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Developments in Delegations on the Safety Assessment of Novel Foods and Feeds, April 2021 – May 2022

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Developments in Delegations on the Safety Assessment of Novel Foods and Feeds, April 2021 – May 2022

Environment Directorate

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Paris 2022

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)

ABOUT THE OECD

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

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

This publication is available electronically, at no charge.

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

or contact:

OECD Environment Directorate,
Environment, Health and Safety Division
2, rue André-Pascal
75775 Paris Cedex 16
France

E-mail: ehscont@oecd.org

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 occasion of the 29th WP-SNFF meeting (16-18 May 2022). It aims at summarising relevant information on activities related to the safety assessment of novel foods and feeds since the previous meeting (March 2021) 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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1. New legislations in the regulatory framework

There are some reviews related with GMO Biosafety regulations by National Advisory Commission on Agricultural Biotechnology in 2021:

1. Res. Secretary of Food, Bioeconomy and Regional Development N° 32/2021. Scope of the regulatory framework and procedures for the analysis of commercial authorisation of plant GMOs. https://magyp.gob.ar/sitio/areas/biotecnologia/conabia/_pdf/RES_032-2021_3%20anexos.pdf
2. Res. Secretary of Food, Bioeconomy and Regional Development N° 49/2021. Guideline for the Insect Resistant Management Plan for the commercial release of Plants Incorporated Protectants (PIPs). https://magyp.gob.ar/sitio/areas/biotecnologia/conabia/_pdf/RES_049_2021_3%20anexos.pdf

2. Events for confined field trails

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

Crops: During 2021, 63 authorisations were granted for different crops:

	FIELD TRAILS	PRODUCTION	GREENHOUSE
QUANTITY	38	7	18
CROP			
Wheat	1		
Corn	6	3	4
Sugarcane	1		
Citrus			2
Soy	18	4	3
Cotton	4		1
Tobacco	1		1
Beet	1		
Rice	1		3
Safflower	1		1
Alfalfa	2		1
Apple	1		
Lettuce			1
Potatoe	1		1

Microorganisms:

Product	Phenotype	Institution	Activity
Vaccine Virus vaccinia Ankara modified	Expresses rabies virus glycoprotein (MVA-RG)	INTA	field trials

Animals:

Animal	Phenotype	Institution	Activity
Bovine	Expression in milk of Human Growth Hormone	INTA	field trials since 2005
Bovine	Expression in milk of Antibodies against rotavirus	INTA	field trials since 2005
Bovine	Expression in milk of human lysozyme and lactoferrin	INTA	field trials since 2011

3. Events for Commercial Approvals

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

Crops:

Unique Identifier	Applicant	Organism Common Names	Traits	Type of use	Date of approval	Decision name	OECD BioTrack
MON-87427-7 x MON-89Ø34-3 x SYN-IR162-4 x MON-87411-9 x MON-87419-8 x MON-ØØ81Ø-6	MONSANTO ARGENTINA S.R.L	Maize	Lepidoptera and Coleoptera resistance, tolerance to herbicides based on glyphosate, glufosinate ammonium and dicamba.	Cultivation, Food and Feed	17/11/21	Resolución 138/2021 https://www.magyp.gob.ar/sitio/_pdf/Resolucion-138-2021.pdf	MON-87427-7 x MON-89Ø34-3 x SYN-IR162-4 x MON-87411-9 x MON-87419-8 x MON-ØØ81Ø-6
MON-ØØ163-7	INDEAR S.A	Alfalfa	Glyphosate tolerance.	Cultivation, Food and Feed	17/11/21	Resolución 139/2021 https://www.magyp.gob.ar/sitio/_pdf/Resolucion-139-2021.pdf	MON-ØØ163-7
MON-87427-7 x MON-87419-8 x MON ØØ6Ø3-6	MONSANTO ARGENTINA S.R.L.	Maize	Herbicide tolerance based on glyphosate, glufosinate ammonium and dicamba.	Cultivation, Food and Feed	19/11/21	Resolución 141/2021 https://www.magyp.gob.ar/sitio/_pdf/Resolucion-141-2021.pdf	MON-87427-7 x MON-87419-8 x MON ØØ6Ø3-6

HB4 Wheat:

- By resolution 27/2022 Argentina allows the INSTITUTO DE AGROBIOTECNOLOGÍA ROSARIO S.A. (INDEAR S.A.) to commercialize the seed, and the products and by-products derived from it, coming from the IND-ØØ412-7 wheat, and all the progeny derived from the crosses of this material with any non-genetically modified wheat.
- Having complied with Article 2 of Resolution No. 41 dated October 7, 2020 of the SECRETARIAT OF FOOD, BIOECONOMY AND REGIONAL DEVELOPMENT of the MINISTRY OF AGRICULTURE, LIVESTOCK AND FISHERIES, which stipulated full approval in Brazil, varieties will be able to marketed of wheat with event IND-ØØ412-7 after its corresponding registration in the NATIONAL SEED INSTITUTE (INASE), a decentralised body in the orbit of the aforementioned Ministry.
- It is worth mentioning that HB4 wheat had commercial approval in Brazil, Australia, New Zealand and Colombia.

Microorganisms:

Product	Phenotype
Recombinant virus cPC V1-2b present in vaccine Fostera Gold PCV-MH	Protection of pigs against Porcine Circovirus Type 2a and Type 2b (PCV2) and respiratory disease due to Mycoplasma hyopneumoniae
Recombinant virus cPC V1-2b present in vaccine Fostera Gold PCV	Protection of pigs against Porcine Circovirus Type 2a and Type 2b (PCV2)
Recombinant virus vHVT310 present in the Vaxxitek HVT + IBD + NDEI vaccine	Protects against Marek disease (MD), infectious bursitis (or Gumboro) and Newcastle disease (ND).
Nexhyon inactivated recombinant vaccine strain, present in the MHYOSPHERE PCV ID pig vaccine	Protection of pigs against Porcine Circovirus Type 2a and respiratory disease due to Mycoplasma hyopneumoniae
EXP INTA EX-2021-104052660- -APN-DLA#SENASA. Virus de leucosis bovina	

4. New Breeding Techniques

There were 9 consultations for plants, animals, and microorganisms. Those products were considered by CONABIA to attend the characteristics established on the NBTs Normative and do not consider to fall under the scope of the Resolution 763/11 that regulates genetically modified organisms.

Finally, we can mention that since 2015 until now, around 36 ICPs have been carried out for the different organism.

5. Participation in International Activities

2021 - 11 bilateral, regional and multilateral high-level meetings:

a. VII Meeting of the Commission for Agricultural Biotechnology of SGT No. 8 "Agriculture" of MERCOSUR, held on March 11, 2021.
b. VIII Meeting of the Commission for Agricultural Biotechnology of SGT No. 8 "Agriculture" of MERCOSUR, held on August 20, 2021.
c. IX Argentina-China Working Group Meeting on Agricultural Biotechnology held on March 16, 2021.
d. Bilateral Meeting between Argentina and Philippines on products derived from gene editing, held on October 6, 2021.
e. Bilateral Meeting between Argentina and Mexico regarding biosafety and development of NBT products held on October 12, 2021.
f. VIII Argentina-EU Bilateral Dialogue Meeting on biotechnology applied to agriculture, held on October 15, 2021.
g. Bilateral Meeting Argentina-Pakistan: Cooperation in Agriculture Biotechnology between Argentina and Pakistan held on December 12, 2021.
h. Bilateral Meeting between Argentina and United Arab Emirates regarding to the Food Development Strategy within the Food Security Plan of that country, held on December 16, 2021.
i. Bilateral meeting between Argentina and Thailand: "Webinar: Exchange of experiences in Agricultural Biotechnology in Argentina and Thailand", held on December 20, 2021.
j. Argentine representatives in UN Biodiversity Conference (COP15/COP-MOP10/COP-MOP4) - Part 1 (Virtual), first part of the United Nations Conference of the Convention on Biological Diversity, held every two years. Held on October 11 to 15, 2021.
k. Meetings GT5 "Public policies in biotechnology" of the Southern Agricultural Council (CAS)

2022 - 5 bilateral, regional and multilateral high-level meetings:

a. Meetings of the Subsidiary Body for Scientific, Technical and Technological Advice (CBD), the Subsidiary Body for Implementation (SBI) and the Working Group on the subsequent Global Biodiversity Framework to 2020 (WG2020) of the Convention on Biological Diversity (CBD), held on March 13 to 30, 2022, in Geneva, Switzerland.
b. Meetings GT5 "Public policies in biotechnology" of the Southern Agricultural Council (CAS)
c. 8th Meeting of the Global Low Level Presence Initiative (GLI)
d. XI Meeting of the Commission for Agricultural Biotechnology of SGT No. 8 "Agriculture" of MERCOSUR, held on April 20, 2022.
e. Meeting of Specialists in Bioinputs of SGT No. 8 "Agriculture" of MERCOSUR, held on April 28, 2022.

Other international activities held on 2021 and 2022

- Dissertation on updates and public policies in the field of bio-inputs in Argentina: Virtual Workshop IICA-FUSAGRI-Venezuela: "Las políticas públicas y el rol del sector privado en el desarrollo de los bioinsumos. Caso Argentina"
- International Virtual Workshop Series on Regulatory Approaches for Animal Biotechnology IICA - USDA for Latin-Americans.
- Training for Cuban technicians and officials in biotechnology and biosafety within the framework of the FOAR Cooperation Project between Argentina and Cuba. Financed by the Argentine Foreign Ministry, held on 2-4 Nov 2021.
- Meeting between Argentina and The Regulatory Horizons Council (UK), held on April 12, 2021. Exhibition on new genetic improvement techniques in Argentina.
- Representation at ICABR Webinar: The Benefits from GMO Regulatory Harmonization held on April, 2021. Exhibition on regulation in modern biotechnology in Argentina.
- Bilateral meeting between Argentina and Germany, at the Future bilateral cooperation meeting between BMEL and MAGyP (ARG), held on April 21, 2021.
- Representation at the Twenty-fourth meeting of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA-24) of the Convention on Biological Diversity, held from May 3 to 16, 2021.
- Cooperation Meeting Consultation between the Argentine Republic and the Eurasian Economic Commission in the field of agro-industrial complex, held on May 27, 2021.
- Organisation together with IICA of the international conference "Conversation on Analysis Criteria and Opportunities for Precision Biotechnology" with related countries in regulation to show the future importance of promoting NBT, held on May 28, 2021.
- Representation at the event: 'Experiences and perspectives on new genetic technologies for plant breeding in Argentina, Colombia and France: adoption, perception and regulation' organised by the Montpellier Advanced Knowledge Institute on Transitions (MAK'IT), held virtually on June 1, 2021.
- Representation at the international conference "Effective Communication of Agricultural Biotechnology" activity carried out within the High-level Dialogue on policies related to agricultural biotechnology for the APEC Asia-Pacific Economic Cooperation Forum, organised by Cornell University, held from June 8 to 10, 2021.
- Presentation of strengths and opportunities of agricultural biotechnology in Argentina, meeting held between MAGyP and the Bill and Melinda Gates Foundation, held on June 23, 2021.

- Exhibition at the Chinese 4th Round Table (virtual) on Genome editing event, organised by the International Seed Federation (ISF), Chinese Seed Association and Chinese Seed Trade Association, held on June 28, 2021.
- Participation in "G20 OECD BNCT WORKSHOP: Bioeconomy in the G20 and OECD countries: sharing and comparing the existing national strategies and policies for co designing more effective Bioeconomy governance mechanisms and monitoring systems", held on July 16, 2021.
- Representation at the "Third meeting of the Open-ended Working Group on the post-2020 global framework for biological diversity", organised by the Secretariat of the Convention on Biological Diversity (CBD) from August 23 to September 3, 2021.
- Representation at the virtual Intersessional Meeting of Global Low Level Presence Initiative (GLI) held on Nov.11, 2021.
- Video Conference and multilateral meeting between South Africa, Argentina, USA and Brazil, in relation to the change in South African regulations in relation to NBT, held on December 3, 2021.
- Representation at IICA Virtual Sessions on Biotechnology and Biosafety of the Convention on Biological Diversity and preliminary sessions of the Cartagena Protocol.
- Active participation in WTO SPS Working Group on Approval Procedures.
- Part of the team which organised the International Workshops Series on Regulatory Approaches for Animal Biotechnology, organised by USDA-IICA.
- Participation and contribution to the Ad hoc group for the NBT Project Proposal to the OECD WP-HROB/WP-SNFF.
- Representation at the OECD AD HOC Working Group for the Safety of Novel Foods and Feeds.
- Representation at OECD Ad Hoc Group "Safe by Design" in Biotechnology.
- Interventions in specialized intergovernmental and multilateral high-level meetings to discuss the negotiation of the SPS chapter and on Biotechnology and LLP in the MERCOSUR - CANADA Agreement.

6. Communication and education

2021

- Training for Cuban technicians and officials in biotechnology and biosafety within the framework of the FOAR Cooperation Project between Argentina and Cuba. Financed by the Argentine Foreign Ministry and held from November 2 to 4, 2021.
- Edition and publication of the book "30 años de la Comisión Nacional Asesora de Biotecnología Agropecuaria. Un homenaje a su trayectoria" which compiles the history of the Commission and the testimonies of its members since its foundation in 1991.

2022

- Publication of an article in the journal Frontiers: "Genomic Editing: The Evolution in Regulatory Management Accompanying Scientific Progress" (https://www.frontiersin.org/articles/10.3389/fbioe.2022.835378/full)
- Publication of an article in the journal Frontiers: "Update of Argentina's Regulatory Policies on the Environmental Risk Assessment" (https://www.frontiersin.org/articles/10.3389/fbioe.2021.834589/full)
- Southern Agricultural Council (CAS) Declaration: "Regional Position on Biotechnologies linked to the Agricultural Sector", document that was shared for the CBD Geneva negotiations: http://consejocas.org/wp-content/uploads/2022/03/Declaraci%C3%B3n-CAS-Posici%C3%B3n-regional-sobre-las-biotecnolog%C3%ADas-ligadas-al-sector-agropecuario.pdf
- Publication of the article "Spaces for dialogue on Innovation in the Bioeconomy", in the 19th edition of the magazine Alimentos Argentinos. Article written by several members of the National Directorate of Bioeconomy: http://www.alimentosargentinos.gob.ar/HomeAlimentos/Publicaciones/Revista/AA_79.pdf

7. Products derived from agriculture

7.1 Biomaterials and Biobased materials

The use of resources of fossil origin for the production of industrial products is ending. The shortage of oil and the problem of microplastics in the sea, added to the ecological interests demanded by society, such as climate change, sustainability, the circular economy, etc.; they show the need for a comprehensive change in the way we consume and manufacture products.

In this context, "biomaterials" or "biobased materials" appear, understood as those obtained in their greatest proportion from renewable raw materials of agro-industrial origin, as substitutes for products made with conventional materials from polluting industrial processes and non-degradable materials. Within the range of biomaterials, some specific categories can be identified: biopolymers and bioplastics (biobased plastics or biopolymers made from

starch); biocomposites (or composite materials formed by a matrix and natural fibres); biosurfactants (such as bio-based detergents, bio-based cleaning products); cellulose; cultivated materials (or biofabrication).

The Argentine biomaterials sector is in the process of formation and expansion. The advantage of having renewable raw materials and waste from local production tends to build the foundations for the creation of a fertile field to be intervened by incorporating innovation through the production of biomaterials and bioproducts.

In this sense, the Coordination of Innovation and Biotechnology of the Directorate of Bioeconomy of the Ministry of Agriculture, Livestock and Fisheries of the Nation, is actively working on the subject in which the following actions have been developed:

- The formation of the National Advisory Commission on Biomaterials (COBIOMAT) Resolution 13/2018. This Commission was created in order to create technical criteria and formulate public policies for shaping the biomaterials sector. It also provides advice to the Secretariat of Food, Bioeconomy and Regional Development. It is made up of expert members from state agencies, private representatives, and the academic sector.
- Roundtable on Innovation in Biomaterials: Space for exchange between researchers and entrepreneurs with the objective of discussing the limitations for development and the elaboration of proposals for the formulation of public policies that promote biomaterials.
- "Action Plan for the Biomaterials and Bioproducts Sector" Resolution 33/2019. This Plan was prepared in conjunction with the Commission in order to build the biomaterials and bioproducts sector in Argentina.

7.2 Bio-inputs

The current world scenario combines the possibilities offered by biotechnology with consumer demand for healthier foods, in addition with greater global awareness of protecting the environment and public health.

- In 2013, the Advisory Committee on Bioinputs for Agricultural Use (CABUA) was created in the scope of the Ministry of Agriculture, Livestock and Fisheries, under the Coordination of Innovation and Biotechnology.
- In 2019, The Action plan for the Bioinputs sector for agricultural use was released. Resolution RESOL-2019-105-APN-SAYBI#MPYT.

7.3 Argentine Bioproducts Seal

- Argentine Bioproducts Program Resolution 235/2017 and “Argentine Bioproducts Seal”: The objective of the Seal is to highlight those products that were made with a high percentage of bio-based content and provide elements of innovation and sustainability in their formation. At present, the "Argentine Bioproduct" Seal has been awarded to 5 local institutions.

Company	Products	Raw material
Ciclo Sin Fin	Cutlery	Castile cane (weed)
Radha Colors	Cotillon	Cornstarch
Malón Bikes	Bikes	Bamboo
Get Wild	Cothing	Bamboo (textile)
Ecoderm	Facial emulsion	Biobased oils and extracts (apple, sunflower, orange, etc.)

- In 2022, Incorporation of bio-inputs for agricultural use to the Argentine Bioproduct Seal.

AUSTRALIA

1. GM food regulation in Australia

Food Standards Australia New Zealand (FSANZ; 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/Details/F2018C00169.
- Schedule 26 is available here: https://www.legislation.gov.au/Details/F2021C00093.

2. GM food assessments and approvals in Australia

A full list of the GM foods that have been assessed by FSANZ, as well as links to relevant assessment reports, are available from the FSANZ website at https://www.foodstandards.gov.au/consumer/gmfood/applications/Pages/default.aspx

Approvals since the 28th Meeting and applications currently under assessment by FSANZ include:

Food derived from:	**Current Status:**
Herbicide tolerant canola line MON94100	Approved April 2021
Insect protected corn line MON95379	Approved February 2022
Drought and herbicide tolerant wheat line IND00412	Approved April 2022
EPA+DHA and herbicide tolerant canola line LFBLFK	Under assessment

3. 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/science/international/Pages/gm-food-safety.aspx

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.

The first product assessed under the arrangement was herbicide tolerant canola line MON94100. The safety assessment was prepared by Health Canada and then reviewed and subsequently used by FSANZ to inform its own assessment of MON94100. The food authorisation process for MON94100 was completed in both Australia and Canada in April 2021.

By relying on a safety assessment done by Health Canada, FSANZ was able to reduce the authorisation process from 9 months down to 5 months. Because FSANZ uses a cost recovery process, this resulted in both time and cost savings for the company as well as significant resource savings for FSANZ. The synchronised authorisations in both countries was an added benefit, although not the primary goal of the sharing process.

FSANZ and Health Canada are in the process of identifying a suitable candidate for future safety assessment sharing where FSANZ will be the primary assessor.

4. New breeding techniques - update

In February 2020, FSANZ commenced a proposal (Proposal P1055 – Definitions for gene technology and new breeding techniques) to amend the definitions in the *Australia New Zealand Food Standards Code* (the Code) for 'food produced using gene technology' and 'gene technology'. These definitions determine what foods require pre-market safety assessment and approval as GM foods. The proposal was initiated after a previous review by FSANZ, completed in 2019, found the current definitions are unclear and outdated and did not reflect the diversity of techniques currently in use.

FSANZ publicly released a first Call for Submissions report on its preferred approach to amending the definitions in Oct. – Dec. 2021: https://www.foodstandards.gov.au/code/proposals/Documents/P1055%201st%20Call%20for%20Submissions.pdf. The preferred approach is based on the conclusions of a detailed safety assessment of NBTs compared to other methods of genetic modification:
https://www.foodstandards.gov.au/code/proposals/Documents/P1055%20SD1%20Safety%20Assessment.pdf

As part of its assessment, FSANZ also considered a range of other matters including: technology development, enforcement, alignment of gene technology definitions, international developments and how the preferred approach relates to current GM labelling requirements in Australia and New Zealand.

In response to the consultation, a total of 1734 submissions were received. FSANZ is in the process of considering the issues raised by submissions, which will be used to finalise the proposed approach. A 2nd Call for Submissions report, containing the revised legal definitions, is anticipated to be released for a further round of consultation later in 2022. The submissions and full set of consultation documents are available from the FSANZ website at:

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

Proposed approach

FSANZ's assessment under P1055 concluded that NBT food and refined ingredients derived using gene technology should not be GM food for Code purposes (i.e. not require an application to FSANZ for pre-market approval as GM foods) if they are equivalent in characteristics and risk to conventional food with a history of safe use.

Based on this assessment, FSANZ has proposed:

- expanding the existing process-based definition for 'gene technology' to capture all methods for genetic modification other than conventional breeding; and
- revising the definition for 'food produced using gene technology' to exclude foods that are equivalent in risk to conventional food from pre-market safety assessment and approval as GM food. Exclusions would be based on specific product-based criteria. Food not meeting all exclusion criteria would require an application to FSANZ as a GM food.

These proposed changes to definitions will extend the reach of the Code to new and emerging genetic technologies while at the same time adopting a more proportionate regulatory approach to foods that are no different to conventional food in terms of risk.

In addition to changes to definitions, FSANZ proposed the establishment of an advisory committee on NBT foods and the development of specific guidance material. These measures will help facilitate implementation of revised definitions by Australian and New Zealand government jurisdictions with responsibility for enforcing food law, and also assist product developers to interpret and comply with the new provisions.

Consumer research

To supplement information from submissions and to inform FSANZ's public engagement and communication strategy, FSANZ commissioned research on consumer attitudes to NBTs. Reports from this work are available on the FSANZ website:

- Systematic literature review on consumer responses to the use of NBTs in food production: https://www.foodstandards.gov.au/code/proposals/Documents/NBT%20Literature%20Review.pdf
- Focus groups on consumer responses to the use of NBTs in food production: https://www.foodstandards.gov.au/code/proposals/Documents/FSANZ%20NBT%20final%20report.pdf

Additional consumer research will be undertaken during the course of 2022.

Communication material

To support the proposal process and raise awareness about GM foods and the work on NBTs, FSANZ developed a range of communication material (factsheets and videos) which are also available on the FSANZ website: https://www.foodstandards.gov.au/consumer/gmfood/Pages/Education-materials-on-GM-foods-and-NBTs.aspx

BELGIUM

1. Notifications for commercialisation

Belgium remains actively involved in the European Food Safety Authority (EFSA) consultation for placing on the market of genetically modified organisms (GMOs). Input in the risk assessment is provided through the Biosafety Advisory Council, which besides food and feed aspects also evaluates environmental impacts of GMOs. The Service Biosafety and Biotechnology (SBB) of Sciensano (the Belgian institute for health) ensures the secretariat of the Biosafety Advisory Council and provides permanent scientific support to its activities. Assessment reports and relevant documents can be consulted on https://www.bio-council.be and https://www.biosafety.be. The OECD consensus documents on compositional considerations for new varieties of crops (the series on the safety of Novel Foods and Feeds) are used as reference documents during the evaluations.

2. GMO detection in Belgium

Detection, identification and quantification of GMOs present in food and feed is conducted by the service "Transversal activities in Applied Genomics" (TAG) of Sciensano. TAG 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) in food enzyme (FE) preparations: Between 2017 and 2021, TAG coordinated a national project, SPECENZYM (RT17/5), on the purity of food enzyme. In this project, studies on the purity of FE for the development of general purity criteria were performed, in the context of the implementation of Regulation (EC) 1332/2008. Prior to this project, there was no strategy for an efficient and accurate control and monitoring of contaminants in FE and FE preparations. This project has collected information related to FE and available methods existing in Belgian enforcement laboratories to detect FE impurities including GMM and recombinant DNA. Evidence-based results were provided on the contaminations present in 50 FE preparations. In particular living GMM or DNA were present in several samples. This has led to several RASFF (EU Rapid Alert System for Food and Feed). In the frame of this project a strategy to detect GMM in food and feed fermentation products has been developed and implemented for enforcement purposes. As a consequence of this project, microbial fermentation products such as enzyme preparations or feed and food additives have been included in the official control programme starting from 2021. TAG has also collected information in order to create the FEDA database which is a web application gathering information about food enzyme preparations available on the European market.

TAG coordinates a new Belgian federal project on development of new open strategy for impurity surveillance of commercial microbial fermentation food products (ENSURED), which will start in 2022.

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 characterization of GMMs used in fermentation products or as a bioweapon, ii) quality control of vaccines and medicinal products and iii) characterization of microbiomes. In the frame of this project, a theoretical assessment of the risks associated with the presence of GMMs and antibiotic resistance genes in fermentation products will be conducted.

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 Illimina technology is foreseen.

Networking: TAG coordinates a networking project with ICAR-National Bureau of Plant Genetic Resources in India, focused on UGM events and novel analytical tools for their detection (e.g. NGS).

Peer-reviewed publications:

F. Buytaers, M.A. Fraiture, B. Berbers, E. Vandermassen, S. Hoffman, N. Papazova, K. Vanneste, K. Marchal, **N.H.C. Roosens,** and **S.C.J. De Keersmaecker.** A shotgun metagenomics approach to detect and characterize unauthorized genetically modified microorganisms in microbial fermentation products. Food Chemistry: Molecular Sciences 2021; 2 (100023). https://doi.org/10.1016/j.fochms.2021.100023.

J. D'aes, M.A. Fraiture, B. Bogaerts, S.C.J. De Keersmaecker, N.H.C. Roosens, K. Vanneste. Characterization of Genetically Modified Microorganisms Using Short- and Long-Read Whole-Genome Sequencing Reveals Contaminations of Related Origin in Multiple Commercial Food Enzyme Products. Foods 2021; 10 (11), 2637. https://doi.org/10.3390/foods10112637.

M. Deckers, J. Van Braekel, K. Vanneste, D. Deforce, **M.A. Fraiture, N.H.C. Roosens.** Food Enzyme Database (FEDA): A Web Application Gathering Information about Food Enzyme Preparations Available on the European Market. Database 2021; 2021, 1-7. https://doi.org/10.1093/database/baab060.

M. Deckers, M. De Loose, N. Papazova, D. Deforce, **M.A. Fraiture, N.H.C. Roosens.** First Monitoring for Unauthorized Genetically Modified Bacteria in Food Enzymes from the Food Market. Food Control 2021; 108665. https://doi.org/10.1016/j.foodcont.2021.108665.

M.A. Fraiture, L. Joly, **E. Vandermassen, M. Delvoye, D. Van Geel,** J.Y. Michelet, E. Van Hoeck, N. De Jaeger, **N. Papazova,** and **N.H.C. Roosens.** Retrospective Survey of Unauthorized Genetically Modified Bacteria Harbouring Antimicrobial Resistance Genes in Feed Additive Vitamin B2 Commercialized in Belgium: Challenges and Solutions. Food Control 2021; 119 (107476). https://doi.org/10.1016/j.foodcont.2020.107476.

M.A. Fraiture, U. Marchesi, D. Verginelli, **N. Papazova,** and **N.H.C. Roosens.** Development of a real-time PCR method targeting an unauthorized genetically modified microorganism producing alpha-amylase. Food Analytical Methods 2021; 14. https://doi.org/10.1007/s12161-021-02044-x.

M.A. Fraiture, N. Papazova, and **N.H.C. Roosens.** DNA Walking Strategy to Identify Unauthorized Genetically Modified Bacteria in Microbial Fermentation Products. International Journal of Food Microbiology 2021; 337 (108913). https://doi.org/10.1016/j.ijfoodmicro.2020.108913.

M.A. Fraiture, A. Gobbo, U. Marchesi, D. Verginelli, **N. Papazova, N.H.C. Roosens.** Development of a Real-Time PCR Marker Targeting a New Unauthorized Genetically Modified Microorganism Producing Protease Identified by DNA Walking. International Journal of Food Microbiology 2021; 109330. https://doi.org/10.1016/j.ijfoodmicro.2021.109330.

3. New Techniques

Prior to the ruling of the European Court of Justice of 25 July 2018, it was considered that genome edited plants to be released in the field should be excluded from the scope of the GMO legislation in the same way as plants developed through conventional mutagenesis techniques, although a case-by-case approach was applied. Since the ECJ ruling, Belgium has aligned itself with the European position, which considers that organisms obtained through new mutagenesis techniques are subject to Directive 2001/18/EC on the deliberate release of GMOs in the environment. Belgium is actively involved in the ongoing policy action on plants produced by targeted mutagenesis and cisgenesis initiated by the European Commission.

Since the last WP meeting three new field trials with maize modified by CRISPR-Cas have been authorised (https://www.biosafety.be/search-gm-plants):

- Field trial evaluation of maize with increased resistance against environmental stress causing DNA damage (B/BE/22/V1)
- Field trial evaluation of maize modified with modified growth characteristics (reduced lignin) (B/BE/22/V2)
- Field trial evaluation of maize modified with modified growth characteristics (increased drought tolerance) (B/BE/22/V3)

Belgium supported the following activities:

- COST Action CA18111 "PlantEd" - Genome editing in plants - a technology with transformative potential (2019 – 2023): Several Belgian institutions (including Sciensano) are contributing to this European project (EU Framework Programme Horizon 2020) that aims to bring together expertise from a wide range of disciplines to evaluate new genomic modification techniques in plants. It will help define future research priorities by stimulating transnational and transdisciplinary collaborations.

Belgian scientists were involved in the following publication, relevant for the risk assessment of NBT:
Sturme et al. (2022). Occurrence and Nature of Off-Target Modifications by CRISPR-Cas Genome Editing in Plants. ACS Agricultural Science & Technology, https://doi.org/10.1021/acsagscitech.1c00270.

BRAZIL

1. Developments related to implementation of national biosafety framework

1.1. Risk assessment/regulatory decisions

Since last OECD meeting in 2021, 27 new GM events were approved for commercial release in Brazil. (http://ctnbio.mctic.gov.br/liberacao-comercial#/liberacao-comercial/consultar-processo):

GM Plants:

- ✓ GMB151: nematode resistance and herbicide tolerant soybean (BASF S.A.);
- ✓ DP4114-3: insect resistance and herbicide tolerant maize (Corteva Agriscience do Brasil Ltda);
- ✓ 3272 x Bt11 x MIR162 x GA21: insect resistance and herbicide tolerant maize (Syngenta Seeds Ltda.)
- ✓ DAS-59122-7: insect resistance maize (Corteva Agriscience do Brasil Ltda);
- ✓ CTC95019-5: insect resistance sugarcane (Centro de Tecnologia Canavieira - CTC);
- ✓ 751K032: herbicide tolerant eucalyptus (Suzano S.A.)
- ✓ IND-ØØ412- 7: drought resistant and herbicide tolerant wheat flour (TMG)

GM Microorganisms:

- ✓ *Saccharomyces cerevisae* microorganism strains SCY015 e SCY016: industrial application (Novozymes Latin America Ltda.);
- ✓ *Saccharomyces cerevisae* microorganism CelluXTM 4: ethanol production (BioSpringer do Brasil Indústria de Alimentos S.A.);
- ✓ *Saccharomyces cerevisae* microorganism M24296: ethanol production (Lallemand Brasil Ltda.)
- ✓ *Saccharomyces cerevisiae* microorganism GICC03578 and GICC03588: ethanol production (Danisco Brasil LTDA);
- ✓ *Saccharomyces cerevisiae* microorganism M23541: ethanol production (Lallemand Brasil LTDA)
- ✓ *Saccharomyces cerevisiae* microorganism SCY017: ethanol production (Novozymes Latin America Ltda.)
- ✓ *Saccharomyces cerevisiae* microorganism strain Y67383: Reb-M esteviol glycoside production (Amyris Biotecnologia do Brasil Ltda.)
- ✓ *Saccharomyces cerevisiae* microorganism SCY018: ethanol production (Novozymes Latin America Ltda.)
- ✓ *Saccharomyces cerevisiae* microorganism SCY014: ethanol production (Novozymes Latin America Ltda.)

Vaccines and gene therapy:

- ✓ ChAdOx1+nCoV19 vaccine: vaccine against SARS-CoV-2 (Covid-19) developed by Institute of Technology in Immunobiologicals (Bio Manguinhos FIOCRUZ, Brazil);
- ✓ G608 vaccine: vaccine against edema disease of swine (Ceva Saúde Animal);
- ✓ Ad26.COV2.S1 vaccine: vaccine against SARS-CoV-2 (Covid-19) (Janssen-Cilag Farmacêutica Ltda)
- ✓ Recombinant vaccine CIRCOGARD: recombinant vaccine against porsine circovirus type 2 – PCV2 (Eco Animal Health do Brasil, Comércio de Produtos Veterinários Ltda.);
- ✓ Vaccine FVAX-20SA01: specific vaccine against *Strepstococcus* for captive bred tilapia (Tevah Consultoria Empresarial, Regulatória, Governamental e Engenharia Ltda.);
- ✓ Vaccine GAMCOV-VAC (SPUTNIK V): vaccine against SARS-CoV-2 (Covid-19) developed by Gamleya Institute of Russia (União Química Farmacêutica Nacional S.A)
- ✓ Kymriah®: gene therapy, treatment against adult lymphoblastic leukemia (Novartis Biociências S.A);
- ✓ Poulvac® Procerta: live frozen vectorized vaccine against the Gumboro and Marek's Diseases (Zoetis Indústria de Produtos Veterinários Ltda.)
- ✓ Ciltacabtagene autoleucel (cilta-cel, JNJ-68284528): gene therapy, treatment against multiple myeloma (Janssen-Cilag Farmacêutica Ltda.)

GM animals:

- ✓ *Spodoptera frugiperda* strain OX5382G (Oxitec do Brasil Ltda.)
- ✓ Salmon from Atlantico (*Salmo salar*): transgenic salmon developed for growth hormone (AquaBounty Participações Ltda)

The total number of commercial approvals of GMOs in Brazil are: 104 genetically modified plants (55 maize, 22 cotton, 18 soybean, 6 sugarcane, 2 eucalyptus and 1 common bean), 56 recombinant vaccines, 1 genetically modified mosquito, 1 genetically modified fish and 43 genetically modified microorganisms, and derivatives. Further information can be accessed at http://ctnbio.mctic.gov.br/liberacao-comercial#/liberacao-comercial/consultar-processo.

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

- ✓ Normative Resolution CTNBio Nº 32, published in June 15th 2021: provides for the rules for commercial approval and monitoring of genetically modified animals and plants – GMO and their derivatives of plant and animal origin.
- ✓ Normative Resolution CTNBio Nº 35, published in October, 15th 2021: provides for the authorisation by CIBio for field release liberation into environment of GMO and their derivatives risk class 1 that had been already approved by CTNBio for experimental evaluations for field release.
- ✓ Normative Resolution CTNBio Nº 36, published in October, 26th 2021: establishes the conditions for field release into environment of genetically modified maize (*Zea mays* L.) and its derivatives.

2. Updates regarding international activities

- ✓ Working Party on Harmonisation of Regulatory Oversight in Biotechnology / OECD
- ✓ Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA / CBD)
- ✓ Cartagena Protocol: Risk Assessment AHTEG and Socio-Economic Considerations AHTEG
- ✓ Convention on Biological Diversity: Synthetic Biology (on line forum and AHTEG)
- ✓ China-Brazil Joint WG on Agriculture, Biotech and Biosafety
- ✓ US-Brazil High-Level Biotechnology Working Group
- ✓ Canada-Brazil Bilateral Meeting on Biotech
- ✓ Canada/Mercosul Agreement on Agricultural Biotechnology (LLP)
- ✓ Brazil-Argentina Bilateral Dialogue on Biotech
- ✓ CAS – Southern Agricultural Council
- ✓ GLI – Global Low Level Presence Initiative
- ✓ MERCOSUL – SGT-8 Agricultural Biotechnology Commission

3. Developments related to new breeding techniques (NBTs)

The Normative Resolution No 16 (NR16) was published on January 15th 2018 and has the technical requirements for a consultation process, evaluated in case-by-case base by CTNBio on the use of Precision Breeding Innovative

Techniques, or also known as New Breeding Technologies. There were 13 consultations in 2021. The dsRNA would be used to silence genes in *Spodoptera frugiperda* and *Helicoverpa armigera*, insects that attack cultivated crops; four microorganism lines of *Saccharomyces cerevisiae*, bull semen with increased muscle mass by gene edition; RAW 264.7 cell line, one microorganism lines of *Bacillus thuringiensis* 4Q7 strain, one cimatec HDT vaccine, one ALS herbicide tolerant soybean, active ingredient for nematode control BCS-DF76745 with proteins from two species of genus *Bacillus*, angus for genome edition for slick, and sugar cane modified with the CRISPR/Cas9 technique were not considered to fall under the scope of the Law 11.105/2005 that regulates genetically modified organisms in Brazil.

4. Additional Information

GMO Inspections

The Ministry of Agriculture, Livestock and Food Supply (MAPA) is one of the institutions responsible for GMO inspections to check the compliance with biosafety normative requirements. The MAPA carried out 354 inspections in 2021 related to field trials and commercial use of GMOs to check the biosafety requirements.

GMO Research

In 2021 there were 31 field trials approved in Brazil, with different plant species, including maize, soybean, cotton, sugarcane, eucalyptus, rice and citrus. The characteristics of the biotech crops included insect resistance, herbicide tolerance, disease resistance, drought tolerance, increased yield, reduced lignin content, increased growth and fibre quality.

In 2021 there was a total number of 472 private and public institutions registered and approved by CTNBio to conduct research with GMOs under containment, according to CTNBio website.

CANADA

Novel Food Approvals

Since 1999, Health Canada (HC) has permitted 248 novel foods to be sold in the Canadian marketplace. Since April 2021, the following novel foods have been authorised:

- Camelina oil derived from thifensulfuron tolerant camelina line 14CS0851-01-14
- Event EF2-114 pineapple (PinkGlow™ pineapple)
- Dicamba tolerant canola – MON 94100
- Abiotic stress and herbicide tolerant HB4 soybean (IND-00410-5)
- Soybean event GMB151
- 2'-Fucosyllactose (2'-FL) in toddler formulas
- Insect resistant and herbicide tolerant maize event DP-023211-2
- Lepidopteran protected corn – MON 95379
- D-tagatose
- Quizalofop tolerant rice – RTA1
- 2'-Fucosyllactose from genetically engineered *E. coli* K12 MG1655 strain
- Napin-rich canola protein isolate (Puratein® HS)
- Soy leghemoglobin (LegH) preparation as an ingredient in all simulated meat and poultry products
- Plum pox virus (PPV) resistant C5 plum
- High oleic soybean (Calyxt Inc.)
- High oleic soybean line SVX-4003
- Herbicide tolerant and insect resistant DP915635-4 corn
- Herbicide tolerant DT sorghum (S&W Seed Company)

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 plants sources and over 40 novel feeds from microbial sources.

Since the last Task Force meeting in March 2020, eleven novel feeds from plant sources have been authorised. These include:

- Smart Earth Thifensulfuron-Tolerant Camelina Line 14CS0851-01-14
- Dicamba tolerant canola – MON 94100
- Abiotic stress and herbicide tolerant HB4 soybean (IND-00410-5)
- Soybean event GMB151
- Insect resistant and herbicide tolerant maize event DP-023211-2
- Lepidopteran protected corn – MON 95379
- Quizalofop tolerant rice – RTA1
- High oleic soybean (Calyxt Inc.)
- High oleic soybean line SVX-4003 (Sevita)
- Insect resistant and herbicide tolerant maize event DP915635
- Herbicide tolerant Sorghum (S&W seeds)

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 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 recombinant DNA (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 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 held a 60-day public consultation on proposed new guidance related to the *Novel Food Regulations*, focused on products of plant breeding from March 25, 2021 to May 24, 2021. This new guidance provides greater clarity as to what products of plant breeding (including those developed using gene editing techniques) are considered novel and require pre-market assessment under the regulations. The Department received over 4,600 comments through the consultation. Health Canada reviewed these comments and where relevant, revised the guidance accordingly.

Health Canada published its new guidance 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 the new guidance, Health Canada has also published a 'What We Heard' report, summarizing the comments received through the consultation, and a Scientific Opinion on the Regulation of Gene-edited Plant Products within the Context of the *Novel Food Regulations*. The scientific opinion is based on a comprehensive review of the available scientific literature on gene editing techniques, how they may be used in plant breeding, and how gene-edited plant products should be related under Canada's product-based regulatory framework.

Both documents are available on the Health Canada website:

'What We Heard' report: https://www.canada.ca/en/health-canada/programs/consultation-guidance-novel-foods-regulation-plant-breeding/what-we-heard.html

Scientific Opinion: https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/scientific-opinion-regulation-gene-edited-plant-products-within-context-division-28-food-drug-regulations.html

Additionally, Health Canada has launched a new 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 will also help developers better understand how the novel foods regulatory framework applies to different types of gene-edited plant products and ensure 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

Lastly, with the publication of the new guidance, Health Canada published its 'Notice of Intent' to propose amendments to Division 28 of the *Food and Drug Regulations* (Novel Foods) to provide greater clarity, predictability, and transparency for all novel foods under the regulations. Health Canada will seek engagement from stakeholders across the food system to identify where Division 28 might benefit from amendments and key issues that need to be considered as part of the development of the proposed amendments. The 'Notice of Intent' is available on the Health Canada website: https://www.canada.ca/en/health-canada/services/food-nutrition/public-involvement-partnerships/notice-intent-propose-amendments-division-28-food-drug-regulations-novel-foods.html

The CFIA held a 120-day public consultation on proposed new guidance for determining whether a plant is subject to Part V of the *Seeds Regulations* from May 19, 2021 to September 16, 2021. The purpose of the draft guidance was to clarify which plants are subject to Part V and which are not. Updated guidance will help the CFIA regulatory programs for agricultural biotechnology keep pace with new technologies like gene editing. Over 500 comments were received through the consultation. The CFIA has reviewed these comments and is currently preparing updated guidance in light of the consultation feedback. In addition, the CFIA intends to publish a "What We Heard" report that summarizes the comments received through the consultation.

The CFIA and Health Canada have published a joint webpage describing Canada's regulatory framework for the environmental release of Plants with Novel Traits (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 Update

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). Canada and the Philippines co-hosted the 8th meeting of the GLI virtually in March 2022. The event focused on trade facilitative approaches to the prevention and management of LLP; opportunities and examples of international regulatory collaboration and streamlining; a value chain panel discussion on LLP and current global challenges; and, an update on the various activities taking place in international organisations, including the OECD, on the subject of agricultural biotechnology.

GLI members' engagement on LLP goes beyond the development of guidance or reference document on how best to manage the issue. 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 now has its own website: https://llp-gli.org/. This public interface 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 to minimize 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

During 2021/22, the CFIA has continued to make progress on its comprehensive feed regulatory renewal project. The proposed regulations were published in Canada Gazette Part 1 for public consultation from June to October 2021. Approximately 80 sets of comments were received. Comments were generally in favour of the proposed regulations. However, a number of suggestions for changes were also received. All of the comments are published on the Gazette web page for review. The CFIA will publish a What We Heard report that summarizes the comments and how they are being addressed. The CFIA is working towards publication in Canada Gazette, Part 2, which includes updating the draft regulations based on the comments received. Gazette 2 publication will be the point when the new regulations come into effect. Transition time and delayed coming into force are a part of this, to provide stakeholders with time to bring their practices into compliance. In addition, a suite of guidance materials and stakeholder information sessions are anticipated to accompany the final publication. These will be aimed at helping stakeholders understand the new regulations and how to comply.

Other Feed Related Information

The CFIA in conjunction with Health Canada launched on a pilot project for allowing some veterinary health products to be used in feeds. This pilot resulted in 12 veterinary health products that may be used in feeds.

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 (NMs). 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 Canadian Food Inspection Agency (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 (new project)

As highlighted during the OECD Webinar on Animal Cell Culture for Food Production (October 2021), products of cellular agriculture are nearing pre-commercial stages. Canada has already engaged with a few stakeholders who are either developing or have interest in developing these products. Under Canada's *Novel Food Regulations*, many of these products will likely be considered as 'novel foods' and thus require pre-market safety assessment prior to their sale and/or advertisement in Canada for food use. To provide clarity and predictability for cellular agriculture manufacturers, Health Canada has initiated a project for the development of guidance for the pre-market safety assessment of cellular agriculture products. This guidance will help inform manufacturers of the information required for the assessment of these products. Health Canada is presently conducting an analysis of this emerging industry to understand the type of products intended for commercialization and how the safety of these products will be assessed.

COLOMBIA

1. Developments related to implementation of national biosafety framework

1.1. Risk assessment/regulatory decisions

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 2021 by the Instituto Colombiano Agropecuario - ICA:

Unique identifier	Decision	Organism	Trait	Authorised for
MON-Ø4Ø32-6	94973 https://www.ica.gov.co/getattachment/c7c304ac-d3f4-451c-8e79-aaa37e0d1bfb/2021R94973.aspx	Soybean	Herbicide tolerance	Cultivation
MON-87427-7 x MON-89Ø34-3 x MON- ØØ81Ø-6 x SYN-IR162-4 x MON-87411-9 x MON-87419-8	94974 https://www.ica.gov.co/getattachment/fb0f7725-9856-4d73-a10d-8d60895af656/202194974.aspx	Maize	Insect resistance Herbicide tolerance	Feed
MON-Ø4Ø32-6	95613 https://www.ica.gov.co/getattachment/d0c34ff6-d377-4f83-93f9-4c7b5c43d877/2021R95613.aspx	Soybean	Herbicide tolerance	Cultivation
MON-Ø4Ø32-6	95614 https://www.ica.gov.co/getattachment/8ddd6816-9a53-411e-badd-bca657d53095/2021R95614.aspx	Soybean	Herbicide tolerance	Feed
MON-Ø4Ø32-6	102580 https://www.ica.gov.co/getattachment/d43640b7-365c-4306-9a21-c677a6257265/2021R102580.aspx	Soybean	Herbicide tolerance	Cultivation
BCS-GM151-6	102581 https://www.ica.gov.co/getattachment/fb450463-0be6-40fc-af41-ba01c1ed231f/2021R102581.aspx	Soybean	Insect resistance Herbicide tolerance	Feed
DP-ØØ4114-3 x MON-89Ø34-3 x MON-87411-9 x DAS-4Ø278-9	102582 https://www.ica.gov.co/getattachment/1f947c90-2837-45bb-972b-b900a93dc198/2021R102582.aspx	Maize	Insect resistance Herbicide tolerance	Feed
MON-15985-7 x MON-88913-8	102583 https://www.ica.gov.co/getattachment/3573e2e8-8b27-41c7-823d-82647b67ec30/2021R102583.aspx	Cotton	Insect resistance Herbicide tolerance	Feed
NA	102584 https://www.ica.gov.co/getattachment/b74a9b98-fe13-490b-975d-352286251bbf/2021R102584.aspx	Rice	Transformed plants to be edited genetically	Confined trials in Lab.
DP- Ø23211-2	113673 https://www.ica.gov.co/getattachment/82c149bc-1e60-4ee7-9af4-2ea7356765aa/2021R113673.aspx	Maize	Insect resistance Herbicide tolerance	Feed
DP-915635-5	113674 https://www.ica.gov.co/getattachment/6fa06869-9b72-4624-aec3-a74455f36969/2021R113674.aspx	Maize	Insect resistance Herbicide tolerance	Feed

Authorisations granted in 2021 by the Instituto Nacional de Vigilancia de Medicamentos y Alimentos - INVIMA:

Unique identifier	Decision	Organism	Trait	Authorised for
MON-87427-7 x MON-89Ø34-3 x MON-ØØ81Ø-6 x SYN-IR162-4 x MON-87411-9 X MON-87419-8	2021014502	Maize	Herbicide tolerance Insect resistance	Food
MON-87427-7 × MON-89Ø34-3 × DAS-Ø15Ø7-1 × MON-88Ø17-3 × DAS-59122-7	2021053748	Maize	Herbicide tolerance Insect resistance	Food
MON-87427-7 x MON-89Ø34-3 x SYN-IR162-4 x MON-ØØ6Ø3-6	2021005561	Maize	Herbicide tolerance Insect resistance	Food
BCS-GHØØ4-7 x BCS-GHØØ5-8 x SYN-IR1Ø2-7	2021038704	Cotton	Herbicide tolerance Insect resistance	Food
MON-877Ø5-6 x MON-89788-1	2021005632	Soybean	Herbicide tolerance Modified Fatty Acid	Food
MON-877Ø8-9 x MON-89788-1	2021005562	Soybean	Herbicide tolerance	Food
MON-87769-7 x MON-89788-1	2021005563	Soybean	Herbicide tolerance Modified Fatty Acid	Food
MON-ØØ6Ø3-6 x ACS-ZMØØ3-2 x DAS4Ø278-9	2021012389	Maize	Herbicide tolerance	Food
MON-89Ø34-3	2021005567	Maize	Insect resistance	Food
MON-88913-8 x MON-15985-7	2021005564	Cotton	Insect resistance	Food
MON 89Ø34-3 x MON-ØØ6Ø3-6	2021005565	Maize	Herbicide tolerance Insect resistance	Food
MON-89788-1	2021005568	Soybean	Herbicide tolerance	Food
MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-88Ø17-3 x DAS-59122-7	2021053747	Maize	Herbicide tolerance Insect resistance	Food
DP-2Ø2216-6	2021012391	Maize	Herbicide tolerance	Food
DP-Ø232111-2	2021045472	Maize	Herbicide tolerance Insect resistance	Food
BCS-GM151-6	2021023145	Soybean	Herbicide tolerance Insect resistance	Food
BCS-GHØØ5-8	2021023285	Cotton	Herbicide tolerance Insect resistance	Food
BCS-GHØØ4-7	2021023286	Cotton	Herbicide tolerance Insect resistance	Food
BCS-GHØØ2-5	2021023287	Cotton		Food
ØØ4114-3	2021023289	Maize	Herbicide tolerance	Food
ØØ4114-3 x MON 89Ø34-3 x MON 87411-9 x DAS 4Ø278-9	2021023291	Maize	Herbicide tolerance Insect resistance	Food
MON-887Ø1-3	2021023288	Cotton	Herbicide tolerance	Food
SYN-IR1Ø2-7	2021023292	Cotton	Insect resistance	Food
SYN-IR162-4	2021038688	Maize	Insect resistance	Food
SYN-E3272-5	2021038673	maize	Modified Alpha Amylase	Food
SYN-BTØ11-1 x SYN-IR162-4 x SYN-IR6Ø4-5 x MON-ØØØ21-9	2021038695	Maize	Herbicide tolerance Insect resistance	Food
SYN-BTØ11-1 x DAS-59122-7 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x MON-ØØØ21-9	2021045475	Maize	Herbicide tolerance Insect resistance	Food
SYN-E3272-5 x SYN-BTØ11-1 x SYN-IR6Ø4-5 x DAS-Ø15Ø7-1 x SYN-Ø53Ø7-1 x MON-ØØØ21-9	2021045476	Maize	Herbicide tolerance Insect resistance	Food
DAS444Ø6-6	2021045617	Soybean	Herbicide tolerance	Food
DAS-59122-7	2021045473	Maize	Herbicide tolerance Insect resistance	Food
ACS-GHØØ1-3	2021045474	Cotton	Herbicide tolerance	Food
MON-8746Ø-4	2021053742	Maize	Drought Stress	Food
MON-88Ø17-3	2021053743	Maize	Herbicide tolerance	Food
MON-89Ø34-3 x MON-88Ø17-3	2021053745	Maize	Herbicide tolerance Insect resistance	Food
MON-88Ø17-3 x MON-81Ø-6	2021053746	Maize	Herbicide tolerance Insect resistance	Food

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

Starting in 2020 the Ministry of Agriculture and Rural Development, through the Colombian Agriculture and Livestock Institute (ICA), coordinated a Working Group to discuss and analyse the required update of the regulation related to the authorisations of Living Modified Organisms (LMOs) in Colombia, exclusively for agricultural, livestock, fishing, commercial forest plantations and agro-industry purposes. As a result, ICA granted the Resolution No. 91505 (February 15, 2021). This regulatory framework update was based on two main aspects: first, to stimulate the efficiency of the authorisation process, and secondly, to include two different types of applications, Similar genetic constructions, and authorised events (off-patent).

1.3. Risk management measures

According to the 102584 decision, some risk management measures were required in order to work in confined trials in laboratory conditions:

a) Authorise the Colombian Corporation for Agricultural Research – AGROSAVIA, the import of between 1 and 50 seeds for each line that is part of the T2, T3 and T4 generations of the Nipponbare variety from rice plants transformed via *Agrobacterium tumefaciens* using the CRISPR/cas9 gene editing system for silencing the SPDT gene.
b) In laboratory and greenhouse under confined conditions, confirm the silencing and rule out the presence of the transgene (Cas9 or other elements of the transformation vector), which can be confirmed by PCR and Sanger sequence.
c) The terms for this authorisation corresponds to the duration of the tests according to the crop cycle (approximately six (6) years).
d) Assessments will be conducted by AGROSAVIA, at Km 14 Carretera Occidente via Bogotá – Mosquera Cundinamarca C.I. Tibaitatá, with the required measures to avoid, prevent, mitigate, correct and/or compensate for potential risks, including any emergency measures that arise. In the event where the environment is disturbed, all genetically modified material shall be destroyed immediately.
e) The decision to authorise the import and research trials in a confined environment with the proposed technology is made 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). On the other hand, INVIMA has a national surveillance and monitoring annual plan for genetically approved maize, soy and wheat events for food for human consumption. In 2021, no unapproved events were detected and no additional actions were performing in this matter.

1.4. Public engagement

ICA and INVIMA, in association with AGROBIO, produced during 2021 informative material (posters and brochures) to disseminate, to the different actors involved in the use of LMOs, the information on the biosafety plan and monitoring of commercial plantings of genetically modified crops. This activity took place in the different natural subregions.

2. Updates regarding international activities

2.1. Participation in/hosting international symposia/fora

First virtual session 2021 for COP MOP preparation
II virtual session for COP-MOP Preparation 2021
III virtual session for COP-MOP Preparation 2021
IV virtual session for COP-MOP Preparation 2021
V virtual session for COP-MOP Preparation 2021
VI virtual session for COP-MOP Preparation 2021
VIII virtual session for COP-MOP Preparation 2021

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).

2.2. Specific cases of use of OECD tools and information

As ICA, during 2021 we have used the BioTrack Database to consult approvals granted from other countries, Risk Assessments and Consensus Document of maíze, cotton and soybean. Additionally, ICA has been developing 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.

In the case of INVIMA, it sporadically consulted the Biotrack website, however, updating and simplifying it could be a possibility for improvement, in addition to contemplating unifying efforts with similar platforms (BCH and FAO).

3. Developments related to new breeding techniques (NBTs)

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

The 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 above framework, ICA has been working to modify this regulation to include the animal component, so it allows to receive applications of products from NBTs related to livestock. As a result, the draft document of this project is in the process of international public consultation and below we share the link to review it: (https://members.wto.org/crnattachments/2022/SPS/COL/22_3336_00_s.pdf)

3.2. Specific cases of application, assessment, and decision

Applicant	Organism	Trait	Date of the technical concept	Decision / Status
DUPONT DE COLOMBIA S.A.	Maize	Waxy Corn	Feb. 26, 2020	Not considered LMO
AGROSAVIA	Rice	Increase the bioavailability of iron (Fe) in rice plants	Pending	In process - Authorisation was granted to import genetically modified rice for genome editing in Colombia
CIAT – BIOVERSITY	Rice	Resistance to bacterial blight *Xanthomonas oryzae* pv. *oryzae* (Xoo)	Aug. 27, 2020	Not considered LMO
PAIRWISE	Mustard	Improved flavor	Dec. 14, 2021	Not considered LMO

COSTA RICA

Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

Currently, in Costa Rica, GMOs are only authorised for planting and production of seeds, fruits or products for export. During the current reporting period (March 2021 – May 2022) no new genetically modified crop events were approved, however, the State Phytosanitary Service authorised the planting of 69 hectares of GM cotton SYN-IR1Ø2-7 × MON-15985-7 × MON-88913-8 × MON-887Ø1-3, with the purpose of producing seed for export. Likewise, the planting of 59 hectares of GM pineapple FDP-ØØ114-5 was authorised, to carry out field trials, as well as production and marketing tests.

2. National Regulatory Framework on the Safety of Novel Foods and Feeds

In Costa Rica, there is no clear regulatory framework to authorise GMOs for import and use as food/feed products. For this reason, the Ministry of Health and the National Animal Health Service are developing a proposal for a National Regulatory Framework on the Safety of Novel Foods and Feeds. This regulatory

framework will establish the procedures for the safety assessment and authorisation of living modified organisms intended for direct use as human and/or animal food or for food/feed processing.

Currently, the regulatory proposal is in the process of being reviewed by the legal departments of the entities that are developing it

Once this regulatory framework is signed, published and enforced, we will gladly inform the OECD for its information.

3. Developments related to new breeding techniques (NBTs)

During the last period between meetings, the State Phytosanitary Service has continued working on the draft of the national legal framework for NPBT. Basically, this regulatory framework will establish the procedures to define whether a crop obtained using NPBT is or is not a LMO and therefore should be regulated under the current regulation for LMO (N° 7664: Phytosanitary Protection Law).

The definitions used in the framework for NPBT, in particular the LMO definition; correspond to those of the Cartagena Protocol on Biosafety. In this sense, a LMO is "An organism that has a novel combination of genetic material obtained through the application of modern biotechnology".

To achieve the analysis, a new combination of genetic material is defined as "stable insertion in the genome of one or more genes or DNA sequences that encode proteins, RNA, double-stranded RNA or regulatory sequences".

The analysis will not be restricted to a list of NPBTs, 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.

This regulatory proposal are in the process of being reviewed by the Department of Rules and Regulations of the State Phytosanitary Service. Once this regulatory framework is signed, published and enforced, we will gladly inform the OECD for its information.

FINLAND

Legislation

As an EU Member State, Finland 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, Finland 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 June 2021, Finland made amendments to the national Gene Technology Act (377/1995), necessary for the implementation of Regulation (EU) 2019/1381 of the European Parliament and of the Council, and notified the amendments to the European Commission.

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 authorised 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.

New genomic techniques

In April 2021, the Commission published a study on new genomic techniques. The study gave strong indications that the applicable legislation is not fit for purpose for some NGTs and products produced using them, and that it needs to be adapted to current scientific and technological progress. As a follow-up to this study, an impact assessment will be carried out to examine potential policy options. According to a preliminary plan of the Commission, a legislative proposal concerning plants derived from targeted mutagenesis and cisgenesis would be published in spring 2023. Finland does not yet have a coordinated position on the issue.

A government study "Utilisation of New Genome Editing Techniques in Finland" was published in May 2021 (https://julkaisut.valtioneuvosto.fi/handle/10024/163140, in Finnish, Swedish and English). The primary objective of this study was to clarify the current and future needs and applications of genome editing techniques. Authorities will be able to utilise this information in their decisions on potential changes regarding regulations.

Non-GM novel foods

Consumers and food business operators in Finland have continued to show interest in hemp and hemp-derived products, such as cannabinoids. Synthetic cannabidiol (CBD) products are in the novel food authorisation process, but none is authorised so far. EFSA's opinion on challenges related to the assessment of CBD applications will be finalised in spring 2022. The discussion on the novel food status of different products derived from *Cannabis sativa* will continue at the EU level. Finland will follow any interpretations regarding hemp-derived products that have been commonly agreed upon in the EU. In Finland, interest has also been shown towards the use of wild plants as food and the novel food status of them.

The national Nanosafety Network is preparing a review publication "Nanomaterials as part of the society". The aim of the review is to provide information on nanomaterials and their use, safety issues, regulation and research in Finland, covering also novel foods. It will be published in summer 2022.

GERMANY

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

Germany as a member of the European Union (EU) implements EU community-level decisions and regulations on genetically modified (GM) food and feed at the national level. Regulation (EC) No 1829/2003 regulates the placing on the market of GM food and feed. In this context, Germany is actively involved in the Member State consultation process conducted by the European Food Safety Authority (EFSA) and provides input in the risk assessment through its national Competent Authority, the German Federal Office of Food Safety and Consumer Protection (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/dyna/gm_register/index_en.cfm). 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://ec.europa.eu/food/safety/novel_food/catalogue/search/public/index.cfm) provides an overview (non-exhaustive list) of products of animal and plant origin and other substances subject to the Novel Food Regulation. In 2021, two insect products (yellow mealworm *Tenebrio molitor* dried larvae, and frozen, dried and powder forms of migratory locust *Locusta migratoria*) have been approved for their commercialization in the EU.

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

2. GM food and feed detection

Food and feed safety inspections are organised 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 GM food and feed 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.

3. New breeding techniques

NBT products in the EU are GMOs according to the ruling of the Court of Justice (ECJ) of 25 July 2018, thus fall under the scope of Directive 2001/18/EC and are subject to the obligations laid down therein. Currently, no NBT products are 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 of publications are listed below.

- Metje-Sprink, J., Sprink, T., Hartung, F. (2020). **Genome-edited plants in the field**. *Current opinion in biotechnology*, 61, 1-6. DOI: 10.1016/j.copbio.2019.08.007
- Wilhelm, R., Bartsch, D., Consmüller, N., de Witte, T., Ehlers, U., Feike, T., Gocht, Al., Hartung, F., Kahrmann, J., Kehlenbeck, H., Leggewie, G., Lehnert, H., Ordon, F., Sprink, T., et al. (2021): **Report on possible synergies of the use of new genomic techniques for sustainable agriculture** (in German). Berichte aus dem Julius Kühn-Institut, 215; DOI: 10.5073/20211215-094810

4. 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.
- From 6 to 7 October 2021, the German BVL hosted the online symposium "Modern Biotechnology in a Changing World: Health, Environment and Regulation", which addressed, among other things, the contribution of modern biotechnology to sustainability in health and food production. (https://www.bvl.bund.de/EN/Events/Archiv/Symposium2021/01_overview/overview_node.html)

IRELAND

As part of the European Union, Ireland implements EU legislation on GM food and feed. Although GM crops are not cultivated in Ireland, the animal feed sector remains very reliant on imported protein sources which include 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.

In accordance with the novel food Regulation (EU) No 2015/2283 which came into effect on January 1st of 2018, three insects may now be placed on the Irish market (*Tenebrio molitor* - yellow meal worm, *Acheta domesticus* - house cricket and *Locusta migratoria* - migratory locust). A number of hemp-derived and synthetic cannabinoids have been identified on the Irish market even though they are unauthorised novel foods in the EU and regulatory action is underway to resolve this situation. A number of food fraud incidents are also being investigated in relation to the lucrative cannabinoid market.

ITALY

Genetically modified organisms (GMO)

As a member of the European Union, EU regulations on biotech products also apply to Italy. The status of GM products remains unchanged. GM crops are not grown and there has been no deliberate release of GMOs for field trials.

Research activities on genetic improvement and NBTs in Italy:

1) Italian research activities on NBTs have in recent years benefited from a project funded by Italian Ministry of Agricultural, Food and Forestry Policies (MIPAAF), involving several research centres in Italy and working on different agricultural species since 2018 (https://www.crea.gov.it/-/biotech). The project is coordinated by the Italian Council for Agricultural Research and the Analysis of Agrarian Economy **(CREA)** in collaboration with several **Italian universities**, The National Research Council **(CNR)** and the **Mach Foundation**, that will end in August 2022. The aim was to apply cisgenesis and genome editing in crop plants to acquire knowledge on gene functions, to develop new genotypes and to promote the diffusion of new breeding techniques in the Italian scientific community.

   The main lines of research, with results already obtained in the laboratory, include:

   - Seedless aubergines, obtained by the Experimental Institute for Horticulture, tomato plants that are able to inhibit the germination of certain weeds and kiwi seedlings that contain mutations on genes involved in controlling bacterial susceptibility.
   - University of Milan has developed some tomato lines resistant to water stress by partial silencing with gene editing of a gene that regulates the opening of stomata and it is working with the same aim on grapevine.

   Production of cisgenic/edited plants aimed at improving biotic stress resistance (Oidium and Peronospora in grapevine, fire blight in apple and pear, bacterial canker in kiwifruit, Peronospora in sweet basil), quality (accumulation of secondary metabolites in tomato and sweet orange, reduction of seed size in sweet orange and grapefruit, reduction of browning in fresh-cut eggplant) or agronomic traits (seed size in durum wheat, self-compatibility in pear, early flowering in sweet orange, re-flowering in strawberry) is underway.

2) Collaboration between Marche Polytechnic University **(UNI MARCHE)** and University of Bologna **(UNIBO)** (in the MIPAAf project, but also in other projects) has produced vine plants resistant to fungal diseases (botrytis and downy mildew). They have also produced stone fruit plants resistant to sharka with the approach of modifying only the rootstocks, so that the aerial part is protected but not genetically modified.

   The same group is working on strawberry with interfering RNA for fungal resistance and has started a programme for resistance to *Drosophila suzukii*. They are also working with cisgenesis to speed up the obtainment of re-flowering strawberry varieties.

3) University of Milan **(UNIMI)**, has been using CRISPR/CAS on rice for eight years for disease resistance and growth efficiency traits while waiting for field trials.

4) Italian national Agency for New technologies, Energy, and Sustainable Development (**ENEA**) has been involved in the genetic improvement of species of agricultural interest since the late 1950s. Currently different research groups continue to do so using innovative biotechnology:

- Transgene-free tetraploid potato plants (cv. Desiree) have been generated in which the eIF4E-1 gene, responsible for interaction with the potyvirus VpG protein, has been inactivated by Cas9. Currently in collaboration with CREA, have highlighted how CRISPR-Cas9 targeting of the eIF4E-1 gene extends the PVY resistance spectrum of the *Solanum tuberosum* L. cv. Desirée (doi.org/10.3389/fmicb.2022.873930).
- At a preliminary stage the development of tomato lines with reduced allergen content.

5) The Research and Innovation Center of the Foundation Edmund Mach **(FEM)**, a research Institute, carries out research in the field of plant biotechnologies. In particular, FEM is applying new breeding technologies to counteract the major biotic and abiotic stresses affecting grapevine and apple and to study gene function. Currently, the main research lines in grapevine are: (i) the study of the genetic basis of stomatal density, which is a key trait for plant response to drought; (ii) the study of lipoxygenase-mediated resistance to fungal pathogens; (iii) the editing of genes of susceptibility to powdery mildew and downy mildew, to obtain clones of commercial varieties more tolerant to these diseases. In apple, a project is in progress which applies cisgenesis to introduce resistance genes for apple scab into commercial varieties. In addition, efforts are ongoing to develop more efficient and exogenous DNA-free gene editing protocols.

6) Several Italian research groups (Universities, ENEA, The National Research Council (CNR) actively participated in the COST action iPlanta program: modifying plants to produce interfering RNA. The final conference of the project took place on 25 March 2021. The COST Action iPlanta (iplanta.univpm.it) is the largest network of European scientists actively engaged in research on RNAi systems and applications, including host-induced gene silencing (HIGS) and spray induced gene silencing (SIGS). Among the goals of iPlanta are the identification of the specific biosafety data requirements for the risk assessment and risk management of RNAi plants and their products (i.e. food and feed) and the elucidation of knowledge gaps arising in the area of potential food and feed and/or environmental risks specific to RNAi applications.

Publications 2021/2022:

"CRISPR-Cas9 Targeting of the eIF4E1 Gene Extends the Potato Virus Y Resistance Spectrum of the *Solanum tuberosum* L. cv. Desirée" Lucioli A., Tavazza R., Baima S., Fatyol K., Burgyan J.and Tavazza M. Front. Microbiol., 01 June 2022 | https://doi.org/10.3389/fmicb.2022.873930

"VvEPFL9-1 Knock-Out via CRISPR/Cas9 Reduces Stomatal Density in Grapevine"

Clemens M., Faralli M., Lagreze J., Bontempo L., Piazza S., Varotto C., Malnoy M., Walter Oechel W., Rizzoli A. and Dalla Costa L. Front. Plant Sci., 17 May 2022 https://doi.org/10.3389/fpls.2022.878001

"The Arabidopsis pattern recognition receptor EFR enhances fire blight resistance in apple". Piazza S., Campa M., Pompili V., Dalla Costa L., Salvagnin U. e Nekrasov V.

Horticulture Research (2021) 8:204 https://doi.org/10.1038/s41438-021-00639-3

XIth International Symposium on Grapevine Physiology and Biotechnology 2021 31 Oct – 5 Nov Stellenbosch, South Africa:

- **Edited grapevine knocked-out for VvEPFL9-1 showed reduced stomatal density.** Oral presentation. Molly Clemens, Michele Faralli, Claudio Varotto, Mickael Malnoy, Walter Oechel, Lorenza Dalla Costa.
- **Generation of non-transgenic mildew-resistant grapevine clones via gene-editing: potentials and hurdles. Oral presentation**. Lisa Giacomelli*, Simone Scintilla, Umberto Salvagnin, Tieme Zeilmaker, Lorenza Dalla Costa, Mickael Malnoy, Jeroen Rouppe van der Voort, Claudio Moser. Fondazione Edmund Mach, Italy
- **Functional Study of Lipoxygenase-mediated Resistance against Erysiphe necator in Grapevine. Poster.** Mikias Damtew Guche , Lorenza Dalla Costa , Francesco Trenti , Graziano Guella , Mickael Malnoy , Claudio Moser , Stefania Pilati Centro Agricoltura Alimenti Ambiente, Via Edmund Mach, Department of Physics, University of Trento, Italy

"Biosafety of bee pollinators in genetically modified agro-ecosystems: Current approach and further development in the EU". S. Arpaia, G. Smagghe, J.B. Sweet. (2021) Pest Management Science, DOI: 10.1002/(ISSN)1526-4998.

Moreover, there are 2 notifications on gene drive modified organisms contained use legislation (Directive 2009/41/EC):

Type of organism	Scope	Classification of contained use
Anopheles gambiae, Contained use notification - authorised on 11/01/2021	Development of genetically modified mosquitoes for the malaria control	Class 2 (Premise: Polo d'Innovazione di Genomica Genetica e Biologia SCaRL, authorised on 26/07/2017, Via Mazzieri, 05100 Terni - Arthropod Containment Level 2 (ACL2)
Aedes aegypti, *Drosophila suzukii*, Contained use notification submitted on 23/11/2021. Positive opinion issued by MiTE - authorisation pending.	Development of *Aedes aegypti* mosquitoes and *Drosophila suzukii* genetically modified with reduced reproductive capacity of offspring.	Class 2 (Premise: Polo d'Innovazione di Genomica Genetica e Biologia SCaRL, authorised on 26/07/2017, Via Mazzieri, 05100 Terni - Arthropod Containment Level 2 (ACL2)

Finally, the number of contained uses of GMMs (including combined uses of GMMs and GMOs) with a valid notification or approval as per December 2021 are 425 and the number of premises for contained uses of GMMs (as referred to in Article 6) with a valid notification are 148 (for the last three years), divided by Research Development and Production, cover all Biotech Sectors (red-white and green). All GMM, according to the classification of contained use, belonging to risk class 1 and 2 except 17 which belong to risk class 3 but used for research.

Most of the authorised uses make use of editing techniques (CRIPR Cas 9 but also other techniques), short interfering RNA, microRNA, etc. All constructs for the development of advanced therapy medicinal products (ATMP) are authorised.

JAPAN

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

Safety assessment of GM foods and food additives is mandatory under the Food Sanitation Act. 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 March 2022, 330 GM foods (12 potato; 28 soybean; 3 sugar beet; 209 maize; 24 oilseed rape (canola); 48 cotton; 5 alfalfa; and 1 papaya) and 68 GM food additives have undergone safety assessment and been announced in the Official Gazette; out of these foods and food additives, 7 foods and 19 food additives have undergone safety assessment and been announced in the Official Gazette since the last meeting in March 2021.

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

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

As of March 2022, 100 GM feeds (19 oilseed rape (canola); 32 maize; 18 soybean; 21 cotton; 3 sugar beet; 3 alfalfa; and 4 potato) and 20 feed additives have undergone safety assessment and been announced in the Official Gazette;

out of these feeds and feed additives, 6 feeds and 2 feed additives have undergone safety assessment and been announced in the Official Gazette since the last meeting in March 2021.

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

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

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

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

Detailed information will be available on the MAFF website: https://www.maff.go.jp/e/policies/ap_health/petfood/

4. Notification of food and feed derived from genome editing technique

Red sea bream (*Pagrus major*) with increased edible part (September 2021) and Japanese pufferfish/tiger puffer/tiger pufferfish (*Takifugu rubripes*) with growth enhancement (October 2021) which had been produced using genome editing techniques were notified to the MHLW as food and to MAFF as feed, respectively.

KENYA

1. Background information on Biosafety regulatory framework

Kenya is a signatory to the Cartagena Protocol on Biosafety having signed in the year 2000 followed by its ratification in 2003. The National Biotechnology Policy which provided policy direction for the development and safe applications of Biotechnology in the country was subsequently approved in 2006. The policy proposed the enactment of the relevant Biosafety laws and establishment of the National Biosafety Authority as a way of domesticating the provisions of the Cartagena Protocol. In 2009, Biosafety Act No. 2 of 2009 was enacted. The overall mandate of NBA as provided for in the Act, is to exercise general supervision and control over development, transfer, handling and use of genetically modified organisms (GMOs) so as to ensure safety of human and animal health and provide adequate protection of the environment. This includes all activities of GMO for food, feed, industrial, research or any other use. To achieve this mandate, the Authority has developed the following biosafety regulations which are now fully operational;

i) The Biosafety (Contained use) Regulations, 2011;
ii) The Biosafety (Environmental Release) Regulations, 2011;
iii) The Biosafety (Import, Export and Transit) Regulations, 2011 and
iv) The Biosafety (Labelling) Regulations, 2012

2. Status of GM approvals in Kenya

Since its inception the Authority has approved a number of projects including; 37 laboratory/green house projects, 14 confined field trials, 28 import/transit of GM derived products. Four applications have been reviewed for environmental release and placement in the market. Bt cotton has since been released to the farmers for cultivation while Bt maize has gone through the National performance Trials awaiting the final approvals. GM cassava application has also since been approved for National Performance Trials. Details of these decisions are available on our website; (http://www.biosafetykenya.go.ke/).

In the intervening period since the last OECD meeting in 2021, the following decisions have been made;

i) Environmental release

The Bt cotton MON 15985 (BollGuard II) was approved for commercialization in January 2020. Following this approval, the developer, Monsanto Ltd/Bayer has embarked on country wide demonstration farms within the cotton growing regions of the country. These demonstration plots have had a positive impact with pioneer farmers in the management of cotton bollworm. The first cultivation of the Bt cotton was carried out during the long rains period of April-May 2021. The current planting period April-May, 2022 will therefore be the third session when the farmers are planting the crop. While there has been continued adoption of the crop challenges with the supply of seeds continues since the licensed company has continued to rely on importation of seeds with inherent delays during the planting period. During the first on- farm trials, the farmers had free seeds supplied by the Government. This raised farmers expectations that the Government will continue to subsidize their inputs. This however, has not been the case leading to discontent among the initial farmers. The first full report on adoption rates is due by the end of the year 2022.

The Bt maize MON 810 was given limited environmental release in 2016. In the reporting period, the developers/applicants KALRO and AATF conducted National Performance Trials in all representative ecological zones where maize is planted during the short rains of August- October, 2020. Three varieties were subsequently

recommended for release. The NBA Board recommended the approval of the Bt maize varieties on 30th October, 2021 and has since sought for concurrence from the Cabinet for the commercialization of the product.

Following the review of an application for cassava modified for cassava brown streak disease (CBSD) that is utilizing the RNAi technology (Cassava Event 4046), an approval for purposes of conducting National Performance was given by the NBA board on 15th June, 2021. Preparations are already at an advance stage to conduct the National Performance Trials within the cassava growing zones in Kenya. Kenya is indeed the first country to consider an environmental release application involving cassava.

ii) Confined field trials

The National Biosafety Authority has so far approved 14 Confined field trials involving a number of crops and traits as shown in the table below;

CROP/ANIMALS TARGETED FOR IMPROVEMENT	INTRODUCED / MODIFIED TRAIT(S
Maize	Drought tolerance: Water Efficient Maize for Africa (WEMA) Stacked maize event for Bt and Drought tolerant
Cotton	Insect resistance (Cotton bollworms)
Gypsophila	Color modification
Cassava	Virus resistance (CBSD and CBD) Nutritional change; Vitamin A enhanced cassava
Sorghum	Nutritional enhancement through Biofortification
Sweet Potato	Resistance to Sweet potato virus disease
Banana	Disease Resistance -Banana *Xanthomonas* Wilt (BXW)
Sheep, goats, cattle and camels	Animal vaccines rationally designed for the specific control and eradication of diseases

The projects that were approved earlier are at different stages of implementation with some having progressed to environmental release e.g. Bt cotton, Bt maize, CBSD Cassava, and Gypsophila.

iii) Contained use approvals

The Authority has so far approved 37 contained use applications since inception in 2010. These applications are at different stages of development with some proceeding to environmental release. In the intervening period, four contained use applications have been approved. Details of the various projects can viewed through our website at; www.biosafetykenya.go.ke/

3. Development of Biosafety Regulatory Manuals/Guidelines

The Authority is finalized the following key guidelines crucial for commercialization of GMOs into the country. The documents include; i) Post Release Monitoring Manual, ii)) LLP and AP Guidelines and iii) Guidelines for regulation of genetically modified animals under containment and confinement and iv) Guidelines on regulation of Genome Editing. The process of development of the above documents included; a gap analysis of existing documents, drafting, followed by a series of stakeholder consultations before approval by the Board of Management.

4. Regulation of products derived from New Plant Breeding techniques

The guidelines for regulation of Genome Editing was approved by the NBA Board and published in March, 2022. The approval came after a series of stakeholder consultations which began in 2020. The guidelines provides for case by case consideration of the Genome editing projects with the determination of the regulatory status determined through an early consultation form which supposed to be submitted by the developer. The guidelines exempts applications that involves deletions/knockouts provided that the regulatory elements used are from the same species.

In the meantime, Kenya has proceeded with review applications using the New Plant Breeding Techniques with ten of such projects already approved as contained use projects under BSLII laboratory and greenhouse containment

facilities. The approved projects include use of CRIPR/Cas9 (**development of virus and or diseases resistance, and nutritional enhancement, striga resistance, or vaccines development**) in crops such as banana, cassava, yam, sorghum, grass pea potato and animals; use of virus induced gene silencing for resistance to cassava brown streak virus and use of RNAi for development of virus resistant cassava.

Details of the various projects currently being undertaken in Kenya can be accessed through NBA website (www.biosafetykenya.go.ke/).

LATVIA

1. Developments related to implementation of national regulatory framework

Risk assessment/regulatory decisions

There has not been any application submitted to the Competent Authority of Latvia in respect to the deliberate release or placing on the market of GMOs. However, GM food and feed approved for marketing in the EU is available on Latvian market, the animal feed sector is very dependent on imported protein, which includes GM soya and maize ingredients. There is no GM crops cultivation in Latvia.

In 2021 the State Scientific Institute "Institute of Food Safety, Animal Health and Environment "BIOR"" took part regularly at centralised GMO risk assessment procedure. BIOR provided opinion on four applications in respect of GMO placing on the EU market.

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

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

Draft on amendments to the Law on handling of GMO is elaborated 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. 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. In April 2021, in the frame of monitoring of seeds and plant propagating material for the presence of GMOs in Latvia, a low-level presence of GM oilseed rape line RT73 (also used as GT73) was found in seed samples of one batch of summer oilseed rape. In Latvia, qualitative and quantitative tests for the presence of GMO screening genes were performed by the Scientific Institute for Food Safety, Animal Health and the Environment (BIOR). The batch was inspected for the presence of GMOs prior to import into Latvia, which was also confirmed by the accompanying documents submitted by the importer of seeds, and the presence of GMOs was not detected in it. This is one of the several cases during last years in EU Member States where unauthorised GMO lines have been placed on the market and spread in the environment unintentionally, with impurities in seeds mostly below the level of quantification.

2. Updates regarding international activities

Participation in/hosting international symposia/fora

On May 14th, 2021 European Plant Science Organisation (EPSO) organised 4th informal science – policy meeting on genome editing. The meeting focused on the EC study on NGTs. In addition, the following topics were discussed: flagship projects towards genome edited products with consumer benefits for the European market and ensuring equal opportunities for all approaches to contribute to and to be combined to better address climate change, achieve food and nutritional security, and establish a sustainable agriculture in Europe and world-wide.

On May 27th, 2021 the online Conference: the European Enforcement Project on Contained Use and Deliberate Release of GMOs.

On November 4th, 2021 the EPSO organised 5th conference on Genome editing, Improving legislation and start flagships to better address climate, environmental, food and health challenges. The aim was exchanging the 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.

3. Developments related to new breeding techniques (NBTs)

Research projects on biosafety of NBT products

The research project "Detection of food, feed and food additives obtained by NBTs and scientific risk assessment of such products" initiated by Ministry of Agriculture of Latvia was finished in 2021. The main objective of the project was evaluating of diagnostic methods and potential risks of food, feed and additives obtained with help of NBTs. This was two-year project. The main tasks done in the frame of the project: the research of diagnostic possibilities and scientific risk analysis of organisms obtained by new mutagenesis methods and such new technologies as gene drive and other NBTs according with Latvian economy, the exposure assessment according to the current situation using new scientific analytical methods, development of risk management recommendations for such products.

NETHERLANDS

The Netherlands would like to share the outcomes of a study exploring different scenarios of product- *versus* process-based policies on new biotechnologies involving genome editing. This project led by Dr Lianne Bouwman focused in particular on safety assessment practices, regulation, and enforcement under these scenarios, as well as the experiences gained by various nations across the globe. Details will be presented by her during the Tour de Table.

Highlights:

- Experiences of authorities worldwide with safety assessment and regulation of new biotechnologies involving genome editing (experts interviewed)
- Viewpoints of experts (academic, industrial, regulatory) from three different branches (microbial, crop, livestock) within the Dutch agri-food-biotechnology sector (consulted during various workshops, interviews)
- SWOT analysis for four envisaged policy approaches based on these interviews and workshops

Background:

The experiences of various national authorities worldwide with their safety assessment and regulatory approaches towards new biotechnologies (in particular targeted mutagenesis using gene editing) have been gauged by researchers from Wageningen Food Safety Research. These were explored through interviews with anonymous experts from Argentina Australia, Canada, Japan, South Africa, and USA.

This was part of a national policy-support project funded by the Dutch government (Ministry of Agriculture, Nature Conservation and Food Quality). In this project, the implications of four different scenarios of product-versus process-based policy approaches for the ways safety assessments could be carried out were analysed. Additional points of attention included the possibility to enforce traceability and detection requirements (if applicable), and more broadly, safety, technical, innovation, and acceptability issues.

In addition, consultations were held with industrial, academic and regulatory stakeholders from three different branches (microbial, crop, livestock) within the Dutch food and agricultural biotech sector. Notably, different viewpoints from the different branches emerged. These were accommodated into SWOT (strengths-weaknesses-opportunities-threats) analyses for the respective branches.

EUginius database

EUginius (http://www.euginius.eu) is a freely accessible, online resource. It is an up-to-date, searchable database containing information on the modifications, detectability (especially through DNA-based methods) and regulatory status of genetically modified organisms (GMOs). Whilst EUginius particularly covers plants, it also features data on animals and microorganisms, which have received regulatory approval worldwide or are in an advanced stage

towards receiving this. A start has been made to provide data on genome-edited organisms as well. EUginius is a joint initiative of the German Federal Office of Consumer Protection and Food Safety (BVL, Germany), Wageningen Food Safety Research (WFSR, Netherlands), the Austrian Agency for Health and Food Safety (AGES, Austria), the Plant Breeding and Acclimatization Institute (IHAR, Poland), and the Experimental Zooprophylactic Institute of Lazio and Tuscany (IZSLT, Italy).

PARAGUAY

1. Regulatory Framework

1.1. New Plant-Breeding Techniques (NBTs)

Paraguay's Ministry of Agriculture and Livestock (MAG) approved the application form (Form 3, approved by Ministerial Decision No. 840/19). Therefore, applicants can consult whether agricultural biotechnology products obtained through NBTs should be subjected to biosafety risk assessment. In Paraguay, whether or not these products will be subject to the risk assessment process will focus on the presence of novel traits in the NBT organism so that the risk assessment is based on adequate, concrete and plausible risk assumptions.

1.2. A Simplified Approval Procedure

Since 2019, the MAG has implemented the Commercial Release mechanism for GMOs that have been commercially released in other countries through Ministerial Decision No. 1030/19. Through this mechanism, the National Commission for Agricultural and Forestry Biosafety can consider safety assessments previously carried out for GMO crops commercially released in other countries and meet specific requirements. Such requirements are: food and feed safety assessments conducted in other countries were based on the CODEX Guidelines; approvals were granted in countries with experienced regulatory systems and which have authorised GMOs for commercial planting; the GMO evaluated has been studied under different environmental conditions, behaving in the same way as its conventional counterpart; the GMO will be managed agronomically in a similar way to any GMO or conventional variety/hybrid of the species; Paraguay is not a centre of origin of the crop; and that there are no related weeds in Paraguay with which the GMO can cross.

2. Commercial Approvals

The following events were released from 2019 to 2021:

Decision No.	Organism	Event
272/2022	Maize	SYN-E3272-5 x SYN-BTØ11-1 x SYN-IR162-4 x MON-ØØØ21-9
272/2022	Maize	SYN-E3272-5
270/2022	Maize	MON-95379-1
268/2022	Maize	MON-ØØ6Ø3-6 x ACS-ZMØØ3-2 x DAS-4Ø278-9
266/2022	Soybean	BCS-GM151-6
265/2022	Maize	MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6 x SYN-IR162-4 x DAS-4Ø278-9
1158/2021	Maize	ACS-ZMØØ3-2
278/2019	Cotton	BCS-GH811-4
277/2019	Maize	MON-87427-7 X MON-89Ø34-3 X SYN-IR162-4 X MON-87411-9
277/2019	Maize	MON-87427-7
277/2019	Maize	MON-87411-9
276/2019	Soybean	MON-87751-7 x MON-877Ø1-2 x MON-877Ø8-9 x MON-89788-1
276/2019	Soybean	MON-87751-7
276/2019	Soybean	MON-877Ø8-9
275/2019	Soybean	MON-877Ø8-9 x MON-89788-1
274/2019	Soybean	DAS-81419-2 X DAS-444Ø6-6
274/2019	Soybean	DAS-81419-2
274/2019	Soybean	DAS-444Ø6-6

273/2019	Soybean	SYN-ØØØH2-5
272/2019	Maize	MON-87427-7 X MON-89Ø34-3 X SYN-IR162-4 X MON-ØØ6Ø3-6
272/2019	Maize	MON-87427-7
271/2019	Maize	MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6 x DAS-4Ø278-9
271/2019	Maize	DAS-4Ø278-9
270/2019	Maize	SYN-ØØØJG-2
269/2019	Soybean	IND-ØØ41Ø-5
269/2019	Soybean	IND-ØØ41Ø-5 x MON-Ø4Ø32-6
268/2019	Soybean	MST-FGØ72-3 x ACS-GMØØ6-4
267/2019	Maize	SYN-BTØ11-1 X SYN-IR162-4 X MON-89Ø34-3 X MON-ØØØ21-9
266/2019	Cotton	BCS-GHØØ2-5 X BCS-GHØØ4-7 X BCS-GHØØ5-8 X SYN-IR1Ø2-7

3. International Collaboration

3.1. Mechanism to decrease the occurrence of Low-Level Presence (LLP) of Genetically Modified Organisms (GMOs) among the Member States (MERCOSUR)

In 2022, in compliance with Article 40 of the OPP and Article 3 of GMC Decision No. 23/00 "Incorporation of MERCOSUR Regulations into the legal system of the Member States", the Republic of Paraguay communicated by Note PPTP/No. 70/2022, the incorporation into its national legal system of Resolution GMC No. 23/19 "Mechanism to decrease the occurrence of Low Level Presence (LLP) of Genetically Modified Organisms (GMOs) among the Member States", by means of Decree No. 6532. With said communication, the aforementioned Resolution will enter into force simultaneously for the Member States, on 06/02/22, in accordance with Article 40 of the Ouro Preto Protocol.

3.1.1. Scope and Description

This Resolution establishes an operational mechanism that States Member States shall implement in situations of Low-Level Presence (LLP) of Genetically Modified Organisms (GMOs). This Resolution applies to GMOs authorised in a Member State for use in human food and/or animal feed in accordance with the risk assessment procedure of the guidelines established by the Codex Alimentarius (GAG / GL 45/2003) but which have not yet been approved in at least one Member State of MERCOSUR.

3.1.2. Operation

When there is a commercial authorisation that includes the use of a GMO in human food and/or animal feed in a Member State, the latter must inform the other Member States, within the Commission on Agricultural Biotechnology (CAB) of Sub-Working Group No. 8 "Agriculture" (SWG No. 8), within thirty (30) calendar days from the date of authorisation, about said authorisation.

When communicating on the above authorisation, the Member State shall send to the CAB the risk assessment duly carried out by the competent national agency on GMO biosafety, the information it may have on the approval status of the event in the main export markets, and the information submitted by the applicant, excluding the information classified as "confidential".

To implement this mechanism, the developers of the authorised event must have previously submitted the application for commercial evaluation of the product in the other Member States.

Having all the aforementioned information, the CAB, in each case, shall:

- Analyse possible GMO LLP situations that may occur in the region;
- Recognise the Member State's risk assessment as an input for decision making;
- Prepare a report in which it may recommend exclusive approval for GMO LLP situations;
- In said report, each Member State may define or not maximum tolerance limits, according to its convenience, as well as any other technical recommendation it deems relevant. Said report shall be included as an Annex to the Minutes of the CAB;
- Submit the aforementioned report to SWG N° 8 so that the corresponding highest authorities of the Member States take cognisance of it.

4. Relevant publications

- Benítez Candia, N., Fernández Ríos, D., & Vicién, C. (2021). Paraguay's Path Toward the Simplification of Procedures in the Approval of GE Crops. In K. Hokanson, A. F. Roberts, J. Romeis, J. Smith, & A. Raybould (Eds.), Biosafety of Genetically Modified Organisms 3 (pp. 176–181). Lausanne: Frontiers Media SA. https://doi.org/10.3389/978-2-88971-493-3
- Benítez Candia, N., Ulke Mayans, G., Gómez Paniagua, P., Rezende Ribeiro, C., Velázquez Franco, J., Kamada, D., … Fernández Ríos, D. (2021). Perception of genetically engineered crops in Paraguay. GM Crops & Food. https://doi.org/10.1080/21645698.2021.1969835

SLOVAK REPUBLIC

In the Slovak Republic, the authorities continue in a rigid controls of food and feed produced from GMOs or using the NGTs (new genomic techniques). Regarding the GMOs and NGTs, the public, and in reflection to it, also the authorities support rather conservative and careful attitudes.

The system for the controls and the supervision is stable and works well and therefore the authorities follows the rules, given by the European Commission and the National Authorities. In 2021, there was no problem or incompliance, regarding the controls of the products, detected in the Slovak Republic in 2021.

Ministry of Agriculture and Rural Development of the Slovak Republic, in cooperation with the European Commission and EFSA, offers to GMO producers a possibility to apply for new GM product to be approved for food or feed production and placing on the EU market. In 2021 there was no such application submitted.

No new NGT for food and/or feed uses was developed in the area of the Slovak Republic in 2021.

In 2021, some specific NGTs were approved for academic and research projects at Universities and the Slovak National Academy of Sciences. Each of them was critically checked by the experts and control bodies and will be strictly controlled during duration of the project. There was confirmed no threat of a release to the environment. In charge of the supervision is the Ministry of the Environment of the Slovak Republic.

SLOVENIA

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

GMOs in food and feed

The Competent Authority for GMOs in food and in feed is The Administration of the Republic of Slovenia for Food Safety, Veterinary Sector and Plant Protection, which is the body within the Ministry of Agriculture, Forestry and Food. Slovenia has no commercial cultivation of GMOs, neither field trials. 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 2021, we tested samples of feed and food. In 2022, Slovenia is continuing the testing of the presence of GMOs in food, feed and plants.

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 2022, 22 samples of seeds of maize, rapeseed and alfalfa were analysed. Among them, 13 samples of maize seed, 4 samples of rapeseed and 5 samples of alfalfa were tested for the presence of GMOs. All samples were 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, rapeseed or alfalfa). In case of maize additionally DAS40278 was tested, because it is not covered by five-target method. All the 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 2021, 12 samples of plants were planned for testing and tested for the presence of GMOs under the law on the coexistence of crops with genetically modified plants. We are planning to collect approximately 10 samples in 2022.

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 and Spatial Planning 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. At the moment 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 and further methods are yearly in the process of verification, and 3 methods for quantification by dPCR. In 2021 NIB accredited three screening methods for detection of genetically modified microorganisms.

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. NIB also contributed to the general MIQE guidelines for dPCR (Alexandra S Whale, Ward De Spiegelaere, Wim Trypsteen, Afif Abdel Nour, Young-Kyung Bae, Vladimir Benes, Daniel Burke, Megan Cleveland, Philippe Corbisier, Alison S Devonshire, Lianhua Dong, Daniela Drandi, Carole A Foy, Jeremy A Garson, Hua-Jun He, Jan Hellemans, Mikael Kubista, Antoon Lievens, Mike G Makrigiorgos, Mojca Milavec, Reinhold D Mueller, Tania Nolan, Denise M O'Sullivan, Michael W Pfaffl, Stefan Rödiger, Erica L Romsos, Gregory L Shipley, Valerie Taly, Andreas Untergasser, Carl T Wittwer, Stephen A Bustin, Jo Vandesompele, Huggett JF. The Digital MIQE Guidelines Update: Minimum Information for Publication of Quantitative Digital PCR Experiments for 2020. Clin Chem. 2020 Aug 1;66(8):1012-1029. doi: 10.1093/clinchem/hvaa125). 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

NIB is following the developments in Genome editing in Plants as a member of COST Action CA18111 Genome Editing in Plants (https://plantgenomeediting.eu). Moreover, as a member of European Network of GMO Laboratories (ENGL), NIB is following and contributing to discussions at this level.

NIB is also a member of European Initiative for Sustainable Agriculture through Genome Editing (EU-SAGE; https://www.eu-sage.eu/). EU-SAGE is a network representing 131 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).

NGT (New Genomic Techniques) products are, according to the ruling of the Court of Justice (ECJ) of 25 July 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 authorised as food/feed or for cultivation in the EU. The discussion continues at the EU level and a need for amending current legislation is being assessed through an impact assessment which is underway.

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.

SOUTH AFRICA

1. GM crop production in South Africa update

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

In the field of biotechnology, South Africa is the leader in Africa. No updated figures for 2021/2022 could be found. Thus, it remains as reported in 2017: South Africa grew 2.73 million hectares of maize, soya and cotton crops in 2017. South Africa still ranks 9th in the adoption of genetically modified organisms (GMOs) (ISAAA brief 53 of 2017).

The area per biotech crop comprised of maize (1.96 million hectares – 72%), soybeans (736 535 hectares – 27%), and cotton (37 406 hectares – 1%) (ISAAA brief 53 of 2017).

The area under GM crop production is estimated to be 2.73 million hectares. About 54.69% was biotech white maize and 45.31% was biotech yellow maize. Maize is the main field crop in South Africa and is used for both human consumption (mainly white maize) and animal feed (mainly yellow maize) (ISAAA brief 53 of 2017). Genetically modified (GM) maize has greatly improved food security in South Africa, reduced environmental damage and helped smallholder farmers achieve significant gains in earnings over the past two decades. This marks South Africa as a success story in the cultivation of insect-resistant Bt white maize, given that it was the first GM subsistence crop producer in the world following its adoption of the cultivar in 2001-2002.

At least 95% (736 535 hectares) of the soybean planted in 2017 in South Africa was biotech varieties (herbicide tolerant). All the cotton planted in South Africa in 2017 was genetically modified (37 406 hectares) (ISAAA brief 53 of 2017).

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

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

Application of the Act

This Act shall apply to:

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

Executive Council

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

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.

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

Biosafety:

Mission

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

Functions

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

Role as the Competent National Authority

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

4. New GM approvals in South Africa

The new commodity clearance approvals since the last meeting are presented in Table 1 and are indicated in bold text. The new general release approvals since the last meeting are presented in Table 2 and are indicated in bold text.

Table 1. Commodity clearance imports approved for food and feed in South Africa 2016-2021. Source: http://www.dalrrd.gov.za/

Event	Crop	Trait	Company	Year approved
NK603 x T25 x DAS-40278-9	**Maize**	**Herbicide tolerance**	**Corteva Agriscience RSA**	**2021**
DAS-81419-2 x DAS-44406-6	**Soybean**	**Insect resistance Herbicide tolerance**	**Pioneer Hi-Bred RSA**	**2021**
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	Maize	Insect resistance	Monsanto SA	2018

MON87411 x DAS 59122-7 x MON87419		Herbicide tolerance		
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
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 2015-2021. Source: http://www.dalrrd.gov.za/

Event	Crop	Trait	Company	Year approved
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

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

PUBLIC NOTICE: 27 October 2021
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.

In line with the above, the application templates for contained use, trial release, commodity clearance and general release have been revised and the use of the revised application forms will be effective as of 01 December 2021.

6. Genome editing research and activities in South Africa

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

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

Project title: Developing 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 homologues repair that is part of the CRISPR/Cas9 technology. They are also investigating different delivery systems for the CRISPR construct and donor templates, including Agrobacterium transformation.

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.

Update: Limited progress in the project to get resistance to BBTV in banana, as the culturing of banana suspension cells has been a major bottleneck. They are now collaborating with laboratories in India and Belgium to obtain cells that they can transform. However, they have constructed CRISPR vectors for four genes (dynamin related protein gene and three versions of the kinesin related protein), which were identified in their RNASeq study as responding to BBTV infection, and which were also picked up in other studies in literature in response to other viruses in other plants.

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 proposal 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.

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. They are currently generating stable knockouts of key genes that influence protein yields in *N. benthamiana* (tobacco) plants using NBTs. They are also routinely performing these edits transiently.

In addition to this project, they have a work package that involves the use of NBTs for altering the post-translational modification pathways within *N. benthamiana*.

They also perform genome editing in bacteria in order to enhance yields for desirable molecules used in various industries. Many protein-based vaccines and monoclonal antibodies (mAbs) require glycosylation. Their intent is to use NBTs to perform glycoengineering by either the downregulation or elimination of pathways to obtain predominantly mammalian post-translational structures that decorate these protein-based vaccines and mAbs for efficacy and regulatory approval.

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.

Currently, they are trying to establish protoplast regeneration so that they have a non-transgenic way of making the mutants, but they are also starting to make constructs for a transgenic method if the non-transgenic route fails.

CRISPR research in the Vitis Lab at Stellenbosch University (Manuela)

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. As a proof of concept, one gene central to grapevine secondary plant metabolism was targeted both in grapevine and *Nicotiana benthamiana* as a model system. Grapevine regeneration is a slow process and *N. benthamiana* was used as a system to test the construct and the targets selected.

Grapevine has been successfully edited with CRISPR/Cas9 in collaboration with Italy, the construct was built in South Africa and the transformation was performed in Italy. The gene edited is phytoene desaturase (PDS), so they could easily prove the editing, indeed the edited plants have the albino phenotype. They are busy setting up the grapevine transformation for more interesting grapevine editing, but it takes time to have the right material for the transformation. They are focusing mainly on water stress and drought resistance. Another aspect that they are interested in is virus resistance, and for that purpose they are are using CRISPR/Cas13 which targets RNA and the model plant *N. benthamiana*. They are are currently evaluating the transgenic plants stably expressing Cas13 and the gRNAs, which will then be infiltrated with a grapevine virus to assess the virus resistance.

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.

A project on genome editing of wheat started, but it is again just for proof of concept. A reporter gene will be targeted with CRISPR/Cas9 to set up the methodology.

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 has now developed a 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 assist in the gathering and sharing of information on genome editing research being performed in South Africa at the OECD WP-HROB and the OECD WP-SNFF meetings. This is important because it was previously agreed that delegations will continue with information sharing on NPBTs and other new technologies at these meetings, and that delegations will include in the written *Tour de Table* their experiences in NPBTs and other new technologies.

7. Usefulness of the OECD Biology documents

Biosafety South Africa is a platform within the national Technology Innovation Agency (TIA), which is an initiative of the national Department of Science and Innovation (DSI). Biosafety South Africa is an independent national authority and service provider for all regulatory and biosafety issues related to biotechnological products.

Biosafety South Africa indicate that the OECD consensus documents for the work on harmonising the regulatory oversight in biotechnology are probably one of the best resources available to risk assessors.

Biosafety South Africa (https://www.biosafety.org.za) states that a biology document is intended to:

- provide background information on the biology of a particular plant species,
- its centres of origin,
- its related species,
- the potential for gene introgression from the plant into relatives, as well as details on the life forms with which it interacts.

The conclusions drawn in a biology document only relate to knowledge and experience of plants with no novel traits of the species concerned. Information on the untransformed species assist in defining the baseline and scope (comparator against which transformed organisms will be compared). Although the document is not an environmental risk/safety assessment of the species, information in a biology document is used to specifically address the environmental risk/safety of genetically modified or engineered i.e. GM/ GE (transformed) plants. Species specific information will be used to determine whether there are significantly different/altered interactions with other life forms resulting from presence of GM plants.

The information described in biology documents are in a format readily accessible to regulators. Biology documents are categorised into several sections ranging from species specific information to information on the potential effects of the crop species on human health and biosafety. The information in the biology document is essentially an assessment of the information applicable to the environmental risk/safety assessment from collective peer reviewed sources. In addition, a complete list of references and appendices are included at the end of the document.

Below is a list of published biology consensus documents on commercially released GM crops, as well as those GM crops with potential for commercialisation in South Africa.

Cassava
- http://biovisioneastafrica.com/publications/Cassava%20biology%20document.pdf

Cotton
- http://www.olis.oecd.org/olis/2008doc.nsf/LinkTo/NT0000794A/$FILE/JT03257

Maize/ Corn
- http://www.inspection.gc.ca/english/plaveg/bio/dir/dir9411e.pdf
- http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/650f3eec0dfb990fca25692100069854/330c90ca0496618fa2574d0001d4dd6/$FILE/biologymaize08.pdf
- http://www.olis.oecd.org/olis/2003doc.nsf/LinkTo/NT0000426E/$FILE/JT00147699.PDF

Potato
- http://www.oecd.org/dataoecd/25/62/27854542.pdf

Soybean
- http://www.inspection.gc.ca/english/plaveg/bio/dir/t11096e.pdf
- http://www.olis.oecd.org/olis/2000doc.nsf/LinkTo/NT00002C3A/$FILE/00085953.PDF

Sugar Beet
- http://www.olis.oecd.org/olis/2001doc.nsf/LinkTo/NT0000096E/$FILE/JT00118011.PDF

Sugar Cane
- http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/sugarcane-3/$FILE/biologysugarcane.pdf

Sunflower
- http://www.olis.oecd.org/olis/2004doc.nsf/LinkTo/NT000092F2/$FILE/JT00177388.PDF

Wheat
- http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/wheat-3/$FILE/biologywheat08.pdf
- http://www.olis.oecd.org/olis/1999doc.nsf/LinkTo/NT00002B2A/$FILE/04E94444.PDF

SPAIN

1. Developments related to implementation of national biosafety framework

1.1. Risk assessment/regulatory decisions

General information about activities with genetically modified organisms (GMOs) which have been approved in Spain, as contained use or deliberate release into the environment, and relevant reports are available from the Ministry of Agriculture, Food and Fisheries and Ministry for the Ecological Transition and the Demographic Challenge. Web Pages:
https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/omg/registro-publico-omg/
https://www.miteco.gob.es/es/calidad-y-evaluacion-ambiental/temas/biotecnologia/organismos-modificados-geneticamente-omg-/

a) Contained use activities in research facilities

Since the last meeting in March 2021, sixty-one (61) new facilities for different contained use activities have been notified in Spain and assessed by the National Biosafety Commission (25 BSL1 and 36 BSL2).

128 different activities have been notified to be carried out in these facilities: 26 are classified as risk 1 (BSL 1); 97 as risk 2 (BSL2) and 5 as biological level of risk 3 activities (BSL3).

Main GMOs used are viruses or viruses infecting/transfecting human or animal cells lines (65%), bacteria (26%) and plants (9%).

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

b) Experimental deliberate release into the environment

Since March 2021, thirty-five (35) applications for deliberate release trials (including field trials with genetically modified plants and human an animal clinical trials with GMOs) have been notified and assessed by the National Biosafety Commission:

- Three field trials with plants: two field trials with gene edited tobacco (CRISP/Cas) which are used as a biofactory plants, and one salinity and drought tolerant broccoli (CRISP/Cas).
- On the other hand, twenty nine human clinical trials have been notified, many of them are different genetically modified viruses and others human cells (T lymphocytes, some CAR-T).
- Three (3) animal field trials:
  - Vaccination of chickens with a herpes virus of turkey vaccine carrying a VP2 gene of infectious bursal disease virus,
  - Vaccination of chickens with a herpes virus of turkey vaccine carrying a VP2 gene of infectious bursal disease virus and a F gene of Newcastle disease virus.
  - Immune response and vaccine efficacy in sheep vaccinated with the candidate *Brucella melitensis* vaccine Rev1Δwzm.

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

c) Placing on the market

In 2021, the estimated growing area for Bt maize (MON10) in Spain was 96.605,87 ha. The monitoring plan for the commercial cultivation of this Bt maize continues ongoing and for the time being, no insect resistant populations have been detected in farmlands after more than 20 years of growth in the main maize cropping area in Spain.

- 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/

Regarding the detected presence of teosinte in Europe remarked by EFSA by the end of 2021, monitoring and control activities are being carried out by the national and regional Spanish Competent authorities. As teosinte is considered a noxious agricultural weed, activities performed by Spanish Regional Government have been implemented with the aim of eradication. Moreover, other research/monitoring activities pertaining to teosinte, performed or commissioned by the ES and other Competent Authorities will continue and expand. This will be critical for the generation of empirical data on EU teosinte, which could be used to further test specific risk hypotheses of the devised pathway to harm, and confirm the previously made ERA and RM assumptions reached at European level.

A new EFSA Scientific Opinion has been publishes very recently in March 2022 "Update of environmental risk assessment conclusions and risk management recommendations of EFSA (2016) on EU teosinte", where it is concluded that "*…the ERA conclusions and RM recommendations of EFSA (2016) remain applicable, except those pertaining to the use of glyphosate-based herbicides on maize GA21 which should be considered under Regulation (EC) No 1107/2009. In infested agricultural areas (especially in regions where maize MON810 is widely grown), weed management measures implemented to monitor, control and/or eradicate teosinte must remain in place, as they will contribute to further reduce the low vertical gene flow potential between GM maize and EU teosinte.*"

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

1.2.1 Royal Decree 406/2021, on 8 of June, amending Royal Decree 178/2004, establish the legal framework for contained use, deliberate release and placing on the market of GMOs. This Royal Decree updates the structure of the two competent authorities in Spain: Interministerial Council of GMO (decision-making body) and National Biosafety Commission (risk assessment body). In addition it transposes the provision on confidentiality included in

Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain into national law. https://boe.es/diario_boe/txt.php?id=BOE-A-2021-10229

1.2.2 National control plan on deliberate release of GMOs for food and feed production. This plan includes official control to verify the compliance of GMO regulation in seeds, field trials and cultivation of MON 810 maize.

PNCOCA 2021-2025 (mapa.gob.es)

1.2.3 Order APA/455/2021, of 30 April, which designates the national reference laboratory for the detection and identification of genetically modified organisms in seeds.
BOE.es - BOE-A-2021-7832 Orden APA/455/2021, de 30 de abril, por la que se designa el laboratorio nacional de referencia para la detección e identificación de organismos modificados genéticamente en semillas.

1.3. 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 voluntary 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)

2. Updates regarding international activities

Spain is included in the list of Parties to Cartagena Protocol on Biosafety. Therefore national experts had participated in different meeting, on-line forum and webinar related to the different key issues included in this Protocol (risk assessment, socioeconomic consideration, synthetic biology…).

In addition, Spain is included in the FAO GM Foods Platform and periodically updates its profile

3. Developments related to new breeding techniques (NBTs)

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

The Interministerial Council of GMO, chaired by the Ministry of Agriculture, Food and Fisheries, is the competent authority responsible for monitoring and follow-up the revision of EU regulation for NBT (targeted mutagenesis and cisgenesis). This involves participation in different stages of the regulatory process within EU.

More detailed information can be found on these links:
https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/mejora-genetica/regulacion_d.aspx
https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/mejora-genetica/Informe%20COM.aspx
https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/mejora-genetica/Iniciativa%20.aspx

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

3.2. Any other information related to NBTs.

The Ministry of Agriculture, Food and Fisheries' website includes an specific section on NBTs to inform on these technologies, including frequently ask questions, reports on the regulatory framework in third countries, reports on the role of NBTs in different EU policies, a follow up of the regulatory process in the EU, detection an identification issues, amongst other relevant issues related to this topic.

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

SWITZERLAND

Food control 2020 and 2021

Foods derived from genetically modified plants (GMPs) are not imported on a large scale. The authorities responsible for food control test food samples with respect to the presence of food materials derived from GMPs. The results of the analyses of 2020 and 2021 have been published in September 2021 and May 2022, respectively, by the Federal Food Safety and Veterinary Office.

year	2021		2020		2019		2018		2017	
total	307	100%	216	100%	336	100%	244	100%	493	100%
negative	283	92%	198	92%	305	91%	228	93%	434	88%
positive	24	8%	18	8%	31	9%	16	7%	59	12%

Of the 18 samples tested positive in 2020, 10 contained GMOs authorised or tolerated at low level in Switzerland. Of the 24 samples tested positive in 2021, 16 contained GMOs authorised or tolerated at low level in Switzerland.

As sampling may focus on specific product categories, and may be based on the likelihood of the materials to contain traces of GMP derived materials, the results should not be considered as being representative of the Swiss food market.

The reports are available (in French) under
https://www.blv.admin.ch/blv/en/home/lebensmittel-und-ernaehrung/publikationen/statistik-und-berichte-lebensmittelsicherheit.html

Feed control 2019

Feed materials derived from GMPs for farm animals have not been imported in 2020, according to the Agricultural Report 2021 published by the Federal Office for Agriculture. Actually, no such imports have been reported since 2008.

The report is available (in French) under https://www.agrarbericht.ch/fr
(Rapport agricole 2020>Production> OGM dans les aliments pour animaux importés).

Moratorium on commercial cultivation of GM plants, novel breeding techniques

Since 2005, a transitional period (i.e., moratorium) for putting GMOs into circulation for agricultural, horticultural or forestry purposes is in place. On 18 March, 2022, the Parliament adopted the prolongation of the moratorium until 2025, with the provision that the Federal Council (government) deliver, until mid 2024, a draft regulation on authorisation of plants obtained using novel breeding techniques without transgenic material, and with a proven/real benefit for agriculture, environment and consumers. See
21.049 | Loi sur le génie génétique. Modification | Objet | Le Parlement suisse (parlament.ch) (French)
Gene Technology Act: https://www.fedlex.admin.ch/eli/cc/2003/705/en

Field trials with GM crop plants

In 2014, a three-hectare test field in Zurich equipped to counter the threat of violence ('Protected Site'), financed by the Federal budget, has been set up in order to conduct experimental field trials with GM plants safe from vandalism. Field trials with GMPs are ongoing since then. See also
https://www.agroscope.admin.ch/agroscope/en/home/topics/environment-resources/biosafety/gv-pflanzen/protectedsite.html

According to Swiss regulation, announcement, risk assessment documents, field trials authorisations and reports regarding GMOs are publicly available and may be submitted upon request. See also
https://www.bafu.admin.ch/bafu/en/home/themen/thema-biotechnologie/biotechnologie--daten--indikatoren-und-karten/biotechnologie--indikatoren/indikator-biotechnologie.pt.html/aHR0cHM6Ly93d3cuaW5kaWthdG9yZW4uYWRtaW4uY2gvUHVibG/ljL0FlbURldGFpbD9pbmQ9QlQwMTgmbG5nPWVuJlN1Ymo9Tg%3d%3d.html

Three trials are currently running:

A multi-year field trial with GM spring wheat with increased resistance to the fungal disease powdery mildew (*Blumeria* ex *Erysiphe graminis*), using genetic material from wheat and rye (alleles of *Pm3*, *Pm8*, and *Pm17* genes and combinations of these alleles) and conducted by the University of Zurich and Agroscope, is currently under way (field release code: B18001). These lines were sown in 2019 for the first time. The trial will be continued until 2023. The trial is a follow-up to the earlier multi-year field trial conducted between 2014 and 2018 (B13001) which has ended, with post-trial monitoring ongoing.

Multi-year field trials with GM maize and GM barley, both with increased resistance to fungal diseases, using the *Lr34* gene from wheat, are being conducted by the University of Zurich (B18003 and B18004, respectively). The plant lines have been sown in 2020 for the first year. The trials will be continued until 2023.

Further information is available under
https://www.agroscope.admin.ch/agroscope/en/home/topics/environment-resources/biosafety/gv-pflanzen/protectedsite/projects.html and
https://www.bafu.admin.ch/bafu/en/home/topics/biotechnology/info-specialists/experimental-releases/experimental-releases-of-genetically-modified-organisms--gmos-.html

Nanotechnology

InfoNano is the Swiss federal authorities central information hub for nanotechnology. It provides information on the opportunities and risks associated with nanomaterials, illustrates where nanomaterials are used and describes the goals and milestones of the Action plan for synthetic nanomaterials. Key topics include guidelines on safe use, promotion of public dialogue, key research and regulatory updates.

Publishers are several government bodies, namely the Federal Office of Public Health, the Federal Office for Agriculture, the Federal Food Safety and Veterinary Office, the Federal Office for the Environment and the State Secretariat for Education, Research and Innovation, the commission for Technology and Innovation and Swissmedic.
https://www.bag.admin.ch/bag/en/home/gesund-leben/umwelt-und-gesundheit/chemikalien/nanotechnologie.html

UNITED STATES

U.S. Food and Drug Administration Regulatory Update

Plant Biotechnology

Since the last meeting of OECD Working Party for the Safety of Novel Foods and Feeds in March 2021, the Food and Drug Administration (FDA) completed consultations on the following new plant varieties:

1. GMB151 soybean (BCS-GM151-6) from BASF Corporation was engineered to express the Cry14Ab-1 protein from *Bacillus thuringiensis* to confer resistance to soybean cyst nematodes, and to express a modified 4-hydroxyphenylpyruvate dioxygenase protein (HPPD-4) derived from *Pseudomonas fluorescens* strain A32 as a selectable marker and to confer tolerance to HPPD-inhibitor herbicides.
2. LBFLFK canola from BASF Plant Science, L.P. (BASF) was genetically engineered to enable biosynthesis of long chain polyunsaturated fatty acids (LCPUFAs), including eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA), through expression of fatty acid desaturases and elongases in the seed. LBFLFK canola was also engineered to express a modified acetohydroxy acid synthase derived from *Arabidopsis thaliana* that confers imidazolinone herbicide tolerance. According to BASF, oil derived from LBFLFK canola is intended for use in human food subject to the limitations in the Generally Recognized As Safe (GRAS) affirmation regulation for menhaden oil (21 CFR 184.1472), which are related to the intake of EPA and DHA from menhaden oil. In addition, solvent-extracted meal from LBFLFK canola is intended for use in animal food.
3. NS-B5ØØ27-4 canola from NuSeed America Inc. (NuSeed) was genetically engineered to enable biosynthesis of LCPUFAs, including DHA and EPA through expression of fatty acid desaturases and elongases in the seed. NS-B5ØØ27-4 canola was also engineered to express the phosphinothricin N-acetyltransferase (PAT) derived from *Streptomyces viridochromogenes* to confer glufosinate ammonium herbicide tolerance. According to

NuSeed, oil derived from NS-B5ØØ27-4 canola is intended for use in human food subject to the limitations in the GRAS affirmation regulation for menhaden oil (21 CFR 184.1472), which are related to the intake of EPA and DHA from menhaden oil. In addition, solvent-extracted meal from NS-B5ØØ27-4 canola is intended for use in animal food.

4. DBN9858 corn (DBN-Ø9858-5) from Beijing DaBeiNong Biotechnology Co. Ltd. (DBNBC) was engineered to express a modified 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) derived from *Agrobacterium* sp. strain CP4 and the PAT protein derived from *S. viridochromogenes*. EPSPS protein provides tolerance to the herbicide glyphosate, and PAT protein provides tolerance to the herbicide glufosinate ammonium. DBNBC informed FDA that although DBN9858 corn is not currently intended for cultivation or marketing in the United States, it anticipates that human food products derived from DBN9858 corn may enter the U.S. food supply via imports. FDA evaluated the safety and regulatory status of DBN9858 corn in human food, and at intermittent low levels in animal food.
5. Z6 potato (SPS-ØØØZ6-5) from J.R. Simplot Company (Simplot) is derived from V11 potato (SPS-ØØV11-6). V11 potato was modified to reduce free asparagine levels, lower reducing sugars, and reduce black spot. Z6 potato was engineered to further reduce the levels of reducing sugars by introducing inverted repeat segments of the *vacuolar invertase* gene (*VInv*), which produces double-stranded RNAs to reduce the RNA transcript levels of *VInv*. Vacuolar invertase participates in converting sucrose to its component reducing sugars. Z6 was also engineered to express the resistance protein VNT1 from *Solanum venturii*, a wild potato species, which confers resistance to late blight caused by *Phytophthora infestans*.
6. DP202216 corn (DP-2Ø2216-6) from Pioneer Hi-Bred International, Inc. was engineered for enhanced grain yield potential through the expression of an additional copy of the native ZMM28 protein, a MADS-box transcription factor. DP202216 corn also expresses the PAT protein from *S. viridochromogenes* which confers tolerance to glufosinate-ammonium herbicides.
7. DBN9936 corn (DBN-Ø9936-2) from DBNBC was engineered to express a Cry1Ab protein derived from *Bacillus thuringiensis* to confer resistance to lepidopteran insects and an EPSPS protein derived from *Agrobacterium* sp. strain CP4 as a selectable marker and to confer tolerance to glyphosate herbicides. DBNBC informed FDA that although DBN9936 corn is not currently intended for cultivation or marketing in the United States, it anticipates that human food products derived from DBN9936 corn may enter the U.S. food supply via imports. FDA evaluated the safety and regulatory status of DBN9936 corn in human food, and at intermittent low levels in animal food.
8. PY203 corn (AGV-PY203-4) from Agrivida, Inc. (Agrivida), genetically engineered to express the enzyme Ph02 derived from a modified AppA phytase from *Escherichia coli* strain K-12, is the subject of a completed consultation with FDA. PYo2 corn also expresses the *E. coli* phosphomannose isomerase protein used as a selectable marker. Ground corn grain from PY203 corn is intended for use as a source of a phytase enzyme when added to animal food. Agrivida had previously submitted to FDA's Center for Veterinary Medicine GRAS notices AGRN 21 and 27 regarding its conclusions about the use and regulatory status of the Phyo2 enzyme in ground PY203 grain in poultry and swine diets, respectively. Agrivida concluded that human and animal food derived from PY203 corn are not materially different in composition, safety, and other relevant parameters from corn-derived human and animal food currently on the market.

Additional information regarding FDA consultations on food from new plant varieties is available at https://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon.

Animal Biotechnology

On March 7, 2022, FDA announced its low-risk determination for the marketing of products, including food, from two genome-edited beef cattle and their offspring (PRLR-SLICK cattle). The intentional genomic alteration (IGA) in the prolactin receptor gene truncates the prolactin receptor protein in *Bos taurus* cattle and results in a short, slick haircoat. The IGA is equivalent to naturally occurring slick mutations that occur in several breeds of conventionally raised cattle where they likely developed as an adaptation to being raised in tropical or subtropical environments; cattle with the slick phenotype have been reported to be better at withstanding heat.

FDA evaluated data and information including whole genome sequencing data, animal health information, and data supporting the history of safe use of conventionally bred cattle containing naturally occurring SLICK mutations. FDA concluded that the IGA poses low risk to humans, animals, and the environment, as it results in the equivalent

genotype and same phenotype as observed in some conventionally bred cattle with a history of safety. For its food safety evaluation, FDA did not identify any human food safety concerns associated with the IGA contained in PRLR-SLICK cattle. In addition, there is a history of safe human consumption of food products derived from conventionally raised cattle with slick phenotypes. FDA determined that food products derived from PRLR-SLICK cattle are as safe as food products derived from conventionally raised cattle with the slick haircoat that are commonly consumed by the public.

Based on its low-risk conclusion, FDA does not expect the developer to pursue FDA approval prior to marketing (enforcement discretion). This was FDA's first low risk determination for an IGA in an animal for food use. However, FDA has made low-risk determinations for enforcement discretion for many other IGAs in animals for non-food uses (these decisions are listed on our website Intentional Genomic Alterations in Animals: Enforcement Discretion | FDA).

Update for the U.S. Environmental Protection Agency (EPA)
Office of Pesticide Programs, Biopesticides and Pollution Prevention Division (OPP/BPPD)

EPA Proposed Exemption for "Plant-incorporated protectants based on sexually compatible plants created through biotechnology"

On October 9, 2020 EPA published a proposed rule that would exempt certain PIPs, called "PIPs based on sexually compatible plants created through biotechnology," from regulation under FIFRA and FFDCA. Associated with this action was a 60-day public comment period. EPA's proposed rule would allow these PIPs to be exempt under existing regulations in cases where they: 1) pose no greater risk than PIPs that EPA has already concluded meet safety requirements, and 2) could have otherwise been created through conventional breeding.

On September 28, 2020, EPA held a webinar to present an overview of the proposed exemption and associated exemption process. The proposed rule and associated documents are available in Docket# EPA-HQ-OPP-2019-0508 on www.regulations.gov/. EPA is in the process of finalizing the rule and is anticipating its publication later in 2022.

Weblink for the webinar:

https://www.youtube.com/watch?v=8cj34z8d9Gw&feature=youtu.be&app=desktop

Weblink for the docket:

https://www.regulations.gov/docket?D=EPA-HQ-OPP-2019-0508

https://beta.regulations.gov/document/EPA-HQ-OPP-2019-0508-0002

- ***Regulatory Update for Plant-Incorporated Protectants***
  - Experimental Use Permit and Temporary Tolerance Petition: Extension of the EUP and Temporary Tolerance Exemption for Spinach defensin (SoD) plant-incorporated protectants expressed in citrus. This permit was issued to allow testing of SoD PIPs for control of citrus greening disease in Florida. The permit is effective from September 2021 through May 2025.
  - Receipt of an application to register Darling 58 Chestnut and a petition for an exemption from the requirement of a tolerance for oxalate oxidase in chestnut: On March 23, 2022, in the Federal Register EPA announced both the notice of filing for the petition and receipt of an application for registration for the Darling 58 Chestnut plant-incorporated protectant. Darling 58 chestnut trees were engineered to resist chestnut blight disease by expressing oxalate oxidase, which counters the deleterious effects of the pathogen (*Cryphonectria parasitica*). EPA will review the application and anticipates making a regulatory decision later in 2022 or 2023.

EUROPEAN COMMISSION

1. Developments related to GM Food and Feed

1.1. Risk assessment/regulatory decisions

a. Risk assessment

Since 1st March 2021, the European Food Safety Authority (EFSA GMO Panel) has adopted and published 5 new scientific opinions, of which 1 renewal application:

- EFSA-GMO-NL-2012-109 (Oilseed rape 73496) [05/05/2021]
- EFSA-GMO-NL-2018-150 (Maize DP4114 x MON810 x MIR604 x NK603) [26/01/2022]
- EFSA-GMO-ES-2018-154 (cotton GHB811) [08/07/2021]
- EFSA-GMO-NL-2019-164 (Maize NK603 x T25 x DAS-40278-9) [28/10/2021]
- RX-018 (cotton GHB614) [28/05/2021]

EFSA GMO Panel also published a GMO Panel Statement on 11 March 2022 complementing its Scientific Opinion on oilseed rape MS11.

b. 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 58 GM food and feed (including 46 sub-combinations) and has renewed 4 authorisations.

New authorisations:

- maize MON 87427 x MON 87460 x MON 89304 x 1507 x MON 87411 x 59122 and 39 sub-combinations
- maize 1507 x MON 810 x MIR162 x NK603 and 4 sub-combinations
- maize MZIR098
- maize NK603 × T25 × DAS-40278-9 and 1 sub-combination
- soybean GMB151
- soybean DAS-81419-2
- soybean DAS–81419–2 x DAS–44406–6
- soybean MON 87769 × MON 89788
- oilseed rape Ms8 x Rf3 x GT73 and 2 sub-combinations (with the exclusion of isolated seed proteins for food uses)
- oilseed rape 73496
- cotton GHB119 x GHB614 x T304-40
- cotton GHB811

Renewals:

- maize Bt11
- maize MON 88017 x MON 810
- oilseed rape GT73 (for feed uses)
- cotton GHB614

More applications for authorisations are in the pipeline.

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

EFSA has published a statement and further work on allergenicity and protein safety assessment is ongoing:

- Statement on in vitro protein digestibility tests in allergenicity and protein safety assessment of genetically modified plants, available at: https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2021.6350

- Adopted a scientific opinion on development needs for the allergenicity and protein safety assessment of food and feed products derived from biotechnology, available at: https://doi.org/10.2903/j.efsa.2022.7044

EFSA has published two scientific opinions on synthetic biology:

- Scientific opinion on the evaluation of existing guidelines for their adequacy for the molecular characterisation and environmental risk assessment of genetically modified plants obtained through synthetic biology, available at: http://onlinelibrary.wiley.com/doi/10.2903/j.efsa.2021.6301/full
- Scientific opinion on the evaluation of existing guidelines for their adequacy for the microbial characterisation and environmental risk assessment of microorganisms obtained through synthetic biology, available at: https://www.efsa.europa.eu/en/efsajournal/pub/6263

In addition, work is ongoing in EFSA on the following guidance documents:

- Scientific Opinion on "Evaluation of existing guidelines for their adequacy for the food and feed risk assessment of genetically modified plants obtained through synthetic biology" – adoption foreseen June 2022
- Scientific Opinion on "Evaluation of existing guidelines for their adequacy for the food and feed risk assessment of microorganisms obtained through synthetic biology" – adoption foreseen June 2022

1.3. Risk management measures

Following a request of the European Commission, EFSA evaluated whether the environmental risk assessment (ERA) conclusions and risk management (RM) recommendations of EFSA's 2016 technical report on EU teosinte remain applicable or require revision in light of new scientific evidence. The update concluded that the ERA conclusions and RM recommendations of the 2016 technical report remain applicable. In infested agricultural areas (especially in regions where maize MON810 is widely grown), weed management measures implemented to monitor, control and/or eradicate teosinte must remain in place, as they will contribute to further reduce the low vertical gene flow potential between GM maize and EU teosinte. The update is available at:
https://www.efsa.europa.eu/en/efsajournal/pub/7228

1.4. Public engagement and outreach activities;

EFSA is in close contact with its industry stakeholders. EFSA organised two meetings in 2021 to also address concerns and explain in detail the implementation of the Transparency Regulation as well as other Scientific aspects. In 2022, EFSA plans to have another two meetings, one being on the 19th of May (remotely) and the second one in November (hybrid).

Each Scientific opinion on GM products 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

Further public engagement and outreach activities related to new genomic techniques, see section 3.

2. Developments related to novel foods and feeds

2.1. Risk assessment/regulatory decisions

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 476 requests (426 applications and 50 traditional foods from third countries) for authorisation since the regulation became applicable. To date, the Union list of novel foods has been amended 82 times, including the authorisation of seven traditional foods.

2.2. New and emerging regulatory challenge(s) for Novel food / feed

The use of alternative feed sources and circular economy on the integrity of the food / feed chain: the feed sector is considering the use of alternative feed sources (e.g. insects, former food products, algae) and products of food/feed production technologies of increasing relevance (e.g. biofuel by-products). The implementation of more sustainable agro-zootechnical and food/feed policies, such as the circular economy, also give an important input in this direction. As highlighted in the FAO report on Hazards associated with animal feed (FAO 2019), there is a need to better target the risk assessment for these new products (e.g. insects, former food products, biofuel by-products, aquatic products of animal or plant origin).

3. Developments related to new genomic techniques (NGTs)

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

Following the ruling of the Court of Justice of the European Union in Case C-528/16, the Council of the European Union requested[1] the European Commission to submit, by 30 April 2021, "a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law". The Council also asked the Commission, if appropriate in view of the outcome of the study, to submit a proposal or otherwise to inform the Council on other measures required as a follow-up to the study.

The study[2] was published on 29 April 2021 and identified limitations to the capacity of the legislation to keep pace with scientific developments; these cause implementation challenges and legal uncertainties. The study demonstrated that there are strong indications that the applicable legislation is not fit for purpose for some NGTs and their products, and that it needs to be adapted to scientific and technological progress. It may not be justified to apply different levels of regulatory oversight to similar products with similar levels of risk, as is the case for plants conventionally bred and obtained from certain NGTs. The study further confirmed that NGT products have the potential to contribute to sustainable agri-food systems in line with the objectives of the European Green Deal and Farm to Fork Strategy.

Based on the outcome of the study, the Commission has initiated a policy initiative on plants produced by targeted mutagenesis and cisgenesis. The initiative aims for a proportionate regulatory oversight for the concerned plant products, ensuring a high level of protection of human and animal health and the environment, and enabling innovation and the contribution of safe new genomic techniques to the objectives of the European Green Deal and the Farm to Fork Strategy. An inception impact assessment was published on 24 September 2021[3].

An impact assessment is on-going and possible legal proposal, if warranted by the impact assessment, would be adopted in 2023.

As regards public engagement and outreach related to this initiative, the European Commission

- hosted a high-level event "New genomic techniques – way forward for safe and sustainable innovation in the agri-food sector" on 29 November 2021, with 855 registered participants from over 50 countries representing Members of the European Parliament, the Council Presidency, Member States, EFSA, researchers and academia, breeders, farmers, organic and GM-free sector and environmental NGOs.
- Organised a 4-week public consultation on inception impact assessment. During this consultation, over 70.000 contributions were received from citizens, economic operators along the agri-food chain, academia and research institutions, NGOs and environmental and consumer organisations, public authorities. Contributions originated from 91 countries (27 EU-Member States and 64 non-EU countries).
- Currently has a public consultation[4] ongoing. This consultation remains open for comments until 22 July 2022.

EFSA has published a scientific opinion

- Scientific opinion on the applicability of the EFSA Opinion on site-directed nucleases type 3 for the safety assessment of plants developed using site-directed nucleases type 1 and 2 and oligonucleotide-directed mutagenesis, available at: https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2020.6299

In addition, work is ongoing in EFSA on the following guidance document:

- Scientific opinion on plants developed through cisgenesis and intragenesis – adoption foreseen December 2022 and currently under public consultation

As regards EFSA's public engagement and outreach, on 16 May 2022, EFSA launched a 6-week public consultation on the draft opinion on plants developed through cisgenesis and intragenesis endorsed on 4 May 2022. This draft

[1] Council Decision (EU) 2019/1904 of 8 November 2019 requesting the Commission to submit a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law, and a proposal, if appropriate in view of the outcomes of the study (OJ L 293, 14.11.2019, p. 103–104)

[2] https://ec.europa.eu/food/plants/genetically-modified-organisms/new-techniques-biotechnology/ec-study-new-genomic-techniques_en

[3] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en

[4] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques/public-consultation_en

opinion is an update of the 2012 EFSA opinion on cisgenesis/intragenesis. It takes into account the recent developments of new genomic techniques to produce cisgenic and intragenic plants. This consultation is accessible at: https://connect.efsa.europa.eu/RM/s/publicconsultation2/a0l7U0000011Zb2/pc0176

3.2. Specific cases of application, assessment and decision;

- One application on 2′-Fucosyllactose using CRISPR-Cas9 for targeted insertion was submitted to the EU. The application is currently under risk assessment by EFSA as a novel food according to Reg. (EU) 2015/2283.
- Application EFSA-GMO-NL-2019-162. This is a GMM category 3 application for the production of soy Leghemoglobin in *Pichia pastoris*. This application is currently under risk assessment.
- Application EFSA-GMO-NL-2020-172, DP-915635-4 maize was created by site-specific integration (SSI) using two sequential transformation steps to (1) insert an integration site sequence, at a specific location of the maize genome using CRISPR-Cas9-mediated targeted insertion, and to (2) insert, via recombination, the intended expression cassettes in the maize genome. This application is currently under risk assessment.

Business at OECD (BIAC)

1. Developments related to biosafety activities

CropLife International shares regulatory harmonisation project

Industry has continued the conversation on science-based regulatory harmonisation, building on the publication of several articles in the Journal of Regulatory Science in early 2021. Those publications included science-based recommendations for food/feed assessments, environmental risk assessment, and stacked trait products. Throughout 2021, CropLife International engaged with the broader scientific community, presenting on the modernized regulatory approach described in these papers at several virtual scientific conferences including Plant science for Climate Emergency, Plant Biology 2021, and the American Chemical Society – AGRO Division Meeting. In addition, CropLife International presented on regulatory harmonisation at a webinar organised by the International Consortium on Applied Bioeconomy Research (ICABR) and CropLife International. The webinar drew on experts from Europe, North America, and South America, providing participants with insights about the importance of both trans-Atlantic and globally compatible regulatory frameworks. Other related outreach activities included presentations during CropLife Canada's 2021 Spring Dialogue days, joining a panel at the APEC High-Level Policy Dialogue on Agricultural Biotechnology, and presenting at a workshop organised by Kenya's National Biosafety Authority.

Time-and-Cost to Market Study

AgbioInvestor has recently completed an updated time-and-cost to market study that assessed the cost and duration associated with the discovery, development, and authorisation of a new GM trait that has received cultivation approval in at least two countries and import approvals from at least five countries. The study, commissioned by CropLife International, builds upon a similar study done in 2012, and found that although the cost of discovery, development, and authorisation of a new GM trait has declined by $21 million over the past 10 years which is primarily driven by greater efficiency in the trait discovery phase (from $136 million in the 2008–2012 period to the current value of $115 million), the time to market has increased from 13.1 years to 16.5 years.

The report also noted that the regulatory phase, the longest duration of the overall process, accounted for almost 40% (37.6%) of the total cost of commercialization and more than half (51.1%) of the time. This increase in time reflects an increase of almost 140% over the 2008-2012 study.

Additional publications, reports, and resources

In 2021, CropLife International published a peer-reviewed paper titled "Recommendations for Maximum Incorporation Rates of Whole Food in 90-Day Rat Feeding Studies" in the Journal of Regulatory Science. When rat feeding studies are required, the genetically modified (GM) crop being tested must be included in the diet at a rate that does not cause nutritional imbalance or negative health outcomes from exposure to naturally occurring anti-nutrients or toxins (e.g., leptins in soybeans). The paper makes recommendations for the maximum incorporation rates for the major GM crops: maize, soybean, rice, canola, and cottonseed.

Over the past year, CropLife International has updated biosafety resources such as the detection-methods database, which provides methods to detect GM events and related materials, and the celiac peptide database, a list of peptides that have been implicated in triggering celiac disease.

Emphasis on Sustainability

CropLife International recognizes the challenges of climate change, and the important role that plant science innovations will continue to play in contributing to agricultural sustainability and protecting biodiversity. In the past year, CropLife International published a report providing a systematic overview of members' activities related to biodiversity and climate. Other activities over the past year included serving on the scientific advisory panel of the Food and Agriculture Organization (FAO) Global Conference on Green Development of Seed Industries, held in November 2021; joining the Agricultural Innovation Mission for Climate (AIM4C); serving as an advisory board member to the Purdue University/USDA Global Agriculture Innovation Forum; joining the Coalition for Sustainable Productivity Growth for Food Security and Resource Conservation; co-hosting a WTO Public Forum Session with the Grain and Feed Trade Association (GAFTA) on Advancing Sustainable Trade Across the Agricultural Sector; as well as a number of communication resources (see below) that emphasize the use of innovative tools, such as plant biotechnology, as a means of improving sustainability.

Global Communications Resources on GMOs

CropLife International translated two of the informational videos that it developed with the Global Alliance for Ag Biotech Trade (GAABT) into Mandarin (Process Controls and Low Level Presence) and into Spanish (Process Controls and Low Level Presence)

CropLife International actively engaged throughout the United Nations Food Systems Summit process and held an Independent Food Systems Summit Dialogue on "Unleashing innovation to transform local food systems that stressed the importance of access to innovation to enable the sustainable food systems of the future. CropLife International also ran a social media campaign during the Pre-Summit and the Summit that centered on innovation, technology, and the Sustainable Development Goals (SDGs) in partnership with Thought For Food.

CropLife International continues to support the GMO Answers online platform. New resources from GMO Answers include GMOs and Sustainability, meeting the SDGs, Biodiversity and Land Conservation, Food Security, the benefits of Public Private Partnerships, and the Science Behind GMOs.

Other communications resources available on the CropLife website include:

- An updated page on the CropLife International website with the latest facts and figures about the benefits of plant biotechnology.
- A roundup of CropLife International members' efforts around sustainability, including innovations in plant biotechnology along with corresponding #FoodSystemsHeroes profiles.
- A dialogue between two farmers from around the world on challenges currently facing farmers, including access to biotechnology and shifting to no-till agriculture.
- A World Food Prize event highlighting farmers from around the world that focused on sustainability, and promoted the use of plant biotechnology as a means to improve sustainability.

2. Updates regarding international activities

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

CropLife International continues to lead industry engagement in the implementation negotiations of the Convention on Biological Diversity, Nagoya Protocol on Access and Benefit-sharing (ABS) and Cartagena Protocol on Biosafety. For the past two years this has also included the development of the Post2020 Global Biodiversity Framework, with CropLife International providing industry views on Targets relating to pollution/pesticide use, biosafety and ABS. Also of note is the contributions made by CropLife International to the Sharm El-Sheikh to Kunming Action Agenda for Nature and People, which is a voluntary commitment platform that aims to raise public awareness, 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 Post-2020 Global Biodiversity Framework. CropLife International has further supported the Action Agenda through moderating an online discussion forum on the topic and presenting the CropLife International commitments in a webinar. These commitments include:

- https://www.cbd.int/action-agenda/contributions/action?action-id=620a915c071ffe00018687a5 (biodiversity report)
- https://www.cbd.int/action-agenda/contributions/action/?action-id=6148e1a9d043d500014639d3 (access to innovation)
- https://www.cbd.int/action-agenda/contributions/action/?action-id=610daba6d520d800010dc3ed (stewardship)
- https://www.cbd.int/action-agenda/contributions/action/?action-id=610da5285140b80001cc48a9 (GIC and biosafety website work)

CropLife International also worked with CBD to develop a social media card outlining our commitments to the Action Agenda. It was posted to the UN Biodiversity Twitter account, as well as the Cartagena Protocol Twitter and Facebook accounts.

3. Developments related to new breeding techniques (NBTs)

Industry Recognizes Progress Related to Plant Breeding Innovation

The global seed industry (represented through the International Seed Federation 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. Further, we encourage the processes used to determine whether products fall in or out of scope of genetically modified organism (GMO) regulations to be transparent, time-efficient, and considering already existing regulatory mechanisms for new plant varieties (such as, for example, plant variety registration, national seed laws, or general food safety laws). The adoption of common approaches across countries can be facilitated through alignment of definitions, standardization of information requirements in support of a regulatory status determination, adoption of predictable and efficient assessment timelines, and recognition of other countries' determinations on regulatory status. These common approaches are essential to maintain a functional trading system that facilitates food security enabled by innovative products including those derived from genome editing.

As noted in 2021 by the seed industry, and even more relevant in 2022, governments and industry need to continue open and transparent dialogue on the new applications and use cases of genome editing in plant breeding. A recent publication (linked here) surveys advancements in both genome editing tools and how they are being applied in plant breeding. Industry recommends continued exchange with governments and policy makers on the relevance and implication of these types of examples on the policy development process.

The seed industry recognizes the continued development and finalization of policies for genome edited products in Nigeria, the Philippines and Kenya in 2021 (and thus far in 2022) as well as ongoing discussions in England, EU, Uruguay, India, Korea, Indonesia, Malaysia, Thailand, Singapore, and Switzerland, and further modernization of regulatory frameworks pending in Canada and Australia. The seed industry also recognized the continued function of established policies in more than a dozen markets where several products continue to undergo scope determinations for exclusions from GMO regulation. Of note are the genome editing policies established in Japan in 2019-20, followed by notifications of the non-GMO status of the gene-edited nutritionally enhanced tomato and two enhanced growth fish species (link).

At the same time, the seed industry has voiced its concern with the approach taken by the Government of South Africa regarding genome edited products. The Dept of Agriculture and Rural Development has stated that all genome edited products, regardless of whether a product could have been similarly accomplished with conventional breeding techniques, are governed by existing GMO rules, thereby setting a higher barrier to entry in South Africa than most other markets. The seed industry notes that this diverging interpretation has the potential to cause future trade issues. The seed industry also notes recently published trial guidelines from the Ministry of Agriculture and Rural Affairs (MARA) in China and looks forward to further dialogue on the potential operationalization of these guidelines and making them in greater alignment with the global trend.

The seed industry continues to recognize 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.

Global Communications Resources Genome Editing

As a cooperative effort of the International Seed Federation, CropLife International, and several national and regional seed associations, one-pager documents were developed to dispel some misconceptions and unscientific allegations around genome editing. The Fact Sheets are aimed for a broader audience and provide science-based talking points written in an easy-to-understand language. The documents were published on the International Seed Federation website, and a 12-week social media campaign was built around them called "#FridayFacts", using visuals (social media cards and short videos) to build awareness and inform interested stakeholders. The materials were further amplified throughout the national networks of the seed sector and CropLife.

AUDA NEPAD-ABNE (African Biosafety Network of Expertise)

AUDA-NEPAD and its biosafety program

The African Union Development Agency-NEPAD (AUDA-NEPAD) aims to ensure implementation of Agenda 2063, Africa's long-term socio-economic development blueprint. By and large, the Agency focuses in three priority areas: increasing agricultural production and ensuring food and nutrition security (Food Systems), building capacities to improve health care services (Health Systems), and interventions to enhance infrastructure development, trade and markets and productivity enhancing innovations (Economic Growth and Jobs). The African Biosafety Network of Expertise (ABNE) is a program of AUDA-NEPAD mandated with biosafety capacity building and provision of biosafety advisory services to African Union member states for the safe adoption and use of modern biotechnology to enhance Africa's food systems, health systems, and economic growth and jobs, while ensuring safety to the environment, human and animal health.

ABNE discharges its mandate through the conduct of national training workshops for regulators, sensitization and awareness creation events for policy makers and other key stakeholders, policy dialogue visits, and through technical and logistical backstopping during the development of biosafety regulatory tools and the review of and decision making on biosafety applications for confined field trials, environmental release or import/export of genetically modified organisms. In addition, AUDA-NEPAD ABNE in collaboration with international partners, notably, Michigan State University facilitates international study tours for regulators and policy makers.

Overall focus and delivery during the reporting period

The AUDA-NEPAD biosafety programmatic activities are outcome based and focus on supporting AU member states to make measurable decisions for the conduct of confined field trials or for environmental release approval of safe and useful technologies. Moreover, ABNE provides capacity building support to ensure good regulatory stewardship practices for technologies that have been approved for commercial cultivation.

Since the last WP-HROB and WP-SNFF meetings, AUDA-NEPAD ABNE provided support for the conduct of more than seventy (70) national biosafety activities in twelve (12) AU member states (Burkina Faso, eSwatini, Ethiopia, Ghana, Kenya, Malawi, Mozambique, Nigeria, Rwanda, Senegal, Uganda and Zambia).

AUDA-NEPAD provided support to AU member states to build functional policy guidelines on gene editing and improve biosafety policy formulation at national and regional levels to facilitate farmers' access to safe technologies. AUDA-NEPAD has prepared a model draft guideline for the regulation of gene editing applications. The guideline has been endorsed by the African Union High Level Panel on Emerging Technologies (APET). The guideline will go through the AU political process for adoption in order to ensure buy-in by the biosafety regulatory systems of AU member states. ABNE along with other partners provided support for training of biosafety regulators on the regulation of gene editing applications and for the development of guidelines in countries such as Nigeria, Kenya, Ethiopia, Malawi and Ghana. Gene editing guidelines have been finalized in Nigeria, Kenya and Malawi.

In addition, training and technical support were provided for the development of guidelines for the regulation of stacked traits in four countries (Nigeria, Ethiopia, Kenya and Malawi) that have started commercial cultivation of GM crops.

Moreover, AUDA-NEPAD ABNE undertook about twenty-five (25) engagements, mostly to support the African Groups of Negotiators (AGN) in articulating Africa's interest and Africa's common position in international negotiations pertaining to biosafety and biodiversity, which includes participation in Conference of Parties and Meeting of Parties (COP-MOP) meetings. Along the way, such engagement at international level of AGNs is hoped to narrow substantive differences in regulatory provisions in member states' biosafety regulatory systems and may lead to harmonisation within Regional Economic Communities.

Progress in functionality of biosafety systems in Africa and emerging challenges

The number of countries with functional biosafety systems with decisions for commercial cultivation of GM crops in Africa has grown to seven (eSwatini, Ethiopia, Kenya, Malawi, Nigeria, South Africa and Sudan). However, the level of functionality and the range of GM crops commercialized are variable; apparently, South Africa having the most mature system.

With the deregulation of Bt cotton and exposure of farmers with GM seeds in several countries, there have been emerging experiences of producers looking for better technologies that address multiple production constraints. Hence, there are instances of unauthorised GM seeds crossing borders and quickly overtaking both non-GM and authorised GM seeds (single gene event). To overcome such challenges and ensure safe adoption and sound stewardship, both technology providers and national regulators may need to make access to technology timely and cost-effective.

Information sharing on Biosafety Clearing House and OECD's product database

For several of AU member states that have approved commercial cultivation of GM crops, information on approvals have not been shared adequately with the Biosafety Clearing House of the UN CBD and inclusion in the OECD's Biotrack product database is scant.

Synergy through global partnership for biosafety service delivery in AU member states

There had been frequent engagement with PBS, regional offices of Bayer Crop Science and Corteva Agriscience, Michigan State University, CropLife and AATF in planning and delivery of stacked traits GM events regulatory training for regulators in Ethiopia, Kenya, Malawi and Nigeria. Biosafety experts with rich experiences in the regulation of stacked traits from Argentina, Australia, Brazil and Canada delivered presentations. Industry perspectives were also shared.

Virtual Courses and Study Tours organised through MSU /AUDA-NEPAD Partnership

- **Food Safety Virtual Short Course** at Michigan State University, July 26 – August 1, 2021.
- **Agricultural Biotechnology and Biosafety Virtual Short Course** at Michigan State University, August 2 to 14, 2021.
- **Agricultural Biotechnology and Biosafety Virtual Global Study Tour**, March 7 – 12, 2022. Organised by Michigan State University, in collaboration with partners in USA, Brazil, India, Argentina, Bangladesh, and Nigeria.

Participation in OECD events

- Participated in OECD Webinar on Animal Cell Culture for Food Production, 4th October 2021.
- Participated in OCED Webinar on Hazards Associated with Animal Feed, 18th November 2021.
- Participated in the development of the OECD draft document on *Anopheles gambiae* Mosquito Biology.

Country status update

Considering the many biosafety activities and interventions AUDA-NEPAD is supporting in its focus AU member states, country updates will focus only on those countries that have approved commercial cultivation of GM crops in recent years.

Nigeria

- Nigeria has granted commercial release approvals for cowpea (AAT-7Ø9AA-4) and Bt cotton (MON-15985-7 - Bollgard II™ cotton).
- Nigeria has authorised environmental release of MON-8746Ø-4 × MON-89Ø34-3 - TELA® Maize in October 2021.

Eswatini

- eSwatini has approved the commercial cultivation of a Bt cotton event of JK Seeds of India (Event1, cry1Ac gene).

Ethiopia

- Ethiopia authorised commercial cultivation of a Bt cotton event of JK Seeds of India (Event1, cry1Ac gene), which has not expanded, inter alia, because of seed shortage.
- Ethiopia granted environmental release approval for MON 810 X MON 87460 maize in April 2022.

Malawi

- Malawi has approved the commercial cultivation of insect resistant cotton (MON-15985-7 - Bollgard II™ cotton).

Kenya

- Kenya has approved commercial cultivation of insect resistant cotton (MON-15985-7 – Bollgard II™ cotton).
- Kenya has authorised environmental release for national performance trial of virus disease resistance cassava.

Sudan

- Sudan authorised cultivation of insect resistant cotton (Chinese technology and Event1, cry1Ac gene of JK Seeds of India).

The Agriculture & Food Systems Institute (AFSI)

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.

1. Developments related to biosafety activities

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

AFSI has convened an Expert Working Group (EWG) with experts from Bangladesh, Bhutan, India, and Sri Lanka that is working towards Regional Harmonisation for the Safety Assessment of Foods Derived from GE Plants. The EWG members, who are working in an individual capacity, have met virtually multiple times since September of 2020. The EWG recognizes the similarities among the respective national guidelines as all are based on Codex and agreed to develop a mechanism to harmonise 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 has been finalized after multiple rounds of discussion. AFSI is working on

stakeholder engagement with plans tailored towards each of the participating countries' needs for the adoption and operationalization of the regional guidance. This will include in-person training opportunities for relevant stakeholders in the four participating countries.

2. Updates regarding international activities

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

AFSI is working with the U.S. government to facilitate intercessional workshops for the APEC HLPDAB as part of the U.S.'s self-funded projects. AFSI hosted a workshop on *The Role of Agricultural Biotechnology to Address Climate* (HLPDAB 01 2022S) on April 20 -21, 2022, which was co-sponsored by Thailand and Canada. Speakers and panelist from the following APEC economies presented: Australia, Canada, Chile, Japan, New Zealand, The Philippines, Singapore, US, and Viet Nam. The events page and full agenda for the event can be found at https://foodsystems.org/event/apec-agbiotech-1/. The objective of this workshop was to increase the knowledge of participants on how agricultural biotechnology can be used to adapt and mitigate the impacts of climate change on agriculture. The workshop provided participants with real-life examples of how agricultural biotechnology is one tool that is part of a larger systems approach that can help farmers adapt to and mitigate the effects of climate change and ultimately increase food security. Overall, 83 participants from 15 member economies participated in the two-day workshop.

AFSI is currently working to put together an agenda for a workshop on *Agricultural Biotechnology: Operationalizing Resource Sharing, Communication Strategies, and Lessons Learned* to be hosted in August 2022. The agenda and concept note for the self-funded project submitted to the APEC Secretariat on March 29, 2022, is currently under consideration. We intend on having OECD's BioTrack database presented as a valuable resource at this workshop.

Webinar series on Microbial Biotechnology

AFSI is developing a series of seminars and workshops focused on bringing increased attention to the development, use, and safety assessment process for microbial biotechnology. The goal is to help countries implement informed polices that meet the need for governments, producers, and consumers to assess and access products produced using microbial biotechnologies. The *Microbial Biotechnology for Novel Foods Webinar Series* was a rescheduling of the workshop that was initially planned to be hosted at OECD headquarters immediately following the 2020 meeting of the WP-SNFF. Taking place over four, non-consecutive days between July 9-17th 2020, the webinars included a keynote presentation, and three technical sessions dealing with the science of microbial products, industry, and consumer perspectives and trade. The webinars attracted 330 registered participants, from 43 countries including China, EU Member States and both developed and developing countries. AFSI is in the process of hosting a series of regional workshops.

First, AFSI organised a follow-on webinar on *Microbial Biotechnology for the European Union*. This regional European Union webinar featured four 20-minute presentations, followed by a facilitated panel discussion with audience participation and presented the potential that microbial biotechnology has in addressing EU's Green Deal. The webinar took place on July 8, 2021, attracting nearly 170 registrants, with 88 attending live from 23 different countries. AFSI then organized a webinar targeting audiences in India on January 11, 2022 entitled *Microbial Biotechnology for Novel Food and Food Ingredients*. Co-organised with Biotech Consortium India Limited (BCIL), the webinar convened scientists and policymakers from academia, industry, and government in India to discuss regulatory policies and science communication around low-risk, well-characterized food ingredients that have been derived from genetically modified microbes, algae, and fermented products. The plenary session began with a discussion of emerging trends in India's food processing industry, followed by a presentation on the science of microbial biotechnology. The program then shifted to regulatory requirements for food ingredients and processing aids, including those derived from microbial biotechnology, before concluding with some firsthand experience of navigating the regulatory system in India. The webinar attracted more than 1,700 registrants, with 833 live attendees from 38 countries, and over 100 subsequent video views.

3. Developments related to new breeding techniques (NBTs)

Webinars and Workshops on gene editing for Korean Scientists

AFSI has organised a series of workshops entitled "Gene Edited Plants: Context and Communication for Plant Breeding Innovation" on gene editing intended to provide Korean stakeholders an opportunity to better understand

the technology of gene editing and varying regulatory approaches to products of gene editing. Translated into Korean, the introductory webinar took place in April 2021, and featured presentations by six experts from around the world on different aspects of gene editing, followed by a Q&A session, and set the stage for discussions on regulatory approaches and communication elements around gene editing. The second webinar took place in July 2021 and featured 10 talks by international speakers. The webinar focused on examples of genome edited plants that have been developed around the world, as well as the approach to their regulation in different countries. In addition to the presentations, attendees had the opportunity to participate in breakout groups, where facilitated discussions on different case studies including non-browning mushroom, high-oleic soybeans and virus resistant tomato took place. The next activity will be an in-person workshop hosted in Seoul in July 2022 and will address other topics related to problem formulation, new plant breeding techniques, context for consideration of risk for gene editing, and whole safety assessment.

4. Additional Information

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.

Version 9.0 of the CCDB was released in January 2022 with additional data for existing crops and inclusion of data for new crops, including sugarcane, mustard, and strawberry. Brown rice data was also added to the CCDB under a new tissue type for rice. A new data output feature was added to enable users to generate sample-specific reports in both a tabular and detailed format. This feature allows a view of all recorded component levels for a given sample. Data for new crops including cassava, cowpea, and red pepper are under preparation.

eLearning courses

Self-paced, interactive eLearning courses developed by AFSI serve as a complementary resource to in-person 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. All courses will be available in Spanish at the end of Q4.

AFSI offers the following eLearning courses:

- ***NEW Food Safety of Genetically Engineered Animal Products:*** This course covers the safety measures employed to evaluate the risk of genetically engineered animal products and how genetically engineered animal products are evaluated against non-genetically modified products. It discusses the safety measures employed to evaluate the risk of genetically engineered animal products. *(Being translated into French, Spanish and Portuguese).*
- ***NEW Genetic Variability in Crops:*** This course discusses genetic variability in crops, providing a basic review of genetics and plant breeding, an overview of modern breeding technologies, and a discussion of how new plant cultivars are released.
- ***NEW Environmental Risk Assessment of Non-Target Organisms for GE Crops:*** This course discusses when, why, and how environmental risk assessments for GE crops are informed by testing of non-target organisms.
- ***NEW Genetic Engineering in Livestock Production:*** This course covers advancements in genetic engineering in animals that have been demonstrated in laboratory settings and their application in livestock production. The course provides an overview on conventional livestock breeding as well as presents techniques that can be used to delete or alter existing genes or introduce new genetic sequences into livestock. The course also highlights obstacles in genetic improvement in animals and discusses opportunities for improved production for genetically engineered and gene edited livestock. *(Being translated into French, Spanish and Portuguese).*
- ***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.
- ***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.

- ***Understanding Low Level Presence in Agricultural Biotechnology:*** This course teaches what low level presence is and how associated environmental risks can be assessed.
- ***Application of Problem Formulation to the Environmental Risk Assessment of Genetically Engineered Crops:*** This course introduces the key concepts of problem formulation for the environmental risk assessment of genetically engineered crops.
- ***Confined Field Trials of Genetically Engineered Plants:*** This course provides a comprehensive discussion of risk management methods for confined field trials of genetically engineered plants and how those methods may be incorporated into a regulatory framework.

The following eLearning courses are under development:

- *Regulatory Modalities for Genetically Engineered Organisms* will provide an overview of the different regulatory mechanisms being employed around the world for making decisions about food and feed safety, and environmental release of GE organisms. This will also allow for a discussion of how regulatory mechanisms may be quite different, but ultimately the science and risk assessment principles that inform decision making are well established and scientifically robust.
- *Microbial Biotechnology for Novel Foods*
- *Risk Assessment of Product of Microbial Biotechnology*

Health and Environmental Sciences Institute (HESI)

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 the engagement of scientists from academia, government, industry, NGOs, and other strategic partners. Since its creation in 1989, HESI has produced scientific research that informs applied health protection decision making around the globe. Today, HESI's team of 12 scientific staff provides leadership to more than fifty scientific projects distributed across > 15 Technical Committees and programs that benefit human and environmental health. 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.

- Mission: The committee's mission is to advance the scientific understanding of the relevant parameters defining allergenic proteins and protein toxicity in 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, South America and the USA, as well as molecular biologists, toxicologists and bioinformaticians from agricultural biotechnology companies who share real world experiences and common challenges.

Developments since April 2021

1. Experimental research

The committee has concluded the experimental work of two projects (a. and b.), as part of a multi-year collaboration with the University of Amsterdam's Academic Medical Center (Netherlands), and has started a new research project (c.) in collaboration with the Copenhagen University Hospital at Gentofte (Denmark). These studies are aimed to provide 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.

a) **Food Matrix project:** This research project was undertaken to study the impact of food matrices on the digestibility of proteins and complements previous committee work on *in-vitro* digestibility models (Akkerdaas et al., 2018) by testing whether protocols that take food matrices into account would provide a better discrimination of allergens and non-allergens than protocols focusing on purified proteins in solution. Two pairs of "allergens vs. non- (or weak) allergens" in presence of one of three food matrices were tested in both gastric

and duodenal digestion conditions *in vitro*. Results indicate that food matrices rich in protein content have a protective effect against pepsin digestion. Spiking experiments with a strong allergen and weak allergen did not reveal any differential protective effect that could explain differences in allergenicity. Findings have been published in May 2022 in Frontiers in Allergy, Food Allergy section (Akkerdaas et al., 2022; open access).

b) **Allergen Rebuild project:** This project aims 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 modeling. A manuscript is in preparation to publish results in the peer-review literature.

c) **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. The project is anticipated to be concluded at the end of 2022, at which time results will be shared via publication and scientific presentations.

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

a) **COMPARE Allergen Database, www.comparedatabase.org/ (sixth iteration released Jan. 2022):** This HESI program is a collaborative public-private effort, in partnership with the Joint Institute for Food Safety and Nutrition at the University of Maryland (http://jifsan.umd.edu), which provides programmatic support. The 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.

COMPARE 2022 comprises 2,463 protein sequences and associated metadata. A detailed description of the updates made in this 2022 version is available on the database website under the documentation page. 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").

COMPARE DB usage has increased consistently over the years and is being used globally (> 90 countries and > 4000 users worldwide in 2021). Of note for example is the inclusion of the COMPARE Allergen Database among *"databases capable of implementing the FAO/WHO allergenicity prediction method"* in the "GMO-db", a comprehensive repository of tools, resources, and guidelines related to biotechnology products, developed by the Japanese National Institute of Health Sciences (NIHS).

b) **COMPASS Tool:** "COMPASS" (**COMP**are **A**nalysis of **S**equences with **S**oftware) is the COMPARE database bioinformatics companion tool, released in July 2019. It is equipped with a comparative sequence search software allowing users to conduct website-based, real-time searches in the COMPARE database to produce amino acid sequence alignments (between two or more amino acid sequences). The intended use of the built-in COMPASS tool is to provide users the possibility of assessing the degree of shared sequence similarity between an amino acid sequence of interest ("query sequence") and allergen sequences within the COMPARE database. To this end, the user can perform three different types of sequence searches, informed by internationally recognized guidelines [FAO/WHO (2001)[5] and CODEX Alimentarius (2003[6],2009[7])]: full length sequence search; 80-mer

[5] FAO/WHO. (2001) Evaluation of Allergenicity of Genetically Modified Foods. Report of a Joint FAO/WHO Expert Consultation on Allergenicity of Foods Derived From Biotechnology. Food and Agriculture Organization of the United Nations, January 22−25, 2001, Rome, Italy.

[6] Codex Alimentarius Commission. (2003) Appendix III (Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants) and Appendix IV (Annex on the assessment of possible allergenicity). In (eds.), Alinorm 03/34: Joint FAO/WHO Food Standard Programme, Codex Alimentarius Commission, Twenty-Fifth Session, Rome, 30 June−5 July, 2003. Codex Alimentarius Commission, Rome, Italy, pp. 47–60.

[7] Codex Alimentarius Commission (2009). Codex Alimentarius: Foods Derived from Modern Biotechnology. 2nd ed. Joint FAO/WHO Food Standards Programme. Rome: World Health Organization. pp1-85. ISBN 978−92−5−105914−2.

sliding window FASTA search; and 8-mer FASTA search. In July 2020, the tool was upgraded with the addition of a visualisation option to view results in a color-coded graphic display.

c) The PATB's Protein Toxins Task Force published a report of the committee's 2020 workshop "From Protein Toxins to Applied Toxicological Testing" in the journal Regulatory Toxicology and Pharmacology (Bauman et al. 2022) and started drafting preliminary materials to address needs identified at the public workshop (i.e., the development of a harmonised framework for using bioinformatic tools, interrogating available public databases, and aid in the interpretation of sequence similarities for the assessment of potential protein toxicity of novel proteins). An Ad-hoc Expert group will be formed mid-2022 to develop this framework in a collaborative way and to include relevant stakeholder, sectors and geographical areas. Individuals with relevant technical expertise interested in joining the Ad-hoc group should contact HESI PATB Committee's scientific program manager (see contact information below).

3. International Outreach: presentations and publications

Upcoming presentation at EFSA One 2022 Conference (https://www.one2022.eu/):

- Poulsen LK, Beuf L., Gadermaier G., Gao Z., Gietl E., Hoffman-Sommergruber K., Koski L., McDonald J., Narrod C., Posada-Campos E., Silvanovich A., Song P., Striegel W., Teuber S., van Ree R., Pereira Mouriès, L. *The COMPARE Database: A Comprehensive Public Resource for Allergen Identification and Protein Allergenicity Assessment*. (Link to conference poster gallery: https://www.one2022.eu/posters/gallery?field_session_category_target_id=All&field_assigned_session_title=All&combine=Poulsen)

2021-2022 Publications:

- van Ree R, Ballerda DS, Berin MC, Beuf L, Chang A, Gadermaier G, Guevera PA, Hoffman-Sommergruber K, Islamovic E, Koski L, Kough J, Ladics GS, McClain S, McKillop KA, Mitchell-Ryan S, Narrod CA, Pereira Mouriès L, Pettit S, Poulsen LK, Silvanovich A, Song P, Teuber SS, & Bowman C. 2021. The COMPARE Database: A Public Resource for Allergen Identification, Adapted for Continuous Improvement. *Frontiers in Allergy*, 2: 39. https://doi.org/10.3389/falgy.2021.700533
- Bauman PA, Doxey AC, Eberini I, Islamovic E, Jungo F, Kessenich C, Kough J, Krishanh M, Palazzolo L, Privalle L, Rodriguezi CE, Satchell KJF, Silvanovich A, Pereira Mouriès L. 2022. "From Protein Toxins to Applied Toxicological Testing" virtual workshop identifies the need for a bioinformatic framework to assess novel food protein safety. *Regulatory Toxicology and Pharmacology*, 131: 105146. https://doi.org/10.1016/j.yrtph.2022.105146
- Akkerdaas JH, Cianferoni A, Islamovic E, Kough J, Ladics GS, Mcclain S, Poulsen LK, Silvanovich A, Pereira Mouriès L and van Ree R. 2022. Impact of Food Matrices on Digestibility of Allergens and Poorly Allergenic Homologs. *Frontiers in Allergy*, 3. https://doi.org/10.3389/falgy.2022.909410

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 is welcoming new public and private sector participants with relevant technical expertise. 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.

Solving complex challenges in food and feed safety and sustainability requires dialogue, collaboration, and innovation. HESI's PATB Committee provides a neutral platform where stakeholders can share experiences and knowledge in order to address contemporary and emerging needs common to the broader community. It also 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.

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.