.
3. The evaluations will be carried out by the Federación Nacional de Cultivadores de Cereales, Leguminosas y Soya - FENALCE, at the farm Las Bendiciones, Vereda El Toro, municipality of Puerto López - Meta, as part of its research programmes, adopting the necessary measures to avoid, prevent, reduce, correct and/or compensate for potential risks and management measures, including emergency measures, that may arise. In the event of environmental incidents, all genetically modified material will be immediately destroyed.
4. The decision to authorise the planting of limited field trials of genetically modified soybean (*Glycine max*) (similar genetic construction) with tolerance to the application of the herbicide glyphosate (cp4epsps) is taken within the current regulatory framework, Law 740 of 2002, Decree 4525 of 2005 and ICA Resolution 91505 of 2021.

It is important to inform that Colombia, in terms of cultivation approvals, has a specific regulation related to the Biosafety and Monitoring plan for genetically modified crops with resistance to target pests of the technology and / or tolerance to herbicide application (Resolution No. 72221 - 28/07/2020).

New and emerging regulatory challenge(s) for products of modern biotechnology

N/A

Public engagement and outreach activities.

During 2023 ICA carried out seven (7) training and socialisation activities for the target audience on the Biosafety Plan and monitoring of Genetically Modified commercial crops in different natural regions of Colombia. During the conferences, information was provided on the responsibilities of the different actors involved in the use of Living Modified Organisms (LMOs) for agricultural and livestock purposes, raising awareness about the international and national regulatory framework that exists in the matter. Farmers, seed distributors, technical assistants and seed and biotechnology companies participated.

Research projects on biosafety; relevant publications.

N/A

Updates regarding international activities

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

INVIMA

- Risk Assessment Workshop, Montreal Canada (30-31 October 2023)
- AHTEG (Ad Hoc Technical Expert Group) on Risk Assessment, Montreal Canada (1- 3 November 2023)

ICA

- First Virtual Session 2023: Post-COP15 and pre-COP16-MOP11
- Second Virtual Session 2023 Preparatory to COP-MOP
- Third Virtual Session pre-COP16-MOP11

These virtual sessions aim to support the delivery and foster the continuous exchange of technical information on issues relevant to countries' biosafety performance under the Convention on Biological Diversity and the Cartagena Protocol on Biosafety (CPB).

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

INVIMA

- Digital Sequencing and Genetic Resources (DSI), internal Colombian workgroup, for proposal to be shared on the COP16.

Specific cases of use of OECD tools and information

As ICA, during 2023 we have used the BioTrack Database to consult approvals granted from other countries, Risk Assessments and Consensus Document of maize, cotton, soybean, and canola (rapeseed). Additionally, ICA continues to develop a virtual platform for LMO´s applications and has required a review of the BioTrack database to reinforce our tool draft in search of the efficiency and ease of authorisation procedures.

Developments related to new breeding techniques (NBTs)

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

ICA

The first Regulatory framework to NBTs was published in 2018 (Decision 29299), "By which the procedure of applications before the ICA for an improved cultivar with innovation techniques in plant breeding through modern Biotechnology is established in order to determine if the cultivar corresponds to a Living Modified Organism or a conventional organism".

Following the publication of the previous framework, the ICA worked to amend this regulation to broaden the scope to other organisms used for agricultural or livestock purposes. As a result, the ICA issued a new regulatory framework (Resolution No. 00022991, 11/11/2022) with adjustments and updates titled: "By which the procedure for the applications before the ICA for new products obtained by Innovation techniques in breeding is established, in order to determine if they correspond to Living Modified Organisms (LMOs) or Conventional organisms."

Specific cases of application, assessment, and decision.

Since 2020 ICA has received nine (9) applications related to New Breading Techniques (NBTs) products. For eight (8) of them the technical concept was "conventional organism", taking into account the objective of the ICA regulatory framework, mentioned above. The remaining application is still in process and pending concept.

The following are the applications submitted during the period 2020 - 2024: Three (3) applications for rice; two (2) applications for corn; one (1) application each for mustard, soybean, banana and pork.

It is important to mention that these applications are related to ICA's functions of technical control of the production and marketing of agricultural inputs, animal genetic material and seeds for planting, in order to prevent risks that may affect agricultural health, food safety and agricultural production in the country.

Research projects on biosafety of NBT products; relevant publications

N/A

Any other information related to NBTs

N/A

COSTA RICA

Developments related to implementation of national biosafety framework

1.1Risk assessment/regulatory decisions

Currently, in Costa Rica, LMO are only authorised for planting and production of seeds, fruits or products for export.

During the current reporting period (March 2023 to March 2024), there were no submissions for the use of any organisms produced by modern biotechnology.

However, the SFE authorised 259 hectares for the planting of LMOs, which are distributed as follows:

Table 1. Living Modified Organisms planting projects registered in Costa Rica. March 2023-March 2024.

Crop	ID	Hectares
Pineapple	DP-ØØ114-5	100.5
Cotton	SYN-IR1Ø2-7 x MON-15985-7 x MON-88913-8 x MON-887Ø1-3	46.5
Cotton	MON-887Ø2-4 x MON-88913-8 x MON-15985-7 x SYN-IR1Ø2-7 x MON-887Ø1-3	14
Cotton	MON-00531-6 X MON-15985-7 X SYN-IR-1Ø2-7 X MON-88913-8 X MON-887Ø1-3 X MON-887Ø2-4	21
Cotton	MON-88701-3	15

1.2 National Regulatory Framework on the Safety of Novel Foods and Feeds

Costa Rica's regulatory framework is limited to the release into the environment of plants improved with modern biotechnological techniques, including NBT, for research or export purposes. At the moment, there are no regulations for feed and food derived from these organisms. However, there is an initiative led by the Ministry of Agriculture and Livestock as well as the Ministry of Health, to prepare a draft on this matter, the first version is expected to be ready by the end of this year.

This regulatory framework will establish the procedures for the safety assessment and authorisation of organisms produced by modern biotechnology Techniques intended for direct use as human and/or animal food or for food/feed processing.

Once this regulatory framework is published, we will share our progress in this matter with the OECD.

1.3 Developments related to new breeding techniques (NBTs)

As mentioned above, Costa Rica's regulatory framework is limited to the release into the environment of plants improved with modern biotechnological techniques, including NBTs, for research or export purposes.

In this sense, on November 10, 2023, the State Phytosanitary Service published the regulatory framework for New Breeding Techniques (NBTs). This regulatory framework establishes the procedures to define whether a crop obtained using NBTs is or is not a LMO and therefore should be regulated under the current regulation for LMO (N° 7664: Phytosanitary Protection Law).

The criteria to discriminate relies on the presence or absence of additional DNA sequences compared to conventional breeding methods and spontaneous mutation. The additional DNA sequence is described as a "novel combination of genetic material" to match the legal definition of LMO of the Cartagena Protocol. If the final product does not contain a "novel combination of genetic material," it is equivalent to an organism obtained by conventional breeding methods and spontaneous mutation.

In addition, a new combination of genetic material is defined as a “stable insertion in the genome, of one of more genes or DNA sequences encoding double stranded DNA, RNA, proteins or regulatory sequences that could not be obtained by conventional breeding”.

The analysis will not be restricted to a list of NBTs, the applicants must submit information regarding the methodology used to modify the crop, the innovative trait introduced, evidence of the genetic changes present in the product, evidence of elimination of the transitory transgene employed to achieve the product (if necessary), and any additional information that Regulators consider necessary.

If it is determined that the organism does not has a novel combination of genetic material, it is not regarded as LMO specified in the Protocol of Cartagena on Biosafety (no subject to the regulations) and is recognized as organism equivalent to those obtained through conventional improvement technique.

To request the use of organisms resulting from new genetic breeding techniques, including genome editing, the interested party must submit the application to the SFE as a sworn statement, providing information on the qualities, legal representation and contact information of the interested party, technical and scientific information of the organism, information related to the genetic modification or improvement process, and information related to authorisation in other countries, if applicable.

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. Only 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.

FINLAND

Legislation

As a European Union (EU) Member State, Finland applies the 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 the EU legislation.

In the EU, products produced by new genomic techniques (NGTs) are subject to the legislation on GMOs. On 5 July 2023, the European Commission adopted a legislative proposal for a regulation on plants produced by certain new genomic techniques and their food and feed (COM (2023) 411 final). 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. In the meantime, the plants and products covered by this proposal continue to be regulated under the legislation on GMOs.

The nanomaterial definition in the EC Recommendation 2011/696/EU has been updated in June 2022 (C(2022)3689). The revision of the recommendation provides the needed technical and scientific basis to adapt also the “engineered nanomaterial” definition of the Novel Food Regulation (EU) 2015/2283. The aim is to adopt a delegated regulation in the next few months.

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 on the market. 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 MON810 maize 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

The 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 monitored regularly and increasingly by Customs and municipal control authorities.

GERMANY

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://webgate.ec.europa.eu/dyna2/gm-register/). 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 authorised so far are listed in the Annex to Regulation (EU) No 2017/2470. The Annex represents the Union list of novel foods and is constantly updated with new entries. The products in the list may be placed on the market, if the conditions of use, specific labelling requirements, specifications, and other requirements indicated are met.

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.

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 25 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 unauthorised 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 generalised, AI-supported bioinformatics approach for the evaluation of next generation sequencing data as a GMO screening tool.

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

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

- Guertler, P., Pallarz, S., Belter, A., Eckermann, K.N., Grohmann, L. (2023): Detection of commercialized plant products derived from new genomic techniques (NGT) - Practical examples and current perspectives. Food Control, https://doi.org/10.1016/j.foodcont.2023.109869
- Tuncel, A., Pan, C., Sprink, T., Wilhelm, R., Barrangou, R., Li, L., Shih, P.M., Varshney, R.K., Tripathi, L., Van Eck, J., Mandadi, K., Qi, Y. (2023): Genome-edited foods. Nature Reviews Bioengineering, 1, 799-816. Doi: 10.1038/s44222-023-00115-8
- Stetkiewicz, S., Menary, J., Nair, A., Rufino, M., Fischer, A.R.H., Cornelissen, M., Guichaoua, A., Jorasch, P., Lemarié, S., Nanda, A.K.; Wilhelm, R., Davies, J.A.C. (2023): Food system actor perspectives on future-proofing European food systems through plant breeding. Scientific Reports, 13, 5444. Doi: 10.1038/s41598-023-32207-1
- TRIP. The focus of this project is on indigenous crops as an alternative to proteins (milk and meat) from animals. The aim is to analyse the market-relevant as well as socio-economic impact of an increase in plant-based protein drinks (oat/soy milk) as well as plant "meat". Furthermore, breeding measures will be carried out on a mutant population and new molecular breeding techniques will be used to address important traits for the plant-based protein market.
- Bioinformatics analyses for the prediction of the reproducibility of whole genome sequencing data. The study demonstrated that Next Generation Sequencing data (Whole Genome Sequencing (WGS) and Targeted Sequencing, both short and long read) produced by different service providers is highly reproducible. The study further analysed the detection limits of GMO traces in a seed mixture, showing that traces of 0.1% GMO is detectable in every case.
- Pallarz, S., Fiedler, S., Wahler, D., Lämke, J., Grohmann, L. (2023): Reproducibility of next generation-sequencing-based analysis of a CRISPR/Cas9 genome edited oil seed rape. Food Chemistry: Molecular Sciences, https://doi.org/10.1016/j.fochms.2023.100182

International activities

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

- On the occasion of the 20th anniversary of the entry into force of the **Cartagena Protocol on Biosafety**, BVL has created a webpage with information on the Protocol (https://www.bvl.bund.de/EN/Events/2023-20yearsCartagenaProtocol/20yearsCP_node.html).
- Within the **Public Administrative Cooperative Exchange (PACE) program** of the European Commission, BVL took the opportunity to visit the Dutch sister agency RIVM in November 2023 to exchange on administrative digitalisation (databases), current strategies of risk assessment, evaluating the possibilities of machine learning therefore and communication strategies.

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.

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 no 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. Trials will be possible until the end of 2025, while waiting for the European Union's new Regulation on the topic.

A notification of this type of plants has been presented in January 2024 and March 27, was officially authorized by the Ministry of Environment and Energy Security (MASE)

(https://webgate.ec.europa.eu/fip/GMO_Registers/GMO_Part_B_Others.php)

Notification Number: B/IT/24/01

Field trial of NGT (CRISPR/Cas9 technology) rice experimental lines for resistance to rice blast

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

Name of the Institute: University of Milan (UNIMI)

Purpose of the release: Test in an open rice growing field new experimental lines that present deletions in three genes that should confer resistance to rice blast. Blast characteristic lesions will be scored and compared on Telemaco Ris8imo plants and on the parental Telemaco

Considering that the last notification for experimental release in Italy dates back to 2004, that decree actually encouraged field trial in Italy.

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 past year 90 installations and 194 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 authorisation, 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

1) The Italian project "**Innovative approaches to biosafety for the protection of human health and the environment**" has recently come to an end. The project saw the participation of INAIL (National Institute for Insurance against Accidents at Work, project leader), the Saint Lucia Foundation I.R.C.S. and the CNR's Institute of Agricultural Biology and Biotechnology and was carried out in collaboration with the Ministry of Health, whose priority objective was to create a network between operators in the sector, biosafety experts and institutions, to encourage the exchange of experiences, motivate a culture of prevention and provide training and information on legislation and good laboratory practices for the use of biotechnologies, which can be found at https://www.biotechsafety.org/. Through digital tools, collaborations with qualified partners and a participative and innovative approach to training, the aim was to minimise risks without hindering research. In parallel, the activities included updating the inspection team and training new inspectors to assess and control the installations and activities carried out by researchers using GMMs on national territory in compliance with Legislative Decree 206/2001. Inspection activities started in December 2023 and are currently ongoing.
2) **OnFoods** (Research and innovation network on food and nutrition Sustainability, Safety and Security) is the Italian research and innovation network for sustainable food and nutrition. Funded under the National Recovery and Resilience Plan (NRRP), € 114.500.00, Mission 4 Component 2 Investment 1.3, Theme 10. The project, coordinated by University of Parma (UNIPR), involves around 600 people, including professors, researchers, executives, and employees from top companies in the Italian agri-food sector. This group also includes 129 new researchers, as well as 200 PhD students and post-doctoral scholars. OnFoods works as a coordinating hub for seven thematic spokes, each focused on a specific and crucial aspect of the food system, yet working together to achieve common goals regarding food safety and quality, nutrition, and malnutrition prevention. Among the seven Spokes through which the ONFOODS consortium will work to achieve its objectives is Spoke 3: Food Safety of Traditional and Novel Foods with a focus on new and sustainable processing technologies, considering the rise of novel food consumption.
3) Horizon 2020 Project, **FS4EU** ended on 31 December 2023, a Multi-Stakeholder Platform for Food Safety In Europe, Coordinated by National Research Council of Italy (CNR), Institute of Sciences of Food Production (ISPA). Its overall objective was to design, develop and release a multi-stakeholder platform and establish a long-term science-policy-society interface where citizens, scientists, companies, the EC, EFSA and food safety authorities co-design new schemes to advance the FSS (food safety system) from a reactive to an interactive system. The overall ambition is to lay the foundations for a Knowledge Centre for Food Safety in Europe and provide co-created inputs for policies and strategies (including SRIA, -strategic research and innovation agenda).

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 second 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 22 notifications for commercial purposes (with a focus on environmental risk assessment), 1 notification for experimental purposes on salmon and 22 notifications for experimental purposes on plants. 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

EU Economic Security Strategy

Italy contributed to the report presenting the first joint risk assessment of Member States and the European Commission of biotechnologies following the European Economic Security Strategy of 20 June 2023 and the Commission Recommendation on critical technology areas for the EU's economic security for further risk assessment with Member States, adopted on 3 October 2023. Biotechnology is one of the 4 technology areas considered in this first report.

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- 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)**

JAPAN

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. The Ministry of Health, Labour and Welfare (MHLW) receives applications for GM foods and food additives, and the Food Safety Commission (FSC) evaluates the safety of GM foods and food additives in terms of human health.

As of February 2024, 333 GM foods (12 potato; 29 soybean; 3 sugar beet; 210 maize; 25 oilseed rape (canola); 48 cotton; 5 alfalfa; and 1 papaya) and 80 GM food additives have undergone safety assessment and been announced in the Official Gazette; out of these foods and food additives, 2 foods and 5 food additives have undergone safety assessment and been announced in the Official Gazette since the last meeting in April 2023.

Update information of safety assessment for GM Feeds and Feed Additives

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

As of February 2024, 103 GM feeds (20 oilseed rape (canola); 33 maize; 19 soybean; 21 cotton; 3 sugar beet; 3 alfalfa; and 4 potato) and 15 feed additives have undergone safety assessment and been announced in the Official Gazette; out of these feeds and feed additives, 1 feed additive have undergone safety assessment and been announced in the Official Gazette since the last meeting in April 2023.

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 commercialisation. 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[7] by a traditional breeding method with respect to the item notified as a genome edited feed (amended in April 2021).

Detailed information will be available on the MAFF website:

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

[7] 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

KOREA

Developments related to implementation of national biosafety framework

1.1 Risk assessment/regulatory decisions;

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

To the present, Korea has granted approval for 182 LMO events for feed purposes, 200 events for food applications, 103 events for industrial uses, and 2 events for health-related applications. It is noteworthy that there have been no approvals for environmental release or cultivation to date.

In the year 2023, the following new LMO approval events were recorded:

For food use, 4 new events were approved, including 3 events for maize and 1 event for soybean. LMOs for food must be reevaluated every 10 years in Korea, and 12 events were reevaluated in 2023.

For feed use, 7 new events were approved, encompassing 2 events for maize, 3 events for cotton, 1 event for soybean, and 1 event for canola.

For industrial use, 2 new events involving microbes were approved.

Table. List of LMO approved for commercial use in Korea during 2023

Organisms	Event	Type of use	Traits	Company
Cotton	MON88702×MON15985×COT102×MON88701×MON88913	Feed	Insect Resistance & Herbicide Tolerance	Monsanto
Soybean	GMB151	Feed, Food	Insect Resistance & Herbicide Tolerance	BASF
Cotton	GHB811×LLCotton25×MON88701	Feed	Herbicide Tolerance	BASF
Maize	MON87429	Feed	Herbicide Tolerance	Monsanto
Maize	3272×Bt11×MIR162×GA21	Feed, Food	Insect Resistance & Herbicide Tolerance	Syngenta
Canola	MON94100	Feed	Herbicide Tolerance	Monsanto
Cotton	T304-40	Feed	Insect Resistance & Herbicide Tolerance	BASF
Maize	DP-202216-6	Food	Herbicide Tolerance & Yield Improvement	Corteva
Maize	MON87429	Food	Herbicide Tolerance	Monsanto
Microbe	GF-PK101	Industrial	Production of Proteinase K	GenoFocus
Microbe	GC005	Industrial	Enzyme Production for 6'-Sialyllactose Process	GeneChem

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

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

Act on the Trans-boundary Movements, etc., of Living Modified Organisms (hereinafter referred to as the 'LMO Act'):

Since its initial enactment in 2001, the LMO Act has undergone 14 amendments, the latest being on December 11, 2018. On July 22, 2022, amendments were submitted to the Trade, Industry, Energy, SMEs and Startups Committee of the National Assembly of the Republic of Korea. The amendments, which include the introduction of foreign genes from LMOs, risk assessment in cases where LMOs are not residual, and various exemptions from authorisation, are currently under review.

The 4th Plan for the Safety Management of Living Modified Organisms (2023-2027):

Based on the LMO Act, ministries such as the Ministry of Trade, Industry and Energy; Ministry of Science and ICT; Ministry of Agriculture, Food and Rural Affairs; Ministry of Health and Welfare; Ministry of Environment; Ministry of Oceans and Fisheries; and the Ministry of Food and Drug Safety, are required to establish and implement a safety management plan for living modified organisms every five years. The 4th safety management plan is currently in effect, having commenced in 2023. Additionally, a detailed implementation plan for safety management is established annually to conduct overall safety measures of LMOs. This includes research and development, safety management, risk assessment, post-monitoring, and distribution.

1.3 Risk management measures

LMO cultivation is not permitted in Korea and is only imported for food, feed, and other purposes. To prevent unintentional release of imported LM crops into the environment, periodic monitoring of LMO transportation routes and unauthorised cultivation sites is conducted every year.

1.4 Public engagement and outreach activities;

Government agencies, academia, research institutions, and the industry in Korea are engaged in the following activities to enhance communication and understanding of LMOs with the public.

Joint Public-Private Investigation of Unauthorised LMO Cultivation Sites:

In Korea, an annual joint investigation is conducted by related agencies including the Ministry of Agriculture, Food and Rural Affairs, local governments, and non-governmental organisations on the cultivation sites of unauthorised LMO seeds the occurrence of down-grain and native plants along the transport routes of LMOs used for feed. The joint public-private investigation for unauthorised rapeseed have been carried out twice a year since 2017, with the 14th investigation completed, while the first investigation for zucchini pumpkin took place in 2023. All investigation results are shared with relevant institutions and civic groups to foster communication and enhance understanding.

In 2023, unauthorised LMOs were identified in zucchini squash seeds produced in South Korea. The Korean government responded by conducting a full survey of zucchini squash and processed food products made from it during cultivation and distribution. The identified LMOs were destroyed, and post-monitoring was conducted.

KBCH Forum Seminars:

The Korea Biosafety Clearing House (KBCH) leads a continuous and open forum with participants from government agencies, academia, research institutions, the industry, and non-governmental organisations.

Regular seminars are held, with a total of 35 domestic and international seminars conducted up to 2023. In that year, three seminars were successfully held, including the '4th Public Hearing on the Safety Management Plan for Living Modified Organisms,' with the participation of stakeholders from all sectors.

Updates regarding international activities

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

APEC Agricultural Biotechnology Seminar:

On June 20, 2023, the National Institute of Agricultural Sciences and the Agricultural Food Systems Institute (AFSI) of the United States co-hosted a webinar under the theme "Trends in Research and Development of Agricultural Breeding Materials Using Genome Editing Technologies" to share research and policy trends in agricultural biotechnology among APEC member countries and domestically. The webinar was attended online by delegations from 18 APEC member countries and 287 researchers from home and abroad. The seminar shared extensive information on the latest trends in genome editing technology, including an introduction to Korea's genome-edited crop research program (NBT Center), and trends in genome editing research in animals and plants.

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

National Institute of Agricultural Sciences-AFSI Crop Composition Database Sharing Agreement:

In 2018, the National Institute of Agricultural Sciences signed an agreement with the United States Agriculture & Food Systems Institute (AFSI) to share databases, providing information on 21,330 components of three crops: rice, chili pepper, and soybeans. As of 2024, the data for rice and chili peppers have undergone standard verification and have been published in AFSI's Crop Composition Database (CCDB).

LATVIA

Developments related to implementation of national biosafety framework

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

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 2023 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 4 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.

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

Draft on amendments to the Law on handling of GMO is elaborated:

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 draft was elaborated 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.

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

- New and emerging regulatory challenge(s) for products of modern biotechnology (other than NBTs);
- Public engagement and outreach activities;
- Research projects on biosafety; relevant publications.

In 2023 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 started. It is two-year project, implemented by the State Scientific Institute "Institute of Food Safety, Animal Health and Environment "BIOR"".

The aim of the project is 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.

Updates regarding international activities

Participation in/hosting international symposia/fora relating to biosafety

On May 15th 2023, European Plant Science Organisation (EPSO) organized 7th informal science – policy meeting online "Genome editing improving legislation and start flagships to better address climate, environmental, food and health challenges". The aim of the meeting was exchanging views on the current situation of genome editing in Europe and possible next steps to enable Europe better addressing climate change, achieving food and nutritional security and establishing a sustainable agriculture in Europe and world-wide;

On May 25th online meeting of European Enforcement Project on Contained Use and Deliberate Release of GMOs was organized to share knowledge and experience in the field.

Developments related to new breeding techniques (NBTs)

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.

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 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').

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 defined in the EU legislation.

NETHERLANDS

The delegation of The Netherlands wishes to inform the Working Party of the following recent developments, about which a presentation will also be given during the Tour de Table:

January 2024 marked the kick-off of the Dutch National Growth Fund's Cellular Agriculture initiative. This initiative with an overall budget of 85 million Euros will facilitate the establishment of an ecosystem surrounding cellular agriculture. This includes, for example, the production of animal proteins using genetically modified microorganisms, as well as the culturing of animal cells. It will build the "pillars" as a foundation for this ecosystem, including education (*e.g.,* curriculum development in universities and technical educational institutions), research (*e.g.,* scientific investigations, investment in laboratory infrastructure), upscaling (*e.g.,* "open-access" facilities for testing and piloting), and knowledge sharing. More details can be found at: https://en.cellulaireagricultuur.nl/

FAO and IAEA jointly hosted a workshop on sustainable animal production and health in Vienna in 2021. Recently, the book of proceedings was published with 47 contributions*. The topic of animal health and productivity was approached from different angles, such as biotechnologies and genomics for health improvement, breeding, and animal feed safety.

*Reference:

G. Viljoen, M. Garcia Podesta, P. Boettcher (Eds.), International Symposium on Sustainable Animal Production and Health – Current Status and Way Forward, Vienna, Austria, 28 June to 2 July 2021. c/o Food and Agriculture Organisation of the United Nations, Rome, ISBN 978-92-5-137052-0 https://doi.org/10.4060/cc2530en

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, analysing, 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 2023-2024, Paraguay approved the use of several GM yeasts for ethanol production. As yeast-derived products and distiller's dried grains with soluble 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[8]. 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.

Commercial Approvals

The following events were released from 2023 to 2024.

Decision No.	Organism / Product	Event	Proposed commercial use	Characteristics	Regulatory mechanism
93/2024	*Saccharomyces cerevisiae*	FS0436 (PRCH20080)	Ethanol production	Optimisation 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 027/2015)
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 027/2015)
894/2023	Vaccine	VECTORMUNE® HVT NDV	Vaccines express the key protective antigen of Newcastle	Recombinant vaccine in which the F gene of a NDV lentogenic strain has been inserted into the HVT genome	Veterinary vaccine

[8] 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].

Decision No.	Organism / Product	Event	Proposed commercial use	Characteristics	Regulatory mechanism
			Disease Virus (NDV), which facilitates the prevention and control of both Marek's Disease Virus (MDV) and NDV infections		
666/2023	*Saccharomyces cerevisiae*	GPY10138 (GICC03587)	Production of high volumes of ethanol	Expression of the glucoamylase enzyme, eliminating the need for external addition of said enzyme to the fermentation broth	Commercial release of novel GM (Resolution MAG 027/2015)
658/2023	*Saccharomyces cerevisiae*	GPY010240 (GICC03636)	Production of ethanol for biofuel from grains	Enhanced production of ethanol for fuel, reduced output of acetate and glycerol during fermentation	Commercial release of novel GM (Resolution MAG 027/2015)
556/2023	Wheat	IND-ØØ412-7	Tolerance to drought, tolerance to Glufosinate	For tolerance to drought and salinity, the wheat expresses Helianthus annuus homeodomain-leucine zipper 4, which enhances the plant's natural abiotic stress response	Differentiated treatment for the commercial release of GM crops that have been approved in third countries (Resolution MAG 1030/2019 and 1071/2019)
550/2023	*Saccharomyces cerevisiae*	M23541	Increase bioethanol production from corn starch	The expression of recombinant glucoamylase enzyme offers a parallel pathway for ethanol production, which optimizes the volume of ethanol obtained and enhances yeast tolerance to acidity	Commercial release of novel GM (Resolution MAG 027/2015)
549/2023	*Saccharomyces cerevisiae*	M12156	Production of ethanol from starch	Elimination of the need to add glucoamylase during fermentation, optimize ethanol production	Commercial release of novel GM (Resolution MAG 027/2015)
548/2023	*Saccharomyces cerevisiae*	SCY014	Production of ethanol as fuel	Optimisation of ethanol production	Commercial release of novel GM (Resolution MAG 027/2015)
341/2023	*Saccharomyces cerevisiae*	GPY010272 (GICC03661)	Ethanol production	Expression of the recombinant enzyme glucoamylase for the optimisation of ethanol production, parallel pathway for obtaining a high volume of ethanol by reducing the volume of glycerol produced	Commercial release of novel GM (Resolution MAG 027/2015)
340/2023	Maize	SYN-BTØ11-1 x SYN-IR162-4 x MON-ØØ6Ø3-6	Resistance to insect, Tolerance to herbicide, Promoting of mannose metabolism	CP4 EPSPS (MON-ØØ6Ø3-6) and PAT (SYN-BTØ11-1) provide glyphosate and glufosinate-ammonium tolerance, while Cry1Ab (SYN-BTØ11-1) and Vip3Aa20 (SYN-IR162-4) offer protection against Lepidoptera	Differentiated treatment for stacks (parental approved)
319/2023	Cotton	BCS-GHØØ2-5 x	Resistance to Lepidoptera,	Protection against the following lepidopteran insect pest species:	Differentiated treatment for the commercial

Decision No.	Organism / Product	Event	Proposed commercial use	Characteristics	Regulatory mechanism
		BCS-GHØØ4-7 x BCS-GHØØ5-8 x SYN-IR1Ø2-7	Tolerance to Glufosinate, Tolerance to Glyphosate	*Heliothis virescens*, *Helicoverpa* spp., *Pectinophora gossypiella*, *Chrysodeixis includens* and *Spodoptera* spp. provided by the expression products of cry1Ab (BCS-GHØØ4- 7), cry2Ae (BCS-GHØØ5-8) and vip3Aa19 (SYN-IR1Ø2-7) genes	release of GM crops that have been approved in third countries (Resolution MAG 1030/2019 and 1071/2019)

Participation in International Activities

Date	Activities
March 20-21, 2023	Face-to-face meeting of the Agricultural Biotechnology Commission of SGT 8 "Agriculture" of the GMC-MERCOSUR in Buenos Aires, Argentina.
March 21-22, 2023	Meeting of the Commission on Bioinputs for Agricultural Use of the SGT8 "Agriculture" of the GMC-MERCOSUR, Buenos Aires, Argentina.
April 17-21, 2023	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, Paris, France.
April 28-29, 2023	Like Minded Countries Meeting (Like Minded Group), St. Louis, United States.
April 30 – May 4, 2023	16th ISBR Symposium (The International Society for Biosafety Research), St. Louis, United States.
May 16-17, 2023	Presential Meeting WG5 "Public Policies in Biotechnology" in Buenos Aires, Argentina.
May 8, 2023	Multilateral Memorandum of Understanding between Argentina, Brazil, Paraguay, and Uruguay for cooperation in the biosafety of modern biotechnology products.
May 18-19, 2023	Workshop on Gene Edition, Buenos Aires, Argentina.
June 30, 2023	Bilateral meeting between Argentina and Paraguay (biosafety officers).
July 30-31, 2023	APEC HLPDAB SOM3 Workshop: Reducing Redundancies and Facilitating Efficiencies: Regulatory and Policy Solutions for Oversight of Agricultural Biotechnologies, Seattle, United States.
August 23-25, 2023	Taller de Colaboración SUR-SUR en Innovaciones, realizado en Nairobi, Kenia. South-South Collaboration Workshop on Innovations, held in Nairobi, Kenya.
November 15-16, 2023	Paraguayan Symposium on Advances in Agricultural Biotechnology, Asuncion, Paraguay.
November 30, 2023	Like Minded Group Meeting.

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SINGAPORE

GM food and feed regulations in Singapore

The Singapore Food Agency (SFA; www.sfa.gov.sg) is Singapore's statutory agency that oversees food safety and food security from farm-to-fork. SFA was formed on 1 Apr 2019 under the Ministry of Environment and Water Resources (now renamed Ministry of Sustainability and the Environment, MSE).

SFA requires developers seeking to sell GM food in Singapore to undergo pre-market evaluation prior to sale. Only GM foods that have received SFA's pre-market approval are allowed for sale.

SFA is currently working on the Food Safety and Security Bill (FSSB), which will enhance SFA's capabilities to ensure the safety of foods, including GM foods and provide further clarity on the need for GM foods to undergo pre-market approval.

GM food and feed approval process in Singapore

GMO developers seeking to approval for use of GMO as food and/or feed in Singapore must first submit a proposal to Singapore's Genetic Modification Advisory Committee (GMAC). GMAC is a non-regulatory advisory committee that provides scientific advice on the production, research, use and release of GMOs to statutory agencies in Singapore. GMAC conducts a holistic biosafety assessment based on Singapore's guidelines on the release of agriculture-related GMOs, looking at the impact of the GMO on humans, animals, plants, and the environment.

For stacked event GM crops derived via conventional breeding from approved parental events, GMAC requires a bridging document to prove:

- Absence of interaction between individual GM events
- Genetic and protein expression stability
- Compositional analysis

In this "high covers low" assessment approach, prior endorsement of a highest order stacked event exempts lower order sub-combinations of said highest order stacked from assessment. Developers are still required to submit a notification to GMAC for exemption from assessment.

Further details on GMAC's guidelines may be found here: https://www.gmac.sg/guidelines/?tab=singapore-guidelines-on-the-release-of-agriculture-related-gmos

GMAC's assessment and recommendations will be forwarded to SFA, who will make further food safety assessment on the GMO according to Codex guidelines, such as "CAC/GL 45-2003 Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA plants."

As of Feb 2024, SFA has approved:

- 106 GM crops for use as food. Full list can be found here: https://www.sfa.gov.sg/food-import-export/conditions-for-specific-types-of-food-for-import [under "Conditions related to Genetically Modified Crops", click on "List of approved Genetically Modified Crops for use as food or as food ingredients in Singapore"]

- 107 GM crops for use as feed. Full list can be found here: https://www.sfa.gov.sg/food-import-export/import-export-transshipment-of-live-poultry-livestock [under "Animal Feed for Livestock", click on "List of approved Genetically Modified Crops for use as animal feed in Singapore"]

Updates on implementation of a regulatory framework for genome-edited crops used as food and/or feed

Since 2020, SFA has been undertaking work to implement a regulatory framework for genome- edited (GEd) crops used as food and/or feed. SFA initiated a public consultation on said regulatory framework from 20 Dec 2023 – 19 Feb 2024. Details of the public consultation may be found here: https://www.sfa.gov.sg/food-information/public-consultation/others [click on "Consultation On Proposed Regulatory Framework for the Use of Genome Edited Crops for Food and Animal Feed"]. Contemporaneously, trading partners and interested parties were notified via World Trade Organization (WTO) SPS notification G/SPS/N/SGP/84.

SFA's regulatory framework for GEd crops denotes two regulatory pathways for GEd crops:

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

Crops that fall under **Pathway A** can be notified to SFA on a voluntary basis by submitting an Information Checklist to support the developer's claim that the GEd crops are equivalent to crops derived from conventional breeding techniques. Crops that fall under **Pathway B** will be subject to the prevailing GMO pre-market assessment and approval process.

SFA is currently consolidating and taking into consideration comments received from the public consultation. SFA will inform interested parties when the regulatory framework for GEd crops has been implemented.

SLOVENIA

Slovenia, as a member of the EU is bound by the common European legislation.

GMOs in food and feed

The competences and the status of GM products in Slovenia remains unchanged. 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. Despite the good results of the annual monitoring of the presence of GMO's, we continue to monitor the situation in our market. On an annual monitoring basis on GMOs in food and feed, we are establishing that feed consisting of or containing GMO is often on the Slovenian market, but we can rarely find the food consisting of or containing GMOs, same goes for presence of unapproved GMOs. In 2023 we tested samples of food and feed. Last year Slovenia continued monitoring the presence of genetically modified microorganisms (GMM) with antibiotic resistance marker genes in food and feed. In 2024, Slovenia is continuing the testing of the presence of GMOs in food and feed.

Monitoring of GMOs in seed

In the framework to ensure safety in the use of products of modern biotechnology the Competent Authority for contained use, deliberate release and placing GMOs on the market is in Slovenia Ministry of the Environment and Spatial Planning. In that respect it is also responsible for monitoring of GMOs presence in seeds, which is taking place in Slovenia for many years. In 2024, 27 samples of seeds of maize, rapeseed, soybean and alfalfa are planned for GMO analysis: 15 samples of maize seed, 5 samples of rapeseed, 5 samples of soybean seeds and 2 samples of alfalfa seeds. All samples will be first analysed by screening analysis with the five-target method for the presence of genetic elements: CaMV 35S promoter, NOS terminator, bar, pat and CTP2-CP4-EPSPS and determination of the reference gene (presence of DNA, maize, soybean, rapeseed or alfalfa). In case of maize additionally DAS40278 is tested, because it is not covered by five-target method. Till now we have tested 6 maize samples. All the 6 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 2023 ten plant samples (5 maize and 5 rapeseed) were tested for the presence of GMOs under the law on the coexistence of crops with genetically modified plants. All of them was 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 2023 NIB accredited 6 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. 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 breeding techniques

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 2023 NIB contributed to an update of ENGL report from 2019 "Detection of food and feed plant products obtained by new mutagenesis techniques").

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. Moreover, the use of these technologies is further being expanded to grapevine within research project financed by Slovenian National Research

Agency: J4-2544 CRISPR/CAS9-mediated targeted mutagenesis for resistance of grapevine and potato against phytoplasmas (1.11.2020—31.10.2023).

NIB prepared a report on the determination of the impact of new genomic techniques in the field of agriculture based on the project launched by Ministry of Agriculture, Forestry and Food in 2023 to provide expert arguments when drafting EU legislation.

In 2023 the European project “DETECTIVE – Detection of NGT products to promote innovation in the European union” was approved for financing and started on 1.1.2024. 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.

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 authorisation 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.

SOUTH AFRICA

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.

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.

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].

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.

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.

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. The new general release approvals since the last meeting are presented in Table 1 and are indicated in black bold text.

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

Event	Crop	Trait	Company	Year approved
DP202216 x NK603 x DAS-40278-9	Maize	Enhanced grain yield Herbicide tolerance	Corteva	2023

Event	Crop	Trait	Company	Year approved
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 MON87708 x MON89788	Soybean	Insect resistance Herbicide tolerance	Monsanto SA	2018
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

Event	Crop	Trait	Company	Year approved
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/

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

Event	Crop	Trait	Company	Year approved
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 tolerance	DowAgroSciences	2019
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

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.

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 a haploid inducer system for sunflower (in collaboration with the University of Pretoria)

Aim: This study aims to develop a haploid induction system in sunflower by targeting known mutations in the target gene using directed homologous repair that is part of the CRISPR/Cas9 technology. Different delivery systems for the CRISPR construct and donor templates, including *Agrobacterium* transformation and viral delivery, were tested. Some success was achieved with homology-directed repair (HDR) in sunflower.

The project was concluded at the end of last year with a PhD awarded for the work and a paper published. Research papers are still being drafted. The project was able to get partial HDR in sunflower, but since the mutation caused lethal chromosome elimination, they were not able to generate a maintainer line. The viral system was better than the bacterium system and is really promising.

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. They are in the process of writing a paper on their findings prior to the GE work.

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. Currently conducting functional studies on candidate susceptibility genes from that study by knocking them out using CRISPR/Cas9. Identification of susceptibility genes whose knockout leads reduced BBTV titers and symptoms may lead recessive resistance/tolerance to BBTV in banana.

They have cloned CRISPR/Cas9 vectors targeting 6 genes. Banana transformation remains a major bottleneck. They are currently running experiments on using meristem transformation using morphogenic regulators as an alternative method.

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.

The CRSIPR/Cas9 T-DNA vectors targeting eIF4E were assembled and transformed into sweet potato meristems. Initial transformation excitements did not work well. An alternative method in which auxiliary buds are injected with *Agrobacterium* was used. PCR tests indicated presence of Cas9 in shoots from the buds 10 weeks after injection. Sequencing of the target region suggested a high of 6% indels in the shoots. Transformation experiments are being repeated for higher editing efficacies.

As can be seen, tissue culture and transformation expertise are bottlenecks.

CRISPR/Cas9 research at the *Council for Scientific and Industrial Research* (CSIR) and the University of Pretoria

The aim is to optimize tobacco transformation and, subsequently, harness CRISPR/Cas9 genome editing technology to edit target plant protease genes to allow increased recombinant protein yields. The team has performed extensive work on the generation of an *N. benthamiana* plant devoid of protease activity and produced an initial 53 putative mutants. Phenotypic observations were made for each of these plants, as well as gDNA extractions using an optimized protocol. Seeds were collected and stored for 51 plants. T7EI assays indicated that there could be in edits in 24 plants. PCR amplicons containing the guide regions were sequenced for these 24 plants, and eight of these showed multiple peaks in one of the guide regions. These eight plants likely carry heterologous edits in this region. This will be confirmed by single amplicon sequencing. The seeds from these eight plants can then be screened for homozygous edits. If any of the seeds display homozygous editing within the region, then the goal of generating an *N. benthamiana* plant that lacks protease activity will be partially achieved.

Work has also been performed on the generation of an *N. benthamiana* plant devoid of fucosyltransferase and xylosyltransferase activity. In the first round of editing, the plantlets in tissue culture looked stressed and did not survive the hardening-off procedure. This was then repeated using an improved hardening-off process, which allowed more plants to survive. A total of 51 plants survived. Phenotypic observations were made for each of these, and leaf material for DNA extraction was collected for 43 plants. The seed was collected for about 40 plants. The T7EI screening and subsequent sequencing will be done in future work. Should the screening reveal edited plants, this goal will be achieved.

In addition, they have performed agroinfiltration using constructs for serine protease in a single and combination convention in order to confirm the editing of the subtilisin-like protease targets. Attempts were also made to combine the gene sequences into a single vector. They have now achieved that and will be transforming that into *Agrobacterium* for further testing.

Overall, this work has facilitated the development of a range of technical procedures within their research group, which can be further built upon in future projects. Although not all of their goals were fully achieved, this work has led to the creation of new projects and modified goals.

They have also made more progress on using tools for Crispr/Cas9 gene regulation in *Rhodococcus*. Preliminary data is suggesting that they have transformed cells with Crispr/Cas9 vectors for downregulation of their target gene expression. Testing is currently underway to confirm this.

Lactobacillus editing with new genome editing vectors is planned but has not yet commenced.

CRISPR research at the Stellenbosch University

Introduce resistance to potato virus Y by mutating eukaryotic initiation factor 4E (eIF4E) genes.

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

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.

They have given up on the protoplast regeneration and are just using the transgenic route. The genes are the same (eIF4E and GWD1), but they will also start working on starch phosphorylase also for cold induced sweetening purposes. They will do this in both potato and *Nicotiana tabacum*.

CRISPR research in the Vitis Lab at Stellenbosch University

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 aims to establish CRISPR technology in grapevine.

They have published a paper titled ‘CRISPR-based resistance to grapevine virus A. Authors: Katarina P. Spencer, Johan T. Burger and Manuela Campa – all from the Department of Genetics, Stellenbosch University, Stellenbosch, South Africa.

Citation: Spencer KP, Burger JT and Campa M (2023) CRISPR-based resistance to grapevine virus A. Front. Plant Sci. 14:1296251. doi: 10.3389/fpls.2023.1296251

Extract from the paper:

Introduction: Grapevine (*Vitis vinifera*) is an important fruit crop which contributes significantly to the agricultural sector worldwide. Grapevine viruses are widespread and cause serious diseases which impact the quality and quantity of crop yields. More than 80 viruses plague grapevine, with RNA viruses constituting the largest of these. A recent extension to the clustered regularly interspaced, short palindromic repeat (CRISPR) armory is the Cas13 effector, which exclusively targets single-strand RNA. CRISPR/Cas has been implemented as a defense mechanism in plants, against both DNA and RNA viruses, by being programmed to directly target and cleave the viral genomes. The efficacy of the CRISPR/Cas tool in plants is dependent on efficient delivery of its components into plant cells.

Methods: To this end, the aim of this study was to use the recent Cas13d variant from *Ruminococcus flavefaciens* (CasRx) to target the RNA virus, grapevine virus A (GVA). GVA naturally infects grapevine,

but can infect the model plant *Nicotiana benthamiana*, making it a helpful model to study virus infection in grapevine. gRNAs were designed against the coat protein (CP) gene of GVA. *N. benthamiana* plants expressing CasRx were co-infiltrated with GVA, and with a tobacco rattle virus (TRV)-gRNA expression vector, harbouring a CP gRNA.

Results and Discussion: Results indicated more consistent GVA reductions, specifically gRNA CP-T2, which demonstrated a significant negative correlation with GVA accumulation, as well as multiple gRNA co-infiltrations which similarly showed reduced GVA titre. By establishing a virus-targeting defense system in plants, efficient virus interference mechanisms can be established and applied to major crops, such as grapevine.

Another project was started on the application of CRISPR without the insertion of any foreign DNA in the grapevine genome. This would potentially lead to generate edited plants that are not GMO, but resistant to the different type of stresses.

They are continuing with CRISPR in grapevine to improve drought and pathogen resistance, but they are also starting with traits more linked to quality. They successfully edited grapevine and they will publish hopefully soon.

They are working on using Viruses as a way to deliver CRISPR components and on the other hand on the use of CRISPR to detect viruses.

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 (WG-HROB) and the OECD Working Party on the Safety of Novel Foods and Feeds (WG-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.

4th Sustainable Bio-Innovation Symposium: Enabling Genome Editing Based Innovation in South Africa, 28 September 2024

The symposium aimed to bring together stakeholders to discuss the current state of genome editing (GEd) in South Africa and explore ways to foster a sustainable GEd innovation system in the country.

Objectives:

Provide a platform for all stakeholders to discuss the prerequisites for a sustainable genome editing (GEd) innovation system in South Africa.

Develop an intervention priority list to facilitate this.

Topics presented included:

- GEd regulation
  - Keynote: Kenyan GEd regulatory framework and activities – Dr Roy Mugiira, CEO of the Kenya National Biosafety Authority, presented an overview of the Kenyan regulatory framework for GEd, highlighting their experience in establishing a functional system.
  - South African regulatory framework for Ged – This presentation provided an update on the status of GEd regulation in South Africa, including the ongoing discussions around the distinction between SDN1 and 2 and GMOs. Dr Hennie Groenewald, from Biosafety South Africa, argued for a risk-based approach to GEd regulation, suggesting that SDN1 and 2 should not be subject to the same regulations as GMOs.
- GEd in practice
  - CRISPR for dummies – The presentation provided a basic introduction to CRISPR technology, explaining its applications in GEd.
  - CRISPR-based GEd in microorganisms and plants – Presentations showcased various applications of CRISPR-based GEd in different organisms, including improving the shelf life of wine grapes and developing disease-resistant crops.
- GEd innovation management
  - Concept to market for a GEd product – Concept to market for a GEd product. Dan Jenkins, VP of Regulatory and Government Affairs at Pairwise USA, presented a pre-recorded talk on the challenges and considerations involved in bringing a GEd product to market.
  - South African perspectives on GEd innovation management – Discussions on the challenges and opportunities for GEd innovation in South Africa from the perspectives of academia, the seed industry, and bio-entrepreneurship.

Recommendations and Way Forward

The symposium concluded with a panel discussion and closing remarks, highlighting the need for continued collaboration between stakeholders to address the regulatory uncertainties surrounding GEd and foster a supportive environment for GEd innovation in South Africa. The specific recommendations included:

- Aligning the regulatory approval process for GEd products in South Africa with international best practices.
- Advocating for a science-based distinction between SDN1 and 2 type, and SDN3-type edits and using the term “precision bred organisms” for the first-mentioned to emphasise the fundamental difference between these two classes of products.
- Providing funding and support for GEd research and development.
- Raising public awareness and building public trust in GEd technology. By addressing these challenges and recommendations, South Africa can position itself as a leader in responsible GEd innovation and reap the potential benefits of this technology for agriculture, medicine, and other sectors.

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 currently applies a zero tolerance in this regard.

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.

The Organisation of Economic Cooperation and Development's (OECD's) 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 here (right click to open the hyperlink to the documents):

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

SPAIN

Developments related to implementation of national biosafety framework

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-/

Contained use activities in research facilities

Since the last meeting in April 2023, sixty-seven (67) new facilities for different contained use activities have been notified in Spain to the Competent Authorities (Interministerial Council of GMO or Regional Government) and assessed by the risk assessment competent authority, the National Biosafety Commission (30 of biosafety level (BSL) 1, 46 of BSL 2 and 1 of BSL 3.

157 different activities have been notified to be carried out in these facilities: 23 are classified as risk 1 (BSL 1); 113 as risk 2 (BSL2) and 21 as biological level of risk 3 activities (BSL3).

The two major GMOs used in these activities are viruses or viruses infecting/transfecting human or animal cells lines (50%), and animals (including animal cell lines) (22%), followed by bacteria (17%), fungus (8%) and the last one are plants (4%).

For detailed information:

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

a) Experimental deliberate release into the environment

Since April 2023, thirty-three (33) applications for deliberate release trials (including field trials with genetically modified plants and human and animal clinical trials with GMOs) have been notified to the national competent Authorities (Interministerial Council of GMO and Regional Government) and assessed by the National Biosafety Commission:

Three field trials with plants: (B/ES/23/34 and B/ES/23/36, both of them are genetically modified tobacco as biofactory plants to produce industrially useful substances. The last one was developed using gene editing).

On the other hand, thirty (30) human clinical trials have been notified. Many of them are different genetically modified viruses (Adenovirus, AAV, MVA, VSV, etc.), others 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/

b) Placing on the market

There are no new licenses issued since April 2023 regarding the placing on the market of GMO´s.

In 2023, the growing surface for Bt maize (MON810) in Spain was 46.327,42 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/

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

1.2.1 Legal framework applicable to GMOs

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

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

1.2.2 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 for the production of food and feed
2) GMO field trials for the production of 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

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

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 23 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.

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

1.4 Public engagement and outreach activities

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

For detailed information on the public consultation of the notifications:

Consulta e información al público (miteco.gob.es)

1.5 Research projects on biosafety; relevant publications

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

The PEICTI 2021-2023 comprises four state programmes that correspond to the general objectives set out in the EECTI 2021-2027. The programmes include:

- State programme to address the priorities of our environment.
- State programme to promote scientific and technical research and its transfer.
- State programme to develop, attract and retain talent.
- State programme to catalyse innovation and business leadership.

The plans include the state aid for R&D&I implemented by the State Administration in different fields, including biotechnology.

Updates regarding international activities

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

The Ministry of Agriculture, Fisheries and Food follows the evolution of the different components of the Cartagena Protocol. In particular, during the last year, it has followed the online seminars and forums on risk assessment and risk management, synthetic biology and on the discussion related to the development of the indicators of target 17 of the Monitoring Framework of the Kunming-Montreal Global Biodiversity Framework.

Likewise, the Ministry 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 attends the meetings of the Working Group of the International Environmental Affairs Council on Biosafety of the European Council.

Developments related to new breeding techniques (NBTs)

3.1 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, which held eight meetings between July and December, 2023. At the end of the Spanish Presidency, at the Council meeting on December 11, the transactional proposal of the Spanish Presidency was presented.

The transactional proposal of the Spanish Presidency can be consulted at the following link: www.consilium.europa.eu/es/meetings/agrifish/2023/12/10-11/

In addition, the legislative proposal was addressed in two Council meetings, in its Agriculture and Fisheries formation, and during an informal agriculture ministerial meeting that took place in Córdoba (September, 2023). Information about these meetings can be found at:

https://spanish-presidency.consilium.europa.eu/es/eventos/reunion-informal-ministerial-de-agricultura-3-59/

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 report is available at the following link:

https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/notagrupocnbsobrengtfinal_tcm30-675213.pdf

This *Ad-hoc* working group at the CNB also provide scientific advice in the preparatory process, particularly an analysis of the EFSA GMO Panel (2022) “Statement on criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis. EFSA Journal 2022;20(10):7618, 12 pp. https://doi.org/10.2903/j.efsa.2022.7618.

The National Commission of Biosafety continues to evaluate the files with GMOs obtained by new techniques (such as genetic editing techniques) as GMOs, applying the European Court of Justice ruling of 25th July 2018. Therefore, the assessment requirements of the European regulations on GMOs are followed.

1.2 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 STATES

U.S. Food and Drug Administration Regulatory Update

Plant Biotechnology

On February 22, 2024, the U.S. Food and Drug Administration (FDA) issued a guidance for industry that describes how firms can voluntarily engage with the FDA before marketing food from genome-edited plants. The guidance reaffirms that the risk-based approach the FDA has taken for foods derived from new plant varieties also applies to foods from genome-edited plants. In addition, this guidance describes two processes through which developers may voluntarily inform the FDA of the steps they have taken to ensure the safety of foods from their genome-edited plant varieties: voluntary premarket consultations and voluntary premarket meetings. These processes can help ease the pathway to market for foods from genome-edited plants, while keeping FDA safeguards in place.

The FDA's voluntary premarket Plant Biotechnology Consultation Program enables developers to engage with the agency to determine the appropriate oversight pathways to bring safe, innovative plant-based products to market. Foods from genome-edited plants must meet the same food safety requirements as foods derived from traditionally bred plants.

In this guidance, the FDA continues to recommend voluntary premarket engagement with the agency. The recommended pathway for engagement is based on a food's risk-based characteristics. The guidance describes two processes through which developers may voluntarily inform the FDA of the steps they have taken to ensure the safety of foods from their new genome-edited plant varieties: voluntary premarket consultations and voluntary premarket meetings. The voluntary premarket meeting pathway is recommended for developers to inform the agency of their foods when a voluntary premarket consultation is not warranted based on the food's risk-based characteristics. The agency expects this voluntary premarket meeting pathway to take less time than a voluntary premarket consultation, including because the meeting pathway is recommended for foods that are less likely to raise safety questions. The FDA continues to suggest voluntary premarket consultations for foods that have certain risk-based characteristics, as described in the guidance.

Since the last meeting of OECD Working Party for the Safety of Novel Foods and Feeds in April 2023, FDA completed consultations on the following new plant varieties:

1. DAS1131 corn (DAS-Ø1131-3) from Pioneer Hi-Bred International, Inc. (Pioneer) was genetically engineered to express: the Cry1Da2 protein from *Bacillus thuringiensis* that confers resistance to certain susceptible lepidopteran insects; and the DGT-28 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) protein from *Streptomyces sviceus* that confers tolerance to glyphosate herbicides.
2. DP910521 corn (DP-91Ø521-2) from Pioneer was genetically engineered to express: the Cry1B.34 protein from *B. thuringiensis* that confers resistance to certain susceptible lepidopteran insects; the phosphinothricin N-acetyltransferase (PAT) protein from *Streptomyces viridochromogenes* that confers tolerance to glufosinate ammonium herbicides; and the phosphomannose isomerase (PMI) protein from *Escherichia coli* which served as a selectable marker.

3. JA36 potato from J.R. Simplot Company (Simplot) was genome edited to have each plant produce more tubers, also known as high tuber set.
4. DP915635 corn (DP-915635-4) from Pioneer was genetically engineered to express: the IPD079Ea protein from *Ophioglossum pendulum* that confers resistance to certain corn rootworm pests; PAT from *S. viridochromogenes* that confers tolerance to glufosinate ammonium herbicides; and PMI from *E. coli* which served as a selectable marker.
5. MON 95275 corn (MON-95275-7) from Bayer CropScience LP (Bayer) was genetically engineered for resistance to targeted coleopteran insect pests, including western corn rootworm and northern corn rootworm. To confer insect resistance, Bayer introduced: the Mpp75Aa1.1 protein from *Brevibacillus laterosporus*; the Vpb4Da2 protein from *B. thuringiensis*; and the *DvSnf7.1* double-stranded ribonucleic acid transcripts, derived from the *DvSnf7* gene of the western corn rootworm *Diabrotica virgifera virgifera*, that trigger an RNA-mediated silencing mechanism.
6. *Del/Ros1*-N tomato (*Del/Ros1*-N) from Norfolk Plant Sciences was genetically engineered to express: the Delila and Rosea1 transcription factors from *Antirrhinum majus* to induce anthocyanin biosynthesis in the fruit; and the neomycin phosphotransferase II (NPTII) protein from *E. coli* transposon Tn5 which served as a selectable marker. The *Del/Ros1*-N tomato is only intended for human consumption.

Animal Biotechnology

FDA has two animal-related updates.

The first concerns our guidance for industry (GFI) on regulation of genetic modifications in animals, which we first issued in 2009. That GFI discussed heritable modifications made with rDNA technology. In 2017 we 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 has put into the USG clearance process the 2017 draft GFI now split 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 will be published in final form while Part B will be published as a draft so that FDA can gain additional input that will further improve its approval process. We expect that these two documents will be published in the near future.

Second, in early 2023, FDA's Center for Veterinary Medicine received an Investigational Food-Use Authorization (IFUA) request from an IGA developer at Washington State University to put five pigs containing an investigational IGA into the food supply. FDA reviewed the data and determined that the food from the five pigs was safe and authorized it for food use. The research team at WSU generated the IGA using CRISPR-Cas genome editing to knock out the *NANOS2* gene from the pig genome, making the male pigs infertile. The edit does not affect the pork derived from the pigs. This decision did not authorize commercialisation of this line of genome-edited pigs; it covered only the specific pigs involved in ongoing research. CVM also released a webinar for developers who are interested in learning more about the process of requesting an IFUA for animals with investigational IGAs (https://www.fda.gov/animal-veterinary/center-veterinary-medicine-cvm-animal-biotechnology-products-resource-center/fda-animal-biotechnology-case-study-webinar-investigational-food-use-authorizations-animals).

Updates from the U.S. Department of Agriculture, Food Safety and Inspection Service

Animal Cell Cultured Food Products Derived from Meat and Poultry Cell Lines

- Oversight of cultured animal cell foods in the United States is shared between the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture, Food Safety and Inspection Service (USDA FSIS), as outlined in a March 2019 agreement: https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/Formal-Agreement-FSIS-FDA.pdf.
- FDA's responsibilities under this agreement include oversight of the cell banking and culture phases of food production, as well as premarket consultation with individual firms. For cultured animal cell foods derived from meat (including fish of the order Siluriformes) and poultry cell lines, USDA FSIS' oversight begins following harvest of the cellular material. For cultured animal cell foods derived from non-amenable species and seafood cell lines, FDA's oversight continues beyond harvest.
- Both FDA and USDA FSIS apply its existing authorities to ensure the safety of cultured animal cell foods. FDA and USDA FSIS will also develop joint principles for the labelling of cell-cultured food products under their respective labelling jurisdictions.
- USDA FSIS requires that any establishment that harvests, packages, or labels cell-cultured meat and poultry food products obtains a grant of inspection. Accordingly, upon successful completion of an FDA pre-market consultation, a firm wishing to produce, process, package, or label cell-cultured meat and poultry food products for interstate U.S. commerce must apply for a FSIS grant of inspection.
- In June 2023, USDA FSIS issued the first three grants of inspection to establishments producing FSIS-regulated products derived from animal cell-culture technology, and these establishments are producing cell-cultured poultry food products.
- In 2024, USDA FSIS will be proposing new labelling regulations for meat or poultry food product comprised of or containing cultured animal cells derived from species subject to FSIS jurisdiction and inspection. For establishments that receive a grant of inspection and are ready to market cell-cultured meat or poultry food products before USDA FSIS' cell-cultured labelling regulations are finalised, USDA FSIS will review these labels under its general labelling authority to ensure that labels are not false or misleading or otherwise misbranded.
- USDA FSIS also intends to issue labelling guidance to assist establishments that produce FSIS-regulated food products that contain or are comprised of meat or poultry made using animal cell culture technology in meeting USDA FSIS statutory and regulatory labelling requirements.

EPA Office of Pesticide Programs (OPP) Regulatory Update

Biotechnology Submission Decisions

- EPA issued a new experimental use permit for field testing for PVY coat protein RNAi, VNT1 protein (Rpi-vnt1 gene), BLB2 (Rpi-blb2 gene), and AMR3 (Rpi-amr3 gene) in potatoes to the JR Simplot Company. The experimental use permit was issued March 15, 2023 for testing through April 1, 2024

EPA Finalised 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 finalised a rule exempting a class of plant-incorporated protectants (PIPs) created using genetic engineering from pesticide registration requirements under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and from the food or feed residue tolerance requirements under the Federal Food, Drug, and Cosmetic Act (FFDCA). The exemption reflects the biotechnological advances made since 2001, when EPA first exempted PIPs derived through conventional breeding from pesticide registration and residue tolerance requirements but did not at that time exempt PIPs created through biotechnology. The rule includes:

- Exemptions from FIFRA registration and FFDCA tolerance requirements for:
    - PIPs in which genetic engineering has been used to insert or modify a gene to match a gene found in a sexually compatible plant; and,
    - Loss-of-function PIPs in which the genetically engineered modification reduces or eliminates the activity of a gene, which then helps makes the plant resistant to pests.

A required notification process to increase transparency and public confidence in these products. Developers of PIPs in the first exempted category additionally require an EPA confirmation that their PIP is eligible for the exemption, whereas developers of PIPs in the second exempted category can determine on their own whether the exemption applies.

EUROPEAN UNION

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

Risk assessment

Since 1st March 2023, the European Food Safety Authority (EFSA GMO Panel) has adopted and published 9 new scientific opinions, of which 3 renewal applications:

- AP141 EFSA-Q-2017-00271(cotton COT102) [10-05-2023]
- AP149 EFSA-Q-2018-00292 (maize Bt11 x MIR162 x MIR604 x MON89034 x 5307 x GA21) [18-04-2023]
- AP159 EFSA-Q-2019-00419 (maize DP-202216-6) [07-02-2024]
- AP163 EFSA-Q-2019-00807 (maize DP-023211-2) [29-11-2023]
- AP172 EFSA-Q-2020-00834 (maize DP-915635-4) [30-11-2023]
- AP182 EFSA-Q-2023-00106 (maize MON 94804) [13-03-2024]
- RX-27 EFSA-Q-2022-00845 (maize MON 89034 x 1507 x MON 88017 x 59122) [13-03-2024]
- RX-28 EFSA-Q-2022-00867 (maize MON810; food uses including pollen) [30-11-2023]
- RX-29 EFSA-Q-2022-00868 (maize MON89034×1507xNK603) [13-03-2024]

In addition, EFSA completed the assessment of the 2021 post-market environmental monitoring report on the cultivation of genetically modified maize MON 810 in the EU [06-12-2023] https://www.efsa.europa.eu/en/efsajournal/pub/8411

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:

- the Community Register of GM food and feed (http://ec.europa.eu/food/dyna/gm_register/index_en.cfm), and
- the GMO register for placing on the market of GMOs as or in products if authorised under Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms (https://webgate.ec.europa.eu/fip/GMO_Registers/).

Since the last WG-HROB meeting, the European Commission has authorised 54 GM food and feed (including 47 subcombinations) and has renewed 7 authorisations.

New authorisations:

- Maize MON 87429
- Maize MON 95379

- Maize DP4114 x MON 89034 x MON 87411 x DAS-40278-9 and subcombinations
- Maize MON 87419
- Maize GA21 x T25
- Maize 89034 x1507 x MIR162 x NK603 x DAS-40278-9 and subcombinations
- Maize Bt11 x MIR162 x MIR604 x MON89034 x 5307 x GA21 and subcombinations

Renewals:

- Cotton 281-24-236 x 3006-210-23
- Soybean MON 88701
- Soybean MON 87701 × MON 89788
- Soybean 40-3-2
- Maize MIR162
- Oilseed rape Ms8, Rf3 and MS8 x Rf3
- Oilseed rape GT73

More applications for authorisations are in the pipeline.

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.

***Public engagement* and outreach activities**

EFSA public outreach:

- EFSA is in close contact with its industry stakeholders in the GMO area. In 2023 EFSA organised two Stakeholder's meetings: 18th of April (in presence) and 5-6th October (online) to address concerns and explain in detail the implementation of the Transparency Regulation as well as other Scientific aspects (i.e. Protein Safety, Human Dietary Exposure, Toxicology).
    - https://www.efsa.europa.eu/en/events/ad-hoc-meeting-gmo-industry-representatives [18 April 2023]
    - https://www.efsa.europa.eu/en/events/ad-hoc-meeting-industry-representatives-gmo-applicants [5-6 October 2023]
- The publication of each Scientific Opinion on GM products is followed by a one-month Public Consultation. The outcome of the Public Consultations is available here: https://ec.europa.eu/food/plant/gmo/public_consultations_en
- Ad-hoc meeting with GMO industry representatives on a software tool for peptide binding prediction [27-02-2023] https://www.efsa.europa.eu/en/events/ad-hoc-meeting-gmo-industry-representatives-software-tool-peptide-binding-prediction
- GMO Member States Network Meetings 8-9th June 2023, 13th December 2023 [discussions on NGT, GMM-NGT, GMA]
- Survey on new biotechnologies in microorganisms [07/03/2023 - 30/04/2023] https://www.efsa.europa.eu/en/call/survey-new-biotechnologies-microorganisms

- preDQ – a software tool for peptide binding prediction to HLA-DQ2 and HLA-DQ8 [10-07-2023] https://www.efsa.europa.eu/en/supporting/pub/en-8108
- Horizon scanning on microorganisms and their products obtained by new developments in biotechnology https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2023.EN-8503
- Webinar on protein safety assessment in GMOs [19-12-2023] https://www.efsa.europa.eu/en/events/webinar-protein-safety-assessment-gmos
- Refinement of the Risk Assessment Methodology for Open Reading Frames in GMO Applications [16-01-2024] https://www.efsa.europa.eu/en/supporting/pub/en-8561
- Public Consultation with deadline 8th of April 2024 was launched on the 23rd of February on the "Draft Scientific Opinion on new developments in biotechnology applied to microorganisms" https://connect.efsa.europa.eu/RM/s/publicconsultation2/a0lTk000000C3VB/pc0848

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).***

Developments related to new breeding techniques (NBTs)

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.

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 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 main measures of the proposal include:

1. The proposal (in Chapter I) makes the deliberate release and placing on the market of NGT plants and products subject to one of two procedures: verification procedure to establish equivalence with conventional plants/products or authorisation in accordance with EU legislation on GMOs:

2. Chapter II of the proposal provides for a verification procedure and criteria to verify whether NGT plants/products obtained by targeted mutagenesis or cisgenesis could also have been obtained naturally or by conventional breeding techniques, based on the criteria laid down in Annex I ('category 1 NGT plants'). Category 1 NGT plants/products are exempted from the requirements of the GMO legislation, and subject to the rules on conventionally bred plants. Transparency is ensured in a public database, through labelling of the seeds and through the relevant registers on plant varieties.

3. Chapter III of the proposal applies to NGT plants/products which do not meet the criteria to consider that they could also be obtained naturally or by conventional breeding ('category 2 NGT plants'). They remain subject to the rules on GMOs with adaptations as regards risk assessment, detection method, monitoring and renewal requirements. They are made subject to traceability and labelling requirements of the GMO legislation, with the possibility of a voluntary label to indicate the purpose of the genetic modification. The proposal includes regulatory incentives for Category 2 NGT plants/products featuring traits that could contribute to the overall performance of varieties as regards sustainability (Annex III to the proposal).

4. The proposal provides that NGT plants/products are prohibited in organic production.

5. The proposal includes provisions for the monitoring of economic, environmental and social impacts of NGT plants and products, supporting implementation reports and the future evaluation of the legislation.

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. 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.

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
- Application EFSA-GMO-NL-2019-162. GMM category 3) for the production of soy Leghemoglobin in *Pichia pastoris*. This application is currently under risk assessment. https://open.efsa.europa.eu/questions/EFSA-Q-2019-00651
- Application EFSA-GMO-DE-2019-157. GM specialty canola with a fatty acid profile containing the omega-3 LC-PUFAs EPA and DHA. This application is currently under risk assessment. https://open.efsa.europa.eu/questions/EFSA-Q-2019-00394

Developments related to novel foods and feeds

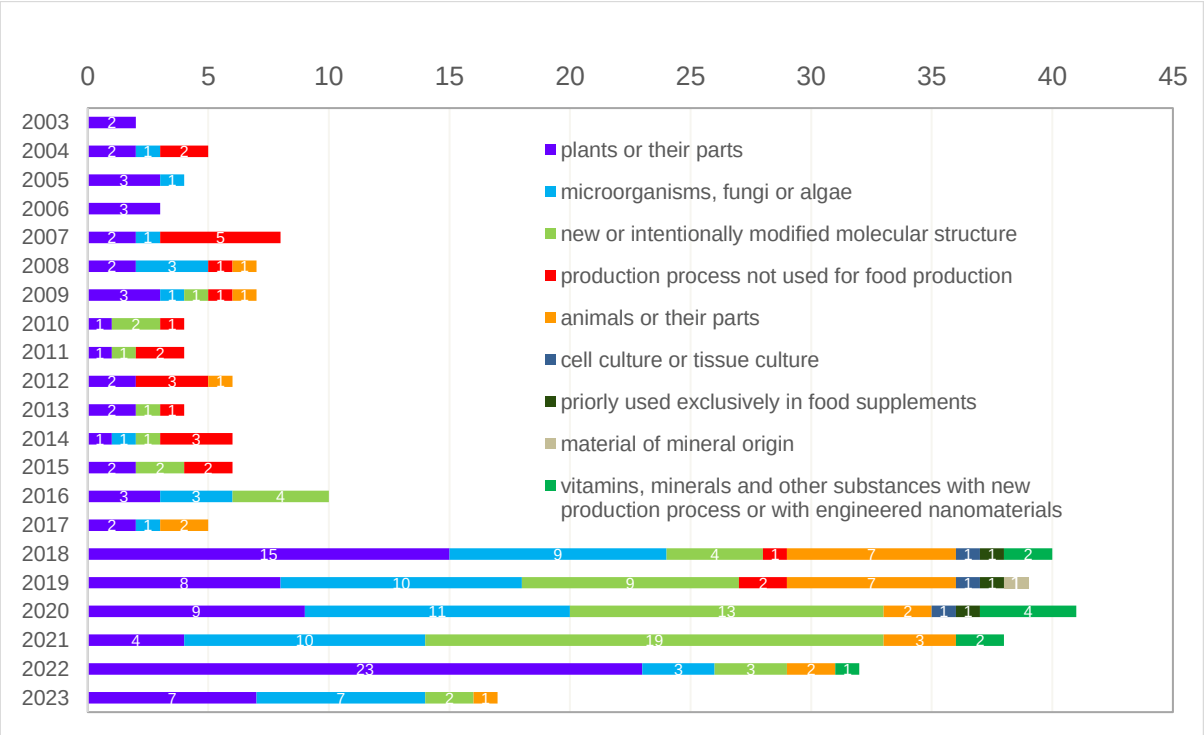
Novel foods

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 607 (513 by April 2023) applications and 114 (109 by April 2023) traditional foods from third countries for authorisation since the regulation became applicable. To date, the Union list of novel foods has been amended 129 (107 times by April 2023), including the authorisation of eleven traditional foods.

Risk assessment

The graph below illustrates the number of applications validated for EFSA risk assessment since 2003 by different categories established.



Between 1 April 2023 and 6 March 2024 EFSA has received 41 NF applications, validated for risk assessment 33 applications and EFSA – NDA panel adopted **21 opinions**. Currently there are 98 applications under risk assessment.

Question Number	Subject
EFSA-Q-2020-00806	Request for a scientific opinion on Barley Rice Protein as a novel food (NF 2020/2195)
EFSA-Q-2020-00488	Request for a scientific opinion on Apple fruit cell culture extract as a novel food (NF 2020/1621)
EFSA-Q-2018-00609	Request for a scientific opinion on Isomaltulose syrup (dried) (NF 2018/0330).
EFSA-Q-2019-00748	Request for a scientific opinion on UV-treated powder of whole yellow mealworm (*Tenebrio molitor*) larvae (NF 2019/1142)
EFSA-Q-2020-00491	Request for a scientific opinion on *Yarrowia lipolytica* yeast biomass as a novel food (NF 2020/1908)
EFSA-Q-2019-00091	Request for a scientific opinion on extract of the microalgae *Phaeodactylum tricornutum* as a novel food (NF 2018/0626).
EFSA-Q-2020-00850	Request for a scientific opinion on *Schizochytrium* sp. oil as a novel food (NF 2020/2242)
EFSA-Q-2019-00388	Request for a scientific opinion on Helix Complex Snail Mucus (HSM) as a novel food (NF 2019/1077)
EFSA-Q-2021-00079	Request for a scientific opinion on Monosodium salt of L-5-methyltetrahydrofolic acid as a novel food (NF 2020/2160)
EFSA-Q-2019-00593	Request for a scientific opinion on paramylon as a novel food (NF 2019/1261)
EFSA-Q-2021-00168	Request for a scientific opinion on *Schizochytrium* sp. oil as a novel food (NF 2021/2445)
EFSA-Q-2021-00170	Request for a scientific opinion on Lacto-N-fucopentaose I / 2'-fucosyllactose mixture (LNFP-I / 2'-FL) as a novel food (NF 2021/2371)
EFSA-Q-2021-00185	Request for a scientific opinion on Isomalto-oligosaccharide as a novel food (NF 2021/2469)
EFSA-Q-2021-00201	Request for a scientific opinion on Yellow/orange tomato extract as a novel food (NF 2021/2369)
EFSA-Q-2021-00354	Request for a scientific opinion on 3-Fucosyllactose (3-FL) as a novel food (NF 2021/2463)
EFSA-Q-2021-00407	Request for a scientific opinion on 2'-Fucosyllactose as a novel food (NF 2021/2394)
EFSA-Q-2021-00445	Request for a scientific opinion on 3'-Sialyllactose (3'-SL) sodium salt as a novel food (NF 2021/2457)
EFSA-Q-2021-00447	Request for a scientific opinion on 6'-Sialyllactose (6'-SL) sodium salt as a novel food (NF 2021/2458)
EFSA-Q-2021-00551	Application for modification of use of Xia Powder 435 as a novel food
EFSA-Q-2021-00643	Application for modification of use of 2'-Fucosyllactose as a novel food
EFSA-Q-2022-00588	Safety of a change in specifications of the novel food oleoresin from *Haematococcus pluvialis*

Food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae; are considered novel food according to Regulation (EU) 2015/2283, unless the technique used falls within the scope of the GMO Regulation.

To date, no application for cell culture derived from animals, has been submitted to the Commission, while two applications for cell culture derived from plants have been submitted (one authorised [Apple fruit cell culture biomass]).

Development/review/amendment of Risk assessment guidance

The NDA panel is currently revising the "EFSA Guidance on the preparation and submission of an application for authorisation of a novel food in the context of Regulation (EU) 2015/2283"

Deadline: June 2024

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. 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 on the placing on the market and use of feed regulates some aspects related to the placing on the market and use of feed. Article 4 of Regulation (EC) No 767/2009 provides for the general safety and marketing requirements concerning feed and requires, amongst others, that the feed business operator marketing insects or products derived therefrom for feed use must guarantee their safety. In accordance with Article 6 of that Regulation, the list of materials whose placing on the market or use for animal nutrition purposes, including of farmed insects, is restricted or prohibited is set out in Annex III to the Regulation ('negative list').

Commission Regulation (EU) 2017/1017 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". The Catalogue also includes an entry for processed animal protein (PAP), including from invertebrates. 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 on undesirable substances, as well as Regulation (EC) No 396/2015 establishing pesticide residue limits, apply to feed derived from insects.

Regulation (EC) No 183/2005 laying down requirements for feed hygiene applies to (as far as insects used as/in feed are concerned): the activities of feed business operators at all stages, from and including primary production of feed, up to and including, the placing of feed on the market; the feeding of food-producing animals; imports and exports of feed from and to third countries. In accordance with Article 10, point (2) of Regulation (EC) No 183/2005, Member States may require the approval of certain feed business establishments located on their territory, where those establishments carry out certain activities which are not already provided for in point (3) of Article 10. Therefore, establishments performing any activity (manufacture, placing on the market etc) in relation to the use of insects as/in feed might be subject to a national approval requirement (including specific hygiene requirements related to the activity concerned). Member States requiring such national approval of certain establishments must inform the Commission and the other MS thereof (cf. Article 12 of Regulation (EC) No 183/2005). In addition, it should be noted that Member States may adopt hygiene rules and guidance concerning activities excluded from the scope of Regulation (EC) No 183/2005, such as for instance the feeding of animals not kept for food production.

In conclusion, the current legislative framework on animal nutrition provides for the production, marketing, and use of insects (live, killed or processed).

Animal by-products regulatory framework

Regulation (EC) No 1069/2009 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 material, including former foodstuffs and catering waste.

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 frozen insects' but not 'processed' to the extent of altering the physical characteristics of the product, according to Regulation (EC) No 1069/2009) are not authorised for use as feed for farmed animals other than fur animals.

Furthermore, the manufacture of pet food (e.g. dog and cat food) with killed insects is allowed by the ABP Regulation (Art. 35) provided that simple treatments like freezing or drying are applied (production in accordance with the provisions foreseen in Annex XIII of Regulation (EU) No 142/2011).

However, national competent authorities may, in accordance with Article 18 of Regulation (EC) No 1069/2009, authorise the use of treated and untreated whole killed insects (on their territory) as feed for fur animals or for other feeding purposes (including zoo and circus animals, reptile, birds of prey, wild animals and fur animals, as well as for fishing bait) provided that the absence of health risks is guaranteed.

Regulation (EU) No 142/2011 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 species 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 protein derived from animals to ruminants (Article 7(1)) which, consequently, prohibits feeding ruminants with insects (live, dead or processed into PAP).

The feed ban also includes, inter alia, a prohibition to feed any PAP to farmed animals, other than fur animals. However, by derogation, Commission Regulation (EU) 2017/893 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. The analytical methods for the control of these feed ban rules are laid down in Annex VI to Commission Regulation (EC) No 152/2009.

The feed ban laid down in the TSE Regulation does not apply to fats and oils derived from insects.

AFSI (THE AGRICULTURE & FOOD SYSTEMS INSTITUTE)

About the Agriculture & Food Systems Institute

The *Agriculture & Food Systems Institute* (AFSI) is an independent nonprofit, scientific organisation 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.

Developments related to biosafety activities

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

Building on a history of collaborative engagement around harmonisation in South Asia which originated in a series of workshops at the South Asia Biosafety Conference, AFSI assembled an Expert Working Group (EWG) with experts from Bangladesh, Bhutan, India, and Sri Lanka to address the potential for harmonisation of food safety assessment for foods resulting from genetically engineered (GE) plants in South Asia. The EWG members, acting in their individual capacity met virtually over the course of 2020 - 2022. The EWG recognized the similarities among the respective national guidelines as all are based on Codex and agreed to develop a mechanism to harmonize the process for safety assessment. To this end a guidance document entitled 'Towards a harmonised approach to Food Safety Assessment of Genetically Engineered plants in South Asia' that describes a consensus approach to the safety assessment of foods derived from GE crops for application across the participating countries was finalised after multiple rounds of discussion. This report of the EWG also includes an application form for developers and a risk assessment summary template for use by risk assessors.

AFSI continued to work on stakeholder engagement with plans tailored towards each of the participating countries' needs for the adoption and operationalisation of the regional guidance. AFSI conducted a capacity building workshop on GE food safety assessment for officials of the Department of Environment (DOE) in Bangladesh in September 2023 as the DOE officials are responsible for food safety applications in Bangladesh and AFSI is supporting them to build their capacity for risk/safety assessment. This workshop titled 'Food Safety Concepts and the Bangladesh Guidelines for Safety Assessment of Food Derived from Genetically Engineered Plants' was structured to provide risk assessors with in-depth technical information about the purpose, design, and conduct of studies used to inform safety assessments of foods and feeds derived from GE plants. The topics covered helped establish a baseline understanding of relevant concepts and principles and included the whole food safety assessment paradigm, problem formulation, discussion of toxicity and allergenicity testing, compositional assessment, and animal feeding studies.

Members of the EWG from the former Bhutan Agriculture and Food Regulatory Authority (BAFRA), now Food Quality and Safety Division, Bhutan Food and Drug Authority (BFDA), indicated their willingness in December 2021 to update Bhutan's guidelines to align with international best practices and the consensus document developed by the EWG and requested support from AFSI. Following formal approval of this request from the Ministry of Agriculture and Forests, a Drafting Committee comprising of BFDA officials supported by SABP and AFSI has been working to update the guidelines. The first complete draft of the guidelines was shared with a broad group of stakeholders during a consultation and workshop on foods derived from modern biotechnology with BFDA officials in October of 2023. Further work on finalizing this draft with stakeholder feedback is ongoing.

The application form developed by the EWG was adopted as Form IA in the official GM regulation notified by the Food Safety and Standards Authority of India (FSSAI). Following this, at the request of FSSAI, a two-day 'Capacity Building Workshop on Food Safety Assessment of Genetically Engineered Plants' in collaboration with FSSAI and Biotech Consortium India Limited was organized in September of 2023. This event provided 20 officials at FSSAI and scientists on the FSSAI Panel on Genetically Modified Organisms and Foods with in-depth technical information aligned with the consensus approach. This workshop enabled FSSAI officials to strengthen their knowledge of GE food safety, international regulatory best practices, develop risk assessment reports, develop tools for regulators, draft SOPs relevant to food safety, and risk communication.

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 2023' for the APEC HLPDAB as part of the U.S.'s self-funded projects. We implemented three seminars, each of which was led by an APEC economy. This seminar series 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 seminar series was cosponsored by Australia, the Republic of Korea, Malaysia, the Republic of the Philippines, Singapore, and Thailand. As part of this series, the following virtual seminars were facilitated by AFSI:

'Development of Agricultural Resources Through Genome Editing Platforms' led by the Republic of Korea was held on June 20, 2023. This event attracted 205 participants from 23 economies. This virtual seminar was a one-day event led by experts on the development of agricultural biotechnology and efforts to develop improved varieties using genome editing. The program highlighted recent trends in genome editing, showcased research on the use of genome editing in breeding programs, and provided a forum for economies to share experiences and discuss how genome editing can help improve the quality of crops and livestock.

The second seminar, 'Ensuring the Safety of Products from Agricultural Biotechnology' was held on August 30, 2023 discussed the progress in scientific tools, methodologies, and frameworks used in the safety assessment of genetically engineered and genome edited organisms used in food production. This virtual seminar was sponsored and hosted by Singapore and attended by 196 participants from 23 economies. Speakers from the United States, Canada, and Singapore discussed approaches and considerations in GMO assessment, modernizing data requirements for food and feed safety assessment, and bioinformatics tools that could guide allergenicity risk assessment of novel proteins.

The third seminar in this series led by the Republic of the Philippines titled 'Enabling Biotechnological Innovations and Policies in Agriculture – Promoting Food Availability and Security' was hosted on November 13, 2023. This seminar had 197 attendees from 15 economies and speakers from the Philippines shared their experiences fostering modern innovations in agriculture for crops, livestock, and

fisheries in the country, as well as highlighted the importance of facilitative regulatory policies and science communication in advancing innovation.

In addition to the Agricultural Biotechnology Seminar Series 2023, AFSI implemented two in-person events in July in Seattle, USA. 'The Early Career and Innovative Start-ups Symposium' on July 29, 2023, shared new developments in agricultural biotechnologies and emphasized the role of youth in innovation. Sixteen early career researchers and developers from a dozen APEC economies delivered both lightning talks and poster presentations on their agricultural biotechnology research, highlighting innovations in the field. Additionally, speakers from agricultural biotechnology start-ups discussed market positioning and regulatory considerations, and industry panellists exchanged ideas on enabling policy environments, current research and development, and career opportunities.

The symposium was followed by the two-day, in-person 'Workshop on Reducing Redundancies and Facilitating Efficiencies: Regulatory and Policy Solutions for Oversight of Agricultural Biotechnologies' on July 30-31, 2023, which was organized to help APEC economies identify regulatory and policy solutions for science-based and risk-proportionate oversight of agricultural biotechnologies that mitigate climate change, strengthen supply chains, increase food security, and facilitate trade. During the activity, speakers introduced key concepts and success stories of regulatory cooperation and delivered talks on the benefits of knowledge sharing and regulatory cooperation for products of agricultural biotechnology and its role in global trade. Through breakout exercises, participants explored various pathways for regulatory cooperation in the HLPDAB. 102 individuals from 18 countries attended the symposium and workshop in person, with each attracting an additional 6 and 19 virtual attendees, respectively.

Viticulture

Supported by the United States Department of Agriculture (USDA) Foreign Agricultural Service (FAS), AFSI organized a virtual workshop on 'Harnessing Genome Editing Technologies for Viticulture' on May 29, 2023, for the European Union. This activity showcased the potential of genome editing as a tool for adapting grape varieties to changing climates, focusing on applications relevant to a broad base of stakeholders in the European Union, such as scientists, risk assessors, regulators, farmers, and private sector professionals from the wine industry. The first session of the workshop included talks on the science of genome editing and use of these technologies to improve grapevine disease resistance. The second session focused on challenges to the commercialisation of grape varieties developed using genome editing, with talks on potential consumer acceptance of wines made using fungus-resistant grapes and the views of young farmers on new genomic techniques. 97 participants from 32 countries attended the event, and the video recording has logged 83 views.

Developments related to new breeding techniques (NBTs)

Genome Editing in Plants: Harnessing the Benefits for Bangladesh

AFSI, through its South Asia Biosafety Program (SABP), at the request of the Bangladesh Academy of Sciences (BAS) and Bangladesh Agricultural Research Council (BARC) has collaborated with them on a series of webinars and conferences on the topic of genome editing in plants. These activities which began in October 2021 have raised the profile of new plant breeding techniques in Bangladesh and spurred a discussion on the appropriate regulatory framework for genome edited plants, particularly within the Ministry of Agriculture. Supported by SABP, BAS assembled a technical committee for Gene Edited Plants which upon invitation by the Secretary of the Ministry of Agriculture proposed an appropriate mechanism to allow the use and introduction of gene edited plants in Bangladesh. Ensuing discussions which included the members of the BAS technical committee, Director Generals, and senior scientists from research institutions within the National Agricultural Research System in Bangladesh, and academics, led

to drafting of 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 SABP, in collaboration with BARC, Ministry of Agriculture organized a Conference on Genome Editing for Agriculture in Bangladesh on February 11, 2024 in Dhaka. The event highlighted the potential of genome editing and the opportunities for Bangladesh to address challenges in agriculture through precise and efficient targeted modification in the genome of plants, accelerating the pace of plant breeding in different crops. The program consisted of a series of presentations on the science of genome editing, the products that have been developed, the regulations around these technologies, and considerations for intellectual property. Following this conference, a Workshop on Standard Operating Procedures for Research and Release of Genome Edited Plants in Bangladesh was held on February 13, 2024, focused on the Ministry of Agriculture's recently drafted "Standard Operating Procedures (SOPs) for Research and Release of Genome Edited Plants of Categories SDN-1 and SDN-2 in Bangladesh". The topics covered included 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.

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 16 crops obtained from controlled field trials done over 26 years across 17 countries.

Version 9.1 of the CCDB was released in February 2023 with data for new crops, including canola – *Brassica juncea*, cassava – *Manihot esculenta*, and red pepper – *Capsicum annum*, along with additional data for sugar beet. AFSI is preparing to release Version 10.0 of the CCDB this year, which will contain compositional data from cowpea and 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 assessment:

- *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 GE animal products and how GE animal products are evaluated against non-genetically modified 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.

AUDA NEPAD-ABNE (AFRICAN BIOSAFETY NETWORK OF EXPERTISE)

In the year 2023/24, the Biosafety Division of the AUDA-NEPAD has provided technical support and training in several African Union member states that included Nigeria, Ethiopia, Kenya, Malawi, Mozambique, Zambia, Ghana, Zimbabwe, Eswatini, Rwanda, and Burkina Faso. AUDA-NEPAD's work to create a favourable policy environment for genome edited products in several AU member states is underway focussing on countries such as Nigeria, Ethiopia, Kenya, Malawi, Mozambique, Zimbabwe, Ghana and Rwanda. A few of the country summaries and participation in regional and international undertakings are given hereunder.

Ethiopia

AUDA-NEPAD conducted consultative workshops on the stewardships of GM cotton and GM maize in Ethiopia around mid-2023. For cotton, the objective was to share information on the status of commercial cultivation of GM cotton in Ethiopia. The consultation on the stewardship of maize focussed on the issue of co-existence of GM and non-GM maize once commercial cultivation of GM maize is underway. In the period under reporting, the biosafety regulatory in Ethiopia reviewed and approved the biosafety application for confined field trials of TELA maize (MON-87460 × MON-89034) and GM enset (*Ensete ventricosum*) tolerant to enset bacterial wilt.

Ethiopia also developed draft guidelines for the regulation of stacked traits GM events, but the guidelines are awaiting validation by stakeholders before approval by decision makers at the biosafety regulatory of the country. Likewise, the guidelines for genome editing have been finalised and still awaiting to be signed by the DG of Environmental Protection Authority to be released for use. Nonetheless, Ethiopia has already embarked on the work on genome edited teff (*Eragrostis tef*) for the control of lodging in the crop in collaboration with Donald Danforth Plant Science Centre supported by the BMGF.

Kenya

The Kenyan biosafety has declared that a genome edited maize resistant to the maize lethal necrosis (MLN) is non-GMO. As a result, genome edited maize resistant to MLN is under national performance trial, a step which normally precedes variety registration and commercialisation. Court cases are still underway to settle case against introduction into the country or development within of genetically modified crops for food and feed uses. AUDA-NEPAD along with other biosafety service providers are providing technical backstopping to see the case through the courts.

Nigeria

Due to anticipated capacity challenges in the review of and decision-making on biosafety applications that may be submitted for GM stacked events, technical support was provided to the Nigeria Biosafety Management Agency (NBMA) in the review of an application for the commercial release of genetically

modified Cowpea event 245F containing Cry2Ab gene conferring resistance to Maruca. The NBMA successfully reviewed and issued a permit on 27 April 2023.

Ghana

A stakeholder review meeting on draft national guidelines on regulating GM stacked events was held on 8 May 2023 and attended by 50 participants. This enhanced participants' understanding of gene stacking, policies currently being applied in other geographies and the rationale for such policies, the regulatory considerations in risk assessment of, and decision-making on GM stacked events. The revised draft will be subjected to a final review and then validation. Following this, on 9 May 2023, stakeholders reviewed a draft national guideline on genome editing, which along the line improved understanding of the applications of genome editing in the agriculture sector. Consensus was achieved on key regulatory considerations and inputs were captured for an improved version of the draft guidelines. The revised draft will be subjected to a final review and then validation.

Technical support was provided for the review of applications for a CFT application for Bruchid resistance in cowpeas from 10 – 12 May 2023. AUDA-NEPAD facilitated the review of the application and the drafting and finalisation of the risk assessment and recommendation reports. AUDA-NEPAD also facilitated the decision-making meeting of the Board of the National Biosafety Authority and the drafting of the decision documents. Approval was granted, the decision documents were finalised, and the decision was gazetted.

Rwanda

Rwanda has published in its Official Gazette the law governing biosafety - Law no. 025/2024 of 16/02/2024 on 21 February 2024, which comes into force on the date of its publication. AUDA-NEPAD is providing support to ensure the Ministerial Orders and Regulations are put in place towards the effective implementation of the law in line with best practices.

Zambia

AUDA-NEPD supported Zambia develop its biotech and biosafety policy, and draft biosafety law. The first draft of the biosafety law is awaiting validation.

Burkina Faso

Burkina Faso is taking steps to re-introduce GM cotton which was previously commercially cultivated for 10 years until 2016 when the decision was made to discontinue. However, any re-introduction would require clarification of the current regulatory process as the Competent National Authority for biosafety, Agence National de Biosécurité (ANB), regulates both the biosafety event approval and the variety registration of an approved event. This is cumbersome and contrary to international best practices. Thus, there is a need to decouple the biosafety event approval process from that of variety registration. Another priority is the need for guidelines to provide clarity on the determination of the regulatory status of genome editing activities. Burkina Faso previously approved experiments for genome-edited rice resistant to vascular bacteriosis caused by *Xanthomonas oryzae pv. Oryzae*. The approval, however, assumed that the activity would be a GMO and as such regulated by the biosafety law. The experiment is on hold awaiting the determination of its regulatory status with an understanding that some genome-edited organisms or products are conventional and must be regulated as such.

A stakeholder consultation and review workshop was held on the guidelines for the determination of regulatory pathways for genome editing on 15 – 16 May 2023. There were 30 participants. The meeting resulted in an improved stakeholder understanding and buy-in. Consensus was thus achieved on key provisions to be considered in the guidelines to ensure improved language and for the guidelines to reflect international best practices. Consequently, the guideline was validated.

A stakeholder consultation and review workshop was held on the guidelines for de-coupling biosafety event approval from variety registration on 17 May 2023 and was attended by 30 persons. Regulatory clarity between processes for event approval and variety registration was achieved and the guideline was validated.

International Activities

AUDA-NEPAD participated in the 25th meeting of the Subsidiary Body on Scientific, Technical and Technological Advice that took place from 15–19 October 2023 in Nairobi, Kenya.

ECOWAS Regulations: AUDA-NEPAD participated in and provided technical support for the regional workshop for the validation of the implementing regulations of the Community Regulation on Biosafety in the ECOWAS region in Ouagadougou, from 31 July to 4 August 2023.

Participation in OECD events

Attended virtually the 2023 WP meetings of HROB and SNFF

Participated in the development of the OECD Consensus Document on Considerations for Collaborative Work on the Safety Assessments of Foods and Feeds Derived from rDNA Plants, which was declassified in September 2023.

Attended several conference calls pertaining to the development of *Anopheles albimanus*/*stephensi* consensus documents. Nominated African experts that contribute to the development of the consensus documents.

Short Courses Organized in Partnership with MSU

Food Safety Virtual Short Course at Michigan State University, July 23 –30, 2023.

Agricultural Biotechnology and Biosafety Short Course at Michigan State University, August 5 to 18, 2023.

BIAC (BUSINESS AT OECD)

CropLife International & International Seed Federation

Developments related to biosafety activities (for BIAC and observer organisations)

Reports and technical resources:

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

AgbioInvestor GM Monitor

In 2024, the AgbioInvestor GM Monitor, supported by CropLife International, was updated with 2023 planting areas and 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 as BioTradeStatus which provides market status information on commercialised GM crops developed by CropLife International member companies.

Updates to Other Databases

Recent updates to other CropLife International databases include an update to the Detection Methods Database to include endogenous methods for canola, maize, cotton, and soybean. These endogenous methods are taxon-specific assays that amplify a specific sequence of known copy number in the host plant genome and are an essential control method when detecting GM events by polymerase chain reaction (PCR). CropLife International also completed the annual update to the Celiac Peptide Database, a list of peptides that have been implicated in triggering celiac disease.

The Economic Impacts of a Mexican Ban on GM Corn Imports

A 2022 study commissioned by CropLife International found that Mexico's proposed genetically modified (GM) Corn ban would force North American grain handling systems into two streams (GM and non-GM corn), an approach that is costlier, disincentivizes innovation, and subjects supply chains to greater volatility. An infographic outlining some of the impacts of such a ban was shared with the value chain of exporting countries working to support the continued open and free trade of inputs, such as GM corn, that are critical for food security. CropLife International has recently commissioned a study that examines the potential impact and delays on new crop innovations resulting from the GM corn ban in Mexico that will be available in June 2024.

Global Communications Resources

In 2023, CropLife International unveiled a revamped website designed to enhance user experience and accessibility. With a focus on simplicity and efficiency, the updated platform boasts easier navigation and streamlined content delivery. A standout feature is the resource library, offering a wealth of valuable materials such as infographics, reports, guidance documents, and studies. These resources serve to underscore the safety and importance of plant biotechnology in advancing sustainable agricultural practices. CropLife International's commitment to providing comprehensive information aligns with its mission to foster innovation and promote responsible stewardship in the realm of agriculture.

Working in partnership with the Global Farmer Network, CropLife International highlighted farmers from around the world helping to transform our food systems in in the face of climate change our 2023 Climate #FoodHeroes campaign.

CropLife International continues to support the GMO Answers online platform by updating content with the latest data available.

Other communications resources included a special issue of our Plant Science Post that focused on the UNFCCC COP 28 Climate Change conference, with features on the importance of agricultural innovation in combatting climate change and our work with the Sustainable Pesticide Management Framework

Updates regarding international activities

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

CropLife International continues to lead plant science industry's engagement in the implementation negotiations of the UN Convention on Biological Diversity, Nagoya Protocol on Access and Benefit-sharing (ABS) and Cartagena Protocol on Biosafety. CropLife International and the CropLife network were pleased to participate in the meetings of the Convention on Biological Diversity and its Protocols in December 2022 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. Parties adopted the Kunming-Montreal Global Biodiversity Framework that sets ambitious goalposts, and CropLife International looks forward to continuing to work with Parties to establish measurable goals around the Framework's targets.

CropLife International has already begun work on the 2024 intersessional period before the next meeting of the Parties to the Convention, providing input and information to the Convention Secretariat and Parties on the horizon scanning process for synthetic biology and on risk assessment and risk management of living modified organisms containing gene drives. CropLife International will continue to contribute meaningful commitments to the Sharm El-Sheikh to Kunming Action Agenda for Nature and People, building on the existing and growing momentum, of urgent action from a broad base of sub and non-state actors in support of the implementation of the Kunming-Montreal Global Biodiversity Framework. CropLife International's commitments include preserving biodiversity by stressing the importance of stewardship through farming training, promoting sustainability via knowledge sharing, collaborating to increase awareness of solutions, and safeguarding the environment and public health through responsible use.

CropLife International hosted a side event to present information on our four commitments to the CBD Action Agenda, focusing on areas and examples where we support the implementation of the Post2020 Global Biodiversity Framework. We will plan to provide similar support at 16th meeting of the Parties to the Convention in Cali, Colombia in October 2024.

Gene Drives

In response to the OECD Secretariat's call for written summaries of recent developments on gene drives, CropLife International highlights the extensive work undertaken in the risk assessment and risk management of living modified organisms (LMOs) containing engineered gene drives under the Cartagena Protocol on Biosafety. CropLife International has contributed to this work through providing an extensive analysis of general considerations of LMOs containing engineered gene drives that may be useful for risk assessment. We are pleased to see that the developments in this work are framed by a "problem formulation" approach, consistent with the OECD Consensus Document on Environmental Considerations for the Release of Transgenic plants published in 2023 to which CropLife International contributed its expertise for more than two decades. We also note that it is critical that approaches to environmental risk assessment of LMOs containing engineered gene drives continue to apply the fundamental principles established in the Cartagena Protocol of case-by-case assessment, with a basis in sound and best available scientific evidence, also taking into account the relevant knowledge and experience gained in LMO risk assessment and best practices such as problem formulation.

16th Symposium of the International Society for Biosafety Research (ISBR)

In April of 2023 CropLife International participated in the ISBR Symposium in St. Louis organizing two parallel sessions, one on fit-for-purpose regulatory frameworks for GM crops and the second, co-organized with the International Seed Federation (ISF) and the American Seed Trade Association (ASTA) on plant breeding and genome editing. CropLife International also organized two workshops. The first workshop explored the recommendations of the CropLife International Regulatory Modernization Project through a hands-on activity in which participants conducted an environmental risk assessment and a food and feed safety assessment for a hypothetical GM crop. The second workshop, also co-organized with ISF and ASTA, discussed global policy for genome editing and how to best "future proof" policies to prolong their relevance to continuously evolving technologies. Dr Abby Simmons of CropLife International also participated in a session on data transportability for confined field testing of GM crops and a conference paper based on that session was recently published in Frontiers in Bioengineering and Biotechnology. We look forward to the 2025 symposium in Ghent, Belgium.

FAO's World Food Forum Science & Innovation Forum

Together with Agriculture and Agri-Food Canada, CropLife International was pleased to host a virtual side event during FAO's World Food Forum Science & Innovation Forum that discussed breaking down regulatory barriers to bring new technology and innovation to farmers. The panel explored the regulatory barriers leading to a lengthening in time for GMO crops to get to market, the impact this is having on farmers, and ways in which these barriers can be overcome.

CropLife International's Impact at COP28: Fostering Sustainable Agriculture Innovation

At the UNFCCC's COP28, CropLife International showcased its dedication to addressing climate challenges, fostering innovation, and advancing sustainable agriculture practices through a range of impactful activities:

1. **Devex Climate+ Summit**: Collaborating with Devex, CropLife International engaged in a fireside chat to highlight key messages on sustainable agriculture, demonstrating the strength of its network and the value of industry programs like the Sustainable Pesticide Management Framework.
2. **World Soils Day**: Through collaboration with the International Fertiliser Association, CropLife International emphasized the role of technology in improving soil health during

COP28's World Soils Day programming, contributing to the recognition of soil health in the UAE COP28 Declaration.

3. **Bilateral Meetings**: CropLife International held over 15 bilateral meetings with influential stakeholders and decision-makers, including representatives from the WTO, FAO, and various government bodies, facilitating dialogue on sustainable agriculture.
4. **Communications Outreach**: Leveraging social media and daily briefings, CropLife International kept stakeholders informed and engaged with over 100 social media posts, 65K impressions, and 1,500 engagements, ensuring broad participation in its COP28 activities.
5. **Partnering for On-Farm Solutions**: Hosting a UNFCCC side event with key partners, CropLife International showcased the role of its programs, like the Sustainable Pesticide Management Framework, in empowering farmers to combat pests and diseases sustainably amidst climate challenges.

Intellectual Property

The worldwide plant breeders' community (represented by the International Seed Federation (ISF), the International Community of Breeders of Horticultural Varieties (CIOPORA), Croplife International, Euroseeds, Seed Association of the Americas (SAA), the Asia and Pacific Seed Association (APSA) and the African Seed Trade Association (AFSTA)) welcomed the adoption of the new Explanatory Notes by the UPOV Council in October of 2023, noting important clarifications in the document with regards to essential derived varieties (EDV). Innovation in agriculture is vital to combatting rising global challenges, such as climate change and food security, and improved biodiversity. Society must enable and provide for an effective and balanced protection of intellectual property rights (IPR) to ensure innovators of all types are able to continue to drive innovations that address global challenges.

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[9]. 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, 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, standardisation of information requirements in support of a regulatory status determination, adoption of predictable and efficient assessment timelines, and recognition of other countries' determinations on regulatory status. These common approaches are essential to maintain a functional trading system that facilitates food security enabled by innovative products including those derived from genome editing.

Both organisations welcome the EU Commission's legislative proposal on NGT plants, note the European Parliament position supporting the proposal voted in February 2024 and await the adoption of an EU Council position so that the Trialogues can start leading to a new Regulation establishing an enabling and

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

risk-proportionate path to EU markets for products developed using genome editing technology. We remain attentive to the discussions and will continue to engage in providing input in the process to achieve a truly enabling regulatory framework. We also welcome early decisions for locally developed genome-edited traits made under the genome editing guidelines from the Ministry of Agriculture and Rural Affairs (MARA) in China and continues to look forward to furthering dialogue to operationalise these guidelines for all developers. Furthermore, we acknowledge ongoing policy development regarding genome edited products in various countries, including Canada (CFIA), Costa Rica, the United Kingdom, Ethiopia, Ghana and, most recently, the US FDA since the last meeting of the working parties. We are also cognizant of ongoing discussions in Korea, Indonesia, Malaysia, Uruguay, Thailand, Singapore, and Switzerland. We recognize that there are on-going determinations for inclusion/exclusion from GMO regulatory oversight in more than a dozen countries for several products. 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 not hindered.

The global seed industry 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 unlikely to be a global "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 has crafted a comprehensive statement titled "Navigating the Evolution of Plant Breeding Innovation" commemorating a century of advancements in plant breeding. This statement not only celebrates the remarkable achievements of plant breeding over the past century but also underscores its profound impact on society by enhancing access to quality seeds and food. It elucidates pivotal milestones in plant breeding innovation and various transformative methods employed during this period.

For further exploration, the statement can be accessed on the ISF website via the following link: 100 years of Plant Breeding Innovation-A Statement by ISF.

Furthermore, the International Seed Federation has extended its efforts by expanding the Frequently Asked Questions (FAQs) section. These FAQs were the cornerstone of the second #FridayFacts campaign initiated by ISF, tailored for the agricultural community and the wider public. This campaign, conducted on social media platforms from September to November 2023, featured engaging short videos and graphic cards focusing on plant breeding innovation. These valuable resources are not only accessible to the public but are also provided to ISF members to bolster their communication efforts. Through initiatives like these, ISF continues its commitment to fostering awareness and understanding of plant breeding innovation across various stakeholders.

HESI (HEALTH AND ENVIRONMENTAL SCIENCES INSTITUTE)

Protein Allergens, Toxins and Bioinformatics (PATB) Technical Committee

About HESI: The Health and Environmental Sciences Institute (HESI) is a non-profit institution whose mission is to collaboratively identify and help to resolve global health and environmental challenges through multi-stakeholder engagement, bringing together scientists from academia, government, industry, NGOs, and other strategic partners. Since its creation in 1989, HESI has produced scientific research, via a diverse range of technical committees, that informs applied health protection decision making around the globe. HESI is based in Washington D.C., USA, but operates globally.

HESI PATB: The Protein Allergens, Toxins and Bioinformatics (PATB) committee is a longstanding HESI committee (formerly known as "Protein Allergenicity Technical Committee" or PATC) and the only committee at HESI focusing exclusively on scientific research relating to food safety and agricultural biotechnology, with particular emphasis on safety evaluation of genetically modified crops.

- Mission: The committee's mission is to advance the scientific understanding of the relevant parameters defining allergenic proteins and protein toxicity in novel foods and feeds by: (i) encouraging the development of reliable and accurate methodologies for characterizing the allergenic potential and "toxicity" potential of novel sources of proteins, and (ii) leveraging the power of bioinformatics approaches in accomplishing these efforts.
- To fulfill its mission, the committee brings together expertise from public and private sector scientists, with participants from the US FDA, US EPA, expert academics and clinicians with representatives from China, Europe, and the USA, as well as molecular biologists, toxicologists and bioinformaticians from agricultural biotechnology companies who share real world experiences and common challenges.

Scientific resources and tools to support safety assessment of novel foods and feeds

COMPARE Allergen Database, www.comparedatabase.org (8th iteration released Jan. 2024):

This collaborative public-private initiative was launched in 2016 in response to the widespread use of genomic sequencing technology and the need to develop a coordinated process implementing a cutting-edge and high-throughput bioinformatic pipeline to identify a meaningful subset of "candidate sequences" which are then submitted to scientific review and curation by an independent panel of public-sector allergy experts. The database has been updated on an annual basis since then through a comprehensive and systematic process, described in Ree et al, 2021. "The COMPARE Database: A Public Resource for Allergen Identification, Adapted for Continuous Improvement". Front. Allergy 2, 39.

The database includes a built-in bioinformatics tool, **COMPASS (COMPare Analysis of Sequences with Software)**, which allows website-based, real-time use of the COMPARE database to run comparative sequence analysis, as per FAO/WHO & Codex Alimentarius guidelines on the testing of genetically

modified plants for allergenicity (full length sequence search; 80-mer sliding window FASTA search; and 8-mer FASTA search).

COMPARE 2024 comprises 2,748 protein sequences and associated metadata (including official IUIS names where available). A detailed description of the updates made in this 2024 version is available on the database website under the documentation page. This year, as part of COMPARE's commitment to continuous improvement, we have enhanced the visibility of Mass Spectrometry (MS) fragments by including a graphical representation on the allergen record page. To learn about more updates, visit the "Documentation 2024" file.

In agreement with HESI's and the COMPARE database program commitment to transparency, decisions and comments from the reviewers recorded during the review process are made available via the website in a downloadable spreadsheet (also in the documentation page, under "Transparency section", e.g., "COMPARE 2024 Transparency").

COMPARE DB usage has increased consistently over the years and is being used globally (> 130 countries and > 4800 users worldwide in 2023).

Framework development: in silico evaluation of potential toxicity of novel proteins (2022-2024)

In a previous HESI public workshop (2020 workshop "From Protein Toxins to Applied Toxicological Testing"; report published in the journal Regulatory Toxicology and Pharmacology by Bauman et al. 2022) stakeholders identified the need for the development of a harmonized framework for the assessment of potential protein toxicity of novel proteins, namely to clarify the process for *in silico* screenings (using bioinformatic tools, interrogating available public databases), and aid in the interpretation of sequence similarities.

The committee formed an international Ad-Hoc expert group to take on that task, composed by 24 experts from 9 countries (Belgium; Brazil; Canada; Ethiopia; Japan; Kenya; Singapore; Switzerland; USA), representing the academic (3), government (10), industry (10) and non-profit (1) sectors. The Ad-hoc expert group had their first meeting in November of 2022 and continues meeting quarterly, working towards developing the framework by end of 2024, for publication in the peer-reviewed literature. Currently the group is evaluating case-studies to illustrate a variety of possible scenarios and outputs from the framework.

Experimental research

Resources permitting, the committee undertakes experimental work aimed at providing a greater understanding of the underlying mechanisms of allergenicity, which are relevant to regulatory considerations related to the evaluation of novel proteins or novel foods and feeds derived from biotechnology. Results of such projects are published in the peer-review literature. A full list of HESI PATB committee publications is accessible via the PATB committee website, under the "Publications" tab.

A **new pilot project related to Celiac Disease** was launched in October 2023, to evaluate the clinical relevance of non-gluten peptides that share similarity with the disease-causing gluten peptides, in triggering Celiac disease. In this project, we will be testing the potential of microbial derived peptides to mimic gluten peptides in activating early events in the cascade triggering Celiac Disease, using organoid models derived from Celiac patients and healthy individuals. Experimental work will be conducted thanks to a collaboration with leading Celiac Disease experts at the Massachusetts General Hospital.

Two research projects are currently in publication development stage:

- **Immunogenicity of allergens vs. non-allergen proteins**: This project aims to detect if allergens have an inherent type of immunogenicity compared to non-allergens from the same protein family, based on a defined *in-vitro* protocol for identification of specific T cells and antibodies from normal and allergic patients.
- **"Allergen Rebuild" project:** This project aimed to evaluate the impact of amino acid (aa) replacement, at a single dominant epitope level (in an otherwise intact, full-length major protein allergen) on the overall molecular structure as well as the IgE-binding to the epitope, to improve the understanding of the biology of allergen IgE-binding at the molecular level. The impact of the aa substitution was also evaluated at the structural level with NMR and computational modelling.

International Outreach: presentations and publications

Presentation at the International Society for Biosafety Research 2023 Symposium:

https://isbr.info/symposium

- Silvanovich A, van Ree R., Pereira Mouriès L. Role of International Multi-Stakeholder Collaborative Platforms in Supporting Development of Safe Foods: Examples from the HESI PATB committee. 30 April-4 May 2023. Poster presentation.

2023 Publications:

- Zhao Lan and Gao Zhong-Shan. 2023. Introduction and application of the COMPARE allergen database [article in Chinese]. *Journal of Food Safety & Quality*, Vol. 14 Issue 2, p43-49.

A complete list of past events and publications of the PATB Committee can be found in the committee public webpage: https://hesiglobal.org/protein-allergens-toxins-and-bioinformatics-committee-patb/.

Open to new collaborators

The PATB committee / COMPARE Database Steering team welcome new public and private sector participants with relevant technical expertise. Solving complex challenges in food and feed safety and sustainability requires dialogue, collaboration, and innovation. HESI provides a neutral platform where stakeholders can share experiences and knowledge in order to address contemporary and emerging needs common to the broader community. HESI PATB committee specifically, offers a strong basis of expertise and knowledge accumulated over the past +20 years, from the early days of biotechnology products development, to present. As such, the PATB is a valuable venue to facilitate public-private interactions and help address new questions developing from these emerging fields, collaboratively.

All geographic areas welcomed. With the emergence of new biotechnologies (e.g., gene editing, microbial protein production) and the growing use of proteins from novel food sources in food production, PATB recognizes the need to include these new topic areas in its activities.

Contacts: Dr. Lucilia Mouriès (lmouries@hesiglobal.org), HESI Senior Scientific Program manager for the PATB Committee and COMPARE database; Ms. Liisa Koski (lkoski@hesiglobal.org) HESI Scientific Program manager for the COMPARE database.

Annex. Obituary for Dr. Kenichi Hayashi

Dr. Kenichi Hayashi (Japan), one of the long-time contributors to the biotechnology area in OECD, passed away on November 1, 2023, at the age of 94.

He was one of the leading experts in Japan in safety/risk assessment of biotechnology, especially genetically modified (GM) crops. After his Ph.D. study at the University of Tokyo, Dr. Hayashi was engaged in crop science at a national research institute of the Ministry of Agriculture, Forestry and Fisheries in Japan. In addition, he has contributed to domestic legislation and regulations regarding the utilisation of GM organisms. Dr. Hayashi's first assignment in this area was to participate in the drafting group for the OECD document "Safety Considerations for Biotechnology: Scale-up of Crop Plants" in 1992. He had abundant international experience. Starting from a long-term fellowship in the United Kingdom, he served for the Food and Agriculture Organization of the United Nations (FAO), the Consultative Group on International Agricultural Research (CGIAR), the Center for Environmental Risk Assessment (CERA) and other international organizations. At the OECD, following the drafting committee mentioned above, he contributed to the Working Group (currently Working Party on the Harmonisation of Regulatory Oversight in Biotechnology: WG-HROB). He served as a Vice-Chair of the WG-HROB from 1996 to 2011. In addition, he actively participated in various relevant meetings and fora organized by the OECD

In addition to his work with the OECD, he actively participated in various conferences, symposiums and workshops on biotechnology, and he provided valuable advice to the world. He remained active after his retirement providing practical scientific information on biotechnology; he was a consultant of ILSI Japan until shortly before death.

Dr. Hayashi's extensive experience, sophisticated expertise, and excellent leadership have contributed greatly to the information exchange and harmonisation on safety/risk assessment and regulations in biotechnology at the domestic and international meetings.

He was gentle and he talked with everyone with kindness and courtesy, he brought up many successors. He was the source of many excellent ideas based on his broad knowledge and his philosophy. One of his key principles was “international harmonisation”. Therefore, he was truly worthy of acting as the Vice-Chair of the WP-HROB at the OECD.

Offering our condolences for the loss of Dr. Hayashi, we would like to pay tribute to his's efforts and achievements in the field of biotechnology. We promise to continue his legacy and to promote for the international harmonisation in biotechnology.

Farewell, Dr. Hayashi. May he rest in peace.

OECD WP-HROB and WP-SNFF Bureau and the Secretariat