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ENVIRONMENT DIRECTORATE  
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**Developments in Delegations on the Safety Assessment of Novel Foods and Feeds,  
June 2022 – April 2023**

**Series on the Safety of Novel Foods and Feeds  
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**Environment Directorate**

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

- [No. 1, Consensus Document on Key Nutrients and Key Toxicants in Low Erucic Acid Rapeseed (Canola) (2001) – ***REPLACED with revised consensus document No. 24 (2011)***]
- [No. 2, Consensus Document on Compositional Considerations for New Varieties of Soybean: Key Food and Feed Nutrients and Anti-nutrients (2001) – ***REPLACED with revised consensus doc. No. 25 (2012)***]
- No. 3, Consensus Document on Compositional Considerations for New Varieties of Sugar Beet: Key Food and Feed Nutrients and Anti-nutrients (2002)
- [No. 4, Consensus Document on Compositional Considerations for New Varieties of Potatoes: Key Food and Feed Nutrients, Anti-nutrients and Toxicants (2002) – ***REPLACED with revised consensus document No. 33 (2020)***]
- No. 5, Report of the OECD Workshop on the Nutritional Assessment of Novel Foods and Feeds, Ottawa, Canada, February 2001 (2002)
- No. 6, Consensus Document on Compositional Considerations for New Varieties of Maize (Zea mays): Key Food and Feed Nutrients, Anti-nutrients and Secondary Plant Metabolites (2002)
- No. 7, Consensus Document on Compositional Considerations for New Varieties of Bread Wheat (Triticum aestivum): Key Food and Feed Nutrients, Anti-nutrients and Toxicants (2003)
- No. 8, Report on the Questionnaire on Biomarkers, Research on the Safety of Novel Foods and Feasibility of Post-Market Monitoring (2003)
- No. 9, Considerations for the Safety Assessment of Animal Feedstuffs Derived from Genetically Modified Plants (2003)
- [No. 10, [Consensus Document on Compositional Considerations for New Varieties of Rice (Oryza sativa): Key Food and Feed Nutrients and Anti-nutrients (2004) ***REPLACED with revised consensus document No. 28 (2016)***]
- No. 11, Consensus Document on Compositional Considerations for New Varieties of Cotton (Gossypium hirsutum and Gossypium barbadense): Key Food and Feed Nutrients and Anti-nutrients (2004)
- No. 12, Consensus Document on Compositional Considerations for New Varieties of Barley (Hordeum vulgare L.): Key Food and Feed Nutrients and Anti-nutrients (2004)
- No. 13, Consensus Document on Compositional Considerations for New Varieties of Alfalfa and Other Temperate Forage Legumes: Key Feed Nutrients, Anti-nutrients and Secondary Plant Metabolites (2005)
- No. 14, An Introduction to the Food/Feed Safety Consensus Documents of the Task Force for the Safety of Novel Foods and Feeds (2006)
- No. 15, Consensus Document on Compositional Considerations for New Varieties of the Cultivated Mushroom Agaricus Bisporus: Key Food and Feed Nutrients, Anti-nutrients and Toxicants (2007)
- No. 16, Consensus Document on Compositional Considerations for New Varieties of Sunflower: Key Food and Feed Nutrients, Anti-nutrients and Toxicants (2007)
- No. 17, Consensus Document on Compositional Considerations for New Varieties of Tomato: Key Food and Feed Nutrients, Anti-nutrients, Toxicants and Allergens (2008)
- No. 18, Consensus Document on Compositional Considerations for New Varieties of Cassava (Manihot esculenta Crantz): Key Food and Feed Nutrients, Anti-nutrients, Toxicants and Allergens (2009)
- No. 19, Consensus Document on Compositional Considerations for New Varieties of Grain Sorghum [Sorghum bicolor (L.) Moench]: Key Food and Feed Nutrients and Anti-nutrients (2010)
- No. 20, Consensus Document on Compositional Considerations for New Varieties of Sweet Potato [Ipomoea batatas (L.) Lam.]: Key Food and Feed Nutrients, Anti-nutrients, Toxicants and Allergens (2010)
- No. 21, Consensus Document on Compositional Considerations for New Varieties of Papaya (Carica papaya L.): Key Food and Feed Nutrients, Anti-nutrients, Toxicants and Allergens (2010)

- No. 22, Consensus Document on Molecular Characterisation of Plants Derived from Modern Biotechnology (2010)
- No. 23, Consensus Document on Compositional Considerations for New Varieties of Sugarcane (*Saccharum* spp. hybrids.): Key Food and Feed Nutrients, Anti-nutrients and Toxicants (2011)
- No. 24, Revised Consensus Document on Compositional Considerations for New Varieties of Low Erucic Acid Rapeseed (Canola): Key Food and Feed Nutrients, Anti-nutrients and Toxicants (2011)
- No. 25, Revised Consensus Document on Compositional Considerations for New Varieties of Soybean [*Glycine max* (L.) Merr.]: Key Food and Feed Nutrients, Anti-nutrients, Toxicants and Allergens (2012)
- No. 26, Consensus Document on Compositional Considerations for New Varieties of Oyster Mushroom (*Pleurotus ostreatus*): Key Food and Feed Nutrients, Anti-nutrients and Toxicants (2013)
- No. 27, Consensus Document on Compositional Considerations for New Varieties of Common Bean (*Phaseolus vulgaris* L.): Key Food and Feed Nutrients, Anti-nutrients and Other Constituents (2015)
- No. 28, Revised Consensus Document on Compositional Considerations for New Varieties of Rice (*Oryza sativa*): Key Food and Feed Nutrients, Anti-nutrients and Other Constituents (2016)
- No. 29, High-throughput DNA Sequencing in the Safety Assessment of Genetically Engineered Plants: Proceedings of the OECD Workshop held in April 2016 (2016)
- No. 30, Consensus Document on Compositional Considerations for New Varieties of Cowpea (*Vigna unguiculata*): Key Food and Feed Nutrients, Anti-nutrients and Other Constituents (2018)
- No. 31, Consensus Document on Compositional Considerations for New Cultivars of Apple (*Malus × domestica* Borkh.): Key Food and Feed Nutrients, Allergens, Toxicants and Other Metabolites (2019)
- No.32, Developments in Delegations on the Safety Assessment of Novel Foods and Feeds, April 2019 - March 2020 (2020)
- No.33, Revised Consensus Document on Compositional Considerations for New Varieties of Potato (*Solanum tuberosum*): Key Food and Feed Nutrients, Toxicants, Allergens, Anti-nutrients and Other Plant Metabolites (2020)
- No.34, Developments in Delegations on the Safety Assessment of Novel Foods and Feeds, April 2020 - March 2021 (2021)
- No.35, Developments in Delegations on the Safety Assessment of Novel Foods and Feeds, April 2021 - May 2022 (2022)

## 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 parties 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 parties 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/](http://www.oecd.org/chemicalsafety/)).

**This publication is available electronically, at no charge.**

**For the complete text of this and many other Biosafety publications, consult the OECD's World Wide Web site ([www.oecd.org/env/ehs/biotrack/](http://www.oecd.org/env/ehs/biotrack/))**

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## 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/](http://www.oecd.org/env/ehs/biotrack/).

Of different content, this information document compiles elements provided by delegations on the occasion of the 30<sup>th</sup> WP-SNFF meeting (19-21 April 2023). It aims at summarising relevant information on activities related to the safety assessment of novel foods and feeds since the previous meeting (May 2022) at the international level, by collating individual contributions from OECD Members, partner countries and observer organisations participating in the work.

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

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## ARGENTINA

### 1. New legislations in the regulatory framework

There are some reviews related with GMO Biosafety regulations by National Advisory Commission on Agricultural Biotechnology in 2022:

Res. Secretary of Food, Bioeconomy and Regional Development N ° 45/2022.

ASSESSMENT OF CONTAINED OR CONFINED ACTIVITIES WITH REGULATED PLANT-BASED GMOS <https://www.argentina.gob.ar/normativa/nacional/resoluci%C3%B3n-45-2022-367208/texto>

#### Agreement between Argentina and Brazil on biosafety

Memorandum of understanding between the regulatory agencies of Argentina (CONABIA) and Brazil (CTNBIO) for cooperation in biosafety of products of modern biotechnology.

On 20th October of 2022, the Brazilian Minister of Science and Technology and the Argentine Minister of Economy signed the biotechnology agreement.

Argentina and Brazil are committed to start working together and to build the necessary mechanisms and procedures for the joint evaluation and authorisations of products of agricultural biotechnology.

#### FAO-CONABIA Agreement

Renewal of the FAO-CONABIA agreement (2023-2027) Since 2014, the third consecutive renewal of the agreement that enables Argentina to provide training to third countries in strengthening regulatory capacities for the biosafety of modern biotechnology.

#### Biodesarrollar Program

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

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

### 2. Events for confined field trails

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

During 2022, 36 authorisations were granted for different crops:

	FIELD TRAILS	PRODUCTION	GREENHOUSE
<b>QUANTITY</b>	23	3	10
<b>CROP</b>			
Wheat	1		1
Corn	8	1	
Soy	9	2	2
Tobacco	1		1
Beet	1		
Rice	1		
Safflower	1		1
Lettuce			2
Potato	1		
Alfalfa			1
Tomato			1
Barley			1

**Animals:**

Animal	Phenotype	Institution	Activity
Bovine	Expression in milk of Human Growth Hormone	Biomill	field trials since 2005
Bovine	Expression in milk of Antibodies against rotavirus	Biomill	field trials since 2011
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 in 2022-2023:

Unique Identifier	Applicant	Common Names	Traits	Type of use	Date of approval	Decision name
MON-87419-8	Monsanto Argentina	Maize	Tolerance to herbicides based on glyphosate, glufosinate ammonium and dicamba.	Cultivation, Food and Feed	20/11/2021	<a href="#">141/2021</a>
MON 87751-7	Monsanto Argentina	Soybean	Resistance to Lepidoptera insects, especially <i>Rachiplusia nu</i> , <i>Chrysodeixis includens</i> and <i>Anticarsia gemmatilis</i> , as well as other minor pests in soybeans such as <i>Helicoverpa</i>	Only for processing	12/05/2022	<a href="#">28/2022</a>
MON-ØØ6Ø3-6 x ACS-ZMØØ3-2 x DAS-4Ø278-9, acumulados intermedios	CORTEVA AGRISCIENCE ARGENTINA S.R.L.	Maize	Tolerance to herbicide	Cultivation, Food and Feed	28/07/22	<a href="#">51/2022</a>
IND- ØØ412-7	INDEAR	Wheat	Tolerance to drought, Tolerance to the herbicide glufosinate ammonium	Cultivation, Food and Feed	11/05/22	<a href="#">27/2022</a>
DNB-Ø8ØØ2-3	INDEAR	Soybean	Resistance to Lepidoptera insects, Tolerance to herbicides based on glufosinate ammonium.	Cultivation, Food and Feed	11/05/22	<a href="#">5/2023</a>
SYN-E3272-5	Syngenta Agro S.A.	Soybean	Expresses the enzyme AMY797E alpha-amylase, Tolerance to glyphosate and glufosinate ammonium herbicides, Better behavior against attack by lepidopteran insects	Cultivation, Food and Feed	23/01/23	<a href="#">5/2023</a>
SYN-E3272-5 x SYN-BTØ11-1 x SYN-IR162-4 x MON-ØØØ21-9	Syngenta Agro S.A.	Soybean	Expresses the enzyme AMY797E alpha-amylase, Tolerance to glyphosate and glufosinate ammonium herbicides, Better behavior against attack by lepidopteran insects	Cultivation, Food and Feed	23/01/23	<a href="#">5/2023</a>

**HB4 Wheat:**

By resolution 27/2022 Argentina allows the INSTITUTO DE AGROBIOTECNOLOGÍA ROSARIO S.A. (INDEAR S.A.) to commercialise 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 (largest importer of Argentine wheat), varieties of wheat

with event IND-00412-7 will be able to be marketed 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, Colombia, South Africa, Nigeria, Indonesia, and United States.

### Microorganisms

Product	Phenotype
Fermboost™ MR.	Genetically modified yeast ( <i>Saccharomyces cerevisiae</i> ), with improved ethanol production capacity from starch.
Recombinant HVT-ND virus present in Poulvac Procerta HVT-ND vaccine.	Protects against Marek's (MD) and Newcastle (ND) diseases in chickens.
Recombinant HVT-IBD virus present in Poulvac Procerta HVT-IBD vaccine.	Protects against Marek's (MD) and gumboro disease (infectious bursitis)
INTA vaccine BLV DX 6073	Vaccine against bovine leukosis

## 4. NEW BREEDING TECHNIQUES

A total of 32 Prior Consultation Instance (PCI) forms were submitted for the period May 2022 and February 2023. Thereof 15 forms were submitted for hypothetical products and 17 for real products.

According to organisms it can be said that out of the 32 forms, 1 PCI was submitted for a micro-organism and the rest for plants.

These products were considered by CONABIA to meet the characteristics established in the Regulatory Framework for NTBs (Resolution No. 21/21) and not to fall under the scope of the Resolution that regulates Genetically Modified Organisms.

Finally, we can mention that since 2015 to date around 71 PCIs have been carried out for different organisms (plants, animals, and microorganisms)

## 5. Participation in International Activities

- 11 bilateral, regional and multilateral high-level meetings in 2022:

- a. Representation at the OECD 36<sup>th</sup> Meeting of the Working Party on the Harmonisation of Regulatory Oversight in Biotechnology and the OCDE 9<sup>th</sup> Meeting of the Working Party for the Safety of Novel Foods and Feeds, held on May 16-20.
- b. Bilateral meeting between Argentina and Egypt regarding biosafety on agricultural biotechnology held on May 5.
- c. Meeting of the Commission for Agricultural Biotechnology of SGT No. 08 of MERCOSUR, under the pro tempore presidency of Paraguay, held on April 20.
- d. Bilateral meeting between Argentina and Brazil for the Memorandum of understanding between the regulatory agencies of Argentina (CONABIA) and Brazil (CTNBIO) for cooperation in biosafety of products of modern biotechnology, held on July 14 and 15, Buenos Aires, Argentina.
- e. Technical mission of government officials from Argentina, Paraguay, and Uruguay to the United States held on September in Washington, USA.
- f. Bilateral meeting between Argentina and Brazil for the Memorandum of understanding between the regulatory agencies of Argentina (CONABIA) and Brazil (CTNBIO) for cooperation in biosafety of products of modern biotechnology, held on October 20, Buenos Aires, Argentina.
- g. Meeting GT5 "Public policies in biotechnology" of the Southern Agricultural Council (CAS), held on October 25-26 in Montevideo, Uruguay.
- h. Meeting of the Commission for Agricultural Biotechnology of SGT No. 08 of MERCOSUR, under the pro tempore presidency of Uruguay, held on October 26-27 in Montevideo, Uruguay.
- i. Representation at the 5<sup>th</sup> Meeting of the Working Group (WG2020-5), 15<sup>th</sup> Conference of the Parties (COP-15), 10<sup>th</sup> meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena

Protocol on Security of Information Biotechnology (MOP-10), of the United Nations Convention on Biological Diversity, to be held from December 3 to 20 in Montreal, Canada.

- j. X Argentina-China Working Group Meeting on Agricultural Biotechnology held on November 11.
- k. XI Argentina – EU Bilateral Dialogue Meeting on biotechnology applied to agriculture, held Nov.18.

- 3 bilateral, regional and multilateral high-level meetings **in 2023**:

- a. Bilateral meeting between Argentina and England regarding Gene Editing and biosafety on agricultural biotechnology held on February 7.
- b. Bilateral meeting between Argentina and Brazil for the Memorandum of understanding between the regulatory agencies of Argentina (CONABIA) and Brazil (CTNBIO) for cooperation in biosafety of products of modern biotechnology, held from January 30 to February 1, Brasilia, Brazil.
- c. Meeting of the Commission for Agricultural Biotechnology of SGT No. 08 of MERCOSUR, under the pro tempore presidency of Argentina, held on March 20 and 21, Buenos Aires, Argentina.

#### Other international activities held on 2022-2023

- Representation at 4th International Workshop on Regulatory Approaches for Agricultural Applications of Animal Biotechnologies held on September 12-19 in San Pablo, Brazil.
- On December 10, the DNB co-organised with Brazil, Paraguay, Uruguay, Kenya, Nigeria, Bangladesh and the Alliance for Science, a side event on "The contribution of local LMOs to the Sustainable Development Goals".
- Representation at the Global Biotechnology Regulators Meeting held on November 15-16.
- Coordination of the Symposium Four realities: Latin American regulations applied to genetically modified (GM) insects used in agricultural and livestock context at the II Latin American Congress of the Vector Ecology Society "Control of endemic zoonotic and vector-borne emerging and re-emerging diseases: Current challenges in Latin America" La Plata, Argentina, October 31, 2022.
- Representation on Argentine Regulation applicable to insects obtained by Modern Biotechnology for use in agriculture, livestock and poultry in the Symposium Four realities: Latin American regulations applied to genetically modified (GM) insects used in agricultural and livestock context in the II Congress Latin American Society of Vector Ecology "Control of endemic zoonotic and vector-borne emerging and re-emerging diseases: Current challenges in Latin America" La Plata, Argentina, October 31, 2022.
- Representation on Argentina "Regulatory Framework for animals obtained by Modern Biotechnology in Argentina", in the Workshop Building knowledge and regulatory capacity in animal (livestock and aquaculture) biotech (GE and GnEd) in response to climate change, ISAAA, USDA and APEC Feb 2023.

## **6. Communication and education**

### 2022

- FOAR project "Strengthening of capacities for activities with new breeding techniques (NBT), including gene editing" with Peru for technical assistance and training in gene editing that was carried out in two missions in 2022: held on June in Buenos Aires and on August in Lima.
- Capacity building and Training on biosafety of biotechnology gave to Egypt regulators and officials, held on October 11-13.
- Edition and publication of the Bidesarrollar Magazine, which seeks to communicate the latest developments and innovation in bioeconomy:  
[https://www.argentina.gob.ar/sites/default/files/revista\\_bidesarrollar\\_-\\_num\\_0\\_y\\_1.pdf](https://www.argentina.gob.ar/sites/default/files/revista_bidesarrollar_-_num_0_y_1.pdf)
- Publication of the article "Status of situation regarding the sentence of the European Justice Court on News Breeding Techniques":  
[https://www.magyp.gob.ar/sitio/areas/biotecnologia/conabia/\\_pdf/ESTADO\\_DE\\_SITUACION\\_SOBRE\\_NBT.pdf](https://www.magyp.gob.ar/sitio/areas/biotecnologia/conabia/_pdf/ESTADO_DE_SITUACION_SOBRE_NBT.pdf)
- Virtual talk "Regulation of Insects for agricultural use or impact modified by Modern Biotechnology" at the Argentine Entomological Society August 2022.
- Video of Dissemination on the regulation of agricultural insects obtained by Modern Biotechnology (<https://drive.google.com/file/d/1byAW44xtcqcPdA0OpABEC0zR74rYSth/view?usp=sharing>)

## 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. 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).

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

- In 2022 progress was made in the creation of a New Action Plan, updated by the new formation of National Advisory Commission on Biomaterials (COBIOMAT).

- During 2022, 37 applications from bioproduct companies have been evaluated to acquire the Argentine Bioproduct Seal

### 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 this sense, the Coordination of Innovation and Biotechnology of the National Directorate of Bioeconomy of the Ministry of Agriculture, Livestock and Fisheries of the Nation, is lately working in the following actions have been developed:

- In 2021, the Advisory Committee on Bioinputs for Agricultural Use (CABUA) was modified by Resolution 41 / 2021. On the other hand, it is very important to point out that the bio-inputs were included in the regulation of the "BIOPRODUCTO ARGENTINO" and the "Certificate of Interest" RESOL-2021-132-APN-SABYDR#MAGYP. Therefore, since then bio-inputs are eligible to obtain these distinctions.
- In 2021, the ARGENTINE AGRICULTURAL BIOINPUTS PROGRAM (PROBIAAR) was created (Res. 144/2021), intended to encourage the development, production, processing, registration, marketing and consumption of bioinputs for agricultural use.
- Bio-inputs for agricultural use and CABUA, as evaluation committee, were included in Res. 132/2021 that regulates the "Argentine Bioproduct Seal".
- In 2022 The “Action plan for the Bioinputs sector for agricultural use” was revised by CABUA and modified by DI-2022-20-APN-SSABDR#MEC.
- Unification of technical and administrative criteria for Bioinputs regarding the selection, approval and granting processes of the Argentine Bioproduct Seal.

### 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. Since last report, the "Argentine Bioproduct" Seal has been awarded 30 local companies and institutions.

- In 2022, the Coordination of Innovation and Biotechnology of the National Directorate of Bioeconomy submits a new regulation with two categories.

One of them is the category: "Argentine Seal of Bioproducts" that can only reach companies that have the bioproduct in a state of commercialisation. The seal is awarded in the following subcategories:

- Argentine Bioproduct Seal for Export,
- Argentine Bioproduct Seal for Innovation and,
- Argentine Bioproduct Seal for Sustainability.

Likewise, and with the intention of incorporating more actors for the conformation of the bioproducts and biomaterials sector, a category of "certificates" was incorporated in which the venture or research group is distinguished in the following categories:

- "Bio-based content" when the Product does not have sustainability characteristics and/or innovation characteristics.
- "Research certificate", for projects and developments that are not yet in a state of commercialisation.

These distinctions are granted by the Secretary of Agriculture, Livestock and Fisheries of the Nation and have the endorsement of COBIOMAT.

In this sense, the following information list the stamps and certificates of Argentine Bioproduct Seal and Certificates granted in 2022:

Argentine Bioproduct Seal:

Company	Products	Raw material
<b>Ciclo Sin Fin</b>	Cutlery	Castile cane (weed)
<b>Radha Colors</b>	Cotillon	Cornstarch
<b>Malón Bikes</b>	Bikes	Bamboo
<b>Get Wild</b>	Cothing	Bamboo (textile)
<b>Ecoderm</b>	Facial emulsion	Biobased oils and extracts (apple, sunflower, orange, etc.)
<b>Natwash</b>	Antimicrobial solution for cleaning fruits and vegetables	Citric acid, ascorbic acid, lactic acid, caramel coloring
<b>Soltec</b>	Line of ecological cleaning creams for industrial, artistic and domestic use	Organic acids, oils and vegetable essences.
<b>Fauna Brava</b>	Line of cotton cloth dolls	Cotton cloth for the elaboration of the product and packaging.
<b>BIOZ</b>	Bioplastic straws	Biopellets
<b>NEO-PLAST</b>	Spoons and straws made with bioplastics	Biopellets
<b>BIOPINTURAS ARGENTINAS</b>	Biobased latex paint	Concentrated whey protein (milk residue) and stalk mucilage
<b>RUNA SUSTENTABLE</b>	Line of packaging in contact with food	Bilayer, made up of a cellulose sheet (FSC certified) and a bioplastic sheet of corn starch, joined by a water-based adhesive
<b>APIWRAP</b>	Waxed cloth for preserving food	Cotton cloth, beeswax
<b>BIOGRÁFICA</b>	Biobanner y biovinilo	biopellets
<b>PRINT A LOT</b>	filament line for 3d printing	PLA / PLA 3Di/PLA MAX/ PLA ART
<b>FUNGIPOR</b>	Pots and corners made with biomanufacturing techniques	Mycelium, waste from the agricultural industry
<b>PULPACK</b>	Manufacture of parts for protection	Recycled cellulose
<b>AIN VEGAN</b>	Vegan products for personal care (skin and hair)	Essential oils of rosehip, neneo, romeo, sage and senecio. Other components such as walnut shell, seaweed and olive oil

<b>MARAÑA ESTAMPAS</b>	Textile objects made with natural dyes	Cotton fabrics and natural dyes of onion, avocado, among others
<b>BIOT</b>	Wood-fired loaves of fruit pomace	Waste from the cider industry (pear and apple)
<b>BIOVITA SUDAMERICANA S.A.</b>	Liquid plant fertilizer/biostimulant with an organic structure.	Amino acids from collagen protein from solid protein residues from cow skin.
<b>HMA4 S.A.</b>	Plant growth biostimulant product line.	Nutrients, amino acids and autochthonous beneficial microorganisms, promoters of plant growth.
<b>BENEFICAL GERMS</b>	Line of non-nutritional additives for the conservation of forage in silage and stimulants of plant development.	Native beneficial microorganisms, plant growth promoters.
<b>BENEFICAL GERMS</b>	Line of freeze-dried starters for the industry of curing raw meat products.	Native beneficial microorganisms, plant growth promoters.
<b>DESARROLLO BIOTECNOLÓGICOS S.A.</b>	Fertilizer/Biostimulant for plant growth, for foliar application.	Beneficial microorganisms, micronutrients, growth factors, hormones, vitamins, amino acids, antibiotics and other metabolites.
<b>MICROVIDAS</b>	Fertilizer/Biostimulant product line for plant growth. .	Beneficial microorganisms, plant growth promoters.

Certificates:

<b>Company</b>	<b>Products</b>	<b>Raw material</b>
<b>IQUIMEFA-UBA-CONICET</b>	Flexible hydrogel based on keratin	Meat discards
<b>IMBIV CONICET UNC, CIAD-CONACYT-Mexico</b>	Active component of multilayer packaging for hermetic storage. essential oil, mixture of terpenic compounds	essential oil, mixture of terpenic compounds
<b>SUPERBOL SRL</b>	Line of biocompostable bags	biopellets corn starch
<b>ALAS DE OVEJA</b>	Felt products	discarded sheep wool
<b>ABRIGA</b>	Thermo acoustic blankets	discarded sheep wool
<b>BIOLEÑA</b>	fire starter sawdust, wood shavings	wood shavings
<b>NOBAC</b>	Filtering system for domestic use	wood, coconut
<b>HMA4 S.A.</b>	Line of biocontrollers for plant pathogens and pests.	beneficial microorganisms and plant extracts.
<b>HMA4 S.A.</b>	Plant growth biostimulant product line.	Nutrients, minerals, vitamins and microorganisms that promote plant growth.
<b>BENEFICIAL GERMS</b>	Recombinant lactase for the dairy market. beneficial microorganisms.	beneficial microorganisms.
<b>CAMPO LAVALLE S.A.</b>	Biofertilizer for vegetable crops	Worm humus, enriched with amino acids of plant origin.
<b>MICROVIDAS</b>	Line of biostimulant, biofertilizer and biological control products for vegetable crops..	beneficial microorganisms
<b>INTA</b>	Biocontroller for strawberry cultivation.	Ethanol extract of propolis
<b>INTA</b>	Biocontroller of the eucalyptus bug. parasitoid	macroorganisms of insect pests.
<b>CONICET</b>	ArgenGreen Enzymes product line. plant lipase powder, plant proteases in solution, plant protease powder, Biocatalyst with lipase activity, Biocatalysts with protease/peptidase activity	Fruit of a native plant.
<b>MOSQUITA FEED Co SAS</b>	Product line: bio-inputs for agro-industrial use. Additives and dietary supplements that stimulate the immune system, feeding and growth of mono and multi gastric animals.	Macroorganism: soldier fly

## AUSTRALIA

### 1. GM food regulation in Australia

Food Standards Australia New Zealand (FSANZ; [www.foodstandards.gov.au](http://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/F2023C00138>

### 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 29<sup>th</sup> Meeting and applications currently under assessment by FSANZ include:

Food derived from:	Current Status:
EPA+DHA and herbicide tolerant canola line LFBLFK	Approved September 2022
Insect protected corn line MON95275	Under assessment
Drought and herbicide tolerant soybean line IND-00410-5	Under assessment
Herbicide tolerant and insect protected corn line DP51291	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.

Following the successful completion of the first shared safety assessment between FSANZ and Health Canada in 2021, a further two shared safety assessments are planned for 2023. For these applications it has been agreed that FSANZ will undertake the assessment and provide it to Health Canada for review and subsequent use in their decision-making process. A common template has been developed for when applications are being assessed under the sharing arrangement.

#### New breeding techniques - update

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

A first round of public consultation was undertaken by FSANZ at the end of 2021 with 1736 submissions being received in response. For this consultation, FSANZ proposed that the existing definition for *gene technology* be

expanded to capture a broader range of genetic technologies, and the definition for *food produced using gene technology* be revised to include specific product-based exclusions for certain low risk products based on their equivalence to conventional foods.

Since the 29<sup>th</sup> WP-SNFF meeting, FSANZ has completed an analysis of the 1736 submissions and has decided to affirm its assessment and conclusion that certain foods and substances added to food will be equivalent to conventional products in terms of risk and should not be GM foods for regulatory purposes.

After examining feedback from submitters in relation to the specific definitional criteria proposed in the first consultation round, FSANZ has undertaken further assessment and explored a variety of different options for refining the original approach. The purpose of this was to further simplify the approach, improve clarity and enforceability, and ensure that consistent and scientifically supportable regulatory outcomes would be achieved.

This refined approach will be outlined in a second round of consultation, which is anticipated for May or June 2023. The second consultation documents will also include a full response to all the issues raised in submissions, as well as the proposed draft amendments to the *Australia New Zealand Food Standards Code*, including a new definition for genetically modified food.

In addition to the consultation process and to further support Proposal P1055, FSANZ commissioned a nationally representative survey of consumers' perceptions of and attitudes towards genetically modified foods and new breeding techniques used in food production. A report was published in December 2022.

The full set of publicly available 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>

## 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 characterise unauthorised GMOs. This can be applied in isolated GMO or complex matrices using enrichment steps for targeted DNA by DNA walking.

- Detection of genetically modified microorganisms (GMM): As a result of the national research project SPECENZYM (RT17/5), TAG has developed the FEDA database (Food Enzyme Database - <https://bioit-webapp-prod.sciensano.be/specenzyme/>) which is a web application gathering information about food enzyme preparations available on the European market.
- TAG coordinates a Belgian federal project on development of new open strategy for impurity surveillance of commercial microbial fermentation food products (ENSURED), which started in 2023.
- In parallel, another research project (AMRSEQ) involved in the characterisation of plasmids, financed by Sciensano, is on-going. Plasmids are elements that are often present in GMM and may carry antibiotic resistance genes, and are particularly difficult to characterise. Therefore, in this project, the specific abilities of different NGS platforms are combined, such as aligning high-quality short reads generated by the Illumina® technology to substitutes for reference sequences created by the long reads generated by the Pacific Biosciences® and/or Oxford Nanopore® technologies.
- A research project focusing on metagenomics approaches (sequencing the whole sample) was also initiated in order to strengthen the current GMO detection system for unauthorised GMO (UGM) as well the feasibility to integrate the MinION NGS.
- “METAMORPHOSE”: The objective of this research project (financed by Sciensano) is to develop the shotgun metagenomics approach generically (at the wet and dry lab levels) and to deliver a proof-of-concept of the potential of the approach to answer public health questions using three case studies: i) detection and characterisation of GMMs used in fermentation products or as a bioweapon, ii) quality control of vaccines and medicinal products and iii) characterisation of microbiomes. In the frame of this project, a theoretical assessment of the risks associated with the presence of GMMs and antibiotic resistance genes in fermentation products will be conducted.
- Development and evaluation of approaches for detection of organisms modified by new genome editing techniques (GenEdit): The Belgian federal project on development of novel approaches and strategies for detection of GE plants in food and feed products started in 2021. TAG has worked on the application of ddPCR for detection of GE plants. Next year, targeted NGS using Illumina technology is foreseen.

### Peer-reviewed publications:

Fraiture, M.-A. et al., 2023. Targeted high-throughput sequencing enables the detection of single nucleotide variations in CRISPR/Cas9 gene-edited organisms. *Foods*, 12, 455, <https://doi.org/10.3390/foods12030455>

Marie-Alice Fraiture, Andrea Gobbo, Nina Papazova and Nancy H.C. Roosens. Development of a taxon-specific real-time PCR method targeting the *Bacillus subtilis* group to strengthen the control of genetically modified bacteria in fermentation products. *Fermentation* 2022, 8(2): 78. <https://doi.org/10.3390/fermentation8020078>

Assia Saltykova, Julien Van Braekel, Nina Papazova, Marie-Alice Fraiture, Dieter Deforce, Kevin Vanneste, Sigrid C.J. De Keersmaecker (\*), Nancy H. Roosens (\*) Detection and identification of authorised and unauthorised GMOs using high-throughput sequencing with the support of a sequence-based GMO database. *Food Chemistry: Molecular Sciences* 4: 100096.

Jolien D’aes, Marie-Alice Fraiture, Bert Bogaerts, Sigrid C. J. De Keersmaecker, Nancy H. C. J. Roosens, Kevin Vanneste. Metagenomic Characterisation of Multiple Genetically Modified *Bacillus* Contaminations in Commercial Microbial Fermentation Products. *Life* 2022, 12, 1971. <https://doi.org/10.3390/life12121971>

Marie-Alice Fraiture, Emmanuel Guiderdoni, Anne-Cécile Meunier, Nina Papazova, Nancy H.C. Roosens. ddPCR strategy to detect a gene-edited plant carrying a single variation point: Technical feasibility and interpretation issues. *Food Control* 2022, 137: 108904

### 3. New Techniques

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 one new field trial with maize modified by CRISPR-Cas for reduced height has been submitted for authorisation and is under evaluation (B/BE/23/V1, see <https://www.biosafety.be/search-gm-plants>).

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.

## BRAZIL

### 1. Regulatory Framework

For the past couple of years, a quite a few GMO Biosafety regulations have had reviewed by the National Biosafety Technical Commission – CTNBio, and in this way in the last November it was released the Normative Resolution nº37 about Biosafety Certificate at all.

### 2. Commercial Approvals

A several GMO commercial approvals went through in the last year such as:

- SYN-E3272-5 x SYN-BTØ11-1 x SYN-IR6Ø4-5 x MON-ØØØ21-9: Insect resistance and herbicide tolerant maize; **Developer:** Syngenta Seeds Ltda;
- MON-87429-9: Herbicide tolerant maize; **Developer:** Monsanto do Brasil Ltda;
- EH-BRS913-2: Insect resistance maize; **Developer:** Helix Sementes e Mudas Ltda;
- 3272: Insect resistance maize; **Developer:** Syngenta Seeds Ltda;
- MON 15947: Insect resistance cotton; **Developer:** Monsanto do Brasil;
- 955S019: Herbicide resistant eucalyptus; **Developer:** Suzano S.A;
- FGN-K: Herbicide tolerant eucalyptus; **Developer:** Suzano S.A;
- 955S024: Herbicide tolerant eucalyptus; **Developer:** Suzano S.A;
- CTC-92015-7: Insect resistance sugarcane; **Developer:** Centro de Tecnologia Canavieira
- IND-ØØ412-7: Drought resistant and herbicide tolerant wheat; **Developer:** Tropical Melhoramento Genético;
- *Saccharomyces cerevisiae* strain PRCH20080 - FS0436; Yeast for biofuel production; **Developer:** Danisco Brasil Ltda;
- *Saccharomyces cerevisiae* strain M32292; Yeast for biofuel production; **Developer:** Lallemand Soluções Biológicas Ltda;
- *Saccharomyces cerevisiae* strain M32376; Yeast for biofuel production; **Developer:** Lallemand Soluções Biológicas Ltda;
- *Saccharomyces cerevisiae* strain M32379; Yeast for biofuel production; **Developer:** Lallemand Soluções Biológicas Ltda;
- *Saccharomyces cerevisiae* strain M12156; Yeast for biofuel production; **Developer:** Lallemand Soluções Biológicas Ltda;
- Oncept; canine melanoma vaccine; **Developer:** Boehringer Animal Health do Brasil Ltda;
- Roctavian; Gene therapy for hemophilia; **Developer:** Biomarin Farmacêutica Ltda.
- Yescarta; Gene Therapy for large B-cell lymphoma; **Developer:** Gilead Sciences Farmacêutica do Brasil Ltda.

### 3. GMO Research

In 2022, The CTNBio approved 87 field trials with different plant species, including maize, soybean, lettuce, wheat, citrus, sugarcane, eucalyptus etc. The characteristics of the biotech crops depicts insect resistance, herbicide tolerance, disease resistance, drought tolerance, increased yield and folic acid.

### 4. GMO Crops Production

Currently, Brazil is the second-largest producer of biotech crops around the world with 112 events approved for commercial cultivation, of which 58 events are for corn, 24 for cotton, 18 for soybeans, six for sugarcane, four for eucalyptus, one for a virus resistant variety dry edible beans and one for drought-tolerant wheat.

Therefore, for the 2022/2023 crop season a 65 million hectares are expected to be planted with GE traits - to be confirmed once final numbers are published. The widespread adoption of GE events in Brazil has contributed to record soybean (153 million metric tons) and corn (125 million metric tons) production.

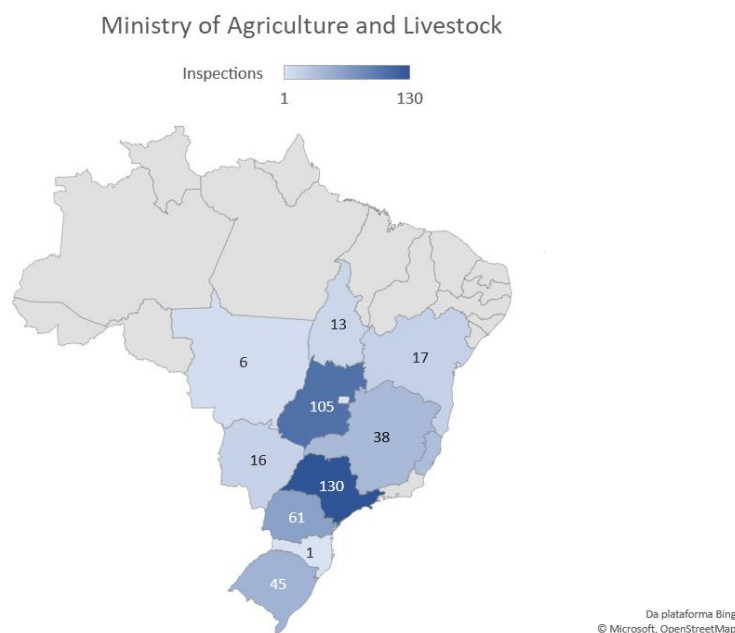
The Biotec-Latam reports the following adoption rates in Brasil:

- Soybeans: The adoption rate of GE soybean seeds in 2021 was around to 95 percent;
- Corn: The adoption rate of GE corn seeds in 2021 was 95 percent;

- Cotton: The adoption rate of GE cotton in 2021 was 99 percent;
- Sugarcane: The adoption rate of GE sugarcane in 2021 was 0.45 percent;
- Dry Edible Beans: the adoption rate of GE dry edible beans in 2021 was 0.17 percent;

## 5. GMO Inspections

The Ministry of Agriculture and Livestock (MAPA) is one of the institutions responsible for inspections in the activities related with GMO use and manipulation to check the compliance with biosafety normative requirements. The MAPA carried out 392 inspections in field trials all over the country and 77 inspections in the commercial use of GMOs in 2022.



## 6. Developments related to new breeding techniques (NBTs)

The CTNBio Normative Resolution n° 16 is applicable to all types of organisms and establishes a consultation system, on a case-by-case basis, for products obtained from Innovative Precision Breeding Techniques defined as a set of new methodologies and approaches that differ from the genetic engineering strategy by transgenics, as they result in the absence of recombinant DNA/RNA in the final product. In practical terms, products obtained either by site-directed random mutation involving the joining of non-homologous ends (SDN1 mutation), or site-directed homologous repair involving one or few nucleotides (SDN2 mutation) meets the conditions established in Normative Resolution n° 16 to be designated as not GM in a case-by-case analysis, but then again, site-directed transgene insertions (SDN3 mutation) are designated GM according to the provisions of the normative and will have to go through all biosafety requirements.

Since last meeting in 2022 the following products were developed under the CTNBio Normative Resolution n° 16 definitions, therefore not GM:

- **Product:** Drought tolerant soybean; **Developer** GDM Genética do Brasil S.A;
- **Product:** dsRNA insect control; **Developer:** Evolutna Agro Biotecnologia Ltda;
- **Product:** Sugar Cane; **Developer:** Embrapa Agroenergia;
- **Product:** Biofertilizer; **Developer:** Mosaic Fertilizantes do Brasil Ltda.;
- **Product:** Biofertilizer; **Developer:** Mosaic Fertilizantes do Brasil Ltda.;
- **Product:** dsRNA insect control; **Developer:** Evolutta Agro Biotecnologia Ltda.;
- **Product:** N fixation microorganism; **Developer:** Tevah Consultoria Regulatória;
- **Product:** Soybean's lectin gene silencing; **Developer:** Embrapa Soja;

- **Product:** Yeast for biofuel production; **Developer:** Lallemand Soluções Biológicas Ltda;
- **Product:** Protein based product; **Developer:** CJ do Brasil Indústria e Comércio de Produtos Alimentícios Ltda;
- **Product:** dsRNA insect control; **Developer:** Evolutta Agro Biotecnologia Ltda;
- **Product:** Biofertilizer; **Developer:** Tevah Consultoria Regulatória;
- **Product:** dsRNA insect control; **Developer:** Evolutta Agro Biotecnologia Ltda;
- **Product:** dsRNA insect control; **Developer:** Sempre Agtech Ltda.

## 7. GM data bank

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

## CANADA

### Novel Food Approvals

Since 1999, Health Canada (HC) has permitted 249 novel foods to be sold in the Canadian marketplace. Since May 2022, the following novel foods have been authorised:

- Insect resistant sugarcane CTC5064-3
- Canola protein isolate and cruciferin-rich canola protein isolate
- Fy Protein™
- Oxyfluorfen herbicide tolerant ROXY® rice

A list of authorised novel foods, each summarised 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 May 2022, one novel feed from a plant source have been authorised:

- Oxyfluorfen herbicide tolerant ROXY® rice

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 recognise 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*. CFIA will publish a “What We Heard” report that summarises the comments received through the consultation. Once additional targeted follow-up conversations with key stakeholder groups have concluded, the CFIA will publish its updated guidance for plants with novel traits. This update will provide additional clarity for the agricultural biotechnology sector when it comes to new technologies like gene editing.

The Animal Feed Program has drafted a supplementary guidance document aimed at clarifying which plant derived feed ingredients require a pre-market assessment. As part of the process to develop clearer and more predictable guidance for feeds developed from plant breeding, the Canadian Food Inspection Agency (CFIA) will be seeking feedback on the proposed guidance which will supplement the existing guidance document on our website. The feed policy approach draws from and aligns with many scientific principles found in Health Canada’s guidance. Similarly, to the food novelty determination policy, the feed guidance aims to elaborate and describe a set of criteria, that will

help developers self-determine whether their plant product is novel and would require a pre-market assessment. The new guidance is science-based and in keeping with Canada's product-based regulatory approach for feeds.

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 (No update since last meeting)**

The Global Low Level Presence Initiative (GLI) is a group of 15 importing and exporting countries committed to working collaboratively to develop practical approaches to facilitate the management of Low-Level Presence (LLP). Canada and the Philippines co-hosted the 8<sup>th</sup> 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](mailto:GLI-IMP@canada.ca).

### **Feed Regulatory Renewal Project**

During 2022/23, the CFIA has continued to work 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 has published a what we heard report that summarises the comments and how they are being addressed. The CFIA is working towards publication in Canada Gazette, Part 2 in fall 2023. 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.

### **Whole Genome Sequencing and Developments in Taxonomy**

Whole Genome Sequencing (WGS) has become the gold standard approach for identifying bacteria at the strain level as it allows for the discrimination of closely related bacterial strains. WGS is a comprehensive method that analyses entire genomes (all genetic information of an organism) of organisms which enables more precise and accurate identification of these. WGS can also produce useful information for the characterisation of relevant traits in microorganisms, such as virulence factors, antimicrobial resistance, and production of antimicrobials, toxins or other metabolites. WGS data and WGS bioinformatics analysis can also be used to meet multiple data requirements for the characterisation of microbial strains during pre-market assessments.

With respect to livestock feeds, the CFIA is working with industry stakeholders regarding the accuracy of microbial strain identification. As such, the CFIA is requesting WGS data to be submitted by applicants in order to substantiate

the taxonomic identification of strains as livestock feeds during the registration process. The new taxonomic identification of strains will have an impact on ingredient descriptions found in *Feeds Regulations*. The ingredient descriptions will require an update.

#### *Nanotechnology (No update since last meeting)*

Currently, Health Canada is using existing legislative frameworks to regulate applications of nanotechnology. However, it recognises 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*

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 been engaging with stakeholders who are either developing or have interest in developing these products. Under Canada's *Novel Food Regulations*, these products will be considered 'novel foods' and thus require pre-market safety assessment prior to their sale and/or advertisement in Canada for food use. Health Canada is presently conducting an analysis of this emerging industry to understand the type of products intended for commercialisation and how the safety of these products will be assessed. This analysis will be used to develop additional guidance or materials to support clarity and predictability for cellular agriculture manufacturers, in particular guidance on the information required for the pre-market assessment of these products.

Similarly, if products of cellular agriculture or intended to be sold, manufactured or imported as livestock feed, these products will be considered novel feeds thus requiring a pre-market assessment by the Canadian Food Inspection Agency.

## COLOMBIA

### *Developments related to implementation of national biosafety framework*

#### **1. Risk assessment/regulatory decisions**

Authorisations granted in 2022 by the Instituto Colombiano Agropecuario (ICA):

Unique Identifier	Decision	Decision (+web link, if any)	Organism	Trait	Authorised for
DP-Ø73496-4	7887	<a href="https://www.ica.gov.co/getattachmen t/cb7a63c6-aeda-4436-a676-17904af13597/2022R0007887.aspx">https://www.ica.gov.co/getattachmen t/cb7a63c6-aeda-4436-a676-17904af13597/2022R0007887.aspx</a>	Canola	Herbicide tolerance	Feed
SYN-E3272-5 X SYN-Ø53Ø7-1 X SYN-IR6Ø4-5 X SYN-BTØ11-1 X DAS-Ø15Ø7-1 X MON-ØØØ21-9 X SYN-IR162-4	7888	<a href="https://www.ica.gov.co/getattachmen t/5cab994f-618b-4db7-bd29-6ca19fdc5a9e/2022R0007888.aspx">https://www.ica.gov.co/getattachmen t/5cab994f-618b-4db7-bd29-6ca19fdc5a9e/2022R0007888.aspx</a>	Maize	Insect resistance Herbicide tolerance	Feed
DAS-Ø15Ø7-1 x MON-ØØ81Ø-6 x SYNIR162-4 x MON-ØØ6Ø3-6	7889	<a href="https://www.ica.gov.co/getattachmen t/aa37e9ae-1656-4855-9e22-819ba12dcaba/2022R0007889.aspx">https://www.ica.gov.co/getattachmen t/aa37e9ae-1656-4855-9e22-819ba12dcaba/2022R0007889.aspx</a>	Maize	Insect resistance Herbicide tolerance	Cultivation
MON89Ø34-3 x DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6 x SYN-IR162-4	7890	<a href="https://www.ica.gov.co/getattachmen t/48add5fb-0f23-46d0-bb15-7128b586a1ee/2022R0007890.aspx">https://www.ica.gov.co/getattachmen t/48add5fb-0f23-46d0-bb15-7128b586a1ee/2022R0007890.aspx</a>	Maize	Insect resistance Herbicide tolerance	Cultivation
MON-Ø4Ø32-6	13534	<a href="https://www.ica.gov.co/getattachmen t/177db72a-2eba-445d-b174-79a45a705417/2022R0013534.aspx">https://www.ica.gov.co/getattachmen t/177db72a-2eba-445d-b174-79a45a705417/2022R0013534.aspx</a>	Soybean	Herbicide tolerance	N/A (rejected)
SYN-E3272-5 x SYN-BTØ11-1 x SYN-IR162-4 x MON-ØØØ21-9	13535	<a href="https://www.ica.gov.co/getattachmen t/2b9c5206-9b8a-40e0-b76c-c34fd480e773/2022R0013535.aspx">https://www.ica.gov.co/getattachmen t/2b9c5206-9b8a-40e0-b76c-c34fd480e773/2022R0013535.aspx</a>	Maize	Insect resistance Herbicide tolerance	Feed
BCS-BNØ12-7	15185	<a href="https://www.ica.gov.co/getattachmen t/9e905a39-4681-49a3-b7b1-1f547d50272/2022R0015185.aspx">https://www.ica.gov.co/getattachmen t/9e905a39-4681-49a3-b7b1-1f547d50272/2022R0015185.aspx</a>	Canola	Insect resistance Herbicide tolerance	Feed
BCS-GH811-4 x BCS-GHØØ4-7 x BCS-GHØØ5-8 x SYN-IR1Ø2-7 x MON887Ø1-3	25687	<a href="https://www.ica.gov.co/getattachmen t/605b50d7-7ef6-4cbd-bf28-fe59aac749e2/2022R0025687.aspx">https://www.ica.gov.co/getattachmen t/605b50d7-7ef6-4cbd-bf28-fe59aac749e2/2022R0025687.aspx</a>	Cotton	Insect resistance Herbicide tolerance	Feed
BCS-GH811-4 x ACS-GHØØ1-3 x MON-887Ø1-3	25688	<a href="https://www.ica.gov.co/getattachmen t/b07ceed4-9475-45ec-819a-3908da68aadd/2022R0025688.aspx">https://www.ica.gov.co/getattachmen t/b07ceed4-9475-45ec-819a-3908da68aadd/2022R0025688.aspx</a>	Cotton	Herbicide tolerance	Feed
BCS-GH811-4 x BCS-GHØØ4-7 x BCS-GHØØ5-8 x SYN-IR1Ø2-7	25689	<a href="https://www.ica.gov.co/getattachmen t/4998ed35-fe4b-494f-9b33-51db6d76fa82/2022R0025689.aspx">https://www.ica.gov.co/getattachmen t/4998ed35-fe4b-494f-9b33-51db6d76fa82/2022R0025689.aspx</a>	Cotton	Insect resistance Herbicide tolerance	Feed

On the year 2022, the National Institute for the Surveillance of Medicines and Food (INVIMA) authorised 23 LMO events for food, as follows:

ORGANISM	LMO EVENT	IDENTIFIER	DECISION	REGULATION NUMBER	REGULATION DATE (DD/MM/YYYY)
Wheat	HB4	IND-ØØ412-7	Authorised	2022500206	15/02/2022
Maize	Fenaltec22	NA/NR	Authorised	2022500207	15/02/2022
Maize	DP4114 X MON810 X MIR604 X NK603	DP-ØØ4114-3 x MON-ØØ81Ø-6X SYN-IR6Ø4-4 X MON-ØØ6Ø3-6	Authorised	2022500204	15/02/2022
Maize	DP-915635	DP-915635-4	Authorised	2022500205	15/02/2022
Cotton	281-24-236	DAS-24236-5	Authorised	2022005637	29/03/2022
Maize	Bt11 X MIR162	SYN-E3272-5 x SYN-BTØ11-1	Authorised	2022005639	29/03/2022
Cotton	MON 88701 x MON 88913	MON-887Ø1-3 x MON-88913-8	Authorised	2022005640	29/03/2022
Cotton	COT 102 X MON 15985 X MON 88913 X MON 88701	SYN-IR1Ø2-7 x MON-15985-7 x MON-88913-8 x MON-887Ø1-3	Authorised	2022009522	2/05/2022

Maize	MON 89034 X TC 1507 X MON 88017 X DAS 59122 X DAS 40278	MON-89034-3 x DAS-01507-1 x MON-88017-3 x DAS-59122-7 x DAS-40278-9	Authorised	2022009523	2/05/2022
Canola	DP73496	DP-073496-4	Authorised	2022009524	2/05/2022
Maize	MON 89034 x TC1507 x NK603 x DAS40278	MON-89034-3 x DAS-01507-1 x MON-00603-6 x DAS-40278-9	Authorised	2022009525	2/05/2022
Soy	FG72	MST-FG072-3	Authorised	2022014893	31/05/2022
Soy	FG72 X A5547-127	MST-FG072-3 x ACS-GM006-4	Authorised	2022600205	10/10/2022
Maize	MON 87411	MON-87411-9	Authorised	2022600206	10/10/2022
Soy	DAS 81419	DAS-81419-2	Authorised	2022600207	10/10/2022
Soy	305423	DP-305423-1	Authorised	2022600208	10/10/2022
Cotton	81910	DAS-81910-7	Authorised	2022600209	10/10/2022
Canola	MS11	BCS-BN012-7	Authorised	2022600210	10/10/2022
Maize	59122 x TC1507 X NK603	DAS-59122-7xDAS-01507-1x MON-00603-6	Authorised	2022600252	1/11/2022
Cotton	DAS21023 (3006-210-23)	DAS-21023-5	Authorised	2022600253	1/11/2022
Maize	T25	ACS-ZM003-2	Authorised	2022600254	1/11/2022
Soy	MON 87701 x MON 89788	MON-87701-2 x MON-89788-1	Authorised	2022600255	1/11/2022
Maize	NK603 X T25	MON-00603-6 x ACS-ZM003-2	Authorised	2022600256	1/11/2022

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

In 2022, INVIMA did not issue any new regulations associated to LMOs.

However, inside our organisation, different actions were taken in terms of updating the authorisation LMO procedure, publishing all available decisions and LMO information on the official INVIMA's website, and adjusting the National Surveillance and Control plan actions, regarding products declaring to be "LMO Free".

Additionally, INVIMA acting as the general secretariat of the National Biosecurity Committee for LMO used exclusively for Health and Human Consumption – CTNSalud, established a simplified procedure applicable to contained uses of LMOs of nonnegligible risk.

The above allows the applicant to be able to be authorised, to carry on its experimental actions, if preliminary information clearly states it is being done in a bio secure facility and only for experimental purposes.

## 3. Risk management measures

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 year 2022, INVIMA continued with its National Surveillance and Control LMO plan actions, focused on:

1. Food products declaring to be "LMO Free" which must comply with Colombia's Regulation 4254 of 2011.
2. Food products declaring to be either organic or ecological produce which must comply with Colombia's Regulation 187 of 2006.
3. Surveillance of LMO's unauthorised events being import to Colombia.

Additionally, the LMO INVIMA's Laboratory continued to strengthen their analytical methods as one of the top reference laboratories in this matter.

On the other hand, Low Level Presence (LLP) associated to LMO was discussed between different government authorities, in an effort for issuing a national regulatory guideline. Meanwhile, a consensus is reached, both INVIMA and the Ministry of Health and Social Protection as the representatives of the health sector, will continue performing measures based on a case-by-case basis.

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

No comments from ICA and INVIMA.

#### 5. Public engagement and outreach activities

During 2022 ICA carried out seven (7) training and socialisation activities for the target audience on the Biosafety Plan and monitoring of Genetically Modified commercial crops in different natural regions of Colombia. During the conferences, information was provided on the responsibilities of the different actors involved in the use of Living Modified Organisms (LMOs) for agricultural and livestock purposes, raising awareness about the international and national regulatory framework that exists in the matter. Farmers, seed distributors, technical assistants and seed and biotechnology companies participated.

INVIMA engaged in virtual and live meetings on the following topics:

1. Food products declaring to be “LMO Free” which must comply with Colombia’s Regulation 4254 of 2011
2. Authorisation of LMO procedure for food.
3. Outline and results for the National Surveillance and Control LMO Plan.
4. LMO - General Information.

#### *Updates regarding international activities*

#### **Participation in/hosting international symposia/fora relating to biosafety**

##### **ICA**

First Virtual Session on Biotechnology and Biosafety 2022

Second Virtual Session on Biotechnology and Biosafety 2022

Third Virtual Session on Biotechnology and Biosafety 2022

Fourth Virtual Session on Biotechnology and Biosafety 2022

Fifth Virtual Session on Biotechnology and Biosafety 2022

Technical meetings regarding Convention on Biological Diversity and Cartagena Protocol

These 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).

In addition, ICA participated in 29th Meeting of the Working Party for the Safety of Novel Foods and Feeds 16-18 May 2022 and the 36th Meeting of the Working Party on the Harmonisation of Regulatory Oversight in Biotechnology 18-20 May 2022. All meetings taking place at the OECD headquarters in Paris, France.

As ICA, during 2022 we have used the BioTrack Database to consult approvals granted from other countries, Risk Assessments and Consensus Document of maize, cotton, soybean, and canola (rapeseed). Additionally, ICA continues to develop a virtual platform for LMO’s applications and has required a review of the BioTrack database to reinforce our tool draft in search of the efficiency and ease of authorisation procedures.

##### **INVIMA**

Additional to OCDE’s related activities, INVIMA took part in the following international activities regarding LMO and/or Biotechnology:

1. GLI (Global Low Level Presence Initiative)
2. SPS bilateral meeting with the United States of America
3. Technical meetings regarding Convention on Biological Diversity
4. DSI – COP 14 (Conference of Parties) related meetings

#### *Developments related to new breeding techniques (NBTs)*

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

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

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

### **Specific cases of application, assessment, and decision**

Organism	Trait	Decision / Status
Herbicide tolerant soybean	Low Raffinose content	Does not have a new combination of genetic material for the new trait

## **COSTA RICA**

### **Developments related to implementation of national biosafety framework**

#### **1. Risk assessment/regulatory decisions**

Currently, in Costa Rica, LMOs are only authorised for planting and production of seeds, fruits or products for export. During the current reporting period (May 2022 – March 2023) Costa Rica extended approvals of two cotton traits to new users based on previous analysis of the same LMO, safe history of use, and similar risk management provided by the new user. It should be noted that these events have been approved to other users in previous years. Therefore, they already have a history of safe use in the country.

The first is the LMO named MON-887Ø2-4, containing gene cry51Aa2, providing protection hemipterans *Lygus hesperus* and *Lygus lineolaris*, and *Thysanopteran Franklaniella* spp to the company Nutrien Ag Solutions Costa Rica S. A. Published in the official gazette 230, December 1st, 2022. Available at <https://www.imprentanacional.go.cr/Gaceta/?date=01/12/2022>

The second is the GMO named MON-887Ø1-3, containing genes DMO from *Stenotrophomonas maltophilia* and bar from *Streptomyces hygrosopicus* producing DMO protein (dicamba mono-oxygenase) and PAT (fosfinotricine N-acetyl-transferase) that provides tolerance to herbicides dicamba and ammonium glufosinate to the company BASF de Costa Rica S. A. December 15th, 2022. Available at <https://www.imprentanacional.go.cr/Gaceta/?date=15/12/2022>.

In addition, the State Phytosanitary Service authorised the planting of the following events:

1. 55 hectares of GM cotton SYN-IR102-7 X MON-15985-7 X MON-88913-8 X MON-88701-3, with the purpose of producing seed for export.
2. 80 hectares of GM cotton MON-887Ø2-4 X MON-15985-7 X SYN-IR1Ø2-7 X MON-887Ø1-3 X MON-88913-8, with the purpose of producing seed for export.
3. 21 hectares of GM cotton MON-00531-6 X MON-15985-7 X SYN-IR-102-7 X MON-88913-8 X MON-88701-3 X MON-88702-4, with the purpose of producing seed for export.
4. 11 hectares of GM cotton MON-887Ø2-4, with the purpose of producing seed for export.
5. 63 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 LMOs 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. It is possible that, during this year, the state phytosanitary service will be involved in the preparation of this regulatory proposal. Our idea is that in the future we can authorise planting projects with living modified organisms, which can be used for human and animal food, as well as for 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 NBT. Basically, this regulatory framework will establish the procedures to define whether a crop obtained using NBT 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 NBT, 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 NBTs, the applicants must submit information regarding the methodology used to modify the crop, the innovative trait introduced, evidence of the genetic changes present in the product, evidence of elimination of the transitory transgene employed to achieve the product (if necessary), and any additional information that Regulators consider necessary.

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

## **CROATIA**

### **1. Genetically Modified Food and Feed/Novel Food Legislative Framework**

The Republic of Croatia as a Member of the European Union, implements EU legislation on GM food and feed at the national level. Regulation (EC) No 1829/2003 regulates the placing on the EU market GM food and feed. The Republic of Croatia is involved in the Member States consultation process conducted by the European Food Safety Agency. Ministry of Health is the central and coordinative body for all duties in the fields of GMOs especially for the GM food and feed.

In July 2022, Croatia made amendments to the national Act on implementation of European Union Regulation on Traceability and Labeling Genetically modified Food and Feed (Official Gazette, No 18/13, 47/14, 114/18, 83/22), necessary for the implementation of Regulation (EU) 2019/1381 of the European parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC.

In the EU and in the same time in the Republic of Croatia, 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 to a significant degree within the Union 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://webgate.ec.europa.eu/fip/novel\\_food\\_catalogue/](https://webgate.ec.europa.eu/fip/novel_food_catalogue/) provides overview of products of animal and plant origin and the other substances subject to the Novel Foods.

### **2. GMO detection in the Republic of Croatia**

All products that are authorised for placing on the market can be found in the EU Register of GM food and feed. Since Croatia have operationalised an EU “opt-out” clause in relation to the cultivation of genetically modified crops, GMOs are only authorised for import and use as food and feed.

State Inspectorat of the Republic of Croatia is competent authority responsible for conducting official control of GMOs in food, feed and seed on the Croatian market and to check compliance with the Act of GMO s (Official Gazette, No 126/19). In accordance with the national annual monitoring plan samples of seeds and seedlings, food

and animal feed are taken. Samples are collected by the agricultural inspection, veterinary inspection, sanitary and border sanitary inspection. Samples are collected from the Croatian market, from agricultural areas, as well as at border crossings. The samples taken are delivered to laboratories authorized for official controls in the field of GMOs.

In accordance with the Regulation (EU) 1981/2006, the Implementing Regulation (EU)120/2014 and the Regulation (EU) 2017/625 the Croatian Ministry of Health has authorized two following laboratories for GMO detection as National Reference Laboratories for genetically modified organisms in the Republic of Croatia: **Croatian Institute of Public Health and Croatian Agency for Agriculture and Food**. Both of these National Reference Laboratories are member of the European Network of Genetically modified Laboratory (ENGL). List of analysed samples in 2022 of for the purposes of official controls are presented in Table 1.

The Republic of Croatia has no commercial cultivation of GMOs and so far in Croatia no permits have been granted for the deliberate release of GMOs neither for field trials or commercial cultivation.

Table1: List of analysed samples for the purposes of official controls in 2022

Sample	Total	Positive	Events identified
<b>Agricultural inspection</b>			
Total	60	0	
Maize seed	14	0	
Maize green leaf	8	0	
Soybean seed	6	0	
Soybean green leaf	15	0	
Oilseed rape seed	4	0	
Oilseed rape green leaf	7	0	
Sugar beet seed	2	0	
Wheat seed	4	0	
<b>Sanitary inspection</b>			
Total	184	2	
Soybean products	87	2 ≤ 0,9%	A5547-127, MON89788, MON87708-9; MON87701, MST-FG072-2, DAS-44406-6
Rice products	21	0	
Maize products	20	0	
Wheat products	47	0	
Papaya products	3	0	
Flax	6	0	
<b>Border Sanitary Inspection</b>			
Total	6	0	
Rice products	2	0	
Maize products	3	0	
Wheat products	1	0	
<b>Ministry of Agriculture</b>			
Analysis of soybean seeds for placing on the Croatian market - Program of the Ministry of Agriculture	570	0	
<b>TOTAL</b>	<b>820</b>	<b>2</b>	<b>A5547-127, MON89788, MON87708-9; MON87701, MST-FG072-2, DAS-44406-6</b>

### 3. New Breeding Techniques (NBT)

NBT products in the European Union are GMOs according to the ruling of the Court of Justice (ecj) of 25 July 2018, thus fall under scope of Directive 2001/18/EC and are subjected to the obligations laid down therein. Currently, no NBT products authorised as food and feed or cultivation in the European Union and in the Republic Croatia.

### 4. NON –GM novel foods

As in the others European countries, also in the Republic of Croatia very current topics are breeding and use of different kinds of insects and use of hemp –derived products and syntetic cannabinoïdes. Such products are mainly, considered as novel foods and they require a novel food authorisation before entering the market in European Union.

## FINLAND

### Legislation

As a European Union (EU) Member State, Finland applies the EU legislation to novel foods, genetically modified (GM) food and feed, contained use of genetically modified organisms (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 GM foods and feeds, Directive 2001/18/EC on deliberate release into the environment of GMOs and Regulation (EU) 2015/2283 on novel foods.

In the EU, products produced by new genomic techniques (NGTs) are subject to the legislation on GMOs. According to the work programme of the European Commission (EC) a legislative proposal on plants obtained by targeted mutagenesis and cisgenesis and their food and feed products is published during the second quarter of 2023.

The nanomaterial definition in the EC Recommendation 2011/696/EU has been updated in June 2022 (C(2022)3689). The revision of the recommendation provides the needed technical and scientific basis to adapt also the “engineered nanomaterial” definition of the Novel Food Regulation (EU) 2015/2283. This preparation of a delegated act on the definition of nanomaterials in food is ongoing on the EU level.

### GM food and feed

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

### Cultivation and field trials

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

### New genomic techniques

Finland has set up a national Working Group on New Genomic Techniques to establish the Government’s common position on the issues raised in the forthcoming legislative proposal of the EC on NGTs and its preparation.

### Non-GM novel foods

The discussion on the novel food status of different products derived from *Cannabis sativa* has continued at the EU level. Cannabidiol (CBD) products are in the novel food authorisation process, but none are authorised yet. EFSA’s statement on safety of CBD as a novel food focusing on the data gaps and uncertainties has been published in June 2022. Finland will follow any interpretations regarding hemp-derived products that have been commonly agreed upon in the EU.

The national Nanosafety Network has published a review publication “Nanomaterials as part of society: Towards a safe future of nanotechnology” (<https://julkaisut.valtioneuvosto.fi/handle/10024/164177>). The review contains information on the use of nanomaterials and safety issues, regulation and research related to nanomaterials in Finland, covering also novel foods.

## 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/dyna2/gm-register/>). Currently, GMOs are only authorised for import and use as food/feed products in Germany. If appropriate, a post-market monitoring plan (PMM) regarding the use of the GM food/feed for human/animal consumption is requested in the authorisation to verify that the conditions of use are properly applied and to monitor the consumption of the product.

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

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

## 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](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 are listed below.

- Sprink, T., Wilhelm, R., Hartung, F. (2022). **Genome editing around the globe: An update on policies and perceptions.** *Plant Physiology*, Volume 190/3, 1579–1587, <https://doi.org/10.1093/plphys/kiac359>
- Will, S., Vangheluwe, N., Krause, D., Fischer, A. R. H., Jorasch, P., Kohl, C., Nair, A., Nanda, A. K., Wilhelm, R. (2022): **Communicating about plant breeding and genome editing in plants: Assessment of European stakeholders, sources, channels and content.** *Food and Energy Security*. e415. <https://doi.org/10.1002/fes3.41>
- **DETECT – RapsNMT.** The feasibility study on detection and identification methods for genome edited plants and plant products aims to evaluate whether two specific GMOs generated by NBT (barley and oilseed rape) can be unambiguously detected and identified by DNA-based methodologies, when the respective parent line is known.
- **Bioinformatics analyses for the prediction of the reproducibility of whole genome sequencing data.** The study evaluates the reproducibility of Next Generation Sequencing data (Whole Genome Sequencing (WGS) and targeted Sequencing) produced by different service providers. The study further analyses the detection limits of GMO traces in a seed mixture.
- **Fact Finding Study.** Services of the EU Commission carried out a so-called “fact finding study” in Germany in March 2022. The study aimed at obtaining information on the implementation of the controls of organisms and products obtained by NBTs. (Official report: <https://ec.europa.eu/food/audits-analysis/audit-report/details/4543>)

#### 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](http://www.euginius.eu)) in close cooperation with official GMO detection and identification laboratories in Austria, Italy and Poland. EUGinius’ intention is to support competent authorities and private users who seek accurate information on GMOs. It provides detailed information of major and relevant issues regarding the presence, detection and identification of GMOs worldwide, with a focus on the situation in the EU.
- **International Conference on GMO Analysis and New Genomic Techniques.** The German institutes BfR, BVL and JKI together with the Joint Research Centre of the European Commission (EC-JRC) and the Secretary of the Convention of Biological Diversity (SCBD) organised the international conference in March 2023 in Berlin, Germany. Scientists from all over the world discussed the status of detection methods with a particular focus on the detection of mutations introduced with NBTs. (For more information see: <https://www.bfr-akademie.de/gmo2023/>)
- The working group "Modern Biotechnology in Integrated Plant Production" of the International Organisation for Biological and Integrated Control (IOBC-WPRS) conducted its 9<sup>th</sup> meeting from 28 to 30 September 2022 in Berlin, Germany. The meeting provided a platform for exchange of research results and to stimulate collaborative projects dealing with biotechnological applications including genetically modified organisms in agriculture, their potential for integrated production systems and their impact on the environment. (For more information see: <https://iobc-wprs.org/product/iobc-wprs-bulletin-vol-163-2023/>)

## IRELAND

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

As a member of the European Union, Ireland implements EU legislation on GM food and feed as well as novel food. Although GM crops are not cultivated in Ireland, imported feed consisting of or containing GM maize and soya among others, remain an important and reliable source of animal nutrition. The biopharmaceutical industry plays a significant role in the Irish economy and is heavily dependent on the contained use of GMMs to produce various medicines and pharmaceuticals.

Food from a total of four insect species may now be placed on the Irish market following their authorisation as novel foods in the EU (*Tenebrio molitor*-yellow meal worm, *Acheta domesticus*-house cricket, *Locusta migratoria*-migratory locust and *Alphitobius diaperinus*-lesser mealworm).

Although there is a considerable amount of information available about the purported benefits of synthetic meat (also known as cellular, cultivated, lab-grown meat), there has been no application for its authorisation as a novel food in the EU to date.

## ITALY

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

### Novel Food

- 1) As EFSA cope with the continuous increase in the number of mandates for novel foods, it has put in place collaboration schemes with external experts through framework partnership agreements.

Under the "GP/EFSA/NUTRI/2021/01" call for support activities in the safety evaluation of novel foods and nutrient sources, three Italian research groups were selected among the applicants:

- National Research Council of Italy (CNR ROME),
- Council For Agricultural Research And Economics - Research Centre For Food And Nutrition (CREA-AN Rome); Competence area "Characterization of Products (identity, composition analysis and production process)" in the application area: foods isolated or produced from plants or their parts; Absorption, Distribution, Metabolism, Excretion (ADME)" in the scope: nutrients, including vitamins, minerals and other substances.
- University Of Parma (UNIPR) Via Università 12, Parma, Italy.

Under the "GP/EFSA/MESE/2022/01-LOT 2" call for integration of new approach methodologies (NAMs) results in chemical risk assessments- risk assessment case studies, one Italian research institute was selected:

- Italian National Institute of Health (ISS) Rome.

Each case study should include a comprehensive risk assessment for a nanoengineered material or nanoform and/or a conventional material containing a fraction of nanoparticles or with internal nanostructure (nanostructured materials).

Under the "GP/EFSA/MESE/2022/01-LOT 3" call for methodological and generic case studies, one Italian research institute was selected:

- Italian National Institute of Health (ISS) Rome.

These case studies should include the development of tools and methods to cover nanoscale considerations in a particular phase of the risk assessment, e.g. for the characterisation of the material, for assessing gastrointestinal uptake; cellular internalisation; role of microbiome; etc.

The activities under this framework agreement began only in late 2022 and will continue for the next 4 years. These are risk assessment support activities in which art.36 organisations contribute in support of the EFSA WG. As the program entered its implementation phase only a few months ago, none of the assessments have yet been completed so no official data are available at the moment.

2) The Italian National Reference Laboratory (NRL) for mycotoxins and plant toxins based in ISS carries out institutional and research activities to address key issues in the area of risk assessment, specifically providing advisory activities on risk/exposure assessment, evaluation of sampling plans, evaluation of risk management strategies of mycotoxins and plant toxins. Under the remit of the LNR the exposure assessment is carried out. At present, however, there is not sufficient data available for cannabinoids in general including **cannabidiol**, which is considered a novel food by the EC (19 applications are under assessment at EFSA).

### New breeding techniques – update

Italy is actively involved in the ongoing policy action on plants produced by targeted mutagenesis and cisgenesis initiated by the European Commission.

1) In the past year, the first project funded by the Italian Ministry of Agriculture (BIOTECH\_from 2018 to 2023), which invested about 6 million euros to apply NGTs on several crops, including fruit trees, has been concluded (subprojects named CITRUS for Citrus spp., VITECH for Vitis spp. (rootstocks, wine, and table grapes), and BioSOSFru for stone fruit, strawberry, apple, pear, and kiwifruit.

Nerva, L.; Dalla Costa, L.; Ciacciulli, A.; Sabbadini, S.; Pavese, V.; Dondini, L.; Vendramin, E.; Caboni, E.; Perrone, I.; Moglia, A.; et al. The Role of Italy in the Use of Advanced Plant Genomic Techniques on Fruit Trees: State of the Art and Future Perspectives. *Int. J. Mol. Sci.* 2023, 24, 977. <https://doi.org/10.3390/ijms24020977>

2) Competent Authorities (CA) under Directive 2009/41/EC, regarding the contained use of Genetically Modified Microorganisms (GMMs) is the Ministry of Health (MoH). In compliance with the Italian Legislative Decree 206/2001, the CA authorizes GMMs installations and activities in accordance with the opinions of the Biotechnology Health Technical Committee (BHTC) of the MoH. The BHTC was established on 20th May 2015 and it has replaced, with the same functions, the previous "Inter-ministerial Commission for the GMM Evaluations" that had been laid down by Legislative Decree 206/2001. The Italian Legislative Decree 206/2001 does not regulate the contained use of GMOs other than GMMs, i.e. GM plants and GM animals. Each month about 40 notifications, covering the three areas Research, Development and Production, have to be evaluated by the BHTC for their approval.

Contained use of GMMs evaluated for authorization, hold all areas Biotech Sectors (red-white and green) and belong mostly to containment classes 1 and 2, except for a small number that belong to containment class 3, often used for research. Most of those GMMs authorized have been obtained by editing techniques (CRIPR Cas 9 and also other techniques), short interfering RNA, microRNA, etc. In some cases, editing techniques have also been used and authorized for advanced therapy drug development (ATMP).

#### Other related activities

1) In collaboration with the National Institute for Insurance against Accidents at Work (Inail), the CA is carrying out the scientific research project entitled: "**Prevention and protection of health and the environment in case of use of advanced biotechnological techniques**". The project aims to carry out a study aimed at training and sensitizing research staff, persons responsible for supervision and safety and employees, in order to ensure compliance with Directive 2009/41/EC. The main project objectives therefore consist in: increase the culture and skills for the prevention and protection of health and the environment in the case of contained use of GMMs through the creation of a network between the RSPPs of the Universities and Hospitals and the Institutions for an effective and systematic comparison on the basic knowledge and on the new work evidence. The tool for the creation of the network is the website [www.biotechsafety.org](http://www.biotechsafety.org). Furthermore an interactive application was also developed, called "SafLab", as a database that collects suitable checklists for the evaluation of contained use of GMM (<http://ec2-35-180-134-84.eu-west-3.compute.amazonaws.com:8080/>). It can also be used for training purposes.

2) The METROFOOD-IT project funded with 17.8 million euros from the National Recovery and Resilience Plan (PNRR) and coordinated by ENEA (Italian National Agency for New Technologies, Energy and Sustainable Economic Development) aims to strengthen Italian scientific excellence in food safety through the development of platforms and services for quality, authenticity and traceability of raw materials and products and for the digitization of the sector. ENEA will provide 11 infrastructures and laboratories located in 5 research centers, 6 operational units as well as ICT technologies, such as apps, software and models to provide services and develop an open data platform useful to researchers, inspection and control agencies, policy makers, companies and citizens to increase quality, safety, traceability but also "food transparency" and circular economy. The National Institute of Metrological Research (INRiM) and several Italian universities (Bari, Federico II of Naples, Molise, Parma, Sapienza of Rome and Siena) are participating in the project. Specifically, to achieve these goals ENEA will deploy: the metabolomics, atomic spectroscopy, mass spectrometry and nanoparticle characterization, microbiology laboratories and the Calliope gamma irradiation facility at the Casaccia Research Center (Rome); the Smart sensors & IoT laboratory at the Frascati Research Center (Rome); the Agrifood Reference Materials and NMR Facility at the Trisaia Research Center (Matera); the Circular Bioeconomy Facility at the Brindisi Research Center; and the CRESCO6 supercomputer at the Portici Research Center (Naples).

## 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 February 2023, 331 GM foods (12 potato; 29 soybean; 3 sugar beet; 209 maize; 24 oilseed rape (canola); 48 cotton; 5 alfalfa; and 1 papaya) and 75 GM food additives have undergone safety assessment and been announced in the Official Gazette; out of these foods and food additives, 1 foods and 7 food additives have undergone safety assessment and been announced in the Official Gazette since the last meeting in May 2022.

### 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 2023, 103 GM feeds (20 oilseed rape (canola); 33 maize; 19 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, 3 feeds have undergone safety assessment and been announced in the Official Gazette since the last meeting in March 2022.

### 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 commercialisation. Feeds or feed additives obtained through recombinant DNA technology are not subject to the notification.

Notification is not required for crossbred progeny that has been obtained by crossbreeding conventional products and others\* 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/](https://www.maff.go.jp/e/policies/ap_health/petfood/)

## KOREA

### 1. Developments related to implementation of national biosafety framework

#### 1.1 Risk assessment/regulatory decisions

In Korea, Living Modified Organisms (LMOs) are regulated under "Act on Trans-boundary Movement, etc. of Living Modified Organisms." The objective of the Act is to aid the prevention of any adverse effects of LMOs on public health and the conservation of sustainable biological diversity. The Act also ensures safety in the development, production, import, export and distribution of LMOs. Assigned government departments are in charge of the risk assessment and management of LMOs dependent on the use

To date, 176 events for feed, 197 events for food, 102 events for industrial use, and 2 events for health have been approved in Korea, except for environmental release or cultivation.

During 2022, new approval events include:

- 6 events have been approved for food: Maize (1), Cotton (5)
- 3 events have been approved for feed: Maize (2), Cotton (1)
- 5 events have been approved for industrial uses: Microbes (5)

Organisms assessed	event	Company	Type of use	Introduced trait
Maize	3272xBt11xMIR162xMIR604 xTC1507x5307xGA21	Syngenta	Food, Feed	Insect resistance, herbicide tolerance, $\alpha$ -amylase activation
<i>E.coli</i>	GC001, GC002, GC003, GC004	GeneChem	Industrial use	3'-Sialyllactose sodium salt process enzyme production
Microbe	KCCM80236	CJ	Industrial use	PHA production
Maize	DP-202216-6	Corteva	Feed	Herbicide tolerance, yield
Cotton	GHB811xT304-40xGHB119 xCOT102xMON88701	BASF	Feed	Herbicide tolerance, insect resistance
Cotton	GHB811xLLcotton25xMON88701	BASF	Food	Herbicide tolerance
Cotton	MON88702xMON15985xCOT102 xMON88701xMON88913	Monsanto	Food	Herbicide tolerance, insect resistance
Cotton	T304-40xGHB119xCOT102	BASF	Food	Herbicide tolerance, insect resistance
Cotton	GHB811xT304-40xGHB119 xCOT102xMON88701	BASF	Food	Herbicide tolerance, insect resistance
Cotton	281/3006xCOT102xDAS-81910-7	Corteva	Food	Herbicide tolerance, insect resistance

(KBCH)

Further information is available at [http://www.biosafety.or.kr/portal/page/f\\_02](http://www.biosafety.or.kr/portal/page/f_02)

### 1.2 Public engagement and outreach activities on risk management

Unapproved LM rapeseed was discovered for the first time at a flower festival in 2017, raising concerns about the safety and environmental impact of living modified organisms (LMOs). To address these concerns and engage the public in LMO safety management, Ministry of Agriculture, Food and Rural Affairs (MAFRA) collaborated with NGOs to conduct post-safety management and environmental impact assessments.

By working together on joint investigations and ongoing monitoring, the management area for unapproved LM rapeseed is getting gradually smaller. In addition, to prevent the environmental release of LMO for feed, MAFRA partners with NGOs on annual investigations of feed factories and transportation routes.

These public engagement and outreach activities have helped to strengthen communication between LMO safety management and NGOs, fostering a greater understanding of the potential risks and benefits of genetically modified organisms.

## **2. Developments related to new breeding techniques (NBTs)**

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

As the initiative of the Ministry of Trade, Industry and Energy (MOTIE), a partial amendment bill to the Transboundary Movement, etc. of Living Modified Organisms Act (LMO Act) has been submitted to the National Assembly in July 2022 to allow the request for exemption from risk assessment if the novel living modified organisms(LMO) using new technologies such as genome editing techniques are confirmed to be safe at a level similar to natural mutation or traditional breeding through the preliminary review system.

#### **Main contents**

##### **A. Exemption from risk assessment for new LMOs (new Article 7.3)**

(1) A person who has developed a novel LMO may apply to the head of the competent national authority for "exemption from risk assessment" if the novel LMO does not introduce foreign genes during its development process, or if any foreign genes introduced during development are not present in the final product and are at a level similar to traditional breeding or natural mutation.

(2) If the head of the competent national authority receives an application for exemption from risk assessment and recognises that the novel LMO has ensured safety at the level of natural mutation, the head of the competent national authority may exempt it from risk assessment.

## **LATVIA**

### **1. Developments related to implementation of national biosafety framework**

#### *1. Risk assessment/regulatory decisions*

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

In March 2023 Competent Authority of Latvia received the first application for field trials of GM potatoes resistant to Colorado beetles. Currently there is no GM crops fields or cultivation in Latvia 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.

In 2022 the State Scientific Institute "Institute of Food Safety, Animal Health and Environment "BIOR" regularly took part at centralised EU GMO risk assessment procedure. BIOR provided opinion on 4 applications in respect of GMO placing on the EU market.

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

## *2. 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.

## **2. Updates regarding international activities**

### *1. Participation in/hosting international symposia/fora*

- On May 24<sup>th</sup> 2022, European Plant Science Organisation (EPSO) organised 6<sup>th</sup> informal science – policy meeting on genome editing - Improving legislation and start flagships to better address climate, environmental, food and health challenges. The aim of the meeting was exchanging views on the current situation of genome editing in Europe and possible next steps to enable Europe better addressing climate change, achieving food and nutritional security and establishing a sustainable agriculture in Europe and world-wide.
- On June 21<sup>st</sup> 2022, Expert Event on New Genomic Techniques – Regulation, Risk assessment, Sustainability and Challenges for the Food Chain took place in Vienne. This event was organised by Environment Agency Austria. On 24 September 2021 the European Commission published the inception impact assessment “legislation for plants produced by certain new genomic techniques”. The goal of this event was to discuss this legislative initiative and its implications for a) risk assessment, b) organic and GM-free production and c) the link to the goals of the European Green Deal. Accordingly, three sessions were organised where those issues were addressed by keynote speakers, panel and plenary discussions.
- On November 15-16<sup>th</sup>, 2022 the Global Biotechnology Regulators Forum was organised by the U.S. Food and Drug Administration in Brussels. The aim was to reconvene and exchange experiences in plant and animal biotechnology, including genome editing, and discuss challenges and opportunities in this area.
- On November 28-29<sup>h</sup>, 2022 the Ministry of Agriculture of the Czech Republic supported by the European Food Safety Authority (EFSA) hosted the international scientific conference "European Agri-Food Sustainability & Innovation. The main topics of the conference were: Strategies of Security European Agri-Food production, Safety and Sustainable Agri-Food sector, Challenges for modern agriculture - e.g. new genomic techniques and Climate-smart agriculture.

## **3. Developments related to new breeding techniques (NBTs)**

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

In the European Union, products of NBTs (usually referred to as new genomic techniques, NGTs) are subject to the legislation on genetically modified organisms (GMOs) which is contained in several main legislative acts (Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No 1830/2003, Directive 2009/41/EC). They establish procedures requiring an authorisation for the deliberate release of GMOs into the environment for experimental purposes as well as for the placing on the market and cultivation of GMOs and GM food and feed. This authorisation system is based on an assessment of the risks to human and animal health and the environment, and includes requirements for post-authorisation monitoring, labelling and traceability.

In April 2021, the European Commission published a study regarding the status of New Genomic Techniques under Union law and the Commission 2023 work programme includes the adoption of a legislative proposal on plants obtained by targeted mutagenesis and cisgenesis and their food and feed products during the second quarter of 2023. An Inception impact assessment was published in 2021 outlining the objectives and main issues to be considered. A public consultation was conducted (29 April 2022 - 22 July 2022) to seek views and evidence from the public and interested parties on a possible new regulatory framework for plants derived from these techniques.

*Specific cases of application, assessment and decision*

One application for placing on the market of genetically modified maize DP-915635-4 (Application EFSA-GMO-NL-2020-172) produced by NBT for food and feed uses is currently under risk assessment. This event was created by site-specific integration using two sequential transformation steps to insert an integration site sequence, at a specific location of the maize genome using biolistic and a CRISPR- Cas9-mediated targeted insertion process, and to insert the intended expression cassettes in the maize genome using Agrobacterium-mediated transformation.

## NETHERLANDS

The Netherlands would like to share the outcomes of a national four-year research undertaking on the safety of biotechnology, which was finalised recently.

This research focused on the potential molecular effects of gene editing on crops. It comprised two projects, which were funded by the Dutch Ministry of Infrastructure and Water Management through the Research Programme “Biotechnology and Safety” within the National Research Council’s Applied and Engineering Sciences domain (2018-2022, overall budget 7 million Euros for 10 projects). More information on the program can be found at the following website: <https://www.nwo.nl/en/researchprogrammes/research-programme-biotechnology-and-safety>

The outcomes were also presented jointly during the Tour de Table session. In more detail, the projects were structured as follows:

**Project #1** (led by Dr J Vossen): Assessing safety-by-design in novel plant breeding techniques by comparing native gene based modification with classical breeding:

*This project used conventional, gene-editing- and cisgenesis-based approaches for introducing late blight resistance genes into potato and their impact on the characteristics of the resulting potato lines. A safe-by-design strategy was followed by limiting the options for the selection of genes and methods of modification that could be used for this purpose. Statistical approaches were studied for their ability to support the interpretation of the wealth of data coming from extensive omics analyses performed on these crops. Moreover, the possibility to further refine the statistical approaches recommended by the EU guidelines for the safety assessment of GM crops has been explored (website: <https://www.nwo.nl/en/projects/15815>)*

**Project #2** (led by Dr R. de Maagd): Specificity and side-effects of mutagenesis by nuclease-induced breaks and Cas9-mediated epigenome editing in plants; identifying hazards, analysing risks and creating inherent safety

*This project investigated the precision and potential unintended effects of site-directed nucleases (CRISPR Cas-based) used for both gene editing in Arabidopsis thaliana and tomato. These potential unintended effects include chromosome instability, chromosome deletions, and off-target mutations. Within its overview, it also took stock of such effects reported by others. The outcomes are considered to provide useful background information to the risk assessment community. (website: <https://www.nwo.nl/en/projects/15792>)*

## PARAGUAY

Activities involving agricultural biotechnology are regulated in Paraguay, with the first set of regulations established in 1997 and subsequently complemented by additional legal instruments. The most recent of these, a 2012 Decree, established the National Agricultural and Forestry Biosafety Commission (CONBIO), which is coordinated by the Ministry of Agriculture and Livestock (MAG). This Commission has the responsibility of assessing, analysing, and issuing recommendations on all issues pertaining to the introduction, field trials, pre-commercial and commercial release, and other intended uses of genetically modified crops.

### Commercial Approvals

The following events were released from 2022 to 2023:

Decision No.	Organism	Event	Regulatory mechanism
556/2023	Wheat	IND-ØØ412-7	Differentiated treatment for the commercial release of GM crops that have been approved in third countries (Resolution MAG 1030/2019 and 1071/2019).
550/2023	<i>Saccharomyces cerevisiae</i>	M23541 (Genetically modified yeast for ethanol production)	Commercial release of novel GM (Resolution MAG 027/2015).
549/2023	<i>Saccharomyces cerevisiae</i>	M12156 (Genetically modified yeast for ethanol production)	Commercial release of novel GM (Resolution MAG 027/2015).
548/2023	<i>Saccharomyces cerevisiae</i>	SCY014 (Genetically modified yeast for ethanol production)	Commercial release of novel GM (Resolution MAG 027/2015).
272/2022	Maize	SYN-E3272-5 x SYN-BTØ11-1 x SYN-IR162-4 x MON-ØØØ21-9	Differentiated treatment for the commercial release of GM crops that have been approved in third countries, (Resolution MAG 1030/2019 and 1071/2019).
272/2022	Maize	SYN-E3272-5	Differentiated treatment for the commercial release of GM crops that have been approved in third countries, (Resolution MAG 1030/2019 and 1071/2019).
270/2022	Maize	MON-95379-1	Differentiated treatment for the commercial release of GM crops that have been approved in third countries, (Resolution MAG 1030/2019 and 1071/2019).
268/2022	Maize	MON-ØØØ3-6 x ACS-ZMØØ3-2 x DAS-4Ø278-9	Differentiated treatment for the commercial release of GM crops that have been approved in third countries, (Resolution MAG 1030/2019 and 1071/2019).
266/2022	Soybean	BCS-GM151-6	Differentiated treatment for the commercial release of GM crops that have been approved in third countries, (Resolution MAG 1030/2019 and 1071/2019).
265/2022	Maize	MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-ØØØ3-6 x SYN-IR162-4 x DAS-4Ø278-9	Differentiated treatment for the commercial release of GM crops that have been approved in third countries, (Resolution MAG 1030/2019 and 1071/2019).

### Participation in International Activities

Date	Activities
May 16-20, 2022	36th Meeting of the Working Party on the Harmonisation of Regulatory Oversight in Biotechnology and the OCDE 9th Meeting of the Working Party for the Safety of Novel Foods and Feeds, Paris, France.
April 20, 2022	Meeting of the Commission for Agricultural Biotechnology of SGT No. 08 of MERCOSUR, Asunción, Paraguay.
August 29 to September 2, 2022	Technical mission of government officials from Argentina, Paraguay, and Uruguay to the United States held in Washington, USA.
September 12-19, 2022	4th International Workshop on Regulatory Approaches for Agricultural Applications of Animal Biotechnologies, San Pablo, Brazil.
October 14, 2022	Breaking down regulatory barriers to bring new technology and innovation to farmers (CropLife International and Agriculture, Agri- Food Canada).
October 25-26, 2022	Meeting GT5 "Public policies in biotechnology" of the Southern Agricultural Council (CAS), Montevideo, Uruguay.
October 26-27, 2022	Meeting of the Commission for Agricultural Biotechnology of SGT No. 08 of MERCOSUR,

	Montevideo, Uruguay.
December 10, 2022	Side event on "The contribution of local LMOs to the Sustainable Development Goals" (Co-organised with Brazil, Argentina, Uruguay, Kenya, Nigeria, Bangladesh and the Alliance for Science), Montreal, Canada.
December 20, 2022	15th Conference of the Parties (COP-15), 10th meeting of the Conference of the Parties, Cartagena Protocol on Security of Information Biotechnology (MOP-10), of the United Nations Convention on Biological Diversity, Montreal, Canada.
March 20-21, 2023	Meeting of the Commission for Agricultural Biotechnology of SGT No. 08 of MERCOSUR, Buenos Aires, Argentina.

## PHILIPPINES

### 1. Developments related to implementation of national biosafety framework

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

Issuance of the DOST-DA-DENR-DOH-DILG Joint Department Circular No.1, series of 2021 on March 2022.

#### **Salient provisions of the new JDC include:**

- Joint Assessment Group composed of qualified representatives from concerned Departments' Biosafety Committees, is being established to evaluate GM applications
- Timeline of processing of application is shorter (max. 40 days) pursuant to the Ease of Doing Business Act
- Biosafety Permit for direct use and commercial propagation has no expiration and shall be valid unless revoked
- No biosafety permit application required for stacked trait products
- Data Transportability -applications for permits for regulated articles developed in other countries may be filed directly for a Biosafety Permit for Field Trial

#### 2. Risk assessment/regulatory decisions

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

Transformation event	Type of Use	Trait
Soybean GMB151	For food and feed, or for processing	Herbicide Tolerant
EE-1 eggplant	For commercial propagation/planting	Resistant to Insect Eggplant Fruit and Shoot Borer (EFSB)
High Iron and Zinc Rice 1030-031	For field trial	Increased iron (Fe) and zinc (Zn) trait in the endosperm
High Iron and Zinc Rice 1030-039	For field trial	Increased iron (Fe) and zinc (Zn) trait in the endosperm

Regulatory decisions are uploaded in the BPI Biotech Website: <http://biotech.da.gov.ph/index.php>

#### 3. Risk management measures

The BPI imposed the following measures as indicated in the permit issued:

- For food and feed, or for processing
  - The regulated article shall be imported solely and exclusively for direct use as food and feed, or for processing and not to be used for field trial or commercial propagation
  - In case of accidental release (e.g. road spillage) of seeds not approved for commercial propagation, the permit holder shall assist the importers in the management of spillage and report to BPI immediately
- For field trial

- Implementation of temporal or isolation distance
  - Ensuring security of experimental area (only authorized person can access the site, free from stray animals, birds, rodents, etc.)
  - Disposal of regulated planting materials after harvest
  - Monitoring of volunteer plants (fallow period monitoring)
  - Implementation of contingency measures when necessary
  - For commercial propagation
    - Prohibition of planting GM crop in areas that are not identified as agricultural lands and in areas with known ordinance prohibiting the propagation of GM crops
    - Indicating in the seed bag label that product is not intended for propagation in prohibited areas
4. New and emerging regulatory challenge(s)
- Identification and detection of unauthorized/unapproved GMOs
  - Low level presence still a concern on trade disruption due to delay in the drafting of policy
5. Public engagement
- Serving as resource person to face-to-face public hearing conducted as a requirement of field trial

## 2. Updates regarding international activities

- a. Participation in/hosting international symposia/fora relating to biosafety
- ASEAN Genetically Modified Food Testing Network (19TH GMFNET) on July 7, 2022
  - International short-course for Agricultural Biotechnology, and Product Stewardship Program on July 31 to August 12, 2022
  - Agriculture biotechnology seminar series – Seminar 4: Development of regulatory guidance for products of agricultural biotechnology on November 22, 2022
  - International Conference on GMO Analysis and New Genomic Technologies on March 14 to 16, 2023
- b. Specific cases of use of OECD tools and information
- The assessors referred to OECD consensus documents during the assessment of GM applications

## 3. Developments related to new breeding techniques (NBTs)

- a. Development/review/amendment of national strategies, regulations and guidance
- Memorandum Circular No. 8, series of 2022 was issued in 2022 which provides rules and procedure to evaluate and determine when products of plant breeding innovations (PBIs) are covered under the GMO regulations. Products of PBIs that do not contain novel combinations of genetic materials obtained through the use of modern biotechnology are not covered by GMO regulations and will be considered as conventional products
- b. Specific cases of application, assessment and decision
- BPI issued a decision on the regulatory status of reduced browning banana. Certificate of Non-Coverage from the GMO regulations was issued on March 15, 2023.

## SLOVENIA

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

### GMOs in food and feed

The competences and the status of GM products in Slovenia remains unchanged. The Competent Authority for GMOs in food and in feed is The Administration of the Republic of Slovenia for Food Safety, Veterinary Sector and Plant Protection, which is the body within the Ministry of Agriculture, Forestry and Food. Despite the good results of the

annual monitoring of the presence of GMO's, we continue to monitor the situation in our market. On an annual monitoring basis on GMOs in food and feed, we are establishing that feed consisting of or containing GMO is often on the Slovenian market, but we can rarely find the food consisting of or containing GMOs, same goes for presence of unapproved GMOs. In 2022, we tested samples of feed and food. Last year Slovenia started monitoring the presence of genetically modified microorganisms (GMM) with antibiotic resistance marker genes in food and feed. In 2023, Slovenia is continuing the testing of the presence of GMOs in food and feed.

### **Monitoring of GMOs in seed**

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

### **GMOs in cultivation**

Slovenia has no commercial cultivation of GMOs, neither field trials. The Competent Authority for coexistence of crops is The Ministry of Agriculture, Forestry and Food.

In 2022 there were no plant samples tested for the presence of GMOs under the law on the coexistence of crops with genetically modified plants. We are planning to collect and test approximately 10 samples in 2023.

### **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. Department of Biotechnology and Systems biology at NIB has 80 qPCR accredited methods for qualitative and quantitative testing of genetically modified organisms in foodstuffs and agricultural products of plant origin (further methods are yearly in the process of verification), 3 methods for quantification by dPCR and 6 methods for detection of genetically modified microorganisms (3 methods for the screening of antibiotic resistance marker genes (AMR genes) and 3 methods for specific gene detection (Protease 1, Protease 2 and  $\alpha$ -amylase). In 2022 NIB accredited 7 methods for detection of genetically modified organisms.

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

### **New Genomic Techniques (NGT)**

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 still underway. Slovenia participates in the discussion about NGT.

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. In 2023 an update of ENGL report from 2019 "Detection of food and feed plant products obtained by new mutagenesis techniques" is in preparation.

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

NIB has participated at International Conference on GMO Analysis and New Genomic Techniques from 14-16 March 2023 in Berlin.

NIB has also been using one of the new breeding techniques, CRISPR/cas9, for functional analysis of potato genes and miRNAs involved in biotic stress response. Moreover, the use of these technologies is further being expanded to grapevine within research project financed by Slovenian National Research Agency: J4-2544 CRISPR/CAS9-mediated targeted mutagenesis for resistance of grapevine and potato against phytoplasmas (1.11.2020—31.10.2023).

NIB is preparing a report on the determination of the impact of new genomic techniques in the field of agriculture based on the project launched by Ministry of Agriculture, Forestry and Food in 2022 to provide expert arguments when drafting EU legislation.

### **Non-GM Novel foods**

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

### **Nano**

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

## **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 9<sup>th</sup> 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 **black bold text**. There were no new general release approvals since the last meeting (Table 2). In both Tables 1 and 2, the details for those events indicated in **blue bold text** were submitted to the OECD Secretariat for updating the information for South Africa in the OECD BioTrack Database.

**Table 1.** Commodity clearance imports approved for food and feed in South Africa (2021-2022).

Source: <http://www.dalrrd.gov.za/>

Event	Crop	Trait	Company	Year approved
<b>HB4 (IND- 00410-5)</b>	<b>Soybean</b>	<b>Abiotic stress tolerant Herbicide tolerant</b>	<b>Bioceres Crop Solutions</b>	<b>2022</b>
<b>HB4 (IND-00412-7)</b>	<b>Wheat</b>	<b>Abiotic stress tolerant Herbicide tolerant</b>	<b>Trigall Genetics SA</b>	<b>2022</b>
<b>3272 x Bt11 x MIR162 x MIR604 x TC1507 x 5307 x GA21</b>	<b>Maize</b>	<b>Insect resistance Herbicide tolerance</b>	<b>Syngenta SA</b>	<b>2022</b>
<b>DAS-44406-6</b>	<b>Soybean</b>	<b>Herbicide tolerance</b>	<b>Corteva Agriscience RSA</b>	<b>2022</b>

DAS-81419-2 x DAS-44406-6	Soybean	Insect resistance Herbicide tolerance	Pioneer Hi-Bred RSA	2022
NK603 x T25 x DAS-40278-9	Maize	Herbicide tolerance	Corteva Agriscience RSA	2022
GMB151	Soybean	Insect resistance Herbicide tolerance	BASF	2021
GHB811	Cotton	Herbicide tolerance	BASF	2021

**Table 2.** General release approved for importation/exportation, commercial planting, and for food and/or feed in South Africa (2021-2022). 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

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

### South Africa's Regulatory Approach for New Breeding Techniques

*Department of Agriculture, Land Reform and Rural Development (DALRRD)*

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

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

### 6. Genome editing research and activities in South Africa

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

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

Project Title: Developing a haploid inducer system for sunflower (in collaboration with the University of Pretoria)

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

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

Aim: This study aims to develop virus resistance in a cucurbit species using single base pair editing. The project has just started with both the plant and virus involved currently being evaluated.

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.

There is 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 (dynamain 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.

Update: The CRISPR/Cas9 T-DNA vectors targeting eIF4E were assembled and transformed into sweet potato meristems. Plantlet regeneration is currently underway.

*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. Their team has produced 53 putative mutants with indications of some edits. They are also routinely performing these edits transiently and have now published a provisional patent, paper, and technology demonstrator around their work.

Paper: Advaita Acarya Singh, Priyen Pillay, Previn Naicker, Kabamba Alexandre, Kanyane Malatji, Lukas Mach, Herta Steinkellner, Juan Vorster, Rachel Chikwamba and Tsepo L. Tsekoa. 2022. Transient proteolysis reduction of *Nicotiana benthamiana*-produced CAP256 broadly neutralising antibodies using CRISPR/Cas9. *Frontiers in Plant Science*. Volume 13 | <https://doi.org/10.3389/fpls.2022.953654>

Patent: South African Provisional Patent Application No. 2021/06641  
PLANT-BASED RECOMBINANT PROTEIN EXPRESSION SYSTEM

Inventors: 1. Priyen PILLAY; 2. Advaita Acarya SINGH; 3. Tsepo Lebiletsa TSEKOA; 4. Rachel Kerina CHIKWAMBA; 5. Juan Barend VORSTER; 6. Karl Josef KUNERT.

Technology Demonstrator: A method for performing transient CRISPR/Cas9-mediated genome editing in *Nicotiana benthamiana*: targeting deleterious protein-degrading proteases for improving the quality and quantity of recombinant plant-produced proteins

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*. 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.

Phenotypic observations were made for each of these plants and leaf material for DNA extraction was collected for 43 plants. Screening of plants is currently underway.

They are also performing genome editing in bacteria in order to enhance yields for desirable molecules used in various industries. Thus far, they have managed to develop a protocol for genome editing in *Rhodococcus*. They are also developing a protocol for genome editing in *Lactobacillus* and they are currently screening putative mutants to test its efficacy.

#### *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 have also started a transgenic approach, transforming potatoes with constructs to mutate GWD1.

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

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

#### **South African database on genome editing**

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

## **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 ([www.biosafety.org.za](http://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://biovisioneastfrica.com/publications/Cassava%20biology%20document.pdf>

#### **Cotton**

- [http://www.oalis.oecd.org/olis/2008doc.nsf/LinkTo/NT0000794A/\\$FILE/JT03257](http://www.oalis.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.ogtr.gov.au/internet/ogtr/publishing.nsf/650f3eec0dfb990fca25692100069854/330c90ca0496618fa2574d0001d4dd6/$FILE/biologymaize08.pdf)
- [http://www.oalis.oecd.org/olis/2003doc.nsf/LinkTo/NT0000426E/\\$FILE/JT00147699.PDF](http://www.oalis.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.oalis.oecd.org/olis/2000doc.nsf/LinkTo/NT00002C3A/\\$FILE/00085953.PDF](http://www.oalis.oecd.org/olis/2000doc.nsf/LinkTo/NT00002C3A/$FILE/00085953.PDF)

#### **Sugar Beet**

- [http://www.oalis.oecd.org/olis/2001doc.nsf/LinkTo/NT0000096E/\\$FILE/JT00118011.PDF](http://www.oalis.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](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/sugarcane-3/$FILE/biologysugarcane.pdf)

#### **Sunflower**

- [http://www.oalis.oecd.org/olis/2004doc.nsf/LinkTo/NT000092F2/\\$FILE/JT00177388.PDF](http://www.oalis.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.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/wheat-3/$FILE/biologywheat08.pdf)
- [http://www.oalis.oecd.org/olis/1999doc.nsf/LinkTo/NT00002B2A/\\$FILE/04E94444.PDF](http://www.oalis.oecd.org/olis/1999doc.nsf/LinkTo/NT00002B2A/$FILE/04E94444.PDF)

## **SPAIN**

### **1. Developments related to implementation of national biosafety framework**

#### ***Risk assessment/regulatory decisions***

Talking about risk assessment/regulatory decisions and procedures applicable in Spain, activities of contained use and deliberate release into the environment with genetically modified organisms (GMOs) follows the scope of the EU legislation framework. Nevertheless, national legislation and procedures have been drafted to adequately apply EU provisions. This information can be consulted in the following links:

<https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/omg/>

<https://www.miteco.gob.es/es/calidad-y-evaluacion-ambiental/temas/biotecnologia/organismos-modificados-geneticamente-omg/>

In this context, resolutions authorizing the above-mentioned activities are available in the national public register of GMO's: <https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/omg/registro-publico-omg/>

#### **a) Contained use activities in research facilities**

Since the last meeting in May 2022, sixty-six (66) new facilities for different contained use activities have been notified in Spain and assessed by the National Commission of Biosafety (39 of biosafety level (BSL) 1 and 27 of BSL 2).

153 different activities have been notified to be carried out in these facilities: 41 are classified as risk 1 (BSL 1); 79 as risk 2 (BSL2) and 33 as biological level of risk 3 activities (BSL3).

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.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 of GMO's into the environment

Since May 2022, twenty-six (26) applications for deliberate release trials (including field trials with genetically modified plants and human and animal clinical trials with GMOs) have been notified and assessed by the National Commission of Biosafety:

- Just only one field trial with plant: Comparative study of two transgenic tobacco lines with Thaumatin-2 protein expression in seed in relation to its growth rate, production of seeds and yield of recombinant protein in seeds.
- On the other hand, twenty-five (25) human clinical trials have been notified, many of them are different genetically modified viruses (Adenovirus, AAV, MVA, VSV, etc.), and others using human cells (T lymphocytes, CAR-T).

For detailed information:

[https://www.miteco.gob.es/es/calidad-y-evaluacion-ambiental/temas/biotecnologia/organismos-modificados-geneticamente-omg-notificaciones-y-autorizaciones/liberac\\_voluntaria.aspx](https://www.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 2022, the estimated growing area for Bt maize (MON10) in Spain was 67.620,05 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](https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/omg/registro-publico-omg/superficie_cultivada.aspx)

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 was published 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.”

During 2023, Spanish competent authorities will continue to enforce different measures to control teosinte as a noxious agricultural weed in those regions where this plant is detected.

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

National Official Control plan on deliberate release of GMOs for food and feed production. This plan provides rules for official control with the objective to verify the compliance of the GMO regulation in seeds, field trials and cultivation of maize. This plan is in force since 2020. A report on the application of this plan is published yearly.

[PNCOCA 2021-2025 \(mapa.gob.es\)](https://www.mapa.gob.es/pnco2021-2025).

#### ***Risk management measures***

In the case of deliberate release of GMO for experimental purposes, once the field trial is authorized, it is compulsory that the competent authority performs several official controls. The objective is to verify that all the requirements set by the National Commission of Biosafety are met. These monitoring activities can be consulted in the annual report of the National Official Control plan on deliberate release of GMOs for food and feed production.

**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 \(miteco.gob.es\)](https://www.miteco.gob.es/consultas)

**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.

**2. Developments related to new breeding techniques (NBTs)****Development/review/amendment of national strategies, regulations and guidance**

The Interministerial Council of GMO (CIOMG), 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. During 2022 and 2023, Spain has attended to a high number of experts meetings celebrated in the EU Commission to discuss a future initiative for plants produced by certain new genomic techniques. Several consultation processes with stakeholders, Member States and General Public have taken place in 2022 and a new Commission proposal is expected to be published during the second quarter 2023. The detailed roadmap of the legislative procedure can be followed here: [https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en)

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/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>

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

On the other hand, and taking into account that discussions have continued at the EU committees of Member States Competent Authorities on various issues related to NGT, the CNB has worked in an *Ad-hoc* group of experts on these techniques to identify equivalence criteria that may be useful to guide which products should not be regulated as classic GMOs, although in any case, the case-by-case approach should always prevail and be applied.

This *Ad-hoc* working group at the CNB also made comments to the EFSA GMO Panel (2022) on “Statement on criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis. EFSA Journal 2022;20(10):7618, 12 pp. <https://doi.org/10.2903/j.efsa.2022.7618>.

These two CNB Reports were sent to the CIOMG and to the European Commission.

**Any other information related to NBTs.**

The Ministry of Agriculture, Food and Fisheries’ website includes a 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/>

In June 2022, the Ministry of Agriculture organised a webinar to promote awareness of the initiative at national level. It was focused on the public consultation and different stakeholders were invited to contribute by giving their views on the main elements of the regulatory proposal like risk assessment, traceability, enforcement etc.

[https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/mejora-genetica/jornada\\_nbt.aspx](https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/mejora-genetica/jornada_nbt.aspx)

## UNITED STATES

### Executive Order

On September 12, 2022, President Biden issued [Executive Order \(E.O.\) 14081](#), “Advancing Biomanufacturing and Biotechnology Innovation for a Sustainable, Safe, and Secure Bioeconomy,” with the goal of accelerating biotechnology innovation and growing America's bioeconomy across multiple sectors, including health, agriculture, and energy. Among other objectives, E.O. 14081 aims to support the safe use of biotechnology by clarifying and streamlining regulations in service of a science- and risk-based, predictable, efficient, and transparent regulatory system to support the safe use of products of biotechnology. E.O. 14081 directs the Environmental Protection Agency (EPA), the Food and Drug Administration (FDA), and the U.S. Department of Agriculture (USDA) to:

- identify any regulatory ambiguities, gaps, or uncertainties in the Coordinated Framework for the Regulation of Biotechnology, through engaging with developers and stakeholders and through horizon scanning for novel biotechnology products;
- provide plain-language information on the regulatory roles, responsibilities, and processes of each agency;
- provide a plan with processes and timelines to implement regulatory reform; and build upon the Unified website for Biotechnology Regulation.

On December 20, 2022, the White House Office of Science and Technology Policy (OSTP) in coordination with EPA, FDA, and USDA issued a [Request for Information](#) for relevant data and information, including case studies, to help identify regulatory ambiguities, gaps, or uncertainties in the Coordinated Framework for Regulation of Biotechnology, particularly as related to new and emerging biotechnology products. Information provided will help regulatory agencies improve the clarity and efficiency of the regulatory processes for biotechnology products as described in E.O. 14081. The comment period closed on February 3, 2023.

### 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 May 2022, FDA completed consultations on the following new plant varieties:

1. MON 95379 corn (MON-95379-3) from Bayer CropScience LP (Bayer) was genetically engineered to express the Cry1B.868 protein and a modified Cry1Da<sub>7</sub> protein from *Bacillus thuringiensis* to confer resistance to lepidopteran pests.
2. MON 94100 canola (MON-94100-2) from Bayer was genetically engineered to express a modified dicamba monooxygenase from *Stenotrophomonas maltophilia* that confers tolerance to the herbicide dicamba.
3. DP23211 corn (DP-Ø23211-2) from Pioneer Hi-Bred International, Inc. (Pioneer) was genetically engineered for resistance to western corn rootworm by introducing DNA sequences containing inverted repeat segments of the *smooth septate junction protein 1* (*dvssj1*) gene from western corn rootworm *Diabrotica virgifera virgifera*, which produces double-stranded RNA transcripts that trigger RNA-mediated silencing of *dvssj1*. DP23211 corn was also engineered to express the IPD072a protein, which confers protection against certain coleopteran pests. In addition, DP23211 corn was engineered to express phosphinothricin N-acetyltransferase (PAT) from *Streptomyces viridochromogenes* which confers tolerance to glufosinate ammonium herbicide, and phosphomannose isomerase from *Escherichia coli* which served as a selectable marker.
4. MON 87429 corn (MON-87429-9) from Bayer was genetically engineered to express: dicamba monooxygenase from *S. maltophilia* that confers tolerance to dicamba herbicide; a modified R-2,4-dichlorophenoxypropionate dioxygenase from *Sphingobium herbicidovorans* which confers tolerance to aryloxyphenoxypropionate acetyl coenzyme A carboxylase inhibitors (“FOPs” herbicides such as quizalofop) and to some synthetic auxin herbicides, including 2,4-dichlorophenoxyacetic acid (2,4-D); the PAT protein from *S. viridochromogenes* which confers tolerance to glufosinate ammonium herbicides; and the CP4 5-enolpyruvylshikimate-3-phosphate synthase (*CP4 epsps*) from *Agrobacterium* sp. strain CP4 which confers tolerance to the herbicide glyphosate. The CP4 EPSPS expression cassette includes a tassel specific regulatory element which targets CP4 EPSPS mRNA for degradation in tassel tissues, and results in non-viable pollen with appropriately timed glyphosate applications.

5. IND-ØØ412-7 wheat from Bioceres Inc. was genetically engineered to express a modified HaHB4 transcription factor from *Helianthus annuus*, which enables yield improvement compared to controls under environmental stress. IND-ØØ412-7 wheat was also engineered to express PAT/*bar* protein from *Streptomyces hygroscopicus*, which confers tolerance to glufosinate herbicides. FDA evaluated the safety and regulatory status of IND-ØØ412-7 wheat in human food, and at intermittent low levels in animal food.

For more information on these or other consultations, see [FDA's inventory of completed consultations on food from new plant varieties](#).

### **Letter to Industry on the Food Safety Risks of Transferring Genes for Proteins that are Food Allergens to New Plant Varieties Used for Food**

- On April 13, 2023, the U.S. Food and Drug Administration [issued a letter](#) reminding developers and manufacturers of new plant varieties who intend to transfer genes for proteins that are food allergens (including allergens from foods identified as major food allergens) into new plant varieties used for food of the relevant legal requirements for these products.
- The FDA is not aware of any foods currently in the U.S. market from these types of new plant varieties, but we are aware of research and development in this area. Because adverse reactions to food allergens can be severe and life-threatening, including when the allergen is present at low levels, we think it is important to reach out to developers and manufacturers now, while such plant varieties are still in early research and development stages.
- The FDA is asking developers to consider the food safety risks posed by such allergens and plan early in development to manage the risks. In addition to the food safety risks, if unexpected and unlabelled allergens enter the food supply, this could have other consequences for food producers, such as needing to recall the affected products.
- The FDA is reminding industry of the relevant legal requirements and potential food safety concerns related to producing, processing, packaging, and holding these types of plant varieties and industry's responsibility to ensure that they do not become unintended or unexpected allergens in final food products. We are specifically reminding those developers who are now exploring development of these types of plant varieties of their responsibility for food safety. In particular, we are reminding them to consider the allergenicity issues related to their products, and how they would be stewarded from production to manufacturing to consumption so that they do not inadvertently or unexpectedly enter the food supply. We are also reminding them that they need to be properly labelled when intentionally part of the food supply.
- The FDA encourages developers of new plant varieties to consult with us prior to marketing. Since 1994, the FDA has operated a voluntary premarket consultation program for foods from new plant varieties. This program is intended to protect the public by helping the food industry ensure that foods from their new plant varieties meet all relevant requirements under the Federal Food, Drug, and Cosmetic Act before marketing.

### **Animal Biotechnology**

- FDA Center for Veterinary Medicine (CVM) is collaborating with the U.S. National Institute of Standards and Technology to address the lack of validated measurements and standards for characterising intentional genomic alterations in animals. The collaboration will generate resources including standardized measurements for characterising both intended and unintended alterations in cattle and swine that are developed using genome editing and access to suitable comparator materials. These resources will provide animal biotechnology product developers and regulators with example characterisation approaches that they could use as part of the development and regulatory process for animal biotechnology products.
- FDA CVM has granted an investigational food-use authorisation allowing five genome-edited pigs to be introduced into the food supply. These swine carry an alteration in the *NANOS2* gene, which, when homozygous, results in male infertility. The sponsor, Washington State University, submitted data and information demonstrating that the pigs only contain the intended genomic alteration and do not contain unintended on- or off-target alterations; and that the intended alteration is not expected to impact the edible tissues of the animal, as the gene is only expressed in the testes, and all male animals were castrated. This decision does not authorise commercialisation of these genomically altered pigs; it only covers food use of the specific pigs involved in an ongoing investigation.

## Global Biotechnology Regulators Workshop

FDA hosted a Global Biotechnology Regulators Workshop on November 15-16, 2022, in Brussels to exchange information on current regulatory developments related to agricultural applications of genome editing.

### Animal Cell Culture Consultations Conducted by US FDA

- Oversight of cultured animal cell foods in the United States is shared between the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture (USDA), as outlined in a March 2019 agreement: <https://www.fda.gov/food/domestic-interagency-agreements-food/formal-agreement-between-fda-and-usda-regarding-oversight-human-food-produced-using-animal-cell>.
- FDA’s responsibilities under this agreement include oversight of the cell banking and culture phases of food production, as well as premarket consultation with individual firms. For cultured animal cell foods derived from meat (including fish of the order Siluriformes) and poultry cell lines, USDA’s oversight begins following harvest of the cellular material. For cultured animal cell foods derived from non-amenable species and seafood cell lines, FDA’s oversight continues beyond harvest.
- FDA applies its existing authorities to ensure the safety of cultured animal cell foods.
- FDA has completed consultations with two firms to date. Both products are comprised of cultured poultry cells intended for use as human food and thus under USDA oversight beginning at harvest. An inventory of completed consultations is accessible at: <https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=AnimalCellCultureFoods>.
- CCC 002 is a cultured myocyte and fibroblast chicken cell product that is harvested as adherent sheets of cells. The cell lines are isolated from adult chickens or mid-stage fertilised eggs, and adapted to sustained culture through either selection or genetic engineering to express a cisgenic telomerase reverse transcriptase protein. The consultation was completed, and FDA issued a response letter stating that it had no questions about the firm’s safety conclusion, on November 16, 2022.
- CCC 001 is a cultured fibroblast chicken cell product that is harvested as a cell paste. The cell line originated from a third party, internationally recognised culture collection (i.e., the American Type Culture Collection; ATCC) where it had previously been adapted to sustained culture through selection. The consultation was completed, and FDA issued a response letter stating that we had no questions about the firm’s safety conclusion, on March 20, 2023.
- FDA is committed to being transparent regarding its completed premarket consultations. FDA posts, for each completed premarket consultation, the following documents to its Human Food Made with Cultured Animal Cells Inventory: (1) the firm’s publicly-disclosable safety assessment, (2) the Agency’s scientific review memorandum that summarises the Agency’s evaluation of the firm’s safety conclusion, and (3) the response letter to the firm.
- FDA intends to issue guidance to assist firms in engaging in the premarket consultation process.

### Cultured Animal Cell Products Intended for Use in Animal Food

FDA’s Center for Veterinary Medicine oversees the safety of cultured animal cell products intended to be used in animal food, and has regulatory processes through which firms can submit information to FDA regarding the safety and regulatory status of the product.

### Additional "Feed Your Mind" outreach and education materials

On August 4, 2022, the U.S. Food and Drug Administration released new “[Feed Your Mind](#)” educational materials to provide science-based information on genetically engineered organisms to consumers, health educators, dietitians, and other health care professionals. “Feed Your Mind” is an [education initiative launched in 2020](#) to help increase consumer understanding of genetically engineered organisms and was developed in partnership with the U.S. Department of Agriculture and the U.S. Environmental Protection Agency.

The new materials include:

- A video and infographic for **consumers**:  
Video: “[GMOs, Farm to Table](#)”  
Infographic: “[Where Can You Find GMOs?](#)”

- A video and discussion guide for **health educators**:  
Video: “[GMOs and Food Safety: A Guide for Health Educators](#)”  
Discussion Guide: “[A Question of GMOs](#)”
- A video and factsheet developed in partnership with the Academy of Nutrition and Dietetics for **registered dietitians (RDs)/registered dietitian nutritionists (RDNs) and nutrition and dietetics technicians, registered (NDTRs)**. Interested RDs/RDNs and NDTRs can earn free continuing education units through the Academy of Nutrition and Dietetics’ [EatRight® Store](#)  
Video: “[Understanding GMOs](#)”  
Factsheet: “[Understanding GMOs](#)”

## Updates for the United States Environmental Protection Agency (EPA)

### Office of Pesticide Programs, Biopesticides and Pollution Prevention Division (OPP/BPPD)

#### ❖ *EPA proposal on plant-incorporated protectants (PIP).*

#### **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 FFDC. 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](http://www.regulations.gov). EPA is in the process of finalizing the rule and is anticipating its publication later in 2023.

#### *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 (524-EUP-117): On September 20, 2022, EPA issued an EUP for Event MON 94804, a new plant-incorporated protectant in corn. Event MON 94804 contains an RNA interference trait (GA20ox\_SUP miRNA) that downregulates GA20ox gene expression leading to a reduction in the internode length of the plant and consequently reduced overall plant height compared to conventional corn. “Short stature” corn is thought to better resist lodging (fall over) from wind or insect damage. This permit was issued to allow testing of phenotypic and agronomic properties, efficacy, and yield, and to generate data for regulatory studies in 27 states and Puerto Rico. The permit is effective until February 28, 2025.
- Experimental Use Permit (8917-EUP-3): On March 15, 2023, EPA issued an EUP for “Gen 3” potatoes, a potato product containing four plant-incorporated protectants: PVY coat protein RNAi, VNT1 protein (*Rpi-vnt1* gene), BLB2 (*Rpi-blb2* gene), and AMR3 (*Rpi-amr3* gene). PVY coat protein RNAi targets Potato Virus Y, while VNT1, BLB2, and AMR3 are resistance (R) proteins intended to control late blight disease. (VNT1 was previously approved by EPA for commercial production but was also included in this EUP with the other traits.) This permit was issued to allow testing of efficacy against the target pests, agronomic properties, and to generate data for regulatory studies in 11 states. The permit is effective until April 1, 2024.
- New Plant-incorporated Protectant Applications Received and Under Review (announced in the Federal Register):
  - DP910521 (Cry1B.34) corn (FR Notice of Receipt – February 23, 2023) – Trait intended for control of lepidopteran pests
  - DAS1131 (Cry1Da2) corn (FR Notice of Receipt – February 23, 2023) – Trait intended for control of lepidopteran pests

- DP915635 (IPD079Ea protein) corn (FR Notice of Receipt – January 4, 2023) – Trait intended for control of corn rootworm

## EUROPEAN UNION

### 1. Developments related to implementation of national biosafety framework

#### 1. Risk assessment/regulatory decisions

##### i. Risk assessment

Since 1<sup>st</sup> March 2022, the European Food Safety Authority (EFSA GMO Panel) has adopted and published 15 new scientific opinions, of which 7 renewal application:

- EFSA-GMO-NL-2020-169) (Oilseed rape MON 94100) [22/07/2022]
- EFSA-GMO-NL-2018-151) (Maize MON 89034 × 1507 × MIR162 × NK603 × DAS-40278-9) [12/08/2022]
- EFSA-GMO-RX-026/2 (isolated seed proteins produced from oilseed rape GT73 for food) [04/11/2022]
- EFSA GMO-NL-2020-171 (Maize DP4114 × MON 89034 × MON 87411 × DAS-40278-9) [09/11/2022]
- EFSA-GMO-NL-2020-170 (Maize MON 95379) [15/11/2022]
- EFSA-GMO-NL-2019-161 (Maize MON 87429) [18/11/2022]
- EFSA-GMO-NL-2017-140 (Maize MON 87419) [20/01/2023]
- EFSA-GMO-DE-2016-137 (Maize GA21× T25) [27/01/2023]
- RX-020 (soybean A5547-127) [20/06/2020]
- RX-025 (maize MIR162) [22/09/2022]
- RX-026/1 (oilseed rape GT73) [06/10/2022]
- RX-019 (cotton 281-24-236 × 3006-210-23) [10/11/2022]
- RX-021 (soybean MON 87701) [19/12/2022]
- RX-022 (soybean MON 87701 × MON 89788) [19/12/2022]
- RX-023 (soybean 40-3-2) [19/12/2022]

##### ii. Regulatory decisions

Regulation (EU) 1829/2003 on genetically modified food and feed regulates the placing on the market of GM food and feed in the EU. All EU authorised products are listed in two online registers:

- the Community Register of GM food and feed ([http://ec.europa.eu/food/dyna/gm\\_register/index\\_en.cfm](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/](https://webgate.ec.europa.eu/fip/GMO_Registers/)).

Since the last WG-HROB meeting, the European Commission has authorised 14 GM food and feed (including 10 subcombinations) and has renewed 1 authorisation.

New authorisations:

- Maize NK603 × T25 × DAS-40278-9 and 1 subcombination
- Soybean MON 87769 × MON 89788
- Maize DP4114 × MON 810 × MIR604 × NK603 and 9 subcombinations
- Oilseed rape MON 94100

Renewals:

- Soybean A5547-127

More applications for authorisations are in the pipeline.

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

EFSA has updated the following opinion:

- Animal dietary exposure in the risk assessment of feed derived from genetically modified plants: (<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2023.7732>)

## 3. **Public engagement and outreach activities**

EFSA is in close contact with its industry stakeholders. EFSA organised two meetings in 2022 to also address concerns and explain in detail the implementation of the Transparency Regulation as well as other Scientific aspects. In 2023, EFSA plans to have another two meetings, one being on the 18th of April (remotely) and the second one in October (hybrid). EFSA also organised a stakeholder event on 12 December 2022 on “The safety of plants derived from New Genomic Techniques: looking into future risk assessment challenges”.

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](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 new breeding techniques (NBTs)**

### 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<sup>1</sup> 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” and, if appropriate, to submit a proposal or otherwise to inform the Council on other measures required as a follow-up to the study.

The resulting study<sup>2</sup> was published on 29 April 2021. The Commission initiated a policy initiative on plants produced by targeted mutagenesis and cisgenesis. The inception impact assessment was published on 24 September 2021<sup>3</sup>.

An impact assessment is on-going and possible legal proposal, if warranted by the impact assessment, would be adopted in Q2 2023.

As regards public engagement and outreach related to this initiative since the previous meeting, the European Commission opened a public consultation<sup>4</sup> which remained open for comments until 22 July 2022.

Since the previous meeting, EFSA has published:

- Criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7618>
- Updated scientific opinion on plants developed through cisgenesis and intragenesis <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7621>

<sup>1</sup> 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)

<sup>2</sup> [https://ec.europa.eu/food/plants/genetically-modified-organisms/new-techniques-biotechnology/ec-study-new-genomic-techniques\\_en](https://ec.europa.eu/food/plants/genetically-modified-organisms/new-techniques-biotechnology/ec-study-new-genomic-techniques_en)

<sup>3</sup> [https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques\\_en](https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13119-Legislation-for-plants-produced-by-certain-new-genomic-techniques_en)

<sup>4</sup> [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](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)

- Evaluation of existing guidelines for their adequacy for the food and feed risk assessment of genetically modified plants obtained through synthetic biology  
<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7410>
- Evaluation of existing guidelines for their adequacy for the food and feed risk assessment of microorganisms obtained through synthetic biology  
<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2022.7479>

In addition, work is ongoing in EFSA on the following Scientific Opinion:

- Scientific Opinion on new developments in biotechnology applied to animals (including synthetic biology and new genomic techniques) – adoption foreseen June 2025  
<https://open.efsa.europa.eu/questions/EFSA-Q-2023-00050>

## 2. **Specific cases of application, assessment and decision**

- 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.

## 3. **Developments related to novel foods and feeds**

### 1. **Novel foods**

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

Overall, the European Commission has received, to date, through the e-submission system 513 applications and 109 traditional foods from third countries for authorisation since the regulation became applicable. To date, the Union list of novel foods has been amended 107 times, including the authorisation of eight traditional foods.

Food products obtained by animal cell culture are considered novel food unless the technique used falls within the scope of the GMO Regulation. Before such products could be authorised in the EU, they would have to go through a thorough safety assessment by the European Food Safety Authority.

To date, no application for such type of products has been submitted to the Commission.

### 2. **Novel feeds**

The European Food Safety Authority (EFSA) adopted in 2015 an opinion on the risk profile related to products and consumption of insects as food and feed<sup>5</sup>. This opinion is one of the elements that served as a basis to regulate the use of these products from different angles.

#### **Animal Nutrition regulatory framework**

Regulation (EC) No 767/2009<sup>6</sup> on the placing on the market and use of feed regulates some aspects related to the production and placing on the market of insects. It requires, amongst others, that the feed business operator marketing insects or products derived therefrom for feed use must guarantee their safety. It also prohibits certain products to be used as substrates for the feeding of insects.

<sup>5</sup> EFSA Journal 2015;13(10):4257

<sup>6</sup> Regulation (EC) No 767/2009 of the European Parliament and of the Council of 13 July 2009 on the placing on the market and use of feed (OJ L 229, 1.9.2009, p. 1).

Commission Regulation (EU) 2017/1017<sup>7</sup> on the Catalogue of Feed Materials has split the former feed material “Terrestrial invertebrates” into two different feed materials: “Terrestrial invertebrates, live” and “Terrestrial invertebrates, dead”. Therefore, live insects are permitted as feed under the national legislation in accordance with Regulation (EC) No 767/2009 and pets. In addition, if a feed material is labelled with a name in the Catalogue (e.g. processed animal protein), the name must be supplemented as appropriate by certain indications. For insects, the life stage (e.g. larvae) is one of these indications.

Directive 2002/32/EC<sup>8</sup> on undesirable substances, as well as Regulation (EC) No 396/2015<sup>9</sup> establishing pesticide residue limits, apply to feed derived from insects.

### **Animal by-products regulatory framework**

Regulation (EC) No 1069/2009<sup>10</sup> on animal by-products (the ABP Regulation) lays down that insects reared in the EU are farmed animals; this has also implications on the substrates for them, as it prohibits feeding insects with category 1 and 2 material, including former foodstuffs and catering waste. However, the ABP Regulation allows insects not processed in accordance with the specific ABP methods (e.g. simple treatments like freezing or drying) for pet food.

Regulation (EU) No 142/2011<sup>11</sup> implementing Regulation (EC) No 1069/2009 laid down requirements for the production of processed animal protein (PAP) from insect, including a positive list of eligible insect species (4 as of November 2021), as well as import conditions that reflect these EU internal standards.

### **TSE regulatory framework**

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

However, by derogation, Commission Regulation (EU) 2017/893<sup>12</sup> authorised insect PAP in feed for aquaculture animals. The use of insect PAP was further extended to poultry and porcine animals by Commission Regulation (EU) 2021/1372<sup>13</sup>. The analytical methods for the control of these feed ban rules are laid down in Annex VI to Commission Regulation (EC) No 152/2009<sup>14</sup>.

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

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<sup>7</sup>Commission Regulation (EU) 2017/1017 of 15 June 2017 amending Regulation (EU) No 68/2013 on the Catalogue of feed materials (OJ L159, 21.6.2017, p. 48).

<sup>8</sup> Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed - Council statement (OJ L 140, 30.5.2002, p. 10).

<sup>9</sup> Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1–16)

<sup>10</sup> Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (OJ L 300, 14.11.2009, p. 1).

<sup>11</sup> Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1)

<sup>12</sup> Commission Regulation (EU) 2017/893 of 24 May 2017 amending Annexes I and IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council and Annexes X, XIV and XV to Commission Regulation (EU) No 142/2011 as regards the provisions on processed animal protein. (OJ L 138, 25.5.2017, p. 92).

<sup>13</sup> Commission Regulation (EU) 2021/1372 of 17 August 2021 amending Annex IV to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the prohibition to feed non-ruminant farmed animals, other than fur animals, with protein derived from animals (OJ L 295, 18.8.2021, p. 1–17)

<sup>14</sup> Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 054 26.2.2009, p. 1)

## BIAC (BUSINESS AT OECD)

### 1. Developments related to biosafety activities

#### Reports and technical resources:

Innovation in agriculture is vital to combatting rising global challenges, such as climate change and food security, and improved biodiversity. Innovations such as [plant biotechnology](#), including [genome editing](#), help plants adapt to environmental stresses and help farmers improve their climate resilience. Two studies commissioned by CropLife International this year – one from [Dr. Stuart Smyth](#) and one from [Dr. Daniel Voytas](#) – explored the quantitative impacts that plant biotechnology products have had around climate adaptation and mitigation to date and synthesised the opportunities that genome editing can deliver on in the future. CropLife International has incorporated these findings into ongoing work and shared them further via [op-eds](#), and twitter [campaigns](#).

#### Climate Change Contributions from Seed and Crop Technologies

One of the highlights from the Smyth report is that without genetically modified (GM) crops, crop protection products and fertiliser, at least 10% more land would be required to produce current food volumes. This additional crop production land would need to come from reducing wetlands, deforestation or conversion of environmentally sensitive land. The same report showed that innovations in seed technology, like herbicide tolerance and improved weed control have resulted in over 300 million tonnes of CO<sub>2</sub> sequestration from reductions in tillage, over the past 25 years.

#### The Economic Impacts of a Mexican Ban on GM Corn Imports

A [2022 study](#) commissioned by CropLife International found that Mexico's GM Corn proposed ban would force North American grain handling systems into two streams (GM and non-GM corn), an approach [that is costlier, disincentivizes innovation, and subjects supply chains to greater volatility](#). An [infographic](#) outlining some of the impacts of such a ban was shared with the value chain of exporting countries working to support the continued open and free trade of inputs, such as GM corn, that are critical for food security.

#### Databases

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

#### Launch of New Approvals Database

In 2022, [the AgbioInvestor GM monitor](#), was launched with support from CropLife International. The AgbioInvestor GM Monitor provides information about GM Crop approvals and production in a comprehensive and searchable database, which is updated on a regular basis. Users can easily find details such as which traits have been approved in which countries. The database also includes links to the relevant regulatory authorities. In addition, the entire database can be downloaded as an excel sheet for more advanced analysis. This new database complements other resources supported by CropLife International such as BioTradeStatus which provides market status information on commercialized GM Crops developed by CropLife International member companies.

#### Updates to Other Resources

Recent updates to other CropLife International databases include an annual update to the [Celiac Peptide Database](#), a list of peptides that have been implicated in triggering celiac disease, as well as changes to [the Detection Methods Database](#). The detection methods database was updated to improve integration with the Cartagena Protocol Biosafety Clearing House (BCH). Records in the BCH database that match with a product in the database (i.e. same OECD Unique Identifier), are automatically linked to the detection method listed in the database. The integration allows users of the BCH database to easily access the most up-to-date detection methods, directly from the technology providers.

#### Additional Global Communications Resources

Building on the findings in the [2022 Time and Cost to Market Report](#), CropLife International created communications resources to support the Time and Cost to Market study, including an [infographic](#) and other [visual assets](#).

Working in partnership with Thought For Food, Global Farmer Network, and member companies, CropLife International spotlighted dozens of young entrepreneurs, academics, and biotechnology scientists helping to transform our food systems in our [2022 #FoodHeroes campaign](#).

CropLife International continues to support the GMO Answers online platform by updating content with the [latest data available](#). Updated resources from GMO Answers include [What Does GMO Stand For?](#), [GMOs Improve Soil Health](#), [3 Big Ways GMOs Support the Environment](#), [How GMOs Can Improve Air Quality](#), [How Do We Preserve Our Habitat?](#), [GMOs' Impact on Climate Change](#), [GMOs and Animal Feed](#), [GMOs and the Environment](#), and [How GMOs Help Reduce Food Waste](#).

Other communications resources available on the CropLife website include:

- A [story on the CropLife International website](#) about how Canola contributes to sustainable agriculture, while offering health benefits to consumers and economic opportunities to producers.
- A [profile of a Mexican farmer](#) discussing how biotechnology is helping their farm, and how threats to innovation could hinder their ability to farm sustainably.
- A dialogue between a [Canadian academic and farmer](#) on how public-private partnerships help innovations like GM crops promote sustainability, food security, and fair and open trade.
- A new [infographic](#) outlining five of the most common types of plant breeding terms to help discussions around issues like synthetic biology and gene drives

## 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 plant science industry's engagement in the implementation negotiations of the UN Convention on Biological Diversity, Nagoya Protocol on Access and Benefit-sharing (ABS) and Cartagena Protocol on Biosafety. CropLife International and the CropLife network were pleased to participate in the meetings of the Convention on Biological Diversity and its Protocols in December 2022, working to support decisions at that were firmly grounded in science, allowing for the use of modern agricultural practices and tools while ensuring they are leveraged in ways that support biodiversity conservation and sustainability. Parties adopted the Kunming-Montreal Global Biodiversity Framework that sets ambitious goalposts, and CropLife International looks forward to continuing to work with Parties to establish measurable goals around the Framework's targets.

CropLife International has already begun work on the 2023-2024 intersessional period before the next meeting of the Parties to the Convention, providing detailed information to the Convention Secretariat and Parties on the horizon scanning process for synthetic biology and on risk assessment and risk management of living modified organisms containing gene drives. CropLife International will continue to contribute [meaningful commitments to the Sharm El-Sheikh to Kunming Action Agenda for Nature and People](#), building on the existing and growing momentum, of urgent action from a broad base of sub and non-state actors in support of the implementation of the Kunming-Montreal Global Biodiversity Framework. CropLife International's commitments include preserving biodiversity by highlighting stewardship through farming training, promoting sustainability via knowledge sharing, collaborating to increase awareness of solutions, and safeguarding the environment and public health through responsible use.

### **Advocating for Science-based Solutions**

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

As detailed in the section above, the CropLife International delegation also worked at the UN Biodiversity Conference (COP15) in Montreal to ensure that these technologies were fairly and accurately recognized for their important role in [protecting and enhancing biodiversity](#). CropLife International hosted a side event to present information on our [four commitments to the CBD Action Agenda](#), focusing on areas and examples where we support the implementation of the Post2020 Global Biodiversity Framework.

CropLife International also led a delegation to the United Nations (UN) Framework for Climate Change Convention (UNFCCC) in Sharm-el-Sheik, Egypt (COP27). Increasing agriculture's visibility as part of the solution to climate change was central to CropLife International's engagement and as was highlighting the role plant biotechnology plays in helping farmers and food systems [adapt to and mitigate climate change](#) while improving productivity and delivering food security. CropLife International hosted side events during COP27 to ensure that the tangible and potential impacts of these technologies are understood and remain part of the conversation as stakeholders discuss solutions for agricultural sustainability and climate resilience.

### 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<sup>15</sup>. Further, the seed industry recommends that the processes used to determine whether products fall in or out of scope of genetically modified organism (GMO) regulations are transparent, time-efficient, and consider existing regulatory mechanisms for new plant varieties (such as, for example, plant variety registration, national seed laws, or general food safety laws). The adoption of common approaches across countries can be facilitated through alignment of definitions, standardisation of information requirements in support of a regulatory status determination, adoption of predictable and efficient assessment timelines, and recognition of other countries' determinations on regulatory status. These common approaches are essential to maintain a functional trading system that facilitates food security enabled by innovative products including those derived from genome editing.

As noted for several years, governments and industry need to continue open and transparent dialogue on the new applications and use cases of genome editing in plant breeding. [Recent publications](#) survey 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 also applauds the FAO for working to bring a [factual and evidence based assessment](#) of the potential positive impacts of genome editing toward food security, the environment, and economics. Last year also saw a significant advancement in the literature base documenting potential positive impacts of this technology on [climate](#), [nutrition and poverty reduction](#), and [sustainable agriculture in developing countries](#). CropLife International also contributed to this body of evidence by commissioning a report from Dr. Daniel Voytas on the [potential impacts of genome editing on climate adaptation and mitigation](#).

The seed industry recognises the continued development and finalisation of policies for genome edited products in Canada, England, India, Malawi, and Costa Rica in 2022 (and thus far in 2023) as well as ongoing discussions in Korea, Indonesia, Malaysia, Uruguay, Thailand, Singapore, and Switzerland. The seed industry also recognised the continued function of established policies in more than a dozen markets where several products continue to undergo determinations for inclusion/exclusion from GMO regulation.

Further, the seed industry remains optimistic on the prospects of a more fit for purpose approach toward new genomic techniques (NGT's) in the European Union this summer such that these technologies can fully contribute to goals set forth in the Farm to Fork strategy. The seed industry also remains optimistic on the implementation of trial guidelines from Ministry of Agriculture and Rural Affairs (MARA) in China and continue to look forward to furthering dialogue on this operationalization in alignment with many other jurisdictions.

The seed industry continues to recognise 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.

<sup>15</sup> <https://worldseed.org/document/plant-breeding-innovation-consistent-criteria-for-the-scope-of-regulatory-oversight/>

### **Global Communications Resources Genome Editing**

ISF together with the American Seed Trade Association (ASTA), CropLife International, and Euroseeds, developed a series of fact sheets based on scientifically validated, peer-reviewed articles. The aim is to clarify concepts and debunk common myths around gene editing. From these fact sheets, ISF created a #FridayFacts campaign on social media aimed at the agriculture community and the public in general, featuring short videos and graphic cards on gene editing. These resources are also made available to ISF members to support their own communications.

All the [#FridayFacts communications assets](#) are available on the ISF website.

Additionally, the [Frequently Asked Questions \(FAQs\)](#) on the ISF website were expanded. These FAQs will form the content for the continuation of the #FridayFacts campaign this year, which is planned to run July-September 2023.

## **AFSI (AGRICULTURE & FOOD SYSTEMS INSTITUTE)**

### ***About the Agriculture & Food Systems Institute***

The [Agriculture & Food Systems Institute](#) (AFSI) is an independent nonprofit, scientific organisation based in Washington DC, United States, that advances science for public benefit. Our mission is to achieve safe and sustainable agri-food, health, and environmental systems that improve the world. We do this through applied research, capacity-building, education, information dissemination, and outreach. Our work is being used to advance understanding and inform policy on agricultural systems, products of biotechnology, sustainable nutrition security, food safety, and related issues.

### ***Upcoming webinar on ‘Harnessing Genome Editing Technologies for Viticulture’***

Register using the link:

[https://foodsystems-org.zoom.us/webinar/register/4316802682068/WN\\_JFbOwBOBS9yxrFGzSjVgpA](https://foodsystems-org.zoom.us/webinar/register/4316802682068/WN_JFbOwBOBS9yxrFGzSjVgpA)

A virtual workshop on ‘Harnessing Genome Editing Technologies for Viticulture’ will be organised on May 29, 2023 (2:00 pm Central European time zone). This workshop will focus on the use of genome editing to improve practices for grape cultivation towards specific end uses. The goal for this workshop is to demonstrate to traditional agriculturalists the potential of using genome editing tools in breeding programs and its application to adapt grape varieties to a rapidly changing climate. This workshop is supported by a grant from the United States Department of Agriculture. The target audience will include a broad base of stakeholders like scientists, risk assessors, regulatory folks, private sector, farmers, people from the wine industry.

## **1. Developments related to biosafety activities**

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

Building on a history of collaborative engagement around harmonisation in South Asia which originated in a series of workshops at the South Asia Biosafety Conference, AFSI has assembled an Expert Working Group (EWG) with experts from Bangladesh, Bhutan, India, and Sri Lanka to address the potential for harmonisation of food safety assessment for foods resulting from genetically engineered plants in South Asia. The EWG members, acting in their individual capacity met virtually over the course of 2020 - 2022. The EWG recognised 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 was finalised after multiple rounds of discussion. This report of the EWG also includes an application form for developers and a risk assessment summary template for use by risk assessors.

AFSI continues to work on stakeholder engagement with plans tailored towards each of the participating countries’ needs for the adoption and operationalisation of the regional guidance. A [Biotechnology Outreach Conference](#) was organised in June of 2022 during which the report of the EWG was showcased at one of the sessions. The conference provided the stakeholders in Bangladesh an opportunity to discuss current developments, learn about the use of biotechnology including research and development in the country, regulations, trade in products of modern biotechnology, and science communication. The event served as a forum to better understand how research is being

conducted in compliance with environmental and human health protection goals in Bangladesh, while providing a pathway for safe technologies to receive authorisation so that the benefits of biotechnology can be realised.

## 2. Updates regarding international activities

### *APEC High-level Policy Dialogue on Agricultural Biotechnology (APEC HLPDAB)*

AFSI worked with the U.S. government to implement the ‘Agricultural Biotechnology Seminar Series’ for the APEC HLPDAB as part of the U.S.’s self-funded projects. We supported four seminars each of which was led by an APEC economy. This seminar series brought together scientists, regulators, and policy makers to discuss recent advances in genetic engineering and genome editing and products developed using these technologies. The project’s objectives were to create foundational knowledge of how genetic engineering and genome editing can be used to improve agricultural breeding programs and commercially available crops and livestock and create an enabling environment for adoption of products of agricultural biotechnology. As part of this series, the following virtual seminars were facilitated by AFSI:

‘[Genetic Engineering and Genome Editing in Agriculture, Application and Challenges](#)’ led by Thailand as the sponsoring economy and Canada as the Co-sponsor was held on May 11, 2022. This event attracted over 100 attendees.

‘[The Regulation of Genome Edited Products and Its Challenges](#)’ held on July 22, 2022, facilitated delivery of presentations on the adoption of genome editing into breeding programs. In addition, the regulation of products of agricultural biotechnology using this technology were also discussed. This seminar was led by Indonesia and co-sponsored by Canada and Thailand. The event was attended by 126 participants, who benefited from real-life examples of research and commercialisation of genome edited crops, including bananas and orchids, as well as presentations on the regulation of genome edited products in the United States and Brazil.

The seminar titled ‘[Outreach to Enhance Public Awareness and Confidence on Agricultural Biotechnology](#)’ hosted on August 5, 2022 was led by Vietnam and co-sponsored by Canada and Thailand, and focused on efforts to communicate with the public about varieties developed using agricultural biotechnology. The 80 participants at this event benefited from talks on the global status of biotechnology and biotech crops in Vietnam, factors shaping public perception and effective communication about agricultural biotechnology, and the global regulation of genome edited plants.

The seminar led by Canada titled ‘[Development of Regulatory Guidance for Products of Agricultural Biotechnology](#)’ was hosted on November 22, 2022. This event outlined the activities carried out by Canadian regulators for the purpose of developing new guidance focused on plant breeding, including those developed through genome editing, in order to enhance clarity and predictability surrounding the oversight of these products. The webinar focused on the actions and steps taken over the course of this initiative, as well as insights into recommended best practices, challenges encountered, and opportunities for complementary initiatives, so economies embarking on or contemplating similar endeavors may learn from Canada’s experiences. 104 participants from 24 countries attended the virtual seminar.

In addition to the Agricultural Biotechnology Seminar Series, AFSI organised a two-day virtual workshop to discuss the potential for developing a webpage for information sharing among members of the APEC HLPDAB on August 16-17, 2022. With the United States as the sponsoring economy and host of the event, ‘[Agricultural Biotechnology: Sharing Resources, Experiences, and Lessons Learned](#)’ attracted over 100 participants, who benefited from a series of lightning talks highlighting examples of regional collaboration, regulatory harmonisation, and online biosafety tools. Breakout groups guided by practical examples gave participants hands-on experience applying and using the provided resources (including OECD’s BioTrack database among others), and moderated group discussions solicited feedback on how the HLPDAB can facilitate information and resource sharing, as well as the next steps for APEC 2023.

AFSI organised a two-day virtual workshop on January 18-19, 2023 on ‘[Tackling Climate Change Challenges with Agriculture Technology and Innovation](#)’ with an objective to enable stakeholders in various roles from APEC economies to obtain, share, and develop knowledge needed for accelerating the rate of agricultural technology innovation and its implementation in order to adapt to and mitigate the impacts of climate change on agriculture. This activity supported the implementation of the Food Security Roadmap Towards 2030 through its focus on digitalisation and innovative technologies and was attended by 62 participants from 9 APEC economies.

### ***Workshops on Safety Assessment of Foods Derived from Genetically Engineered Plants: Engagement with Bangladesh Food Safety Authority***

The South Asia Biosafety Program (SABP) has been working in Bangladesh since 2005 in cooperation with the Government of Bangladesh to strengthen and support institutional governance of biotechnology. The collaboration resulted in the publication of several guidelines by the Government of Bangladesh, including the guidance document “[Bangladesh Guidelines for Safety Assessment of Foods Derived from Genetically Engineered Plants](#).” This guidance was published by the then Ministry of Environment and Forests in 2012 and was adopted by the Bangladesh Standards and Testing Institution as a national standard in 2013.

The [Bangladesh Food Safety Authority](#) (BFSA) has been identified in the Food Safety Act as the responsible body for ensuring that foods derived from GE plants that enter Bangladesh are safe. SABP is organising a series of workshops with BFSA and the Ministry of Food to ensure that BFSA has operational capacity to implement safety assessments for foods derived from GE plants in accordance with the guidelines. The [introductory workshop](#) on May 17, 2022 was organised for BFSA staff, committee members, and other relevant stakeholders to improve understanding of the global status of GM food in Bangladesh, as well as the safety assessment paradigm for whole foods.

The [second workshop](#) in this series, an in-person event, took place on June 12, 2022. This workshop covered topics pertaining to technical concepts in the safety assessment of foods derived from genetically engineered plants. In addition, there was a discussion on the global experience with genetically engineered food and feed, as well as regulations pertaining to products of modern biotechnology in Bangladesh.

### ***Microbial Biotechnology***

In continuation of its virtual outreach on microbial biotechnology, on September 13-15, 2022, AFSI organised the ‘[Virtual Workshop on Microbial Biotechnology for Novel Food and Food Ingredients for Southeast Asia](#)’ with the aim of introducing scientific and regulatory issues related to the use of microbial biotechnology for the production of food and food ingredients and providing a forum for an open, informed dialogue with international faculty about microbial biotechnology. The workshop was attended by 183 participants.

Earlier workshops in this segment include ‘[Microbial Biotechnology for Novel Foods Webinar Series](#)’ on July 9-17, 2020 and regional webinars targeting audiences in the [European Union](#) and [India](#), which took place on July 8, 2021 and January 11, 2022, respectively.

## **3. Developments related to new breeding techniques (NBTs)**

### ***Genome Editing in Plants: Harnessing the Benefits for Bangladesh***

AFSI is collaborating with the Bangladesh Academy of Sciences (BAS) to raise awareness around the science and regulatory status for products of genome editing in Bangladesh. Several institutions in Bangladesh have initiated research projects aimed at accelerating genetic improvement through new plant breeding techniques in different crops. Dating back to October 2021, two webinars, a conference, and a Round Table Discussion have been organised through this collaboration to provide a platform for discussion amongst stakeholders, including international experts and domestic scientists from the public sector, academia, and the private sector with a focus on informing enabling policies on handling the products of genome editing in Bangladesh. The [first webinar on genome editing and the way forward in Bangladesh](#), held on October 4, 2021, was a knowledge-sharing initiative focused on developments in genome editing and the need for enabling policies in Bangladesh, so as to make use of this new technology in order to meet the urgent need for improved crops. On June 1, 2022, a [second webinar](#) was conducted to continue the discussion of this key technology. AFSI organised the Conference on ‘[Genome Editing in Plants: Harnessing the Benefits for Bangladesh](#)’ on October 18-19, 2022, in collaboration with the BAS, Bangladesh Agriculture Research Council, and Biotech Consortium India Limited.

### ***Webinars and Workshops on gene editing for Korean Scientists***

The third workshop in the series ‘Gene Edited Plants: Context and Communication for Plant Breeding Innovation’ for Korean stakeholders was held on July 25-26, 2022. This was an in-person workshop on ‘[Problem Formulation and Safety Assessment of Foods Derived from Modern Biotechnology](#)’ organised by AFSI in Seoul. This event built on the webinar series ‘[Gene Edited Plants: Context and Communication for Plant Breeding Innovation](#)’, which took place in 2021. The goal of this series of activities was to improve understanding of the technology of gene editing, highlight varying regulatory approaches to products of gene editing, encourage dialogue between Korean government officials, scientists, and other stakeholders, and support effective communication on issues related to new plant breeding technologies.

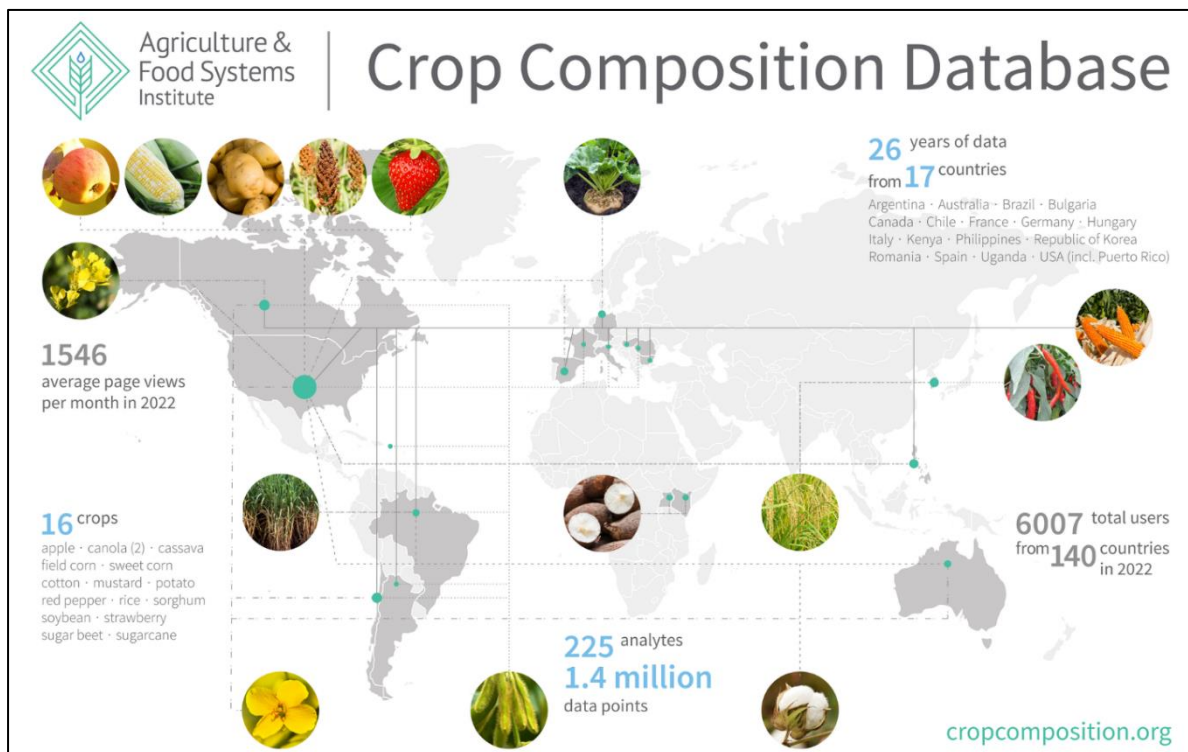
The in-person workshop covered key concepts on problem formulation, codex principles, and the basics of food and feed safety assessment for whole foods, with a focus on gene editing. It also included a session on current global practices related to approaches for the regulation of gene edited organisms. The participants, through a series of lectures and practical exercises, gained experience in applying safety assessment concepts to products of gene editing. Participants were provided with a resource document containing case studies translated to Korean, and the presentations benefited from live translation. A total of 38 participants attended.

#### 4. Additional Information – AFSI Resources

##### *Crop Composition Database*

AFSI's [Crop Composition Database](#) (CCDB) is a curated, open access resource that provides compositional data on the natural variability in nutrients, anti-nutrients, and secondary metabolites of some conventionally bred crop species that form the world's food and feed supply. The data can be applied to improve overall knowledge of human nutrition, inform the development of diets that promote the healthy growth of livestock, and improve global datasets related to food security and nutrition modelling. The database contains compositional data from 16 crops obtained from controlled field trials done over 26 years across 17 countries.

[Version 9.1 of the CCDB](#) was released in February 2023 with data for new crops, including canola – *Brassica juncea*, cassava – *Manihot esculenta*, and red pepper – *Capsicum annum*, along with additional data for sugar beet. Compositional dataset for cowpea is in the pipeline for publication. The following infographic summarises the salient features of Version 9.1 of the CCDB:



##### *eLearning courses*

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

## AUDA NEPAD-ABNE (AFRICAN BIOSAFETY NETWORK OF EXPERTISE)

### 1. Developments related to biosafety activities

#### 1. Risk assessment/regulatory decisions:

During the period under review, AUDA-NEPAD implemented several capacity strengthening activities in biosafety and the management of genome editing applications in several AU member states including Zambia, Zimbabwe, Eswatini, Malawi, Kenya, Ethiopia, Rwanda, Ghana, Nigeria, Senegal and Burkina Faso. The highlight of the reporting period is that Ethiopia granted an environmental release approval for MON 810 X MON 87460 maize in April 2022. It may be recalled that Nigeria had earlier authorized the environmental release of MON-87460-4 × MON-89034-3 - TELA Maize in October 2021. In addition, Ghana authorized the environmental release of pod borer resistant cowpea. Zimbabwe is currently conducting multi-location trials of Bt cotton. In countries that had already granted approvals for confined field trials (CFTs), several new CFTs were approved such as insect resistant and herbicide tolerant cotton, herbicide tolerant soyabean and leaf blight resistant potato in Ethiopia, and late blight resistant (LBR) potato in Rwanda.

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

Malawi and Ethiopia developed guidelines for safety assessment of food and feed derived from genetically modified crops. Further to this, support provided to the focus countries resulted in the validation of guidelines on labelling of GM food/ingredients in Ghana, adoption of guidelines for regulating staked genes in Kenya, Nigeria, Malawi and Ethiopia, and adoption of a common guideline on Institutional Biosafety Committee by 15 West Africa member states.

### 2. Updates regarding international activities

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

AUDA-NEPAD supported the African Group of Negotiators (AGN) in several preparatory meetings and intersessional activities in the lead up to the 2022 UN Convention on Biological Diversity (UNCBD) and its protocols. Furthermore, AUDA-NEPAD supported the participation of the national focal points and national competent authorities for biosafety, access and benefit-sharing and biodiversity during the 4th Meeting of the Open-Ended Working Group Meeting on the post-2020 global biodiversity framework that was held in Nairobi from 21-26 June 2022 and in the 15th Meeting of the Conference of the Parties to the Convention on Biological Diversity that was held in Montreal, Canada from 7 - 19 December 2022.

International experience and study tours are important for African regulators, policy- and decision-makers to help them build confidence towards making science-based decisions on biosafety applications. A biotechnology and biosafety study tour to India was organised in collaboration with Michigan State University and the Earth and Resources Institute of India for regulators and decision makers drawn from Eswatini, Zambia, Zimbabwe, Kenya, Ghana, Nigeria, Burkina Faso and Ethiopia.

#### 2. Specific cases of use of OECD tools and information:

Biosafety regulators are being supported to streamline the process for approval of GMOs for direct use for food, feed or for processing (FFPs) as well as for GM food and feed imports. This is based on the principle of reliance on / recognition of conclusions from food/feed safety assessment reviews done by other jurisdiction(s). This approach enables regulators to access decision documents, safety assessment summaries and other information on authorized GM events in various countries, via platforms such as the OECD Biotrack product database, Biosafety Clearing House (BCH), Food and Agriculture Organization (FAO) GM Foods platform. During the reporting period, the approval of Maize event T25 (ACS-ZM003-2), Soybean event A2704-12 (ACS-GM005-3), Soybean event A5547-127 (ACS-GM006-4) for direct use for food, feed or for processing in Ghana considered information accessed on the OECD Biotrack product database along with other considerations. In addition, AUDA-NEPAD submitted a synopsis of this approach as a scenario together with the ECOWAS biosafety regulation, in the draft Considerations for Collaborative Work on the Safety Assessment of Foods and Feeds Derived from rDNA plants – OECD Consensus document, for experience sharing.

### 3. Developments related to new breeding techniques (NBTs)

AUDA-NEPAD conducted awareness creation and sensitisation workshops in focus AU member states and provided support for the development or launching of guidelines for the regulation of genome edited crops in Nigeria, Kenya, Malawi and Ethiopia.

Regarding management of emerging technologies, AUDA-NEPAD initiated a genome editing project that focuses on communication and advocacy about the technology to a cross section of stakeholders including policy makers, scientists, regulators, and the media with the objective of creating a buy-in for technology uptake and scaling up. The project also seeks to establish communities of practice for scientists and science communicators. This is hoped to foster the responsible development and use of the technology for agricultural development and economic growth.

So far, policy dialogue visits, sensitisation workshops and working group meetings for the development of genome editing communication strategies have been conducted in countries such as Nigeria, Ethiopia, Zimbabwe, Zambia, Kenya, Burkina Faso and Ghana. The project held a regional workshop in Lagos, Nigeria from 12-16 December 2022 and an experience sharing visit to R&D and policy institutions in Ethiopia from 13-17 February 2023 to foster networking and creation of communities of practice.

Regarding R&D on genome editing, Ethiopia is working towards testing of genome edited tef (*Eragrostis tef*) in collaboration with the Donald Danforth Plant Science Centre. Kenya is working towards the development and testing of genome edited maize that is resistant to maize lethal necrosis disease in collaboration with Corteva AgricScience and CIMMYT with financial support from BMGF. Burkina Faso has conducted trials of genome edited rice resistant to bacterial blight disease, but further progress appears to have been curtailed pending the adoption of guidelines that would determine the regulatory status of genome editing guidelines.

Furthermore, genome editing research activities has already started or in the pipeline for African crops of interest such as sorghum (Kenya, Ethiopia), brassica (Ethiopia), and Cassava (Kenya).

### 4. Challenges

African producers recognize the potential biotech crops offer for circumventing some of their agricultural challenges on the continent. However, technology access and its commercial deployment may be hindered by absence of a conducive biosafety regulatory environment. As occurred elsewhere in the world, with farmers realizing lost opportunities because of difficulty in accessing the technology, cases of unauthorized access to technology have been observed due to porous borders in some jurisdictions, thus posing challenges for biosafety regulatory systems and threatening ideal post-release stewardship of the technology to protect the integrity of the product and to manage the development of insect resistance. Hence, there is a need for timely and regulated access and which requires effective and continuous stakeholder engagement to make quality GM seeds available for African farmers on reasonable terms.

## HESI (HEALTH AND ENVIRONMENTAL SCIENCES INSTITUTE)

**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, via a diverse range of technical committees, that informs applied health protection decision making around the globe. HESI is based in Washington D.C., USA, but operates globally.

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

- **Mission:** The committee’s mission is to advance the scientific understanding of the relevant parameters defining allergenic proteins and protein toxicity in novel foods and feeds by: (i) encouraging the development of reliable and accurate methodologies for characterizing the allergenic potential and “toxicity”

potential of novel sources of proteins, and (ii) leveraging the power of bioinformatics approaches in accomplishing these efforts.

- To fulfil its mission, the committee brings together expertise from public and private sector scientists, with participants from the US FDA, US EPA, expert academics and clinicians with representatives from China, Europe, and the USA, as well as molecular biologists, toxicologists and bioinformaticians from agricultural biotechnology companies who share real world experiences and common challenges.

## **Developments since May 2022**

### ***1. Scientific resources and tools to support safety assessment of novel foods and feeds***

- a) **COMPARE Allergen Database**, [www.comparedatabase.org](http://www.comparedatabase.org) (7<sup>th</sup> iteration released Jan. 2023): This collaborative public-private initiative was launched in 2016 in response to the widespread use of genomic sequencing technology and the need to develop a coordinated process implementing a cutting-edge and high-throughput bioinformatic pipeline to identify a meaningful subset of “candidate sequences” which are then submitted to scientific review and curation by an independent panel of public-sector allergy experts. The database has been updated on an annual basis since then through a comprehensive and systematic process, described in [Ree et al, 2021. “The COMPARE Database: A Public Resource for Allergen Identification, Adapted for Continuous Improvement”](#). *Front. Allergy* 2, 39.

The database includes a built-in bioinformatics tool, **COMPASS (COMPare Analysis of Sequences with Software)**, which allows website-based, real-time use of the COMPARE 2023 database to run comparative sequence analysis, as per FAO/WHO & Codex Alimentarius guidelines on the testing of genetically modified plants for allergenicity (full length sequence search; 80-mer sliding window FASTA search; and 8-mer FASTA search).

COMPARE 2023 comprises 2,631 protein sequences and associated metadata. A detailed description of the updates made in this 2023 version is available on the database website under the [documentation page](#). This year, as part of COMPARE’s commitment to continuous improvement, we have updated the descriptions of over 1700 entries to generate meaningful description lines for allergen database users. This includes adding official IUIS names where possible, removing irrelevant text and including the parent accession for partial sequences where feasible.

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 (> 100 countries and > 4400 users worldwide in 2022).

- b) **Framework development: *in silico* evaluation of potential toxicity of novel proteins (new activity)**

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

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

### ***2. Experimental research***

Resources permitting, the committee undertakes experimental work aimed at providing a greater understanding of the underlying mechanisms of allergenicity, which are relevant to regulatory considerations related to the evaluation of novel proteins or novel foods and feeds derived from biotechnology. Results of one such project were published in 2022:

- Akkerdaas, J. H., Cianferoni, A., Islamovic, E., Kough, J., Ladics, G. S., McClain, S., Poulsen, L. K., Silvanovich, A., Pereira Mourìès, L., & van Ree, R. (2022). Impact of Food Matrices on Digestibility of Allergens and Poorly Allergenic Homologs. *Frontiers in Allergy*, 3, 909410. <https://doi.org/10.3389/falgy.2022.909410> (open access)
- 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.

Two other projects are in final stages or in publication development stage:

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

### 3. *International Outreach: presentations and publications*

#### **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 Mourìès, L. *The COMPARE Database: A Comprehensive Public Resource for Allergen Identification and Protein Allergenicity Assessment*. June 2022. (Link to conference poster gallery: [https://www.one2022.eu/posters/gallery?field\\_session\\_category\\_target\\_id=All&field\\_assigned\\_session\\_title=All&co mbine=Poulsen](https://www.one2022.eu/posters/gallery?field_session_category_target_id=All&field_assigned_session_title=All&co mbine=Poulsen))

#### **Presentation at the International Society for Biosafety Research 2023 Symposium (<https://isbr.info/symposium>):**

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

#### **2022 Publications:**

- Bauman PA, Doxey AC, Eberini I, Islamovic E, Jungo F, Kessenich C, Kough J, Krishanh M, Palazzolo L, Privalle L, Rodriguez CE, Satchell KJF, Silvanovich A, Pereira Mourìès 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 Mourìès 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 committee welcomes 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.

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