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Developments in Delegations on Biosafety Issues, May 2023 – February 2024

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Environment Directorate

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Paris 2024

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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)

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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)

No. 72, Developments in Delegations on Biosafety Issues, June 2022 – April 2023 (2023)

No. 73, Consensus Document on Environmental Considerations for Risk/safety Assessment for the Release of Transgenic Plants (2023)

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

This publication is available electronically, at no charge.

For this and many other Biosafety publications, consult the OECD's World Wide Web site (www.oecd.org/env/ehs/biotrack/)

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OECD Environment, Health and Safety Publication

FOREWORD

The Working Party 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 38th WP-HROB meeting (20-22 March 2024). It aims at summarising relevant information on activities related to biosafety issues since the previous meeting (April 2023) at the international level, by collating individual contributions from OECD Members, partner countries and observer organisations participating in the work.

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

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ARGENTINA

1. New legislations in the regulatory framework

There were no reviews or updates related to GMO Biosafety regulations by the National Advisory Commission on Agricultural Biotechnology.

Agreement between Argentina and Brazil on biosafety:

Memorandum of understanding between the regulatory agencies of Argentina (CONABIA) and Brazil (CTNBIO) for cooperation in biosafety of products derived from modern biotechnology. Signed on 20th October of 2022 by the Ministry of Science and Technology of Brazil and the Ministry of Economy of Argentina. Under this agreement Argentina and Brazil are committed to start working together and to build the necessary mechanisms and procedures for the joint evaluation and authorizations of products of agricultural biotechnology.

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

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

Biodesarrollar Program

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

During 2023, the Program provided financial assistance to 23 bioeconomy projects (biotechnologies, bioenergies, bioinputs and biomaterials) for a total of 250 million pesos with an average assigned amount of 10.5 million pesos per project. The list of beneficiaries, areas, amounts and objectives were published on the website of the Secretary of Agriculture, Livestock and Fisheries: https://www.argentina.gob.ar/sites/default/files/listado-de-entidades-seleccionadas-de-la-primera-convocatoria-del-programa-biodesarrollar.pdf

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

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

2. Events for confined field trials

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

During 2023, 50 authorizations were granted for different crops:

	FIELD TRAILS	PRODUCTION	GREENHOUSE
QUANTITY	39	4	7
CROP			
Wheat			1
Corn	8	2	1
Soy	20	2	1
Tobacco	1		
Beet	1		
Ryegrass	1		
Cameline	1		1
Lettuce	1		
Alfalfa	4		2
Sorghum			1
Sugar cane	2		

Animals:

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

3. Events for Commercial Approvals

Since last Meeting, genetically modified events were approved for commercial release in Argentina in 2023-2024:

Unique Identifier	Applicant	Organism Common Names	Traits	Type of use	Date of approval	Decision name	OECD BioTrack
MON-Ø4Ø32-6 x ACSGMØØ6-4	GDM	Soybean	Tolerant to herbicides based on glyphosate and glufosinate ammonium	Cultivation, Food and Feed	31/05/2023	https://www.boletinoficial.gob.ar/detalleAviso/primera/287682/20230602	MON-Ø4Ø32-6 x ACSGMØØ6-4
SYN-BTØ11-1 x SYN-IR162-4 xMON-ØØ6Ø3-6	Syngenta Agro S.A.	Maize	Resistance to certain Lepidoptera and tolerance to glyphosate and glufosinate ammonium	Cultivation, Food and Feed	29/09/23	https://www.boletinoficial.gob.ar/detalleAviso/primera/295411/20231003	SYN-BTØ11-1 x SYN-IR162-4 xMON-ØØ6Ø3-6
DNB-Ø9ØØ4-3xDNB-Ø8ØØ2-3	INDEAR S.A.	Soybean	Tolerance to glyphosate and glufosinate ammonium	Cultivation, Food and Feed	02/10/23	https://www.boletinoficial.gob.ar/detalleAviso/primera/295503/20231004	DNB-Ø9ØØ4-3xDNB-Ø8ØØ2-3

			and resistance to certain Lepidoptera				
BCS-GHØØ4-7 x BCS-GHØØ5-8 x BCS-GH811-4 x SYN-IR1Ø2-7	BASF	Cotton	Tolerant to HPPD, glyphosate, glufosinate ammonium and protected against certain lepidopterans	Cultivation, Food and Feed	02/11/23	https://www.magyp.gob.ar/sitio/_pdf/Disposicion-50-2023.pdf	BCS-GHØØ4-7 x BCS-GHØØ5-8 x BCS-GH811-4 x SYN-IR1Ø2-7
MON-87751-7 x MON-877Ø1-2 x MON-877Ø8-9 x MON-89788-1	MONSANTO	Soybean	Raw material for agroindustrial processing and for human and animal food use	Only for processing	06/02/24	https://www.argentina.gob.ar/sites/default/files/disposicion-n-3-2024-soja-mon-87751-7-x-mon-877o1-2-x-mon-877o8-9-x-mon-89788-1.pdf	MON-87751-7 x MON-877Ø1-2 x MON- 877Ø8-9 x MON-89788-1

Microorganisms

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

				production from starch."		
Saccharomyces cerevisiae	Yeast Saccharomyces cerevisiae strain Fermboost MR Bioethanol production from grain fermentation	Fermboost MR	LALLFERM S.A.	Genetically modified yeast with improved capacity for bioethanol production from starch fermentation	24/01/24	https://www.argentina.gob.ar/sites/default/files/di-2024-1-apn-ssabdr-mec.pdf

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

4. NEW BREEDING TECHNIQUES

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

According to organisms, it can be said that out of the 64 PCI forms, 1 (one) PCI was submitted for a microorganism, 9 (nine) for animals and the rest for plants.

CONABIA considered that these products complied with characteristics established in the Policy Approach for NTBs (Resolution No. 21/21) and did not fall within the scope of the Regulatory Framework of Genetically Modified Organisms.

Since 2015 to date, 135 PCIs have been analysed for different organisms (plants, animals, and microorganisms).

5. Participation in International Activities

2023:

- 3 bilateral, regional and multilateral high-level meetings:
    a. Meeting GT5 “Public policies in biotechnology” of the Southern Agricultural Council (CAS) held on March 16-17 in Buenos Aires, Argentina.
    b. Like-Minded countries meeting (Like Minded Group) April 28 and 29 in Saint Louis, United States. Argentina co-organizer of the event.
    c. Participation in the 16th ISBR Symposium (The International Society for Biosafety Research) event from April 30 to May 4 in Saint Louis, United States.
    d. International Gene Edition Workshop held on May 18 and 19 in Buenos Aires, Argentina: cooperation with regulators and officials from Latin America and Africa.
    e. Bilateral meeting between Argentina and Saudi Arabia: On May 11th Bilateral meeting with the regulatory agency of Saudi Arabia to coordinate positions regarding the regulation of modern biotechnology and advance future cooperation criteria in the matter.

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

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

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

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

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

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

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

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

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

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

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

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

Other international activities held on 2023-2024

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

6. Communication and education

2023

- FOAR project "Strengthening of capacities for activities with new breeding techniques (NBT), including gene editing" with Peru for technical assistance and training in gene editing that was carried out during four missions in 2023 and 2023:

  - 1st Mission of 2023: Week in March of training for officials and technicians from Peru: 3rd FOAR Mission in Lima, Peru.
  - 2nd Mission of 2023: training for officials and technicians from Peru: 4th FOAR Mission held in Buenos Aires, Argentina, on October 16 and 17.

- Document publication of GT5 “Policies for Biotechnology” of the Southern Agricultural Council (CAS): “Evolution of the use of biotechnology in the countries of the Southern Agricultural Council[5]”
- On May 6, training for boys in their last year of high school from all over the country, an activity organized together with the Junior Achievement Argentina Program Partners association (https://junior.org.ar/programas/)
- Publication of three editions of the magazine Biodesarrollar[6]. A way to communicate and share all the advances in the bioeconomy.
- Training given to National Public Universities, to provide basic knowledge about agricultural biotechnology, its journey to modern biotechnology in production animals and its regulatory system in Argentina.
  - June 29, 2023 - Faculty of Veterinary Sciences of the National University of Buenos Aires (UBA): "INTRODUCTION TO MODERN BIOTECHNOLOGY IN ANIMALS IN THE AGRICULTURAL FIELD".
  - October 5, 2023 - Veterinary Medicine of the National University of Rio Negro (UNRN): "INTRODUCTION TO MODERN BIOTECHNOLOGY IN ANIMALS IN THE AGRICULTURAL FIELD".
  - October 25, 2023 - Faculty of Veterinary Sciences of the National University of La Pampa (UNLPam): "INTRODUCTION TO MODERN BIOTECHNOLOGY IN ANIMALS IN THE AGRICULTURAL FIELD".

[5] http://consejocas.org/wp-content/uploads/2023/07/Publicaci%C3%B3n-Evoluci%C3%B3n-del-uso-de-la-biotecnolog%C3%ADa-en-los-pa%C3%ADses-del-CAS.pdf

[6] https://www.argentina.gob.ar/agricultura/alimentos-y-bioeconomia/revista-biodesarrollar

AUSTRALIA

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

1.1. Environmental release - approvals, since April 2023

Licences for environmental release (at 15 April 2024):

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, Risk Assessment and Risk Management Plans (RARMPs) and approvals are available on the OGTR website: https://www.ogtr.gov.au/what-weve-approved/dealings-involving-intentional-release

Since April 2023, the Regulator has authorised 3 licences for commercial release and 4 limited and controlled release licences. These included the first commercial licences in Australia to grow a GM fruit (banana) and for the industrial scale production of proteins using GMO 'precision fermentation' technology, see Table 1 for details. The environmental risk assessment of the GM banana by OGTR was conducted in parallel with the food safety assessment undertaken by Food Standards Australia New Zealand, which involved considerable coordination between the two agencies.

Table 1. Licences authorising environmental release of GMOs - since April 2023

Type of GMO	Commercial release approvals	Limited and controlled release approvals
GM plants	**GM banana** – genetically modified for resistance to Fusarium wilt tropical race 4 (TR4) (DIR 199)	**GM wheat & GM barley** – genetically modified for yield enhancement (DIR 201)
GMO therapeutics (human)	**Commercial supply of a live, attenuated vaccine against dengue fever in humans** (live, attenuated GM dengue fever virus) – (DIR 196)	**Clinical trial** of a GMO treatment for inflammatory bowel disease in humans using **GM *Lactobacillus brevis* bacteria** (DIR 197).
GMO therapeutics (veterinary)	**Commercial supply of a vaccine against infectious laryngotracheitis virus (ILTV) in chickens** (live, attenuated GM ILT virus)- (DIR 193)	**Trial of a vaccine against devil facial tumour disease in Tasmanian devils** (DIR 195)
GMOs used for large scale protein production	None	**Large scale production** of recombinant animal proteins using **GM yeast *Pichia pastoris*** (DIR 200)

1.2. Environmental release - applications under assessment, at 15 April 2024

GMO Register applications currently 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 was 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 in the GMO Register is yet to be made by the Regulator.

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 - currently under assessment:

As of 15 April 2024, there is currently one commercial release application under assessment and 3 limited and controlled release applications under assessment, please see Table 2 for details.

Table 2. Applications for environmental release of GMOs currently under assessment – at 15 April 2024

Type of GMO	Commercial release licence applications currently under assessment	Limited and controlled release licence applications currently under assessment
GM plants	None	**Field trial of GM cotton** genetically modified for herbicide tolerance and insect resistance (DIR 203)
		Field trial of GM wheat (HB4) genetically modified for environmental stress tolerance (DIR 204)
GMO therapeutics (human)	None	**Clinical trial** of a GMO treatment for cancer in humans using a **GM Getah virus** - (DIR 198)
GMO therapeutics (veterinary)	**Commercial supply of a live attenuated vaccine (GM parvovirus)** against canine parvovirus in dogs - (DIR 202)	

1.3. Risk assessment guidance documents

One revised biology document has been published since April 2023:

- The Biology of *Gossypium hirsutum L*. and *Gossypium barbadense L*. (cotton). (February 2024)

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

1.4. Modernisation of application processes – OGTR Online Services Portal

The OGTR is continuing work to modernise information management systems and enhance digital service delivery. The recently released OGTR Online Services Portal streamlines application creation and submission, and enables access to information holdings for authenticated users: https://portal.ogtr.gov.au/

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

2.1 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 37th WPHROB meeting in April 2023. 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

2.2 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.

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

2.3 New application forms and guidance

Since April 2023, the OGTR has published 17 revised forms for applicants, including new guidance forms, to assist in the application processes for: the accreditation of organisations, DIR licence applications for the limited and controlled release of GM plants, variation or surrender of DNIR or DIR licences and for the declaration of commercial information (CCI). Revised forms for reporting of Notifiable Low Risk Dealing (NLRDs) and annual reports have also been published, along with user guidance forms for the new online OGTR Online Services Portal. These forms are available at: https://www.ogtr.gov.au/resources

2.4 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 ministers from all 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

3. Risk management and compliance activities

The OGTR continued to undertake monitoring and compliance activities throughout 2023-24. Details of OGTR monitoring activities are published in OGTR Annual Reports and are available at: https://www.ogtr.gov.au/resources/publications/operations-gene-technology-regulator-annual-report-2022-23 . OGTR also publishes quarterly summaries of monitoring and compliance activities: https://www.ogtr.gov.au/resources/collections/quarterly-activities-reports

4. Regulated stakeholder and public engagement and outreach activities

4.1 Fact sheets and other documents

The OGTR publishes Fact Sheets, Policies and Guidance Notes to provide information to the public and to regulated stakeholders on operation and requirements of the regulatory scheme. A number of documents have been published on the OGTR website since April 2023:

- A revision of a Fact Sheet on Genetically modified (GM) crops in Australia was published in April 2023, which provides the public information about the types of GM crops authorised to be grown in Australia.
- An Infographic outlining OGTR and FSANZ regulatory remits was published in May 2023. This infographic gives a brief description of the difference between OGTR and Food Standards Australia New Zealand (FSANZ) regulatory responsibilities for assessment of disease resistant GM banana, where the OGTR conducts risk analysis and licensing for commercial cultivation, while FSANZ conducts food safety assessments, approves food for sale and sets labelling requirements.
- A Fact Sheet on Construction, repair, and maintenance work in a low-level certified facility and decision tree were published September 2023. This fact sheet aims to clarify what level of

notification and advanced warning is required for low-level (PC1 and PC2, excluding PC2 Large Scale) certified facilities that undergo maintenance work.

- A statement Addressing misinformation on the regulation of mRNA vaccines was published in December 2023.
- A Fact Sheet explaining myGovID with the OGTR Online Services Portal was published January 2024. This fact sheet explains what myGovID is and why it is required to access the OGTR Online Services Portal.
- A Guidance Note was published in March 2024 for regulated organisations OGTR Contact Roles and Authorisation about the requirements for appropriate persons for key contact roles.
- A Policy on scope for variation of GMO licences was published in March 2024 which outlines the types of changes that are likely to be authorised as a variation of a licence (rather than a new application).

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

4.2 OGTR Regulatory Science Strategy

The OGTR Regulatory Science Strategy 2024-2027 was also published in February 2024. This document describes the scientific priorities of the Office of the Gene Technology Regulator (OGTR) over the next 3 years from 2024 to 2027.

4.3 National Institutional Biosafety Committee (IBC) Forum

The OGTR will host the 10th National Institutional Biosafety Committee (IBC) Forum in Canberra on 16-18 September 2024. 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.

4.4 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

2. Updates regarding international activities

Participation in/hosting international symposia/fora relating to biosafety

In October 2023, an OGTR officer presented on the Regulatory panel at the Association of Biosafety for Australia and New Zealand (ABSANZ) conference. The meeting took place in Queenstown, New Zealand from 31 October – 3 November 2023.

The OGTR also participated in several other international forums and conferences since April 2023, including:

- Presented at Sustainability in Agriculture & Food Systems: Innovation, Indicators and Implementation Conference, Brussels, Belgium. 23-24 May 2023
- Virtual attendance, Update on Australian GM Food and GMO regulation to Belgian Directorate Animals, Plants & Foodstuffs and Biosafety & Biotechnology Unit, Brussels, Belgium, 21 June 2023
- Presented at Asia-Pacific Economic Cooperation (APEC) Third Senior Officials' meeting and Related Meetings (SOM3) in Seattle, USA: 29 July-1 August 2023

- APEC Webinar - Ensuring the Safety of Products from Agricultural Biotechnology, 30 August 2023
- Webinar - 20th Anniversary of the Cartagena Protocol on Biosafety, 12 September 2023
- International Plant and Animal Genome Conference Australia, 19-22 September 2023
- Virtual attendance American Society of Gene & Cell Therapy - Risk Assessment of Lentiviral and AAV Gene Therapy Vectors, 17 October 2023
- Virtual presentation for Indonesian workshop - Overview National and International Biosafety Regulation II, 31 January 2024
- Gene Drive Research Forum Meeting, Marina del Rey, USA, 19-21 March 2024.

3. Developments related to new breeding techniques (NBTs)

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.

Food Standards Australia New Zealand and New Breeding Techniques and food

Food Standards Australia New Zealand (FSANZ) has raised a proposal to update the definitions in the Australia New Zealand Food Standards Code (the Code) for 'food produced using gene technology' and 'gene technology'. These definitions determine which foods are classed as GM foods and require pre-market safety assessment and approval by FSANZ before entering the food supply.

Proposal *P1055 – Definitions for gene technology and new breeding techniques* intends to make the definitions clearer and better able to accommodate food produced by existing, emerging and future genetic technologies, including genome editing.

FSANZ has completed the first of two rounds of public consultation for P1055 (October-December 2021), analysed the 1736 submissions received and published a report on its website summarising the main issues raised by submitters (November 2022). FSANZ is now preparing the second public consultation for mid-2024. Documents released as part of this consultation will contain responses to the issues raised in submissions, a full description and rationale for a refined approach, as well as a proposed draft definition and other proposed amendments to the Code. Information about the proposal is available at: https://www.foodstandards.gov.au/food-standards-code/proposals/p1055-definitions-for-gene-technology-and-new-breeding-techniques

4. Additional Information

Engineered gene drives

There is ongoing interest engineered gene drives in Australia, paralleling international discussions. Activity in Australia includes consideration of regulatory and policy issues as well as active research. regarding the development of organisms (in containment).

Regulation (laboratory based research) – organisms containing engineered gene drives (e.g. based on CRISPR-Cas constructs) would be classified as GMOs under the GT Act and any environmental release would require a DIR licence from the Regulator. Since October 2019, any contained work with gene drive GMOs (GD-GMOs) requires a DNIR licence and OGTR published guidance for researchers regarding classification - https://www.ogtr.gov.au/sites/default/files/files/2021-06/guidance_on_gene_drives.pdf

There have been no applications for environmental release of GD-GMOs. Four DNIR licences have been issued for contained research work with GD-GMOs to date: potential control of plant pathogenic fungi (DNIR-618); model organism work in *Drosophila melanogaster* (DNIR-646); potential control of invasive mice (DNIR-665); and potential control of malaria vector *Anopheles farauti* (DNIR-670). A significant focus of assessment of such applications is appropriate containment of the GMOs. DNIR licences issued by the Regulator are listed at https://www.ogtr.gov.au/what-weve-approved/dealings-not-involving-intentional-release-dnir

International engagement – Australia made a submission (March 2023) to the Cartagena Protocol on Biosafety work regarding risk assessment of gene drives in mosquitoes and participated in the Online forum in May 2023. Submissions are available at https://bch.cbd.int/en/submissions-to-notifications?schema=submission&currentPage=1&notification=2023-007 and details of the Online Forums are at https://bch.cbd.int/en/portals/risk-assessment/forum

Policy work – in December 2023, a **draft National Gene Drive Policy Guide** was released for public consultation (closed 3 March 2024). This policy guide was prepared by the Gene Technology Policy Section (distinct from OGTR) in consultation with State and Territory governments, and experts from research and industry. The guide aims to help understanding of how gene drive technology and organisms are regulated in Australia, and other considerations that would be relevant for any gene drive proposals (e.g. environmental benefits, societal consultation, other applicable legislation).

Research work – academic research work in Australia includes development of engineered gene drives (e.g. for possible rodent control https://invasives.com.au/research/genetic-technology-for-mouse-management/ , Gierus et al. 2022, for possible malaria control (Ambrose et al. 2024) and laboratory work using *Drosophila melanogaster* as a model organism (Hernandes et al. 2024)) but also stakeholder engagement activities (e.g. CSIRO 2020 Public perceptions of using synthetic biology to manage invasive pests) and decision frameworks for future gene drive work (e.g. Carter et al. 2022 Conditions for Investment in Genetic Biocontrol of Pest Vertebrates in Australia).

Ambrose et al. 2024 Genetic and geographic population structure in the malaria vector, *Anopheles farauti*, provides a candidate system for pioneering confinable gene-drive releases. Heredity https://doi.org/10.1038/s41437-024-00677-2

Gierus et al. 2024 Leveraging a natural murine meiotic drive to suppress invasive populations. PNAS https://doi.org/10.1073/pnas.2213308119

Hernandes et al. 2024 Acetylcholine esterase of Drosophila melanogaster: a laboratory model to explore insecticide susceptibility gene drives. Pest management Science https://doi.org/10.1002/ps.8003

AUSTRIA

1. Developments related to implementation of national biosafety framework

(1) Risk assessment/regulatory decisions:

During the current reporting period (April 2023 – March 2024) 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:

No legislative amendments were introduced or implemented at the Austrian Federal level during this reporting period.

(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

(6) Research projects on biosafety; relevant publications:

The following reports, scientific papers or other documents addressing issues related to biosafety were published (since April 2023):

Dassler, T., Myhr, A. I., Lalyer, C. R., Frieß, J. L., Spök, A., Liebert, W., et al. (2023). Structured analysis of broader GMO impacts inspired by technology assessment to inform policy decisions. Agriculture and Human Values. doi: 10.1007/s10460-023-10519-2

Eckerstorfer, M.F.; Dolezel, M.; Miklau, M.; Greiter, A.; Heissenberger, A.; Engelhard, M. Scanning the Horizon for Environmental Applications of Genetically Modified Viruses Reveals Challenges for Their Environmental Risk Assessment (2024). International Journal of Molecular Sciences 25/3, 1507. https://doi.org/10.3390/ijms25031507

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. doi: 10.1016/j.ecolmodel.2023.110285

Pascher, K., Hainz-Renetzeder, C., Jagersberger, M., Kneissl, K., Gollmann, G., and Schneeweiss, G. M. (2023). Contamination of imported kernels by unapproved genome-edited varieties poses a major challenge for monitoring and traceability during transport and handling on a global scale: inferences from a study on feral oilseed rape in Austria. Front Genome Ed 5

Teufel, J.; López Hernández, V.; Greiter, A.; Kampffmeyer, N.; Hilbert, I.; Eckerstorfer, M.; Narendja, F.; Heissenberger, A.; Simon, S. (2024). Strategies for Traceability to Prevent Unauthorised GMOs (Including NGTs) in the EU: State of the Art and Possible Alternative Approaches. Foods 13/3, 369. https://doi.org/10.3390/foods13030369

2. Updates regarding international activities

- Environment Agency Austria coordinates the Austrian activities for implementation of the Cartagena Protocol on Biosafety and the participation to the upcoming 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 11, 21 October–1 November 2024).
- 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).

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 comments to the Ad Hoc Working Group of the EU council and are actively participating in the discussions addressing the proposal of the European Commission (EC) on a new regulation of NGT plants.

Austria identified many critical issues related to the proposal and the need for further discussion. These issues include the criteria used to classify NGTs, the lack of labelling requirements, the lowered risk assessment standards, incentives related to claimed sustainability, patents, the possible impact on organic and GM-free production, and subsidiarity issues related to coexistence and the possibility to prohibit cultivation of NGTs.

At the parlamentary level the Committee for EU Affairs of the second chamber of the Austrian parliament discussed the proposal of the EC on a new regulation of NGT plants in November of 2023:

The Committee took note of an joint opinion of the Austrian Bundesländer (the Austrian Federal States) on the EC proposal. This unanimous opinion states that the proposed regulation (i) violates the principle of subsidiarity, because it effectively eliminates the Member States' previous freedom of choice to authorise, restrict or prohibit the cultivation of genetically modified organisms (GMOs) on their territory, (ii) curtails the Member States' powers to participate in EU legislation by giving the EU Commission broad permission to adopt delegated and implementing acts and (iii) uses the wrong legal instrument due to the choice of a EU regulation instead of a EU directive. According to the Austrian constitution the Austrian Federal Government shall be bound by such an joint opinion adopted by the Bundesländer regarding negotiations and votes in the EU on legislative proposals within the framework of the EU, which concern matters that are subject to legislation implemented by the Bundesländer.

Based on the mentioned opinion the members of the Committee unanimously rejected the proposal of the EC and required that the Austrian government shall demand compliance with the following principles: The possibility of measures concerning the cultivation of all plants obtained using genetic engineering, including NGTs, in individual EU member states on the basis of national decisions ("opt-out regulation") and

mandatory labelling and authorisation procedures for all organisms obtained using genetic engineering, including NGTs, which include a risk assessment in accordance with the precautionary principle.

EU-Ausschuss des Bundesrats spricht sich einstimmig gegen neue genomischen Techniken in der Landwirtschaft aus (PK1147/07.11.2023) | Parlament Österreich

(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:

Further activities initiated by the Austrian authorities and policymakers to involve national stakeholders in discussions on and in preparation of a national position towards a policy on applications of new genomic techniques (NGT) were pursued. These activities included the following events:

A symposium for national and European stakeholders addressing issues related to the proposal of the European Commission (EC) for a regulation of NGT plants was held in Vienna on October 11th 2023. The event consisted of several sessions addressing the regulatory proposal of the EC, the risk assessment of NGT plants,the precautionary principle, consumer protection, and impacts on organic agriculture and the production of GM free agricultural products.

The participants represented a wide range of different stakeholders, such as the European Commission and authorities from different EU Member States including Hungary, Slovenia, Belgium, France, Poland and the Netherlands, associations for GM-free food production and organic farming, scientists, and NGOs . The discussion addressed the following topics:

The proposal of the EC and issues regarding the Risk Assessment of NGT plants and application of the precautionary principle

Impacts of NGT applications on Organic and GM-free Production and on IPR protection by patents

The main results include:

The entrepreneurial freedom and consumer freedom of choice remain central aspects of the discussion. The use of new genetic engineering products (both NGT1 and NGT2) is not seen as an option for organic farming and the GMO-free sector. Accordingly, labelling and traceability are of great importance in order not to jeopardize these sectors.

Questions of liability and coexistence are also central for assessing the impacts of the EC proposal. The proposed reversal of the burden of proof in the event of contamination is viewed critically. Another key point that is particularly important for stakeholders from the GMO-free sector is that the EC's proposal would no longer allow exemptions from GMO cultivation in individual Member States ("opt-out").

The patentability of NGT products is also an important issue in the framework of the discussion. The potential benefits of NGTs must also be available to small breeders, without restricting the accessibility to breeding materials. However, the possibilities for implementation of such policies remain unclear, as patents on NGT products are possible in principle under current legislation and the European Patent Office is not governed by EU institutions.

The safety of NGT products for humans and the environment is of great importance. Unlike the proposed EC regulation of NGT plants the implementation of the precautionary principle by the current EU GMO

legislation and the Cartagena Protocol on Biosafety mandates a case-by-case risk assessment. The proposed deviation from the current GMO legislation is controversially discussed.

The categorisation of NGT1 and NGT2 plants and the assumption of the EC proposal that NGT1 plants are equivalent to conventionally bred plants, was intensively discussed. It was stressed that the actual properties of individual NGT plants as well as unintended changes and risks are not taken into account by the technical criteria proposed by the EC.

Aspects regarding the policy proposal of the European Commission were also discussed at an information and discussion event with Members of the European Parliament, i.e. Thomas Waitz, Greens, and Günther Sidl, Social Democrats, held at the EU representation in Vienna (Haus der EU) on Jan 22nd 2024:

The event "New genetic engineering: future technology or greenwashing?" co-organised by Global2000 and the Austrian Chamber of Labour (Arbeiterkammer) addressed the question what a deregulation of new genetic engineering in the EU would mean for the environment, consumer transparency and GMO-free agriculture in Austria.

The event featured presentations by Margret Engelhard, (Federal Agency for Nature Conservation, Germany), Katherine Dolan (ARCHE NOAH, Austria) and Andreas Heissenberger (Environment Agency Austria) addressing newly published studies concerning the impacts of the regulations for NGT plants proposed by the EC, the impacts of patents on NGT plants and the lack of an adequate risk assessment of unintended effects of NGT plants according to the regulation proposed by the EC, respectively. The presentations and the activities of the EU parliament were further discussed in a panel with Thomas Waitz and Günther Sidl.

A webcast of the event in German language is available at: Klare Kennzeichnung und Sicherheits-Checks bei Neuer Gentechnik in Lebensmitteln nötig! | GLOBAL 2000

Representatives of Austrian Universities and research institutions published an open letter calling for a non-ideological and science-based approach to regulating green biotechnology and applications of new genomic techniques: Grüne Gentechnik: Offener Brief für eine wissenschaftsbasierte Beurteilung (oeaw.ac.at)

(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 April 2023):

One of the publications listed below (Eckerstorfer & Heissenberger 2023) was presented at the event organised by two Austrian Members of the European Parliament indicated above. The study commissioned by the Austrian Chamber of Labor (Arbeiterkammer) and conducted by Environment Agency Austria (Umweltbundesamt) addresses how the current GMO legislation or the proposal of the EC for NGT plants deal with potential unintended risks of GM / NGT products. Although the safety of NGT products is of considerable importance for developers, consumers and legislators, respectively, this aspect is not a focal issue of the current debate on the EC proposal for a new regulation for NGT products. The study examines this topic on the basis of representative examples of NGT plants. The analysis intends to direct the focus of attention on possible unintended effects, which may be associated with individual NGT products.

Eckerstorfer, M. and Heissenberger, A. (2023). "New Genetic Engineering - possible unintended effects." Wien: Verlag Arbeiterkammer Wien. urn:nbn:at:at-akw:g-6550206, DOI: 10.13140/RG.2.2.12482.969694

Available at:
(22) (PDF) NEW GENETIC ENGINEERING - POSSIBLE UNINTENDED EFFECTS (researchgate.net)

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 a 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, four new field trials have been handed in.

Field trials (3) notified since April 2023

- *Field trial with gene-edited poplars with a decreased lignin content (B/BE/24/V1)*
- *Field trial with GM poplars with a modified wood composition (B/BE/24/V2)*
- *Field trial with gene-edited maize with improved digestibility (B/BE/24/V3)*

Field trial approved since April 2023

- *Field trial with gene-edited maize with an optimised plant architecture (B/BE/23/V4)*

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 April 2023

- Phase 1 Yellow Fever & Rabies candidate vaccine trial (B/BE/23/BVW3)
- Phase 3 Limb Muscular Dystrophy gene therapy trial (B/BE/24/BVW4)
- Phase 3 Hemophilia B gene therapy trial (B/BE/24/BVW5)

Clinical trials (3) approved since April 2023

- 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)

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 meetings of the Subsidiary Bodies.

3. Developments related to new breeding techniques (NBTs)

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

Since the last WP-HROB meeting, a legislative proposal on new genomic techniques was published by the European Commission on July 5th, 2023 and is under discussion. Belgium, presiding the Council of the EU since January 1, 2024, is currently leading the discussions (for more information on the initiative, we refer to the following link).

Specific cases of application, assessment and decision

One field trial with gene-edited maize (generated via CRISPR-Cas technology), authorised in 2022, will continue in 2024. Since April 2023, three new field trials with gene-edited plants, maize and poplar (generated via CRISPR), have been handed in and are under evaluation (for more information see link).

Publications

Report of March 2024 of the Superior Health Council on the proposal of European Regulation on plants produced by certain New Genomic Techniques (NGTs). Brussels: SHC; 2024. Report 9801(link full report).

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 nº38 about international cooperation in biosafety. This Normative establishes procedures for cooperation between the CTNBio and counterpart international institutions.

2. Commercial Approvals

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

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

3. GMO Research

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

4. GMO Crops Production

Currently, Brazil is the second-largest producer of biotech crops around the world with 125 events approved for commercial cultivation, such as corn (62 events), cotton (24), soybeans (21), Eucalyptus (8), edible beans (1) and drought-tolerant wheat (1).

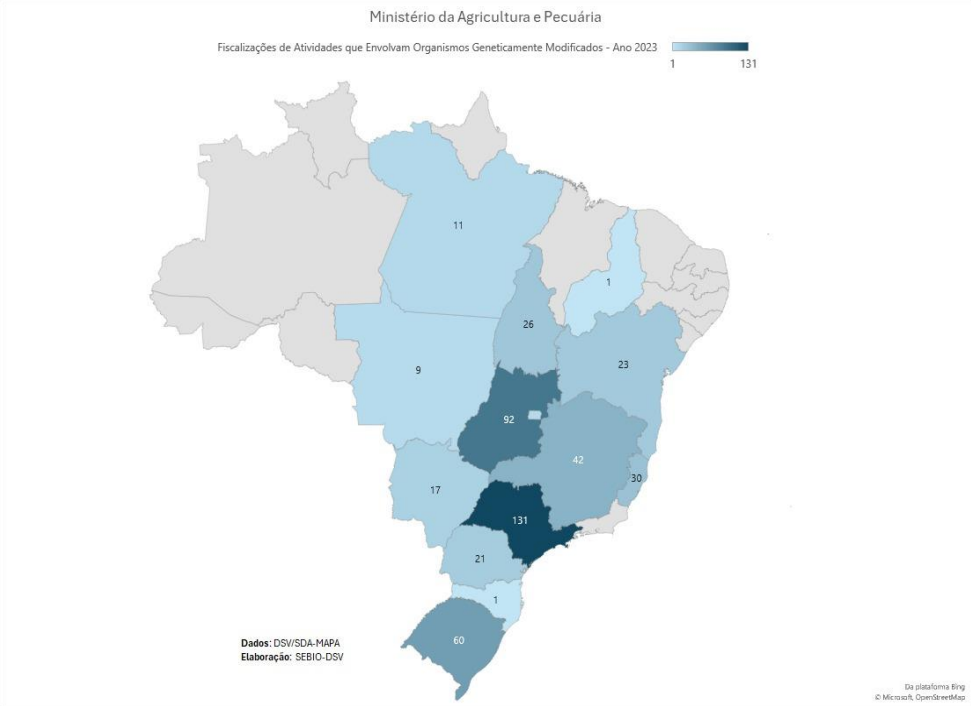
Therefore, for the 2023/2024 crop season a 56 million hectares planted with GE traits. The widespread adoption of GE events in Brazil has contributed to record soybean (155.3 million metric tons) and corn (117.6 million metric tons) production.

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

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

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



6. Developments related to new breeding techniques (NBTs)

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

The following IPB products (link below) were considered as conventional in 2023:
https://ctnbio.mctic.gov.br/tecnologias-inovadoras-de-melhoramento-genetico-rn16-

7. GM data bank

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

CANADA

CANADIAN FOOD INSPECTION AGENCY AND HEALTH CANADA (NOVEL FOODS)

Regulatory Decisions: Confined Field Trials of Plants with Novel Traits

The Canadian Food Inspection Agency authorized 267 confined field trials of plants with novel traits in the 2023 growing season. Trials were conducted at 34 locations across Canada. Crop species tested included barley, camelina, canola, corn, poplar, poppy, soybean, potato, wheat, and sugar beet. There were no notable trends in the 2023 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 2024 growing season and expects to receive a similar number of applications and range of crop types as in the 2023 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. This table includes information on when the products have been authorized for unconfined environmental release (e.g. cultivation), livestock feed use, use as food, whether the plant is an LMO, and whether varieties containing the trait have received variety registration. The database 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 April 2023, Canada has authorized 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
Borage ST-1 and ST-2	Herbicide tolerance; imidizolinone	Bioriginal Food and	mutagenesis	2023/05/18	N/A*	N/A**

		Science Corp				
Soybean MON 94313	Herbicide tolerance; glufosinate ammonium, dicamba, 2,4-D, and mesotrione herbicides	Bayer Crop Science	Agrobacterium-mediated transformation	2023/10/03	2023/10/03	2023/10/03
Yellow Mustard YM-ALS-205	Herbicide tolerance; imidizolinone and sulfonylurea	Mustard 21 Canada Inc.	mutagenesis	2023/10/19***	N/A	N/A
Sugar Beet KWS20-1	Herbicide tolerance; glufosinate, glyphosate, dicamba	Bayer Crop Science	Agrobacterium-mediated transformation	2023/12/29	2023/12/29	2023/12/19
Corn MON 94804	Short stature	Bayer Crop Science	Agrobacterium-mediated transformation	2024/02/20	2024/02/20	2024/02/20

*Not assessed for livestock feed in Canada

**Not considered to be a novel product of plant breeding for food use as indicated in https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/transparency-initiative/list-non-novel-products-plant-breeding-food-use.html

*** YM-ALS-205 was the first product authorized for environmental release in Canada using the updated Directive 2009-09 for 60-day authorizations of plants with a new commercially-viable herbicide tolerance trait but no inclusion of foreign DNA as outlined in https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/applicants/directive-2009-09/eng/1304466419931/1304466812439#a4_2_2

Regulatory Decisions: Applications Currently Under Review

The Canadian Food Inspection Agency, together with Health Canada, coordinates a voluntary “Notices of Submission” process. This process allows product developers to provide a public-facing summary of the product and the types of data submitted (e.g. description of the inserted genes, agronomic data from field trials, etc.). Comments about the product that are of a scientific nature will be considered in the assessment, and other comments may be shared with the product developer. Notices of Submission are available at: http://inspection.gc.ca/english/plaveg/bio/subs/subliste.shtml.

- Since April 2023, Canada has posted seven new Notices of Submission.
- Nine 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.

CFIA Biology Documents

The CFIA has not published any new biology documents since April 2023. All available biology documents are available on the CFIA website:
https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/applicants/directive-94-08/biology-documents/eng/1330723572623/1330723704097

The CFIA has updated the *Triticum turgidum* ssp. *durum* (Durum Wheat) biology document: https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/applicants/directive-94-08/biology-documents/triticum-turgidum-ssp-durum/eng/1330983955477/1330984025320

Developments related to new breeding techniques (NBTs)

Canada's regulatory approach is based on the characteristics of the product (novelty) and not the method of development. Novel products are subject to the *Seeds Regulations*, the *Feeds Regulations*, and/or the *Food and Drug Regulations*. Novel products can be developed through a range of technologies, including 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.

The CFIA and Health Canada recognize that product developers require clear guidance on the regulatory status of gene-edited products in Canada, and that regulatory decisions must be communicated in a transparent, consistent, and predictable manner. Canadian regulators are working 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.

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

Updated guidance for novel foods

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

- *Guidance on the Novelty Interpretation of Products of Plant Breeding* https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/guidelines-safety-assessment-novel-foods-derived-plants-microorganisms/guidelines-safety-assessment-novel-foods-2006.html#a5
- *Guidance on the Pre-Market Assessment of Foods Derived from Retransformants* https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/guidance-documents/guidelines-safety-assessment-novel-foods-derived-plants-microorganisms/guidelines-safety-assessment-novel-foods-2006.html#a6

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

Updated guidance for novel feeds

The Animal Feed Program has drafted a supplementary guidance document to offer greater clarity to the industry regarding which plant-derived feed ingredients require a feed pre-market assessment. This guidance also outlines procedures for determining how to make a novelty determination of a plant-derived ingredient in accordance with the *Feeds Act* and *Regulations*. The feed guidance specifically establishes a set of criteria for developers to self-assess the novelty of their plant products, adhering to Canada's product-based regulatory framework for feeds. This feed policy approach draws from and aligns with many scientific principles found in Health Canada`s guidance.

Presently, the CFIA is in the process of reviewing feedback received during the consultation period for this guidance, with the expectation of publishing a What We Heard Report in late winter to early summer 2024. This initiative is in line with the CFIA's objective of providing clearer and more predictable guidance for feeds derived from plant breeding.

Updated guidance for environmental release of plants with novel traits

The CFIA's updated guidance for determining whether a plant is novel was published on May 3, 2023. This guidance is available on the CFIA website: https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/applicants/directive-2009-09/eng/1304466419931/1304466812439

In summary, the guidance outlines that products developed with gene editing are not anticipated to have different risks than products developed through conventional breeding methods. Based on the thirty year history of the program and familiarity with the outcomes of conventional breeding, CFIA considers plants with new herbicide tolerant traits and foreign DNA to be novel, but does not otherwise foresee significant negative impacts on environmental safety. Despite this, it remains the proponent's responsibility to notify the CFIA of any plant that could pose a negative environmental impact. When a product developed using gene editing is not novel, proponents are also expected to fully participate in non-regulatory transparency measures.

To develop the guidance, the CFIA held discussions with plant breeders and conducted a comprehensive review of the scientific literature on gene editing. CFIA used this information to determine how editing technologies fit within the overall context of plant breeding and CFIA's experience in the assessment of novel plant products. The conclusions of this work are summarized in a published rationale for the updated guidance: https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/applicants/directive-2009-09/rationale-for-updated-guidelines/eng/1682425597052/1682425597973

The CFIA held a public consultation on the draft guidance, and continued targeted follow-up conversations with key stakeholder groups. A "What We Heard" report, summarizing the comments received was published on the CFIA website: https://inspection.canada.ca/about-the-cfia/transparency/consultations-and-engagement/completed/guidance-for-part-v-of-the-seeds-regulations/what-we-heard/eng/1682345500276/1682345500947

Transparency for non-novel products

During the CFIA's consultation on environmental release, a number of organizations, most notably those representing Canada's organic sector, sought a mandatory system for disclosing the use of editing in seed breeding. A mandatory approach based on method of development would not be in keeping with Canada's product-focused regulatory approach. However, Canada supports that there should be full transparency for the marketplace, and believes that the seed industry is best-placed to provide this information. When CFIA's updated guidance was published, the Minister of Agriculture and Agri-Food issued a news release about further strengthening transparency measures for products of plant breeding innovation: https://www.canada.ca/en/agriculture-agri-food/news/2023/05/the-government-of-canada-moves-forward-with-plant-breeding-innovation-while-upholding-the-integrity-of-the-organic-sector.html

In May 2023, Industry-Government Technical Committee on Plant Breeding Innovation Transparency released its Chair's Report, which outlined several key recommendations to improve transparency around seed varieties including establishing a Government-Industry Steering Committee to advance recommended transparency initiatives: https://agriculture.canada.ca/en/department/transparency/chairs-report-minister-industry-government-technical-committee-plant-breeding-innovation

Agriculture and Agri-Food Canada's Government-Industry Steering Committee on Plant Breeding Innovation Transparency was launched in June 2023, and continues to meet regularly to advance key measures including developing an audit framework, enhancing the oversight and data of the Canadian Variety Transparency Database, as well as explore any other options to improve overall awareness and transparency.

International Presentation of the OECD Consensus Document "Environmental Considerations for Risk/Safety Assessment for the Release of Transgenic Plants"

The Secretariat of the Convention on Biological Diversity, under the United Nations Environment Programme, organized a "Global Risk Assessment Workshop" in Montreal, Canada on October 30-31, 2023. As part of the program, Canada was invited to deliver a presentation on the recent completion of the OECD consensus document, Environmental Considerations for Risk/Safety Assessment for the Release of Transgenic Plants. The presentation highlighted the project's history and raison d'être, the structure of the document (including its purpose, scope, and key concepts), and finally an overview of the seven environmental considerations themselves. The presentation concluded with information on its declassification and publication in July 2023. A point that was reflected upon was that the drafting process in and of itself had significant value. The project provided a venue for individuals around the world to share knowledge, debate concepts, build relationships, and understand each other's approaches and perspectives, laying a solid foundation for continuing to build consensus in the years to come.

ENVIRONMENT AND CLIMATE CHANGE CANADA AND HEALTH CANADA (NEW SUBSTANCES PROGRAM)

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

New Substances Notifications

Between April 2023 and February 2024, 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, 21 were for various environmental or industrial uses, while 21 were for food and drugs uses (including genetic therapies and vaccines) of which 15 were for cell and gene therapies, 4 for vaccines, 2 for food additives. The types of organisms that were assessed ranged from bacteria to viruses, virus-like particles, animal cells, fungi and higher organisms (GM fish, GM *Drosophila*).

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.

2. 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 17th, 2023 the NS Program published a "What We Heard" report (found here) summarising the feedback received from various stakeholders as part of a pre-consultation on a Discussion Paper outlining the various issues to be addressed by proposed regulatory amendments on the online platform PlaceSpeak. The NS Program has been working on modifying proposals for regulatory amendments based on this initial feedback and is currently planning for information sessions for stakeholders (in English and French) as well as more targeted stakeholder engagements to discuss more specific issues for sometime in the Spring of 2024.

Consultations on certain living organisms new to Canada

The Government of Canada is promoting public engagement in the risk assessment of higher organisms (such as genetically modified fish, insects and livestock animals) conducted by the NS program. Amendments to CEPA introduced in June 2023 now require that all notifications of new living organisms that are vertebrate animals, or a prescribed living organism or group of living organisms, undergo a mandatory public consultation process. When these consultation requirements do not apply, the NS program continues to encourage notifiers of other higher organisms to participate voluntarily in a public consultation process. As such, the NS program publishes non-confidential summaries of notifications for certain organisms that are notified 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-four lines of genetically modified fish and two lines of genetically modified *Drosophila* and has recently concluded the first mandatory consultation process for four new lines of Glofish. Information on current and past consultations 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 the assessment of micro-organisms on the Domestic Substances List (DSL) but was very qualitative in nature. The work to revise this framework was the result of the need 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). Following consultations with other governmental groups that have an interest/mandate to manage products of biotechnology, the program plans to publish (Spring 2024) an outward facing document on the website addressed to stakeholders.

3. Research projects on biosafety; relevant publications.

Micro-algae Consensus Document

The NS Program in partnership with the U.S. EPA/OPPT completed the first full draft of the "Consensus Document on Information used in the Assessment of Environmental Applications Involving Photoautotrophic Microalgae for Biomass Production". Canada presented the draft at the 37th WP-HROB meeting in April 2023 and requested review and comments from delegates.

Feedback was provided by Argentina, Australia, the Business and Industry Advisory Committee to the OECD (BIAC), Brazil, Costa Rica, Japan and PRRI. Comments were incorporated and a second draft of the document is being finalized to present as a room document at the 38th WP-HROB meeting in March 2024 for discussion.

AGRICULTURE AND AGRI-FOOD CANADA

Low Level Presence (No update since last meeting)

The Global Low Level Presence Initiative (GLI) is a group of 15 importing and exporting countries committed to working collaboratively to develop practical approaches to facilitate the management of Low-Level Presence (LLP). As more countries consider products of biotechnology as one of the tools to improve or address issues facing the agricultural sector, GLI members participate in international and regional discussions to raise awareness of asynchronous approvals, and best practices to mitigate trade implications. They also engage in discussions on the importance of a predictable and transparent global trading environment to the benefit of food security and agricultural sustainability.

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

COSTA RICA

The State Phytosanitary Service

The State Phytosanitary Service (SFE by its Spanish acronym) of the Ministry of Agriculture and Livestock, Costa Rica, controls and regulates the commercial exchange of agricultural products for both import and export. Also, the SFE regulates the registration and control of chemical and biological substances for agricultural use (pesticides, fertilizers, biological substances and other related products).

In addition, it controls 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 absent in Costa Rica that may represent a potential threat to national agricultural production.

Likewise, the SFE is the regulatory authority for Living Modified Organisms (LMOs) for agricultural use in Costa Rica.

For more information, you can visit our website: https://www.sfe.go.cr/SitePages/Inicio.aspx

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

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

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

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

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

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

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

The Costa Rican Government published modifications to its agricultural biotechnology regulations on November 10, 2023. The updated regulations were published in the Official Diary “La Gaceta” as Executive

Decree 44244-MAG, articles 111-13 (Spanish language only), is available on the following Government website:
https://www.pgrweb.go.cr/scij/Busqueda/Normativa/Normas/nrm_texto_completo.aspx?nValor1=1&nValor2=43150

The updated regulatory framework includes the following changes:

a. Improvement in the administrative procedures of the Genetically Modified Organisms Unit (UOGM by its Spanish acronym).

b. Reform of the structure and operational aspects of National Biosafety Technical Commission (CTNBio by its Spanish acronym).

c. Clarity regarding procedures: requirements and response times.

d. Regulation of research and development-application of modern biotechnology in plant improvement.

e. Simplified procedures for LMOs with a history of use in Costa Rica.

f. F. Sanctions for non-compliance with the regulatory framework.

g. Regulation of organisms (plants) produced by New Breeding Techniques (NBTs), including gene editing.

3. Risk management measures

During the last year, the SFE, to verify the compliance with biosafety normative requirements, continued with "*in situ*" monitoring and surveillance of authorized projects with LMOs 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. Participation in international activities relating to biosafety:

a. “Current Genome Editing Technologies, Application and Evolution”. International Seed Federation (ISF), March 30, 2023. Online.

b. “16th International Society for Biosafety Research (ISBR) Symposium”. April 30, to May 4, 2023. St. Louis, Missouri. USA.

c. “Regulatory and institutional framework and patenting on gene editing using CRISPR-based technologies”. May 18-19, 2023. Buenos Aires, Argentina.

d. “International Workshop on Biosafety: Lessons learned in the United States and the Central American Region to Promote Biosafety in the Dominican Republic”, November 28 - 29, 2023, Santo Domingo, Dominican Republic.

2. Specific cases of use of OECD tools and information (e.g. Consensus Documents, other guidance materials, BioTrack Product Database…).

Costa Rica often uses OECD resources as part of its evidence-based decision-making process on agricultural organisms produced with modern biotechnology techniques.

3. Developments related to new breeding techniques (NBTs)

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

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

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

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

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

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

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

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

Costa Rica has not yet evaluated any plants improved with NBTs.

Public Universities are researching on NBT rice and coffee with potential further use, for more information, you can visit the followings websites:

a. Salinity and drought tolerance rice https://vinv.ucr.ac.cr/sigpro/web/projects/B7294

b. Coffee with reduced caffeine https://vinv.ucr.ac.cr/sigpro/web/projects/C0462

3. Any other information related to NBTs

Costa Rica welcomes the efforts of Inter-American Institute for Cooperation on Agriculture (IICA) and our public universities (UCR and TEC) to share experiences and training in genome editing in a hands-on lab training done in 2023 within the Central America Region with the participation of representatives of Guatemala, Honduras, Panama, the Dominican Republic and South America from Bolivia and Paraguay.

For more information, you can visit the following website:
https://sites.google.com/iica.int/biotecnologia-y-bioseguridad/actividades-tecnicas/actividades-presenciales/iica-tec-2022

CROATIA

Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

Applications for commercialization

The Republic of Croatia as a member of the European Union (EU) implements EU community- level decisions and regulations on genetically modified (GM) food and feed at the national level. Regulation (EC) No 1829/2003 regulates the placing on the market of GM food and feed. The Republic of Croatia is actively involved in the Member State consultation process conducted by European Food Safety for placing on the market of genetically modified organisms (GMOs). Input in the risk assessment is provided through Competent Authorities, Council of GMOs, Committee for the assessment of the effects of the deliberate release of GMOS into the environment and Committee for contained use of GMOs.

All products that are authorised for placing on the EU market can be found in the EU Register of GM food and feed (http://ec.europa.eu/food/dyna/gm_register/index_en.cfm).

Currently, GMOs are authorised for import and use as food/feed products in the European Union at the same time in the Republic of Croatia, only one GMOs (GM maize MON 810) is authorized for cultivation. According to the authorisations, these require a post-marked environmental monitoring plan (PMEM) as per Annex VII of Directive 2001/18/EC *e.g.* to detect direct and indirect effects which have been identified in the environmental risk assessment.

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

Notifications for field trials

In accordance to the Commission Implementing Decision (EU) 2016/321 of 3 March 2016 adjusting the geographical scope of the authorisation for cultivation of genetically modified maize (Zea mays L.) MON 810 (MON-ØØ81Ø-6) in the Republic of Croatia is not permitted cultivation of GM crops.

During the current reporting period April 2023-April 2024 neither cultivation of GMO crops nor deliberate release of GMOs for field trials occurred in the Republic of Croatia. Accordingly no new risk assessment/regulatory decisions were taken by Croatian Competent authorities.

Notifications for clinical trials

At the beginning of the April 2024, the Republic of Croatia received first notification on clinical trials with investigational medicinal products containing or consisting of GMOs. It has been still in administrative procedure.

The Republic of Croatia is a party to the Convention on Biological Diversity, the Cartagena and the Nagoya Protocol, and has actively participated in the meetings of the Subsidiary Bodies.

Risk management measures

Currently, GMOs are only authorized for import and use as food/feed products in the European Union at the same time in the Republic of Croatia. According to the 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.

State Inspectorate of the Republic of Croatia is responsible body for conducting official controls on GMOs and products that consisting of or containing of or combination GMOs and for deliberate release of GMOs into the environment in line with the rules of the Act on genetically modified organisms (Official Gazette, 126/19). During the period from 1st January 2023 until 31st December 2023 sanitary inspection of State inspectorate conduct official controls in/on foods on the Croatian market, in production and on the border with third countries. Sanitary inspection was taken 184 samples of different type of foods and ingredients, from origin as soybean, maize, sugar beet, oil rape and cotton and sunflower, papayas, flax seeds to test the presence of GMOs in the Croatian market.

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

No legislative amendments were introduced or implemented at the Republic of the Croatia during this reporting period.

2. Updates regarding international activities

The Republic of Croatia is a party to the Convention on Biological Diversity, the Cartagena and the Nagoya Protocol, and has actively participated in the meetings of the Subsidiary Bodies. At the beginning of the February 2024 the Republic of Croatia was hold pre-accessions meeting with OECD Secretariat.

3. Developments related to new breeding techniques (NBTs)

Since the last WP-HROB meeting, a legislative proposal on new genomic techniques was published by the European Commission on July 5th, 2023 and is under discussion. The Republic of Croatia is actively involved in discussions of that proposals.

CZECHIA

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

The Czech Republic as a member of the European Union (EU) shall implement EU community-level decisions and regulations on genetically modified (GM) food and feed at the national level, in accordance to Regulation (EC) No 1829/2003 on the placing on the market of GM food and feed. All the products authorised for placing on the EU market are listed in the EU Register of GM food and feed (https://webgate.ec.europa.eu/dyna2/gm-register/).

The only GM crop authorised for cultivation in the EU is MON 810 maize, which is resistant to the European corn borer. Although it has never been banned at national level, MON 810 has not been cultivated in the Czech Republic since 2017.

Furthermore, field trials and clinical trials with medical products containing GMOs were authorised / carried out in 2023, according to EU Directive 2001/18/EC, on deliberate release of GMOs into the environment.

Concerning **field trials,** only two small-scale field trials were carried out in 2023 and will be continued in 2024:

- 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, cultivated by the company Usovsko, Olomouc region. In 2023, the trial area was 47 m^2 without buffer zones.

The number of **clinical trials** of medicinal products containing GM cells or viruses (adeno-associated virus or human cells genetically modified by means of retroviral or lentiviral vectors, e.g. CAR-T) increased significantly. Last year, the Ministry of the Environment issued ten consents for deliberate release of GMO or a combination of GMOs for the purpose of clinical trials. Of these, six new clinical trials were approved and four previously approved clinical trials were extended to new clinical sites.

Most activities were carried out under **the contained use** regime according to EU directive 2009/41/EC, on contained use of GM microorganisms. The number of premises notified for the contained use of GMOs has increased slightly since 2022, with more than 130 research institutions, universities and companies now using GMOs. Only two laboratories are now classified in BSL 3, the others are BSL 1 or 2.

2. 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 deliberate release of GMOs into the environment (field trials and clinical trials).

2. Developments related to new breeding techniques (NBTs)

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

However, on 5 July 2023, the European Commission has issued a proposal for a Regulation on new genomic techniques (NGT), as part of the 'Food and biodiversity package'. The proposal aims to enable the EU agri-food sector to contribute to the innovation and sustainability objectives of the European Green Deal and Farm to Fork and Biodiversity strategies, and to enhance the sector's competitiveness, while maintaining a high level of protection of health and of the environment. This proposal for a Regulation is still the subject of intensive negotiations at the EU level. The Czech Republic has actively participated in these discussions and supports the adoption of the proposal.

So far, organisms produced by new genomic techniques (gene editing) have only been used under the contained use regime in laboratories, greenhouses, breeding facilities, and industrial premises in the Czech Rrepublic. Most of the activities performed served research purposes.

DENMARK

1. Developments related to implementation of national biosafety framework

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

The Danish Agricultural Agency approved two experimental releases of gene edited potatoes in 2023. The GE-potatoes were modified to have, respectively, increased resistance to potato late blight and a modified starch content. In both cases, the modified traits were introduced through targeted mutations with CRISPR. According to the current EU-regulation such plants are subject to the full GMO-regulation and were thus handled as experimental releases of GMO's. As described in 3., the EU-regulation of NGT-plants such as the ones mentioned here are currently under review.

In 2024 the Agency has received an application for a new experimental release involving more lines of the GE-potato with increased late blight resistance mentioned above.

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

Development of new EU-regulation on NBT (see point 4)

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

The sites of the abovementioned experimental releases are monitored for at least four years or until no potato volunteers are detected.

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

Nothing to report

5. Public engagement and outreach activities;

The Danish Agricultural Agency and the Danish Veterinary and Food Administration arranged three meeting with three stakeholder groups (sector organisations, NGO's and scientists) in May 2023. At these meetings the Agencies gave a status of the negotiations of the NGT-proposal in the Commission.

6. Research projects on biosafety; relevant publications.

Nothing to report.

2. Updates regarding international activities

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

2. Bi-/multi-lateral cooperation with other authorities/organisations (e.g. capacity building, outreach activities);

3. Specific cases of use of OECD tools and information (e.g. Consensus Documents, other guidance materials, BioTrack Product Database…).

No developments to report.

3. Developments related to new breeding techniques (NBTs)

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

The European Commission has tabled a proposal for a new regulation of plants obtained by certain new genomic techniques and their food and feed. This proposal is currently negotiated in the EU. Please refer to the reply from the European Commission for more details on this proposal.

2. Specific cases of application, assessment and decision;

Decisions on experimental releases of potatoes obtained with NBTs (as described in point 1.)

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

Nothing to report.

4. Any other information related to NBTs.

Nothing to report.

4. Additional Information

The control of conventional seeds for adventitious presence of GMOs has in 2023 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 (e.g. organisms assessed, type of use, introduced traits/genes);

a) Mise sur le marché

Des évaluations de risque sont réalisées au niveau national par l'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (Anses) 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 mars 2023 :

OGM	Avis rendus
Soja génétiquement modifié MON94313	https://www.anses.fr/fr/system/files/BIOT2022SA0237.pdf
Maïs génétiquement modifié DAS1131	
Maïs génétiquement modifié DP910521	
Maïs génétiquement modifié MON95275	https://www.anses.fr/fr/system/files/BIOT2022SA0156.pdf
Colza génétiquement modifié NS-B50027-4	https://www.anses.fr/fr/system/files/BIOT2022SA0096.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 de l'Anses 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 d'OGM en milieu ouvert n'a été déposée en France depuis la dernière réunion du Groupe de travail.

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

Environ 730 dossiers de demandes d'utilisations confinées d'OGM ont été examinés en 2023.

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.

Même en l'absence de culture sur le territoire français, les autorités françaises transmettent à la Commission européenne leurs commentaires sur la surveillance environnementale du maïs MON810, sur la base d'avis rendus par l'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (Anses).

Année de surveillance	Avis rendus par l'Anses
2023	https://www.anses.fr/fr/system/files/BIOT2023SA0199.pdf

2. Developments related to new breeding techniques (NBTs)

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

La Commission européenne a présenté le 5 juillet 2023 un projet de règlement sur les végétaux obtenus par certaines nouvelles techniques génomiques ainsi que l'étude d'impact associée (https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology_en).

En tant qu'état membre de l'Union européenne, la France participe aux négociations sur le projet de règlement.

2. Any other information related to NBTs.

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

Dans le cadre du plan de relance et du 4ème programme d'investissements d'avenir, le Gouvernement a décidé en 2021 la mise en place d'un Programme et équipement prioritaire de recherche (PEPR) sur la sélection végétale avancée pour face au défi climatique et assurer 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). Le programme a démarré en 2023.

Le programme a pour mission d'accompagner des transitions agroécologiques en rendant accessible rapidement une plus large gamme de variétés de plantes répondant aux conditions actuelles et futures pour pallier l'urgence des défis qui se posent à l'agriculture (réduction de l'usage pesticides, accès limité aux ressources naturelles, dérèglement climatique). Le programme se focalise sur l'évaluation de la contribution potentielle de l'édition des génomes comme outil de sélection en excluant la transgénèse.

Les axes du programme de recherche sont les suivants :

- Développement de l'édition des génomes pour l'application à un large panel d'espèces ;
- Edition des génomes pour accompagner la transition agroécologique ;
- Intégration de l'édition des génomes dans les schémas de sélection ;
- Etude des dynamiques de régulation de l'édition des génomes et aide à la conception de régime de sélection légitimes.

Les informations relatives à ce programme de recherche sont publiées sur le site : https://www.pepr-selection-vegetale.fr/

Avis et rapports nationaux sur les NBTs

Les avis et rapports suivants sur les NBTs ont été publiés au niveau national :

- Avis de l'Anses du 29 novembre 2023 relatif à l'analyse scientifique de l'annexe I de la proposition de règlement de la Commission européenne du 5 juillet 2023 relative aux nouvelles techniques génomiques (NTG) – Examen des critères d'équivalence proposés pour définir les plantes NTG de catégorie 1, dans le cadre d'une auto-saisine de l'Anses

https://www.anses.fr/fr/system/files/BIOT2023AUTO0189.pdf

- Rapport du Comité technique permanent de la sélection des plantes cultivées (CTPS) de juillet 2023 sur les nouvelles techniques génomiques et la durabilité, en réponse à une saisine du ministère chargé de l'agriculture https://agriculture.gouv.fr/rapport-du-ctps-sur-les-nouvelles-techniques-genomiques-et-la-durabilite
- Avis du Conseil économique, social et environnemental (CESE) du 24 mai 2023 sur les attentes et enjeux sociétaux liés aux NGT, en réponse à une saisine du Gouvernement https://www.lecese.fr/actualites/cese-adopte-avis-nouvelles-techniques-genomiques
- Avis de l'académie des technologies sur l'application des nouvelles techniques génomiques aux plantes : https://www.academie-technologies.fr/wp-content/uploads/2023/02/20230126-Avis-AT-Nouvelles-technologies-genomiques-plantes.pdf

Deux saisines sont toujours en cours, les avis correspondants devant être publiés en 2024 :

- 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.

[English version]

1. Developments related to implementation of national biosafety framework

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

a) Placing on the market

Risk assessments are carried out at the national level by the National Agency for Food, Environmental and Occupational Health and Safety (Anses) on applications for marketing authorisation for GMOs submitted under European Regulation (EC) No. 1829/2003 on genetically modified food and feed.

The following evaluations have been published since March 2023 :

OGM	**Avis rendus**
Genetically modified soybean MON94313	https://www.anses.fr/fr/system/files/BIOT2022SA0237.pdf
Genetically modified maize DAS1131	
Genetically modified maize DP910521	
Genetically modified maize MON95275	https://www.anses.fr/fr/system/files/BIOT2022SA0156.pdf
Colza génétiquement modifié oilseed rape NS-B50027-4	https://www.anses.fr/fr/system/files/BIOT2022SA0096.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 organized 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 authorisation application for experimentation of GMOs in the environment has been filed in France since the last meeting of the WG-HROB.

c) Contained use of GMOs (in laboratory)

Around 730 applications for contained use of GMOs were examined in 2023.

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 authorized 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.

Even in the absence of cultivation on French territory, the French authorities are sending the European Commission their comments on the environmental monitoring of MON810 maize, based on opinions issued by the National Agency for Food, Environmental and Occupational Health and Safety (Anses).

Monitoring year	**Anses opinion**
2023	https://www.anses.fr/fr/system/files/BIOT2023SA0199.pdf

2. Developments related to new breeding techniques (NBTs)

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

On July 5, 2023, the European Commission presented a draft regulation on plants obtained by certain new genomic techniques as well as the associated impact assessment.
(https://food.ec.europa.eu/plants/genetically-modified-organisms/new-techniques-biotechnology_en).

As a Member State of the European Union, France is taking part in the negotiations on the draft regulation.

2. Any other information related to NBTs.

Research programme on advanced plant breeding to meet the climate challenge and ensure agro-ecological transition.

As part of the recovery plan and the 4th future investment programme, the government has decided in 2021 to set up a Priority Research Programme and Equipment (PEPR) on advanced plant breeding to meet the climate challenge and ensure the agro-ecological transition. The programme has been allocated €30 million for 8 years, and will be managed by the French National Research Institute for Agriculture, Food and the Environment (INRAE). The programme started in 2023.

The programme's mission is to support agro-ecological transitions by rapidly making available a wider range of plant varieties that meet current and future conditions, in order to address the urgent challenges facing agriculture (reduced use of pesticides, limited access to natural resources, climate change). The

programme focuses on assessing the potential contribution of genome editing as a selection tool, excluding transgenesis.

The research programme focuses on the following areas:

- Development of genome editing for application to a wide range of species;
- Genome editing to support the agro-ecological transition;
- Integrating genome editing into selection schemes;
- Studying the regulatory dynamics of genome editing and helping to design legitimate selection regimes.

Information on this research programme is published on the website: https://www.pepr-selection-vegetale.fr/

National opinions and reports on NBTs

The following opinions and reports on NBTs have been published at national level:

- Anses opinion of 29 November 2023 on the scientific analysis of Annex I of the European Commission's proposal for a regulation of 5 July 2023 on new genomic techniques (NTGs) - Examination of the equivalence criteria proposed to define category 1 NTG plants, as part of an Anses self-referral.
  https://www.anses.fr/fr/system/files/BIOT2023AUTO0189.pdf
- Report by the Standing Technical Committee for Crop Plant Breeding (CTPS) on new genomic techniques and sustainability, in response to a referral from the Ministry of Agriculture
  https://agriculture.gouv.fr/rapport-du-ctps-sur-les-nouvelles-techniques-genomiques-et-la-durabilite
- Opinion of the Economic, Social and Environmental Council (CESE) of 24 May 2023 on societal expectations and issues relating to NGTs, in response to a Government referral
  https://www.lecese.fr/actualites/cese-adopte-avis-nouvelles-techniques-genomiques
- Opinion of the Academy of technologies on new genomic techniques applied to plants : https://www.academie-technologies.fr/wp-content/uploads/2023/02/20230126-Avis-AT-Nouvelles-technologies-genomiques-plantes.pdf

Two referrals are still ongoing, the corresponding opinions should be published in 2024:

- 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.

GERMANY

1. Developments related to implementation of national biosafety

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

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

All products that are authorised for placing on the EU market can be found in the EU Register of GM food and feed (https://webgate.ec.europa.eu/dyna2/gm-register/).

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.

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

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

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5. Public engagement and outreach activities;

On the occasion of the 20th anniversary of the entry into force of the Cartagena Protocol on Biosafety, BVL created a webpage with information on the Protocol (https://www.bvl.bund.de/EN/Events/2023-20yearsCartagenaProtocol/20yearsCP_node.html).

6. Research projects on biosafety; relevant publications.

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

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

- **AI-supported bioinformatics approach for GMO analysis.** The number of GMOs is steadily increasing. This means that the current (mostly PCR based) screening methods are becoming increasingly complex, while remaining largely limited to the detection of known GMOs. In order to tackle this growing problem, the BVL is currently working on a generalized, AI-supported bioinformatics approach for the evaluation of next generation sequencing data as a GMO screening tool.
- Benevenuto, R F et al. (2023): Integration of omics analyses into GMO risk assessment in Europe: a case study from soybean field trails. Environmental Sciences Europe 35 (1). DOI: 10.1186/s12302-023-00715-6
- Dolezel, M et al. (2024): Agronomic and phenotypic plant traits as indicators for environmental risks of genetically modified plants. Environmental Sciences Europe 36 (1): DOI 10.1186/s12302-023-00828-y.

2. Updates regarding international activities

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

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2. Bi-/multi-lateral cooperation with other authorities/organisations (e.g. capacity building, outreach activities);

- The German BVL and the Dutch WFSR host and maintain **EUginius**, the **EUropean GMO Initiative for a Unified Database System** (www.euginius.eu) in close cooperation with official GMO detection and identification laboratories of Austria, Italy and Poland. EUginius' intention is to support competent authorities and private users who seek accurate information on GMOs. It provides detailed information of major and relevant issues regarding the presence, detection and identification of GMOs worldwide, with a focus on the situation in the EU.

- Within the **Public Administrative Cooperative Exchange (PACE) program** of the European Commission, the BVL took the opportunity to visit the Dutch sister agency RIVM in November 2023 to exchange on administrative digitalisation (databases), current strategies of risk assessment, evaluating the possibilities of machine learning therefore and communication strategies.

3. Specific cases of use of OECD tools and information (e.g. Consensus Documents, other guidance materials, BioTrack Product Database…).

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 authorized 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.

- **Bioinformatics analyses for the prediction of the reproducibility of whole genome sequencing data.** The study demonstrated that Next Generation Sequencing data (Whole Genome Sequencing (WGS) and Targeted Sequencing, both short and long read) produced by different service providers is highly reproducible. The study further analysed the detection limits of GMO traces in a seed mixture, showing that traces of 0.1% GMO is detectable in every case.
- Pallarz S, Fiedler S, Wahler D, Lämke J, Grohmann L (2023): Reproducibility of next generation-sequencing-based analysis of a CRISPR/Cas9 genome edited oil seed rape. Food Chemistry: Molecular Sciences. https://doi.org/10.1016/j.fochms.2023.100182
- **Detection of commercialized plant products produced by use of NBT.** Within a brief review, concrete and practical approaches for the detection and identification of market-relevant plants resulting from NBT have been examined.
- Guertler P, Pallarz S, Belter A, Eckermann K N, Grohmann L (2023): Detection of commercialized plant products derived from new genomic techniques (NGT) - Practical examples and current perspectives, Food Control. https://doi.org/10.1016/j.foodcont.2023.109869

- **GeneBEcon**. 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/)
- Purnhagen K, Ambrogio Y, Bartsch D et al. (2023): Options for regulating new genomic techniques for plants in the European Union. Nat. Plants 9, 1958-1961. https://doi.org/10.1038/s41477-023-01570-2
- **LeGO!**: The project aims to optimize forage legumes (red clover, white clover, lucerne and sainfoin) and to make their genetic potential available for breeding. This should make them more attractive for breeders and farmers and increase their cultivation in Germany. For successful and rapid confirmation of candidate genes, molecular genetic techniques are used. After candidate genes have been confirmed, plants will be mutagenized in a classical procedure and plants will be selected in a TILLING approach. In addition, LeGo is actively seeking collaboration with stakeholders and practitioners and plans to engage in dialogue with both.
- **Risk hypotheses for the environmental impact of genome-edited crops**. This research project focuses on intended and unintended genetic changes that can be caused by the application of NBT plants and their potential impact on the environment. It is concluded that the assessment of intended as well as unintended genetic changes should be part of a mandatory comprehensive molecular characterisation and risk assessment of NBT plants that are meant for environmental releases or for market authorisation.
- Koller, F & Cieslak, M (2023): A perspective from the EU: unintended genetic changes in plants caused by NGT – their relevance for a comprehensive molecular characterisation and risk assessment. Frontiers in Bioengineering and Biotechnology. https://www.frontiersin.org/articles/10.3389/fbioe.2023.1276226/full
- Eckerstorfer, M F, Dolezel, M, Engelhard, M, Giovannelli, V, Grabowski, M, Heissenberger, A, Lener, M, Reichenbecher, W, Simon, S, Staiano, G, et al. (2023): Recommendations for the Assessment of Potential Environmental Effects of Genome-Editing Applications in Plants in the EU. Plants 2023, 12, 1764. https://doi.org/10.3390/plants12091764
- Teufel, J et al. (2024): Strategies for Traceability to prevent unauthorised GMOs (including NGTs) in the EU: State of the art and possible alternative approaches. Foods, 13, DOI: 10.3390/foods13030369
- **DERUST.** The DERUST project is developing barley and wheat lines with unprecedented broad-spectrum resistance against all rust diseases relevant to these two plant species. Its aim is to help ensure a sufficient supply of grain under climate conditions that are increasingly conducive to the spread of rust diseases, while significantly reducing the need for fungicides and agricultural land.
- **Beta King.** European sugar beet cultivation is threatened in particular by the green peach aphid *Myzus persicae*, which transmits the Beet yellows virus (BYV) to sugar beet. The aim of the project is to identify genetic resistance to BYV and make it usable in practice. Precision breeding methods including cross-kingdom RNAi and genome editing will be used to demonstrate feasibility. New varieties will then be created by conventional crossing and selection.
- New **long perspective BMBF Funding Measure on Plant Breeding** (2023-10-19): "Modern breeding research for climate- and site-adapted crops of tomorrow" (https://www.bmbf.de/bmbf/shareddocs/bekanntmachungen/de/2023/10/2023-10-26-

Bekanntmachung-Z%C3%BCchtungsforschung.html). The call aims specifically at alliances from science and industry, primarily small and medium-sized enterprises (SMEs). In addition, young researchers can apply for funding. The deadline for applications was 2024-01-31. Currently, the incoming proposal are under evaluation.

4. Any other information related to NBTs.

On 5 July 2023, the European Commission published a proposal for a Regulation on plants obtained by certain new genomic techniques (NGT) and their food and feed. According to the proposal, two categories of NGT plants should be established and regulated differently as other genetically modified plants (compare section 1.2. above). The proposal is discussed among EU Member States and in the European Parliament (EP).

A common position of the Council of EU Member States is still pending. The EP agreed to the proposal with amendments on 7 February 2024. Next, Commission, Parliament and Council will debate the proposal and amendments, and negotiate a common (amended) Regulation text.

This proposal is further discussed among stakeholders, academia, NGOs and the public; numerous statements, opinions, position papers and policy briefs have been published and enrich the debate.

HUNGARY

1. Developments related to implementation of national biosafety framework

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

Cultivation of GMOs: MON810 GM maize is still the only GM crop authorised for commercial cultivation in the EU. In the course of 2023 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): One permission was granted in the course of 2023 regarding to a clinical trial.

Contained use activities: In the course of 2023 four class 1, nine class 2, and two class 3 premises were authorised for contained use activities. Four contained use activities in class 1 were authorised with GMMs and in some cases GMPs and in one case GMV. Nine contained use activities in class 2 were authorised with GMVs and in some cases GMMs, GMAs and GMP too. Two contained use activities in class 3 were authorised with GMVs (African swine fever virus).

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

In order to comply with and support the implementation of the Kunming-Montreal Global Biodiversity Framework, Hungary has developed its new National Biodiversity Strategy until 2030, which was approved by the Hungarian Government and published on the official website of the Government (https://kormany.hu/hirek/elfogadtak-a-3-nemzeti-biodiverzitas-strategiat) and also on our national CBD Clearing-House Mechanism (https://www.biodiv.hu/hu/hirek/megalkottuk-a-2030-ig-szolo-nemzeti-biodiverzitas-strategiat-1).

Our national strategy starts with an assessment of status and trends of biodiversity together with a SWOT analysis, after which it identifies 3 strategic areas (*I. Reducing threats to biodiversity; II. Sustainable use of biodiversity and sharing of benefits; III. Tools and solutions for implementation*) under which 19 objectives have been set to address issues related to biodiversity in Hungary. The 19 objectives specify 50 targets and actions that help the implementation. These objectives focus on the following areas:

1. Establishing a coherent network of protected areas
2. Restoring degraded ecosystems
3. Improving the status of species with unfavourable conservation status
4. Invasive alien species - control and reduction, prevention of new introductions
5. Species endangered by trade
6. Reducing pollution that threatens biodiversity, including pesticides
7. Genetically modified organisms
8. Pollinators
9. Climate change and biodiversity
10. Sustainable agriculture
11. Conservation of genetic resources

12. Forests and forestry
13. Sustainable game and fish management
14. Sustainable water management
15. Green infrastructure
16. Assessment of ecosystem services
17. Improvement of the biodiversity knowledge base
18. Awareness-raising
19. Strengthening international cooperation

Specific target (target 7) relates to the release of genetically modified organisms (GMO) into the environment including three sub-targets. Concrete implementation measures and monitoring indicators are given for each sub-target.

2. Updates regarding international activities

1. 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 period.

3. Developments related to new breeding techniques (NBTs)

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

In order to comply with and support the implementation of the Kunming-Montreal Global Biodiversity Framework, Hungary has developed its new National Biodiversity Strategy until 2030, which was approved by the Hungarian Government and published on the official website of the Government (https://kormany.hu/hirek/elfogadtak-a-3-nemzeti-biodiverzitas-strategiat) and also on our national CBD Clearing-House Mechanism (https://www.biodiv.hu/hu/hirek/megalkottuk-a-2030-ig-szolo-nemzeti-biodiverzitas-strategiat-1).

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9. Climate change and biodiversity
10. Sustainable agriculture
11. Conservation of genetic resources
12. Forests and forestry

13. Sustainable game and fish management
14. Sustainable water management
15. Green infrastructure
16. Assessment of ecosystem services
17. Improvement of the biodiversity knowledge base
18. Awareness-raising
19. Strengthening international cooperation

Specific target (target 7) relates to the release of genetically modified organisms (GMO) into the environment including three sub-targets. Concrete implementation measures and monitoring indicators are given for each sub-target. The third sub-target relates specifically to new genomic techniques i.e. improving knowledge of detection methods and environmental impacts on organisms obtained by new genomic techniques (NGT) in order to ensure proper monitoring and prevent adverse impacts on biodiversity.

4. Any other information related to NBTs.

On 5 July 2023, the European Commission submitted to the Council and the European Parliament a proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed products. Both the Council and the European Parliament started examining the proposal and the accompanying impact assessment. Hungary has actively participated in the discussions.

Cultivation/deliberate release of new genomic techniques:

In the course of 2023 neither cultivation of GM crops produced by new genomic 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

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

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 one maize events have been newly approved for commercial use since the last WG-HROB meeting held in April 2023.

The number of LM plants approved for commercial use at the end of January 2024 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)	19*2	Rose	2
Carnation	8	Soybean	30*2
Maize	95*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.

3. Developments related to new breeding techniques (NBTs)

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

2. Specific cases of application, assessment and decision;

Since the last WG-HROB meeting held in April 2023, the Ministry of Agriculture, Forestry and Fisheries of Japan (MAFF) accepted the finalized information form of

- Another cultivar of tomato with increased GABA which had been produced using genome editing techniques and
- Flounder with growth enhancement 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, circadian rhythm and metabolism of sugars and starches by genome editing technology and

- Potatoes with low contents of steroidal glycoalkaloids which had been produced using genome editing techniques.

This information is available on the Japan Biosafety Clearing-House website (https://www.biodic.go.jp/bch/bch_8_3.html, in Japanese).

4. Additional Information

Science Communication Activities

MAFF continuously conducts a science communication project focusing biotechnology. In FY 2022, approximately 30 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.

REPUBLIC OF KOREA

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions;

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

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

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

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

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

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

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

Organisms	Event	Type of use	Traits	Company
Cotton	MON88702×MON15985×COT102 ×MON88701×MON88913	Feed	Insect Resistance & Herbicide Tolerance	Monsanto
Soybean	GMB151	Feed, Food	Insect Resistance & Herbicide Tolerance	BASF
Cotton	GHB811×LLCotton25×MON88701	Feed	Herbicide Tolerance	BASF
Maize	MON87429	Feed	Herbicide Tolerance	Monsanto
Maize	3272×Bt11×MIR162×GA21	Feed, Food	Insect Resistance & Herbicide Tolerance	Syngenta
Canola	MON94100	Feed	Herbicide Tolerance	Monsanto
Cotton	T304-40	Feed	Insect Resistance & Herbicide Tolerance	BASF
Maize	DP-202216-6	Food	Herbicide Tolerance & Yield Improvement	Corteva
Maize	MON87429	Food	Herbicide Tolerance	Monsanto

Microbe	GF-PK101	Industrial	Production of Proteinase K	GenoFocus
Microbe	GC005	Industrial	Enzyme Production for 6'-Sialyllactose Process	GeneChem

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

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

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

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

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

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

3. Risk management measures

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

4. Public engagement and outreach activities;

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

Joint Public-Private Investigation of Unauthorized LMO Cultivation Sites:

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

In 2023, unauthorized LMOs were identified in zucchini squash seeds produced in South Korea. The Korean government responded by conducting a full survey of zucchini squash and processed food

products made from it during cultivation and distribution. The identified LMOs were destroyed, and post-monitoring was conducted.

KBCH Forum Seminars:

The Korea Biosafety Clearing House (KBCH) leads a continuous and open forum with participants from government agencies, academia, research institutions, the industry, and non-governmental organizations. Regular seminars are held, with a total of 35 domestic and international seminars conducted up to 2023. In that year, three seminars were successfully held, including the '4th Public Hearing on the Safety Management Plan for Living Modified Organisms,' with the participation of stakeholders from all sectors.

2. Updates regarding international activities

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

APEC Agricultural Biotechnology Seminar:

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

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

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

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

LATVIA

1. Developments related to implementation of national biosafety

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

In 2023 the State Scientific Institute “Institute of Food Safety, Animal Health and Environment “BIOR”” regularly took part at centralized EU GMO risk assessment procedure. BIOR provided opinion on 4 applications in respect of GMO placing on the EU market.

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

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

1. to improve the legal framework regarding the rights of supervisory and control authorities if protective actions are initiated and the requirements of regulatory enactments regulating the handling of GMOs are violated;
2. to complement the legislation on contained use of GMM with requirements that also apply to contained use of GMOs.

The draft was elaborated in view of the rapid spread of GMOs on the world market, which promotes the unintentional release of GMOs into the environment as well as the admixture of GMOs in conventional seeds.

5. Research projects on biosafety; relevant publications.

In 2023 the project “Monitoring of unintended release of genetically modified plants into environment and evaluation of environmental monitoring programs available in Latvia in connection with general supervision of GMOs” was started. It is two year project, implemented by the State Scientific Institute “Institute of Food Safety, Animal Health and Environment “BIOR””.

The aim of the project is to assess the possible unintended release of GMOs in Latvia, to provide an analysis of the environmental monitoring programs available in Latvia, as well as to develop recommendations for adapting the existing environmental monitoring programs and seed/plant propagation material monitoring programs for the general monitoring of GMOs in connection with environmental risk assessment and establishing baselines.

2. Updates regarding international activities

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

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

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

3. Developments related to new breeding techniques (NBTs)

Please see information prepared by European Commission!

LITHUANIA

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions:

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

During the reporting period (April 2023 – March 2024) 7 new notifications were received for contained use of genetically modified microorganisms (one notification for the 2nd Class and others for the 1st Class) and 1 new notification was received for genetically modified organisms (1st level).

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

During the reporting period (April 2023 – March 2024) several amendments of GMO's legislation were approved:

2023-05-27 Amendment of Act on "Approval of the procedure for the control and monitoring of genetically modified crops, consignments of genetically modified plants, plant products and propagating material not intended for human consumption or animal feed, as well as of those crops and consignments that may have been genetically modified in the Republic of Lithuania" No A1-249 https://www.e-tar.lt/portal/lt/legalAct/b73355b0f47111ed9978886e85107ab2

2023-06-06 Amendment of Act on "Approval of the procedure for the deliberate release of genetically modified organisms into the environment and for the control of contained uses of genetically modified micro-organisms or organisms" No D1-180
https://www.e-tar.lt/portal/lt/legalAct/75551f507b0111edbc04912defe897d1

2023-10-18 Amendment of Act on "Establishment of the Genetically modified organisms steering committee and approval of its provisions" No D1-1345
https://www.e-tar.lt/portal/lt/legalAct/20874f706cf511ee8f3cbca2fb16d96d

3. Public engagement and outreach activities:

Information and data on GMO's legislation, notification/permitting and various guidelines are made available on the new Genetically Modified Organisms Database website of the Ministry of the Environment of the Republic of Lithuania via link: https://gmo.biip.lt/

The Ministry of Environment of the Republic of Lithuania has already finished the EU funded project "Development of Biodiversity Information Platform", thus a new Genetically modified organisms database was established.

2. Updates regarding international activities

During the reporting period (April 2023 – March 2024) Lithuania took part in several international events related to NBTs. Lithuania is a party to the Convention of Biological Diversity and a party to the Cartagena Protocol, thus has actively involved in the synthetic biology area and has participated in the

Central and Eastern Europe Regional Training of Trainers workshop for Biosafety Clearing House National Focal Points from 22 to 26 January 2024.

3. Developments related to new breeding techniques (NBTs)

During the reporting period (April 2023 – March 2024) there was no application received of genetically modified organisms developed by new breeding techniques.

Lithuania participates in the discussion of the European Commission's proposal on plants obtained by certain new genomic techniques and their food and feed and amending Regulation (EU) 2017/625, adopted on 5 July 2023 (NBT's proposal). This proposal is a part of package of legislative proposals to support the European Union's Farm to Table and Biodiversity strategies.

The Environment and Rural Affairs Committees of the Parliament of the Republic of Lithuania have discussed and endorsed the NGT's proposal.

2023-10-24 discussions also took place in Genetically modified organisms Steering Committee with representatives of science, farmers, producers, and state authorities, who stressed the importance of this proposal. 2023-10-25 an official position paper on NBT's proposal was defined.

2023-11-17 The Lithuanian Academy of Sciences invited scientists, representatives of the European Parliament, state institutions and associations to a discussion on "The legal regulation of plant varieties obtained by new genomic technologies (NGT's) - benefits and challenges". The event focused on the differences between genetically modified plants and NGT's plants, and their regulatory aspects. A resolution of the discussion was prepared.
https://gmo.biip.lt/en/2023-11-17-a-discussion-on-the-legal-regulation-of-plant-varieties-obtained-by-new-genomic-technologies-ngt-benefits-and-challenges/

2024-01-17 Lithuanian Research Centre for Agriculture and Forestry organized conference „New genomic technologies and skaitmenization in agriculture and farming".

THE NETHERLANDS

1. Developments related to implementation of national biosafety framework

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

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 14 new permits and 18 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).

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

No updates to report.

2. Updates regarding international activities

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

The Netherlands is a party to the CBD and to the Cartagena Protocol, and will actively participate in the upcoming SBSTTA26 and COP16/COPMOP11 meetings and preparatory meetings, in particular the agenda items on Risk assessment / Risk management and synthetic biology.

3. Developments related to new breeding techniques (NBTs)

For details see our contribution to the NBT project and questionnaire.

However, noteworthy may be the advice of the Dutch advisory committee on genetic modification COGEM who issued an advice to amend and clarify the proposed criteria for NGT plants that could also occur naturally or by conventional breeding (so-called 'category 1 NGT plants' in the proposal). See also Opinion to revise the criteria in Annex I of the EC proposal for new legislation for NGT plants (cogem.net)

4. Additional information

The advisory body on genetic modification (COGEM) has commissioned a research project regarding establishment and proliferation potential of cyanobacteria and properties that can inform the risk assessment. The desk study was executed by the Perseus company (Report CGM-2022-3).

The COGEM anticipates a rise in activities with less known cyanobacteria as GM recipient and largescale productions with an increased likelihood of unintentional release. This has triggered the present desktop study which aims at

1) unravelling factors that are critical for cyanobacteria's establishment, dispersal, and proliferation in the Dutch environment,

2) investigating genetic modifications possibly enhancing the potential to establish, proliferate and spread, and

3) mapping (test) strategies that allow extrapolation from a lab setting to a natural environment; these tests must aid to reduce uncertainties on whether or not a given GM cyanobacterium can establish in the Dutch aquatic environment and whether or not this would lead to damage to the environment.

The information from this study is intended to offer practical handles to guide applicants and the COGEM in the environmental risk assessment of activities with GM cyanobacteria.

NEW ZEALAND

1. Developments related to implementation of national biosafety

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

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. The EPA has recently clarified the status of 'null segregants' under the HSNO Act and determined that organisms that have descended from a GMO parent but do not contain the genetic modification are not considered to be a GMO if certain criteria are met. More information can be found at the following links.
https://www.epa.govt.nz/news-and-alerts/latest-news/epa-clarifies-gmo-definition/
https://www.epa.govt.nz/industry-areas/new-organisms/null-segregants/

ii. 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 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).

The Government has sought feedback on proposed changes to Aotearoa New Zealand's legislation and regulations for genetically modified organisms (GMOs) used in laboratory settings and for biomedical therapies.

More information can be found at the Ministry for the Environment (Manatū Mō Te Taiao) website regarding the public consultation process.
https://consult.environment.govt.nz/comms/gmo-regulations/

With the recent election of a new Aotearoa New Zealand government in October 2023, a briefing document for the Minister for the Environment provides a current summary of the roles and activities of the EPA. The "Briefing to the incoming Minister" document can be found at the following link.

https://www.epa.govt.nz/assets/RecordsAPI/Briefing-to-the-Incoming-Minister-for-the-Environment-December-2023.pdf

A potential change in the way that products of modern biotechnology may be regulated (both GMO and non-GMO) was indicated pre-election by the current government. As such, the policy options for regulation of GMOs are currently being examined. More information about the potential proposed changes can be found at the following link.
https://www.national.org.nz/harnessingbiotech

He Whetū Mārama the Mātauranga Framework

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.

As part of our refreshed strategy of applying an 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-2023.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

5. 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 link
https://www.epa.govt.nz/news-and-alerts/latest-news/catchment-groups-receive-epa-funding-for-water-testing/

PARAGUAY

Activities pertaining to agricultural biotechnology are subject to regulations in Paraguay, which established a set of regulations in 1997 and subsequently supplemented them with additional legal instruments. The most recent of these measures, a decree issued in 2012, established the National Agricultural and Forestry Biosafety Commission (CONBIO), which is overseen by the Ministry of Agriculture and Livestock (MAG). This Commission is responsible for evaluating, analyzing, and making recommendations on all matters related to the introduction, field trials, pre-commercial and commercial release, and other intended uses of genetically modified products related to the agri-food system.

Between 2023-2024, Paraguay approved the use of several GM yeasts for ethanol production. As yeast-derived products and distiller's dried grains with solubles can be used as animal feed, a CONBIO safety assessment was required.

By Resolution 92/2024, MAG granted the first commercial release of the GM insect *Spodoptera frugiperda* OX5382G, which contains a self-limiting gene that produces male-only insects[7]. These modified males mate with wild females and transmit the self-limiting gene to their offspring. The continuous release of GM males in a specific area will decrease the number of wild females and the overall population of these insects.

1. Commercial Approvals

The following events were released from 2023 to 2024.

Decision No.	Organism / Product	Event	Proposed commercial use	Characteristics	Regulatory mechanism
93/2024	*Saccharomyces cerevisiae*	FS0436 (PRCH20080)	Ethanol production	Optimization of ethanol production through the expression of glucoamylase enzymes while also providing a parallel route for increased ethanol production and a reduction in glycerol production during fermentation	Commercial release of novel GM (Resolution MAG 027/2015)
92/2024	*Spodoptera frugiperda*	OX5382G	Self-limiting	The released GM males will seek out and mate with wild females. The self-limiting gene will be transmitted to offspring, preventing female offspring from reaching maturity and reproducing	Commercial release of novel GM (Resolution MAG 027/2015)

[7] MAG, *Resolución Nº 92/2024 Por La Cual Se Autoriza La Liberación Comercial de Organismo Genéticamente Modificado Denominado OX5382G 'Spodoptera Frugiperda', a Favor de La Empresa OXITEC LTD.*, *Resolución MAG*, 2024, 92/2024, 3 <https://doi.org/10.5281/zenodo.10688936> [accessed 10 February 2024].

894/2023	Vaccine	VECTORMUNE® HVT NDV	Vaccines express the key protective antigen of Newcastle Disease Virus (NDV), which facilitates the prevention and control of both Marek's Disease Virus (MDV) and NDV infections	Recombinant vaccine in which the F gene of a NDV lentogenic strain has been inserted into the HVT genome	Veterinary vaccine
666/2023	*Saccharomyces cerevisiae*	GPY10138 (GICC03587)	Production of high volumes of ethanol	Expression of the glucoamylase enzyme, eliminating the need for external addition of said enzyme to the fermentation broth	Commercial release of novel GM (Resolution MAG 027/2015)
658/2023	*Saccharomyces cerevisiae*	GPY010240 (GICC03636)	Production of ethanol for biofuel from grains	Enhanced production of ethanol for fuel, reduced output of acetate and glycerol during fermentation	Commercial release of novel GM (Resolution MAG 027/2015)
556/2023	Wheat	IND-ØØ412-7	Tolerance to drought, tolerance to Glufosinate	For tolerance to drought and salinity, the wheat expresses Helianthus annuus homeodomain-leucine zipper 4, which enhances the plant's natural abiotic stress response	Differentiated treatment for the commercial release of GM crops that have been approved in third countries (Resolution MAG 1030/2019 and 1071/2019)
550/2023	*Saccharomyces cerevisiae*	M23541	Increase bioethanol production from corn starch	The expression of recombinant glucoamylase enzyme offers a parallel pathway for ethanol production, which optimizes the volume of ethanol obtained and enhances yeast tolerance to acidity	Commercial release of novel GM (Resolution MAG 027/2015)
549/2023	*Saccharomyces cerevisiae*	M12156	Production of ethanol from starch	Elimination of the need to add glucoamylase during fermentation, optimize ethanol production	Commercial release of novel GM (Resolution MAG 027/2015)

548/2023	*Saccharomyces cerevisiae*	SCY014	Production of ethanol as fuel	Optimization of ethanol production	Commercial release of novel GM (Resolution MAG 027/2015)
341/2023	*Saccharomyces cerevisiae*	GPY010272 (GICC03661)	Ethanol production	Expression of the recombinant enzyme glucoamylase for the optimization of ethanol production, parallel pathway for obtaining a high volume of ethanol by reducing the volume of glycerol produced	Commercial release of novel GM (Resolution MAG 027/2015)
340/2023	Maize	SYN-BTØ11-1 x SYN-IR162-4 x MON-ØØ6Ø3-6	Resistance to insect, Tolerance to herbicide, Promoting of mannose metabolism	CP4 EPSPS (MON-ØØ6Ø3-6) and PAT (SYN-BTØ11-1) provide glyphosate and glufosinate-ammonium tolerance, while Cry1Ab (SYN-BTØ11-1) and Vip3Aa20 (SYN-IR162-4) offer protection against Lepidoptera	Differentiated treatment for stacks (parental approved)
319/2023	Cotton	BCS-GHØØ2-5 x BCS-GHØØ4-7 x BCS-GHØØ5-8 x SYN-IR1Ø2-7	Resistance to Lepidoptera, Tolerance to Glufosinate, Tolerance to Glyphosate	Protection against the following lepidopteran insect pest species: *Heliothis virescens*, *Helicoverpa* spp., *Pectinophora gossypiella*, *Chrysodeixis includens* and *Spodoptera* spp. provided by the expression products of cry1Ab (BCS-GHØØ4-7), cry2Ae (BCS-GHØØ5-8) and vip3Aa19 (SYN-IR1Ø2-7) genes	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**
March 20-21, 2023	Face-to-face meeting of the Agricultural Biotechnology Commission of SGT 8 "Agriculture" of the GMC-MERCOSUR in Buenos Aires, Argentina.
March 21-22, 2023	Meeting of the Commission on Bioinputs for Agricultural Use of the SGT8 "Agriculture" of the GMC-MERCOSUR, Buenos Aires, Argentina.
April 17-21, 2023	OECD Working Party on the Harmonisation of Regulatory Oversight in Biotechnology, OECD Meeting of the Working Party for the Safety of Novel Foods and Feeds, Paris, France.
April 28-29, 2023	Like Minded Countries Meeting (Like Minded Group), St. Louis, United States.

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

3. References

- Benitez Candia, N., Ulke, G., Sotelo Torres, P. H., Nara, E. M., Arrúa Alvarenga, A., & Fernández Ríos, D. (2024). Paraguay's approach to Biotechnology Governance: A comprehensive guide. *Frontiers in Bioengineering and Biotechnology*, *12*. https://doi.org/10.3389/fbioe.2024.1373473
- Fernández Ríos, D., Benítez Candia, N., Soerensen, M. C., Goberna, M. F., & Arrúa, A. A. (2024). Regulatory landscape for new breeding techniques (NBTs): Insights from Paraguay. *Frontiers in Bioengineering and Biotechnology*, *12*, 1332851. https://doi.org/10.3389/fbioe.2024.1332851

PHILIPPINES

A. Developments related to implementation of national biosafety framework

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

- Conduct of review and enhancing the risk assessment instrument used in the evaluation of the safety of GM applications under the DOST-DA-DENR-DOH-DILG Joint Department Circular No.1, series of 2021

2. Risk assessment/regulatory decisions

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

Transformation event	Type of Use	Trait
1.Soybean GMB151	For food and feed, or for processing	Herbicide Tolerant
2. Corn MON 95275	For food and feed, or for processing	Insect Resistant
3. LBFLFK Canola	For food and feed, or for processing	Herbicide tolerant and modified oil/fatty acid
4.EE-1 eggplant	For commercial propagation/planting	Resistant to Insect Eggplant Fruit and Shoot Borer (EFSB)
5.Bt Cotton - GFM cry1A	For commercial propagation/planting	Insect Resistant
6.High Iron and Zinc Rice 1030-031	For field trial	Increased iron (Fe) and zinc (Zn) trait in the endosperm
7.High Iron and Zinc Rice 1030-039	For field trial	Increased iron (Fe) and zinc (Zn) trait in the endosperm
8. Corn MON87427	For field trial	Herbicide Tolerant

Regulatory decisions are uploaded to the BPI Biotech Website: http://biotech.buplant.da.gov.ph

3. Risk management measures

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

a. 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 the case of imported regulated articles, importers are required to present GMO declaration to ensure that only approved transformation events will enter the country

- In the 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
- The permit holder shall provide reference materials (positive and negative controls) of the regulated article

b. For field trial:

- Implementation of temporal or isolation distance
- Ensuring the security of the experimental area (only authorized persons 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

c. For commercial propagation

- Prohibition of planting GM crops in areas that are not identified as agricultural lands and in areas with known ordinances prohibiting the propagation of GM crops
- Indicating in the seed bag label that the product is not intended for propagation in prohibited areas

4. New and emerging regulatory challenge(s)

- Availability of reference materials used for detection of unapproved transformation event(s) in imported consignment.
- Differences in regulatory frameworks governing gene editing among various countries.

5. Public engagement

The Bureau of Plant Industry served as resource person for the following activities:

- Face to face public hearings for field trial
- Conversation with the Media on the Status of Philippine Ag-Biotech – Gene Editing Guidelines in the Philippines
- Twentieth Meeting of the ASEAN of the ASEAN Genetically Modified Testing Network
- Regulation of GM and Ged Crops in the Philippines: Webinar on High GABA Tomato and GM Eggplant: Thailand's Opportunity
- 16th International Society for Biosafety Research (ISBR) Symposium/ Philippine Policy for Products of Plant Breeding Innovations
- 5th National Seed Summit Biotechnology Regulations in the Philippines
- 6th Asian Shortcourse on Agribiotechnology, Biosafety Regulations and Communication
- Workshop on Biotechnology Policies to Bolster ASEAN Food Security
- Capacity Building Workshop for Members of the Genetic Modification Advisory Committee (GMAC) and Sub-Committee Under GMAC for The Year 2024

B. Updates regarding international activities

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

- Regulatory Capacity building for Genome-edited Agriculture
- Agricultural Biotechnology Seminar Series (Development of Agricultural Resources Through genome Editing Platforms
- Training on Agricultural Biotech and Systems in Asia and Africa
- 37th Meeting of the OECD Working Party on the Harmonization of Regulatory Oversight in Biotechnology
- International Conference on GMO Analysis and New Genomic Techniques
- Conversation with the Media on the Status of Philippine Ag-Biotech – Gene Editing Guidelines in the Philippines
- Twentieth Meeting of the ASEAN of the ASEAN Genetically Modified Testing Network
- Regulation of GM and Ged Crops in the Philippines: Webinar on High GABA Tomato and GM Eggplant: Thailand's Opportunity
- 16th International Society for Biosafety Research (ISBR) Symposium/ Philippine Policy for Products of Plant Breeding Innovations
- 5th National Seed Summit Biotechnology Regulations in the Philippines
- 6th Asian Short course on Agribiotechnology, Biosafety Regulations and Communication
- Workshop on Biotechnology Policies to Bolster ASEAN Food Security
- Capacity Building Workshop for Members of the Genetic Modification Advisory Committee (GMAC) and Sub-Committee Under GMAC for The Year 2024

2. Specific cases of use of OECD tools and information

- The assessors referred to OECD consensus documents during the assessment of GM applications

C. Developments related to new breeding techniques (NBTs)

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

- Memorandum Circular No. 8, series of 2022, issued in 2022, provides rules and procedures to evaluate and determine when products of plant breeding innovations (PBIs) are covered under GMO regulations. It is still in effect.

2. Specific cases of application, assessment and decision

- BPI received requests for the technical determination of whether the following products will be covered by GMO regulations in the Philippines:
    - High GABA Sicilian Rouge tomato
    - Reduced Browning Banana

SLOVAK REPUBLIC

1. Developments related to implementation of national biosafety framework

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

In 2023, The Ministry of the Environment of the Slovak Republic extended approval for testing the genetically modified vaccine"FluBHPV^{E6E7}".The GMO "FluBHPV^{E6E7}" 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 FluBHPV^{E6E7}.

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.

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

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.

4. 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 2023 we have participated at obligatory meetings.

SLOVENIA

1. Developments related to implementation of national biosafety framework

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

Contained use of genetically modified organisms (GMOs)

In Slovenia, most of the work in the field of modern biotechnology and GMOs is carried out in contained systems (to date, 105 laboratories and production facilities are registered in the GMO register). The majority of work with GMOs in contained systems, 62% in safety class 1 and 38% in safety class 2, is carried out in universities (45%), institutes (30%) and industry (25%). For research and production purposes, GM microorganisms (bacteria, yeasts, fungi, mammalian, and insect cells), vertebrates (mice), GM insects and GM plants are used in containment class 1, while the work in containment class 2 mainly concerns GM viruses.

From January 2023 to March 2024, the 12 new contained systems will be entered in the GMO register.

Deliberate release and placing on the market of GMOs.

So far, four GMOs have been deliberately released into the environment in Slovenia for experimental purposes, mainly in the field of gene therapy. However, in the current period (March 2023 - March 2024), no GM plants have been cultivated or GMOs intentionally released for field trials in Slovenia.

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

Institutional Capacity

The National Institute of Biology (NIB) is a designated National Reference Laboratory (NRL) in Slovenia. As an accredited laboratory, the NIB carries out analyses for the presence of GMOs in samples and provides professional support in this area to the relevant ministries and control services. Based on the mandate and an adequate quality system, the NIB analysed 273 samples for the presence of GMOs in 2023.

GMOs Monitoring

Slovenia on the basis of regulations monitor the presence of GMOs in products, and on this basis also in seeds and food/feed.

- **seed**

As part of the monitoring framework for the presence of GMOs in conventional seeds, which has been carried out in Slovenia for many years, maize, soya, rapeseed, and alfalfa seeds were tested in 2023. For most samples, the process of analysing seed samples for the presence of GMOs involved two stages. In the first stage, screening analyses were carried out with five screening genetic elements. In parallel, a specific maize line was analysed for maize and oilseed rape samples, as it does not contain the screening elements mentioned. For soya samples, only pre-prepared plates were used to analyse 18 GMO soya beans. In the case of a positive result, the second stage involves analysing the individual GMOs and quantifying the GMOs, i.e., determining the exact amount of GMO present in the seed sample. In this

context, 16 samples of maize, 5 samples of rapeseed, 5 samples of soya beans and 2 samples of alfalfa were analysed. All results were negative, i.e., no genetic elements were detected in the analysed samples.

- **food/feed**

The Slovenian Food Safety Authority regularly monitors the presence of GMOs in food and feed as part of its official monitoring programme.

The selection of samples for monitoring is based on the observation of GMOs on the market over several years and on the occurrence of unauthorised GMOs in the EU. The purpose of sampling is to monitor the compliance of food and feed with the legislation on the authorisation, presence and labelling of GMOs. When selecting samples, particular consideration is given to the probability of the presence of GMOs in the food or feed, the possibility of detection and the origin of the product. Based on data from databases on authorised GMOs and the presence of unauthorised GMOs, the most frequently sampled products contain, consist of or are produced from soybeans, maize, rice, rapeseed, flax and papaya. To reduce the sensitivity of the detection methods in processed samples (the DNA may be degraded or removed during processing), the products should be sampled as far upstream as possible. The country of origin is also considered when selecting samples. For products from countries where the presence of GMOs is more likely, attention is paid to this.

In 2023, a total of 129 samples were analysed for the presence of GMOs, namely 98 samples of food of plant origin (including 77 samples of food, 7 samples of protein food for athletes and 14 samples of organic food) and 31 samples of feed of plant origin (including 15 samples of feed materials and 16 samples of compound feed). Of the total number of samples tested, 4 feed samples were also analysed that were labelled as containing GM soybeans. The remaining 125 food and feed samples were not labelled as GMOs. In 21 cases of these food samples, they were labelled with an organic certificate, including 4 feed samples labelled "Suitable for the production of food according to private standards" and "Produced /manufactured without GMOs". 104 food and feed samples were not labelled with an organic certificate. Of the samples taken, 28 samples were of Slovenian origin, 96 samples were of foreign origin (72 from the EU and 24 from outside the EU) and 5 samples had no indication of origin. All analysed samples of food of plant origin complied with the legal requirements.

According to the results, all feed samples also complied with the legal requirements. Of the samples of feed mixtures, all were compliant with the exception of one sample that contained soya as an ingredient. The sample should have been labelled. All samples of protein-containing foods for athletes complied with the legal requirements. The same applies to all samples of organic food.

In 2023, six samples of food of animal origin were analysed for the presence of GMOs. All samples were first analysed for the presence of reference genes for the respective plant or animal species. Samples from a range of salmon food products were tested for the presence of the construct contained in the GM AquAdvantage® salmon. All samples were negative. For foods of animal origin that also contained ingredients of plant origin, the samples were also analysed. The results were negative, i.e., no genetic elements were detected in the analysed samples.

2. Updates regarding international activities

1. Participation in fora relating to biosafety;

Convention on Biological Diversity

In its Decision 15/31, the Conference of the Parties (COP) to the CBD established a process for broad and regular horizon scanning, monitoring and assessment of the most recent developments in synthetic biology. In the same decision, the COP also established a multidisciplinary Ad Hoc Technical Expert Group (AHTEG) on Synthetic Biology to support the process. The Slovenian member of the multidisciplinary

AHTEG participated in the in person meetings of the mAHTEG in July 2023 and January 2024 in Montreal to develop a methodology and conduct one cycle of broad and regular horizon scanning, monitoring and assessment of the most recent technological developments in synthetic biology.

Cartagena protocol

By Decision CP-10/10, the COP-MOP established an Ad Hoc Technical Expert Group (AHTEG) on Risk Assessment and Risk Management with the mandate to develop additional voluntary guidance materials for conducting case-by-case risk assessments of LMOs containing engineered gene drives in accordance with annex III of the Protocol, to analyse the information submitted by the Parties and to prepare a report including draft additional voluntary guidance materials on LMOs containing engineered gene drives and a list of prioritized topics. The Slovenian member of the AHTEG participated in this process at the in person meetings in November 2023 and February 2024 in Montreal.

3. Developments related to new breeding techniques (NBTs)

Other information related to NBTs.

At a joint meeting on 18 January 2024, the Slovenian Scientific Committee on the Deliberate Release of GMOs into the Environment and Placing on the Market (SCDR) and Slovenian Scientific Committee for the Contained Use of GMOs (SCCU) adopted scientific opinion on the “Proposal for a Regulation of the European Parliament and of the Council on plants produced by certain new genomic techniques (NGTs) and their food and feed and amending Regulation (EU) 2017/625”, which they considered as a first step towards updating the existing EU legislation on GMOs dating back to 2001 and 2003 in the light of the remarkable developments in the biological sciences. Both Scientific Committees agreed that the proposed regulation will contribute to the innovation and sustainability goals of the European Green Deal as well as "from farm to fork" and biodiversity strategies and will increase the competitiveness of the agri-food sector, while at the same time maintaining a high level of health and environmental protection.

SOUTH AFRICA

1. South Africa GM Crop Area: 2021/22 Production Season Estimates

(New report released December 2023: Prepared by the Bureau for Food and Agricultural Policy (BFAP) for CropLife South Africa)

CropLife South Africa is a non-profit industry association that serves and represents responsible manufacturers, suppliers and distributors of sustainable crop protection, public health and plant biotechnology solutions in South Africa. They enable their members to be providers of environmentally compatible solutions that ensure sustainable, safe and affordable food production, and therefore food security, in South Africa. CropLife South Africa offers a wealth of resources, training, regulatory assistance and industry updates to its members. In addition, they are the leading industry voice for their members in matters pertaining to crop protection and plant biotechnology in South Africa.

GM Cotton

In 2022, 100% of the 18 018 hectares of cotton planted in South Africa were genetically modified. There was no conventional cotton seed available for planting in the 2021/22 production season. 95% of the cotton area was planted to stacked cotton seed with Bollgard II insect resistance and Roundup Ready Flex herbicide tolerance. The remaining 5% was planted to Roundup Ready Flex single trait seed as the mandatory refugia area. Driven by the Southern African Sustainable Cotton Cluster and higher international prices, the cotton industry has seen some revival from 2017, but the industry remains a shadow of its former self largely due to the capital requirements and management difficulties of harvesting (compared to grains and oilseeds), and relatively high prices for competing crops.

GM Soybean

Close to 80% of the total soybean area is planted to farm saved seed, and for this reason the GM adoption (still only glyphosate-resistance) estimate errs on the conservative side at 95%. MON87701 x MON89788 soybean seed (IntactaRR2Pro, which is an insect resistance trait stacked with a new glyphosate-tolerance trait) was first planted in 2022 and should see more substantial plantings in the 2023/24 production season.

GM Maize

The South African commercial GM maize area share has seen a steady increase over the years. After settling around the 70% level between 2008 and 2011, the share increased to closer to the 90% level for 2013-2016, and then declined to closer to an 80% level for 2018-2020. The 2021/22 GM maize area is estimated at 84.5%, with 65% of the maize area planted to stacked (insect resistance and herbicide tolerant) maize. South Africa's GM maize area percentage is slightly lower than that of other GM maize producing countries. In 2021, 99.6% of Argentina's maize area was planted to GM seed, while Brazil and the US had estimates of 95%.

GM White Maize

The GM white maize area for 2021/22 is estimated at 89%. It is estimated that the conventional white maize area increased slightly from 9% in 2020/21 to 11% in 2021/22 following the sharp drop from 16% in 2019/20. Bt maize (insect resistant) as a single trait (albeit with two Bt events) continued to decrease, dropping from 5% to 3%. The area under herbicide tolerant single trait maize decreased by 144 000 ha, to a relatively similar level as was observed in 2018 and 2019. Despite the total white maize area decline, the stacked maize (insect resistant and herbicide tolerant) area increased with just over 48 000 ha to cover

an estimated 74% of total commercial white maize plantings in 2021/22. It would seem as if 'additional' white maize hectares that come in to or go out of maize production per season (due to price or other considerations), are largely planted to herbicide tolerant seed in the Free State or North West Provinces.

GM Yellow Maize

The area planted to stacked yellow maize increased by just over 32 400 ha and the single herbicide tolerant trait area by 16 700 ha. As a result, the GM yellow maize area increased from 72% in 2020/21 to 77.2% in 2021/22. This level is similar to 2019 estimations and lower than the above 85% levels observed in 2012/2016. The yellow maize Bt area decreased with about 5 5000 ha to its second lowest level since the technology's first introduction in 1999. Stacked maize adoption amongst yellow maize farmers are lower compared to white maize, while herbicide tolerant single trait adoption is higher.

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

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

Application of the Act

This Act shall apply to:

a. the genetic modification of organisms;

b. the development, production, release, use and application of genetically modified organisms (including viruses and bacteriophages); and

c. the use of gene therapy.

Executive Council

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

Functions of Advisory Committee

(1) The Advisory Committee (AC) shall:

a. act as the national advisory body on all matters concerning or related to the genetic modification of organisms;

b. advise, on request or of its own accord, the Minister of Agriculture, the EC, other Ministries and appropriate bodies, on matters concerning the genetic modification of organisms and, inter alia, advise them:

i. on all aspects relating to the introduction of genetically modified organisms into the environment;

ii. on proposals for specific activities or projects concerning the genetic modification of organisms;

iii. on all aspects concerning the contained use of genetically modified organisms;

iv. on the importation and exportation of genetically modified organisms; and

v. on proposed regulations and written guidelines;

c. liaise through the relevant national departments with international groups or organisations concerned with biosafety; and

d. invite written comments from knowledgeable persons on any aspect of the genetic modification of organisms which lies within the Committee's brief.

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

Appointment of registrar

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

The registrar:

a. is charged with the administration of this Act;

b. may exercise such powers and perform such duties as may be conferred upon or delegated or assigned to him or her by or under this Act or by the EC.

Functions of registrar

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

a. issue a permit as required or prescribed under this Act;

b. where he or she has ascertained or suspects on reasonable grounds that genetically modified organisms are being imported or locally produced or used contrary to the provisions of this Act or the conditions of a permit issued thereunder:

i. serve a notice upon any person by whom or on whose behalf genetically modified organisms are being so imported into, produced or used in the Republic for the removal of such genetically modified organisms to a place or facility and in a manner prescribed by the Council; and

ii. authorise an inspector to destroy such genetically modified organisms or cause it to be destroyed, subject to procedures and other provisions as set out in this Act.

c. amend or withdraw a permit issued under this Act;

d. furnish an inspector with a certificate of appointment;

e. require the cessation of any genetic modification activity at facilities where the provisions of this Act or the conditions of a permit have not been or are not being complied with; and

f. ensure that appropriate measures are undertaken by all users at all times with a view to

the protection of the environment from hazards.

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

Biosafety:

Mission

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

Functions

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

Role as the Competent National Authority

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

4. New GM approvals in South Africa

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

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

Event	Crop	Trait	Company	Year approved
DP202216 x NK603 x DAS-40278-9	Maize	Enhanced grain yield Herbicide tolerance	Corteva	2023
3272 x Bt11 x MIR162 x GA21	Maize	Insect resistance Herbicide tolerance	Syngenta	2023
DP202216	Maize	Enhanced grain yield Herbicide tolerance	Corteva Agriscience RSA	2023
HB4 (IND- ØØ41Ø-5)	Soybean	Abiotic stress tolerant Herbicide tolerant	Bioceres Crop Solutions	2022
HB4 (IND-ØØ412-7)	Wheat	Abiotic stress tolerant Herbicide tolerant	Trigall Genetics SA	2022

3272 x Bt11 x MIR162 x MIR604 x TC1507 x 5307 x GA21	Maize	Insect resistance Herbicide tolerance	Syngenta SA	2022
DAS-44406-6	Soybean	Herbicide tolerance	Corteva Agriscience RSA	2022
DAS-81419-2 x DAS-44406-6	Soybean	Insect resistance Herbicide tolerance	Pioneer Hi-Bred RSA	2022
NK603 x T25 x DAS-40278-9	Maize	Herbicide tolerance	Corteva Agriscience RSA	2022
GMB151	Soybean	Insect resistance Herbicide tolerance	BASF	2021
GHB811	Cotton	Herbicide tolerance	BASF	2021
MON89034 x TC1507 x MIR162 x NK603 x DAS-40278-9	Maize	Insect resistance Herbicide tolerance	Pioneer Hi-Bred RSA (Pty) Ltd	2020
MON87427 x MON89034 x MON810 x MIR162 x MON87411 x MON87419	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2020
MON87427 x MON89034 x MIR162 x MON87419 x NK603	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2020
MON87427 x MON87419 x NK603	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2020
MON87427 x MON89034 x MON87419 x NK603	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2018
MON87427 x MON89034 x TC1507 x MON87411 x DAS 59122-7 x MON87419	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2018
MON87751 x MON87701 x MON87708 x MON89788	Soybean	Insect resistance Herbicide tolerance	Monsanto SA	2018
FG72 x A5547-127	Soybean	Herbicide tolerance	Bayer	2018
MON89034 x TC1507 x MIR162 x NK603	Maize	Insect resistance Herbicide tolerance	DowAgroSciences	2018
BT11 x MIR162 x MIMR604 x MON89034 x 5307 x GA21	Maize	Insect resistance Herbicide tolerance	Syngenta SA	2018
MON87705 x MON87708 x MON89788	Soybean	Herbicide tolerance	Monsanto SA	2018
MON87427 x MON87460 x MON89034 x TC1507 x MON87411 x DAS-59122-7	Maize	Insect resistance Herbicide tolerance Drought or water tolerance	Monsanto SA	2018
MON87427 x MON89034 x MIR162 x MON87411	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2018
MON87427 x MON89034 x TC1507 x MON87411 x DAS-59122-7	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2018
MON87427 x MON87460 x MON89034 x MIR162 x NK603	Maize	Insect resistance Herbicide tolerance Drought or water tolerance	Monsanto SA	2018
MON87708 x MON89788 x A5547-127	Soybean	Herbicide tolerance	Monsanto SA	2018
BT11 x MIR162 x MON89034	Maize	Insect resistance Herbicide tolerance	Syngenta SA	2018

MON87427 x MON89034 x MON88017	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2017
MON89034 x MIR162	Maize	Insect resistance	Monsanto SA	2017
BT11 x MIR162 x MON89034 x GA21	Maize	Insect resistance Herbicide tolerance	Syngenta	2017
DP114 x MON810 x MIR604 x NK603	Maize	Insect resistance Herbicide tolerance	Du Pont Pioneer	2017
TC1507 x MON810 x MIR162 x NK603	Maize	Insect resistant Herbicide tolerant	Du Pont Pioneer	2016
TC1507 x MIR604 x NK603	Maize	Insect resistant Herbicide tolerant	Du Pont Pioneer	2016
TC1507 x MON810 x MIR604 x NK603	Maize	Insect resistant Herbicide tolerant	Du Pont Pioneer	2016
TC1507 x 59122 x MON810 x NK603	Maize	Insect resistant Herbicide tolerant	Du Pont Pioneer	2016
TC1507 X 59122 X MON810 x MIR604 x NK603	Maize	Insect resistant Herbicide tolerant	Du Pont Pioneer	2016
DAS81910-7	Cotton	Herbicide tolerant	DowAgroSciences	2016
DAS-24236-5 x DAS-21023-5	Cotton	Insect resistant	DowAgroSciences	2016
MON89034 x TC1507 x MON88017 x DAS-591227 x DAS-40278-9	Maize	Insect resistant Herbicide tolerant	DowAgroSciences	2016
MON89034 x TC1507 x NK603 x DAS-40278-9	Maize	Insect resistant Herbicide tolerant	DowAgroSciences	2016
DP4114	Maize	Insect resistant Herbicide tolerant	Du Pont Pioneer	2016
NK603 x T25	Maize	Herbicide tolerant	Monsanto	2016
MZHG0JG	Maize	Herbicide tolerant	Syngenta	2016
DP73496	Canola	Herbicide tolerance	Du Pont Pioneer	2016

Table 2. General release approved for importation/exportation, commercial planting, and for food and/or feed in South Africa. Source: http://www.dalrrd.gov.za/

Event	**Crop**	**Trait**	**Company**	**Year approved**
Recombinant Attenuated Salmonella Vaccine -Cp/01	Poultry vaccine	-	Huvepharma South Africa (Pty) Ltd	2023
Nobivac Puppy DP Plus	Canine vaccine	-	Intervet SA (Pty) Ltd	2023
Innovax – ND-ILT	Poultry vaccine	-	Intervet SA (Pty) Ltd	2023
GHB614 x LLCotton25	Cotton	Herbicide tolerance	BASF South Africa (Pty) Ltd	2023
Poulvac Procerta HVT-ND	Poultry vaccine	-	Zoetis South Africa (Pty) Ltd	2023
MON87427	Maize	Herbicide tolerance	Bayer	2023
DP-056113-9	Maize	Pollination control system	Corteva Agriscience RSA	2023
MON89034 x TC1507 x MIR162 x NK603 x DAS-40278-9	Maize	Insect resistance Herbicide tolerance	Corteva Agriscience RSA	2023
DAS-44406-6 x DAS-81419-2	Soybean	Insect resistance Herbicide tolerance	Corteva Agriscience RSA	2022

DAS-44406-6	Soybean	Herbicide tolerance	Corteva Agriscience RSA	2022
MIR162	Maize	Insect resistance	Syngenta	2022
MON87701 x MON89788	Soybean	Insect resistance Herbicide tolerance	Bayer	2021
BT11 x MIR162 x GA21	Maize	Insect resistance Herbicide tolerance	Syngenta	2021
BT11 x MIR162 x MON89034 x GA21	Maize	Insect resistance Herbicide tolerance	Syngenta	2021
MON87427 x MON89034 x MIR162 x NK603	Maize	Insect resistance Herbicide tolerance	Bayer	2020
DAS-40278-9	Maize	Herbicide tolerance	DowAgroSciences	2019
DAS-40278-9 x NK603	Maize	Herbicide tolerance	DowAgroSciences	2019
MON89034 x TC1507 x NK603 x DAS-40278-9	Maize	Insect resistance Herbicide tolerance	DowAgroSciences	2019
Innovax ND - IBD	Poultry vaccine	-	Intervet	2019
VaxSafe TMPM	Poultry vaccine	-	Protectachik	2019
MON89034 x TC1507 x NK603	Maize	Insect resistance Herbicide tolerance	DowAgroSciences	2018
Innovcax-ND	Vaccine	-	Intervet	2015
Vectormune HVT NDT & Ripens	Vaccine	-	Ceva Animal Health	2015
MON87460	Maize	Drought tolerant Antibiotic resistant	Monsanto	2015

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

South Africa's Regulatory Approach for New Breeding Techniques
Department of Agriculture, Land Reform and Rural Development (DALRRD)

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

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

6. Genome editing research and activities in South Africa

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

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

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

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

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

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

Aim: This study aims to develop virus resistance in a cucurbit species using single base pair editing. Virus diversity assessment is still underway. They are in the process of writing a paper on their findings prior to the GE work.

Project Title: Functional genomics towards development of resistance to the banana bunchy top virus in banana

Banana bunchy top disease (BBTD) is currently the most destructive viral disease of banana and there is currently no natural resistance to banana bunchy top virus (BBTV), the causal agent, in the crop. It is present in several countries in Africa, Asia and Australia. There are 200 known virus resistance genes in plants and half of these are recessively inherited. This prominence of recessive genes for resistance to plant viruses stems from the specificity of plant-virus protein interactions that confer susceptibility. Disruption of these interactions by mutating the plant susceptibility factors may lead to virus resistance as demonstrated by resistance to potyviruses *via* natural and induced mutations in eIF4E genes in a number of plants. An RNASeq study was conducted to identify genes differentially expressed in response to BBTV. Currently conducting functional studies on candidate susceptibility genes from that study by knocking them out using CRISPR/Cas9. Identification of susceptibility genes whose knockout leads reduced BBTV titers and symptoms may lead recessive resistance/tolerance to BBTV in banana.

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

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

Sweet potato (*Ipomoea batatas* Lam) is an important food crop in South Africa and is planted by smallholder and rural communities for household consumption and for income generation. Sweet potato virus disease (SPVD) is one of the most important viruses of sweet potato, associated with reduction in yields by 80% to 100%. The research proposes to identify virus strains associated with the potyvirus *Sweet potato feathery mottle virus* (SPFMV) and the crinivirus *Sweet potato chlorotic stunt virus* (SPCSV). A co-infection of the two viruses results in a condition called SPVD. The study also proposes to investigate the possibility of using CRISPR/Cas9 gene editing technology in attaining resistance to the potyvirus SPFMV, which will ultimately confer resistance to SPVD, due to the synergistic effects of the two viruses, which increases the concentration of SPFMV when the two viruses co-infect the plant. The strategy is to knock out eIF4E and eIF4G and their isoforms, whose knock out is well established in the literature to lead to resistance to potyviruses. eIF4E is a eukaryotic translation initiation factor involved in directing ribosomes to the cap structure of mRNAs. Almost all cellular mRNA require eIF4E in order to be translated into protein. The eIF4E polypeptide is the rate-limiting component of the eukaryotic translation apparatus and is involved in the mRNA-ribosome binding step of eukaryotic protein synthesis. Another subunit is eIF4G. Some viruses cut eIF4G in such a way that the eIF4E binding site is removed and the

virus is able to translate its proteins without eIF4E. This is part of the development of integrated disease management strategies to minimize the effects of major viruses of sweet potato.

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

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

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

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

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

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

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

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

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

CRISPR research at the Stellenbosch University

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

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

They were trying to establish protoplast regeneration so that they have a non-transgenic way of making the mutants, but they have also started a transgenic approach, transforming potatoes with constructs to mutate GWD1.

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

CRISPR research in the Vitis Lab at Stellenbosch University

The negative economic impact of biotic and abiotic stresses in vines are recognised by the international viticulture industry. The rapid developments in genome editing technologies over the last few years, and especially the versatility demonstrated in many applications of CRISPR/Cas9-based technology, may impact radically in the ongoing battle with most of these conditions in vineyards all over the world. As a first step to unlock the immense potential of this technology in the local industry, the project aims to establish CRISPR technology in grapevine.

They have published a paper titled 'CRISPR-based resistance to grapevine virus A. Authors: Katarina P. Spencer, Johan T. Burger and Manuela Campa – all from the Department of Genetics, Stellenbosch University, Stellenbosch, South Africa.

Citation

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

Extract from the paper:

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

Methods: To this end, the aim of this study was to use the recent Cas13d variant from *Ruminococcus flavefaciens* (CasRx) to target the RNA virus, grapevine virus A (GVA). GVA naturally infects grapevine, but can infect the model plant *Nicotiana benthamiana*, making it a helpful model to study virus infection in grapevine. gRNAs were designed against the coat protein (CP) gene of GVA. *N. benthamiana* plants expressing CasRx were co-infiltrated with GVA, and with a tobacco rattle virus (TRV)-gRNA expression vector, harbouring a CP gRNA.

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

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

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

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

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

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

South African database on genome editing

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

7. 4th Sustainable Bio-Innovation Symposium: Enabling Genome Editing Based Innovation in South Africa, 28 September 2024

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

Objectives:

- Provide a platform for all stakeholders to discuss the prerequisites for a sustainable genome editing (GEd) innovation system in South Africa.
- Develop an intervention priority list to facilitate this.

Topics presented included:

- GEd regulation
    - Keynote: Kenyan GEd regulatory framework and activities - Dr Roy Mugiira, CEO of the Kenya National Biosafety Authority, presented an overview of the Kenyan regulatory framework for GEd, highlighting their experience in establishing a functional system.
    - South African regulatory framework for Ged - This presentation provided an update on the status of GEd regulation in South Africa, including the ongoing discussions around the distinction between SDN1 and 2 and GMOs. Dr Hennie Groenewald, from Biosafety South Africa, argued for a risk-based approach to GEd regulation, suggesting that SDN1 and 2 should not be subject to the same regulations as GMOs.
- GEd in practice
    - CRISPR for dummies – The presentation provided a basic introduction to CRISPR technology, explaining its applications in GEd.

- CRISPR-based GEd in microorganisms and plants - Presentations showcased various applications of CRISPR-based GEd in different organisms, including improving the shelf life of wine grapes and developing disease-resistant crops.

- GEd innovation management
  - Concept to market for a GEd product - Concept to market for a GEd product. Dan Jenkins, VP of Regulatory and Government Affairs at Pairwise USA, presented a pre-recorded talk on the challenges and considerations involved in bringing a GEd product to market.
  - South African perspectives on GEd innovation management – Discussions on the challenges and opportunities for GEd innovation in South Africa from the perspectives of academia, the seed industry, and bio-entrepreneurship.

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

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

8. LLP

[Please note that this is not an official statement from the South African Government and that I am not the authorised focal point to speak on the matter, but that this is my understanding of the local situation in South Africa]

South Africa continues to participate in ongoing discussions regarding LLP, and endorses the international statement on LLPs, mindful that we are both importers and, albeit, to a lesser extent, exporters of GMOs. We remain convinced that all risk assessments and management should be based on relevant science and that no arbitrary distinction should be made between food and feed. South Africa currently applies a zero tolerance in this regard.

9. Usefulness of the OECD Biology documents

Biosafety South Africa (https://biosafety.org.za/) is a national technology platform in service of the country’s biotech regulators, researchers, technology developers and public.

Their mandate is to enable safe, sustainable and compliant research, development, production, use and application of biotechnology - in particular GMOs. They are an initiative of the Department of Science and Technology (DST) and funded entirely from public sources.

They assist and advise all biosafety stakeholders with regard to regulatory compliance, biosafety and risk analysis best practice and sustainable biotech innovation.

They promote biosafety research and development in support of the national policy and regulatory frameworks and to ensure effective risk management.

They encourage sustainable biotech innovation by creating and enabling environment and investing in the biosafety/sustainability development of biotech products.

They help develop national and regional capacity in sustainability research and development and risk analysis, because they realise that biosafety systems are only as good as the people managing them. They are passionate about communicating the science behind biosafety and biotechnology to all stakeholders; providing answers across the whole spectrum, from the public's general questions to the technical enquiries of biosafety practitioners.

Environmental risk/safety assessments of genetically modified (GM) or genetically engineered (GE) plants are based on a broad body of knowledge and experience with the untransformed species (variety, etc.), i.e. familiarity with the conventional crop plant. The intent of a biology document is to describe portions of this body of knowledge directly relevant to risk/safety assessment in a format readily accessible to regulators.

The biology document is not an environmental risk/safety assessment of the species. Rather, the document provides an overview of pertinent biological information of the untransformed species to help define the baseline and scope (the comparator against which transformed organisms will be compared), in the risk/safety assessment of the transformed organism. Biology documents are not detailed crop handbooks or manuals of agricultural or silvicultural practice or economic botany, but rather focus on the biological information and data that may be clearly relevant to the assessment of newly transformed plants.

Biology documents are categorised into several sections. The sections range from species-specific information to information on the potential effects of the crop species on human health and biosafety. The information contained in the biology document is essentially an assessment of the information pertinent to the environmental risk assessment from collective peer-reviewed sources. In addition, a useful list of references and appendices are usually included at the end of each document.

The Organisation of Economic Cooperation and Development's (OECD's) consensus documents for the work on harmonising the regulatory oversight in biotechnology are probably one of the best resources available to risk assessors.

The OECD's consensus biology documents relevant to South African GM crops can be accessed directly here (right click to open the hyperlink to the documents):

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

SPAIN

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

General information about activities with genetically modified organisms (GMOs) which have been approved/notified in Spain, as contained use or deliberate release into the environment, and other relevant reports are available from the Ministry of Agriculture, Food and Fisheries and the Ministry for the Ecological Transition and the Demographic Challenge. Web pages:

https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/omg/registro-publico-omg/

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

a) Contained use activities in research facilities

Since the last meeting in April 2023, sixty-seven (67) new facilities for different contained use activities have been notified in Spain to the Competent Authorities (Interministerial Council of GMO or Regional Government) and assessed by the risk assessment competent authority, the National Biosafety Commission (30 of biosafety level (BSL) 1, 36 of BSL 2 and 1 of BSL 3.

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

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

For detailed information:

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

b) Experimental deliberate release into the environment

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

- Three field trials with plants: (B/ES/23/34 and B/ES/23/36, both of them are genetically modified tobacco as biofactory plants to produce industrially useful substances. The last one was developed using gene editing).
- On the other hand, thirty (30) human clinical trials have been notified. Many of them are different genetically modified viruses (Adenovirus, AAV, MVA, VSV, etc.), others were developed using human cells (T lymphocytes, CAR-T).

For detailed information:

https://www.miteco.gob.es/es/calidad-y-evaluacion-ambiental/temas/biotecnologia/organismos-modificados-geneticamente-omg-/notificaciones-y-autorizaciones/liberac_voluntaria.aspx

https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/omg/registro-publico-omg/

c) Placing on the market

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

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

- https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/omg/registro-publico-omg/superficie_cultivada.aspx
- http://www.mapa.gob.es/es/estadistica/temas/estadisticas-agrarias/agricultura/esyrce/

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

2.1 Legal framework applicable to GMOs

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

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

2.2 National control plan on deliberate release of GMOs for food and feed production:

The National Plan for Official Control of the Food Chain describes the official control systems throughout the food chain in Spain, from primary production to points of sale to the final consumer. In this context, since 2020, it is applicable the National control plan on deliberate release of GMOs for food and feed production, according to the Regulation 2017/625/UE (OCR). The strategic objective of this program is to guarantee that the deliberate release of GMOs complies with the requirements established in the current regulations. Official controls will be carried out in three areas:

1) cultivation of GMOs for the production of food and feed

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

3) seeds for cultivation with the purpose of producing food and feed.

The Ministry of Agriculture, Food and Fisheries publishes a report annually with the results of the official controls in our country. This information is also shared with the European Commission.

Further information is available at:

https://www.mapa.gob.es/en/agricultura/temas/biotecnologia/omg/PNCOCA%202021-2025.aspx

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

The monitoring plan for the commercial cultivation of MON810 Bt maize continues ongoing and remains without appearing insect resistant populations in farmlands after more than 23 years of growing in the main northeast maize cropping area in Spain.

As it was mentioned in previous questions, since 2020 there is in force a national control plan on deliberate release of GMOs for food and feed production, which includes commercial cultivation of MON 810.

5. Public engagement and outreach activities

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

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

6. Research projects on biosafety; relevant publications

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

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

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

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

2. Updates regarding international activities

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

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

Likewise, the Ministry regularly updates the information related to GMO in the Information Exchange Center of the Convention on Biological Diversity: https://bch.cbd.int/en/countries/ES

The national website related to the Cartagena Protocol and the Nagoya - Kuala Lumpur Supplementary Protocol is available through the following link:

https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/omg/protocolo-cartagena/

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

3. Developments related to new breeding techniques (NBTs)

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

On 5 July 2023, the College of Commissioners of the European Union adopted a legislative proposal on plants obtained by certain genomic techniques (NGT proposal). This initiative applies to plants produced through directed mutagenesis and cisgenesis, to food and feed and other products derived from these plants.

Negotiation of this proposal began during the Spanish Presidency of the Council of the European Union, in the Working Group on Genetic Resources and Innovation in Agriculture, which held eight meetings between July and December, 2023. At the end of the Spanish Presidency, at the Council meeting on December 11, the transactional proposal of the Spanish Presidency was presented.

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

In addition, the legislative proposal was addressed in two Council meetings, in its Agriculture and Fisheries formation, and during an informal agriculture ministerial meeting that took place in Córdoba (September, 2023). Information about these meetings can be found at: https://spanish-presidency.consilium.europa.eu/es/eventos/reunion-informal-ministerial-de-agricultura-3-59/

In the context of these negotiations, in Spain, a working group of scientific experts on this matter was created, within the framework of the National Biosafety Commission. This *Ad-hoc* group of experts provide scientific advice to the Interministerial Council of GMOs as regards certain parts of the NGT proposal, but mainly those aspects related to the Annex I on equivalence criteria between plants obtained by NGT and those conventional ones.

The report is available at the following link:
https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/notagrupocnbsobrengtfinal_tcm30-675213.pdf

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

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

4. Any other information related to NBTs.

The website of the Ministry of Agriculture, Fisheries and Food includes a specific section on NBTs, which contains general information about these technologies, about the regulatory framework related to NBT in third countries, reports on the role of NBTs in different EU policies, detection an identification issues, amongst other relevant issues related to this topic.
https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/mejora-genetica/

The webpage also contains up-to-date information about the regulatory process in the EU to regulate these techniques:
https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/mejora-genetica/iniciativa.aspx

UNITED STATES OF AMERICA

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

Updates for the United States Department of Agriculture (USDA)

- ***USDA Animal and Plant Health Inspection Service's (USDA-APHIS) Biotechnology Modernized Regulations in 7 CFR part 340.*** USDA-APHIS has operated under modernized biotechnology regulations since 2020, which account for advances in genetic engineering and our understanding of the plant pest risks posed by modified organisms. USDA-APHIS now focuses on the organism's characteristics, rather than on the method used to produce it. This risk-proportionate approach enables USDA-APHIS to regulate organisms developed using genetic engineering for increased plant pest risk with greater precision, reducing regulatory burden for developers of organisms that are unlikely to pose increased plant pest risk and allowing USDA-APHIS to continue regulating modified organisms that may pose an increased plant pest risk. Based new information and experience over the past three years, USDA-APHIS seeks to updates to its regulations expand to regulatory exemptions for plants with modifications achievable through conventional breeding methods.

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

  Weblink for USDA-APHIS biotechnology regulations:
  https://www.ecfr.gov/current/title-7/subtitle-B/chapter-III/part-340?toc=1

- ***Confirming Products Exempt from Regulation.*** USDA-APHIS biotechnology regulations exempt certain modified plants that (1) are achievable through conventional breeding techniques and thus are unlikely to pose an increased plant pest risk compared to conventionally bred plants, or (2) have a plant-trait-mechanism of action combination that is the same as a plant that USDA-APHIS previously reviewed and determined to be unlikely to pose plant pest risk.

  Developers may voluntarily request USDA-APHIS confirm 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 2020, USDA-APHIS has issued 80 responses to confirmation request letters as of 04/09/2024 with an average timeframe of 54 days.

  Weblink for information on the confirmation process:
  https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulatory-processes/exemptions-confirmations

  Weblink for table of confirmation letters:
  https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/regulatory-processes/confirmations/responses/cr-table

  USDA-APHIS biotechnology regulations factors in advances in plant breeding innovations, science and technology by allowing USDA-APHIS to 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 November 15, 2023, USDA-APHIS published a notice to advise the public on its proposal to add five exemptions for plants with modifications that could be achieved through conventional breeding. The proposed exemptions would be in addition to those exemptions already in place.

Specifically, the proposed exemptions include:

1. **Plants** that have any combination of loss-of-function modifications (modifications that reduce or eliminate a gene's function) in one to all alleles of a single genetic locus in diploid and autopolyploid plants, or in one or both copies of a single genetic locus on up to four pairs of homoeologous chromosomes in allopolyploid plants.
2. **Diploid or autopolyploid plants** with a single contiguous deletion of any size on one or more chromosomes.
3. Autopolyploid plants containing any modification described in existing exemptions that previously applied only to diploid plants.
4. Plants with up to four modifications made simultaneously or sequentially, provided that each modification individually qualifies for exemption and is at a different genetic locus.
5. Plants that have previously completed a voluntary review confirming exempt status and that have subsequently been produced, grown, and observed consistent with conventional breeding methods appropriate for the plant species, could be successively modified in accordance with the exemptions.

USDA-APHIS received 6,500 public comments during the review period, which closed on January 19, 2024. USDA-APHIS is reviewing the comments and considering next steps.

Weblinks for additional information on the proposed exemptions:
Federal Register: Movement of Organisms Modified or Produced Through Genetic Engineering; Notice of Proposed Exemptions

- ***Regulatory Status Review*** (RSR). USDA-APHIS biotechnology regulations provide developers with the option of requesting an RSR for certain plants developed using genetic engineering that are not otherwise exempt from regulation. We evaluate whether a plant is subject to regulation based on the characteristics of the plant itself and not on the method used to modify the plant.

  The RSR process involves two distinct review steps: 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.

APHIS began accepting RSR requests in 2021 and published the first RSR response in September 2022. USDA-APHIS has received a total of 104 RSR requests and has published 48 RSR response letters as of 04/09/2024 since the implementation of the RSR process.

APHIS has a Guide for Requesting a Regulatory Status Review under 7 CFR part 340, which details the information requirements and process for submitting a 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

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

- ***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.*** On December 1, 2023, USDA APHIS deregulated the Pioneer Hi-Bred International, Inc's Insect Resistant, Herbicide Tolerant Corn.

  Currently there are three pending reviews:1) SUNY ESF Blight Tolerant Chestnut, 2) Bayer Stacked 5 Herbicide Resistant Corn, and 3) Bayer Insect Resistant Corn.

  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) 2023 (10/1/2022 through 09/30/2023), APHIS received 959 permit applications for import, interstate movement, and environmental release through eFile, an automated system for submitting requests. Of those, APHIS issued 774 permits. In addition, 8 applications are pending and 177 were withdrawn. During the portion of FY 2024 that has currently elapsed (10/1/2023 through 02/02/2024), APHIS has received 384 permit applications. Of those, APHIS issued 174 permits. In addition, 161 applications are pending, and 49 were withdrawn.

  On September 28, 2023, USDA-APHIS announced additional APHIS eFile flexibilities and assistance for BRS applicants. Applicants can now submit multi-year interstate movement and import permits for plants. USDA-APHIS also shared a Standard Operating Procedure (SOP) template as an optional format APHIS eFile applicants may elect to use when preparing SOPs to accompany permit applications.

  On March 23, 2023, USDA-APHIS shared a draft *Guide For Submitting Permit Applications For Microorganisms Developed Using Genetic Engineering Under 7 CFR Part 340* detailing the information

requirements and process for submitting permit applications for microorganisms developed using genetic engineering. Public comments on the proposal were accepted until May 22, 2023. USDA-APHIS revised the draft Guide based on public comments and shared a revised draft of the Guide and a *Response to Comments* on the first draft of the Guide on October 13, 2023. The revised draft Guide and Response to Comments are available on the APHIS website. Members of the public may view comments on the first draft guide at https://www.regulations.gov/docket/APHIS-2023-0030/document.

- ***Compliance and oversight.*** From October 1, 2021, through January 24, 2024, USDA-APHIS BRS and Plant Protection and Quarantine (PPQ), along with state partners completed 2,161 inspections of regulated release locations. The inspections serve to assess compliance to 7 CFR 340 and to meet oversight goals for the regulation of environmental releases involving organisms developed using genetic engineering. USDA-APHIS relies mostly on in-person inspections to assess compliance, though virtual inspections are utilized as an available compliance evaluation tool if weather, for example, precludes an on-site inspection.

❖ ***2023 USDA-APHIS Stakeholder Meeting.*** On November 15, 2023, USDA-APHIS held its annual stakeholder meeting. Stakeholder meetings are open to the public to foster engagement and transparency in USDA-APHIS regulatory activities. USDA-APHIS provided updates on the Regulatory Status Review and Confirmation Request processes and shared updates on other activities, including permitting, modified microorganisms, international efforts, and priorities for FY 2024. 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/news/program-updates?page=1&search=

Office of Pesticide Programs (OPP)

❖ Biotechnology Submission Decisions

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

❖ **EPA Finalized a Rule Exempting Plant-Incorporated Protectants Created via Biotechnology that Could have Otherwise Been Created through Conventional Breeding in May 2023**, https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/pesticides-exemptions-certain-plant-incorporated-0

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

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

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

Office of Pollution Prevention and Toxics (OPPT)

❖ **Reviewed Biotechnology Submissions**

- In the last fiscal year, FY23 (Oct. 1, 2022 to Sept. 30, 2023), the U.S. EPA/OPPT, under the authority of the Toxic Substances Control Act (TSCA), reviewed the closed-system manufacture of six genetically engineered microbial strains submitted in Microbial Commercial Activity Notices (MCANs). The identity of most of these microorganisms was claimed as confidential. The one non-confidential microorganism was *Saccharomyces cerevisiae* for ethanol production. Several strains referred to simply as genetically modified microorganisms were used for enzyme production, production of a chemical substance, or production of a recombinant protein. A determination of "not likely to present an unreasonable risk to health or the environment" was made for all of these genetically engineered strains. OPPT reviewed two TSCA Experimental Release Applications (TERAs) which is the submission needed for environmental introduction of genetically engineered microorganisms for research and development purposes. The first TERA was "a bacilli engineered with a barcode" for molecular detection of plant colonization by the microorganism. The second TERA was for two years of open pond testing of two strains of the green microalga *Synechocystis* engineered to produce the fatty acids laurate or methyl laurate. Each of these TERAs were approved based on the determination that the proposed activity did 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 first presented the progress on a draft of this document at the 36th WP-HROB Meeting (May 18-20, 2022). A revised document was sent to all delegates in mid-September 2022, 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 was posted on the O.N.E. site with a request for comments by April 10th prior to the 37th Meeting of the WP-HROB (April 17-19, 2023). Canada again provided a presentation on the document during the 37th meeting. Comments on this First Full Draft were received by PRRI, Japan, Argentina, Costa Rica, Australia, and Brazil prior to the meeting. After the meeting, additional comments were received from Japan. A new revision of the document addressing all the comments was completed by the co-leads in late summer of 2023. Australia provided additional comments on this new version. The co-leads then worked to address Australia's comments resulting in the latest version of the document that was distributed to delegates for discussion at the 38th WP-HROB Meeting (March 20-22, 2024).

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 25-26, 2023. 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 2023, regulators from Japan, South Korea, and Taiwan visited USDA.
3. In September 2023, APHIS-BRS team members attended a regulators workshop and roundtable with industry in Lima, Peru, on regulatory policies for products of new plant breeding techniques, organized by the Inter-American Institute for Cooperation on Agriculture (IICA) and the Seed Association of the Americas (SAA).
4. In November 2023 APHIS-BRS met virtually with regulators from Spain to discuss the proposed expansion of our exemptions from regulation.
5. In December 2023, APHIS-BRS members presented virtually on the topic “U.S.’ Policy for the Environmental Release of Genome Edited Organisms” at the 2023 Genome Editing Policy Roundtable Summit being held in Taiwan.
6. In December 2023, APHIS-BRS virtually attended the Animal Biotech event being held in Brussels. Participants learned regulatory perspective from US, EU, UK, and Argentina as well as practical considerations from industry perspective.

III. Developments in New Breeding Techniques (NBT)

Updates for the United States Department of Agriculture

Exemptions and Confirmation Requests. USDA-APHIS biotechnology regulations exempt certain modified plants that (1) are achievable through conventional breeding techniques and thus are unlikely to pose an increased plant pest risk compared to conventionally bred plants, or (2) have a plant-trait-mechanism of action combination that is the same as a plant that USDA-APHIS previously reviewed and determined to be unlikely to pose plant pest risk.

USDA-APHIS biotechnology regulations do not apply to plants that have been modified such that they contain either a single modification of a type listed below:

(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.

Additional, USDA-APHIS biotechnology regulations do not apply to plants with plant-trait-mechanism of action combinations that USDA-APHIS previously reviewed and found not subject to the regulations. USDA-APHIS continuously updates this list of exemptions as it completes Regulatory Status Reviews and remaining petitions from the legacy regulations.

Developers may voluntarily request USDA-APHIS confirm 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

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 harmonization, 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 (for countries) / or Developments related to biosafety activities (for BIAC and observer organisations)

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

i. Risk assessment

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

- AP141 EFSA-Q-2017-00271(cotton COT102) [10-05-2023]
- AP149 EFSA-Q-2018-00292 (maize Bt11 x MIR162 x MIR604 x MON89034 x 5307 x GA21) [18-04-2023]
- AP159 EFSA-Q-2019-00419 (maize DP-202216-6) [07-02-2024]
- AP163 EFSA-Q-2019-00807 (maize DP-023211-2) [29-11-2023]
- AP172 EFSA-Q-2020-00834 (maize DP-915635-4) [30-11-2023]
- AP182 EFSA-Q-2023-00106 (maize MON 94804) [13-03-2024]

- RX-27 EFSA-Q-2022-00845 (maize MON 89034 x 1507 x MON 88017 x 59122) [13-03-2024]
- RX-28 EFSA-Q-2022-00867 (maize MON810; food uses including pollen) [30-11-2023]
- RX-29 EFSA-Q-2022-00868 (maize MON89034×1507xNK603) [13-03-2024]

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

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 54 GM food and feed (including 47 subcombinations) and has renewed 7 authorisations.

New authorisations:

- Maize MON 87429
- Maize MON 95379
- Maize DP4114 x MON 89034 x MON 87411 x DAS-40278-9 and subcombinations
- Maize MON 87419
- Maize GA21 x T25
- Maize 89034 x1507 x MIR162 x NK603 x DAS-40278-9 and subcombinations
- Maize Bt11 x MIR162 x MIR604 x MON89034 x 5307 x GA21 and subcombinations

Renewals:

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

More applications for authorisations are in the pipeline.

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

Since previous meeting, EFSA has adopted a *Technical Note on the quality of DNA sequencing for the molecular characterisation of genetically modified plants* https://open.efsa.europa.eu/questions/EFSA-Q-2023-00886. All EFSA guidance documents applicable to GMOs can be accessed online.

5. Public engagement and outreach activities

EFSA public outreach:

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

- GMO Member States Network Meetings 8-9th June 2023, 13th December 2023 [discussions on NGT, GMM-NGT, GMA]
- Survey on new biotechnologies in microorganisms [07/03/2023 - 30/04/2023] https://www.efsa.europa.eu/en/call/survey-new-biotechnologies-microorganisms
- preDQ – a software tool for peptide binding prediction to HLA-DQ2 and HLA-DQ8 [10-07-2023] https://www.efsa.europa.eu/en/supporting/pub/en-8108
- Horizon scanning on microorganisms and their products obtained by new developments in biotechnology https://efsa.onlinelibrary.wiley.com/doi/10.2903/sp.efsa.2023.EN-8503
- Webinar on protein safety assessment in GMOs [19-12-2023] https://www.efsa.europa.eu/en/events/webinar-protein-safety-assessment-gmos
- Refinement of the Risk Assessment Methodology for Open Reading Frames in GMO Applications [16-01-2024] https://www.efsa.europa.eu/en/supporting/pub/en-8561
- Public Consultation with deadline 8th of April 2024 was launched on the 23rd of February on the "Draft Scientific Opinion on new developments in biotechnology applied to microorganisms" https://connect.efsa.europa.eu/RM/s/publicconsultation2/a0lTk000000C3VB/pc0848

European Commission public outreach:

Each Scientific opinion on GM products mentioned under point 1.1.i. is followed by a one-month public consultation. The results of the consultations are available here: https://ec.europa.eu/food/plant/gmo/public_consultations_en

For further public engagement and outreach activities related to new genomic techniques, see section 3 and the Commission's contribution to the *Enhanced Information Exchange on New Breeding Techniques (NGTs).*

3. Developments related to new breeding techniques (NBTs)

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

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

On 5 July 2023, the European Commission adopted a legislative proposal for a regulation on plants produced by certain new genomic techniques (NGTs) and their food and feed. The proposal is part of a package of proposals to ensure resilient and sustainable use of the EU's natural resources.

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

The main measures of the proposal include:

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

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

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

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

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

To become law, the Regulation must be adopted by the Member States in the Council of the European Union and the European Parliament, following the ordinary legislative procedure. In the meantime, the plants and products covered by this proposal continue to be regulated under the legislation on GMOs as described in the first paragraph.

2. Specific cases of application, assessment and decision

- On 17 January 2024, the European Food Safety Authority issued a favourable scientific opinion for placing on the market of genetically modified maize DP-915635 produced by NBT for food and feed uses (Application EFSA-GMO-NL-2020-172). The regulatory approval procedure is ongoing for this product. This event was created by site-specific integration using two sequential transformation steps to insert an integration site sequence, at a specific location of the maize genome using biolistic and a CRISPR-Cas9-mediated targeted insertion process, and to insert the intended expression cassettes in the maize genome using Agrobacterium-mediated transformation. It is a transgenic plant. More info on GM maize DP-915635 is available at https://bch.cbd.int/en/database/record?documentID=260914
- Application EFSA-GMO-NL-2019-162. GMM category 3) for the production of soy Leghemoglobin in Pichia *pastoris*. This application is currently under risk assessment. https://open.efsa.europa.eu/questions/EFSA-Q-2019-00651
- Application EFSA-GMO-DE-2019-157. GM specialty canola with a fatty acid profile containing the omega-3 LC-PUFAs EPA and DHA. This application is currently under risk assessment. https://open.efsa.europa.eu/questions/EFSA-Q-2019-00394

BIAC (BUSINESS AT OECD)

1. Developments related to biosafety activities

Reports and technical resources:

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

AgbioInvestor GM Monitor

In 2024, the AgbioInvestor GM Monitor, supported by CropLife International, was updated with 2023 planting areas and approvals. The AgbioInvestor GM Monitor provides information about GM Crop approvals and production in a comprehensive and searchable database. Users can easily find details such as which traits have been approved in which countries. The database also includes links to the relevant regulatory authorities. In addition, the entire database can be downloaded as an excel sheet for more advanced analysis. This new database complements other resources supported by CropLife International such asBioTradeStatus which provides market status information on commercialized GM crops developed by CropLife International member companies.

Updates to Other Databases

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

The Economic Impacts of a Mexican Ban on GM Corn Imports

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

Global Communications Resources

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

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

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

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

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 where they encouraged the adoption of decisions firmly grounded in science, allowing for the use of modern agricultural practices and tools in ways that support biodiversity conservation and sustainability. Parties adopted the Kunming-Montreal Global Biodiversity Framework that sets ambitious goalposts, and CropLife International looks forward to continuing to work with Parties to establish measurable goals around the Framework's targets.

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

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

Gene Drives

In response to the OECD Secretariat's call for written summaries of recent developments on gene drives, CropLife International highlights the extensive work undertaken in the risk assessment and risk management of living modified organisms (LMOs) containing engineered gene drives under the Cartagena Protocol on Biosafety. CropLife International has contributed to this work through providing an extensive analysis of general considerations of LMOs containing engineered gene drives that may be useful for risk assessment. We are pleased to see that the developments in this work are framed by a "problem formulation" approach, consistent with the OECD Consensus Document on Environmental Considerations for the Release of Transgenic plants published in 2023 to which CropLife International contributed its expertise for more than two decades. We also note that it is critical that approaches to environmental risk

assessment of LMOs containing engineered gene drives continue to apply the fundamental principles established in the Cartagena Protocol of case-by-case assessment, with a basis in sound and best available scientific evidence, also taking into account the relevant knowledge and experience gained in LMO risk assessment and best practices such as problem formulation.

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

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

FAO's World Food Forum Science & Innovation Forum

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

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

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

1. **Devex Climate+ Summit**: Collaborating with Devex, CropLife International engaged in a fireside chat to highlight key messages on sustainable agriculture, demonstrating the strength of its network and the value of industry programs like the Sustainable Pesticide Management Framework.

2. **World Soils Day**: Through collaboration with the International Fertilizer Association, CropLife International emphasized the role of technology in improving soil health during COP28's World Soils Day programming, contributing to the recognition of soil health in the UAE COP28 Declaration.

3. **Bilateral Meetings**: CropLife International held over 15 bilateral meetings with influential stakeholders and decision-makers, including representatives from the WTO, FAO, and various government bodies, facilitating dialogue on sustainable agriculture.

4. **Communications Outreach**: Leveraging social media and daily briefings, CropLife International kept stakeholders informed and engaged with over 100 social media posts, 65K impressions, and 1,500 engagements, ensuring broad participation in its COP28 activities.

5. **Partnering for On-Farm Solutions**: Hosting a UNFCCC side event with key partners, CropLife International showcased the role of its programs, like the Sustainable Pesticide Management Framework, in empowering farmers to combat pests and diseases sustainably amidst climate challenges.

Intellectual Property

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

3. Developments related to new breeding techniques (NBTs)

Recognition of Progress Related to Plant Breeding Innovation

The global seed industry represented by the International Seed Federation (ISF) and CropLife International maintains its science-based position that plant varieties developed through the latest plant breeding methods, such as genome editing, should not be differentially regulated if they are similar or indistinguishable from varieties that could have been produced through conventional plant breeding methods8. Further, we recommend that the processes used to determine whether products fall in or out of scope of genetically modified organism (GMO) regulations are transparent, time-efficient, and consider existing regulatory mechanisms for new plant varieties (such as, for example, plant variety registration, national seed laws, or general food safety laws). The adoption of common approaches across countries can be facilitated through alignment of definitions, 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.

Both organizations welcome the EU Commission's legislative proposal on NGT plants, note the European Parliament position supporting the proposal voted in February 2024 and await the adoption of an EU Council position so that the Trialogues can start leading to a new Regulation establishing an enabling and risk-proportionate path to EU markets for products developed using genome editing technology. We remain attentive to the discussions and will continue to engage in providing input in the process to achieve a truly enabling regulatory framework. We also welcome early decisions for locally developed genome-edited traits made under the genome editing guidelines from the Ministry of Agriculture and Rural Affairs (MARA) in China and continues to look forward to furthering dialogue to operationalize these guidelines for all developers. Furthermore, we acknowledge ongoing policy development regarding genome edited products in various countries, including Canada (CFIA), Costa Rica, the United Kingdom, Ethiopia, Ghana and, most recently, the US FDA since the last meeting of the working parties. We are also cognizant of ongoing discussions in Korea, Indonesia, Malaysia, Uruguay, Thailand, Singapore, and Switzerland. We recognize that there are on-going determinations for inclusion/exclusion from GMO regulatory oversight in more than a dozen countries for several products. It's imperative to maintain a focus on practical implementation of regulatory policy and guidance such that investment and development of new varieties using these technologies is not hindered.

The global seed industry recognizes the importance of timely information sharing around plant breeding tools, both at the international and national levels. We support initiatives that provide relevant information to governments, the value chain, and consumers, provided such efforts are both achievable by all users of genome editing in all jurisdictions and that information is not arbitrarily discriminatory toward certain plant

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

breeding approaches versus others. We further note that the content and appropriate systems to share such information are driven, in part, by local context (e.g. national laws) and believe that there is unlikely to be a global "one size fits all" solution but rather a collection of reliable information sources. CropLife International further explains its position on transparency in plant breeding in a position paper available on its website.

Global Communications Resources on Genome Editing

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

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

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

UNEP-CBD (SECRETARIAT OF THE CONVENTION ON BIOLOGICAL DIVERSITY)

1. DEVELOPMENTS RELATED TO BIOSAFETY ACTIVITIES

1.1 Programme of Work

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

- Informal Advisory Committee on the Biosafety Clearing-House (BCH) (scheduled to be held from 15-16 May 2023);
- Multidisciplinary Ad Hoc Technical Expert Group on Synthetic Biology (11-14 July 2023 and 29 January to 2 February 2024);
- Compliance Committee under the Cartagena Protocol on Biosafety (18th and 19th Meetings);
- 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;
- meeting of the Network of Laboratories for the Detection and Identification of Living Modified Organisms;
- Liaison Group on the Cartagena Protocol on Biosafety.

These meetings have all been convened and the outcomes are being prepared for consideration by Parties in further processes.

1.2 Synthetic Biology – key outcomes

In decision 15/31, the Conference of the Parties (COP) established a process for broad and regular horizon scanning, monitoring and assessment of the most recent developments in synthetic biology. A multidisciplinary Ad Hoc Technical Expert Group (AHTEG) on synthetic biology was established to undertake this process. Following a multidisciplinary-expert driven process, a prioritized list of seventeen (17) trends and issues in synthetic biology was identified. Further, of the 17 trends and issues in synthetic biology, the following five (5) were identified for assessment:

- Self-spreading vaccines for wildlife
- Self-limiting insect systems
- Development of engineered gene drives to control vector-borne diseases and invasive species
- Integration of artificial intelligence and machine learning

- Inequity in the participation of developing countries in the context of synthetic biology

The outcome of the horizon scanning, monitoring and assessment undertaken will be reviewed by the upcoming meeting of the Subsidiary Body on Scientific, Technical and Technological Advice.

1.3 Risk Assessment – key outcomes

In decision CP-10/10, the Conference of the Parties serving as a meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP) agreed to develop additional voluntary guidance materials to support case-by-case risk assessment of living modified organisms (LMOs) containing engineered gene drives in accordance with Annex III of the Cartagena Protocol. The COP-MOP decided that this material should have a special focus on engineered gene drive mosquitoes. The Ad Hoc Technical Expert Group (AHTEG) on risk assessment has completed its work.

The additional voluntary guidance materials to support case-by-case risk assessment of living modified organisms (LMOs) containing engineered gene drives will be reviewed by the upcoming meeting of the Subsidiary Body on Scientific, Technical and Technological Advice.

1.4 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 Organization 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*
115346	2nd Generation Friendly™ *Aedes aegypti*
101474	Dominant lethal *Aedes aegypti* mosquito
260490	Male-sterile *Anopheles coluzzii* mosquitoes
260489	Male-sterile *Anopheles gambiae* mosquitoes
105039	Female-specific Dominant Lethal Olive Fly
108045	Domestic goat modified to produce human lactoferrin
260325	Green fluorescent zebrafish
260324	Red fluorescent zebrafish
45406	Glofish
100309	Hybrid tilapia modified with growth hormone gene
103105	Pink Bollworm Modified for the Expression of a Fluorescent Marker
104725	AquAdvantage® Salmon
259122	Friendly™ Fall Armyworm

263132 GalSafe® pig

1.5 Upcoming meetings

- The 26th meeting of the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) of the Convention on Biological Diversity (CBD) will take place 13–18 May 2024. This meeting will consider three agenda items of relevance to this working Party:

  Agenda item 5: Synthetic biology.
  Agenda item 6. Risk assessment and risk management.
  Agenda item 7. Detection and identification of living modified organisms.

- The eleventh Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP-MOP 11) will take place in Columbia from 21 October to 01 November 2024. COP-MOP 11 will be held in parallel with the Conference of the Parties to the UN Convention on Biological Diversity (COP 16) and the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol (COP-MOP 5).

2. UPDATES REGARDING INTERNATIONAL ACTIVITIES

2.1 Global Workshop on Risk Assessment

The Secretariat of the Convention on Biological Diversity organized a global workshop under the theme “Advances in risk assessment – Twenty years of theory and practice”, in Montreal, Canada on 30 and 31 October 2023.

The objective of the workshop was to provide a platform for experts and stakeholders from around the world to come together and exchange knowledge, experiences, and best practices related to the risk assessment of LMOs. The workshop focused on enhancing understanding of regulatory frameworks, methodologies and decision-making processes surrounding LMO risk assessments, as well as exploring emerging challenges and potential solutions.

Ms. Sarah Davies with the Canadian Food Inspection Agency presented the OECD Environmental Considerations for Risk/Safety Assessment for the Release of Transgenic Plant consensus document.

A total of 43 participants from 25 countries and 18 organizations, attended the workshop in person. A report of the workshop will be made available in due course.

2.2 Joint Aarhus Convention/CBD Round table on public participation and access to information regarding LMOs

The roundtable was organized under the auspices of the UNECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention) and the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. The event aimed to build countries’ capacities through sharing knowledge, experiences and lessons learned in promoting public awareness, education, access to information, public participation and access to justice regarding LMOs/GMOs and to make suggestions for future action at the national, regional and international levels.

The meeting featured a training session on procedures and practice on access to justice related to LMOs/GMOs.

AFSI (AGRICULTURE & FOOD SYSTEMS INSTITUTE)

About the Agriculture & Food Systems Institute

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

1. Developments related to biosafety activities

Workshop Series on Biosafety for Department of Environment, Ministry of Environment, Forest and Climate Change, Bangladesh

AFSI, in partnership with the Department of Environment, Ministry of Environment, Forest and Climate Change, Government of Bangladesh, under the auspices of the South Asia Biosafety Program (SABP), conducted a workshop series titled "Origins of Biosafety Internationally, the Relevant Policies and Regulations in Bangladesh, and the Necessary Regulatory Process During Each Phase of Biotechnology Research, Development, and Release." The purpose of these training activities was to engage with experts at the Department of Environment in Bangladesh who are involved with the biosafety regulatory system. This program aimed to help them better understand their regulatory responsibility and how to best work with developers of genetically engineered (GE) organisms. Biosafety compliance while working with GE organisms was discussed throughout this series of workshops.

Thefirst workshop introduced the fundamentals of biosafety, with presentations on the history and context of biosafety, the development process for GE plants, regulatory responsibility, and biosafety obligations during GE plant development. The second workshop focused on the purpose, design, and conduct of studies used to inform safety assessments of foods and feeds derived from GE plants. The third workshop presented the structured approach to environmental risk assessment, beginning with a scoping process called problem formulation. The fourth workshop provided a platform for discussing the considerations that inform the pre-release and post-release regulation of GE plants. This two-day technical training program for risk assessors delivered in-depth technical information about handling GE plants in laboratories during research, transporting plant material to contained facilities such as greenhouses, and regulating and conducting confined field trials (CFTs). Through a series of presentations and exercises, participants gained a deep understanding of biosafety concepts associated with the handling of GE plants prior to and after release into the environment.

Seminars on Genetically Engineered Plants and Biosafety Regulation for Ukraine

AFSI worked with United States Department of Agriculture (USDA) Foreign Agricultural Service (FAS) and BRIDGES, an agricultural extension center in Kyiv, to co-organize two seminars in Kyiv, Ukraine, on September 19 and 22, 2023, with a total of 94 participants attending in person and international experts

joining virtually. Both seminars delivered an overview of the products of modern biotechnology to varying stakeholder groups in Ukraine, with the aim of providing a better understanding of genetic engineering and genome editing, the context for their regulation for agricultural use, the benefits of having a functional regulatory system in place, and the role regulatory frameworks play in addressing the challenges faced in agriculture. The talks also covered the science of genome editing, the global regulatory landscape, and approaches adopted by countries worldwide. The seminar included talks specific to the European Union that provided information on agricultural biotechnology regulations and ongoing discussions, at the time, on genome editing in the bloc.

Workshops on Non-target Organism Testing for Environmental Risk Assessment

AFSI implemented two workshops in 2023 on Non-target Organism (NTO) testing. The first workshop was supported by a grant from USDA FAS Emerging Markets Program (EMP). This was a 5-day technical training workshop organized from June 26-30, 2023, in Iowa, USA, in cooperation with the USDA Agricultural Research Service, Iowa State University, and Corteva Agriscience™. The purpose of this activity was to provide regulatory scientists and environmental risk assessors with an experiential learning opportunity in laboratory and field testing of NTOs. Using laboratory facilities provided by Iowa State University, the workshop participants gained experience setting up bioassays to assess the impacts of insect-resistant corn on corn earworm, the target pest, and on ladybird beetles, a beneficial non-target species. Participants also evaluated the bioassays, collected, and compiled their data, and received feedback on their conclusions. Participants were given the opportunity to review data generated by commercial laboratories, which are typically provided to government regulators in support of applications to authorize commercial planting of insect-resistant crops.

The second NTO workshop 'Risk Assessment for Novel Insect Resistance Technologies in Genetically Engineered Plants' supported by the Agricultural Biotechnology Stewardship Technical Committee, a consortium of Bt registrants was held September 14-15, 2023 in Washington DC, USA . This workshop enabled stakeholders, including risk assessors, product developers, and researchers, to discuss different aspects of NTO assessment, focusing primarily on risk characterization and extrapolating the experience with Bt molecules to novel molecules. Through a series of scientific presentations and case study discussions, participants exchanged ideas on risk assessment for newer and potentially novel insect-resistant genetically engineered plants and how it would best provide value to the community.

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 2023' for the APEC HLPDAB as part of the U.S.'s self-funded projects. We implemented three seminars, each of which was led by an APEC economy. This seminar series brought together policymakers, risk assessors, and scientists, with an objective to foster greater participation and enhance engagement in the APEC HLPDAB outside of the annual meeting. The seminar series was cosponsored by Australia, the Republic of Korea, Malaysia, the Republic of the Philippines, Singapore, and Thailand. As part of this series, the following virtual seminars were facilitated by AFSI:

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

economies to share experiences and discuss how genome editing can help improve the quality of crops and livestock.

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

The third seminar in this series led by the Republic of the Philippines titled 'Enabling Biotechnological Innovations and Policies in Agriculture – Promoting Food Availability and Security' was hosted on November 13, 2023. This seminar had 197 attendees from 15 economies and speakers from the Philippines shared their experiences fostering modern innovations in agriculture for crops, livestock, and fisheries in the country, as well as highlighted the importance of facilitative regulatory policies and science communication in advancing innovation.

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

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

Viticulture

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

3. Developments related to new breeding techniques (NBTs)

Genome Editing in Plants: Harnessing the Benefits for Bangladesh

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

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

4. Additional Information – AFSI Resources

Global Environmental Zones Explorer

AFSI's Global Environmental Zones (GEnZ) Explorer is a simple-to-use online tool that allows users to visualize agroclimatic zonations and their relationships to the locations of CFTs. For any of the 21 included crops, the tool can identify environments at the country, regional, or global level that are important for cultivation to help determine where to best locate CFTs and maximize data utility.

A paper on this resource titled "GEnZ Explorer: A Tool for Visualizing Agroclimate to Inform Research and Regulatory Risk Assessment" was published in *Transgenic Research* on June 6, 2023. The paper presented the use of the GEnZ Explorer as a helpful visualization tool that can inform data transportability along with three case studies that demonstrate how the GEnZ Explorer can contribute to rational decision-making through the use of data from previous CFTs to inform risk assessments in other countries.

eLearning courses

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

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

The following eLearning courses offered by AFSI are related to biosafety and biotechnology:

- *Genetic Variability in Crops*: This course discusses genetic variability in crops, providing a basic review of genetics and plant breeding, an overview of modern breeding technologies, and a discussion of how new plant cultivars are released.
- *Environmental Risk Assessment of Non-Target Organisms for GE Crops*: This course discusses when, why, and how environmental risk assessments for GE crops are informed by testing of non-target organisms.
- *Understanding Low Level Presence in Agricultural Biotechnology*: This course teaches what low level presence is and how associated environmental risks can be assessed.
- *Application of Problem Formulation to the Environmental Risk Assessment of Genetically Engineered Crops*: This course introduces the key concepts of problem formulation for the environmental risk assessment of genetically engineered crops.
- *Confined Field Trials of Genetically Engineered Plants*: This course provides a comprehensive discussion of risk management methods for confined field trials of genetically engineered plants and how those methods may be incorporated into a regulatory framework.
- *Genetic Engineering in Livestock Production*: This course covers advancements in genetic engineering in animals that have been demonstrated in laboratory settings and their application in livestock production. The course provides an overview of conventional livestock breeding as well as presents techniques that can be used to delete or alter existing genes or introduce new genetic sequences into livestock. The course also highlights obstacles in genetic improvement in animals and discusses opportunities for improved production for genetically engineered and gene edited livestock.

AUDA-NEPAD (AFRICAN BIOSAFETY NETWORK OF EXPERTISE)

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

Ethiopia

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

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

Kenya

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

Nigeria

Due to anticipated capacity challenges in the review of and decision-making on biosafety applications that may be submitted for GM stacked events, technical support was provided to the Nigeria Biosafety Management Agency (NBMA) in the review of an application for the commercial release of genetically modified Cowpea event 245F containing Cry2Ab gene conferring resistance to Maruca. The NBMA successfully reviewed and issued a permit on 27 April 2023.

Ghana

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

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

Rwanda

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

Zambia

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

Burkina Faso

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

A stakeholder consultation and review workshop was held on the guidelines for the determination of regulatory pathways for genome editing on 15 – 16 May 2023. There were 30 participants. The meeting resulted in an improved stakeholder understanding and buy-in. Consensus was thus achieved on key

provisions to be considered in the guidelines to ensure improved language and for the guidelines to reflect international best practices. Consequently, the guideline was validated.

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

International Activities

- AUDA-NEPAD participated in the 25th meeting of the Subsidiary Body on Scientific, Technical and Technological Advice that took place from 15–19 October 2023 in Nairobi, Kenya.
- ECOWAS Regulations: AUDA-NEPAD participated in and provided technical support for the regional workshop for the validation of the implementing regulations of the Community Regulation on Biosafety in the ECOWAS region in Ouagadougou, from 31 July to 4 August 2023.

Participation in OECD events

- Attended virtually the 2023 WP meetings of HROB and SNFF
- Participated in the development of the OECD Consensus Document on Considerations for Collaborative Work on the Safety Assessments of Foods and Feeds Derived from rDNA Plants, which was declassified in September 2023.
- Attended several conference calls pertaining to the development of Anopheles albimanus/ stephensi consensus documents. Nominated African experts that contribute to the development of the consensus documents.

Short Courses Organized in Partnership with MSU

- Food Safety Virtual Short Course at Michigan State University, July 23 –30, 2023.
- Agricultural Biotechnology and Biosafety Short Course at Michigan State University, August 5 to 18, 2023.

Annex. Obituary for Dr. Kenichi Hayashi

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

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

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

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

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

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

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

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