Organisation for Economic Co-operation and Development

ENV/CBC/MONO(2023)28

Unclassified

English - Or. English

30 June 2023

ENVIRONMENT DIRECTORATE
CHEMICALS AND BIOTECHNOLOGY COMMITTEE

Development in Delegations on Biosafety Issues, June 2022 – April 2023

Series on the Harmonisation of Regulatory Oversight in Biotechnology
No. 72

JT03522880

OECD Environment, Health and Safety Publications

Series on the Harmonisation of Regulatory Oversight in Biotechnology

No. 72

Developments in Delegations on Biosafety Issues, June 2022 – April 2023

Environment Directorate

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Paris 2023

Also published in the Series on Harmonisation of Regulatory Oversight in Biotechnology:

No. 1, Commercialisation of Agricultural Products Derived through Modern Biotechnology: Survey Results (1995)

No. 2, Analysis of Information Elements Used in the Assessment of Certain Products of Modern Biotechnology (1995)

No. 3, Report of the OECD Workshop on the Commercialisation of Agricultural Products Derived through Modern Biotechnology (1995)

No. 4, Industrial Products of Modern Biotechnology Intended for Release to the Environment: The Proceedings of the Fribourg Workshop (1996)

No. 5, Consensus Document on General Information concerning the Biosafety of Crop Plants Made Virus Resistant through Coat Protein Gene-Mediated Protection (1996)

No. 6, Consensus Document on Information Used in the Assessment of Environmental Applications Involving *Pseudomonas* (1997)

[No. 7, Consensus Document on the Biology of *Brassica napus* L. (Oilseed Rape) (1997) – ***REPLACED with Consensus Document on* Brassica *crops (*Brassica *spp). No. 54 (2012)***]

No. 8, Consensus Document on the Biology of *Solanum tuberosum* subsp. *tuberosum* (Potato) (1997)

No. 9, Consensus Document on the Biology of *Triticum aestivum* (Bread Wheat) (1999)

No. 10, Consensus Document on General Information Concerning the Genes and Their Enzymes that Confer Tolerance to Glyphosate Herbicide (1999)

No. 11, Consensus Document on General Information Concerning the Genes and Their Enzymes that Confer Tolerance to Phosphinothricin Herbicide (1999)

No. 12, Consensus Document on the Biology of *Picea abies* (L.) Karst (Norway Spruce) (1999)

No. 13, Consensus Document on the Biology of *Picea glauca* (Moench) Voss (White Spruce) (1999)

[No. 14, Consensus Document on the Biology of *Oryza sativa* (Rice) (1999) – ***REPLACED with Revised Consensus Document on the Biology of Rice (Oryza sativa L.) No. 70 (2021)***]

No. 15, Consensus Document on the Biology of *Glycine max* (L.) Merr. (Soybean) (2000)

No. 16, Consensus Document on the Biology of *Populus* L. (Poplars) (2000)

No. 17, Report of the OECD Workshop on Unique Identification Systems for Transgenic Plants, Charmey, Switzerland, 2-4 Oct. 2000 (2001)

No. 18, Consensus Document on the Biology of *Beta vulgaris* L. (Sugar Beet) (2001)

No. 19, Report of the Workshop on the Environmental Considerations of Genetically Modified Trees, Norway, September 1999 (2001)

No. 20, Consensus Document on Information Used in the Assessment of Environmental Applications Involving Baculoviruses (2002)

No. 21, Consensus Document on the Biology of *Picea sitchensis* (Bong.) Carr. (Sitka Spruce) (2002)

No. 22, Consensus Document on the Biology of *Pinus strobus* L. (Eastern White Pine) (2002)

No. 23, Revised 2006: OECD Guidance for the Designation of a Unique Identifier for Transgenic Plants (2006)

No. 24, Consensus Document on the Biology of *Prunus* spp. (Stone Fruits) (2002)

No. 25, Module II: Herbicide Biochemistry, Herbicide Metabolism and the Residues in Glufosinate-Ammonium (Phosphinothricin)-Tolerant Transgenic Plants (2002)

No. 26, Output on the Questionnaire on National Approaches to Monitoring/Detection/Identification of Transgenic Products (2003)

No. 27, Consensus Document on the Biology of *Zea mays* subsp. *mays* (Maize) (2003)

No. 28, Consensus Document on the Biology of European White Birch (*Betula pendula* Roth) (2003)

No. 29, Guidance Document on the Use of Taxonomy in Risk Assessment of Micro-organisms: Bacteria (2003)

No. 30, Guidance Document on Methods for Detection of Micro-organisms Introduced into the Environment: Bacteria (2004)

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

No. 32, An Introduction to the Biosafety Consensus Documents of OECD's Working Group for Harmonisation in Biotechnology (2005)

No. 33, Consensus Document on the Biology of Papaya (*Carica papaya*) (2005)

No. 34, Consensus Document on the Biology of *Pleurotus* spp. (Oyster Mushroom) (2005)

[No. 35, Points to Consider for Consensus Documents on the Biology of Cultivated Plants (2006) – ***REPLACED with Revised Points to Consider document No. 67 (2020)***]

No. 36, Consensus Document on the Biology of *Capsicum annuum* Complex (Chili, Hot and Sweet peppers) (2006)

No. 37, Consensus Document on Information Used in the Assessment of Environmental Application involving Acidithiobacillus (2006)

No. 38, Consensus Document on the Biology of Western White Pine (*Pinus monticola* Dougl. ex D. Don) (2008)

No. 39, Abstracts of the OECD Expert Workshop on the Biology of Atlantic Salmon (2006)

No. 40, Consensus Document on the Biology of *Pinus banksiana* (Jack Pine) (2006)

No. 41, Consensus Document on the Biology of the Native North American Larches: Subalpine Larch (*Larix lyallii*), Western Larch (*Larix occidentalis*), and Tamarack (*Larix laricina*) (2007)

No. 42, Consensus Document on the Safety Information on Transgenic Plants Expressing *Bacillus thuringiensis* – Derived Insect Control Protein (2007)

No. 43, Consensus Document on the Biology of Douglas-Fir (*Pseudotsuga menziesii* (Mirb.) Franco (2008)

No. 44, Consensus Document on the Biology of Lodgepole Pine (*Pinus contorta* Dougl. ex. Loud.) (2008)

No. 45, Consensus Document on the Biology of Cotton (*Gossypium* spp.) (2008)

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

No. 47, Guide for Preparation of Biology Consensus Documents (2008)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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/).

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/)

or contact:

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

E-mail: ehscont@oecd.org

FOREWORD

The Working Party on the Harmonisation of Regulatory Oversight in Biotechnology (WP-HROB) is a subsidiary body of the Chemicals and Biotechnology Committee of the OECD.

The WP-HROB aims to assist countries in evaluating the potential risks of genetically-engineered organisms, foster communication and mutual understanding of relevant regulations in countries, and facilitate harmonisation in environmental risk/safety assessment of organisms produced through modern biotechnology. This programme encourages information sharing, promotes harmonised practices and contributes to prevent duplication of efforts among countries, while consolidating high biosafety standards. The WP-HROB's activities and outputs are complementary to those of the Working Party for the Safety of Novel Foods and Feeds, which deals with risk/safety of novel foods and feeds derived from genetically-engineered organisms.

The WP-HROB main outputs are the science-based ***consensus documents***. Dealing with the biology of certain plant (crops, trees) and animal species, selected traits introduced into transformed plants, information on micro-organisms, the consensus documents are mutually acceptable among member countries and partners. These practical tools contain information for use during the regulatory assessment of the environmental safety (or 'biosafety') of a particular product of biotechnology. They are available at www.oecd.org/env/ehs/biotrack/.

Of different content, this information document compiles elements provided by delegations on the occasion of the 37th WP-HROB meeting (17-19 April 2023). It aims at summarising relevant information on activities related to biosafety issues 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-HROB endorsed this document, which is published under the responsibility of the Chemicals and Biotechnology Committee of the OECD.

Table of contents

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 authorizations 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
QUANTITY	23	3	10
CROP			
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

Microorganisms:

Product	Phenotype	Institution	Activity
Inactivated Vaccine, Recombinant *E.coli* (enterotoxigenic pathotype) for Bovine immunisation.	*E. coli* enterotoxic strain that expresses a quimeric protein from an enterohemoragic strain.	INTA	Field trials

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	141/2021
MON 87751-7	Monsanto Argentina	Soybean	Resistance to Lepidoptera insects, especially *Rachiplusia nu*, *Chrysodeixis includens* and *Anticarsia gemmatalis*, as well as other minor pests in soybeans such as Helicoverpa	Only for processing	12/05/2022	28/2022
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	51/2022
IND- ØØ412-7	INDEAR	Wheat	Tolerance to drought, Tolerance to the herbicide glufosinate ammonium	Cultivation, Food and Feed	11/05/22	27/2022
DNB-Ø8ØØ2-3	INDEAR	Soybean	Resistance to Lepidoptera insects, Tolerance to herbicides based on glufosinate ammonium.	Cultivation, Food and Feed	11/05/22	5/2023
SYN-E3272-5	Syngenta Agro S.A.	Soybean	Expresses the enzyme AMY797E alpha-amylase, Tolerance to glyphosate and glufosinate ammonium herbicides, Better behaviour against attack by lepidopteran insects	Cultivation, Food and Feed	23/01/23	5/2023
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 behaviour against attack by lepidopteran insects	Cultivation, Food and Feed	23/01/23	5/2023

HB4 Wheat:

By resolution 27/2022 Argentina allows the INSTITUTO DE AGROBIOTECNOLOGÍA ROSARIO S.A. (INDEAR S.A.) to commercialize the seed, and the products and by-products derived from it, coming from the IND-ØØ412-7 wheat, and all the progeny derived from the crosses of this material with any non-genetically modified wheat.

Having complied with Article 2 of Resolution No. 41 dated October 7, 2020 of the SECRETARIAT OF FOOD, BIOECONOMY AND REGIONAL DEVELOPMENT of the MINISTRY OF AGRICULTURE, LIVESTOCK AND FISHERIES, which stipulated full approval in Brazil (largest importer of Argentine wheat), varieties of wheat with event IND-ØØ412-7 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 (Saccharomyces cerevisiae), with improved ethanol production capacity from starch.
Reconvinant HVT-ND virus present in Poulvac Procerta HVT-ND vaccine.	Protects against Marek's (MD) and Newcastle (ND) diseases in chickens.
Reconvinant 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 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, 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 5th Meeting of the Working Group (WG2020-5), 15th Conference of the Parties (COP-15), 10th 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 in June in Buenos Aires and in 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 Biodesarrollar Magazine, which seeks to communicate the latest developments and innovation in bioeconomy: https://www.argentina.gob.ar/sites/default/files/revista_biodesarrollar_-_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
- 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 commercialization. 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 commercialization.

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**
Ciclo Sin Fin	Cutlery	Castile cane (weed)
Radha Colors	Cotillon	Cornstarch
Malón Bikes	Bikes	Bamboo
Get Wild	Cothing	Bamboo (textile)
Ecoderm	Facial emulsion	Biobased oils and extracts (apple, sunflower, orange, etc.)
Natwash	Antimicrobial solution for cleaning fruits and vegetables	Citric acid, ascorbic acid, lactic acid, caramel coloring
Soltec	Line of ecological cleaning creams for industrial, artistic and domestic use	Organic acids, oils and vegetable essences.
Fauna Brava	Line of cotton cloth dolls	Cotton cloth for the elaboration of the product and packaging.
BIOZ	Bioplastic straws	Biopellets
NEO-PLAST	Spoons and straws made with bioplastics	Biopellets
BIOPINTURAS ARGENTINAS	Biobased latex paint	Concentrated whey protein (milk residue) and stalk mucilage
RUNA SUSTENTABLE	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
APIWRAP	Waxed cloth for preserving food	Cotton cloth, beeswax
BIOGRÁFICA	Biobanner y biovinilo	biopellets
PRINT A LOT	filament line for 3d printing	PLA / PLA 3Di/PLA MAX/ PLA ART
FUNGIPOR	Pots and corners made with biomanufacturing techniques	Mycelium, waste from the agricultural industry
PULPACK	Manufacture of parts for protection	Recycled cellulose
AIN VEGAN	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
MARAÑA ESTAMPAS	Textile objects made with natural dyes	Cotton fabrics and natural dyes of onion, avocado, among others

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

Certificates:

Company	**Products**	**Raw material**
IQUIMEFA-UBA-CONICET	Flexible hydrogel based on keratin	Meat discards
IMBIV CONICET UNC, CIAD-CONACYT-Mexico	Active component of multilayer packaging for hermetic storage. essential oil, mixture of terpenic compounds	essential oil, mixture of terpenic compounds
SUPERBOL SRL	Line of biocompostable bags	biopellets corn starch
ALAS DE OVEJA	Felt products	discarded sheep wool
ABRIGA	Thermo acoustic blankets	discarded sheep wool
BIOLEÑA	fire starter sawdust, wood shavings	wood shavings
NOBAC	Filtering system for domestic use	wood, coconut
HMA4 S.A.	Line of biocontrollers for plant pathogens and pests.	beneficial microorganisms and plant extracts.
HMA4 S.A.	Plant growth biostimulant product line.	Nutrients, minerals, vitamins and microorganisms that promote plant growth.
BENEFICIAL GERMS	Recombinant lactase for the dairy market. beneficial microorganisms.	beneficial microorganisms.
CAMPO LAVALLE S.A.	Biofertilizer for vegetable crops	Worm humus, enriched with amino acids of plant origin.
MICROVIDAS	Line of biostimulant, biofertilizer and biological control products for vegetable crops..	beneficial microorganisms
INTA	Biocontroller for strawberry cultivation.	Ethanolic extract of propolis
INTA	Biocontroller of the eucalyptus bug. parasitoid .	macroorganisms of insect pests.
CONICET	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.
MOSQUITA FEED Co SAS	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. DEVELOPMENTS RELATED TO IMPLEMENTATION OF NATIONAL BIOSAFETY FRAMEWORK

Australia's legislation regulating genetically modified organisms (GMOs), the *Gene Technology Act 2000* (GT Act) and its supporting Gene Technology Regulations 2001 (GT Regulations), is administered by the Gene Technology Regulator (the Regulator) and the Office of the Gene Technology Regulator (OGTR).

1. RISK ASSESSMENT/REGULATORY DECISIONS

ENVIRONMENTAL RELEASE APPROVALS.

GMO REGISTER (UNDER ASSESSMENT)

In February 2022, a risk assessment and risk management plan (RARMP) was prepared in consideration for the inclusion of dealings with MON-ØØØ73-7 **canola**, genetically modified for **herbicide tolerance (glyphosate)**, on the GMO Register. The public consultation period on the RARMP closed in March 2022. This canola event is currently authorised for commercial release in Australia under licence DIR 020/2002.

If this canola event is placed on the GMO Register it would mean that there would no longer be a requirement for there to be a licence holder for this GMO, and anyone could conduct dealings with the GMO (subject to any conditions placed on the registration). A decision on its inclusion is yet to be made by the Regulator as submissions are still being considered.

Details of GMOs placed on the GMO Register, including RARMPs, are available at: https://www.ogtr.gov.au/what-weve-approved/gmo-register

LICENCES FOR ENVIRONMENTAL RELEASE since April 2022 (at 22 May 2023)

Environmental release of GMOs requires authorisation under a licence for GMO dealings involving intentional release to the environment (DIR licence).

Details of all environmental release applications, RARMPs and approvals are available on the OGTR website: https://www.ogtr.gov.au/what-weve-approved/dealings-involving-intentional-release

Commercial release approvals – GM plants

Two (2) GM plant commercial release approvals:

- GM **Indian mustard** (*Brassica juncea*) – **herbicide tolerance** (glufosinate ammonium) (RF3) (DIR 190)
- Import of cut GM c**hrysanthemum** flowers (*Chrysanthemum* × *morifolium*) – **altered flower colour** (DIR 191)

Commercial release approvals – GM veterinary therapeutics

One (1) commercial release approvals of a GMO veterinary therapeutic:

- **Vaccine against infectious laryngotracheitis virus (ILTV) in chickens**, GMO is a **live attenuated ILTV virus with a glycoprotein G gene deletion**, which reduces pathogenicity (DIR 193)

Field Trial approvals - 'limited and controlled' releases

Two new GM plant field trials were approved since April 2022:

- GM **Indian mustard** (*Brassica juncea*) – **altered oil content** and **herbicide tolerance** (glufosinate ammonium) (DIR 188)
- GM **sorghum** (*Sorghum bicolor*) – **asexual seed formation** (DIR 189)

Clinical Trials approvals - 'limited and controlled' releases, human or veterinary GMO therapeutics

One human clinical trial with a GMO:

- **Cancer treatment** – GMO is a modified **chimeric orthopoxvirus** (CF33-hNIS) that preferentially multiplies in and kills cancer cells and can be visualised by medical imaging (DIR 192).

APPLICATIONS UNDER ASSESSMENT (at 22 May 2023)

Commercial release GM plants

As of 22 May 2023, there is one application for commercial release of GM plants under assessment.

- **GM banana** genetically modified for **disease resistance** to *Fusarium* wilt tropical race 4 (TR4) (DIR 199). An application for approval of the GM banana fruit as human food (A1274) is also being assessed by Food Standards Australia New Zealand (FSANZ).

Commercial release GMO therapeutics (human or veterinary)

One application for the commercial supply of a GMO therapeutic for chickens is currently under assessment:

- **Vaccine against infectious laryngotracheitis virus (ILTV) in chickens**, GMO is a **live attenuated ILTV virus with a glycoprotein G gene deletion**, which reduces pathogenicity (DIR 193)

Field trials of GM plants

As of 31 March 2023, there are no applications for the 'limited and controlled' release of GM plants under assessment.

Trials of GMO therapeutics (human or veterinary)

Two applications for trials of GMO therapeutics are currently under assessment:

- **Confined field trial of a vaccine against devil facial tumour disease in Tasmanian devils**, GMO is a replication defective human adenovirus serotype 5 (HAdV-5) vector with deletion of viral early-transcribed region 1 (E1) so that it cannot cause disease, and the deletion of viral early-transcribed region 3 (E3) and insertion of antigen genes to induce an immune response (DIR 195)
- **Clinical trial of a GM *Lactobacillus brevis*** bacteria for **treatment of inflammatory bowel disease** (DIR 197). The GM *L. brevis* has an introduced gene encoding human vasoactive intestinal peptide (VIP) which has anti-inflammatory effects.

Risk assessment guidance documents

Two biology documents have been revised since April 2022:

- The Biology of *Musa* L. (banana)
- The Biology of *Lolium multiflorum* Lam. (Italian ryegrass), *Lolium perenne* L. (perennial ryegrass), *Lolium arundinaceum* (Schreb.) Darbysh (tall fescue)

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

Modernisation of application processes – online forms

OGTR is continuing work on the development of online application and reporting forms as part of digital service delivery: https://www.ogtr.gov.au/resources/collections/application-and-reporting-forms

2. DEVELOPMENT/REVIEW/AMENDMENT OF NATIONAL STRATEGIES, REGULATIONS AND GUIDANCE

Amendments to legislation

No changes have been made to Australia's biosafety legislation, the *Gene Technology Act 2000* (GT Act) and Gene Technology Regulations 2001 (GT Regulations), since the 36th WPHROB meeting in May 2022. Versions of the GT Act and GT Regulations currently in force can be accessed from the OGTR website: https://www.ogtr.gov.au/about-ogtr/legislative-documents

Review of guidelines for certification of Physical Containment (PC) facilities

The OGTR has an ongoing program to revise the Regulator's guidelines for certification of Physical Containment (PC) facilities.

New PC3 guidelines and guidance were issued in September 2022 and they will apply to facilities certified or re-certified from 1 December 2022. Both the guidelines and guidance documents, along with a new version of the annual checklist for PC3 facilities, are available at: https://www.ogtr.gov.au/resources

A review of the PC2 guidelines has been initiated and consultation with PC2 certification holders will be conducted in the future.

New application form and guidance – Certification of a Physical Containment facility

A revised form for applying for certification of a facility to a specified level of Physical Containment was introduced in December 2022. The form is available here https://www.ogtr.gov.au/apply-gmo-approval/have-your-containment-facility-certified. Guidance on certification levels and facility types was published in November 2022 https://www.ogtr.gov.au/resources/publications/explanatory-information-guide-physical-containment-levels-and-facility-types .

New application form and guidance – clinical trials of GMO therapeutics

A new application form, and guidance for applicants, for licences for clinical trials in humans of GMO therapeutics were introduced in September 2022. The application form will be used for both DIR (involving intentional release of GMOs) and DNIR (not involving intentional release of GMOs) licence applications. The form and guidance were developed in light of the experience gained from assessment of an increasing number of clinical trial applications. The form and guidance are available online – https://www.ogtr.gov.au/apply-gmo-approval/apply-licence-conduct-human-clinical-trial-gmo and https://www.ogtr.gov.au/resources/publications/guidance-conducting-human-clinical-trials-involving-gmos

Ongoing Policy Review activities

The implementation of the Third Review of the National Gene Technology Regulatory Scheme is ongoing. This policy work is being undertaken by the Department of Health & Aged Care on behalf of the Gene Technology Ministers Meeting (comprised of all ministers from Australian jurisdictions). OGTR continues to provide technical and operational information to assist the Department of Health & Aged Care team leading the implementation of Review recommendations.

Details about the policy Review and its implementation are available at: https://www.genetechnology.gov.au/reviews-and-consultations/past/2017-third-review

1. RISK MANAGEMENT ACTIVITIES

OGTR continued to undertake monitoring and compliance activities throughout 2022-23. Details of OGTR monitoring activities are published in OGTR Annual Reports https://www.ogtr.gov.au/resources/publications/operations-gene-technology-regulator-annual-report-2021-22 .

2. PUBLIC ENGAGEMENT AND OUTREACH ACTIVITIES

Fact sheets

OGTR publishes Fact Sheets to provide information to the public on operation of the regulatory scheme.

A revision of a Fact Sheet on **Current GM plants authorised for release into the environment (GMO Register)** was published in **February 2023**.

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

National Institutional Biosafety Committee (IBC) Forum

The OGTR hosted the 9th National Institutional Biosafety Committee (IBC) Forum in Canberra on 12-13 May 2022. IBC fora are a major stakeholder engagement activity for the OGTR that provides an opportunity for representatives of accredited organisations and IBCs (i.e. regulated stakeholders) to engage with the OGTR on topics relevant to the regulation of GMOs in Australia.

OGTR newsletter

OGTR has continued its periodic Newsletter to communicate with regulated organisations about key updates, clarification of application processes and compliance requirements and current issues. OGTR newsletters available at: https://www.ogtr.gov.au/resources

3. UPDATES REGARDING INTERNATIONAL ACTIVITIES

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

In December 2022, an OGTR officer supported the Australian delegation to the 15th meeting of the Conference of Parties to the United Nations Convention on Biological Diversity (Convention), and the associated 5th meeting of the Open-ended Working Group on the Post-2020 Global Biodiversity Framework. The meetings took place in Montreal, Canada, from 3-19 December 2022.

In March 2023, Australia submitted information on the risk assessment of engineered gene drives for ongoing work under the UN Cartagena Protocol on Biosafety https://bch.cbd.int/en/submissions-to-notifications?notification=2023-007&schema=submission&currentPage=1

OGTR also participated in several other international forums and conferences since April 2022, including:

- Presentation at APEC webinar 'Outreach to Enhance Public Awareness and Confidence on Agricultural Biotechnology', 5 August 2022
- Presentation in webinar 'Key Considerations for Risk Assessment of Gene Drive Technologies'
- Fourth International Workshop for Regulation of Animal Biotechnology, Sao Paulo, Brazil, 12-16 September 2022
- Meeting of the working group 'Modern Biotechnology in Integrated Plant Production', Berlin, Germany, 28-30 September 2022
- APEC/ISAAA virtual workshop on 'Building knowledge and regulatory capacity in animal biotech in response to climate change', 27-28 February 2023
- International Symposium on Biosafety Research (ISBR), 16th Symposium, St. Louis, USA, 30 April-4 May 2023.

4. DEVELOPMENTS RELATED TO NEW BREEDING TECHNIQUES (NBTS)

1. DEVELOPMENT/REVIEW/AMENDMENT OF NATIONAL STRATEGIES, REGULATIONS AND GUIDANCE

OGTR and GMO regulation.

There have been no new regulatory developments specific to new breeding techniques or genome editing since the 2019 amendments to the Gene Technology Regulations. 'Gene edited' organisms excluded from regulation as GMOs are those resulting from site directed nuclease-1 (SDN-1) type modifications and without any introduced nucleic acid template to guide genome repair from regulation (defined in Schedule 1, Item 4).

Researchers and developers are encouraged to contact OGTR to discuss specific genome editing applications of genome edited organisms to clarify regulatory requirements. OGTR has published general guidance for researchers and potential applicants regarding regulatory coverage of genome editing - https://www.ogtr.gov.au/resources/publications/overview-status-organisms-modified-using-gene-editing-and-other-new-technologies .

New Breeding Techniques and food

The review by FSANZ of how the Food Standards Code applies to food derived using new breeding techniques (NBTs) is ongoing.

In December 2021, FSANZ completed a first round of consultation on a proposal (P1055 Definitions for gene technology and new breeding techniques) to amend the definitions for 'food produced using gene technology' and 'gene technology' in the Australia New Zealand Food Standards Code (the Code). A stakeholder feedback summary report which summarised the views and comments expressed by submitters was released in November 2022. FSANZ will continue to engage with key stakeholders throughout the proposal process, including by undertaking a second public consultation in the first quarter of 2023.

In December 2022, FSANZ released a report on a survey of consumer attitudes towards genetically modified foods and NBTs titled 'Consumer research on new breeding techniques'.

Information about the proposal and the review, including the stakeholder feedback summary report and the consumer survey report, is available at: https://www.foodstandards.gov.au/code/proposals/Pages/p1055-definitions-for-gene-technology-and-new-breeding-techniques.aspx

5. ADDITIONAL INFORMATION

Appointments to expert advisory committees

Current members and Chairs of the Gene Technology Technical Advisory Committee (GTTAC) and the Gene Technology Ethics and Community Consultative Committee (GTECCC) have been reappointed for a three-year term from 1 February 2023 to 31 January 2026.

The Gene Technology Regulator receives expert advice from the two statutory committees, GTTAC and GTECCC. GTTAC provides advice on all environmental release assessments. Communiqués from GTTAC and GTECCC meetings, and other information about the Committees, are available at: https://www.ogtr.gov.au/about-ogtr/australias-gene-technology-regulatory-system#gene-technology-committees

AUSTRIA

1. Developments related to implementation of national biosafety framework

(1) Risk assessment/regulatory decisions

During the current reporting period (May 2022 – March 2023) neither cultivation of GM crops nor deliberate release of GMOs for field trials occurred in Austria. Accordingly no new risk assessment/regulatory decisions were taken by Austrian competent authorities.

Austria, however, participated actively in the targeted consultations involving member states authorities/institutions which are conducted by EFSA for the risk assessment for notifications of GM-products for EU-wide authorisation for import and processing as well as food and feed use.

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

In March 2023 a proposal of the Austrian Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation and Technology to amend provisions of the the Austrian Patent Act (Österreichisches Patentgesetz, 1970) and related laws was submitted to the Austrian parliament.

The proposal addresses the following key points:

- Introduction of supplementary provisions regarding European unitary patents in the national regulations with regard to international agreements in the field of patents
- Requirement to indicate the origin of genetic resources or the source of traditional knowledge in relevant patent applications
- Introducing clarifications regarding the patentability of animals and plants and in particular clarifications concerning the special patent exclusion provision regarding essentially biological processes used to develop new plant and animal varieties
- Procedural changes to accelerate or simplify patent procedures
- Adaptation of the Trademark Protection Act to the amended provisions of Regulation (EU) No. 1151/2012

The proposal is processed further in the responsible parliamentary committee (Committee for Research, Innovation and Digitalization) before it is moved to the plenary of the parliament for a vote.

(3) Risk management measures

No new developments can be reported for the implementation of Directive 2015/412/EU in Austria: All prior decisions regarding the restrictions of geographical scope of GMO applications/authorisations for cultivation in Austria of several GM maize events (MON810, 1507, 59122, 1507x59122, Bt11, GA21, MIR604 and Bt11xMIR604xGA21) are still in place. Respective information is available at:
https://ec.europa.eu/food/plant/gmo/authorisation/cultivation/geographical_scope_en#at

(4) Research projects on biosafety; relevant publications

The following reports, scientific papers or other documents addressing issues related to biosafety were published (since May 2022):

Benevenuto, R. F., Zanatta, C. B., Waßmann, F., Eckerstorfer, M. F., and Agapito-Tenfen, S. Z. (2023). Integration of omics analyses into GMO risk assessment in Europe: a case study from soybean field trials. Environ Sci Eur 35. https://doi.org/10.1186/s12302-023-00715-6

Frieß, J. L., Lalyer, C. R., Giese, B., Simon, S., and Otto, M. (2023). Review of gene drive modelling and implications for risk assessment of gene drive organisms. Ecological Modelling 478, 110285. https://doi.org/10.1016/j.ecolmodel.2023.110285

Pascher, K., Švara, V., and Jungmeier, M. (2022). Environmental DNA-Based Methods in Biodiversity Monitoring of Protected Areas: Application Range, Limitations, and Needs. Diversity 14, 463. https://doi.org/10.3390/d14060463

Racovita, M., and Spök, A. (2022). Strategic science translation in emerging science: genetically modified crops and Bisphenol A in two cases of contested animal toxicity studies. GM Crops Food 13, 142–155. https://doi.org/10.1080/21645698.2022.2103368

2. Updates regarding international activities

- Environment Agency Austria coordinated the Austrian activities for implementation of the Cartagena Protocol on Biosafety and the participation to the rescheduled meeting of the Conference of the Parties to the CBD serving as the Meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 10, December 2022, Montreal, Canada).
- Environment Agency Austria participates in the Liaison Group of the Cartagena Protocol and serves as representative of the WEOG in the Compliance Committee of the Protocol.
- Participation in informal and formal meetings of SBSTTA and SBI of the CBD (relevant topics: synthetic biology, risk assessment and management of LMOs, implementation plan post 2020 for the Cartagena Protocol).
- Experts from Environment Agency Austria will participate in online forums organised by the Secretariate to the CBD dealing with synthetic biology (following a decision by COP15 of the CBD) and Risk Assesment regarding engineered gene drives (following a decision by COPMOP10). These online forums will start in the second quarter of 2023.

3. Developments related to new breeding techniques (NBTs)

(1) Development/review/amendment of national strategies, regulations and guidance:

The Austrian competent authorities and national institutions involved in risk assessment and management of GM products submitted a coordinated response to a statement by EFSA concerning criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis (Mullins et al., 2022).

The Austrian response outlines that the proposed criteria are not sufficiently developed to adequately determine the specific approaches to risk assessment for plant products which may be developed by targeted mutagenesis and cis- or intragenesis, considering the very diverse range of the particular developments. Currently these criteria also do not address some risk assessment issues relevant for a significant number of such plants, e.g. the assessment of unintended genetic modifications. As proposed by EFSA some follow-up work on issues laid out by the EFSA statement seems appropriate. This follow-up process should address the further elaboration of the proposed concept and the questions how appropriate data requirements may be defined and how such requirements could be implemented in a scientifically sound and comprehensive proportionate risk assessment approach.

Mullins, E., Bresson, J.-L., Dalmay, T., Dewhurst, I. C., Epstein, M. M., Firbank, L. G., et al. (2022). Criteria for risk assessment of plants produced by targeted mutagenesis, cisgenesis and intragenesis. EFSA J 20, e07618. https://doi.org/10.2903/j.efsa.2022.7618

(2) Specific cases of application, assessment and decision:

To date, Austria did not receive any applications for authorisation of an NGT-product which is subject to the EU GMO regulations according to the ruling by the European Court of Justice (Case C-528/16).

If any NGT-applications are submitted in the future, the current GMO authorisation procedure and labelling requirements according to the Austrian Gene Technology Act will apply for these products.

(3) Other national activities:

The activities initiated by the authorities to involve national stakeholders in discussions on and in preparation of a national position towards a policy on applications of new genomic techniques (NGT) are pursued.

A symposium for national and European stakeholders addressing NGT-related issues of risk assessment, consumer choice and sustainability considerations for NGT applications was held in Vienna on June 21st of 2022.

The event took place in a hybrid format. Overall, 174 persons participated, 92 on-site in Vienna and 82 online. Participants represented a wide range of different stakeholders, such as authorities from ten different EU Member States and the EU commission, associations for GM-free food production and organic farming, food companies, retailers, scientists, NGOs and consumer organisations. The discussion addressed the following topics:

- Risk Assessment of NGT applications and the proposal of the EC
- Impacts of NGT applications on Organic and GM-free Production
- Links of the NGT initiative to the goals of the European Green Deal

Overall, the need to ensure coexistence of all food production systems based on a transparent system of traceability and labelling became clear. This needs to be supported by adequate funding for research in sustainability (analyses) of food chains and agriculture, risk assessment of NGT products and detection methods. To address the current challenges a participatory approach including a wide range of opinions and perspectives is considered to be fundamental.

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

The following reports, scientific papers or other documents addressing issues related to NGTs are available (since May 2022):

Spök, A., Sprink, T., Allan, A. C., Yamaguchi, T., and Dayé, C. (2022). Towards social acceptability of genome-edited plants in industrialised countries? Emerging evidence from Europe, United States, Canada, Australia, New Zealand, and Japan. Front Genome Ed 4, 899331. https://doi.org/10.3389/fgeed.2022.899331

Eckerstorfer, M.F.; Dolezel, M.; Engelhard, M.; Giovannelli, V.; Grabowski, M.; Heissenberger, A.; Lener, M.; Reichenbecher, W.; Simon, S.; Staiano, G.; Wüst Saucy, A.G.; Zünd, J.; Lüthi, C. (2023). Recommendations for the Assessment of Potential Environmental Effects of Genome-Editing Applications in Plants in the EU. Plants 12, 1764. https://doi.org/10.3390/plants12091764

BELGIUM

1. Developments related to implementation of national biosafety framework

Risk assessment/regulatory decisions

Applications for commercialisation

Belgium is actively involved in the European Food Safety Authority (EFSA) and European Medicine Agency (EMA) consultation for placing on the market of genetically modified organisms (GMOs). Input in the risk assessment is provided through the Biosafety Advisory Council, which besides food and feed aspects also evaluates environmental impacts of GMOs. The Service Biosafety and Biotechnology (SBB) of Sciensano (https://www.sciensano.be/en) ensures the secretariat of the Biosafety Advisory Council and provides permanent scientific support to its activities. Assessment reports and relevant documents can be consulted on http://www.bio-council.be and http://www.biosafety.be. The OECD consensus documents on the biology of plants are consulted during the evaluations.

Notifications for field trials

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

Currently, a field trial with GM maize generated via CRISPR-Cas (B/BE/22/V3) and a field trial with GM poplar are ongoing (B/BE/21/V1). Since the last WP meeting, a new field trial modified by CRISPR-Cas has been handed in.

Field trials notified since May 2022:

- Field trial with a gene-edited maize modified for reduced height (B/BE/23/V1)

Notifications for clinical trials

Three clinical trials with investigational medicinal products containing or consisting of GMOs have been notified and

three of such clinical trials have been approved under the framework of deliberate release since the last WP-HROB meeting (for more information, see: https://www.biosafety.be/content/clinical-trials-gmos-database).

Clinical trials (3) notified since May 2022

- Phase 2 Duchenne Muscular Dystrophy gene therapy trial (B/BE/22/BVW5)
- Phase 3 Duchenne Muscular Dystrophy gene therapy trial (B/BE/22/BVW6)
- Phase 2 Eye degenerative disease gene therapy trial (B/BE/23/BVW2)

Clinical trials (3) approved since May 2022

- Phase 1 Rift Valley Fever candidate vaccine trial (B/BE/21/BVW2)
- Phase 3 Duchenne Muscular Dystrophy gene therapy trial (B/BE/21/BVW5)
- Phase 1/2 cancer immunotherapy trial (B/BE/22/BVW4)

2. Updates regarding international activities

Participation in/hosting international symposia/fora relating to biosafety

Belgium is a party to the Convention on Biological Diversity, the Cartagena and the Nagoya Protocol, and has actively participated in the respective COP15, COP-MOP10 and COP-MOP5 meetings in December 2022 in Montreal, Canada.

3. Developments related to new breeding techniques (NBTs)

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

Since the last WP-HROB meeting, the European Commission published a new impact assessment on plants obtained by targeted mutagenesis and cisgenesis which was open for consultation. Some Belgian entities contributed to this consultation. A legislative proposal for NGTs is foreseen for the second quarter of 2023 (for more information on the initiative, we refer to the following link).

2. Specific cases of application, assessment and decision

Three field trials with genome-edited maize plants (generated via CRISPR-Cas technology) were notified and authorised in 2022 of which one trial will continue in 2023. In 2023, a new field trial with a gene-edited plant (generated via CRISPR) has been handed in and is under evaluation (for more information see link).

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

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.

Project "GeneBEcon" – a project funded under the Horizon Europe programme destination 'Clean environment and zero pollution' focusing on circular bio-based systems in industrial sectors along value chains and supply chains of biological feedstock. By researching and innovating using New Genomic Techniques (NGTs), the researchers aim to provide farmers and bio-based industries with climate-friendly and less polluting agricultural and aquaculture solutions. Potato and microalgae will be used as case-studies. GeneBEcon's results are within the scope of the European Green Deal, the circular economy action plan, and the bioeconomy strategy. The results will be used to inform scientists, policymakers, plant breeders, farmers, industry and consumers. The Belgian institute ILVO is playing a key role in this project.

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 cerevisae* strain PRCH20080 - FS0436; Yeast for biofuel production; **Developer**: Danisco Brasil Ltda;
- *Saccharomyces cerevisae* strain M32292; Yeast for biofuel production; **Developer**: Lallemand Soluções Biológicas Ltda;
- *Saccharomyces cerevisae* strain M32376; Yeast for biofuel production; **Developer**: Lallemand Soluções Biológicas Ltda;
- *Saccharomyces cerevisae* 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.

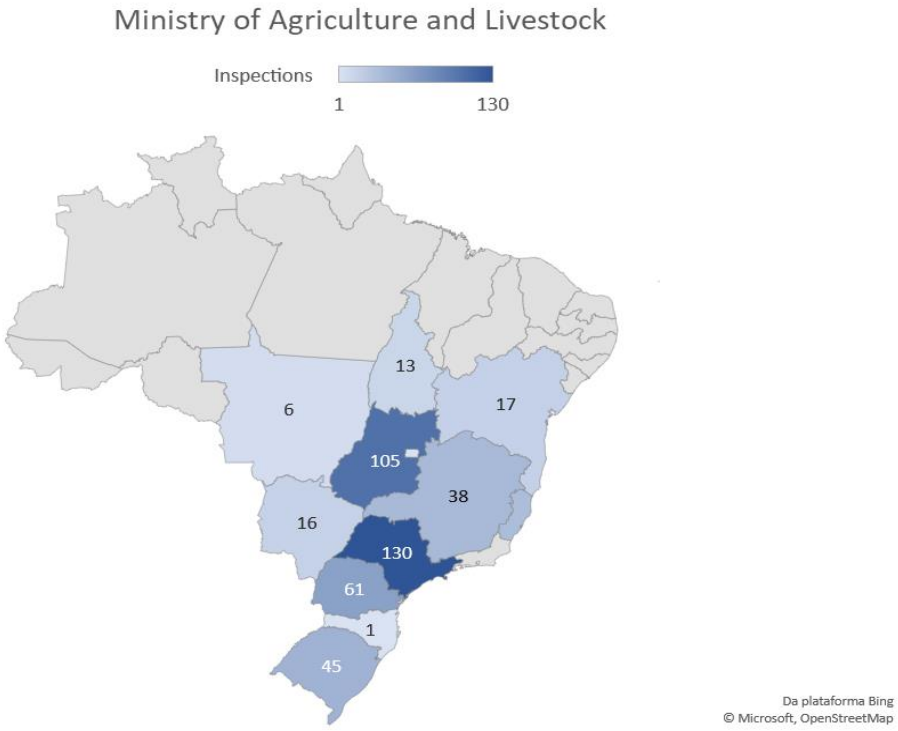
The Biotec-Latam reports the following adoption rates in Brasil:

- 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 nº 16 is applicable to all types of organisms and establishes a consultation system, on a case-by-case basis, for products obtained from Innovative Precision Breeding Techniques defined as a set of new methodologies and approaches that differ from the genetic engineering strategy by transgenics, as they result in the absence of recombinant DNA/RNA in the final product. In practical terms, products obtained either by site-directed random mutation involving the joining of non-homologous ends (SDN1 mutation), or site-directed homologous repair involving one or few nucleotides (SDN2 mutation) meets the conditions established in Normative Resolution nº 16 to be designated as not GM in a case-by-case analysis, but then again, site-directed transgene insertions (SDN3 mutation) are designated GM according to the provisions of the normative and will have to go through all biosafety requirements.

Since last meeting in 2022 the following products were developed under the CTNBio Normative Resolution nº 16 definitions, therefore not GM:

- **Product**: Drought tolerant soybean; **Developer** GDM Genética do Brasil S.A;
- **Product**: dsRNA insect control; **Developer**: Evoluttna 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 microrganism; **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:** Evoluttna Agro Biotecnologia Ltda;
- **Product:** dsRNA insect control; **Developer:** Sempre Agtech Ltda.

7. GM data bank

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

CANADA

1. CANADIAN FOOD INSPECTION AGENCY AND HEALTH CANADA (Novel Foods)

Regulatory Decisions: Confined Field Trials of Plants with Novel Traits

The Canadian Food Inspection Agency authorised 248 confined field trials of plants with novel traits in the 2022 growing season. Trials were conducted at 34 locations across Canada. Crop species tested included canola, soybean, camelina, barley, poppy, potato, corn, wheat and poplar. There were no notable trends in the 2022 growing season as compared with recent years in terms of crop kinds or number or location of trials. The CFIA is still receiving applications for confined field trials for the 2023 growing season and expects to receive a similar number of applications and range of crop types as in the 2022 trials. A detailed list of confined field trials is posted on the CFIA's website: https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/approved-under-review/field-trials/eng/1313872595333/1313873672306

Regulatory Decisions: Authorizations of Novel Plant Products

The Canadian Food Inspection Agency maintains a database on the regulatory status of novel plant products in Canada, including whether the products have been authorised for unconfined environmental release (e.g. cultivation), livestock feed use, use as food, and have received variety registration. The database listings distinguish between plants that are living modified organisms (LMO) and non-LMO plants, and is available at: http://inspection.gc.ca/active/netapp/plantnoveltraitpnt-vegecarnouvcn/pntvcne.aspx

The Canadian Food Inspection Agency prepares "decision documents" whenever regulatory decisions are made about novel plant products, intended for unconfined environmental release and/or livestock feed use. Decision documents describe the introduced traits, explain what information was reviewed to reach a decision, and why certain conclusions were reached. Decision documents are available in hard copy and on the Canadian Food Inspection Agency's web site at: https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/approved-under-review/decision-documents/eng/1303704378026/1303704484236

Health Canada publishes similar summaries for novel foods on their web site at: http://www.hc-sc.gc.ca/fn-an/gmf-agm/appro/index-eng.php.

Although not a Party to the Cartagena Protocol on Biosafety, Canada is responsible for submitting summaries of its decisions with respect to living modified organisms to the Biosafety Clearing-House.

Since our last update in May 2022, Canada has authorised the following plants for release into the environment and/or for use in food and/or for use as livestock feed:

Product designation	Trait	Developer	Development method	Authorization Dates		
				Unconfined environmental release	Livestock Feed use	Human Food use
Sorghum event DT™	Herbicide tolerance: quizalofop	S&W Seed Company	Chemical mutagenesis	2022/04/29	2022/04/29	2022/04/29
Rice event ROXY® ROX1.1	Herbicide tolerance: oxyfluorfen	California Cooperative Rice Research Foundation Inc	Chemical mutagenesis	N/A*	2023/02/10	2023/02/08

*Rice isn't generally grown in Canada: authorization for environmental release in Canada isn't required

Regulatory Decisions: Applications Currently Under Review

The Canadian Food Inspection Agency, jointly with Health Canada, coordinates a voluntary "Notices of Submission" process that describes the product and the types of data (e.g. description of the inserted genes, agronomic data from field trials, etc.) they receive from product developers who have requested pre-market assessments of plant products for unconfined environmental release and assessments of novel feeds and novel foods derived from them. The list of Notices of Submission is available at: http://inspection.gc.ca/english/plaveg/bio/subs/subliste.shtml.

- Since May 2022, Canada has not posted new Notices of Submission. However, several Notices of Submission will be posted in the near term.
- Seven plant products are currently undergoing feed, food and/or environmental assessments. Since the Notices of Submission Process is voluntary, and since the assessment can begin before the notices are posted, not all products currently being assessed are listed.

Developments related to new breeding techniques (NBTs)

In Canada, the approach to regulatory oversight of plants products of biotechnology is under review. Canada's regulatory approach is based on the characteristics of the product and not the method of development. Novel products subject to the *Seeds Regulations*, the *Feeds 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 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 result in both novel and non-novel products. In Canada, only those gene-edited products that are 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 communicated in a transparent, consistent, and predictable manner. 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 summarizes the comments received through the consultation. Once additional targeted follow-up conversations with key stakeholder groups have concluded, 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

CFIA Biology Documents

The CFIA has published a new document on the biology of borage, and updated the sugar beet biology document. Both documents are available on the CFIA website:

- *The biology of Borago officinalis L. (Borage): https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/applicants/directive-94-08/biology-documents/borago-officinalis-l-/eng/1676389317106/1676389317872*
- *The biology of Beta vulgaris L. (Sugar Beet): https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/applicants/directive-94-08/biology-documents/beta-vulgaris-l-/eng/1330725373948/1330725437349*

2. ENVIRONMENT AND CLIMATE CHANGE CANADA AND HEALTH CANADA (New Substances Program)

I. Risk assessment/regulatory decisions

New Substances Notifications

Between May 2022 and March 2023, Environment and Climate Change Canada (ECCC)/Health Canada (HC) (New Substances (NS) Program) completed 42 new living organism assessments under the *Canadian Environmental Protection Act, 1999* (CEPA). Of this number, 24 were for various environmental or industrial uses, while 18 were for food and drugs uses (including genetic therapies and vaccines) of which 8 were for cell and gene therapies, 7 for vaccines, 2 for immunotherapies, and one for phenylketonuria therapy. The types of organisms that were assessed ranged from bacteria, to virus, virus-like particles, animal cells, fungi and higher organisms (GM fish, GM Drosophila).

The Significant New Activity (SNAc) provisions of CEPA were applied to *Aspergillus awamori* and *Aspergillus brasiliensis* when used in a consumer product to which the *Canada Consumer Product Safety Act* applies or in a health care facility, such as a hospital, doctor's office, walk-in clinic, mobile health clinic, long-term care facility or nursing home.

Risk Assessment Summaries

Summaries of selected risk assessments for new living organisms assessed under CEPA can be accessed through the "list or group" function of Substance Search.

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

Regulatory Review

The NS Program is continuing to undertake a comprehensive review and modernization of the New Substances Notification Regulations (Organisms) (NSNR (O)). On October 13th, 2022 the NS Program published a Discussion Paper on PlaceSpeak, an online community consultation platform, to receive feedback from stakeholders. From October 13th until December 5th, the Program held a pre-consultation with interested stakeholders on the PlaceSpeak platform, in which over 300 written comments were received and an additional 7 group discussions were held. The Program is incorporating stakeholder feedback into issue analyses and is pursuing a consultation with stakeholders on proposed regulatory amendments in Fall 2023.

Voluntary Public Engagement Initiative

The Government of Canada's voluntary public engagement initiative aims to improve the transparency and public participation in the assessment of new living organisms. With industry consent, the NS program publishes non-confidential summaries of notifications for higher organisms that are submitted under the NSNR (O) in order to allow for public comment during the risk assessment process. Comments received during the public consultation period are taken into account in the risk assessment and made public after the end of the prescribed assessment period. Since 2018, the NS program has held public comment periods for twenty lines of genetically modified fish. Another engagement initiative for a genetically modified *Drosophila* has recently concluded. Active engagement initiatives and information on past initiatives can be accessed through the **New Substances website.**

Revised Microbial Risk Assessment Framework

The Microbial Risk Assessment Framework, originally developed in 2010, is used as the basis for the CEPA assessment of micro-organisms. The Microbial Risk Assessment Framework has been used for work on the assessment of micro-organisms on the Domestic Substances List (DSL) but was previously very qualitative in nature. The work to revise this framework was the result of wanting to shift to a semi-quantitative approach for risk assessments (especially given that data is provided when risk assessments on new micro-organisms are conducted). Consultations with other governmental groups, that have an interest/mandate to manage products of biotechnology are currently underway. The program aims to publish an outward facing document on the website addressed to stakeholders.

III. Research projects on biosafety; relevant publications.

Micro-algae Consensus Document

The NS Program in partnership with the U.S. EPA/OPPT has authored several sections in the first full draft of the OECD Consensus Document on Microalgae. Canada and the U.S. have also evaluated the comments and feedback

provided by members of the Micro-organisms Sub Working Group, The Netherlands, Germany, Australia, Japan, PRRI, and Business and Industry Advisory Committee to the OECD (BIAC). The consensus document contains extensive text on *Chlorella sorokiniana* that was developed by the U.S. EPA/OPPT, which is being called the "*Chlorella* chapter". The *Chlorella* chapter served as a model for the drafting of additional chapters on other microalgae species by other member countries. The draft document will be discussed at the 37th WP-HROB meeting in April 2023.

3. AGRICULTURE AND AGRI-FOOD CANADA

Low Level Presence (no update since previous 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 8th meeting of the GLI virtually in March 2022. The event focused on trade facilitative approaches to the prevention and management of LLP; opportunities and examples of international regulatory collaboration and streamlining; a value chain panel discussion on LLP and current global challenges; and, an update on the various activities taking place in international organisations, including the OECD, on the subject of agricultural biotechnology.

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

The GLI now has its own website: https://llp-gli.org. This public interface features useful resources and tools to inform practices to minimize asynchronous approvals and practically manage LLP. It includes background information on factors leading to LLP, their impacts, and best management practices; an overview of potential approaches for governments and technology developers to consider to minimize occurrences of asynchronous authorizations; 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 contacte1d at GLI-IMP@canada.ca.

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	https://www.ica.gov.co/getattachment/cb7a63c6-aeda-4436-a676-17904af13597/2022R0007887.aspx	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	https://www.ica.gov.co/getattachment/5cab994f-618b-4db7-bd29-6ca19fdc5a9e/2022R0007888.aspx	Maize	Insect resistance Herbicide tolerance	Feed
DAS-Ø15Ø7-1 x MON-ØØ81Ø-6 x SYNIR162-4 x MON-ØØ6Ø3-6	7889	https://www.ica.gov.co/getattachment/aa37e9ae-1656-4855-9e22-819ba12dcaba/2022R0007889.aspx	Maize	Insect resistance Herbicide tolerance	Cultivation

MON89Ø34-3 x DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6 x SYN-IR162-4	7890	https://www.ica.gov.co/getattachment/48add5fb-0f23-46d0-bb15-7128b586a1ee/2022R0007890.aspx	Maize	Insect resistance Herbicide tolerance	Cultivation
MON-Ø4Ø32-6	13534	https://www.ica.gov.co/getattachment/177db72a-2eba-445d-b174-79a45a705417/2022R0013534.aspx	Soybean	Herbicide tolerance	N/A (rejected)
SYN-E3272-5 x SYN-BTØ11-1 x SYN-IR162-4 x MON-ØØØ21-9	13535	https://www.ica.gov.co/getattachment/2b9c5206-9b8a-40e0-b76c-c34fd480e773/2022R0013535.aspx	Maize	Insect resistance Herbicide tolerance	Feed
BCS-BNØ12-7	15185	https://www.ica.gov.co/getattachment/9e905a39-4681-49a3-b7b1-1f54f7d50272/2022R0015185.aspx	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	https://www.ica.gov.co/getattachment/605b50d7-7ef6-4cbd-bf28-fe59aac749e2/2022R0025687.aspx	Cotton	Insect resistance Herbicide tolerance	Feed
BCS-GH811-4 x ACS-GHØØ1-3 x MON-887Ø1-3	25688	https://www.ica.gov.co/getattachment/b07ceed4-9475-45ec-819a-3908da68aadd/2022R0025688.aspx	Cotton	Herbicide tolerance	Feed
BCS-GH811-4 x BCS-GHØØ4-7 x BCS-GHØØ5-8 x SYN-IR1Ø2-7	25689	https://www.ica.gov.co/getattachment/4998ed35-fe4b-494f-9b33-51db6d76fa82/2022R0025689.aspx	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-89Ø34-3 x DAS-Ø15Ø7-1 x MON-88Ø17-3 x DAS-59122-7 x DAS-4Ø278-9	Authorised	2022009523	2/05/2022
Canola	DP73496	DP-Ø73496-4	Authorised	2022009524	2/05/2022
Maize	MON 89034 x TC1507 x NK603 x DAS40278	MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6 x DAS-4Ø278-9	Authorised	2022009525	2/05/2022
Soy	FG72	MST-FGØ72-3	Authorised	2022014893	31/05/2022
Soy	FG72 X A5547-127	MST-FGØ72-3 x ACS-GMØØ6-4	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-3Ø5423-1	Authorised	2022600208	10/10/2022

Cotton	81910	DAS-8191Ø-7	Authorised	2022600209	10/10/2022
Canola	MS11	BCS-BNØ12-7	Authorised	2022600210	10/10/2022
Maize	59122 x TC1507 X NK603	DAS-59122-7xDAS-Ø15Ø7-1x MON-ØØ6Ø3-6	Authorised	2022600252	1/11/2022
Cotton	DAS21023 (3006-210-23)	DAS-21Ø23-5	Authorised	2022600253	1/11/2022
Maize	T25	ACS-ZMØØ3-2	Authorised	2022600254	1/11/2022
Soy	MON 87701 x MON 89788	MON-877Ø1-2 x MON-89788-1	Authorised	2022600255	1/11/2022
Maize	NK603 X T25	MON-ØØ6Ø3-6 x ACS-ZMØØ3-2	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)

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

The State Phytosanitary Service

The State Phytosanitary Service of the Ministry of Agriculture and Livestock, Costa Rica, controls and regulates the commercial exchange of agricultural products for both import and export, the registration, control and regulation of chemical and biological substances for agricultural use (pesticides, fertilizers, biological substances, living modified organisms and other related products). Also, it control the quality and maximum permitted residue levels (MRL) of pesticides in fresh consumer products, certifies the phytosanitary condition of products for export, maintains surveillance and control of pests of economic importance and those pests not present in the country that may represent a potential threat to national agricultural production. For more information, you can visit our website: https://www.sfe.go.cr/SitePages/Inicio.aspx

Highlight of developments since 2022

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

Currently, in Costa Rica, Living Modified Organisms (LMO) 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 Frankliniella 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 LMO named MON-887Ø1-3, containing genes DMO from Stenotrophomonas maltophilia and bar from Streptomyces hygroscopicus 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:

a. 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.
b. 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.
c. 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.
d. 11 hectares of GM cotton MON-887Ø2-4, with the purpose of producing seed for export.
e. 63 hectares of GM pineapple FDP-ØØ114-5 was authorised, to carry out field trials, as well as production and marketing tests.

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

Costa Rica published a new Ag policy 2023-2032. The new policy states in challenge 6.6 and strategic point 9.3.2 the importance of biotechnology and innovation in seeds and genetic material. Available at http://www.mag.go.cr/bibliotecavirtual/E14-11132.pdf

In addition, the government mandated CINDE to promote the country for further international agricultural investments, including corn seeds and agriculture Research and Development with the Law 10234 providing benefits such as a free trade zone regime. Available at https://www.cinde.org/en/essential-news/costa-rica-takes-another-step-to-bring-foreign-investment-to-the-countrys-rising-cities

The Ministry of Agriculture and Livestock, through the State Phytosanitary Service, began the process of reviewing and updating the regulations related to the biosafety and surveillance for genetically modified crops. As a result, two reform proposals were generated for the following regulatory instruments:

- Updating regulation of crops produced by modern biotechnology.
- Updating audit and surveillance of genetically modified crops.

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

3. Risk management measures

During the last year, the State Phytosanitary Service, in order to verify the compliance with biosafety normative requirements, continued with "in situ" monitoring and surveillance of authorised projects with GM crops.

Post-harvest monitoring was carried out at sites where LMOs were grown in previous years. The monitoring period had been set by the individual authorizations according to the characteristics of each GM crop.

2. Updates regarding international activities

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

The details of Central America regional initiatives were published by Inter-American Institute for Cooperation on Agriculture (IICA) last year. In case of interest, check the following.

Rocha, P. 2022. Regional Initiatives in the Western Hemisphere as a Contribution to the Safe Biotechnology Development. Frontiers in Bioengineering and Biotechnology https://doi.org/10.3389/fbioe.2022.837635

Costa Rica would like to share an example from Central America region. We do have a Central America Agreement Guatemala-Honduras-El Salvador named RT 65.06.01:18 that refers to CODEX in article 3.2. The norm triggers a manual of procedures in Article 5.3.d and simplified procedures in article 13. There already is a manual in place in Guatemala, formally approved in decree 271-MAGA-2019 that recognises in article 13.1 the data and approvals from other countries of the region (page 45).

2. Participation in international activities relating to biosafety:

Costa Rica is a Party to the Convention on Biological Diversity and the Cartagena Protocol on Biosafety, and has actively participated in their meetings:

a. Fifth meeting of the Open-ended Working Group on the Post-2020 Global Biodiversity Framework (Target 17, focused on Biosafety). Dec. 2022. Montreal, Canada.
b. Fifteenth meeting of the Conference of the Parties to the Convention on Biological Diversity (COP-15-PART 2). Dec. 2022, Montreal, Canada.
c. Tenth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (CP-MOP-10-PART 2). Dec. 2022, Montreal, Canada.
d. Biosafety Clearing House Training Workshop. Dec. 2022, Montreal, Canada.

3. Developments related to new breeding techniques (NBTs)

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

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

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

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

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

additional information that Regulators consider necessary.

The draft update is available on the Government website (https://tramitescr.meic.go.cr/Formulario/2473). The proposal passed public hearing and approval from the Ministry of Economy (DMR-DAR-INF-017-2023) and is now in the final approval process to have updated clear rules for Genomic Editing and LMOs foreseen by the following months. Once this regulatory framework is signed, published and enforced, we will gladly inform the OECD for its information.

2. Research projects on biosafety of NBTs products; relevant publications;

Costa Rica would like to share local research information on consumer attitudes, the University of Costa Rica publish a study showing that a higher percentage of people would consume CRISPR foods if (1) the nutritional quality were better (70.8%), (2) they were cheaper than conventional products (61.0%).

Gatica-Arias, A., Valdez-Melara, M., Arrieta-Espinoza, G. et al. Consumer attitudes toward food crops developed by CRISPR/Cas9 in Costa Rica. Plant Cell Tiss Organ Cult 139, 417–427 (2019). https://doi.org/10.1007/s11240-019-01647-x

In addition, public Universities are researching on NBT rice and microorganism with potential further use.

- Salinity and drought tolerance rice http://www.ucrea.ucr.ac.cr/proyectos-vigentes/arroz-y-edicion-de-genomas/
- Coffee with reduced caffeine https://vinv.ucr.ac.cr/sigpro/web/projects/C0462
- Salinity tolerance yeast https://doi.org/10.3390/fermentation8040166
- Microorganism with industrial use https://doi.org/10.1099/mic.0.001002

3. Any other information related to NBTs.

Costa Rica welcomes the efforts of IICA and our public universities (UCR and TEC) to share experiences and training in genome editing in a hands-on lab training done in 2022 within the Central America Region with the participation of representatives of Guatemala, Honduras, Panama, the Dominican Republic and South America from Bolivia and Paraguay. https://sites.google.com/iica.int/biotecnologia-y-bioseguridad/actividades-tecnicas/actividades-presenciales/iica-tec-2022

CROATIA

1. DEVELOPMENTS RELATED TO IMPLEMENTATION OF NATIONAL BIOSAFETY FRAMEWORK

1. Risk assessment/regulatory decisions

The Republic of Croatia as a member of the European Union (EU) implements EU community-level decisions and regulations on genetically modified (GM) food and feed at the national level. Regulation (EC) No 1829/2003 regulates the placing on the market of GM food and feed.

In this context, the Republic of Croatia is 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 Authorities and scientific bodies, which beside 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 (http://ec.europa.eu/food/dyna/gm_register/index_en.cfm).

In context of the contained use of GMOs, the responsibility for implementation of the respective Directive (EC) No 2009/41 lies with the Croatian Ministry of Education and Science and Ministry of Health and independent Committee on contained used that gives to them advice e.g. on biosafety levels. The year 2022 still has impacted by the pandemic situation by SARS-CoV-2. A large proportion of research activities reviewed by the Committee on contained use focused on basic research and development of vaccines against this and other viruses.

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

In the Republic of Croatia, the GMO legal framework of the EU applies. It ensures that the development of modern biotechnology takes place under safe conditions and aims to protect human and animal health and the

environment. It includes *i.a.* a safety assessment before any GMO is placed on the marked, harmonised procedures for risk assessment and authorisation, labelling requirements and ensures traceability of GMOs placed on the market.

Essential elements of the legal framework are Directive (EC) 2001/18 on the deliberate release of GMOs into the environment, Regulation (EC) 1829/2003 on GM food and feed as well as the implementing Regulation (EU) No 503/2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003, Directive (EU) 2015/412 on the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, Regulation (EC) 1830/2003 concerning traceability and labelling, Directive (EC) 2009/41 on contained use of GMOs, and Directive (EC) 1946/2003 on transboundary movements of GMOs.

Additionally, guidance is provided in EFSA scientific opinions and EFSA guidance documents detail e.g. what type of scientific data and other information need to be included in GMO applications (https://www.efsa.europa.eu/en).

3. Risk management measures

Currently, GMOs are only authorised for import and use as food/feed products in the European Union at the same time in the Republic of Croatia. According to the authorisations, these require a post-marked environmental monitoring plan (PMEM) as per Annex VII of Directive 2001/18/EC *e.g.* to detect direct and indirect effects which have been identified in the environmental risk assessment.

In addition, a post-market monitoring plan (PMM) regarding the use of the GM food/feed for human/animal consumption is requested in cases where it is appropriate to verify that the conditions of use are properly applied and to monitor the consumption of the product.

Research projects on biosafety; relevant publications Research on products of modern biotechnology is conducted under contained use conditions only, as there are currently no authorised field trails in The Republic of Croatia.

2. UPDATES REGARDING INTERNATIONAL ACTIVITIES

The Republic of Croatia 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, the Republic of Croatia is included in the FAO GM Foods Platform and periodically updates its profile.

3. DEVELOPMENTS RELATED TO NEW BREEDING TECHNIQUES (NBTS)

On September 24, the European Commission's inception impact assessment for legislation on plants obtained by cisgenesis and targeted mutagenesis was published. The Croatian government has responded to this inception impact assessment.

CZECH REPUBLIC

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

No GM crop has been grown in the Czech Republic since 2017.

Field trials: Only two small-scale field trials were conducted in 2022 and will continue in 2023:

- Plum trees with a modification conferring virus-resistance (resistance to the plum pox virus), notified by the Crop Research Institute, Prague (640 m^2 without buffer zones);

- Spring barley lines producing peptide LL-37, a research project of the Palacky University in Olomouc, the cultivation is carried out by the company Usovsko, region Olomouc. In 2022, the area of the trial was 33 m^2 without buffer zones.

Both field trials will be carried out in 2023.

The number of premises notified for **contained use** of GMOs has increased slightly since 2021, now over 120 research institutions, universities and companies use GMOs. Only 2 laboratories are now classified in BSL 3, the others are BSL 1 or 2.

Three **clinical trials** with medicinal products containing GM cells or viruses have been authorised since May 2022 when the last meeting of this WG took place.

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

   Since the last meeting, no new regulations or amendments have been adopted.

3. Risk management measures;

   Post-release monitoring has been carried out on the sites of the field trials. The period and requirements for the monitoring have been set by the individual authorisations according to the characteristics of the GM plant.

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

   The current GMO legislative framework in the Czech Republic (which is based on EU regulations) covers all GMOs: GM crops, field trials, contained use of micro-organisms, laboratory animals and clinical studies with medicinal products, which is in some aspects inconvenient. Especially for clinical studies, a more flexible authorisation procedure should be adopted.

5. Public engagement and outreach activities

   Information on legislation, issued authorisations, registers of authorised users and GMOs, and various guidelines are made available on the website of the Ministry of the Environment at https://www.mzp.cz/cz/navigace_temata in Czech and http://www.mzp.cz/biosafety in English (the Czech node of the Biosafety Clearing House).

   Public consultations are part of the authorisation process of field trials.

2. Updates regarding international activities

In the second half of 2022, the Czech Republic held the presidency of the Council of the European Union. In this connection, the Czech Republic represented the EU and its Member States at the 15th Conference of the Parties to the Convention on Biological Diversity and the 10th Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (7.-19 December 2022, Montreal, Canada). At this international event of utmost importance, the Parties to the CBD adopted the Kunming - Montreal Global Biodiversity Framework, whereas the Parties to the Cartagena Protocol on Biosafety adopted the Implementation Plan as well as the Capacity Building Action Plan for the period up to 2030.

3. Developments related to new breeding techniques (NBTs)

According to the legislation of the European Union, organisms produced by NBTs are considered to be GMOs and fall under GMO regulations.

In the Czech Republic, organisms produced by new genomic techniques (gene editing) have only been used in contained space so far – in laboratories, greenhouses, breeding facilities, and industrial premises. Most of the activities performed served research purposes.

DENMARK

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

No GM-field field trials have taken place in Denmark since 2012. However, this year we have received two applications for such trials involving CRISPR-modified potatoes (see below).

2. Developments related to new breeding techniques (NBTs)

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

GMO-regulation in the EU is currently under revision. Member States await a proposal from the European Commission regarding plants developed with certain new genomic techniques which is due to arrive medio 2023.

2. Specific cases of application, assessment and decision;

The Danish CA (i.e. the Danish Agricultural Agency, DAA) has received two applications for field trials in the 2023-growing season with gene-edited potatoes (using CRISPR/Cas). DAA is currently evaluating the applications.

3. Additional Information

GMO-control measures in 2022 in Denmark:
The GMO control of seeds in 2022 has focused on imports of Alfalfa (Medicago sativa), Danish production of Oilseed rape (Brassica napus) certified seed and Maize (Zea mays) seed. No GMO's have been found.

FRANCE

[English version follows]

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

a) Mise sur le marché

Des évaluations de risque sont réalisées au niveau national sur les dossiers de demandes d'autorisation de mise sur le marché d'OGM déposés au titre du règlement européen (CE) n°1829/2003 concernant les denrées alimentaires et les aliments pour animaux génétiquement modifiés.

Les évaluations suivantes ont été publiés depuis mai 2022 :

OGM	Avis rendus
Maïs DP4114xMON810xMIR604xNK603	https://www.anses.fr/fr/system/files/BIOT2022SA0054.pdf
Colza GT73	https://www.anses.fr/fr/system/files/BIOT2022SA0007.pdf
léghémoglobine de soja produite par une souche génétiquement modifiée de *Komagataella phaffii*	https://www.anses.fr/fr/system/files/BIOT2022SA0001.pdf

Ces évaluations de risque sont utilisées par les autorités compétentes françaises pour définir les positions de vote de la France sur les projets de décision d'autorisation soumis par la Commission européenne aux États membres.

Les autorités françaises transmettent par ailleurs des commentaires à l'Autorité européenne de sécurité des aliments (EFSA), en charge de l'évaluation des dossiers au niveau européen, dans le cadre des consultations des États membres organisées par celle-ci ;

Les décisions d'autorisation de mise sur le marché des OGM sont adoptées par la Commission européenne après le vote des États membres.

b) Expérimentation en milieu ouvert

Aucune demande d'autorisation pour l'expérimentation de plantes génétiquement modifiées en milieu ouvert n'a été déposée en France depuis la dernière réunion du Groupe de travail.

Une dissémination volontaire d'OGM a été autorisée dans le cadre d'un essai clinique d'un médicament vétérinaire :

OGM	Autorisation et évaluation
Vaccin POULVAC PROCERTA HVT-IBD-ND	Autorisation https://www.anses.fr/fr/system/files/anmv/medicaments/EC-22-463%20final.pdf Evaluation https://www.anses.fr/fr/system/files/BIOT2022SA0078.pdf

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

Environ 500 dossiers de demandes d'utilisations confinées d'OGM ont été examinés en 2022. Ce nombre a diminué en 2022 par rapport aux années précédentes du fait de la mise en œuvre de la simplification de la procédure applicable aux utilisations confinées d'OGM de risque nul ou négligeable (cf. infra).

d) Culture des OGM

Il n'y a pas de cultures commerciales d'OGM ni d'essais au champ d'OGM autorisés en France.
La culture commerciale des OGM est interdite en France depuis 2008. La culture du maïs MON810, seul OGM autorisé à la mise en culture au niveau européen, est interdite en France en application de la Décision d'exécution (UE) 2016/321 de la Commission du 3 mars 2016 modifiant la portée géographique de l'autorisation de cultiver le maïs génétiquement modifié (Zea mays L.) MON 810.

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

a) Nouveau dispositif national d'évaluation des biotechnologies

Le dispositif national d'évaluation des biotechnologies, entré en vigueur le 1er janvier 2022, est le suivant :

- L'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (Anses) est chargée, en plus d'évaluer les risques pour la santé humaine et animale, d'évaluer les risques environnementaux liés à la mise sur le marché et la dissémination d'OGM dans l'environnement. Elle est également chargée d'analyser les aspects socio-économiques liés aux biotechnologies. Un comité de dialogue avec les parties prenantes a été mis en place.
- Un Comité d'expertise des utilisations confinées d'OGM (CEUCO), nouvellement créé et placé auprès du ministère de la recherche, est chargé d'évaluer les dossiers relatifs aux utilisations confinées d'OGM.
- Le Conseil Économique, Social et Environnemental (CESE) est chargé des questions sociétales relatives aux biotechnologies.
- le Comité consultatif national d'éthique pour les sciences de la vie et de la santé (CCNE) traite des questions éthiques liées aux biotechnologies.

Simplification de la procédure applicable aux utilisations confinées d'OGM de risque nul ou négligeable

À compter du 1er janvier 2022, la procédure applicable aux utilisations confinées d'OGM de classe 1 (risque nul ou négligeable) est simplifiée, en accord avec la directive 2009/41/CE relative à l'utilisation confinée de micro-organismes génétiquement modifiés. Il n'est plus nécessaire de déclarer ces utilisations dès lors qu'elles se déroulent dans une installation où une utilisation confinée d'OGM a déjà été déclarée ou autorisée par le ministère chargé de la recherche et qu'un dossier d'évaluation des risques est tenu à disposition des autorités.

Toutefois cette simplification ne s'applique pas aux essais cliniques de médicaments OGM. Depuis le 1er juin 2022, l'Agence nationale de sécurité du médicament et des produits de santé (ANSM) est l'autorité compétente pour l'utilisation confinée de médicaments composés, en tout ou partie, d'OGM dans le cadre d'essais cliniques (recherches impliquant la personne humaine).

b) Arrêt de la Cour de Justice de l'Union européenne du 7 février 2023 sur la mutagénèse

En 2015, neuf associations ont déposé un recours au Conseil d'État sur les variétés tolérantes aux herbicides issues de mutagénèse demandant, notamment, l'abrogation de l'article D.531-2 du code de l'environnement en

ce qu'il exempte les variétés obtenues par mutagénèse de la réglementation sur les organismes génétiquement modifiés (OGM).

Dans le cadre de cette procédure, le Conseil d'État a adressé à la Cour de justice de l'Union européenne (CJUE) plusieurs questions préjudicielles. L'arrêt rendu par la CJUE le 25 juillet 2018 est notamment venu clarifier le champ couvert par la directive 2001/18/CE sur les OGM, et précise que tous les organismes obtenus par une technique de mutagénèse sont des OGM, et que seuls sont exemptés du champ d'application « *les organismes obtenus au moyen de techniques/méthodes de mutagenèse qui ont été traditionnellement utilisées pour diverses applications et dont la sécurité est avérée depuis longtemps.* ».

Dans sa décision rendue le 7 février 2020 suite à l'arrêt de la CJUE, le Conseil d'État a conclu que les techniques de mutagénèse aléatoire *in vitro* soumettant des cellules de plantes à des agents mutagènes chimiques ou physiques, ainsi que les techniques de mutagénèse dite dirigée ou d'édition du génome, ne sont pas des techniques traditionnellement utilisées et dont la sécurité est avérée depuis longtemps, étant apparues ou s'étant principalement développées depuis l'adoption de la directive 2001/18/CE. Il en résultait que les organismes obtenus à partir de ces techniques devaient être soumis à la réglementation relative aux OGM.

Dans une nouvelle décision du 8 novembre 2021, le Conseil d'État a noté que deux approches s'opposent pour déterminer le statut de la mutagénèse aléatoire *in vitro*. Il a décidé de poser deux nouvelles questions préjudicielles à la CJUE sur les critères permettant de déterminer quelles sont les techniques de mutagénèse qui ont été traditionnellement utilisées et dont la sécurité est avérée depuis longtemps.

La CJUE a rendu son arrêt le 7 février 2023 dans lequel elle conclut que les effets inhérents aux cultures *in vitro* ne justifient pas, en tant que tels, que les organismes obtenus par l'application *in vitro* d'une technique de mutagenèse qui a été traditionnellement utilisée pour diverses applications *in vivo* et dont la sécurité est avérée depuis longtemps au regard de ces applications soient soumis aux dispositions de la directive 2001/18/CE.

2. Developments related to new breeding techniques (NBTs)

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

Initiative de la Commission européenne sur les nouvelles techniques génomiques

Dans le cadre de son initiative sur les nouvelles techniques génomiques, la Commission européenne conduit une étude d'impact incluant différentes activités de consultations, auxquelles la France a contribué.

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

Programme de recherche sur la sélection végétale avancée face au défi climatique et à la transition agro-écologique.

Dans le cadre du plan de relance et du 4ème programme d'investissements d'avenir, le Gouvernement a décidé la mise en place d'un Programme et équipement prioritaire de recherche (PEPR) sur la sélection végétale avancée face au défi climatique et à la transition agro-écologique. Le programme est doté de 30 millions d'euros, pour 8 ans, et son pilotage est confié à l'Institut national de recherche pour l'agriculture, l'alimentation et l'environnement (INRAE).

Les recherches soutenues par ce PEPR aborderont les domaines suivants :

- le développement méthodologique et l'application de l'édition des génomes sur une large gamme d'espèces cultivées ;
- l'implémentation de l'édition des génomes pour de nouveaux caractères en lien avec l'adaptation au changement climatique et la transition agro-écologique ;
- l'intégration de l'édition des génomes dans les schémas de sélection ;
- l'identification et l'élaboration des conditions socio-économiques, éthiques et réglementaires pour l'adoption de ces nouvelles technologies.

3. Any other information related to NBTs

Les autorités françaises ont engagé des consultations de différentes instances nationales afin de disposer d'un éclairage sur les différents aspects liés aux NBT :

- Un rapport du comité scientifique du Comité technique permanent de la sélection des plantes cultivées

(CTPS) sur l'incidence de l'évolution des techniques d'édition du génome sur l'évaluation des variétés et leur mise en marché a été publié en décembre 2022. https://agriculture.gouv.fr/nouvelles-techniques-genomiques-et-evaluation-des-varietes-rapport-du-ctps
Un travail complémentaire a été demandé à ce comité sur l'appréciation de la contribution des plantes issues de NGT aux objectifs de durabilité des stratégies Green Deal et Farm to Fork. Il devra proposer des critères permettant de classer les traits en fonction de leur contribution potentielle aux objectifs de durabilité et d'établir des listes de traits considérés comme contribuant aux objectifs de durabilité ou au contraire considérés comme préjudiciables à ces objectifs de durabilité.

- L'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (Anses) a été saisie afin qu'elle détermine les adaptations possibles des requis en termes d'évaluation des risques sanitaires et environnementaux, pour les plantes obtenues à l'aide de techniques de mutagenèse dirigée ou de cisgénèse. Une analyse des enjeux socio-économiques associés est également prévue dans le cadre de cette saisine.
- Le comité consultatif national d'éthique pour les sciences de la vie et de la santé (CCNE) a été saisi pour lui demander un éclairage sur les aspects éthiques liés aux NGT.
- Le Conseil économique, social et environnemental (CESE) a été saisi sur les attentes et enjeux sociétaux liés aux NGT.

Les avis et rapports en réponse aux saisines en cours devraient être rendus au cours de l'année 2023.

[English translation]

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

a) Placing on the market

Risk assessments are carried out at national level on applications for GMO marketing authorisation submitted under European Regulation (EC) No 1829/2003 on genetically modified food and feed.

The following evaluations have been published since May 2022 :

GMO	Opinion issued
Maize DP4114xMON810xMIR604xNK603	https://www.anses.fr/fr/system/files/BIOT2022SA0054.pdf
Oilseed rape GT73	https://www.anses.fr/fr/system/files/BIOT2022SA0007.pdf
Soybean leghemoglobin produced by a genetically modified strain of *Komagataella phaffii*	https://www.anses.fr/fr/system/files/BIOT2022SA0001.pdf

These risk assessments are used by the French competent authorities to define France's voting positions on the draft authorisation decisions submitted by the European Commission to the Member States.

The French authorities also send comments to the European Food Safety Authority (EFSA), in charge of evaluating the dossiers at European level, as part of the consultations of the Member States organised by the latter.

Decisions to authorize the placing on the market of GMOs are adopted by the European Commission after the vote of Member states.

b) Experimentation in the environment

No authorization application for experimentation of genetically modified plants in an open environment has been filed in France since the last meeting of the WG-HROB.

A deliberate release of GMOs has been authorised in the context of a clinical trial of a veterinary medicinal product:

GMO	Autorisation and assessment
Vaccin POULVAC PROCERTA HVT-IBD-ND	Autorisation https://www.anses.fr/fr/system/files/anmv/medicaments/EC-22-463%20final.pdf Assessment https://www.anses.fr/fr/system/files/BIOT2022SA0078.pdf

c) Contained use of GMOs (in laboratory)

Around 500 applications for contained use of GMOs were examined in 2022. This number decreased in 2022 compared to previous years due to the implementation of the simplification of the procedure applicable to the contained use of GMOs from zero or negligible risk (see below).

d) GMO cultivation

There are no commercial GMO crops or GMO field trials authorised in France.

The commercial cultivation of GMOs has been prohibited in France since 2008. The cultivation of MON810 maize, the only GMO authorised for cultivation at European level, is prohibited in France in application of the Commission Implementing Decision (EU) 2016/321 of 3 March 2016 adjusting the geographical scope of the authorisation for cultivation of genetically modified maize (Zea mays L.) MON 810.

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

a) New biotechnology national assessment system

The national biotechnology assessment system, which came into force on January 1, 2022, is as follows:

- The National Agency for Food, Environmental and Occupational Health and Safety (Anses) is responsible, in addition to assessing the risks to human and animal health, for assessing the environmental risks associated with the placing on the market and the release of GMOs into the environment. It is also responsible for analysing the socio-economic aspects related to biotechnology. A dialogue committee with stakeholders has been set up.
- The newly created Expert Committee for GMO contained uses (CEUCO), attached to the Ministry of Research, is responsible for evaluating applications relating to contained uses of GMOs.
- The Economic, Social and Environmental Council (CESE) is responsible for societal issues relating to biotechnologies.
- The National Consultative Ethics Committee for Life and Health Sciences (CCNE) deals with ethical issues relating to biotechnologies.

Simplification of the procedure applicable to contained uses of GMOs of no or negligible risk

From January 1, 2022, the procedure applicable to contained uses of class 1 GMOs (no or negligible risk) is simplified, in accordance with Directive 2009/41/EC on the contained use of genetically modified micro-organisms. It is no longer necessary to declare these uses when they take place in an installation where a contained use of GMOs has already been declared to or authorised by the ministry in charge of research and a risk assessment record is available to the authorities.

However, this simplification does not apply to clinical trials of GMO medicinal products.

Since June 1, 2022, the National Agency for the Safety of Medicines and Health Products (ANSM) is the competent authority for the contained use of medicinal products composed, in whole or in part, of GMOs in the context of clinical trials (research involving humans).

b) Judgment of the Court of Justice of the European Union of February 7, 2023 on mutagenesis

In 2015, nine organisations brought an action before the Conseil d'Etat on herbicide-tolerant varieties resulting from mutagenesis requesting, in particular, the abrogation of article D.531-2 of the Environmental Code in that it exempts varieties obtained by mutagenesis from the legislation on genetically modified organisms (GMOs).

As part of this procedure, the Conseil d'État requested the Court of Justice of the European Union (CJEU) for a preliminary ruling on several questions. The judgment issued by the CJEU on July 25, 2018 clarified the scope covered by Directive 2001/18/EC on GMOs, and specifies that all organisms obtained by a mutagenesis technique are GMOs, and that only that only are exempted from the scope "organisms obtained by means of techniques/methods of mutagenesis which have conventionally been used in a number of applications and have a long safety record ".

In its decision issued on February 7, 2020 following the judgment of the CJEU, the Conseil d'État concluded that in vitro random mutagenesis techniques subjecting plant cells to chemical or physical mutagens, as well as directed mutagenesis or genome editing, are not techniques that have conventionally been used in a number of applications and have a long safety record, as they appeared or have been mostly developed since directive

2001/18/EC was adopted. As a result, the organisms obtained from these techniques had to be subject to the regulations relating to GMOs.

In a new decision of November 8, 2021, the Conseil d'Etat noted that there were two opposing approaches to determine the status of in vitro random mutagenesis. It has decided to submit two new questions for a preliminary ruling to the CJEU on the criteria for determining which mutagenesis techniques have conventionally been used and have a long safety record.

The CJEU delivered its judgment on 7 February 2023 in which it concluded that the effects inherent in in vitro cultures do not, as such, justify that organisms obtained by the in vitro application of a mutagenesis technique which has conventionally been used in a number of in vivo applications and has a long safety record are subject to the provisions of Directive 2001/18/EC.

2. Developments related to new breeding techniques (NBTs)

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

European Commission initiative on new genomic techniques

As part of its initiative on new genomic techniques, the European Commission is conducting an impact study including various consultation activities, to which France has contributed.

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

Research program on advanced plant breeding in the face of the climate challenge and agro-ecological transition

As part of the national Recovery Plan and the 4th investment program for the future, the Government has decided to set up a Priority Research and Equipment Program (PEPR) on advanced plant breeding in the face of the climate challenge and the agro-ecological transition. The program is endowed with 30 million euros, for 8 years, and its management is entrusted to the National Research Institute for Agriculture, Food and the Environment (INRAE).
Research supported by this PEPR will address the following areas:

- methodological development and application of genome editing on a wide range of cultivated species ;
- the implementation of genome editing for new traits related to adaptation to climate change and agroecological transition ;
- integrating genome editing into selection schemes ;
- the identification and development of the socio-economic, ethical and regulatory conditions for the adoption of these new technologies.

3. Any other information related to NBTs

The French authorities have initiated consultations with different national bodies in order to have insight on the various aspects related to NBTs:

- A report by the Scientific Committee of the Permanent Technical Committee on Plant Breeding (CTPS) on the impact of the evolution of genome editing techniques on the evaluation of varieties and their marketing was published in December 2022. https://agriculture.gouv.fr/nouvelles-techniques-genomiques-et-evaluation-des-varietes-rapport-du-ctps

  Additional work was requested from this committee on the assessment of the contribution of plants from NGT to the sustainability objectives of the Green Deal and Farm to Fork strategies. It should propose criteria for classifying traits according to their potential contribution to sustainability goals and establish lists of traits considered to contribute to sustainability goals or, on the contrary, considered to be detrimental to these sustainability goals.
- The National Agency for Food, Environmental and Occupational Health and Safety (ANSES) has been asked to determine possible adaptations of the requirements in terms of health and environmental risk assessment, for plants obtained using targeted mutagenesis or cisgenesis techniques. An analysis of the associated socio-economic issues is also planned as part of this referral.
- The National Consultative Ethics Committee for Life and Health Sciences (CCNE) has been asked to clarify the ethical aspects related to NGT.
- The Economic, Social and Environmental Council (CESE) was consulted on the societal expectations and issues

related to NGT.

Opinions and reports in response to ongoing referrals should be delivered in 2023.

GERMANY

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

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

In context of the contained use of GMOs, the responsibility for implementation of the respective Directive (EC) No 2009/41 lies with the German Federal States. These have to involve the independent Central Committee on Biological Safety (ZKBS) to advice e.g. on biosafety levels. The ZKBS publishes annual overviews about nationwide activities; see https://www.zkbs-online.de/ZKBS/EN/Home/home_node.html.

The year 2022 was still impacted by the pandemic situation by SARS-CoV-2. A significant proportion of research activities reviewed by the ZKBS focussed on basic research and development of vaccines against this and other viruses.

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

In Germany, the GMO legal framework of the EU applies. It ensures that the development of modern biotechnology takes place under safe conditions and aims to protect human and animal health and the environment. It includes i. a. a safety assessment before any GMO is placed on the marked, harmonised procedures for risk assessment and authorisation, labelling requirements and ensures traceability of GMOs placed on the market.

Essential elements of the legal framework are Directive (EC) 2001/18 on the deliberate release of GMOs into the environment, Regulation (EC) 1829/2003 on GM food and feed as well as the implementing Regulation (EU) No 503/2013 on applications for authorisation of genetically modified food and feed in accordance with Regulation (EC) No 1829/2003, Directive (EU) 2015/412 on the possibility for the Member States to restrict or prohibit the cultivation of GMOs in their territory, Regulation (EC) 1830/2003 concerning traceability and labelling, Directive (EC) 2009/41 on contained use of GMOs, and Directive (EC) 1946/2003 on transboundary movements of GMOs.

Additionally, guidance is provided in EFSA scientific opinions and EFSA guidance documents detail e.g. what type of scientific data and other information need to be included in GMO applications (https://www.efsa.europa.eu/en).

3. Risk management measures

Currently, GMOs are only authorised for import and use as food/feed products in Germany. According to the authorisations, these require a post-marked environmental monitoring plan (PMEM) as per Annex VII of Directive 2001/18/EC e.g. to detect direct and indirect effects which have been identified in the environmental risk assessment. In addition, a post-market monitoring plan (PMM) regarding the use of the GM food/feed for human/animal consumption is requested in cases where it is appropriate to verify that the conditions of use are properly applied and to monitor the consumption of the product.

4. Research projects on biosafety; relevant publications

Research on products of modern biotechnology is conducted under contained use conditions only, as there are currently no authorised field trails in Germany.

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

- RNAi_safe - Safety of RNAi technology in plant protection: Method evaluation for estimating effectivity and potential impacts on target and off-target organisms. The project pursues a methodological approach to answer open questions about the safe use of RNAi technology in plant protection. It aims at detecting and evaluating of potential exposure pathways and effects of dsRNA-based plant protection products in target organisms, crops and the extended food web. In addition, it serves to build expertise for the evaluation of methods for testing such plant protection products.
- Selected publications from a series of research projects on horizon scanning, risk assessment and technology assessment of Synthetic Biology (including conventional as well as new and transient genetic engineering approaches):
  - *Chu P; Agapito-Tenfen SZ (2022): Unintended Genomic Outcomes in Current and Next Generation GM Techniques: A Systematic Review. Plants; 11(21): 2997. https://doi.org/10.3390/plants11212997*
  - *Frieß, JL; Lalyer, CR; Giese, B; Simon, S; Otto, M (2023): Review of gene drive modelling and implications for risk assessment of gene drive. Ecological Modelling. https://doi.org/10.1016/j.ecolmodel.2023.110285*
  - *Verma, P; Reeves, RG; Simon, S; Otto, M; Gokhale, CS. (2023): The Effect of Mating Complexity on Gene Drive Dynamics. The American Naturalist 201 (1), Article 722157, E1-E22. https://doi.org/10.1086/722157*
  - *Benevenuto, RF; Venter, HJ; Zanatta, CB; Nodari, RO; Agapito-Tenfen, SZ (2022): Alterations in genetically modified crops assessed by omics studies: Systematic review and meta-analysis. Trends in Food Science & Technology 120, S. 325–337 https://doi.org/10.1016/j.tifs.2022.01.002*
  - *Federal Agency for Nature Conservation (BfN) (ed.) (2022): Genetic engineering, nature conservation and biological diversity: Boundaries of design. Viewpoint. Bonn. https://doi.org/10.19217/pos222en*

2. Updates regarding international activities

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

Examples of international symposia/fora hosted/funded or with participation by the German government are listed below.

- 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 the help of new genomic techniques. (For more information see: https://www.bfr-akademie.de/gmo2023/)
- Side Event on Synthetic Biology at the CBD COP 15.2 in December 2022. The German Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection (BMUV), the German Federal Agency for Nature Conservation (BfN), and the Swiss Federal Office for the Environment (FOEN) presented a side event at COP 15.2 that gave insights into the complex field of Synthetic Biology with expert inputs by the Environmental Agency Austria, the Max Planck Institute for Evolutionary Biology, Germany, and the BfN. (Download report "Synthetic Biology: Scan the horizon for impacts on biodiversity" https://attachments.cbd.int/567962e74dc1af45194e3f51e4acc1ae/SyntheticBiology.pdf).

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

The German BVL and the Dutch WFSR host and maintain EUginius, the EUropean GMO Initiative for a Unified Database System (www.euginius.eu) in close cooperation with official GMO detection and identification laboratories of Austria, Italia 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 with a focus on the situation in the EU as well as worldwide coverage.

3. Specific cases of use of OECD tools and information

German national authorities regularly use OECD tools and information e.g. when evaluating applications for authorisation of GM products. Guidance documents by the EFSA refer to OECD Consensus Documents concerning compositional aspects of GMOs.

Furthermore, German national authorities frequently consult the OECD Verification digit checker that verifies suggested GMO Unique Identifiers and information available in the OECD BioTrack Product Database when enforcing their legal tasks.

3. Developments related to new breeding techniques (NBTs)

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

NBT products in the EU are GMOs according to the ruling of the Court of Justice (ECJ) of 25 July 2018, thus fall under the scope of Directive 2001/18/EC and are subject to the obligations laid down therein.

2. Specific cases of application, assessment and decision

Currently, no NBT products are authorised as food/feed or for cultivation in the EU neither have applications been received for food/feed.

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

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

- CHIC project (EU funded). The project aims to develop, implement and analyse potential off-target effects of new CRISPR-based plant breeding techniques to alter the structure and biosynthetic pathways of chicory roots to improve both the quality and storage of inulin and sesquiterpenes. Inulin can be used as a prebiotic food supplement and the sesquiterpenes as antimicrobial drugs.
- 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.
- GeneBEcon (EU funded). The project's focus is on circular bio-based systems, industrial sectors along value chains and supply chains of biological raw materials within Europe and worldwide and aims to provide innovative "zero-pollutant" bio-based biotechnology solutions. The possible potentials of NBTs are to be examined using case studies: the reduction of pesticides in potato cultivation, the development of chemical-free potato starch processing and the development of resource-efficient and clean production of industrially relevant compositions from microalgae. (Further information: https://genebecon.eu/)

4. Any other information related to NBTs

- 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)
- Expert Opinion: Evaluation of the European Commission's study on new genomic techniques. The European Commission's 2021 publication on new genomic techniques was evaluated by an independent group of experts commissioned by the Federal Agency for Nature Conservation (https://www.bfn.de/sites/default/files/2023-03/bng_finalreport_COMstudy_Feb2023.pdf)
- Position paper of the Permanent Senate Commission on Genetic Research of the Deutsche Forschungsgemeinschaft (DFG, German Research Foundation): In support of a timely and state-of-the-art regulation of the products of new breeding techniques as a contribution to tackling multiple crises in the 21 st century https://www.dfg.de/download/pdf/dfg_im_profil/gremien/senat/genforschung/position_genomeditierte_pflanzen_en.pdf

HUNGARY

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

Cultivation of GMOs: MON810 GM maize is still the only GM crop authorised for commercial cultivation in the EU. In the course of 2022 no cultivation of GM crops occurred in Hungary because of the Hungarian safeguard clause and also the relevant national application of Directive (EU) 2015/412 of the European Parliament and of the Council of 11 March 2015 amending Directive 2001/18/EC as regards the possibility for the Member States to restrict or prohibit the cultivation of genetically modified organisms (GMOs) in their territory.

Deliberate release of GMOs for any other purposes than for placing on the market (field trials, and clinical trials): Two decisions have been published in the course of 2022 regarding clinical trials

Contained use activities: In the course of 2022 two class 1, thirteen class 2, and three class 3 premises received authorisations for contained use activities. Two contained use activities in class 1 have been authorised with GMMs. Thirteen contained use activities in class 2 have been authorised with GMMs and in some cases GMAs. Three contained use activities in class 3 have been authorised with GMVs (African swine fever virus).

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

At the beginning of 2022 a new application system was launched with the introduction of new application forms for all types of gene technology activities. These new forms assist the work of competent authorities responsible for authorisations and inspections, and also the work of Gene Technology Advisory Board while provide help to applicants in compiling their applications.

2. Updates regarding international activities

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

Since Hungary is a party to the Cartagena Protocol on Biosafety, has actively participated in the Tenth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety, and also in Liaison Group on the Cartagena Protocol on Biosafety during the intersessional periods.

3. Developments related to new breeding techniques (NBTs)

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

At the beginning of 2022 a new application system was launched with the introduction of new application forms for all types of gene technology activities. Specific information on the methodology of the relevant new genomic techniques is required in the new applications forms.

2. Any other information related to NBTs.

In the course of 2022 the European Commission started the impact assessment by carrying out public consultations and involving stakeholders and Member States' authorities. Hungary highlighted and expressed its concerns that the targeted consultations for the Member States which was the basis for the impact assessment was a questionnaire which was mainly based on predictions and assumptions instead of on solid data and scientifically sound methodologies. It is of utmost importance for Hungary to ensure the maximum protection for humans and the environment, taking into account the precautionary principle. This requires a rigorous risk assessment and a thorough examination of the effects.

Cultivation/deliberate release of new genomic techniques:

In the course of 2022 neither cultivation of GM crops produced by new techniques nor deliberate release of GMOs produced by new genomic techniques for field trials and for clinical trials occurred in Hungary.

4. Additional Information

Keeping agriculture free from genetically modified organisms (GMOs) is a key objective of the Hungarian

Government, laid down in the Fundamental law of Hungary. Hungary is one of the strongest opponents of agricultural gene technology in the European Union, and this policy has not been changed.

JAPAN

1. Developments related to implementation of national biosafety framework

Risk assessment/regulatory decisions

Latest Situation of Approval for Releasing of LMOs

In accordance with the Cartagena Act (Japanese national law to implement the Cartagena Protocol on the Biosafety to Convention on Biological Diversity), one oilseed rape, and two maize events have been newly approved for commercial use since the last WG-HROB meeting held in May 2022.

The number of LM plants approved for commercial use at the end of March 2023 are described in the Table. Decision documents and summary reports of environmental risk/safety assessments are available*1 at Japan Biosafety Clearing House (J-BCH) (URL; https://www.biodic.go.jp/bch/english/lmo.html).

**1 Some decision documents and assessment reports are available only in Japanese.*

Table LM plants approved for commercial use

Plant Species	Event Number	Plant Species	Event Number
Alfalfa	5	Papaya	1
Oilseed Rape (Canola)	18*2	Rose	2
Carnation	8	Soybean	30*2
Maize	94*2	Sugar Beet	1
Cotton	38*2	Phalaenopsis	1

*2Some of the events counted in the table are not approved for cultivation because no application has been filed for their cultivation.

2. Developments related to new breeding techniques (NBTs)

Specific cases of application, assessment and decision;

Since the last WG-HROB meeting held in May 2022, the Ministry of Agriculture, Forestry and Fisheries of Japan (MAFF) accepted the following finalised information forms:

- Closely related strains of red sea bream (Pagrus major) with increased edible part and Japanese pufferfish/tiger puffer/tiger pufferfish (Takifugu rubripes) with growth enhancement which had been produced using genome editing techniques
- Maize with waxy trait which had been produced using genome editing techniques

At the same time, the information form was released on the MAFF website (https://www.maff.go.jp/j/syouan/nouan/carta/tetuduki/nbt_tetuzuki.html, in Japanese).

For research use, the information forms were submitted to the Ministry of Education, Culture, Sports, Science and Technology for "A group of rice mutants in the genes regulating flowering time or circadian rhythm (Ghd7, Hd1, Hd2, Hd17, OsGI) by genome editing technology" (September 2022). This information is available on the Japan Biosafety Clearing-House website (https://www.biodic.go.jp/bch/bch_8_3.html, in Japanese).

3. Additional Information

Science Communication Activities

MAFF continuously conducts a science communication project focusing biotechnology. In FY 2022, approximately 40 science communication events such as public lectures aimed at consumers, college students, high school students and so on, were held in the project. Additionally, tours for research institutes developing products using genome editing technique were held.

KOREA

1. Developments related to implementation of national biosafety framework

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:

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

Organisms assessed	Event	Company	Type of use	Introduced trait
Maize	3272×Bt11×MIR162×MIR604 ×TC1507×5307×GA21	Syngenta	Food, Feed	Insect resistance, herbicide tolerance, α-amylase activation
E.coli	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	GHB811×T304-40×GHB119 ×COT102×MON88701	BASF	Feed	Herbicide tolerance, insect resistance
Cotton	GHB811×LLcotton25×MON88701	BASF	Food	Herbicide tolerance
Cotton	MON88702×MON15985×COT102 ×MON88701×MON88913	Monsanto	Food	Herbicide tolerance, insect resistance
Cotton	T304-40×GHB119×COT102	BASF	Food	Herbicide tolerance, insect resistance
Cotton	GHB811×T304-40×GHB119 ×COT102×MON88701	BASF	Food	Herbicide tolerance, insect resistance
Cotton	281/3006×COT102×DAS-81910-7	Corteva	Food	Herbicide tolerance, insect resistance

(KBCH)

Further information is available at http://www.biosafety.or.kr/portal/page/f_02

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)

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

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.

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

Participation in/hosting international symposia/fora relating to biosafety

a. On May 24th, 2022 European Plant Science Organisation (EPSO) organised 6th 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.

b. On June 21st, 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.

c. On November 15-16th, 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 28-29h, 2022 he 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.

2. 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.

LITHUANIA

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

The situation in Lithuania regarding deliberate release of GMO's into the environment remains unchanged. No GM crops are cultivated and there has been no deliberate release of GMO's for field trials. Therefore no new risk assessment/regulatory decisions were taken by national competent authorities in this case.

During the reporting period (May 2022 – April 2023) 8 new notifications were received for contained use of genetically modified microorganisms (1st Class) and genetically modified organisms (1st level).

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

During the reporting period (May 2022 – April 2023) several amendments of GMO's legislation were approved:

- 2022-05-11 Amendment of Act on Contained Use of GMO's No D1-131 https://www.e-tar.lt/portal/lt/legalAct/6b387640e7fc11ecb369fde863feb27d

- 2022-06-09 Amendment of Act on GMOs Steering Committee No D1-181 https://www.e-tar.lt/portal/lt/legalAct/6b387640e7fc11ecb369fde863feb27d
- 2022-11-22 Amendment of the Act on the Approval of the Rules for Declaration and Providing Information about Genetically Modified Plant Crops Intended to be Grown in Lithuania No 3D-711 https://www.e-tar.lt/portal/lt/legalAct/TAR.6456285EDC23/asr
- 2022-12-13 Amendment of the Act on the Provision of Control Results for GMOs and their Products No D1-403/B1-852 https://www.e-tar.lt/portal/lt/legalAct/75551f507b0111edbc04912defe897d1

3. Public engagement and outreach activities:

Information on GMO's legislation, notification/permitting and various guidelines are made available on the website of the Ministry of the Environment via link: http://gmo.am.lt/

The Ministry of Environment carries out the EU funded project "Development of Biodiversity Information Platform" in 2021-2023 and one of this project aims – to create a new GMOs Data Base.

2. Updates regarding international activities

During the reporting period (May 2022 – April 2023) Lithuania took part in several international events related to NGTs which were hold on-line.

3. Developments related to new breeding techniques (NBTs)

During the reporting period (May 2022 – April 2023) there was no application received of GMO's developed by NBT's.

Lithuania takes part in the EU process for changing the EU regulation for GMO's for targeted mutagenesis and cisgenesis in plants.

2022-10-25 Scientific Symposium "Gene Editing - From Research to Industry" was organised by ThermoFisher Scientific.

NETHERLANDS

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

The Dutch authorities received several new applications for deliberate release into the environment under directive 2001/18/EC partB. General information about genetically modified organisms that have been approved in the Netherlands for deliberate release into the environment is made available from the website of the Ministry for the Environment / GMO Office (http://www.ggo-vergunningverlening.nl).

Over the last period Netherlands issued 18 new permits and 15 amendments on existing permits for clinical or veterinary trials. The majority of those permits concern clinical trials with adeno-associated virus (AAV) or human cells genetically modified by means of retroviral or lentiviral vectors (e.g. CAR-T). Worthwhile noting is the following:

- Also in 2022 we issued several permits with a broad description of the categories of clinical vectors and/or inserts used in clinical studies. In the past the scope of the GMO notifications were identical to the notifications submitted for the medical-ethical assessment. These so-called broad scope GMO permits may cover in theory an unlimited number of actual individual clinical studies. This means that there is no longer a regulatory need to notify in advance any future clinical applications with an GMO when covered by such a permit. This reduces effectively the number of waiting days for applicants to zero. Another likely effect will be that in the coming years the number of new permits for clinical studies will be reduced significantly.

- Also noteworthy is the issued permit on a broad scope clinical trial application concerning the clinical use of AAV vectors containing targeted nucleases such as CRISPR/Cas. SNIF B/NL/21/011 AAV with targeted nucleases.

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

An amendment of the Dutch GMO Decree went into force on January 1, 2023. This amendment introduces an extended set of criteria for notifications to change/amend existing permits under the condition that these changes have no impact on the environmental risk assessment of the original permit. These kind of notifications will be processed as a simplified procedure with a statutory timeframe of 5 days.

2. Updates regarding international activities

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

The Netherlands is a party to the CBD and to the Cartagena Protocol, and has actively participated in the recent COP15/COPMOP10 meeting, in particular the agenda items on Risk assessment / Risk management and synthetic biology. The Netherland will also be actively involved in the follow-up activities as decided by the COP/COPMOP.

3. Developments related to new breeding techniques (NBTs)

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

The Netherlands is following closely and actively the initiative of the European Commission concerning the status of applications of new genomic techniques (NGTs).

Although the content of the European proposal is not yet known, the Dutch government responded to the earlier published European Inception Impact Assessment and the European public consultation. The Netherlands agrees that current legislation, which dates back to 2001, is not fit for purpose with regard to plants derived from new techniques that do not cross species boundaries. The aim of the new proposal should be to make breeding with NGTs simpler, preserving and ensuring safety for human health and the environment while the innovative potentials and opportunities are not left unexploited. We also recognise that such new techniques may bring challenges also, and the Netherlands wants to pay attention to this in the development of the legislation. The ultimate core of the Dutch effort is safe, future-proof, proportional and science-based legislation.

As in previous years, the Dutch authorities are confronted with an increasing number of questions by companies and (research) institutes regarding the regulatory status of new gene editing techniques and / or products developed using such techniques. This development illustrates the challenge of keeping regulation suit for purpose with the rapid technological advancements being made.

2. Specific cases of application, assessment and decision;

To date, the Netherlands did not receive any applications for authorisation of a NGT-plant product which is subject to the EU GMO regulations according to the ruling by the European Court of Justice (Case C-528/16).

3. Other national activities;

Several activities are initiated by the authorities to involve national stakeholders in discussions on and in preparation of a national position towards a policy on NGT applications. These activities with stakeholders involve not only safety considerations but addresses NGT-related issues as well, such as consumer choice and sustainability considerations for NGT applications.

4. Additional information

The Dutch National Institute for Public Health and the Environment (RIVM) recently published an information guide for safe, sustainable and circular design in industrial biotechnology. Besides indicators and tools, it also provides a rough guide on legal frameworks safety, sustainability and circularity in industrial biotechnology in the Netherlands. See also Safe-sustainable-and-circular-design-in-industrial-biotechnology-TG (2).pdf.

The advisory body on genetic modification (COGEM) has commissioned a research project to obtain insight in the possibilities that gene-editing may offer for the development of abiotic stress tolerant crops. Genetically modified

abiotic stress tolerant crops were also included in the research project. The project was carried out by Wageningen University & Research and Wageningen Food Safety Research. The goal was (1) to obtain an overview of stress-tolerant GM crops that have been brought onto the market and their performance in the field, (2) on which other crop events are in the pipeline, and (3) on how realistic the expectations are for the new gene editing techniques in development of stress-tolerant crops compared to conventional breeding and selection. See also: CGM-2022-4-GE-crops-and-abiotic-stress-tolerance.pdf (cogem.net)

NEW ZEALAND

Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

The Environmental Protection Authority (EPA) is the New Zealand government agency that regulates the assessment and approval of 'new organisms' that also includes any organism that has been genetically modified' under the Hazardous Substances and New Organisms Act 1996 (HSNO).

i. To import for release a genetically modified, chimeric antigen receptor T (CAR-T) cell therapy (CARVYKTI) to treat patients with relapsed or refractory multiple myeloma.

   https://www.epa.govt.nz/database-search/hsno-application-register/view/APP204391

ii. To import for release a genetically modified GS-2829 and GS-6779 alternating 2-vector therapy for use in a Phase 1a/b clinical trial for patients with chronic Hepatitis B. A condition of this approval is the requirement for Gilead Sciences to carry out more extensive consultation with Māori, the first time this condition has been set in relation to a new organism being bought into New Zealand.

   https://www.epa.govt.nz/database-search/hsno-application-register/view/APP204509

   https://www.epa.govt.nz/news-and-alerts/latest-news/genetically-modified-viruses-approved-for-use-in-hepatitis-b-clinical-trial/

iii. Numerous approvals for import or development of GMOs in containment. More information can be found at the EPA HSNO link. https://www.epa.govt.nz/database-search/hsno-application-register/

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

Regulatory Framework

The New Zealand Environmental Protection Authority (Te Mana Rauhī Taiao) is a Crown Agent established under the Environmental Protection Authority Act 2011. The Act helps the Government achieve its goal of growing our economy, while effectively protecting our environment.

We report to the Minister for the Environment and the Minister for Climate Change on issues relevant to their portfolios. The Ministry for the Environment monitors our activities and is the Government's principal advisor on environmental policy and legislation.

In doing our work we carefully balance social, economic, safety, and environmental factors to protect the way of life New Zealanders want now, and in the future. We have particular responsibilities under the environmental Acts we manage.

The EPA is the government agency that regulates the assessment and approval of 'new organisms' that also includes any organism that has been genetically modified under the Hazardous Substances and New Organisms Act 1996 (HSNO).

At the EPA we recognise the unique relationship of Māori with the environment in Aotearoa New Zealand, their place as tāngata whenua – the people of the land – and the important role they play in New Zealand's economic, environmental, social and cultural wellbeing. As land managers, owners, guardians, and governors of significant natural resources, Māori can contribute a range of knowledge, skills and experience invaluable to environmental decision-making.

He Whetū Mārama the Mātauranga Framework

As part of our refreshed strategy of applying a 3, 30, 300 years' intergenerational lens to our role in protecting the environment, we are working to build a stronger partnership with Māori. In growing as a trusted partner of Māori, we are looking to grow our understanding of each other's motivations, interests, and responsibilities.

Our Māori engagement strategy details how we would like to engage with Māori.

More information can be found at the following links.
https://www.epa.govt.nz/assets/RecordsAPI/EPA-Annual-Report-2022.pdf
https://www.epa.govt.nz/te-hautu/maori-engagement-strategy/
https://www.epa.govt.nz/assets/Uploads/Documents/Te-Hautu/Maori-Engagement-Strategy-2022-25.pdf

3. Public engagement and outreach activities;

Since 2020, the EPA has funded 200 groups in its Wai Tuwhera o te Taiao – Open Waters Aotearoa science programme, which helps local groups, iwi and hapū collect environmental DNA (eDNA) samples to learn more about their waterways.

As environmental DNA analysis is being developed it may provide future technical capabilities as a monitoring tool in the future, to amongst other are, evaluate the presence or absence of an organism in the environment as well as monitor potential incursions of an organism not usually present in an environment.

More information can be found at the following links

https://www.epa.govt.nz/community-involvement/open-waters-aotearoa/
https://www.epa.govt.nz/news-and-alerts/latest-news/environmental-dna-monitoring-a-potential-game-changer-for-aotearoa-new-zealand/
https://vimeo.com/771404963/c957874633
https://www.epa.govt.nz/news-and-alerts/latest-news/fresh-funding-for-nationwide-edna-waterways-initiative/

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.

1. 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	*Saccharomyces cerevisiae*	M23541 (Genetically modified yeast for ethanol production)	Commercial release of novel GM (Resolution MAG 027/2015).
549/2023	*Saccharomyces cerevisiae*	M12156 (Genetically modified yeast for ethanol production)	Commercial release of novel GM (Resolution MAG 027/2015).
548/2023	*Saccharomyces cerevisiae*	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-ØØ6Ø3-6 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-ØØ6Ø3-6 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).

2. 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 authorised 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 unauthorised/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.

SLOVAK REPUBLIC

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

Last year was issued a decision for the first-ever clinical trial with GMO in Slovakia.

The GMO "FluBHPVE6E7" is derived from an influenza B virus (=parental virus) and was modified on several levels to be used effectively as a viral vector to eliminate human papilloma virus (HPV) infected cells and cancers induced by HPV by inducing a HPV E6 and E7 antigen specific cellular immune response. No plasmid vector sequences are present in the genome of FluBHPVE6E7.

The most important features of the GMO are a deletion in the interferon-antagonist NS1 from an influenza wild-type virus, and the insertion of the HPV-16 derived tumour antigens E6 and E7. The degree to which E6 and E7 are expressed is correlated with the type of cervical lesion, which can ultimately develop into cancer. The fact that the GMO is an RNA virus with no DNA phase in its replication cycle is excluding the chance of a gene transfer to the host. In contrast to the native protein the shuffled E6/E7 transgene has extremely low stability. Due to fast degradation and transient expression of the shuffled E6/E7 transgene sequences the likelihood that this product is oncogenic is negligible.

Intended outcome of the genetic modification is activation of an immune response against HPV infected cells and tumours.

2. Risk management measures

General rules on the coexistence of genetically modified crops with conventional and organic farming are set by the Act No. 184/2006. The implementing Decree No. 69/2007 sets minimum isolation distances when growing modified

corn, rapeseed, sugar beet and potatoes in agricultural production from plants of the same botanical species grown by conventional farming or by ecological (organic) farming. There are set also minimum requirements for buffer zones, the unmodified plants of the same botanical species can not be grown on the same plot for at least two years and the surroundings of the growing area have to be under monitoring for two years after the harvest of the genetically modified crops.

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

Synthetic biology – risk assessment of products under the EU rules valid for GMMs.

2. Updates regarding international activities

Participation in/hosting international symposia/fora relating to biosafety

In the year 2022 we have participated in conferences of European bodies where it was obligatory and at the tenth meeting of Parties of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (7.-19.12.2022, Montreal, Canada).

3. Developments related to new breeding techniques (NBTs)

Although the using of NBTs is ongoing as contained use in risk class 1 with plant tissues, potential intention of breeding new plant varieties for cultivation has not been indicated.

SOUTH AFRICA

1. GM crop production in South Africa update

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

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

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

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

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

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

To provide for measures to promote the responsible development, production, use and application of genetically modified organisms; to ensure that all activities involving the use of genetically modified organisms (including importation, production, release and distribution) shall be carried out in such a way as to limit possible harmful consequences to the environment; to give attention to the prevention of accidents and the effective management of waste; to establish common measures for the evaluation and reduction of the potential risks arising out of activities involving the use of genetically modified organisms; to lay down the necessary requirements and criteria for risk

assessments; to establish a council for genetically modified organisms; to ensure that genetically modified organisms are appropriate and do not present a hazard to the environment; and to establish appropriate procedures for the notification of specific activities involving the use of genetically modified organisms; and to provide for matters connected therewith**.**

Application of the Act
This Act shall apply to:

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

Executive Council

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

Functions of Advisory Committee

(1) The Advisory Committee (AC) shall:

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

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

Appointment of registrar

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

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

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

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

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

Biosafety:

Mission

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

Functions

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

Role as the Competent National Authority

The Cartagena Protocol on Biosafety, which is an international agreement that aims to ensure an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology, was established under the Convention of Biological Diversity. South Africa acceded to the Cartagena Protocol on Biosafety on August 14, 2003. In terms of the Protocol the DALRRD (Directorate Genetic Resources) is the recognised 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
HB4 (IND- ØØ41Ø-5)	**Soybean**	**Abiotic stress tolerant Herbicide tolerant**	**Bioceres Crop Solutions**	**2022**
HB4 (IND-ØØ412-7)	**Wheat**	**Abiotic stress tolerant Herbicide tolerant**	**Trigall Genetics SA**	**2022**
3272 x Bt11 x MIR162 x MIR604 x TC1507 x 5307 x GA21	**Maize**	**Insect resistance Herbicide tolerance**	**Syngenta SA**	**2022**
DAS-44406-6	**Soybean**	**Herbicide tolerance**	**Corteva Agriscience RSA**	**2022**
DAS-81419-2 x DAS-44406-6	**Soybean**	**Insect resistance Herbicide tolerance**	**Pioneer Hi-Bred RSA**	**2022**
NK603 x T25 x DAS-40278-9	**Maize**	**Herbicide tolerance**	**Corteva Agriscience RSA**	**2022**
GMB151	**Soybean**	**Insect resistance Herbicide tolerance**	**BASF**	**2021**
GHB811	**Cotton**	**Herbicide tolerance**	**BASF**	**2021**

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 BreedingTechniques

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 (dynamin related protein gene and three versions of the kinesin related protein), which were identified in their RNASeq study as responding to BBTV infection, and which were also picked up in other studies in literature in response to other viruses in other plants.

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

Sweet potato (*Ipomoea batatas* Lam) is an important food crop in South Africa and is planted by smallholder and rural communities for household consumption and for income generation.Sweet potato virus disease (SPVD) is one of the most important viruses of sweet potato, associated with reduction in yields by 80% to 100%. The research

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

Update: The CRSIPR/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) states that a biology document is intended to:

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

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

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

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

Cassava

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

Cotton

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

Maize/ Corn

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

Potato

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

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

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

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

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

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

SPAIN

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

Talking about risk assessment/regulatory decisions and procedures applicable in Spain, activities of contained used 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.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 an 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.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

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.

2. 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).

3. Risk management measures

In the case of deliberate release of GMO for experimental purposes, once the field trial is authorised, 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.

4. Public engagement and outreach activities

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

For detailed information on the public consultation of the notifications: Consulta e información al público (miteco.gob.es)

2. Updates regarding international activities

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

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

3. Developments related to new breeding techniques (NBTs)

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

The Interministerial Council of GMO **(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

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

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.

3.2 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

SWITZERLAND

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions since the 36rd WG-HROB meeting

- **Biotechnology activities in contained use:**

The level of biotechnological activities in contained use was in 2022 higher as before 2020, due to the many activities of diagnostic, research with SARS-CoV-2 and production of COVID-19 vaccine components. The number of

activities using genome editing such as CRISPR/Cas-9 has been increasing steadily and are standard tools today. [1,2.] Since 2020 activities of research and development with SARS-CoV viruses increased massively, followed by research activities with Monkeypox virus. Since 2022 number of activities with both pathogens are steady, mostly performed in high security levels P3, P4 laboratory.

Swiss biotech industry response to COVID-19 was high and rapid. A wide range of public/private partnership projects to address the challenges of the Covid-19 pandemic (diagnostics, antibacterial textile treatment, patient monitoring) have been observed in the last two years[3].

It has to be mentioned that regarding the specific regulation (Therapeutic Products Act (TPA), Clinical Trials Ordinance, ClinO) an environmental risk assessment is requested in the approval process for GMO products.

- **Approval of gene and cell therapies:**
  - Gentherapy product,m AVXS-101, Zolgensma, Behandlung von spinaler Muskulärer Atrophie
  - Zelltherapieprodukt KTE-X19, Gilead, Behandlung von rezidiviertem oder refraktärem Mantelzelllymphom Gentherapieprodukt,m AVXS-101, Zolgensma, Behandlung von spinaler Muskulärer Atrophie
  - Influenzaimpfstoff FLUENZ TETRA
  - Ebola Zaire Impfstoff Ervebo: Marktzulassung

- **Approval of COVID-19 vaccine:**
  - Moderna mRNA vaccine against SARS-CoV-2
  - Pfizer / BioNTech mRNA vaccine against SARS-CoV-2
  - VAC31518 COVID-19 Impfstoff
  - Janssen-Cilag AG, CARVYKTI-Car-T, Carvykti medicine used to treat adults with multiple myeloma

- **Approval of clinical trials**
  In 2022, four clinical trials have been reported.
  In 2022 a clinical trial for a GMO vaccine against avian influenza has been authorised

- **GMO Food and Feed**

No new authorization has been granted since 2015. Currently, there are 5 authorizations for GMO food and feed products:[4,5]

  - Soya 40-3-2 (Monsanto)
  - Maize Bt176 (Syngenta)
  - Maize Bt11 (Syngenta)
  - Maize MON810 (Monsanto)
  - Maize DAS 1507 (Pioneer)

However, there is de facto no import of these authorised commodities.
The newly revised regulation on Food products integrates the possibility to tolerate traces of GMO in feed products as far as those GMO are approved in EU. However, potential risks for environment are assessed, and risk management measures can be ordered.

- **Field trials**

In 2014, a "protected site" has been set up, financed by the Federal budget, in order to conduct experimental field trials with GMO plants safe from vandalism.[6] According to Swiss regulation, announcement, risk assessment documents, field trials authorizations and reports regarding GMO are publicly available and may be submitted upon request.[7]

[1] https://www.bafu.admin.ch/bafu/en/home/topics/biotechnology/state/indicators.html
[2] http://www.ecogen.ch/ecogen/Forms/Register/RegisterSearch.aspx
[3] According to the Federal Coordination Centre for Biotechnology and swiss biotech report 2021: Swiss-Biotech-Report-2021-media-presentation.pdf (swissbiotech.org)
[4] https://www.blv.admin.ch/dam/blv/fr/dokumente/lebensmittel-und-ernaehrung/rechts-und-vollzugsgrundlagen/gvo-bewilligungsliste.pdf.download.pdf/f-gvo-bewilligungsliste.pdf
[5]https://www.blw.admin.ch/dam/blw/fr/dokumente/Nachhaltige%20Produktion/Pflanzliche%20Produktion/Getreide%20und%20Futtermittel/Zugelassene%20und%20tolerierte%20GVO%20als%20Futtermittel.pdf.download.pdf/GVO%20Futtermittel%202020%20fr.pdf
[6] www.protectedsite.ch
[7]https://www.bafu.admin.ch/bafu/en/home/themen/thema-biotechnologie/biotechnologie--daten--indikatoren-und-karten/biotechnologie--indikatoren/indikator-biotechnologie.pt.html/aHR0cHM6Ly93d3cuaW5kaWthdG9yZW4uYWRtaW4uY2gvUHVibG/ljL0FlbURldGFpbD9pbmQ9QlQwMTgmbG5nPWVuJlN1Ymo9Tg%3d%3d.html

Three trials are currently running:[8]

- Genetically modified wheat strains with improved mildew resistance is running from 2019 to 2023. Mildew resistance gene: Pm3, Pm8 and Pm17 from wheat and rye; Pm17 and all Pm3 alleles with insertion of a 27 bp long DNA sequence, which codes for the HA epitope tag, before the stop codon; Pm8 with insertion of a 30 bp long DNA sequence, which codes for the myc epitope tag9
- Genetically modified maize strains with improved resistance against phytopathogenic fungi is running from 2019 to 2023 (resistance against phytopathogenic: Lr34 from wheat)
- Genetically modified barley strains with improved resistance against phytopathogenic fungi is running from 2019 to 2023.[10]

- **GMO cultivation**

Since 2005 a moratorium (interdiction) for putting GMO into circulation for agricultural, horticultural or silvicultural purposes has been four times prolonged.
In November 2020, the Federal Council (government) proposed to continue the moratorium in the Gene technology Act[11] for four more years.
The proposal was put out for public consultation and received overwhelming support.[12]
At the beginning of 2022 the Swiss parliament decided to extend the moratorium on GMO cultivation, including products from NTBs, until the end of 2025.
The political discussion on moratorium is highly related to the rapid development of new gene technologies and to the legal status of the so called "genome editing" products in the agriculture (See 2).

2. Regulatory activities

- **Products of modern biotechnology / New breeding techniques NBT (new techniques in biotechnology, genome editing)**

Legal Status:
The development of new techniques in biotechnology, notably genome editing, have raised the question whether organisms issued from such techniques have to be considered as genetically engineered as defined by law.

Since these techniques generally aim to modify the genome, the Federal Council (government) has decided that the precautionary principle, laid down in the Swiss Gene Technology Act (Federal Act on Non-Human Gene Technology),[13] will be respected. Early identification of hazards (risk assessment) and measures to mitigate risks taken are considered as a priority.

Meanwhile in a response to a motion in parliament, the Federal Council has confirmed that genome edited organisms fall under the definition of genetically modified organisms according to the Gene Technology Act. Thus, NBT are considered as gene technology techniques from a technical as well as a legal viewpoint[14].

The Gene Technology Act is a process- and product-triggered regulation, based on a case-by-case approach, which covers all domains of non-human applications (medicine, pharmaceutics, agriculture, food and feed). In addition to environmental risk assessment obligations, the Gene Technology Act gives provisions such as consumer's freedom of choice (protection of GMO-free production), product fraud, public information, taking due care and liability guarantee. These issues are very relevant in the NBT debate too.

So far, no application for authorization of a product derived from new breeding techniques (NBT) has been submitted. But there is an increasing use of CRISPR and other genome editing technologies in contained use[15].

[8] https://www.agroscope.admin.ch/agroscope/en/home/topics/environment-resources/biosafety/gv-pflanzen/protectedsite/projects.html

[9] B/CH/18/01 (B18001): Application to release genetically modified wheat strains with improved mildew resistance for experimental purposes (admin.ch)

[10] B/CH/18/04 (B18004): Application to release genetically modified barley strains with improved resistance against phytopathogenic fungi for experimental purposes (admin.ch); 21.4345 | Procédés de sélection par édition génomique | Objet | Le Parlement suisse (parlament.ch)

[11] SR 814.91 - Federal Act of 21 March 2003 on Non-Human Gene Technology (Gene Technology Act, GTA) (admin.ch)

[12] https://www.parlament.ch/en/ratsbetrieb/suche-curia-vista/geschaeft?AffairId=20194225

[13] https://www.admin.ch/opc/en/classified-compilation/19996136/index.html

[14] https://www.parlament.ch/en/ratsbetrieb/suche-curia-vista/geschaeft?AffairId=20194050

[15] Swiss-Biotech-Report-2021-media-presentation.pdf (swissbiotech.org)

Recent political-legal developments regarding NBT agricultural products

Through three postulates[16], the parliament mandated the Federal Council to provide studies on the legal status, on issues related to coexistence and on regulatory options to allow the use of NBT products in agriculture. The studies are to be publicly available in late 2022 - early 2023.

i. On the 1st. February 2023 the federal Council published the report[17] (in French and German).

On the 8th of March 2022, simultaneously to the prolongation of the moratorium on GMO cultivation[18], the Parliament gave a mandate to the federal council to provide risk-based regulation for NBT agricultural products within two years (mid 2024). This process should result in the provision of a new regulation for plants from new technologies for the post moratorium period (2026), respective the Constitutions principles (Gene technology is regulated at constitutions level in CH).

Thus, the current practice of the competent authorities is to enforce the Gene Technology Act per default. On demand, the competent authority gives case by case decisions, only on the basis of a formal request, deposited by an applicant. Until 2025, no authorization can be granted for putting GMO, including products from NTBs, into circulation (cf. GMO cultivation in section 1).

3. GMO monitoring

The presence of unauthorised GMO plants in the environment is monitored since 2011. The results show that GMO are present in the environment in low quantities.[7] One major reason for their presence is that contaminated agricultural products are imported from countries where GMO plants are grown. Oilseed Rape Monsanto GT73 is regularly identified in imported wheat from Canada and in imported bird feed,[19] indicating that the GMO plants accidentally released into the environment originate from domestic transport of imported food and feed (adventitious presence threshold). As theses GMO plants are not authorised, the competent authorities in the cantons are in charge of their elimination and collaborate for monitoring within their territories.

4. Nanotechnology

The independent, national platform contactpointnano.ch is pooling the scientific and regulatory knowledge and expertise available in Switzerland on the safe handling of synthetic nanomaterials – from production to use and disposal – and conveying it efficiently and in a generally understandable form to companies (start-ups, SMEs, and established firms).

contactpointnano.ch is supported by several government bodies, namely the Federal Office of Public Health, the Federal Office for the Environment and the State Secretariat for Education, Research and Innovation.

Further information is available under https://contactpointnano.ch/

2. Updates regarding international activities

1. Activities within European Protection Agencies EPA and European Conservation Agency ENCA

Switzerland is leading a technical working group dealing with environmental issues related to GMO within the network of the directors of European Protection Agencies EPA and Conservation Agencies ENCA (Joint EPA-ENCA interest group on environmental risk assessment and monitoring of GMOs; IG GMOs). The IG GMOs' working program 2018-2021 includes environmental considerations on gene drive organisms and the elaboration of technical recommendations regarding the monitoring of spontaneous populations of genetically modified plants in the environment and, in doing so, continue to ensure that no new and lasting populations of plants can be created by genetically modified seeds present in the soil. Since the 35rd WG-HROB meeting a technical report on Gene Drive organisms and nature conservation as well as an opinion paper on Gene Drive had been published[2021].

[16] Postulate 20.4211 "application of the law on genetic engineering"; Postulate 21.3980 "Moratorium on GMOs. Good information to make good decisions"; Postulate 21.4345 "Selection processes by genome editing". 20.4211 | Critères d'application du droit sur le génie génétique | Objet | Le Parlement suisse (parlament.ch); 21.3980 | Moratoire sur les OGM. Des bonnes informations pour prendre des bonnes décisions | Objet | Le Parlement suisse (parlament.ch);

[17] Le Conseil fédéral adopte le rapport sur la réglementation des nouvelles techniques de génie génétique (admin.ch)

[18] OGM: le Conseil fédéral chargé d'autoriser les nouvelles techniques (parlament.ch)

[19] https://www.blw.admin.ch/blw/fr/home/services/medienmitteilungen.msg-id-69124.html

[20] ig-gmo-2020-IG GMO technical report on gene drives (4).pdf

[21] IG GMO (admin.ch)

The Activity Report of the IG GMOs' working program 2018-2021 and the new working program 2021-2026 are published [22][23].

In 2022 the IG GMO met in Switzerland (in 2023 the group will meet in Rom). Further meetings were virtually conducted in 2022

2. International Activities under Convention on Biological Diversity CBD

As a Party to CBD, Cartagena Protocol and Nagoya Protocol, Switzerland is actively enforcing these instruments. Topics such as synthetic biology, gene drive processes and digital sequence information (DSI) are of national and international relevance for Switzerland, who ratified the Convention (CBD) and its protocols (Nagoya Protocol, Cartagena Protocol and the Nagoya – Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety).

3. Switzerland hosted the meeting of Biological Diversity Convention CBD Bodies

The resumed sessions of the twenty-fourth meeting of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA 24), the third meeting of the Subsidiary Body on Implementation (SBI 3) and the third meeting of the Open-ended Working Group on the Post-2020 Global Biodiversity Framework (WG2020-3), originally scheduled for 12-28 January 2022 took place on 14-29 March 2022, at the International Conference Center Geneva in Geneva, Switzerland.

3. Developments related to new breeding techniques (NBTs)

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

The development of new techniques in biotechnology, notably genome editing, have raised the question whether organisms issued from such techniques have to be considered as genetically engineered as defined by law.

Since these techniques generally aim to modify the genome, the Federal Council (government) has decided that the precautionary principle, laid down in the Swiss Gene Technology Act (Federal Act on Non-Human Gene Technology),[24] will be respected. Early identification of hazards (risk assessment) and measures to mitigate risks taken will be considered as a priority.

Meanwhile, the Federal Council has confirmed in a response to a motion in parliament that genome edited organisms fall under the definition of genetically modified organisms according to the Gene Technology Act. Thus, NBT are considered as gene technology techniques from a technical as well as a legal viewpoint.[25]

Thus, the current practice of the competent authorities is to enforce the Gene Technology Act per default. On demand, the competent authority gives case by case decisions, only on the basis of a formal request, deposited by an applicant. Until 2021, no authorization can be granted for putting GMO into circulation (cf. GMO cultivation in section 1).

The Gene Technology Act is a process- and product-triggered regulation, based on a case by case approach, which covers all domains of non-human applications (medicine, pharmaceutics, agriculture, food and feed). In addition to environmental risk assessment obligations, the Gene Technology Act gives provisions such as consumer's freedom of choice (protection of GMO-free production), product fraud, public information, taking due care and liability guarantee. These issues are very relevant in the NBT debate too.

So far, no application for authorization of a product derived from new breeding techniques (NBT) has been submitted. But there is an increasing use of CRISPR and other genome editing technologies in contained use.

[22] Activity Report IG GMO : https://www.bafu.admin.ch/dam/bafu/en/dokumente/biotechnologie/fachinfo-daten/ig-gmo-activity-report-2017-2021.pdf.download.pdf/IG%20GMO%20Activity%20Report%202017-2021.pdf

[23] New work programm IG GMO 2022-2026: https://www.bafu.admin.ch/dam/bafu/en/dokumente/biotechnologie/fachinfo-daten/ig-gmo-work-programme-2022-2026.pdf.download.pdf/IG%20GMO%20Work%20Programme%202022-2026.pdf

[24] https://www.admin.ch/opc/en/classified-compilation/19996136/index.html

[25] https://www.parlament.ch/en/ratsbetrieb/suche-curia-vista/geschaeft?AffairId=20194050

The political activity is high regarding new gene technologies. [26,27, 28, 29, 30]

i. In 2021, three postulates[25, 26, 27] coming from parliament request the federal Government to deliver information on the legal status of the NBT, on the coexistence measures regarding NBT and on the possibility to regulate NBT products so that their use in the Swiss agriculture may be initiated. The Federal Concil published the Postulate report on the 1st. February 2023[31] (in french and german).

and will serve the development of the future regulation concerning NBT Products.

2. Specific cases of application, assessment and decision

- Legal Status of TEgenesis technology according to the Swiss law (only in french): L'applicabilité de l'exception de l'Annexe 1, al. 3, let. a ODE à la méthode "TEgenesis": https://www.bj.admin.ch/dam/bj/fr/data/publiservice/publikationen/berichte-gutachten/stellungnahmen/ber-te-genesis-f.pdf.download.pdf/ber-te-genesis-f.pdf

4. Relevant Documents published by Switzerland (in French, German and English)

- Neue Gentechnische Verfahren, Kommerzialisierungs Pipeline und Lizenzvereinbarung im Bereich der Pflanzenzüchtung: https://www.bafu.admin.ch/dam/bafu/de/dokumente/biotechnologie/externe-studien-berichte/endbericht-semnar-gelinsky.pdf.download.pdf/endbericht-semnar-gelinsky.pdf
- Biological experiments, Swiss rules, tips and contacts: https://www.bafu.admin.ch/dam/bafu/en/dokumente/biotechnologie/externe-studien-berichte/biologische-experimente-schweizer-regeln-tipps-und-kontakte.pdf.download.pdf/biologische-experimente-schweizer-regeln-tipps-und-kontakte.pdf
- Magazine «l'environnement» 2/2019 - Génie génétique: Magazine «l'environnement» 2/2019 - Génie génétique (admin.ch)
- Indikatoren für die Erfassung von Trends der aus öffentlicher Hand finanzierten Forschung im Bereich Genforschung: https://www.bafu.admin.ch/dam/bafu/de/dokumente/biotechnologie/externe-studien-berichte/indikatoren-genforschung.pdf.download.pdf/indikatoren-genforschung.pdf
- Technical Report, Gene Drive Organisms – Implications for the Environment and Nature Conservations, IG GMO technical report on gene drives (PDF, 2 MB, 01.01.2020): ig-gmo-2020-IG GMO technical report on gene drives (6).pdf
- Technical Report, Monitoring of Spontaneous Populations of Genetically Modified Plant Species in the Environment (PDF, 3 MB, 28.02.2019): ig-gmo-2019-IG GMOs_Monitoring Genetically Modified Plants (1) (1).pdf
- Technical report on NBT : https://www.bafu.admin.ch/dam/bafu/en/dokumente/biotechnologie/externe-studien-berichte/grundlagen_der_rechtlichenregulierungneuerpflanzenzuchtverfahren.pdf.download.pdf/grundlagen_der_rechtlichenregulierungneuerpflanzenzuchtverfahren.pdf
- Report on intellectual property and NBT: http://www.ekah.admin.ch/fileadmin/ekah-dateien/dokumentation/gutachten/Neue_Pflanzenzuchtverfahren_und_geistige_Eigentumsrechte_E.Gelinsky_aktualisiert_November_2013.pdf
- Ethical considerations Federal Ethics Committee on Non-Human Biotechnology on NBT: http://www.ekah.admin.ch/fileadmin/ekah-dateien/dokumentation/publikationen/EKAH_New_Plant_Breeding_Techniques_2016.pdf
- Opinion of the Swiss Expert Committee for Biosafety on NBT: https://www.efbs.admin.ch/inhalte/dokumentation/Ansichten/F_Bericht_EFBS_Neue_Pflanzenzuchtverfahren.pdf
- Report on a public discussion on NBT, organised by FOEN and FOAG and the Swiss Academy of Science: http://www.naturwissenschaften.ch/uuid/db223854-0011-5649-aadc-548db33ddff8?r=20161005181841_1475028790_6d7a963b-646a-5941-b2c3-0c0a0da45d24

[26] 19.4225 | Moratoire sur les OGM. Prolongation | Bulletin officiel | Le Parlement suisse (parlament.ch)

[27] 21.308 | Pour une Suisse sans OGM! | Objet | Le Parlement suisse (parlament.ch)

[28] 21.3980 | GVO-Moratorium. Belastbare Informationen als Grundlage für gute Entscheide | Geschäft | Das Schweizer Parlament

[29] 21.4345 | Procédés de sélection par édition génomique | Objet | Le Parlement suisse (parlament.ch)

[30] 20.4211 | Critères d'application du droit sur le génie génétique | Objet | Le Parlement suisse (parlament.ch)

[31] Le Conseil fédéral adopte le rapport sur la réglementation des nouvelles techniques de génie génétique (admin.ch)

- Ethical considerations Federal Ethics Committee on Non-Human Biotechnology on precautionary principle: http://www.ekah.admin.ch/fileadmin/ekah-dateien/dokumentation/veranstaltungen/Veranstaltung_7._Mai_2018/EKAH_Broschu__re_Vorsorge_Umweltbereich_e__18_Web_V2.pdf
- Federal Ethics Committee on Non-Human Biotechnology on ethical considerations on synthetic biology: http://www.ekah.admin.ch/en/topics/synthetic-biology/
- Federal Ethics Committee on Non-Human Biotechnology on ethical considerations on the use of gene drives in the environment: https://www.ekah.admin.ch/inhalte/ekah-dateien/dokumentation/publikationen/EKAH_Bericht_Gene_Drives_EN_V2.pdf
- Opinion of the Swiss Expert Committee for Biosafety on biological risks in Switzerland: https://www.efbs.admin.ch/inhalte/dokumentation/Ansichten/Biologische_Risiken_Schweiz/EFBS_Biologische-Risiken_Schlussbericht_E.pdf
- Opinion of the Swiss Expert Committee for Biosafety on risk-related criteria to assess activities in the field of synthetic biology and its regulation: https://www.efbs.admin.ch/inhalte/dokumentation/Ansichten/Ansicht_EFBS_Synthetische_Biologie_E_definitiv.pdf
- Climate change, agriculture and the role of biotechnology - Federal Ethics Committee on Non-Human Biotechnology ECNH (admin.ch)

UNITED STATES

I. Developments related to revision and implementation of national biosafety framework

Updates for the United States Department of Agriculture (USDA)

❖ ***Modernizing USDA's Animal and Plant Health Inspection Service (APHIS) Biotechnology Regulations in 7 CFR part 340.***

USDA-APHIS has fully implemented its revised regulations to update requirements for importation, interstate movement, and environmental release of certain organisms to account for advances in genetic engineering and in our understanding of the plant pest risks posed by organisms developed using genetic engineering. The revised regulations differ from the previous regulatory framework by focusing on an organism's characteristics and not on the method used to produce it. This approach enables USDA-APHIS to regulate organisms developed using genetic engineering for plant pest risk with greater precision than the previous approach. This will reduce regulatory burden for developers of organisms that are unlikely to pose plant pest risks and continue to provide oversight of organisms developed using genetic engineering that pose a plant pest risk.

Weblink for more information on the revised regulations:
https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/revised-rule/revised-regulations

Weblink for the text of the revised rule:
https://www.ecfr.gov/current/title-7/subtitle-B/chapter-III/part-340?toc=1

❖ ***Confirmation Process***

Under the revised regulations, certain categories of modified plants are exempt from the regulations because (1) they are achievable through conventional breeding techniques and thus are unlikely to pose an increased plant pest risk compared to conventionally bred plants, or (2) because plants that have a plant-trait-mechanism of action combination that is the same as in a plant that USDA-APHIS has reviewed and determined to be unlikely to pose a plant pest risk.

Developers may voluntarily request confirmation from USDA-APHIS that a modified plant qualifies for an exemption and is not subject to the regulations in 7 CFR part 340. USDA-APHIS will provide a written response ("confirmation letter") within 120 days of receiving a sufficiently detailed confirmation request. USDA-APHIS posts both the confirmation requests and the issued confirmation letters on its website, with redactions to protect Confidential Business Information and Personal Identifying Information, as appropriate. Since the implementation

of the confirmation process, USDA-APHIS has issued 30 responses to confirmation request letters (6 in FY 2021, 9 in FY 2022 and 15 in FY23) with an average timeframe of 86 days.

Over time, USDA-APHIS expects new plant breeding innovations to evolve with advances in science and technology, along with further developments of scientific information related to conventional plant breeding. To ensure they keep pace with these advances and developments, the biotechnology regulations include a process by which the Administrator can identify additional modifications that plants can contain and be exempt from the regulations, based on what could be achieved through conventional breeding. Such proposals may be APHIS-initiated, or in response to a stakeholder request. On July 19, 2021, USDA-APHIS published a notice to advise the public of such a proposal to exempt plants with additional modifications that could otherwise be achieved through conventional breeding. Public comments on the proposal were accepted until August 18, 2021. USDA-APHIS is reviewing the comments and considering next steps.

On September 1, 2022, USDA-APHIS updated the *Confirmation Request Guidance*. The update provides clarification on preparing and submitting requests to USDA-APHIS to confirm a modified plant qualifies for an exemption and is not subject to the regulations in 7 CFR part 340, including information on how USDA-APHIS treats unintended modifications verses off-target modifications when considering confirmation requests.

Weblink for additional information:

https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulatory-processes/confirmations/confirmation-processhttps://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulatory-processes/confirmations/confirmation-process

Weblink for table of confirmation letters:

https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulatory-processes/confirmations/responses/cr-table

❖ ***Regulatory Status Review*** (RSR)

Under the revised regulations, developers have the option of requesting an RSR for a plant developed using genetic engineering that is not exempt from regulation under 7 CFR part 340. This process replaces the petition process in the legacy regulations. The revised regulations evaluate whether a plant is subject to regulation based on the characteristics of the plant itself and not on the method by which the plant was genetically engineered.

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

If USDA-APHIS does identify a plausible pathway by which the plant or its sexually compatible relatives would pose an increased plant pest risk relative to the comparator(s) in the initial review, the requestor may ask that USDA-APHIS conduct a Plant Pest Risk Assessment (PPRA) to evaluate the factor(s) of concern identified in the initial review to determine the likelihood and consequence of the plausible increased plant pest risk. For those plants for which a PPRA is conducted, and USDA-APHIS does not reach a preliminary finding that the plant is unlikely to pose an increased plant pest risk, the plant will remain subject to the revised regulations. Alternatively, if USDA-APHIS reaches a preliminary finding that the plant is unlikely to pose an increased plant pest risk, USDA-APHIS will publish the RSR request and the preliminary PPRA in the *Federal Register* and will solicit and review comments from the public. If, after reviewing the comments and other information it receives related to the preliminary PPRA, USDA-APHIS determines the plant and its sexually compatible relatives are unlikely to pose an increased plant pest risk relative to their comparator(s), the plant is not subject to 7 CFR part 340. USDA-APHIS will announce such a finding in a second *Federal Register* notice and will post it on its website along with the original request and the final PPRA.

This process was implemented for six crops on April 5, 2021, and fully implemented for all crops on October 1, 2021. USDA-APHIS published the first RSR response in September 2022. USDA-APHIS has received a total of 46 RSR requests and has published a 7 RSR response letters since the implementation of the RSR process (3 in FY 2022 and 4 in FY 2023), as depicted in the table below.

Plant	Trait	Requester
Soybean	Altered Seed Oil Profile and Protein Content	ZeaKal, Inc.
Chrysanthemum	Altered flower color and marker gene (antibiotic resistance)	Suntory Flowers Limited
Corn	Altered peroxidase and Herbicide Resistance	Infinite Enzymes, Inc.
Potato	Altered tuber quality, Altered tuber sugar profile, Herbicide resistance, Fungal resistance, and Virus resistance, Resistance to potato late blight	J. R. Simplot Company
Tomato	Product Quality and Marker Gene	Norfolk Plant Sciences
Corn	Altered enzyme levels and Marker gene (carbon source)	Agrivida, Inc.
Potato	Altered tuber quality	ToolGen

Weblink for table of approved RSRs: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulatory-processes/rsr-table/rsr-table

On December 22, 2022, following public comment, USDA-APHIS posted its final Regulatory Status Review (RSR) guide, which details the information requirements and process for submitting an RSR request under the revised biotechnology regulations at 7 CFR part 340.

Weblink for the text of the final RSR guidance:

https://www.aphis.usda.gov/brs/pdf/rsr-guidance.pdf

❖ ***Regulation of the Movement of Animals Modified or Developed by Genetic Engineering.***

On December 28, 2020, USDA-APHIS published an Advance Notice of Proposed Rulemaking (ANPR) and request for comment on a contemplated regulatory framework that would provide oversight for the movement of certain animals modified or developed by genetic engineering. Comments were accepted through May 7, 2021.

***Weblink for the ANPR and request for comments*:**
https://www.regulations.gov/document?D=APHIS-2020-0079-0001

❖ ***Petitions for non-regulated status.***

Since May 2022, USDA-APHIS has made no determinations of non-regulated status.
Currently there are three pending reviews:1) Pioneer Insect Resistant and Herbicide Resistant Corn, 2) Bayer Stacked 5 Herbicide Resistant Corn, (3) SUNY ESF Blight Tolerant Chestnut.

Weblink for petition documents:
https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulatory-processes/petitions/petition-status/petitions-table

❖ ***Applications for import, interstate movement, and environmental release.***

In Fiscal Year (FY) 2022 (10/1/2021 through 09/30/2022), APHIS received 925 permit applications for import, interstate movement, and environmental release. Of those, APHIS issued 758 permits. In addition, 10 applications are pending, 148 were withdrawn, and 0 were denied for reasons unrelated to risk (e.g., the application was not deemed complete prior to the regulatory deadline). During the portion of FY 2023 that has currently elapsed (10/1/2022 through 03/17/2022), APHIS has received 500 permit applications. Of those, APHIS issued 268 permits. In addition, 245 applications are pending and 84 were withdrawn.

On March 28, 2022, APHIS announced that a newly updated BRS permit application is available on APHIS eFile. The improved permit application is a simple and easy way to apply for BRS importation, interstate movement, and environmental release permits. To assist applicants with the updates, ten training sessions were held from March 29 to April 7, 2022.

On September 1, 2022, USDA-APHIS published *Questions & Answers on working with Microorganisms Developed Using Genetic Engineering Under 7 CFR part 340*. This Q&A covers topics such as what microorganisms are regulated, permit requirements, permit exemptions, and how to contact us and what information to provide if you are uncertain whether your microorganism is regulated. On March 23, 2023, USDA-APHIS published a draft guide detailing the information requirements and process for submitting permit applications for microorganisms developed using genetic engineering and invited public comment for a 60-day period until May 22, 2023. More information on the draft guidance can be found at https://www.aphis.usda.gov/aphis/newsroom/stakeholder-info/sa_by_date/sa-2023/microorganism-guide.

❖ ***Compliance and oversight.***

From October 1, 2021, through March 3, 2023, USDA-APHIS and its state partners completed 872 inspections (663 in FY 2022, and 209 thus far in FY 2023) to meet compliance and oversight goals for the regulation of trials involving organisms developed using genetic engineering. In-person compliance inspections are steadily increasing, with the virtual inspection program (Monitoring & Evaluation Interviews) utilised occasionally as an available compliance evaluation tool.

❖ ***2022 USDA-APHIS BRS Stakeholder Meeting.***

On December 8, 2022, USDA-APHIS Biotechnology Regulatory Services (BRS) held its annual stakeholder meeting. The meeting was open to stakeholders and the public to foster engagement and transparency in BRS regulatory activities. BRS provided updates on the implementation of the revised biotechnology regulations, including the new Regulatory Status Review and Confirmation Request processes. They also shared other fiscal year (FY) 2022 activities, including permitting, questions and answers for microbes, international efforts, and priorities for FY 2023. The agenda, presentation, transcript, and video of the meeting can be found on the USDA-APHIS-BRS websites along with the question and answer in the "News and Announcements" section under "Meetings."

Weblink for USDA-APHIS-BRS activities: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology
Weblink for USDA-APHIS-BRS news and announcements:
https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/brs-news-and-information/brs-news

Updates for the United States Environmental Protection Agency (EPA)

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

❖ ***Two EPA proposals on plant-incorporated protectants (PIP)***

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

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

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

2) PIP Insect-Resistance Management Draft Proposal to Improve Lepidopteran Resistance Management Strategies

On November 23, 2021 EPA published a response to public comments and revised framework to improve lepidopteran resistance management strategies for pests of *Bacillus thuringiensis* (Bt) corn and cotton PIPs to prolong the durability these genetically modified crops. In response to increasing reports of lepidopteran pest resistance to Bt PIP crops, EPA convened a FIFRA Scientific Advisory Panel in 2018. Based on the panel's report and recommendations, EPA in 2020 proposed improvements to resistance monitoring, actionable definitions for insect resistance to Bt PIPs, enhanced mitigation measures for resistant pest populations, an increase in refuge size,

strengthened refuge compliance measures, and a phase-down of at-risk single trait and pyramided PIP products. EPA took public comment on these proposals and after reviewing the comments, revised the resistance management framework accordingly. The response to comments and revised framework document is available in Docket# EPA-HQ-OPP-2019-0682. EPA is currently negotiating the implementation of the framework with Bt PIP registrants, but expects to have portions of the framework in place for the 2023 growing season. Full implementation of the framework is expected later in 2023.

Weblink for the webinar (held September 28, 2020 for the original proposal):

https://www.youtube.com/watch?v=-Cf7ZorPo84&feature=youtu.be

Weblink for the docket:

https://www.regulations.gov/docket?D=EPA-HQ-OPP-2019-0682.

❖ ***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

❖ ***Regulatory Update for genetically engineered mosquitoes***

In March 2022, EPA granted a two-year extension and expansion to the Experimental Use Permit for genetically engineered OX5034 *Ae. aegypti* mosquitoes. The EUP was issued to allow testing of the efficacy of OX5034 to suppress native *Ae. aegypti* populations. The traits engineered into the mosquitoes result in male-only survival of the offspring. With continued environmental releases over several months, the wild population is expected to decline. Releases will be initiated in Florida and California in 2022; testing will continue in these locations during 2023. EPA's decision and the approved permit are available in Docket# EPA-HQ-OPP-2019-0274.

Weblink for the docket:

https://www.regulations.gov/docket?D=EPA-HQ-OPP-2019-0274

EPA Office of Pollution Prevention and Toxics (OPPT)

❖ **Reviewed Biotechnology Submissions**

In the last fiscal year, FY22 (Oct. 1, 2021 to Sept. 30, 2022), the U.S. EPA/OPPT reviewed the closed-system use of 24 genetically engineered microbial strains submitted in Microbial Commercial Activity Notices (MCANs). The identity of many of these microorganisms was claimed as confidential. Of the non-confidential microorganisms, several were *Saccharomyces cerevisiae* for production of chemical substances, a biofuel, or an alcohol. A genetically engineered strain of *Escherichia coli* was also reviewed for production of plasmid-borne DNA. Several strains referred to simply as genetically modified microorganisms or modified yeast were used for enzyme or chemical production. A determination of "not likely to present an unreasonable risk to health or the environment" was made for all of these genetically engineered strains. Four strains of microorganisms were submitted in one TSCA Experimental Release Application (TERA), the submission needed for environmental introduction of genetically engineered microorganisms for research and development purposes. The strains reviewed were bacilli to affect nitrogen production. An approval was also made for allowing an additional three years of testing for several strains of green microalgae tested in open ponds in an on-going TERA. EPA approved the TERA and the TERA modification based on its determination that the proposed activities do not present an unreasonable risk to health or the environment.

❖ **Microalgae Consensus Document**

U.S. EPA/OPPT and Canada (New Substances Program – Environment and Climate Change Canada and Health Canada) continued to work as co-leads on the OECD microalgae consensus document entitled "Consensus Document on Information used in the Assessment of Environmental Applications Involving Photoautotrophic Microalgae for Biomass Production". Canada presented the progress on a draft of this document (Room Document 3) at the 36th WP-HROB Meeting that occurred May 18-20, 2022.

A revised document was sent to all delegates in mid-September, and comments received by the end of 2022 from Japan, the Public Research & Regulation Initiative (PRRI), and Australia were addressed by the co-leads in early 2023. The First Full Draft is now posted on the O.N.E. site with a request for comments by April 10th prior to the 37th Meeting of the WP-HROB that is occurring April 17-19, 2023. Delegates were also asked to consider recommending declassification of the document (amended as appropriate) and to agree on the next steps to its finalization.

II. International Activities

Updates for the United States Department of Agriculture (USDA)

1. ***Technical Trilateral Working Group (TTWG)*.** The TTWG is a technical working group for biotechnology among the United States, Canada, and Mexico. The TTWG annual meeting was held on September 28-29, 2022. The TTWG also conducts quarterly calls throughout the year.

2. USDA hosted meetings with foreign regulators to discuss updates of regulations and confer on technical issues that we have encountered. In 2022, regulators from Japan, Argentina, Uruguay, and Paraguay visited USDA.

III. Developments in New Breeding Techniques (NBT)

Updates for the United States Department of Agriculture

Exemptions and Confirmation Requests. Under the revised regulations, certain categories of modified plants are exempt from the regulations because (1) they are achievable through conventional breeding techniques and thus are unlikely to pose an increased plant pest risk compared to conventionally bred plants, or (2) because plants that have a plant-trait-mechanism of action combination that is the same as in a plant that USDA-APHIS has reviewed and determined to be unlikely to pose a plant pest risk. On August 17, 2020, exemptions from the revised regulations became effective, as did a process for developers to request confirmation from USDA-APHIS that a modified plant meets the criteria for exemption from the biotechnology regulations in 7 CFR part 340.

Specifically, the regulations in 7 CFR part 340 do not apply to plants that have been modified such that they contain

either a single modification of a type listed in paragraphs (b)(1) through (3) of § 340.1, or additional modifications as determined by the Administrator, and described in paragraph (b)(4) of § 340.1.

(1) The genetic modification is a change resulting from cellular repair of a targeted DNA break in the absence of an externally provided repair template; or

(2) The genetic modification is a targeted single base pair substitution; or

(3) The genetic modification introduces a gene known to occur in the plant's gene pool, or makes changes in a targeted sequence to correspond to a known allele of such a gene or to a known structural variation present in the gene pool.

(4) The Administrator may propose to exempt plants with additional modifications, based on what could be achieved through conventional breeding. Such proposals may be Agency-initiated and follow the process in paragraph (b)(4)(i) of this section, or in response to a request made in accordance with paragraph (b)(4)(ii) of this section.
On July 19, 2021, USDA-APHIS published a notice to advise the public of such a proposal to exempt plants with additional modifications that could otherwise be achieved through conventional breeding. Public comments on the proposal were accepted until August 18, 2021. USDA-APHIS is reviewing the comments and considering next steps.

Weblink for guidance for requesting a confirmation or exemption from regulation under 7 CFR part 340:
https://www.aphis.usda.gov/brs/pdf/requesting-confirmation-of-exemption.pdf

IV. Additional Information

Updates on the Executive Order (14081) on Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe and Secure American Bioeconomy

On September 12, 2022, President Biden issued Executive Order (E.O) 14081, "Advancing Biotechnology and Biomanufacturing Innovation for a Sustainable, Safe, and Secure American Bioeconomy." Section 8 of the E.O. calls out the need for clarity and efficiency in the regulatory process and requires, as a first step, that the Secretary of Agriculture, the Administrator of the Environmental Protection Agency, and the Commissioner of the Food and Drug Administration identify areas of uncertainty in the regulatory framework that remain after the 2017 update to the Coordinated Framework for the Regulation of Biotechnology. The three Agencies (USDA-APHIS, EPA, and FDA), in consultation with the Office of Science and Technology Policy (OSTP), published a notice with a Request for Information (RFI) to the public on seven key questions, from December 15, 2022, through February 3, 2023. The agencies have classified public responses in to four themes on regulating the products of biotechnology as 1) requests for greater regulatory clarity, 2) requests for greater regulatory coordination and harmonisation, 3) requests for regulatory reform or revision, and 4) comments on regulatory resources. In some cases, there is overlap among these themes. The agencies are reviewing the comments and considering next steps.

EUROPEAN UNION

1. Developments related to implementation of national biosafety framework

1. **Risk assessment/regulatory decisions**

i. Risk assessment

Since 1st 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), and
- the GMO register for placing on the market of GMOs as or in products if authorised under Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms (https://webgate.ec.europa.eu/fip/GMO_Registers/).

Since the last WG-HROB meeting, the European Commission has authorised 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 x MON 810 x MIR604 x 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

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[32] 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[33] 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[34].

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[35] 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
- 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.

[32] 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)

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

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

[35] 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

BIAC (BUSINESS AT OECD)

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

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 fertilizer, 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_2 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 commercialised 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 him on his farm, and how threats to innovation could hinder his 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 recognised 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 Recognises 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[36]. 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, standardization of information requirements in support of a regulatory status determination, adoption of predictable and efficient assessment timelines, and recognition of other countries' determinations on regulatory status. These common approaches are essential to maintain a functional trading system that facilitates food security enabled by innovative products including those derived from genome editing.

As noted 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 finalization 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.

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

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

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.

UNEP-CBD (CONVENTION ON BIOLOGICAL DIVERSITY)

The Conference of the Parties held its fifteenth meeting in conjunction with the tenth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (the Cartagena Protocol) and the fourth meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (the Nagoya Protocol).

The meetings considered a number of elements relevant to the programme of work of the WP-HROB which are outlined below.

1. Developments related to biosafety activities

(1) Risk Assessment and Risk Management - Decision CP-10/10

The Conference of Parties serving the meeting of Parties to the Cartagena Protocol on Biosafety (COP-MOP) endorsed the Ad Hoc Technical Expert Group on Risk Assessment (AHTEG) recommendation that additional voluntary guidance materials be developed to support case-by-case risk assessment of living modified organisms containing engineered gene drives.

The COP-MOP agreed to develop these additional voluntary guidance materials through a comprehensive process that includes the following steps:

- Establishment of a new Ad Hoc Technical Expert Group on Risk Assessment to develop additional voluntary guidance materials to support case-by-case risk assessment of living modified organisms containing engineered gene drives should be developed;
- Online discussions of the Online Forum on Risk Assessment and Risk Management to review an outline of the additional voluntary guidance materials and to support the work of the AHTEG;
- Invitation to Parties, other Governments, indigenous peoples and local communities and relevant organisations to submit information relevant to the work of the AHTEG;
- Invited Parties to also submit information on their needs and priorities for further guidance materials on specific topics of risk assessment of living modified organisms, including a rationale following the criteria set out in decision CP-9/13, annex I;
- The twenty-sixth meeting of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) will consider the outcomes of the AHTEG and prepare a recommendation to the eleventh meeting of the COP-MOP.

(2) Synthetic Biology

The Conference of the Parties established a multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology (multidisciplinary AHTEG) to support the process for broad and regular horizon scanning. This process is intended to identify and prioritize trends and issues regarding developments of synthetic biology that need to be considered vis-à-vis the three objectives of the Convention. The process agreed for broad and regular horizon scanning, monitoring and assessment consists of the information gathering, compilation, organisation and synthesis of information, assessment and reporting on outcomes.

In this regard, the Executive Secretary convened online discussions of the Open-ended Online Forum on Synthetic Biology to support the work of the multidisciplinary AHTEG in March 2023. Extensive inputs were made that will inform the work to be undertaken by the multidisciplinary ad hoc technical expert group (AHTEG) on synthetic biology to support the process for broad and regular horizon scanning, monitoring and assessment when it convenes for its first session in July 2023.

In addition, the Secretariat launched its *Technical Series No. 100: Synthetic Biology*. The updated the Technical Series on Synthetic Biology provides a peer review of scientific information and other relevant information on advances in synthetic biology and provides an extensive overview of global developments. The updated Technical Series is available at https://www.cbd.int/ts/.

(3) Detection and Identification of Living modified Organisms in the Context of the Cartagena Protocol on Biosafety

At its tenth meeting, the Conference of Parties serving as a meeting of the Parties to the Cartagena Protocol on Biosafety adopted decision CP-10/11. In this decision, the Conference of Parties serving as a meeting of Parties to the Cartagena Protocol on Biosafety recognised the need for capacity-building activities on new detection techniques, as well as on detecting and identifying unauthorised living modified organisms.

Thus, Parties and relevant organisations were requested to submit information on their experience with new detection techniques, detecting newly developed and unauthorised living modified organisms, and developing reference materials, as well as ongoing collaborations involving national and regional laboratories.

In addition, the Secretariat launched its *Biosafety Technical Series No. 5: Training Manual on the Detection and Identification of Living Modified Organisms in the Context of the Cartagena Protocol on Biosafety*. The publication is available on the Biosafety Clearing-House at https://bch.cbd.int/en/database/VLR/BCH-VLR-SCBD-260177-1.

2. Updates regarding international activities

(1) Biosafety Clearing House - Unique identification systems for living modified micro-organisms and animals

Article 20 of the Cartagena Protocol on Biosafety to the Convention on Biological Diversity establishes a Biosafety Clearing-House (BCH) "as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention, in order to: (a) facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and (b) assist Parties to implement the Protocol".

The eleventh meeting of the Informal Advisory Committee (IAC) made specific recommendations to the Secretariat to continue to pursue cooperation with the OECD, regarding the development of unique identification system for living modified animals.

It should also be noted that the Parties to the Cartagena Protocol previously took decisions regarding unique identification system for living modified microorganisms and animals. Decision BS-VI/8 which, in para. 5, "encourages the Organisation for Economic Co-operation and Development to renew efforts to develop unique identification systems for living modified micro-organisms and animals, further to paragraph 3 of section C of decision BS-I/6".

Presently the following Living modified animals are registered on the Biosafety Clearing House:

BCH ID#	Name	Organism
115346	2nd Generation Friendly™ *Aedes aegypti*	Aedes aegypti
101474	Dominant lethal *Aedes aegypti* mosquito	Aedes aegypti
260490	Male-sterile *Anopheles coluzzii* mosquitoes	Anopheles coluzzii
f260489	Male-sterile *Anopheles gambiae* mosquitoes	Anopheles gambiae
105039	Female-specific Dominant Lethal Olive Fly	Bactrocera oleae
108045	Domestic goat modified to produce human lactoferrin	Capra aegagrus hircus
260325	Green fluorescent zebrafish	Danio rerio
260324	Red fluorescent zebrafish	Danio rerio
45406	Glofish	Danio rerio
100309	Hybrid tilapia modified with growth hormone gene	Oreochromis hornorum x Oreochromis aureus
103105	Pink Bollworm Modified for the Expression of a Fluorescent Marker	Pectinophora gossypiella
104725	AquAdvantage® Salmon	Salmo salar

259122	Friendly™ Fall Armyworm	Spodoptera frugiperda
263132	GalSafe® pig	Sus scrofa

(2) Kunming Montreal Global Biodiversity Framework

The Kunming-Montreal Global Biodiversity Framework (GBF) was adopted by Parties to the Convention on Biological Diversity in December 2022. The GBF includes with four goals and 23 action-oriented targets, one of which, target 17 deals specifically with biotechnology and biosafety.

Target 17: Establish, strengthen capacity for, and implement in all countries biosafety measures as set out in Article 8(g) of the Convention on Biological Diversity and measures for the handling of biotechnology and distribution of its benefits as set out in Article 19 of the Convention

The implementation of Target 17 will provide a new focus on biosafety and other related elements of biotechnology

3. Any other information of relevance to the WP-HROB

The programme of work for the biennium 2023-2024 will include the following activities of relevance to the WP-HROB.

- The twelfth meeting of the Informal Advisory Committee on the Biosafety Clearing-House (BCH) (held on 15-16 May 2023);
- A meeting of the multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology (tentatively scheduled to be held 11-14 July 2023);
- The eighteenth meeting of the Compliance Committee under the Cartagena Protocol on Biosafety;
- A meeting of the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management;
- Online discussions of the Network of Laboratories for the Detection and Identification of Living Modified Organisms;
- Joint Aarhus Convention/CBD Round table on public participation and access to information regarding LMOs;
- A second meeting of the multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology;
- A second meeting of the Ad Hoc Technical Expert Group on Risk Assessment and Risk Management;
- A meeting of the Network of Laboratories for the Detection and Identification of Living Modified Organisms;
- The nineteenth meeting of the Compliance Committee under the Cartagena Protocol on Biosafety;
- The fifteenth meeting of the Liaison Group on the Cartagena Protocol on Biosafety.

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
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

IBO Training Program

In partnership with the Ministry of Agriculture, Government of Bangladesh and under the auspices of the South Asia Biosafety Program, AFSI hosted a series of workshops providing training for Institutional Biosafety Officers (IBOs) and Committees (IBCs) at research institutions engaged in biotechnology research and development in Bangladesh. The purpose of the workshop series was to ensure that institutions in Bangladesh are aware of their obligations under the biosafety regulatory system and are empowered to work with researchers to meet these obligations while continuing their research. The IBOs are the liaison between product developers and regulatory authorities in Bangladesh. The program began in December 2021, consisted of five training workshops, and was concluded in February of 2023. The workshop series covered topics including the development of standard operating procedures for greenhouse work, confined field trials with a focus on understanding the requirements and application process for conducting one in Bangladesh and key components for record keeping, handling, storage, transfer, shipment, and disposal of genetically engineered plant material. In addition, topics such as writing meaningful dossiers, and the process of submission to regulatory authorities in Bangladesh were discussed.

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 commercialization 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 digitalization and innovative technologies and was attended by 62 participants from 9 APEC economies.

Animal Biotechnology

AFSI conducted a capacity building workshop on July 28-29, 2022, in Nairobi, Kenya in collaboration with Acceligen, and the International Service for the Acquisition of Agri-biotech Applications (ISAAA) AfriCenter. The objective of this workshop titled 'Regulatory Frameworks for Animal Biotechnology in Africa' was to support the development of the necessary technical and regulatory frameworks to allow for commercialization and trade in the products of animal biotechnology. 38 invited participants from 10 countries and the African Union attended the entire workshop, with 20 additional local participants from the International Livestock Research Institute and the University of Nairobi joined the meeting's public portion, during which regulators from Brazil, Argentina, Kenya, and Nigeria presented on their regulatory frameworks for products of genome editing.

AFSI also co-hosted the Fourth International Workshop on Regulatory Approaches for Agricultural Applications of Animal Biotechnologies alongside USDA, Virginia Polytechnic Institute and State University, Inter-American Institute for Cooperation on Agriculture, ISAAA, and University of São Paulo. The workshop took place in São Paulo, Brazil on September 12-16, 2022, and included a hands-on exercise on problem formulation.

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

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 authorised the environmental release of MON-87460-4 × MON-89034-3 - TELA Maize in October 2021. In addition, Ghana authorised 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 authorised 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 sensitization 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, sensitization 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 recognise 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 unauthorised 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.