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Development in Delegations on Biosafety Issues, April 2021 – May 2022

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No. 71

Developments in Delegations on Biosafety Issues, April 2021 – May 2022

Environment Directorate

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Paris 2022

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

ABOUT THE OECD

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

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

This publication is available electronically, at no charge.

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

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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 36th WP-HROB meeting (18-20 May 2022). It aims at summarising relevant information on activities related to biosafety issues since the previous meeting (March 2021) at the international level, by collating individual contributions from OECD Members, partner countries and observer organisations participating in the work.

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

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DEVELOPMENTS IN DELEGATIONS ON BIOSAFETY ISSUES, April 2021-May 2022

ARGENTINA

1. New legislations in the regulatory framework

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

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

2. Events for confined field trails

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

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

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

Microorganism:

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

Animals:

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

3. Events for Commercial Approvals

Since last Meeting, genetically modified events were approved for commercial release in Argentina in 2021:

Crops:

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

HB4 Wheat:

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

Microorganisms:

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

4. New Breeding Techniques

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

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

5. Participation in International Activities

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

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

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

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

Other international activities held on 2021 and 2022

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

- Exhibition at the Chinese 4th Round Table (virtual) on Genome editing event, organised by the International Seed Federation (ISF), Chinese Seed Association and Chinese Seed Trade Association, held on June 28, 2021.
- Participation in "G20 OECD BNCT WORKSHOP: Bioeconomy in the G20 and OECD countries: sharing and comparing the existing national strategies and policies for co designing more effective Bioeconomy governance mechanisms and monitoring systems", held on July 16, 2021.
- Representation at the "Third meeting of the Open-ended Working Group on the post-2020 global framework for biological diversity", organised by the Secretariat of the Convention on Biological Diversity (CBD), Aug 8 to 3, 2021.
- Representation at the virtual Intersessional Meeting of Global Low Level Presence Initiative (GLI), held Nov. 11, 2021.
- Video Conference and multilateral meeting between South Africa, Argentina, USA and Brazil, in relation to the change in South African regulations in relation to NBT, held on December 3, 2021.
- Representation at IICA Virtual Sessions on Biotechnology and Biosafety of the Convention on Biological Diversity and preliminary sessions of the Cartagena Protocol.
- Active participation in WTO SPS Working Group on Approval Procedures.
- Part of the team which organise the International Workshops Series on Regulatory Approaches for Animal Biotechnology, organised by USDA-IICA.
- Participation and contribution to the Ad hoc group for the NBT Project Proposal to the OECD WP-HROB/WP-SNFF.
- Representation at the OECD Working Party for the Safety of Novel Foods and Feeds.
- Representation at OECD Ad Hoc Group "Safe by Design" in Biotechnology.
- Interventions in specialised intergovernmental and multilateral high-level meetings to discuss the negotiation of the SPS chapter and on Biotechnology and LLP in the MERCOSUR - CANADA Agreement.

6. Communication and education

2021

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

2022

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

7. Products derived from agriculture

7.1 Biomaterials and Biobased materials

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

In this context, “biomaterials” or “biobased materials” appear, understood as those obtained in their greatest proportion from renewable raw materials of agro-industrial origin, as substitutes for products made with conventional materials from polluting industrial processes and non-degradable materials. Within the range of biomaterials, some specific categories can be identified: biopolymers and bioplastics (biobased plastics or biopolymers made from starch); biocomposites (or composite materials formed by a matrix and natural fibres); biosurfactants (such as bio-based detergents, bio-based cleaning products); cellulose; cultivated materials (or biofabrication).

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

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

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

7.2 Bio-inputs

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

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

7.3 Argentine Bioproducts Seal

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

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

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

AUSTRALIA

1. 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. <u>Risk assessment/regulatory decisions</u>

ENVIRONMENTAL RELEASE APPROVALS.

GMO REGISTER (UNDER ASSESSMENT)

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

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

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

LICENCES FOR ENVIRONMENTAL RELEASE since March 2021 *(at 29 April 2022)*

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

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

Commercial release approvals – GM plants

Two (2) GM plant commercial release approvals:

- GM **canola** (*Brassica napus*) – herbicide tolerance (glufosinate ammonium, glyphosate) and hybrid breeding system (RF3 × MS11 and RF3 × MS11 × MON88302) (DIR 178)
- GM **canola** (*Brassica napus*) – herbicide tolerance (glufosinate ammonium) and hybrid breeding system (MS11 line) (DIR 175)

Commercial release approvals – GMO therapeutics

One (1) GMO human therapeutic commercial release approval (note that approvals from the Therapeutic Goods Administration are also required):

- **Vaccine against COVID-19** (Ad26.COV.S), GMO is a replication defective human adenovirus expressing SARS-COV-2 spike protein (DIR 182)

Field Trial approvals - 'limited and controlled' releases

One new field trial was approved since March 2021:

- **Wheat** (*Triticum aestivum* L.) and **barley** (*Hordeum vulgare* L.) genetically modified for yield enhancement and improved abiotic stress tolerance (DIR 186)

Clinical Trials approvals - 'limited and controlled' releases

Four (4) clinical trials with live GMOs:

- **Vaccine against whooping cough** – GMO is an attenuated strain of *Bordetella pertussis* that would be inhaled as a vaccine to prevent whooping cough (DIR 185)
- **Vaccine against COVID 19 –** GMO (SC-Ad6-1) is replication defective human adenovirus expressing SARS-COV-2 spike protein (DIR 184)
- GM ***Escherichia coli*** to reduce antibiotic resistance in patients – GMO is *Escherichia coli* carrying plasmids that when transferred to gut bacteria are designed to restore sensitivity to antibiotics (DIR 183)
- **Cystic fibrosis treatment** – GMO is a replication defective *Herpes simplex virus* expressing the human cystic fibrosis transmembrane conductance regulator (CFTR) gene (DIR 181)

APPLICATIONS UNDER ASSESSMENT *(at 29 April 2022)*

Commercial release GM plants

Two applications for commercial release of GM plants are currently under assessment:

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

Commercial release GMO therapeutics

As of 29 April 2022, there are no applications for commercial release of human GMO therapeutics under assessment.

Field trials of GM plants

Two applications for limited and controlled release of GM plants under assessment:

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

Clinical trials of GMO therapeutics

As of 29 April 2022, there are no applications for human clinical trials of GMO therapeutics under assessment.

Risk assessment guidance documents

A revision of OGTR's biology document on **barley** (*Hordeum vulgare* L.) was published in November 2021. OGTR Biology documents are modelled on the OECD concept and are available at: https://www.ogtr.gov.au/resources

Modernisation of application processes – online forms

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

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

AMENDMENTS TO LEGISLATION

No changes have been made to Australia's biosafety legislation, the *Gene Technology Act 2000* (GT Act) and Gene Technology Regulations 2001 (GT Regulations), since the 35th WPHROB meeting in March 2021. 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

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 on behalf of the Gene Technology Ministers Meeting (comprised of all ministers from Australian jurisdictions).

An updated **Action Plan 2020-23** was published in June 2021. A **Decision Regulatory Impact Statement (DRIS) – Modernising and future-proofing the National Gene Technology Scheme** was endorsed by the Gene Technology Ministerial Meeting in July 2021. The DRIS recommended adoption of a risk tiering model for updating the scheme – dealings with GMOs would be classified into three authorisation pathways based on their indicative risk. Details about the policy Review and its implementation are available at: https://www.genetechnology.gov.au/reviews-and-consultations/past/2017-third-review

GMO Herbicide Tolerance Trait Review report

In January 2022, OGTR published a report '**Genetically Modified Organism Herbicide Tolerance Trait Review**'. OGTR commissioned the report to provide advice on GM crops containing multiple herbicide tolerance traits, impacts on herbicide use, and herbicide resistance management issues in Australia. The report highlighted the importance of maintaining regulatory independence, public transparency and a science-based risk management approach and suggested broadening the role of existing strategic expert stewardship groups. The report is available at: https://www.ogtr.gov.au/news/announcement/release-genetically-modified-organism-herbicide-tolerance-trait-review

3. Risk management activities

OGTR continued to undertake monitoring and compliance activities throughout 2021-22. However, due to the COVID-19 pandemic and border restrictions across Australian states and territories, there was reduced ability to undertake 'on site' inspections. Significant effort was therefore put into 'desk top' reviews and regular communication with regulated stakeholders. Details of OGTR monitoring activities are published in OGTR Annual Reports https://www.ogtr.gov.au/resources/publications/operations-gene-technology-regulator-annual-report-2020-21 .

4. Public engagement and outreach activities

Fact sheets

OGTR publishes Fact Sheets to provide information to the public on operation of the regulatory scheme. Many Fact Sheets were revised in concert with the launch of a new website in September 2021. OGTR Fact Sheets are available at: https://www.ogtr.gov.au/resources

Community Attitudes Survey 2021

Results of the most recent survey of attitudes to biotechnology were published in November 2021. Support for medical applications remained high and positive views of agricultural biotechnology increased slightly. The report is available at: https://www.ogtr.gov.au/resources/publications/community-attitudes-2021-report

The reports for the 2015, 2017 and 2019 Community Attitudes Surveys are available at: https://www.ogtr.gov.au/resources/collections/community-attitudes-gene-technology-reports

2. Updates regarding international activities

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

OGTR participated in a number of online forums and conferences since March 2021, including:

- Biotechnology Regulators Virtual Meeting with overseas regulators including USA, Canada, EU, UK, Argentina, Brazil and South Africa, 13–14 April 2021
- Agriculture and Food Systems Institute webinar: 'Gene Edited Plants: Context and Communication for Plant Breeding Innovation', 22 April 2021
- Online meetings with African countries on stacking of GM traits in plants, 12 July 2021
- ASEAN GMF Testing Network Gene Editing Workshop, 13 July 2021
- Convention on Biological Diversity meeting: Post-2020 Global Biodiversity Framework, 30 July 2021,
- APEC High Level Policy Dialogue on Agricultural Biotechnology plenary, 3 August 2021
- Asia-Pacific Association of Agricultural Research Institutions webinar on enabling policies for genome editing in agriculture, 18 August 2021
- International Service for the Acquisition of Agri-Biotech Applications (ISAAA) virtual workshop on science and opportunities of animal biotechnology for food and agriculture, 31 August to 1 September 2021
- Presentation to the Genetic Modification Advisory Committee of Malaysia, 1 September 2021
- Global Low-Level Presence Initiative intersessional meeting, 15 November 2021
- presentation at the International Cell and Gene Therapy ANZ Regional Meeting, 24-25 February 2022
- Global Low-Level Presence Initiative meeting, 24 March 2022.

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.

Some scientific articles summarising the regulation of genome editing have incorrectly indicated that all gene edited organisms are excluded from regulation as GMOs in Australia. As with any legislation, determining what regulatory requirements apply is best achieved by reference to the provisions of the regulations.

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

New Breeding Techniques and food

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

In October – December 2021, FSANZ consulted on a proposal (P1055 Definitions for gene technology and new breeding techniques) to amend the definitions for 'food produced using gene technology' and 'gene technology' in the Australia New Zealand Food Standards Code (the Code). FSANZ invited comment on its proposed approach to:

- revise and expand the process-based definition for 'gene technology' to capture all methods for genetic modification other than conventional breeding; and
- revise the definition for 'food produced using gene technology' to include specific product-based criteria for excluding certain foods from pre-market safety assessment and approval as GM food. Foods that do not meet all relevant exclusion criteria would still require an application to FSANZ.

Information about the proposal and the review is available at:
https://www.foodstandards.gov.au/code/proposals/Pages/p1055-definitions-for-gene-technology-and-new-breeding-techniques.aspx

4. Additional Information

Reappointment of the Gene Technology Regulator

The Gene Technology Regulator Dr Raj Bhula was reappointed in July 2021 for a further five year term (2021-2026) in the role.

20th Anniversary of OGTR

The *Gene Technology Act 2000* and OGTR commenced on 21 June 2001 and a number of retrospective reports were published in 2021 to mark 20 years of the Australian regulatory system:

Retrospective Report 1 – Overview of the Scheme https://www.ogtr.gov.au/resources/publications/retrospective-report-overview-scheme

Retrospective Report 2 – Changing research landscape https://www.ogtr.gov.au/resources/publications/retrospective-report-changing-research-landscape

Retrospective Report 3 – Public views, communication and regulation https://www.ogtr.gov.au/sites/default/files/files/2021-06/retrospective_report_3.pdf

Retrospective Report 4 – Regulatory adjustments made in response to 20 years of innovation in gene technology https://www.ogtr.gov.au/sites/default/files/files/2021-06/retrospective_report_4.pdf

New OGTR website

A new OGTR website was commenced in September 2021. The main url remains www.ogtr.gov.au The updated website has a new organisation and revised content.

AUSTRIA

1. Developments related to implementation of the Austrian national biosafety framework

1. Risk assessment/regulatory decisions

During the current reporting period (March 2021 – May 2022) 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

During the current reporting period (March 2021 – May 2022) the Austrian Gene Technology Act was amended to implement Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain. The provisions introduced with Regulation (EU) 2019/1381 at the EU level concern the use of standard data formats used for applications in the authorisation process for environmental releases of GMOs and for the placing on the market of products consisting of or containing GMOs. Also the new provisions concerning the confidentiality of information obtained as part of the notifications which were introduced with Regulation (EU) 2019/1381 were transposed in the national Gene Technology Act.

3. Risk management measures

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

4. Research projects on biosafety; relevant publications

The following reports, scientific papers or other documents addressing issues related to biosafety were published (since March 2021)

Greiter A., Heissenberger A. (2021). Sozioökonomische Überlegungen gemäß Gentechnologie-Recht, Wien, 2021, Reports, Band 0779, ISBN: 978-3-99004-602-9

Heissenberger A., Greiter A. (2021). Genome Editing – Endbericht Begriffsdefinition und offene Fragen aus Umweltsicht. Wien, 2021, Reports, Band 0778, ISBN: 978-3-99004-601-2

Pfeifer, K., Frieß, J.L., Giese, B. (2022). Insect allies—Assessment of a viral approach to plant genome editing. Integr Environ Assess Manag. https://doi.org/10.1002/ieam.4577

Bauer, A., Bogner, A. & Fuchs, D. (2021) Rethinking societal engagement under the heading of Responsible Research and Innovation: (novel) requirements and challenges, Journal of Responsible Innovation, 8:3, 342-363, DOI: 10.1080/23299460.2021.1909812

Pavlicek, A.; Part, F.; Gressler, S.; Rose, G.; Gazsó, A.; Ehmoser, E.-K.; Huber-Humer, M. (2021). Testing the Applicability of the Safe-by-Design Concept: A Theoretical Case Study Using Polymer Nanoclay Composites for Coffee Capsules. Sustainability 13, 13951. https://doi.org/10.3390/su132413951

2. Updates regarding international activities:

- Environment Agency Austria coordinates the Austrian activities for implementation of the Cartagena Protocol on Biosafety and preparations for the rescheduled and 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 10).
- 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:**

Austria is following up the study conducted by the European Commission concerning the status of applications of new genomic techniques (NGT-products) which was published on April 29th 2021, taking into account the the Inception Impact Assessment of September 2021 and the High-Level Event held by the European Commission in November 2021 discussing the conclusions from the EC study. The Austrian competent authorities and national institutions involved in risk assessment and management of GM products are working on a coordinated response to a consultation by the European Commission on the forthcoming Impact Assessment opened on April 29th 2022.

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

To date, Austria did not receive any applications for authorisation of an NGT-product which is subject to the EU GMO regulations according to the ruling by the European Court of Justice (Case C-528/16). If any NGT-applications are submitted in the future, the current GMO authorisation procedure and labelling requirements according to the Austrian Gene Technology Act will apply for these products.

3. **Other national activities:**

The activities initiated by the authorities to involve national stakeholders in discussions on and in preparation of a national position towards a policy on NGT applications are pursued. A symposium for national and European stakeholders addressing NGT-related issues of risk assessment, consumer choice and sustainability considerations for NGT applications will be held in Vienna on June 21st 2022.

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 March 2021):

Eckerstorfer, M.F.; Grabowski, M.; Lener, M.; Engelhard, M.; Simon, S.; Dolezel, M.; Heissenberger, A.; Lüthi, C. (2021). Biosafety of Genome Editing Applications in Plant Breeding: Considerations for a Focused Case-Specific Risk Assessment in the EU. BioTech 10, 10. doi. https://doi.org/10.3390/biotech10030010

Ribarits A, Stepanek W, Hochegger R, Narendja F, Prat N, Eckerstorfer, M., Wögerbauer M. (2022). Analyse von Nachweismethoden für genomeditierte und klassische GV-Pflanzen. BfN Schriften 622, ISBN: 978-3-89624-383-6, DOI: 10.19217/skr622

BELGIUM

1. Developments related to implementation of national biosafety framework

1. 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 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/content/field-trials-gm-plants-database). Currently, a field trial with GM maize and a field trial with GM poplar are ongoing, and three new field trials with maize modified by CRISPR-Cas have been approved.

Field trials (5) approved and ongoing since March 2021

- Field trial with maize modified for its growth characteristics, as the result of the expression of transcriptional co-activator that is involved in the regulation of cell proliferation (B/BE/20/V1)
- Field trial with poplars with a modified wood composition as the result of the downregulation of an enzyme involved in the synthesis of lignin (B/BE/21/V1)
- Field trial evaluation of maize with increased resistance against DNA damage causing environmental stress (*B/BE/22/V1*)
- Field trial evaluation of maize with modified growth characteristics (reduced lignin) (*B/BE/22/V2*)
- Field trial evaluation of maize with modified growth characteristics (increased drought tolerance) (*B/BE/22/V3*)

Further, five clinical trials with GM micro-organisms for clinical purposes have been notified and five clinical trials with GM micro-organisms for clinical purposes have been approved under the framework of deliberate release since the last WG-HROB meeting (for more information, see: https://www.biosafety.be/content/clinical-trials-gmos-database).

Clinical trials (5) notified since March 2021

- Phase 1 Rift Valley Fever candidate vaccine trial (B/BE/21/BVW2)
- Phase 3 Duchenne Muscular Dystrophy gene therapy trial (B/BE/21/BVW5)
- Phase 1 solid tumor cancer therapy trial (B/BE/21/BVW7)
- Phase 3 X-linked Retinitis Pigmentosa gene therapy trial (B/BE/21/BVW8)
- Phase 2 Dengue Quadrivalent candidate vaccine trial (B/BE/21/BVW9)

Clinical trials (5) approved since March 2021

- Phase 3 Duchenne Muscular Dystrophy gene therapy trial (B/BE/20/BVW4)
- Phase 1 skin and lung cancer immunotherapy trial (B/BE/20/BVW5)
- Phase 1 & 2 fronto-temporal dementia gene therapy trial (B/BE/21/BVW3)
- Phase 1 colorectal cancer therapy trial (B/BE/21/BVW4)
- Phase 2 Hepatitis B candidate vaccine trial (B/BE/21/BVW6)

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

In 2019, the European Parliament and the Council adopted Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain (Transparency Regulation). From 27 March 2021 on, this Regulation has introduced changes to the procedures for approval of placing on the European market of GMOs as or in products, including for notifications that may be handed in in Belgium under the Directive 2001/18/EC.

2. Updates regarding international activities

Participation in/hosting international symposia/fora relating to biosafety

Belgium is a party to the CBD and to the Cartagena Protocol, and has actively participated in the meetings of the Subsidiary Bodies and the Open-Ended Working Group on the Post-2020 Global Biodiversity Framework.

3. Developments related to new breeding techniques (NBTs)

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

Prior to the ruling of the European Court of Justice (ECJ) of 25 July 2018, it was considered that gene edited plants to be released in the field should be excluded from the scope of the GMO legislation in the same way as plants developed through conventional mutagenesis techniques. Since the ECJ ruling, Belgium has aligned itself with the European position, which considers that organisms obtained through new mutagenesis techniques are subject to Directive 2001/18/EC on the deliberate release of GMOs in the environment. Notifications for field trials with crops modified through CRISPR mutagenesis have since 2018 been authorised in accordance with Part B of Directive 2001/18/EC.

As a follow-up of the ECJ ruling, a Council Decision (EU) 2019/1904 issued a study on the status of New Genomic Techniques in plants, animals and micro-organisms that was published in April 2021. Based on the outcome of the study the Commission published a draft policy initiative on plants obtained by targeted mutagenesis and cisgenesis, accompanied by an impact assessment. End of 2021, this document was submitted for public consultation to which some Belgian entities contributed. The Commission will publish a new impact assessment in the 2nd quarter of 2022 (which will again be open for public consultation).

2. Specific cases of application, assessment and decision

Three new field trials with genome-edited plants were notified and authorised since the last WP meeting (see info above in point 1).

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

Belgium supported the following activities:

- COST Action CA18111 “PlantEd” - Genome editing in plants - a technology with transformative potential (2019 – 2023): Several Belgian institutions (including Sciensano) are contributing to this European project (EU

Framework Programme Horizon 2020) that aims to bring together expertise from a wide range of disciplines to evaluate new genomic modification techniques in plants. It will help define future research priorities by stimulating transnational and transdisciplinary collaborations.

4. Any other information related to NBTs.

Belgian scientists were involved in the following publication:

Sturme et al. (2022). Occurrence and Nature of Off-Target Modifications by CRISPR-Cas Genome Editing in Plants. ACS Agricultural Science & Technology, https://doi.org/10.1021/acsagscitech.1c00270.

BRAZIL

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

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

GM Plants:

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

GM microorganism *Saccharomyces cerevisae*:

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

Vaccines and gene therapy:

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

GM animals:

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

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

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

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

2. Updates regarding international activities

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

3. Developments related to new breeding techniques (NBTs)

The Normative Resolution No 16 (NR16) was published on January 15th 2018 and has the technical requirements for a consultation process, evaluated in case-by-case base by CTNBio on the use of Precision Breeding Innovative Techniques, or also known as New Breeding Technologies. There were 13 consultations in 2021. The dsRNA would be used to silence genes in *Spodoptera frugiperda* and *Helicoverpa armigera*, insects that attack cultivated crops; four microorganism lines of *Saccharomyces cerevisiae*, bull semen with increased muscle mass by gene edition; RAW 264.7 cell line, one microorganism lines of *Bacillus thuringiensis* 4Q7 strain, one cimatec HDT vaccine, one ALS herbicide tolerant soybean, active ingredient for nematode control BCS-DF76745 with proteins from two species of genus *Bacillus*, angus for genome edition for slick, and sugar cane modified with the CRISPR/Cas9 technique were not considered to fall under the scope of the Law 11.105/2005 that regulates genetically modified organisms in Brazil.

4. Additional Information

GMO Inspections

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

GMO Research

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

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

CANADA

1. CANADIAN FOOD INSPECTION AGENCY AND HEALTH CANADA (NOVEL FOODS)

- **Confined Field Trials of Plants with Novel Traits**

The Canadian Food Inspection Agency authorised 271 confined field trials for plants with novel traits in the 2021 growing season that were conducted at 30 locations across Canada. We saw an increased number of field trials for canola, soybean and camelina. Other trials conducted included barley, white mustard, poppy and poplar. We saw no trials for wheat, borage or sugar beet. The CFIA is still receiving applications for confined field trials for the 2022 growing season and expects to receive a similar number of applications and crop types as in 2021 trials.

- **Authorisations of Novel Plant Products**

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

The Canadian Food Inspection Agency also prepares "decision documents" whenever regulatory decisions are made about novel plant products, intended for unconfined environmental release and/or livestock feed use. They explain what information was reviewed to make the decision, and why certain conclusions were reached. They provide background information, describe the introduced traits, and discuss the results of the assessment and evaluation of the potential environmental and livestock feed use impacts. Decision documents are available to the public 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 March 2021, Canada has authorised the following plants with novel traits for release into the environment as well as use in livestock feed and food in Canada:

- Bayer CropScience Inc. (formerly Monsanto Canada ULC) canola event MON94100 which has been genetically modified to be tolerant of the herbicide dicamba.
- BASF Canada Inc. soybean event GMB151 which was genetically modified to be nematode resistant and herbicide tolerant.
- Bioceres Crop Solutions Corp. (formerly Verdeca LLC) soybean event IND-00410-5 which was genetically modified for increased yield, drought tolerance, and tolerance to glufosinate ammonium herbicides.
- Pioneer Hi-Bred Canada Company corn event DP23211 which has been genetically modified for insect resistance and tolerant of glufosinate ammonium herbicides.
- Bayer CropScience Inc. corn event MON95379 which has been genetically modified for insect resistance.
- Pioneer Hi-Bred Canada Company corn event DP915635 which has been genetically modified to be insect resistant and tolerant to glufosinate ammonium herbicides.

- **Applications Currently Under Review**

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

Since March 2021, Canada has not received any new Notices of Submission. One additional plant product are currently undergoing feed, food and/or environmental assessments, however the developers opted not to subscribe to the voluntary Notices of Submission process.

- **Genome Editing Techniques**

In Canada, the approach to regulatory oversight of plants products of biotechnology is under review. Canada's regulatory approach is based on the characteristics of the product and not the means of development. Novel products subject to Part V of the *Seeds Regulations*, the *Feed Regulations*, and/or the *Food and Drug Regulations* may be the result of mutagenesis, recombinant DNA techniques or other methods of plant breeding such as gene/genome editing techniques. Canada views gene editing techniques as additional tools for plant breeders. As with conventional breeding and recombinant DNA (rDNA) techniques, gene editing techniques have the potential to develop both novel and non-novel products. In Canada, only those gene edited products that are deemed novel require a pre-market assessment. By allowing for risk-appropriate decision making and focusing on outcomes, Canada's regulatory system can accommodate new developments in biotechnology techniques.

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

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

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

- **New Substances Notifications**

Since March 2021, 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, 17 were for various environmental or industrial uses, while 25 were for food and drugs uses (including genetic therapies and vaccines) of which 16 were for cell and gene therapies, 6 for vaccines and 3 for COVID-19 vaccines. The types of organisms that were assessed ranged from bacteria, to virus, virus-like particles, animal cells, fungi and whole organisms.

The Significant New Activity (SNAc) provisions of CEPA were applied to four living organisms: *Bacillus amyloliquefaciens* subspecies *amyloliquefaciens* strain W215 and P6T48, as well as *Bacillus subtilis* strain HF2 and 43B6r. As such, reporting obligations apply for any use of these living organisms other than their use for maintaining grease traps in commercial establishments or drains that are connected to a municipal wastewater system; for cleaning floors in commercial establishments; for controlling odours in dumpsters and trash compactors; or for treating water in any artificial environment, such as aquariums and ornamental ponds.

- **Risk Assessment Summaries**

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

- **Regulatory Reviews**

The Government of Canada is involved in several initiatives to modernise and align our regulatory oversight for products of biotechnology, such as animals derived from Somatic Cell Nuclear Transfer cloning, gene editing, and gene drives. The aim is to promote regulations that are more agile, transparent, and responsive. The NS Program is undertaking a comprehensive review of the *New Substances Notification Regulations (Organisms)* (NSNR (O)), which have not been updated in the last 20 years. The Program is pursuing pre-consultations with other government departments and consultations with stakeholders in Spring/Summer 2022.

- **DRAFT International Scan of Regulations Pertaining to Micro-organisms used in Biotechnology Products**

The NSP has conducted an international scan of legislation and regulatory oversight mechanisms related to environmental assessment of micro-organisms used in biotechnology-derived products. The desired outcome is to

gain a broader understanding of how environmental assessment of micro-organisms is conducted in other countries and use this knowledge towards modernisation of policies and regulations (NSNR (O)) related to the CEPA assessment of micro-organisms.

- **Guidance Document for the Notification and Testing of New Substances: Organisms Used in Cell and Gene Therapy under Schedule 1 of the *New Substances Notification Regulations (Organisms)***

In December 2021, the NSP published the guidance to notifiers on addressing NSNR (O) information requirements for substances that are animate products of biotechnology used in cell or gene therapy and administered to human patients. This includes tailored guidance for human cell-based substances, non-replicating substances and replicating substances used in cell and gene therapy.

- **Voluntary Public Engagement Initiative**

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

- **Computational Tool to Support Environmental and Human Health Risk Assessment of Micro-organisms**

The Microbial Risk Assessment Framework used as the basis for the CEPA assessment of micro-organisms, is being revised based on an external review of domestic and international risk assessment approaches and methodologies. An excel-based computational tool developed to help shift towards a semi-qualitative-quantitative estimation of human health burden and environmental risk posed by the micro-organisms, is currently being validated.

- **Micro-algae Consensus Document**

The NSP in partnership with the U.S. EPA/OPPT has authored several sections in the Draft OECD Consensus Document on Microalgae. Canada and the U.S. have also evaluated the comments and feedback provided by Micro-organisms Sub Working Group members, The Netherlands, Germany, Australia, and Business at OECD (BIAC). The consensus document contains extensive text on *Chlorella sorokiniana* that was developed by the U.S. EPA/OPPT, which is being called the "*Chlorella* chapter". The *Chlorella* chapter serves as a model for the drafting of additional chapters on other microalgae species by other member countries. BIAC provided text on cyanobacteria, which has been incorporated into the document. The draft document will be discussed at the 36th WP-HROB meeting in May 2022.

3. AGRICULTURE AND AGRI-FOOD CANADA

- **Low Level Presence Update**

The Global Low Level Presence Initiative (GLI) is a group of 15 importing and exporting countries committed to working collaboratively to develop practical approaches to facilitate the management of Low Level Presence (LLP). Canada and the Philippines co-hosted the 8th meeting of the GLI virtually in March 2022. The event focused on trade facilitative approaches to the prevention and management of LLP; opportunities and examples of international regulatory collaboration and streamlining; a value chain panel discussion on LLP and current global challenges; and, an update on the various activities taking place in international organisations, including the OECD, on the subject of agricultural biotechnology.

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

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

authorisations; as well as key principles to data sharing and collaboration to facilitate the management of LLP. The GLI Secretariat is led by Agriculture and Agri-Food Canada and can be contacted at GLI-IMP@canada.ca.

COLOMBIA

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

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

Authorisations granted in 2021 by the Instituto Colombiano Agropecuario - ICA:

Unique identifier	Organism	Trait	Type of Use	Date of Approval	Decision
MON-Ø4Ø32-6	Soybean	Herbicide tolerance	Cultivation	8 April 2021	94973
MON-87427-7 x MON-89Ø34-3 x MON- ØØ81Ø-6 x SYN-IR162-4 x MON-87411-9 x MON-87419-8	Maize	Insect resistance Herbicide tolerance	Feed	8 April 2021	94974
MON-Ø4Ø32-6	Soybean	Herbicide tolerance	Cultivation	19 April 2021	95613
MON-Ø4Ø32-6	Soybean	Herbicide tolerance	Feed	19 April 2021	95614
MON-Ø4Ø32-6	Soybean	Herbicide tolerance	Cultivation	3 August 2021	102580
BCS-GM151-6	Soybean	Insect resistance Herbicide tolerance	Feed	3 August 2021	102581
DP-ØØ4114-3 x MON-89Ø34-3 x MON-87411-9 x DAS-4Ø278-9	Maize	Insect resistance Herbicide tolerance	Feed	3 August 2021	102582
MON-15985-7 x MON-88913-8	Cotton	Insect resistance Herbicide tolerance	Feed	3 August 2021	102583
NA	Rice	Transformed plants to be edited genetically	Confined trials in Lab.	3 August 2021	102584
DP- Ø23211-2	Maize	Insect resistance Herbicide tolerance	Feed	30 November 2021	113673
DP-915635-5	Maize	Insect resistance Herbicide tolerance	Feed	30 November 2021	113674

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

Unique identifier	Organism	Trait	Type of Use
MON-87427-7 X MON-89Ø34-3 X MON-ØØ81Ø-6 X SYN-IR162-4 X MON-87411-9 X MON-87419-8	Maize	Herbicide tolerance Insect resistance	Food
MON-87427-7 X MON-89Ø34-3 X DAS-Ø15Ø7-1 X MON-88Ø17-3 X DAS-59122-7	Maize	Herbicide tolerance Insect resistance	Food
MON-87427-7 X MON-89Ø34-3 X SYN-IR162-4 X MON-ØØ6Ø3-6	Maize	Herbicide tolerance Insect resistance	Food
BCS-GHØØ4-7 X BCS-GHØØ5-8 X SYN-IR1Ø2-7	Cotton	Herbicide tolerance Insect resistance	Food
MON-877Ø5-6 X MON-89788-1	Soybean	Herbicide tolerance	Food

		Modified Fatty Acid	
MON-877Ø8-9 X MON-89788-1	Soybean	Herbicide tolerance	Food
MON-87769-7 X MON-89788-1	Soybean	Herbicide tolerance Modified Fatty Acid	Food
MON-ØØ6Ø3-6 X ACS-ZMØØ3-2 X DAS4Ø278-9	Maize	Herbicide tolerance	Food
MON-89Ø34-3	Maize	Insect resistance	Food
MON-88913-8 X MON-15985-7	Cotton	Insect resistance	Food
MON 89Ø34-3 X MON-ØØ6Ø3-6	Maize	Herbicide tolerance Insect resistance	Food
MON-89788-1	Soybean	Herbicide tolerance	Food
MON-89Ø34-3 X DAS-Ø15Ø7-1 X MON-88Ø17-3 X DAS-59122-7	Maize	Herbicide tolerance Insect resistance	Food
DP-2Ø2216-6	Maize	Herbicide tolerance	Food
DP-Ø232111-2	Maize	Herbicide tolerance Insect resistance	Food
BCS-GM151-6	Soybean	Herbicide tolerance Insect resistance	Food
BCS-GHØØ5-8	Cotton	Herbicide tolerance Insect resistance	Food
BCS-GHØØ4-7	Cotton	Herbicide tolerance Insect resistance	Food
BCS-GHØØ2-5	Cotton		Food
MON- ØØ4114-3	Maize	Herbicide tolerance	Food
MON-ØØ4114-3 X MON-89Ø34-3 X MON-87411-9 X DAS-4Ø278-9	Maize	Herbicide tolerance Insect resistance	Food
MON-887Ø1-3	Cotton	Herbicide tolerance	Food
SYN-IR1Ø2-7	Cotton	Insect resistance	Food
SYN-IR162-4	Maize	Insect resistance	Food
SYN-E3272-5	maize	Modified Alpha Amylase	Food
SYN-BTØ11-1 X SYN-IR162-4 X SYN-IR6Ø4-5 X MON-ØØØ21-9	Maize	Herbicide tolerance Insect resistance	Food
SYN-BTØ11-1 X DAS-59122-7 X SYN-IR6Ø4-5 X DAS-Ø15Ø7-1 X MON-ØØØ21-9	Maize	Herbicide tolerance Insect resistance	Food
SYN-E3272-5 X SYN-BTØ11-1 X SYN-IR6Ø4-5 X DAS-Ø15Ø7-1 X SYN-Ø53Ø7-1 X MON-ØØØ21-9	Maize	Herbicide tolerance Insect resistance	Food
DAS444Ø6-6	Soybean	Herbicide tolerance	Food
DAS-59122-7	Maize	Herbicide tolerance Insect resistance	Food
ACS-GHØØ1-3	Cotton	Herbicide tolerance	Food
MON-8746Ø-4	Maize	Drought Stress	Food
MON-88Ø17-3	Maize	Herbicide tolerance	Food
MON-89Ø34-3 X MON-88Ø17-3	Maize	Herbicide tolerance Insect resistance	Food
MON-88Ø17-3 X MON-81Ø-6	Maize	Herbicide tolerance Insect resistance	Food

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

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

3. Risk management measures

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

a) Authorise the Colombian Corporation for Agricultural Research – AGROSAVIA, the import of between 1 and 50 seeds for each line that is part of the T2, T3 and T4 generations of the Nipponbare variety from rice plants transformed via *Agrobacterium tumefaciens* using the CRISPR/cas9 gene editing system for silencing the *SPDT* gene.
b) In laboratory and greenhouse under confined conditions, confirm the silencing and rule out the presence of the transgene (Cas9 or other elements of the transformation vector), which can be confirmed by PCR and Sanger sequence.
c) The terms for this authorisation corresponds to the duration of the tests according to the crop cycle (approximately six (6) years).
d) Assesments will be conducted by AGROSAVIA, at Km 14 Carretera Occidente via Bogotá – Mosquera Cundinamarca C.I. Tibaitatá, with the required measures to avoid, prevent, mitigate, correct and / or compensate for potential risks, including any emergency measures that arise. In the event where the environment is disturbed, all genetically modified material shall be destroyed immediately.
e) The decision to authorise the import and research trials in a confined environment with the proposed technology is made within the current regulatory framework, Law 740 of 2002, Decree 4525 of 2005 and ICA Resolution 91505 of 2021.

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

On the other hand, INVIMA has a national surveillance and monitoring annual plan for genetically approved maize, soy and wheat events for food for human consumption. In 2021, no unapproved events were detected and no additional actions were performing in this matter.

4. Public engagement and outreach activities

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

2. Updates regarding international activities

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

Virtual sessions for COP MOP preparation 2021: sessions I, II, III, IV, V, VI and VIII

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

2. Specific cases of use of OECD tools and information

As ICA, during 2021 we have used the BioTrack Database to consult approvals granted from other countries, Risk Assessments and Consensus Document of maíze, cotton and soybean. Additionally, ICA has been developing a virtual platform for LMO´s applications, and has required a review of the BioTrack database to reinforce our tool draft in search of the efficiency and ease of authorisation procedures.

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

3. Developments related to new breeding techniques (NBTs)

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

The Regulatory framework to NBTs was published in 2018 (Decision 29299), "*By which the procedure of applications before the ICA for an improved cultivar with innovation techniques in plant breeding through modern*

Biotechnology is established in order to determine if the cultivar corresponds to a Living Modified Organism or a conventional organism".

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

Specific cases of application, assessment, and decision

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

COSTA RICA

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

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

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

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

- Regulation of crops produced by modern biotechnology.
- Audit and surveillance of genetically modified crops.

Currently, the regulatory proposals are in the process of being reviewed by the Department of Rules and Regulations of the State Phytosanitary Service.

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

Likewise, during the last year, as part of the review process of the national biosafety framework, the Manual of internal organisation and operation of the National Technical Biosafety Commission was approved and published.

3. Risk management measures

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

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

2. Updates regarding international activities

1. Participation in international activities relating to biosafety

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

- Twenty-fourth meeting of the Subsidiary Body on Scientific, Technical and Technological Advice
- Third meeting of the Subsidiary Body on Implementation.
- Third meeting of the Open-ended Working Group on the Post-2020 Global Biodiversity Framework (Target 17 focused on Biosafety).
- Fifteenth meeting of the Conference of the Parties to the Convention on Biological Diversity (COP-15-PART1).
- Tenth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (CP-MOP-10-PART1).
- Third meeting of the Open-ended Working Group on the Post-2020 Global Biodiversity Framework (Target 17 focused on Biosafety) – Online.
- Third meeting of the Subsidiary Body on Implementation – Online.
- Twenty-fourth meeting of the Subsidiary Body on Scientific, Technical and Technological Advice – Online.

2. Specific cases of use of OECD tools and information

- Consensus Document on the Biology of Cotton (*Gossypium* spp.).
- Consensus Document on the Biology of Zea mays subsp. mays (Maize)

3. Developments related to new breeding techniques (NBTs)

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

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

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

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

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

CZECH REPUBLIC

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

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

Field trials: Only two small scale field trials were conducted in 2021 and will continue in 2022:

- 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);
- Three lines of spring barley producing peptide LL-37, research project of the Palacky University in Olomouc, the cultivation is carried out by the company Usovsko, region Olomouc. The area of the trial at the beginning

of the project was only 20 m^2 without buffer zones but it will increase. At the beginning of this year, an authorisation was issued for additional two lines of spring barley in this project.

The number of premises notified for **contained use** of GMOs has been increasing gradually, now it is over 120 research institutions, universities and companies use GMOs. Only 2 laboratories are now classified in BSL 3, the others are BSL 1 or 2.

Four **clinical trials** with medicinal products containing GM cells or viruses have been authorised since March 2021.

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

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

3. Risk management measures

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

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

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

5. Public engagement and outreach activities

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

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

2. Updates regarding international activities

The Czech Republic will hold the presidency of the Council of EU in the second half of 2022. The presidency represents EU and its Member States at international meetings.

Therefore, the Czech Republic takes active role in the preparatory process for the 15th Conference of the Parties to the Convention on Biological Diversity and 10th Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety that will take place in China in the second half of 2022.

3. Developments related to new breeding techniques (NBTs)

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

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

DENMARK

1. Developments related to implementation of national biosafety framework

The situation in Denmark regarding deliberate release of GMO's into the environment remains unchanged. No GM crops are cultivated and there has been no deliberate release of GMO's for field trials.

2. Developments related to new breeding techniques (NBTs)

Denmark takes part in the EU process for changing the EU regulation for GMO's for targeted mutagenesis and cisgenesis in plants. Denmark also support that the EU proceed to find a solution for genetically modified microorganisms (GMM).

3. Additional Information

Control measures in 2021 in Denmark

The GMO control of seeds in 2021 has focused on imports of Alfalfa (*Medicago sativa*), Danish production of Oilseed rape (*Brassica napus*) certified seed and Maize (*Zea mays*) seed. No GMO's have been detected.

FRANCE

[English version follows]

1. Developments related to implementation of national biosafety framework

1. **Risk assessment/regulatory decisions**

a) Mise sur le marché

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

Les évaluations suivantes ont été réalisées depuis mars 2021 :

Espèce	OGM	Avis rendus
Colza	73496	https://www.anses.fr/fr/system/files/BIOT2021SA0124.pdf
Soja	GMB151	https://www.anses.fr/fr/system/files/BIOT2021SA0125.pdf
Maïs	DP-915635-4	https://www.anses.fr/fr/system/files/BIOT2021SA0116.pdf http://www.hautconseildesbiotechnologies.fr/fr/avis/avis-relatif-a-demande-dautorisation-mise-sur-marche-mais-genetiquement-modifie-dp915635-a-fins
Maïs	MON95379	https://www.anses.fr/fr/system/files/BIOT2021SA0074.pdf
Colza	MON94100	https://www.anses.fr/fr/system/files/BIOT2021SA0062.pdf
Soja	DBN9004	https://www.anses.fr/fr/system/files/BIOT2021SA0050.pdf

Ces évaluations de risque sont utilisées par les autorités compétentes françaises pour :
- transmettre des commentaires à l'Autorité européenne de sécurité des aliments (EFSA), en charge de l'évaluation des dossiers au niveau européen, dans le cadre des consultations des États membres organisées par celle-ci ;
- définir les positions de vote de la France sur les projets de décision d'autorisation soumis par la Commission européenne aux États membres.

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 1500 dossiers d'utilisation d'OGM en milieu confiné sont examinés chaque année en France. Ce nombre devrait être amené à baisser significativement en 2022, avec la mise en œuvre de la simplification de la procédure applicable aux utilisations confinées d'OGM de risque nul ou négligeable (cf. infra).

d) Culture des OGM

Il n'y a pas de cultures commerciales d'OGM ni d'essais au champ d'OGM autorisés en France.

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

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

a) Réforme du dispositif national d'évaluation des biotechnologies

Jusqu'au 31 décembre 2021, le dispositif national d'évaluation des biotechnologies était composé :

- de l'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (Anses), qui était chargée d'évaluer les risques pour la santé humaine et animale liés à la consommation des OGM ;
- du Haut Conseil des biotechnologies (HCB), qui était chargé d'éclairer le Gouvernement sur toute question relative aux biotechnologies. Le HCB était composé d'un comité scientifique et d'un comité économique, éthique et social. Il était en particulier chargé d'évaluer les risques liés aux utilisations confinées d'OGM, les risques environnementaux liés à la dissémination des OGM, ainsi que d'analyser les questions économiques, éthiques et sociales liées aux biotechnologies.

Le HCB, créé en 2009, a rencontré des difficultés de fonctionnement interne récurrentes. Afin de consolider et pérenniser les missions d'expertise relatives aux biotechnologies, le Gouvernement a engagé une réorganisation de ce dispositif qui a consisté à transférer les missions du HCB à différentes instances déjà existantes.

Le nouveau dispositif, entré en vigueur le 1er janvier 2022, est le suivant :

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

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

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

Toutefois cette simplification ne s'applique pas aux essais cliniques de médicaments OGM.

c) Décision du Conseil d'État du 7 février 2020 sur la mutagénèse

En 2015, neuf associations ont déposé un recours au Conseil d'État sur les variétés tolérantes aux herbicides issues de mutagénèse demandant, notamment, l'abrogation de l'article D.531-2 du code de l'environnement en ce qu'il exempte les variétés obtenues par mutagénèse de la réglementation sur les organismes génétiquement modifiés (OGM).

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

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

En conséquence, le Conseil d'État a enjoint au Premier ministre de modifier la règlementation qui précise les techniques de mutagenèse exemptées de la réglementation relative aux OGM afin de les distinguer de celles qui,

conformément à son analyse, entrent dans le champ de cette réglementation.

Il enjoint également aux autorités compétentes d'identifier, au sein du catalogue commun des variétés des espèces de plantes agricoles, les variétés qui y auraient été inscrites sans que soit conduite l'évaluation à laquelle elles auraient dû être soumises compte tenu de la technique ayant permis de les obtenir et, s'il y a lieu, d'engager la procédure de retrait des variétés concernées.

D'autres injonctions du Conseil d'État portent sur l'encadrement et le suivi des variétés tolérantes aux herbicides (VTH).

Le Gouvernement a préparé un projet de décret et deux projets d'arrêté afin de répondre aux injonctions du Conseil d'État qui ont été notifiés à la Commission européenne en application de la directive (UE) 2015/1535. La Commission européenne, ainsi que cinq États membres de l'UE, ont émis des avis circonstanciés qui contestent la compatibilité juridique des projets de texte avec la législation de l'Union européenne.

En octobre 2020, le Conseil d'État a été saisi, par les organisations à l'origine du contentieux initial, d'un nouveau recours visant à obtenir l'exécution des injonctions de la décision du 7 février 2020.

Dans une nouvelle décision du 8 novembre 2021, le Conseil d'État note que deux approches s'opposent pour déterminer le statut de la mutagénèse aléatoire in vitro. Il a décidé de poser deux nouvelles questions préjudicielles à la CJUE sur les critères permettant de déterminer quelles sont les techniques de mutagénèse qui ont été traditionnellement utilisées et dont la sécurité est avérée depuis longtemps. (https://curia.europa.eu/juris/document/document.jsf?text=&docid=252564&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=3120403)

Les autorités françaises n'ont pas l'obligation d'adopter les projets de textes notifiés dans l'attente des réponses de la CJUE et d'une nouvelle décision du Conseil d'État.

3. Public engagement and outreach activities

Les projets de textes législatifs et réglementaires relatifs à la réforme de l'évaluation de biotechnologies et à la simplification de la procédure applicable aux utilisations confinées d'organismes génétiquement modifiés présentant un risque nul ou négligeable ont fait l'objet de consultations publiques.

4. Research projects on biosafety; relevant publications

Recherches sur la détection des OGM

Les laboratoires nationaux de référence pour la détection des OGM poursuivent les travaux de recherche sur la détection des OGM inconnus et des séquences ADN non-décrites par des techniques de séquençage, dans le prolongement des publications Boutigny, AL., Fioriti, F. & Rolland, M. Targeted MinION sequencing of transgenes. Sci Rep 10, 15144 (2020) https://doi.org/10.1038/s41598-020-71614-6) et Hurel et al. BMC Bioinformatics (2020) 21:284 - DUGMO: tool for the detection of unknown genetically modified organisms with high throughput sequencing data for pure bacterial samples - https://doi.org/10.1186/s12859-020-03611-5).

2. Developments related to new breeding techniques (NBTs)

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

Initiative de la Commission européenne sur les nouvelles techniques génomiques

La Commission européenne a publié le 29 avril 2021 une étude sur les nouvelles techniques génomiques. Elle a également annoncé une initiative politique pour les plantes issues de cisgénèse et de mutagénèse dirigée. Il s'agirait d'adapter les procédures d'autorisation et d'évaluation des risques ainsi que les exigences de traçabilité et d'étiquetage, tout en maintenant un haut niveau de protection de la santé et de l'environnement.

La Commission européenne a publié le 24 septembre 2021 une feuille de route relative à cette initiative. Une proposition législative pourrait être présentée pour le 2ème trimestre 2023.

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

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

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

Les recherches soutenues par ce PEPR aborderont les domaines suivants :

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

b) Détection

Les laboratoires nationaux de référence poursuivent les travaux d'évaluation et d'optimisation des techniques (génotypage SNP, PCR digitale, séquençage haut débit) qui pourraient être mises en œuvre pour la détection de mutations connues issues de NBT.

3. **Any other information related to NBTs**

Au niveau national, l'Office parlementaire des choix scientifiques et technologiques a organisé en mars 2021 une audition publique sur les nouvelles techniques de sélection végétale suivie de la publication d'un rapport. (http://www.senat.fr/fileadmin/Fichiers/Images/opecst/quatre_pages/OPECST_2021_0044_synthese_rapport_NBT.pdf)

Le comité scientifique du Haut conseil des biotechnologies a publié en décembre 2021 une synthèse sur la détection des produits issus des nouvelles technologies génomiques (NGT) appliquées aux plantes (http://www.hautconseildesbiotechnologies.fr/sites/www.hautconseildesbiotechnologies.fr/files/file_fields/2021/12/31/syntheseh cb-cs211126detectiondesproduitsissusdesngtappliqueesauxplantes.pdf)

Au niveau européen, la Commission européenne a organisé le 29 novembre 2021 un événement de haut niveau sur les nouvelles techniques génomiques, auquel le Ministre français de l'agriculture et de l'alimentation a participé.

(https://ec.europa.eu/info/events/new-genomic-techniques-way-forward-safe-and-sustainable-innovation-agri-food-sector-2021-nov-29_en)

[ENGLISH TRANSLATION]

1. Developments related to implementation of national biosafety framework

1. **Risk assessment/regulatory decisions**

a) Placing on the market

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

The following evaluations have been carried out since March 2021:

Species	GMO	Opinion issued
Oilseed rape	73496	https://www.anses.fr/fr/system/files/BIOT2021SA0124.pdf
Soybean	GMB151	https://www.anses.fr/fr/system/files/BIOT2021SA0125.pdf
Maize	DP-915635-4	https://www.anses.fr/fr/system/files/BIOT2021SA0116.pdf http://www.hautconseildesbiotechnologies.fr/fr/avis/avis-relatif-a-demande-dautorisation-mise-sur-marche-mais-genetiquement-modifie-dp915635-a-fins
Maize	MON95379	https://www.anses.fr/fr/system/files/BIOT2021SA0074.pdf
Oilseed rape	MON94100	https://www.anses.fr/fr/system/files/BIOT2021SA0062.pdf
Soybean	DBN9004	https://www.anses.fr/fr/system/files/BIOT2021SA0050.pdf

Decisions to authorise the placing on the market of GMOs are taken at European level.

b) Experimentation in the environment

No authorisation application for experimentation of GMOs in an open environment has been filed in France since the last meeting of the WG-HROB.

c) Contained use of GMOs (in laboratory)

Around 1,500 dossiers for contained use of GMOs are examined each year in France. This number should decrease significantly in 2022, with the implementation of the simplification of the procedure applicable to contained uses of GMOs of zero or negligible risk (see below).

d) GMO cultivation

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

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

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

a) Reform of the biotechnology national assessment system

Until December 31, 2021, the national biotechnology assessment system consisted of:

- the National Agency for Food, Environmental and Occupational Health and Safety (ANSES), which was responsible for assessing the risks to human and animal health associated with the consumption of GMOs ;
- the High Council for Biotechnology (HCB), which was responsible for informing the Government on any question relating to biotechnology. The HCB was composed of a scientific committee and an economic, ethical and social committee. In particular, it was responsible for assessing applications for contained use of GMOs and the environmental risks associated with the release of GMOs, as well as analysing the economic, ethical and social issues related to biotechnologies.

The HCB, created in 2009, has encountered recurring internal operational difficulties. In order to consolidate and perpetuate the missions of expertise relating to biotechnologies, the Government has undertaken a reorganisation of this system that consisted in transferring the missions of the HCB to various already existing bodies.

The new system, which entered into force on January 1, 2022, is as follows:

- ANSES, in addition to assessing the risks to human and animal health, is now responsible for the environmental risk assessment regarding marketing authorisation applications and the deliberate release of GMOs into the environment. It is also responsible for analysing the socio-economic aspects related to biotechnology. A dialogue committee with stakeholders will also be established.
- An Expert Committee attached to the Ministry of Research is responsible for evaluating applications relating to the contained use of GMOs.
- The Economic, Social and Environmental Council (CESE) is responsible for societal issues relating to biotechnologies.
- the National Consultative Ethics Committee (CCNE) will deal with ethical issues related to biotechnologies.

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

As of January 1, 2022, the procedure applicable to the contained use of class 1 GMOs (no or negligible risk) is simplified, in accordance with Directive 2009/41/EC on the contained use of genetically modified microorganisms. It is no longer necessary to declare these uses as long as they take place in a facility already approved by the Ministry of Research and a risk assessment record is available to the authorities.

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

c) Decision of the Conseil d'Etat of February 7, 2020 on mutagenesis

In 2015, nine organisations brought an action before the Conseil d'Etat on herbicide-tolerant varieties resulting from

mutagenesis requesting, in particular, the abrogation of article D.531-2 of the Environmental Code in that it exempts varieties obtained by mutagenesis from the legislation on genetically modified organisms (GMOs).

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

In its decision issued on February 7, 2020 following the judgment of the CJEU, the Conseil d'État concluded that in *vitro* random mutagenesis techniques subjecting plant cells to chemical or physical mutagens, as well as directed mutagenesis or genome editing, are not techniques that have conventionally been used in a number of applications and have a long safety record, as they appeared or have been mostly developed since directive 2001/18/EC was adopted. As a result, organisms obtained by these techniques must be submitted to the legislation on GMOs.

Consequently, the Conseil d'État enjoined the Prime Minister to modify the regulation that specify the mutagenesis techniques which are exempted from the legislation on GMOs in order to distinguish them from those which, according to its analysis, fall in the scope of this legislation.

It also enjoined competent authorities to identify, in the common catalogue of varieties of agricultural plant species, those that have been registered without the evaluation they should have undergone, given the technique they are issued from, and if necessary to engage in the withdrawal procedure for the varieties concerned.

Other injunctions from the Conseil d'Etat relate to the supervision and monitoring of herbicide tolerant varieties (HTV).

In order to respond to the injunctions of the Council of State, the Government has prepared a draft decree and two draft Ministrer's which have been notified to the European Commission pursuant to Directive (EU) 2015/1535.

The European Commission, as well as five EU Member States, have issued detailed opinions challenging the legal compatibility of the draft texts with European Union law. In October 2020, the Conseil d'Etat was seized, by the organisations at the origin of the initial litigation, of a new appeal aiming at obtaining the execution of the injunctions of the decision of February 7, 2020.

In a new decision of November 8, 2021, the Conseil d'Etat notes that two approaches are opposing to determine the status of random mutagenesis in vitro. It has decided to submit two new questions for a preliminary ruling to the CJEU on the criteria for determining which mutagenesis techniques have conventionally been used in a number of applications and have a long safety record.
(https://curia.europa.eu/juris/document/document.jsf?text=&docid=252564&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=3120403)

The French authorities are not obliged to adopt the notified draft texts pending the responses of the CJEU and a new decision of the Conseil d'Etat.

3. **Public engagement and outreach activities**

The draft legislative and regulatory texts relating to the reform of the evaluation of biotechnologies and the simplification of the procedure applicable to the contained uses of genetically modified organisms presenting no or negligible risk have been the subject of public consultations.

4. **Research projects on biosafety; relevant publications**

Research on GMO detection

The national reference laboratories for the detection of GMOs continue research work on the detection of unknown GMOs and undescribed DNA sequences by sequencing techniques, in the extension of the publications Boutigny, AL., Fioriti, F. & Rolland, M. Targeted MinION sequencing of transgenes. Sci Rep 10, 15144 (2020) https://doi.org/10.1038/s41598-020-71614-6) and Hurel et al. BMC Bioinformatics (2020) 21:284 - DUGMO: tool for the detection of unknown genetically modified organisms with highthroughput sequencing data for pure bacterial samples - https://doi.org/10.1186/s12859-020-03611-5).

2. Developments related to new breeding techniques (NBTs)

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

European Commission initiative on new genomic techniques

On April 29, 2021, the European Commission published a study on new genomic techniques. She also announced a policy initiative for plants derived from cisgenesis and site-directed mutagenesis. This would involve adapting authorisation and risk assessment procedures as well as traceability and labelling requirements, while maintaining a high level of health and environmental protection.

On September 24, 2021, the European Commission published a roadmap for this initiative. A legislative proposal could be presented for the 2nd quarter of 2023.

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

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

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

Research supported by this PEPR will address the following areas:

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

b) Detection

The national reference laboratories are continuing work to assess and optimize techniques (SNP genotyping, digital PCR, high-throughput sequencing) that could be implemented for the detection of known mutations resulting from NBT.

3. Any other information related to NBTs

At the national level, the Parliamentary Office for Scientific and Technological Choices organised a public hearing in March 2021 on new plant breeding techniques followed by the publication of a report.
(http://www.senat.fr/fileadmin/Fichiers/Images/opecst/quatre_pages/OPECST_2021_0044_synthese_rapport_NBT.pdf)

The scientific committee of the High Council for Biotechnologies published in December 2021 a summary on the detection of products resulting from new genomic technologies (NGT) applied to plants
(http://www.hautconseildesbiotechnologies.fr/sites/www.hautconseildesbiotechnologies.fr/files/file_fields/2021/12/31/syntheseh cb-cs211126detectiondesproduitsissusdesngtappliqueesauxplantes.pdf)

At European level, the European Commission organised a high-level event on new genomic techniques on November 29, 2021, in which the French Minister of Agriculture and Food participated.
(https://ec.europa.eu/info/events/new-genomic-techniques-way-forward-safe-and-sustainable-innovation-agri-food-sector-2021-nov-29_en)

GERMANY

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

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

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

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

The year 2021 was impacted by the pandemic situation by SARS-CoV-2. A large proportion of research activities reviewed by the ZKBS focussed on basic research and development of vaccines against this and other viruses.

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

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

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

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

3. Risk management measures

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

4. Research projects on biosafety; relevant publications

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

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

- **RNAi_safe - Safety of RNAi technology in plant protection: Method evaluation for estimating effectivity and potential impacts on target and off-target organisms**. The project pursues a methodological approach to answer open questions about the safe use of RNAi technology in plant protection. It aims at detecting and evaluating of potential exposure pathways and effects of dsRNA-based plant protection products in target organisms, crops and the extended food web. In addition, it serves to build expertise for the evaluation of methods for testing such plant protection products.

- **Detectability and traceability of GMO products**. The project develops proposals for improved traceability of commodity flows (including bulk goods) that may contain GMO, taking into account digital tools. In addition, necessary features of an international database for GMO will be elaborated, which should enable the implementation of the developed traceability strategies.
- Lentzos, F., Rybicki, E. P., Engelhard, M., Paterson, P., Sandholtz, W. A., Reeves, R. G. (2022): **Eroding norms over release of self-spreading viruses**. Science 375 (6576), S. 31–33. DOI: 10.1126/science.abj5593. The publication deals with the best practice of horizon scanning and highlights that the unsolved challenges during the release of GM viruses remain valid, so well-established norms must be kept.

2. Updates regarding international activities

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

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

- Online symposium "Modern Biotechnology in a Changing World: Health, Environment and Regulation" (6-7 Oct. 2021) hosted by the German BVL (https://www.bvl.bund.de/EN/Events/Archiv/Symposium2021/01_overview/overview_node.html)

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

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

3. Specific cases of use of OECD tools and information

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

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

3. Developments related to new breeding techniques (NBTs)

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

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

2. Specific cases of application, assessment and decision;

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

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

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

- **DETECT - RapsNMT.** The feasibility study analyses the discovery possibilities of multiple GMO plants and plant products created by NBT using state of the art technologies.
- **Bioinformatics analyses for the prediction of the reproducibility of whole genome sequencing data**. The reproducibility of NGS data production within a single laboratory and among different independent laboratories is analysed comparing short read amplicon sequencing, long read amplicon sequencing, and long read whole genome sequencing based on state of the art sequencing technologies using GMO created by NBTs and wild type plant material.
- **CHIC project** (EU funded). The project aims to develop and implement new CRISPR-based plant breeding techniques to alter the structure and biosynthetic pathways of chicory roots to improve both the quality and

storage of inulin and sesquiterpenes. Inulin can be used as a prebiotic food supplement and the sesquiterpenes as antimicrobial drugs.

- **CAPITALISE** (EU funded). The project has identified key physiological responses or properties that are promising candidate strategies to improve photosynthesis to meet EU crop breeding needs for increased yields. These are the 'MoVaPs', our Most Valuable Players: (1) tuning of the Calvin cycle, (2) the kinetics of photosynthetic responses to changes in irradiance, and (3) tuning leaf chlorophyll content. The project will specifically focus on barley, tomato and maize to identify the genetic resources needed to improve their photosynthetic properties and will develop and analyse scenarios for environmental and socio-economic impacts.
- **FGU - Genetic Engineering and the Environment.** The project, i. a. highlighted the need for a case-specific risk assessment of crop plants derived from SDN-1 applications considering characteristics of the product and the process to ensure a high level of protection of human and animal health and the environment
- **SeqApp - Continued development of the molecular characterisation of GMO**. With a focus on specific requirements of NBT products, methods for the molecular characterization of GMO are further developed in this project, considering state of the art analytics and databases.
- Ribarits, A., Eckerstorfer, M., Simon, S., Stepanek, W. (2021) **Genome-Edited Plants: Opportunities and Challenges for an Anticipatory Detection and Identification Framework**. Foods 10 (2), S. 430. DOI: 10.3390/foods10020430
  The project concludes that a database should be established that (a) lists, if possible, all classical and GE crops potentially on the global market and (b) collects sufficient information for their identification by laboratory-based methods.
- Wilhelm, R., Bartsch, D., Consmüller, N., de Witte, T., Ehlers, U., Feike, T., Gocht, Al., Hartung, F., Kahrmann, J., Kehlenbeck, H., Leggewie, G., Lehnert, H., Ordon, F., Sprink, T., et al. (2021): **Report on possible synergies of the use of new genomic techniques for sustainable agriculture** (in German). Berichte aus dem Julius Kühn-Institut, 215; DOI: 10.5073/20211215-094810
- Weidner, C., Edelmann, S., Moor, D., Lieske, K., Savini, C., Jacchia, S., Sacco, M. G., Mazzara, M., Lämke, J., Eckermann, K. N., Emons, H., Mankertz, J., Grohmann, L. (2022) **Assessment of the Real-Time PCR Method Claiming to be Specific for Detection and Quantification of the First Commercialised Genome-Edited Plant**. Food Analytical Methods. DOI: 10.1007/s12161-022-02237-y
- Qaim, M. (2020) **Role of New Plant Breeding Technologies for Food Security and Sustainable Agricultural Development**. Applied Economic Perspectives and Policy (42, Number 2, pp. 129–150), DOI: 10.1002/aepp.13044
- Hjort, C., Cole, J., Frébort, I. (2021): **European genome editing regulations: threats to the European bioeconomy and unfit for purpose**. EFB Bioeconomy Journal 1, S. 100001. DOI: 10.1016/j.bioeco.2021.100001
- Gao, H., Gadlage, M. J, H., Lafitte, R., Lenderts, B., Yang, M., Schroder, M., Farrell, J., Snopek, K., Peterson, D., Feigenbutz, L., Jones, S., St Clair, G., Rahe, M., Sanyour-Doyel, N., Peng, C., Wang, L., Young, J.K., Beatty, M., Dahlke, B., Hazebroek,J., Greene, T.W., Cigan, A.M., Chilcoat; N.D., Meeley, R.B. (2020) **Superior field performance of waxy corn engineered using CRISPR–Cas9**. Nature Biotechnology (38), pp. 579–581 DOI: 10.1038/s41587-020-0444-0

HUNGARY

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

Cultivation of GMOs: MON810 GM maize is still the only GM crop authorised for commercial cultivation in the EU. In the course of 2021 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 decision has been published in the course of 2021. This trial has been carried out in order to evaluate

the field safety and efficacy by serology in broilers after vaccination via the subcutaneous route with a herpes virus of turkey vaccine carrying a VP2 Gene of infectious bursal disease (Poulvac Procerta HVTIBD).

Contained use activities: In the course of 2021 one class 1, three class 2, and two class 4 premises received authorisations for contained use activities. Altogether two contained use activities in class 1, three contained use activities in class 2, and three contained use activities in class 4 had been authorised mainly with GMMs.

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

The Hungarian National Biodiversity Strategy for 2021-2030 has been developed in 2021 which also includes a biosafety target with the respective goals, measures and indicators. The strategy is yet to be approved.

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

3. Public engagement and outreach activities

In order to facilitate the communication among the competent authorities and the applicants/users, the competent authority responsible for authorisation of contained used activities (Ministry of Agriculture) have organised a specific informative conference at the beginning of 2022 for the applicants/users in order to present them the new application system with the new applications forms prepared by the competent authority.

2. Updates regarding international activities

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

Hungary is a party to the Cartagena Protocol on Biosafety, and has actively participated in the meetings of the subsidiary bodies of the Convention on Biological Diversity, also in the second open ended working group meeting, and also in Liaison Group on the Cartagena Protocol on Biosafety during the intersessional periods.

3. Developments related to new breeding techniques (NBTs)

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

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

2. Any other information related to NBTs

An inception impact assessment was published by the European Commission on 24 September 2021 as a follow up of the study prepared by the European Commission during the spring of 2021. It is of utmost importance for Hungary to ensure the maximum protection for humans and the environment, taking into account the precautionary principle. This requires a rigorous risk assessment and a thorough examination of the effects. Hungary highlighted that the inception impact assessment did not put sufficient emphasis on the importance of risk assessment of products produced from new genomic techniques. Instead, it focused on the benefits and the contribution to sustainability of such products, despite the fact that their potential for sustainability is not yet been proven. Furthermore the freedom of choice of the consumers had not been properly taken into account in the inception impact assessment. In addition, it is also important to ensure the proper traceability and labelling of these products.

Cultivation/deliberate release

In the course of 2021 neither cultivation of GM crops produced by new techniques nor deliberate release of GMOs produced by new genomic techniques for field trials and for clinical trials occurred in Hungary.

4. Additional Information

Keeping agriculture free from genetically modified organisms (GMOs) is a key objective of the Hungarian Government, laid down in the Fundamental law of Hungary. Hungary is one of the strongest opponents of agricultural gene technology in the European Union, and this policy has not been changed.

JAPAN

1. Developments related to implementation of national biosafety framework

Risk assessment/regulatory decisions

Latest Situation of Approval for Releasing of LMOs

In accordance with the Cartagena Act (Japanese domestic law to implement the Cartagena Protocol on the Biosafety to Convention on Biological Diversity), one oilseed rape, one phalaenopsis, two cotton and three maize events have been newly approved for commercial use since the last WG-HROB meeting held in March 2021.

The number of Living Modified (LM) plants approved for commercial use until the end of April 2022 are described in the Table below. 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 Part of the decision documents and the 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)	17*2	Rose	2
Carnation	8	Soybean	30*2
Maize	92*2	Sugar Beet	1
Cotton	38*2	Phalaenopsis	1

*2 Part o of the events counted in the table are approved for the importation purpose but not for domestic cultivation.

2. Developments related to new breeding techniques (NBTs)

Specific cases of application, assessment and decision

Genome editing technology

Since the last WP-HROB meeting held in March 2021, the Ministry of Agriculture, Forestry and Fisheries of Japan (MAFF) accepted the finalised information form of red sea bream (*Pagrus major*) with increased edible part and Japanese pufferfish/tiger puffer/tiger pufferfish (*Takifugu rubripes*) with growth enhancement. At the same time, the information form was released on the MAFF website in Japanese as shown below.
(website: https://www.maff.go.jp/j/syouan/nouan/carta/tetuduki/nbt_tetuzuki.html)

For research purpose in restricted environments, the information forms for pre-harvest sprouting tolerant wheat (September 2021), a group of rice mutants in florigen genes (June 2021) and potatoes with low contents of steroidal glycoalkaloids (April 2021), were submitted to the Ministry of Education, Culture, Sports, Science and Technology. Information form on *Euglena gracilis* mutant in GSL2 gene was also submitted to the Ministry of Economy, Trade and Industry in November 2021. These information are available on the Japan Biosafety Clearing-House website in Japanese as shown below. (website: https://www.biodic.go.jp/bch/bch_8_3.html)

3. Any other information related to NBTs

Commercially cultivated/grown organisms produced by NBTs

In May 2021, Sanatech Seed Co., Ltd. started to distribute seedlings of "Sicilian Rouge High GABA", the genome-edited tomato strain with increased γ-aminobutyric acid (GABA), free of charge for home garden use. The company thereafter started selling fruits of this tomato strain via its own online store from September 2021, and seedlings for home gardeners from October 2021. (Information confirmed in October 2021 through press releases by the company) https://sanatech-seed.com/en/newslist-en/

In December 2021, Regional Fish Institute, Ltd. started selling the red sea bream with increased edible part and the tiger pufferfish with growth enhancement through its own electronic commerce (EC) site. (Information confirmed in

December 2021 through a press release by the company) https://regional.fish/en#news

Science Communication Activities

MAFF continuously conducts the science communication project focusing biotechnology. In FY 2021, approximately 30 events, such as public lectures aimed at consumers, college students, high school students and others, were held in the project. Additionally, tours for research institutes where have been developing products using genome editing techniques were also held.

KENYA

1. Background information on Biosafety regulatory framework

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

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

2. Status of GM approvals in Kenya

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

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

i) Environmental release

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

The Bt maize MON 810 was given limited environmental release in 2016. In the reporting period, the developers/applicants KALRO and AATF conducted National Performance Trials in all representative ecological zones where maize is planted during the short rains of August-October, 2020. Three varieties were subsequently recommended for release. The NBA Board recommended the approval of the Bt maize varieties on 30th October, 2021 and has since sought for concurrence from the Cabinet for the commercialisation of the product.

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

ii) Confined field trials

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

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

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

iii) Contained use approvals

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

3. Development of Biosafety Regulatory Manuals/Guidelines

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

4. Regulation of products derived from New Plant Breeding techniques

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

In the meantime, Kenya has proceeded with review applications using the New Plant Breeding Techniques with ten of such projects already approved as contained use projects under BSLII laboratory and greenhouse containment facilities. The approved projects include use of CRIPR/Cas9 (**development of virus and or diseases resistance, and nutritional enhancement, striga resistance, or vaccines development**) in crops such as banana, cassava, yam,

sorghum, grass pea potato and animals; use of virus induced gene silencing for resistance to cassava brown streak virus and use of RNAi for development of virus resistant cassava.

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

KOREA

1. Regulatory framework

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

Since the last update in February 2022, the Rural Development Administration (RDA) and the Ministry of Food and Drug Safety (MFDS) have approved new LMO crops for food, feeds and processing use, but none for environmental release or cultivation out of the following:

a. RDA (for feeds, 172 events, up to date):

- soybean (29), corn (89), cotton (32), canola (17), alfalfa (5)

b. MFDS (for foods, 191 events, up to date):

- soybean (29), corn (93), cotton (33), canola (17), alfalfa (5), sugar beet (1), potato (4), microorganisms (9)

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

The MFDS announced its new rules on genetically modified organisms labelling on products, which took effect in February 2017. According to the revised regulation, processed foods containing genetically modified DNA or proteins should be labelled regardless of the amount the certain products have. Before the revision, processed food makers just had to put the label on top five ingredients of food products.

- The labelling policy targets all genetically modified agricultural products approved in Korea such as soybean, corn, canola, cotton, sugar beet, alfalfa, and processed foods made from the same.
- Edible oils, soy sauce, sugars, etc., which do not contain genetically modified DNA due to high purification process such as heat treatment, fermentation, extraction and filtration are excluded.

In addition, MFDS has announced that the standards for labelling Non-GMO foods will be revised

- If the level of unintentional mixing of GMO is below 0.9%, foods can be labelled as Non-GMO or GMO-free. Before the revision, MFDS did not accept the labelling of non-GMO for the below 0.9% level of GMOs.

2. Biosafety Issues

a. Social consensus related to genetically modified food labelling system

Consumers and NGOs have been continuously making a petition to put a change in regulations and sanctions regarding GMO labelling arrangement. The petition from March 2018 demanded that the government revise the GMO regulation to meet international standards. The Petition group has been demanding a complete labelling of GMOs without exception, and ii) the prohibition of GMOs in public school meals.

As a result, the MFDS launched "social council for the improvement of the GMO labelling system" in order to reach social consensus. The council will discuss the current status of the GMO labelling system and its problems and discuss ways to improve it by referring to overseas cases.

b. Monitoring of unauthorised genetically modified canola and cotton

In 2017, genetically modified canola and cotton which were not approved for cultivation were found for the first time

at a flower festival and some province respectively. The government conducted joint-investigation with Non-Government Organisations (NGOs) for the post-safety management as well as an environmental effect evaluation. Through a joint investigation, the government has removed all canola and cotton suspected as LMOs at those sites. To date, the area where the unauthorised LMO were planted illegally is under constant management by the government's joint survey group. Through these activities the communication of GMO safety management has been strengthened with NGOs

3. New Breeding Techniques(NBTs)

In Korea, GMO developers and academic scientists are requesting for a revision of current legislation to develop NBT products. The ministry of Trade, Industry and Energy (MOTIE) of Korea as a representative agency has hosted working group meetings with related interagency regulators and discussed regulation for the NBTs product, especially gene editing products. The Working Group is discussing the direction of regulation of NBTs and will suggest consensus amendment. For the promotion and development of NBTs, a national research program has been launched in 2020.

LATVIA

1. Developments related to implementation of national biosafety framework

Risk assessment/regulatory decisions

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

In 2021 the State Scientific Institute "Institute of Food Safety, Animal Health and Environment "BIOR"" took part regularly at centralised GMO risk assessment procedure. BIOR provided opinion on 4 applications in respect of GMO placing on the EU market.

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

Draft on amendments to the Law on handling of GMO is elaborated to improve the legal framework regarding the rights of supervisory and control authorities if protective actions are initiated and the requirements of regulatory enactments regulating the handling of GMOs are violated. The draft was elaborated in view of the rapid spread of GMOs on the world market, which promotes the unintentional release of GMOs into the environment as well as the admixture of GMOs in conventional seeds. In April 2021, in the frame of monitoring of seeds and plant propagating material for the presence of GMOs in Latvia, a low-level presence of GM oilseed rape line RT73 (also used as GT73) was found in seed samples of one batch of summer oilseed rape. In Latvia, qualitative and quantitative tests for the presence of GMO screening genes were performed by the Scientific Institute for Food Safety, Animal Health and the Environment (BIOR). The batch was inspected for the presence of GMOs prior to import into Latvia, which was also confirmed by the accompanying documents submitted by the importer of seeds, and the presence of GMOs was not detected in it. This is one of the several cases during last years in EU Member States where unauthorised GMO lines have been placed on the market and spread in the environment unintentionally, with impurities in seeds mostly below the level of quantification.

2. Updates regarding international activities

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

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

On November 4th, 2021 the EPSO organised the 5th conference on Genome editing,

Improving legislation and start flagships to better address climate, environmental, food and health challenges. The aim was exchanging the views on the current situation of genome editing in Europe and possible next steps to enable Europe better addressing climate change, achieving food and nutritional security and establishing a sustainable agriculture in Europe and world-wide.

3. Developments related to new breeding techniques (NBTs)

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

NETHERLANDS

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

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

Also in 2021 the Dutch CA has issued a permit for the production of organic acids with cyano bacteria (*Synechocystis* spp) under semi-confined conditions.

Over the last period Netherlands issued 26 permits and 14 amendments on existing permits for clinical or veterinary trials. The majority of those permits concern clinical trials with adeno-associated virus (AAV) or human cells genetically modified by means of retroviral or lentiviral vectors (e.g. CAR-T). Worthwhile noting is the following:

In 2021 we issued several permits with a broad description of the categories of clinical vectors and/or inserts used in clinical studies. In the past the scope of the GMO notifications were identical to the notifications submitted for the medical-ethical assessment. These so-called broad scope GMO permits may cover in theory an unlimited number of actual individual clinical studies. This means that there is no longer a regulatory need to notify in advance any future clinical study with a clinical application with an GMO covered by such a permit. This reduces effectively the number of waiting days for applicants to zero. Another likely effect will be that in the coming years the number of new permits for clinical studies will be reduced significantly.

In the Netherlands we have received the first application for a clinical study making use of CRISPR/Cas. The full title of the study is “Open-Label, Single Ascending Dose Study to Evaluate the Safety, Tolerability, and Efficacy of EDIT-101 in Adult and Pediatric Participants with Leber Congenital Amaurosis Type 10 (LCA10), with Centrosomal Protein 290 (CEP290)-Related Retinal Degeneration Caused by a Compound Heterozygous or Homozygous Mutation Involving c.2991+1655A>G in Intron 26 (IVS26) of the CEP290 Gene (“LCA10-IVS26”)”. EDIT-101 is a recombinant adeno-associated virus (AAV) gene therapy product that utilizes clustered regularly interspaced short palindromic repeats (CRISPR) and CRISPR-associated protein 9 (Cas9) to accomplish highly targeted in vivo editing of the CEP290 gene located in photoreceptor cells of the human retina. A short notification information sheet is available at SNIF B/NL/21/004.

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

An amendment of the Dutch GMO Decree went into force on December 23, 2020. This amendment introduces a simplified and accelerated procedure to grant a permit for clinical studies under fixed provisions for special categories of GMOs for which a standardised environmental risk assessment (ERA) is available. With a recent amendment two new categories are included:

1) human cells genetically modified with viral vectors derived from human immunodeficiency virus 1 and pseudonymised with Vesicular stomatitis virus glycoprotein (VSV-G), where there is no risk of the formation of replication competent virus and where residual infectious SIN lentiviral particles may be present in the medical product;

2) human cells genetically modified by means of adeno-associated viral vectors (AAV) without harmful sequences as transgenes.

2. Updates regarding international activities

Participation in/hosting international symposia/fora relating to biosafety

The Netherlands is a party to the CBD and to the Cartagena Protocol, and has actively participated in the SBSTTA meetings in preparation for the upcoming COP-MOP meeting.

3. Developments related to new breeding techniques (NBTs)

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

On September 24, the European Commission's inception impact assessment for legislation on plants obtained by cisgenesis and targeted mutagenesis was published. The Dutch government has responded to this inception impact assessment. In recent years, the Netherlands' efforts have been focused on reviewing European policy and regulations. This is necessary to enable innovations and sustainable applications in the agricultural, medical and industrial sectors without any prejudice to safety conditions. The Dutch government will continue to make efforts for short-term improvements, as well as for the future-proofing of the entire GMO legislation. In its response, the Dutch government calls for attention to be paid to techniques and sectors that fall under the GMO legislation and are currently not mentioned in the inception impact assessment. For this, too, it is important that the regulations are effective and future-proof. In addition, attention is drawn to public participation and labelling of products in order to enable consumers' freedom of choice. Dutch efforts will continue to focus on policy and regulations regarding medical GMO applications, such as efforts to harmonise, streamline and shorten procedures.

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

2. Specific cases of application, assessment and decision

See also our contribution under Risk assessment/regulatory decisions: the application received concerning a clinical trial a recombinant AAV gene therapy product that utilizes CRISPR/Cas9 to accomplish highly targeted *in vivo* editing of the CEP290 gene located in photoreceptor cells of the human retina.

NEW ZEALAND

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

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

i. To import for release a genetically modified live-attenuated vaccinia virus (TBio-6517) for use in Phase 1 and 2 clinical trials or patients with advanced malignancies. https://www.epa.govt.nz/database-search/hsno-application-register/view/APP204138

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

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

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

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

He Whetū Mārama the Mātauranga Framework

A year after its launch, our Mātauranga Framework is now being fully implemented into our wider work programme. Mātauranga Māori can be broadly defined as a body of knowledge, experience, values and philosophy. It includes the unique knowledge and understanding Māori have of te taiao, the environment.

We take into account Māori interests and the principles of the Treaty of Waitangi (Te Tiriti) when we make decisions about environmental management. We're required to do this under the Environmental Protection Authority Act 2011.

The Mātauranga Framework provides a decision-maker with deeper understanding of Te Ao Māori (the Māori world/worldview), Te Titiri and mātauranga Māori and how this knowledge could be considered in the decision-making process.

More information can be found at the following links:

https://www.epa.govt.nz/news-and-alerts/latest-news/matauranga-part-of-day-to-day-mahi-at-the-epa/
https://www.epa.govt.nz/applications-and-permits/engaging-with-maori/incorporating-maori-perspectives/

Reassessment of Decision regarding dsRNA

A reassessment to reconsider the determination of whether eukaryotic cells that have been treated with externally applied double-stranded RNA molecules for the purpose of inducing small interfering RNA (siRNA)-mediated gene silencing are genetically modified organisms for the purposes of the Hazardous Substances and New Organisms Act 1996 (the HSNO Act).

A decision-making committee reissued its determination to state that eukaryotic organisms (domain Eukaryota) that have not previously been genetically modified and that are treated with externally applied double-stranded RNA molecules to induce a small interfering RNA (siRNA) response do not fulfil the definition of genetically modified organisms detailed in the Act and therefore are not genetically modified organisms in accordance with section 2A(1)(d) of the Act.

The reissued decision also stated that dsRNA molecules may be regulated under the hazardous substances provisions of the HSNO Act, if they are deemed/determined to be hazardous substances.

More information can be found at the following links.

https://www.epa.govt.nz/database-search/hsno-application-register/view/APP203395
https://www.epa.govt.nz/assets/FileAPI/hsno-ar/APP203395/APP203395_Decision.-Reconsidered-and-Reissued-June-2021.pdf
https://www.epa.govt.nz/assets/FileAPI/hsno-ar/APP203395/APP203395-Staff-Assessment-Report.-Reconsidered-and-Reissued-June-2021.pdf

3. Public engagement and outreach activities

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

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

More information can be found at the following link:
https://www.epa.govt.nz/news-and-alerts/latest-news/epa-opens-waterway-testing-to-more-community-groups/

2. Updates regarding international activities

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

CBD information from annual report (see comment)

- Taking up a membership in the Informal Advisory Committee on the Biosafety Clearing-House (BCH).
- Contributing expertise to the COVID-19 Science and Technical Advisory Group, including contributing to over 20 papers relating to COVID-19 genomics, testing, and science information.
- Providing advice, as the National Focal Point for the BCH under the Cartagena Protocol, on the operation of the BCH, including its collaboration with other United Nations and international programmes

PARAGUAY

1. Regulatory Framework

1. **New Plant-Breeding Techniques (NBTs)**

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

2. **A Simplified Approval Procedure**

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

2. Commercial Approvals

The following events were released from 2019 to 2021:

Decision No.	Organism	Event
272/2022	Maize	SYN-E3272-5 x SYN-BTØ11-1 x SYN-IR162-4 x MON-ØØØ21-9
272/2022	Maize	SYN-E3272-5
270/2022	Maize	MON-95379-1
268/2022	Maize	MON-ØØ6Ø3-6 x ACS-ZMØØ3-2 x DAS-4Ø278-9
266/2022	Soybean	BCS-GM151-6

265/2022	Maize	MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6 x SYN-IR162-4 x DAS-4Ø278-9
1158/2021	Maize	ACS-ZMØØ3-2
278/2019	Cotton	BCS-GH811-4
277/2019	Maize	MON-87427-7 X MON-89Ø34-3 X SYN-IR162-4 X MON-87411-9
277/2019	Maize	MON-87427-7
277/2019	Maize	MON-87411-9
276/2019	Soybean	MON-87751-7 x MON-877Ø1-2 x MON-877Ø8-9 x MON-89788-1
276/2019	Soybean	MON-87751-7
276/2019	Soybean	MON-877Ø8-9
275/2019	Soybean	MON-877Ø8-9 x MON-89788-1
274/2019	Soybean	DAS-81419-2 X DAS-444Ø6-6
274/2019	Soybean	DAS-81419-2
274/2019	Soybean	DAS-444Ø6-6
273/2019	Soybean	SYN-ØØØH2-5
272/2019	Maize	MON-87427-7 X MON-89Ø34-3 X SYN-IR162-4 X MON-ØØ6Ø3-6
272/2019	Maize	MON-87427-7
271/2019	Maize	MON-89Ø34-3 x DAS-Ø15Ø7-1 x MON-ØØ6Ø3-6 x DAS-4Ø278-9
271/2019	Maize	DAS-4Ø278-9
270/2019	Maize	SYN-ØØØJG-2
269/2019	Soybean	IND-ØØ41Ø-5
269/2019	Soybean	IND-ØØ41Ø-5 x MON-Ø4Ø32-6
268/2019	Soybean	MST-FGØ72-3 x ACS-GMØØ6-4
267/2019	Maize	SYN-BTØ11-1 X SYN-IR162-4 X MON-89Ø34-3 X MON-ØØØ21-9
266/2019	Cotton	BCS-GHØØ2-5 X BCS-GHØØ4-7 X BCS-GHØØ5-8 X SYN-IR1Ø2-7

3. International Collaboration

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

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

1. **Scope and Description**

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

2. **Operation**

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

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

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

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

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

4. Relevant publications

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

PHILIPPINES

1. Developments related to implementation of national biosafety framework

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

Since March 2021, the Bureau of Plant Industry has issued biosafety permits for 20 events for direct use as food and feed, or for processing, and 3 events for commercial propagation.

Transformation Event	Type of Use	Trait
Soybean A5547-127	Direct Use	Herbicide Tolerance
Soybean MON87769	Direct Use	Herbicide Tolerance
Sugarbeet H7-1	Direct Use	Herbicide Tolerance
Cotton MON88913	Direct Use	Herbicide Tolerance
Cotton MON 15985 x MON 1445	Direct Use	Insect Resistance and Herbicide Tolerance
Corn MON 95379	Direct Use	Insect Resistance
Corn MON 87427 x MON 89034 x MON 810 x MIR 162 x MON 87411 x MON 87419	Direct Use	Herbicide Tolerance and Insect Resistance
Corn MON87460	Direct Use	Drought Tolerant
Cotton MON 88701	Direct Use	Herbicide Tolerant
Corn MON87427 x MON89034 x TC1507 x MON88017 x DAS-59122-7	Direct Use	Insect Resistant and Herbicide Tolerant
Corn MON87427	Direct Use	Herbicide Tolerant
Cotton MON88702	Direct Use	Insect Resistance

Corn MON 87427 x MON 89034 x TC 1507 x MON 87411 x DAS-59122-7	Direct Use	Herbicide Tolerance and Insect Resistance
Corn MON89034 x TC1507 x MON88017 x DAS-59122-7	Direct Use	Herbicide Tolerance and Insect Resistance
Cotton MON531 x MON1445	Direct Use	Insect Resistance and Herbicide Tolerance
Soybean DAS 81419-2 x DAS 44406-6	Direct Use	Insect Resistance and Herbicide Tolerance
Alfalfa KK179 x J101	Direct Use	Glyphosate Herbicide Tolerace, Antibiotic Resistance, Altered legnin Production
Alfalfa J101 x J163	Direct Use	Herbicide Tolerance
Corn MON 87429	Direct Use	Herbicide Tolerance
Eggplant EE-1	Direct Use	Insect Resistance
Corm MON810 x NK603	Commercial Propagation	Herbicide tolerant and Insect Resistance
Corn MON89034	Commercial Propagation	Insect Resistance
GR2E Rice	Commercial Propagation	Enhanced Provitamin A Content

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

Revised Joint Department Circular No. 1 series of 2021

On May 2019, an ad-hoc Technical Working Group was created to take the lead in the review of the Joint Department Circular No. 1 series of 2016 (JDC). Following a series of meetings and consultations, the National Committee on Biosafety of the Philippines adopted the updated version of the JDC. Signed by the Secretaries of the of the Department of Science and Technology (DOST), Department Agriculture (DA), Department of Environment and Natural Resource (DENR), Department of Health (DOH), and Department of Interior and Local Government (DILG), the revised JDC took effect on March 23, 2022, 15 days after its publication in two newspapers.

Salient Features of the Revised JDC:

i. Creation of Joint Assessment Group (JAG) [Section 7]

The JAG is composed of endorsed representatives or personnel from the concerned Departments' Biosafety Committees and external technical experts, as necessary, and is chaired by the DA Biosafety Committee.

Responsibilities of the JAG:

- Evaluate applications to determine whether a regulated article does not pose greater risks to human health and the environment compared to its conventional counterpart.
- Make recommendation to the BPI Director on the approval of the biosafety permit application.
- Assess the suitability of each field trial site for purposes of determining any potential risks to the environment or health.

ii. Specified the role of Bureau of Plant Industry (BPI) in the implementation of the JDC [Section 6]

Role of the BPI:

- Provide frontline services for the processing of applications, which includes opening of an application file for all biosafety permit applications and ensuring that the approval registries for commercial propagation and direct use as well as the repository website are updated.
- Provide technical and administrative assistance to the JAG and prepare consolidated report on the Public Information Sheet.

iii. Onboarding of External Technical Experts [Section 9]

The DOST, DA, DENR, and DOH may appoint one (1) external expert each to act as their Biosafety Committee's consultant to the JAG.

The external expert shall complement the existing technical expertise of the Departments represented in the JAG. Such technical experts must be well-respected in the scientific community as evidenced by positions held in science-based organizations, awards and recognitions, or publications in local and international peer-reviewed scientific journals.

iv. Policy on Field Trial of Regulated Articles [Section 11]

The revised JDC provides that applications for permit for regulated articles developed in other countries may be filed directly for a biosafety permit for field trial if the BPI determines that the data set generated in other countries is applicable to the local setting.

v. Regulation of Stacked Events [Section 20-23]

Plants produced through conventional breeding of GM parental lines with approved individual events are not considered novel.

Stacked events may be listed in the BPI Approval Registry for propagation and direct use only if each parental event has a biosafety permit for commercial propagation and direct use, respectively. The permit holder or an authorized licensee of registered events may also request the BPI for the listing of any sub-stacks or intermediate stacks.

Stacked PIP x PIP must also be registered as a new product under the FPA

based on its own guidelines on the registration of biorational products.

vi. Timeline for the processing of biosafety permits

In compliance with the Ease of Doing Business law, the revised JDC streamlines the regulatory review processes from eighty-five (85) working days to forty (40) working days for biosafety permit applications for commercial release, importation, and field trial of regulated articles.

vii. Validity of Biosafety Permits

Under the new JDC, all biosafety permits for commercial propagation and direct use for food and feed or for processing to be issued shall be valid unless revoked for any of the following reasons:

- Provision of misleading information in the Application,
- Discovery of new, relevant, and significant information that the regulated article poses greater risks to human health and the environment compared to its conventional counterpart,
- Non-compliance with the conditions of the permit, and
- Other grounds that the regulatory agencies may deem necessary to protect human health and the environment.

3. Public engagement and outreach activities;
   - Conduct of Webinar on Basic Biotechnology and Biosafety Regulations in The Philippines
   - Updating of biotech crops information in the BPI Biotech Website and FAO GM Foods Platform

2. Updates regarding international activities

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

   i. Participated to the following seminars:
   - Genome editing for agriculture: Increasing productivity, enhancing traits for consumers, Ensuring Sustainable Development
   - ICABR Webinar: The Benefits from GMO Regulatory Harmonization
   - Review of Policies on Crop Biotechnology, Impacts on Food Security and Agriculture Development in the Climate Change Era
   - ASEAN GMF Testing Network Gene Editing Workshop
   - 15th Pan-Asia Farmers Exchange Program

ii. Organized Webinar on Field Trial Data Transportability

iii. Participated to the Tenth meeting of the Conference of the Parties serving as the meeting of the Parties to the Cartagena Protocol on Biosafety

3. Developments related to new breeding techniques (NBTs)

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

- National Committee on Biosafety of the Philippines Resolution No. 1 – The Regulation of Plant and Plant Products Derived from the Use of Plant Breeding Innovations (PBIs) or New Plant Breeding Techniques (NBTs)

Salient Features of the Revised NCBP Resolution No. 1:

- o PBIs are a new set of molecular, genomics and cellular tools that enable the targeted and efficient development of new varieties of crops with desired traits in a way that is faster and more precise than conventional plant breeding techniques, which PBIs include Site-Directed Nucleases (SDN), Oligonucleotide-Directed Mutagenesis, Cisgenesis and Intragenesis, RNA-dependent DNA Methylation (RdDM), Grafting with GM material, Reverse Breeding, Agroinfiltration, Synthetic Genomics, and other upcoming techniques with the potential to produce non-GM or both non-GM and GM plants as final products.
- o The NCBP recommended that the DA take the lead in evaluating and monitoring plant and plant products derived from the use of modern biotechnology, including PBIs.

- Department of Agriculture Memorandum Circular on Plant Breeding Innovations – Rules and Procedure to Evaluate and Determine When Products of PBIs are Covered under the JDC 01-2021

Salient Features of the DA MC:

i. General Classification of Products as PBIs

PBIs may be classified either as:

1. GMOs, if they contain a novel combination of genetic material obtained through the use of modern biotechnology.

   Novel combination is defined as a resultant genetic combination in a living organism that is not possible through conventional breeding;

2. Non-GMOs or conventional products, if they do not contain a novel combination of genetic material

ii. Mutual Recognition Agreements [Section 11]

The DA, upon the recommendation and facilitation by the BPI, may enhance cooperation with counterpart competent authorities to establish mutual recognition agreements or arrangements on the determination of classification of PBI products under international agreements to which the Philippines is a party.

SLOVAK REPUBLIC

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

One user submitted an application for approval of premises for activities in risk class 3, although the activities there have not started to date.

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

The amendment of the Act on genetic technologies and genetically modified organisms (GMOs) was adopted and became effective last year. Also the Directive (EU) 2015/412 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 was transposed into national law.

3. Risk management measures

General rules on the coexistence of genetically modified crops with conventional and organic farming are set by the Act No. 184/2006. The implementing Decree No. 69/2007 sets minimum isolation distances when growing modified corn, rapeseed, sugar beet and potatoes in agricultural production from plants of the same botanical species grown by conventional farming or by ecological (organic) farming. There are set also minimum requirements for buffer zones, the unmodified plants of the same botanical species can not be grown on the same plot for at least two years and the surroundings of the growing area have to be under monitoring for two years after the harvest of the genetically modified crops.

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

In the year 2021 we have participated in virtual conferences of European bodies where it was obligatory and virtual conferences of bodies under the Convention on biological diversity and its protocols.

3. Developments related to new breeding techniques (NBTs)

Although the using of NBTs is ongoing as contained use in risk class 1 with plant tissues, any potential intention of breeding new plant varieties for cultivation has been indicated.

SOUTH AFRICA

1. GM crop production in South Africa update

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

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

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

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

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

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

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

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

Application of the Act

This Act shall apply to:

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

Executive Council

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

.Functions of Advisory Committee

(1) The Advisory Committee (AC) shall:

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

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

Appointment of registrar

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

The registrar:

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

Functions of registrar

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

a. issue a permit as required or prescribed under this Act;
b. where he or she has ascertained or suspects on reasonable grounds that genetically modified organisms are being imported or locally produced or used contrary to the provisions of this Act or the conditions of a permit issued thereunder:
    i. serve a notice upon any person by whom or on whose behalf genetically modified organisms are being so imported into, produced or used in the Republic for the removal of such genetically modified organisms to a place or facility and in a manner prescribed by the Council; and
    ii. authorise an inspector to destroy such genetically modified organisms or cause it to be destroyed, subject to procedures and other provisions as set out in this Act.

c. amend or withdraw a permit issued under this Act;
d. furnish an inspector with a certificate of appointment;
e. require the cessation of any genetic modification activity at facilities where the provisions of this Act or the conditions of a permit have not been or are not being complied with; and
f. ensure that appropriate measures are undertaken by all users at all times with a view to the protection of the environment from hazards.

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

Biosafety:

Mission

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

Functions

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

Role as the Competent National Authority

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

4. New GM approvals in South Africa

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

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

Event	Crop	Trait	Company	Year approved
NK603 x T25 x DAS-40278-9	**Maize**	**Herbicide tolerance**	**Corteva Agriscience RSA**	**2021**
DAS-81419-2 x DAS-44406-6	**Soybean**	**Insect resistance Herbicide tolerance**	**Pioneer Hi-Bred RSA**	**2021**
GMB151	**Soybean**	**Insect resistance Herbicide tolerance**	**BASF**	**2021**
GHB811	**Cotton**	**Herbicide tolerance**	**BASF**	**2021**
MON89034 x TC1507 x MIR162 x NK603 x DAS-40278-9	Maize	Insect resistance Herbicide tolerance	Pioneer Hi-Bred RSA (Pty) Ltd	2020
MON87427 x MON89034 x MON810 x MIR162 x MON87411 x MON87419	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2020
MON87427 x MON89034 x MIR162 x MON87419 x NK603	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2020
MON87427 x MON87419 x NK603	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2020
MON87427 x MON89034 x MON87419 x NK603	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2018
MON87427 x MON89034 x TC1507 x	Maize	Insect resistance	Monsanto SA	2018

MON87411 x DAS 59122-7 x MON87419		Herbicide tolerance		
MON87751 x MON87701 x MON87708 x MON89788	Soybean	Insect resistance Herbicide tolerance	Monsanto SA	2018
FG72 x A5547-127	Soybean	Herbicide tolerance	Bayer	2018
MON89034 x TC1507 x MIR162 x NK603	Maize	Insect resistance Herbicide tolerance	DowAgroSciences	2018
BT11 x MIR162 x MIMR604 x MON89034 x 5307 x GA21	Maize	Insect resistance Herbicide tolerance	Syngenta SA	2018
MON87705 x MON87708 x MON89788	Soybean	Herbicide tolerance	Monsanto SA	2018
MON87427 x MON87460 x MON89034 x TC1507 x MON87411 x DAS-59122-7	Maize	Insect resistance Herbicide tolerance Drought or water tolerance	Monsanto SA	2018
MON87427 x MON89034 x MIR162 x MON87411	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2018
MON87427 x MON89034 x TC1507 x MON87411 x DAS-59122-7	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2018
MON87427 x MON87460 x MON89034 x MIR162 x NK603	Maize	Insect resistance Herbicide tolerance Drought or water tolerance	Monsanto SA	2018
MON87708 x MON89788 x A5547-127	Soybean	Herbicide tolerance	Monsanto SA	2018
BT11 x MIR162 x MON89034	Maize	Insect resistance Herbicide tolerance	Syngenta SA	2018
MON87427 x MON89034 x MON88017	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2017
MON89034 x MIR162	Maize	Insect resistance	Monsanto SA	2017
BT11 x MIR162 x MON89034 x GA21	Maize	Insect resistance Herbicide tolerance	Syngenta	2017
DP114 x MON810 x MIR604 x NK603	Maize	Insect resistance Herbicide tolerance	Du Pont Pioneer	2017
TC1507 x MON810 x MIR162 x NK603	Maize	Insect resistant Herbicide tolerant	Du Pont Pioneer	2016
TC1507 x MIR604 x NK603	Maize	Insect resistant Herbicide tolerant	Du Pont Pioneer	2016
TC1507 x MON810 x MIR604 x NK603	Maize	Insect resistant Herbicide tolerant	Du Pont Pioneer	2016
TC1507 x 59122 x MON810 x NK603	Maize	Insect resistant Herbicide tolerant	Du Pont Pioneer	2016
TC1507 X 59122 X MON810 x MIR604 x NK603	Maize	Insect resistant Herbicide tolerant	Du Pont Pioneer	2016
DAS81910-7	Cotton	Herbicide tolerant	DowAgroSciences	2016
DAS-24236-5 x DAS-21023-5	Cotton	Insect resistant	DowAgroSciences	2016
MON89034 x TC1507 x MON88017 x DAS-591227 x DAS-40278-9	Maize	Insect resistant Herbicide tolerant	DowAgroSciences	2016
MON89034 x TC1507 x NK603 x DAS-40278-9	Maize	Insect resistant Herbicide tolerant	DowAgroSciences	2016
DP4114	Maize	Insect resistant Herbicide tolerant	Du Pont Pioneer	2016
NK603 x T25	Maize	Herbicide tolerant	Monsanto	2016
MZHG0JG	Maize	Herbicide tolerant	Syngenta	2016
DP73496	Canola	Herbicide tolerance	Du Pont Pioneer	2016

Table 2. General release approved for importation/exportation, commercial planting, and for food and/or feed in South Africa 2015-2021. Source: http://www.dalrrd.gov.za/

Event	Crop	Trait	Company	Year approved
MON87701 x MON89788	**Soybean**	**Insect resistance Herbicide tolerance**	**Bayer**	**2021**
BT11 x MIR162 x GA21	**Maize**	**Insect resistance Herbicide tolerance**	**Syngenta**	**2021**
BT11 x MIR162 x MON89034 x GA21	**Maize**	**Insect resistance Herbicide tolerance**	**Syngenta**	**2021**
MON87427 x MON89034 x MIR162 x NK603	**Maize**	**Insect resistance Herbicide tolerance**	**Bayer**	**2020**
DAS-40278-9	Maize	Herbicide tolerance	DowAgroSciences	2019
DAS-40278-9 x NK603	Maize	Herbicide tolerance	DowAgroSciences	2019
MON89034 x TC1507 x NK603 x DAS-40278-9	Maize	Insect resistance Herbicide tolerance	DowAgroSciences	2019

Innovax ND - IBD	Poultry vaccine	-	Intervet	2019
VaxSafe TMPM	Poultry vaccine	-	Protectachik	2019
MON89034 x TC1507 x NK603	Maize	Insect resistance Herbicide tolerance	DowAgroSciences	2018
Innovcax-ND	Vaccine	-	Intervet	2015
Vectormune HVT NDT & Ripens	Vaccine	-	Ceva Animal Health	2015
MON87460	Maize	Drought tolerant Antibiotic resistant	Monsanto	2015

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

PUBLIC NOTICE: 27 October 2021
South Africa's Regulatory Approach for New BreedingTechniques
Department of Agriculture, Land Reform and Rural Development (DALRRD)

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

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

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

6. Genome editing research and activities in South Africa

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

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

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

Aim: This study aims to develop a haploid induction system in sunflower by targeting known mutations in the target gene using directed homologues repair that is part of the CRISPR/Cas9 technology. They are also investigating different delivery systems for the CRISPR construct and donor templates, including *Agrobacterium* transformation.

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

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

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

plants.

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

Sweet potato (*Ipomoea batatas* Lam) is an important food crop in South Africa and is planted by smallholder and rural communities for household consumption and for income generation.Sweet potato virus disease (SPVD) is one of the most important viruses of sweet potato, associated with reduction in yields by 80% to 100%. The research proposal proposes to identify virus strains associated with the potyvirus *Sweet potato feathery mottle virus* (SPFMV) and the crinivirus *Sweet potato chlorotic stunt virus* (SPCSV). A co-infection of the two viruses results in a condition called SPVD. The study also proposes to investigate the possibility of using CRISPR/Cas9 gene editing technology in attaining resistance to the potyvirus SPFMV, which will ultimately confer resistance to SPVD, due to the synergistic effects of the two viruses, which increases the concentration of SPFMV when the two viruses co-infect the plant. The strategy is to knock out eIF4E and eIF4G and their isoforms, whose knock out is well established in the literature to lead to resistance to potyviruses. eIF4E is a eukaryotic translation initiation factor involved in directing ribosomes to the cap structure of mRNAs. Almost all cellular mRNA require eIF4E in order to be translated into protein. The eIF4E polypeptide is the rate-limiting component of the eukaryotic translation apparatus and is involved in the mRNA-ribosome binding step of eukaryotic protein synthesis. Another subunit is eIF4G. Some viruses cut eIF4G in such a way that the eIF4E binding site is removed and the virus is able to translate its proteins without eIF4E. This is part of the development of integrated disease management strategies to minimize the effects of major viruses of sweet potato.

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

The aim is to optimize tobacco transformation and, subsequently, harness CRISPR/Cas9 genome editing technology to edit target plant protease genes to allow increased recombinant protein yields. They are currently generating stable knockouts of key genes that influence protein yields in *N. benthamiana* (tobacco) plants using NBTs. They are also routinely performing these edits transiently.

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

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

CRISPR research at the Stellenbosch University

Introduce resistance to potato virus Y by mutating eukaryotic initiation factor 4E (eIF4E) genes. Repress cold induced sweetening by blocking starch degradation through mutation of the glucan water dikinase 1 (GWD1) gene.

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

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

The negative economic impact of biotic and abiotic stresses in vines are recognised by the international viticulture industry. The rapid developments in genome editing technologies over the last few years, and especially the versatility demonstrated in many applications of CRISPR/Cas9-based technology, may impact radically in the ongoing battle with most of these conditions in vineyards all over the world. As a first step to unlock the immense potential of this technology in the local industry, the project aims to establish CRISPR technology in grapevine. As a proof of concept, one gene central to grapevine secondary plant metabolism was targeted both in grapevine and *Nicotiana benthamiana* as a model system. Grapevine regeneration is a slow process and *N.benthamiana* was used as a system to test the construct and the targets selected.

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

model plant *N. benthamiana*. They are are currently evaluating the transgenic plants stably expressing Cas13 and the gRNAs, which will then be infiltrated with a grapevine virus to assess the virus resistance.

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

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

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

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

South African database on genome editing

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

7. Usefulness of the OECD Biology documents

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

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

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

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

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

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

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

Cassava

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

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

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

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

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

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

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

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

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

SPAIN

1. Developments related to implementation of national biosafety framework

1. **Risk assessment/regulatory decisions**

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

a) Contained use activities in research facilities

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

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

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

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

b) Experimental deliberate release into the environment

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

- Three field trials with plants: two field trials with gene edited tobacco (CRISP/Cas) which are used as a biofactory plants, and one salinity and drought tolerant broccoli (CRISP/Cas).

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

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

c) Placing on the market

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

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

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

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

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

2.1 Royal Decree 406/2021, on 8 of June, amending Royal Decree 178/2004, establish the legal framework for contained use, deliberate release and placing on the market of GMOs. This Royal Decree updates the structure of the two competent authorities in Spain: Interministerial Council of GMO (decision-making body) and National Biosafety Commission (risk assessment body). In addition it transposes the provision on confidentiality included in Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain into national law.
https://boe.es/diario_boe/txt.php?id=BOE-A-2021-10229

2.2 National control plan on deliberate release of GMOs for food and feed production. This plan includes official control to verify the compliance of GMO regulation in seeds, field trials and cultivation of MON 810 maize.
PNCOCA 2021-2025 (mapa.gob.es)

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

3. Public engagement and outreach activities

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

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

2. Updates regarding international activities

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

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

3. Developments related to new breeding techniques (NBTs)

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

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

More detailed information can be found on these links:

https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/mejora-genetica/regulacion_d.aspx
https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/mejora-genetica/Informe%20COM.aspx
https://www.mapa.gob.es/es/agricultura/temas/biotecnologia/mejora-genetica/Iniciativa%20.aspx

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

2. **2Any other information related to NBTs.**

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

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

SWITZERLAND

1. Developments related to implementation of national biosafety framework

1. **Risk assessment/regulatory decisions since the 35rd WG-HROB meeting**

- **Biotechnology activities in contained use**

The level of biotechnological activities in contained use raised on a high level last year, due to the many activities of diagnostic, research with SARS-CoV-2 and production of COVID-19 vaccine components. The number of activities using genome editing such as CRISPR/Cas-9 has been increasing steadily and are standard tools today. [1,2.] Most activities of research and development with SARS-CoV viruses are performed in high security levels P3, P4 laboratory.

Swiss biotech industry response to COVID-19 was high and rapid. A wide range of public/private partnership projects

[1] https://www.bafu.admin.ch/bafu/en/home/topics/biotechnology/state/indicators.html

[2] http://www.ecogen.ch/ecogen/Forms/Register/RegisterSearch.aspx

to address the challenges of the Covid-19 pandemic (diagnostics, antibacterial textile treatment, patient monitoring) have been observed in the last two years[3].

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

Approval of gene and cell therapies:

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

Approval of COVID-19 vaccine:

- Moderna mRNA vaccine against SARS-CoV-2
- Pfizer / BioNTech mRNA vaccine against SARS-CoV-2
- VAC31518 COVID-19 Impfstoff

Approval of clinical trials

In 2021, four clinical trials have been reported.

[3] According to the Federal Coordination Centre for Biotechnology and swiss biotech report 2021: Swiss-Biotech-Report-2021-media-presentation.pdf (swissbiotech.org)

- **GMO Food and Feed**

No new authorisation have been granted since 2015. Currently, there are 5 authorisations for GMO food and feed products:[4,5]

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

However, there is de facto no import of these authorised commodities.

The newly revised regulation on Food products integrates the possibility to tolerate traces of GMO in feed products as far as those GMO are approved in EU. However, potential risks for environment are assessed, and risk management measures can be ordered.

- **Field trials**

In 2014, a "protected site" has been set up, financed by the Federal budget, in order to conduct experimental field trials with GMO plants safe from vandalism.[6] According to Swiss regulation, announcement, risk assessment documents, field trials authorisations and reports regarding GMO are publicly available and may be submitted upon request.**Error! Bookmark not defined.**,[7]

Three trials are currently running:[8]

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

Since the 34rd WG-HROB meeting, two field trials on the protected came to an end, but a post-trial monitoring had been in place in the last years:[8]

- Cisgenic potatoes with improved late blight resistance
- Cisgenic apple trees with improved fire blight resistance
- Genetically modified wheat strains with increased yield potential

- **GMO cultivation**

Since 2005 and until End of 2021, a transitional period (i.e., moratorium) for putting GMO into circulation for agricultural, horticultural or silvicultural purposes is in place.

In November 2020, the Federal Council (government) proposed to continue the moratorium in the Gene technology

[4]https://www.blv.admin.ch/dam/blv/fr/dokumente/lebensmittel-und-ernaehrung/rechts-und-vollzugsgrundlagen/gvo-bewilligungsliste.pdf.download.pdf/f-gvo-bewilligungsliste.pdf

[5]https://www.blw.admin.ch/dam/blw/fr/dokumente/Nachhaltige%20Produktion/Pflanzliche%20Produktion/Getreide%20und%20Futtermittel/Zugelassene%20und%20tolerierte%20GVO%20als%20Futtermittel.pdf.download.pdf/GVO%20Futtermittel%202020%20fr.pdf

[6] www.protectedsite.ch

[7] https://www.bafu.admin.ch/bafu/en/home/themen/thema-biotechnologie/biotechnologie--daten--indikatoren-und-karten/biotechnologie--indikatoren/indikator-biotechnologie.pt.html/aHR0cHM6Ly93d3cuaW5kaWthdG9yZW4uYWRtaW4uY2gvUHVibG/ljL0FlbURldGFpbD9pbmQ9QlQwMTgmbG5nPWVuJlN1Ymo9Tg%3d%3d.html

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

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

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

Act[11] for four more years. The proposal was put out for public consultation and received overwhelming support.[12]

At the beginning of 2022 the Swiss parliament decided to extend the moratorium on GMO cultivation, including products from NTBs, until the end of 2025.

The political discussion on moratorium is highly related to the rapid development of new gene technologies and to the legal status of the so called "genome editing" products in the agriculture (See 2).

2. Regulatory activities

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

Legal Status:

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

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

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

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

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

Recent political- legal developments regarding NBT agricultural products:

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

On the 8th of March 2022, simultaneously to the prolongation of the moratorium on GMO cultivation[17], the Parliament gave a mandate to the federal council to provide risk-based regulation for NBT agricultural products within two years (mid 2024). This process should result in the provision of a new regulation for plants from new technologies for the post moratorium period (2026).

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

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

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

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

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

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

[16] 20.4211 | Critères d'application du droit sur le génie génétique | Objet | Le Parlement suisse (parlament.ch); 21.3980 | Moratoire sur les OGM. Des bonnes informations pour prendre des bonnes décisions | Objet | Le Parlement suisse (parlament.ch);

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

3. GMO monitoring

The presence of unauthorised GMO plants in the environment is monitored since 2011. The results show that GMO are present in the environment in low quantities.[7] One major reason for their presence is that contaminated agricultural products are imported from countries where GMO plants are grown. Oilseed Rape Monsanto GT73 is regularly identified in imported wheat from Canada and in imported bird feed,[18] indicating that the GMO plants accidentally released into the environment originate from domestic transport of imported food and feed (adventitious presence threshold). As theses GMO plants are not authorised, the competent authorities in the cantons are in charge of their elimination and collaborate for monitoring within their territories.

4. Nanotechnology

The independent, national platform **contactpointnano.ch** is pooling the scientific and regulatory knowledge and expertise available in Switzerland on the safe handling of synthetic nanomaterials – from production to use and disposal – and conveying it efficiently and in a generally understandable form to companies (start-ups, SMEs, and established firms).
contactpointnano.ch is supported by several government bodies, namely the Federal Office of Public Health, the Federal Office for the Environment and the State Secretariat for Education, Research and Innovation.
Further information is available under https://contactpointnano.ch/

2. Updates regarding international activities

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

Switzerland is leading a technical working group dealing with environmental issues related to GMO within the network of the directors of European Protection Agencies EPA and Conservation Agencies ENCA (Joint EPA-ENCA interest group on environmental risk assessment and monitoring of GMOs; IG GMOs). The IG GMOs' working program 2018-2021 includes environmental considerations on gene drive organisms and the elaboration of technical recommendations regarding the monitoring of spontaneous populations of genetically modified plants in the environment and, in doing so, continue to ensure that no new and lasting populations of plants can be created by genetically modified seeds present in the soil. Since the 35rd WG-HROB meeting a technical report on Gene Drive organisms and nature conservation as well as an opinion paper on Gene Drive had been published[19][20].

The Activity Report of the IG GMOs' working program 2018-2021 and the new working program 2021-2026 are published [21][22].

2. International Activities under Convention on Biological Diversity CBD

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

3. Switzerland is hosting the meeting of Biological Diversity Convention CBD Bodies

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

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

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

[20] IG GMO (admin.ch)

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

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

3. Developments related to new breeding techniques (NBTs)

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

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

Since these techniques generally aim to modify the genome, the Federal Council (government) has decided that the precautionary principle, laid down in the Swiss Gene Technology Act (Federal Act on Non-Human Gene Technology),23 will be respected. Early identification of hazards (risk assessment) and measures to mitigate risks taken will be considered as a priority.

Meanwhile, the Federal Council has confirmed in a response to a motion in parliament that genome edited organisms fall under the definition of genetically modified organisms according to the Gene Technology Act. Thus, NBT are considered as gene technology techniques from a technical as well as a legal viewpoint.[24]

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

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

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

The political activity is high regarding new gene technologies. [25,26, 27, 28, 29]

In 2021, three postulates[25, 26, 27] coming from parliament request the federal Government to deliver information on the legal status of the NBT, on the coexistence measures regarding NBT and on the possibility to regulate NBT products so that their use in the Swiss agriculture may be initiated. The Postulate reports are expected until mid-2023 and will serve the development of the future regulation concerning NBT Products.

2. Specific cases of application, assessment and decision

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

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

- Neue Gentechnische Verfahren, Kommerzialisierungs Pipeline und Lizenzvereinbarung im Bereich der Pflanzenzüchtung: https://www.bafu.admin.ch/dam/bafu/de/dokumente/biotechnologie/externe-studien-berichte/endbericht-semnar-gelinsky.pdf.download.pdf/endbericht-semnar-gelinsky.pdf
- Biological experiments, Swiss rules, tips and contacts:
  https://www.bafu.admin.ch/dam/bafu/en/dokumente/biotechnologie/externe-studien-berichte/biologische-experimente-schweizer-regeln-tipps-und-kontakte.pdf.download.pdf/biologische-experimente-schweizer-regeln-tipps-und-kontakte.pdf
- Magazine «l'environnement» 2/2019 - Génie génétique: Magazine «l'environnement» 2/2019 - Génie

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

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

[25] 19.4225 | Moratoire sur les OGM. Prolongation | Bulletin officiel | Le Parlement suisse (parlament.ch)

[26] 21.308 | Pour une Suisse sans OGM! | Objet | Le Parlement suisse (parlament.ch)

[27] 21.3980 | GVO-Moratorium. Belastbare Informationen als Grundlage für gute Entscheide | Geschäft | Das Schweizer Parlament

[28] 21.4345 | Procédés de sélection par édition génomique | Objet | Le Parlement suisse (parlament.ch)

[29] 20.4211 | Critères d'application du droit sur le génie génétique | Objet | Le Parlement suisse (parlament.ch)

génétique (admin.ch)

- Indikatoren für die Erfassung von Trends der aus öffentlicher Hand finanzierten Forschung im Bereich Genforschung: https://www.bafu.admin.ch/dam/bafu/de/dokumente/biotechnologie/externe-studien-berichte/indikatoren-genforschung.pdf.download.pdf/indikatoren-genforschung.pdf
- Technical Report, Gene Drive Organisms – Implications for the Environment and Nature Conservations, IG GMO technical report on gene drives (PDF, 2 MB, 01.01.2020): ig-gmo-2020-IG GMO technical report on gene drives (6).pdf
- Technical Report, Monitoring of Spontaneous Populations of Genetically Modified Plant Species in the Environment (PDF, 3 MB, 28.02.2019): ig-gmo-2019-IG GMOs_Monitoring Genetically Modified Plants (1) (1).pdf
- Technical report on NBT : https://www.bafu.admin.ch/dam/bafu/en/dokumente/biotechnologie/externe-studien-berichte/grundlagen_der_rechtlichenregulierungneuerpflanzenzuchtverfahren.pdf.download.pdf/grundlagen_der_rechtlichenregulierungneuerpflanzenzuchtverfahren.pdf
- Report on intellectual property and NBT: http://www.ekah.admin.ch/fileadmin/ekah-dateien/dokumentation/gutachten/Neue_Pflanzenzuchtverfahren_und_geistige_Eigentumsrechte_E.Gelinsky_aktualisiert_November_2013.pdf
- Ethical considerations Federal Ethics Committee on Non-Human Biotechnology on NBT: http://www.ekah.admin.ch/fileadmin/ekah-dateien/dokumentation/publikationen/EKAH_New_Plant_Breeding_Techniques_2016.pdf
- Opinion of the Swiss Expert Committee for Biosafety on NBT: https://www.efbs.admin.ch/inhalte/dokumentation/Ansichten/F_Bericht_EFBS_Neue_Pflanzenzuchtverfahren.pdf
- Report on a public discussion on NBT, organised by FOEN and FOAG and the Swiss Academy of Science: http://www.naturwissenschaften.ch/uuid/db223854-0011-5649-aadc-548db33ddff8?r=20161005181841_1475028790_6d7a963b-646a-5941-b2c3-0c0a0da45d24
- Ethical considerations Federal Ethics Committee on Non-Human Biotechnology on precautionary principle: http://www.ekah.admin.ch/fileadmin/ekah-dateien/dokumentation/veranstaltungen/Veranstaltung_7._Mai_2018/EKAH_Broschu__re_Vorsorge_Umweltbereich_e__18_Web_V2.pdf
- Federal Ethics Committee on Non-Human Biotechnology on ethical considerations on synthetic biology: http://www.ekah.admin.ch/en/topics/synthetic-biology/
- Federal Ethics Committee on Non-Human Biotechnology on ethical considerations on the use of gene drives in the environment: https://www.ekah.admin.ch/inhalte/ekah-dateien/dokumentation/publikationen/EKAH_Bericht_Gene_Drives_EN_V2.pdf
- Opinion of the Swiss Expert Committee for Biosafety on biological risks in Switzerland: https://www.efbs.admin.ch/inhalte/dokumentation/Ansichten/Biologische_Risiken_Schweiz/EFBS_Biologische-Risiken_Schlussbericht_E.pdf
- Opinion of the Swiss Expert Committee for Biosafety on risk-related criteria to assess activities in the field of synthetic biology and its regulation: https://www.efbs.admin.ch/inhalte/dokumentation/Ansichten/Ansicht_EFBS_Synthetische_Biologie_E_definitiv.pdf

UNITED KINGDOM

1. Current status of Genetically modified organism (GMO) regulations in UK/GB

The UK is made up of the four home nations (England, Scotland, Wales and Northern Ireland) and each has a separate, or devolved, administration with the ability to pass their own laws in several areas; GMOs are one such area. (In addition, Northern Ireland follows some EU processes under the Protocol on Ireland/Northern Ireland). So, although the UK regulations on GMOs are derived from the relevant European Union (EU) directives EC 2001/18 and EC 2009/41 covering deliberate release and contained use respectively, they are transposed into law separately within each home nation. This means that regulatory assessment of GMOs, whether for contained use or deliberate release, are carried out by individual Competent Authorities within each home nation The deliberate release regulations in each home nation include the role for an expert advisory committee and, rather than duplicating such a body, there is just the one, the Advisory Committee on Releases to the Environment (ACRE) who's expertise is available to all four nations. The contained use competent authorities similarly are able to make use of an advisory body, the Scientific Advisory Committee on Genetic Modification (SACGM), who provide both expert advice and published a compendium guide to the undertaking of risk assessment for contained use activities including GMOs and the measures required to meet the different containment levels (CL1-4).

The UK-wide transposition of the contained use directive EC 2009/41 allows for the GMO to be considered contained

if it is 'biologically contained' as well as chemically or physically so. Thus disabled (non-replicating) virus vectors come under this and as a result clinical trial of vaccines and other investigational medical products based on such vectors are regulated under contained use; our incorporation of 'biological containment' as a regulatory criterion in the UK is an example of such a difference between Member States.

During 2021, EU Regulation 2020/1043 remained in operation, which provides a derogation from the majority of the GMO contained use and deliberate release requirements for clinical trials of investigational medical products for the treatment of COVID-19 that contain or consist of GMOs, where certain conditions were met. However, this Regulation is explicit that GMO clinical trials still require compliance with the relevant human medicine regulations and thus oversight by a medical regulatory authority with regards to their clinical safety.

2. GMO research, clinical and field trials in the UK

1. Contained Use

In the UK the number of GMO Contained Use notifications received and approved, that notify premises where contained use activities are undertaken, is significantly greater than for deliberate release. This may in part at least be due to the inclusion of biological containment within the definition of UK contained use regulations in relation to the undertaking of clinical trials involving GMMs as contained use activities. To illustrate this there were: 62 premises notifications, 147 class 2, 22 class 3 and 1 class 4 contained use applications assessed between April 21 – March 22, with activities covering both research, commercial activities and clinical trials. Of the premises notifications received, five described class 1 contained use clinical trial activities and eight class 2 notifications described the undertaking of contained use clinical trials.

2. Ongoing Deliberate Release field trials

There are currently the following on going field trials:

- 19/R8/01 GM camelina trials- This was designed to test the field performance of *Camelina sativa* (false flax) that had been modified using a combination of both older GM and newer GE (CRISPR-CAS) technologies to produce high levels of omega-3 oils. This oil is associated with many fish, but no higher plants are known to produce it, and is beneficial to general health including protection against cardiovascular disease. The oil production in C. sativa was engineered to occur mainly in the seeds as measured in glasshouse experiments. Subsequently, deliberate release field trials investigated this seed-based oil production under field conditions with a view to measuring harvestable levels of this oil.
- 19/R29/01 GM potato trials- This GM potato possesses a stack of three genes conferring resistance to potato late blight, and also a gene-silencing module that prevents potato sweetening while tubers are cold-stored thus lowering the potential for both blackening and acrylamide formation upon cooking. The performance of this GMO is being assessed in ongoing trials under field conditions at different locations across England.

New field trials in 2021 include:

- 21/R08/01 GE winter wheat trials- This winter wheat was gene-edited to knockout the asparagine synthetase gene, thus resulting in lower asparagine in the grain, leading to ultra-low levels of acrylamide when the flour is heated in food production. The trials are designed to assess the agronomic performance of the gene-edited wheat under field conditions as well as segregating out the inserted genetic elements responsible for the gene-editing process.
- 21/R52/01 GM wheat trials- This wheat was genetically modified with two genes to produce both increased iron levels in the endosperm tissue, resulting in biofortified wheat grain and also to increase the bioavailability of iron, zinc and other micronutrients. The deliberate release of this GMO investigates the effect of this genetic modification under field conditions.
- 21/R54/01- GE/GM spring barley trials- This five-year field trial investigates six barley genes involved in the interaction with arbuscular mycorrhizal fungi in the soil. Lines of barely have been both gene-edited to knockout each of these genes, and also genetically modified to constitutively express one of these genes or a homologue of it from a related plant species. The trials will assess the agronomic performance of these lines in the field under both high and low phosphate fertiliser levels.

3. Ongoing and new deliberate release clinical trials

- Vaccine against *Salmonella paratyphi*- 20/R48/01- This phase II clinical vaccine trial using an attenuated GM-

strain of *S. paratyphi* was given consent for in 2020 but did not start due to the current pandemic. This trial applied for a variation to its consent conditions, granted as 20/R48/01a, and started in early 2022.

- Vaccine against *Bordetella pertussis* – 21/R53/01- this phase II clinical vaccine trial was given consent in mid-2021 and investigates the safety and efficacy of an attenuated GM-strain of B. pertussis in 600 6–16-year-olds across 11 different sites.

All the above deliberate release trial details may be viewed on the UK Government website: https://www.gov.uk/government/collections/genetically-modified-organisms-applications-and-consents

In addition, Defra was approached by a clinical trial sponsor wishing to conduct a phase I trial with an attenuated GM-strain of SARS-CoV2. Although this fell under the EU regulation 2020/1043 (outlined above) which derogates from such a trial requiring GMO regulatory assessment, the sponsor sought advise on steps to mitigate against risk to human health and the environment from this vaccine strain.

No marketing applications for GMOs have been received in 2021.

3. Developments related to new breeding techniques (NBTs)

Although the UK officially left the EU at the end of 2020, all the relevant EU directives and regulations were retained under our legislation. This retained legislation requires that all Gene edited (GE) organisms are classified as GMOs irrespective of whether they could be produced by traditional breeding methods. The UK government's view was that organisms produced by GE or other precision breeding techniques should not be regulated as GMOs if they could have been produced by traditional breeding methods. Although, because of the devolved regulation of GMOs, any changes to it would require separate legislative changes by each of the four home nations, and the UK government is able to legislate solely for England.

We held a 10-week consultation of the regulation of genetic technologies seeking views and evidence on gene editing and its application in a wide range of farming and agri-food systems and included questions on the health and environmental impacts of these technologies. The consultation ended on 17 March 2021 and a government response was published in September 2021

The UK Government used the consultation to initiate discussion on the potential for broader reform of regulation of GMOs. To do so we included questions to gather evidence about other regulatory frameworks that GMOs fall under e.g., food and feed, medical product authorisations, crop variety plant breeders' rights. This line of questioning was intended to inform our view of public perception and what understanding there is of the other regulatory processes that are always applied to GMOs regardless of changes in the GMO-specific legislation.

The UK government also used the consultation to inform its approach to reform of the regulation of genetic technologies, the first step being: Reducing regulatory requirements on field trials (in England) of plants developed by genetic technologies, such as gene editing (GE), that could have been produced by traditional methods. To this end Defra introduced legislation in the form of a statutory instrument: The Genetically Modified Organisms (Deliberate Release) (Amendment) (England) Regulations 2022 (legislation.gov.uk) This regulation describes higher plants that may be subject to reduced regulatory requirements prior to their deliberate release for research and development purposes only, as qualifying higher plants. This legislation only applies in England.

To accompany this first step in changing our regulatory requirements, our independent scientific advisory committee, ACRE, published technical guidance related to this regulation: https://www.gov.uk/government/publications/acre-guidance-on-genetic-technologies-that-result-in-qualifying-higher-plants

To date one new notification under this regulation has been published: https://www.gov.uk/government/collections/genetically-modified-organisms-applications-and-consents#notifications-to-release-qualifying-genetically-modified-higher-plants

Our next step aims to create a new regulatory regime for organisms produced through precision breeding technologies where the genetic changes could have arisen through traditional breeding or natural processes. We will be seeking powers to remove precision bred organisms (PBOs) from the regulatory requirements applicable to Genetically Modified Organisms (GMOs) and introduce new measures to enable products to come to market.

We have carefully considered all views and evidence in establishing our approach. That is why we are taking a step-by-step approach, starting with regulatory changes for plants and then introducing such changes in animals later.

We are committed to proportionate, science-based regulations that protect people, animals, and the environment. We will not reduce safety or animal welfare standards.

UNITED STATES

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

Updates for the United States Department of Agriculture (USDA)

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

On May 18, 2020, USDA-APHIS published the Final Rule for its biotechnology regulations 7 CFR part 340 in the Federal Register. This is the first comprehensive revision of USDA-APHIS' biotechnology regulations since they were established in 1987. The revisions enable USDA-APHIS to regulate organisms developed using genetic engineering for plant pest risk with greater precision and reduces regulatory burden for developers of organisms that are unlikely to pose plant pest risks. The USDA-APHIS' revised regulations update requirements for importation, interstate movement, and environmental release of certain organisms to account for advances in genetic engineering and in our understanding of the plant pest risks posed by organisms developed using genetic engineering.

The revised regulations differ from the previous regulatory framework by focusing on an organism's characteristics and not on the method used to produce it. This approach enables USDA-APHIS to regulate organisms developed using genetic engineering for plant pest risk with greater precision than the previous approach. This will reduce regulatory burden for developers of organisms that are unlikely to pose plant pest risks and continue to provide oversight of organisms developed using genetic engineering that pose a plant pest risk.

On April 5, 2021, key provisions of the new rule became effective including new permitting provisions and the Regulatory Status Review (RSR) process for certain crops, including corn, soybean, cotton, potato, tomato, and alfalfa. USDA-APHIS continued to accept petitions for all other crops until September 30, 2021.

On October 1, 2021, the new rule was fully implemented. On this date, the RSR process took effect for all crops and USDA-APHIS stopped accepting petitions.

Weblink for more information on the revised regulations:

https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/biotech-rule-revision

Weblink for the text of the revised rule:

https://www.ecfr.gov/current/title-7/subtitle-B/chapter-III/part-340?toc=1

❖ ***Confirmation Process.***

Under the revised regulations, certain categories of modified plants are exempt from the regulations because they could otherwise have been developed through conventional breeding techniques and thus are unlikely to pose an increased plant pest risk compared to conventionally bred plants. In addition, plants that have a plant-trait-mechanism of action combination that is the same as in a plant that has USDA-APHIS reviewed and determined to be unlikely to pose a plant pest risk, and, thus not regulated, are exempt under the revised regulations. On June 24, 2021, USDA-APHIS notified stakeholders that an updated Plant-Trait-Mechanism of Action Table was available.

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

Since the implementation of the confirmation process, USDA-APHIS has issued eleven responses to confirmation request letters (six in FY 2021 and 5 in FY 2022) and posted them on its website. The first confirmation request letter was signed on April 28, 2021.

On July 19, 2021, USDA-APHIS published a notice to advise the public of its proposal to exempt plants with additional modifications that could otherwise be achieved through conventional breeding. Public comments on the proposal were accepted until August 18, 2021. USDA-APHIS is reviewing the comments and considering next steps.

Weblink for additional information:

https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/confirmations/confirmation-process

Weblink for table of confirmation letters:

https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/confirmations/responses/cr-table

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

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

The RSR process involves two distinct review 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 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 regulated. 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. USDA-APHIS will review the comments and other information it receives related to the preliminary PPRA to produce a final PPRA, and use the final PPRA to determine whether the plant and its sexually compatible relatives are unlikely to pose an increased plant pest risk relative to their comparator(s) and whether the plant is subject to regulation under 7 CFR part 340. If USDA-APHIS determines that a plant is not subject to 7 CFR 340, this will be announced in a second *Federal Register* notice and will also be posted on the USDA-APHIS website along with the original request and the final PPRA.

This process was implemented for certain crops on April 5, 2021 and fully implemented on October 1, 2021. Since the implementation of the RSR process, USDA-APHIS has received 19 RSR requests (7 in FY 2021 and 12 in FY 2022).

On August 25, 2021, USDA-APHIS shared a draft guide detailing the information requirements and process for submitting an RSR request and invited public comments for 60 days until October 25, 2021. In addition, USDA-APHIS hosted a technical webinar on September 28, 2021, to discuss the RSR process and guide and to provide stakeholders with a chance to ask questions.

Weblink for the text of the draft RSR guidance:

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

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

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

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

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

Since March 2021, USDA-APHIS has made determinations of non-regulated status for four products. Determinations for non-regulated status were made for Pioneer SPTA Maize that was genetically engineered for maintenance and recovery of male-sterile maize breeding lines (May 21, 2021); Agrivida Phytase Corn that produces phytase enzyme (September 21, 2021); Okanagan Non-browning Apple (extension) that exhibits a non-browning phenotype (September 22, 2021); BASF Nematode-protected and Herbicide Tolerant Soybean that is resistant to the soybean cyst nematode and tolerant to HPPD-4 herbicides (March 9, 2022).

Currently there are four products pending review: 1) Pioneer Insect Resistant and Herbicide Tolerant Corn, 2) Bayer 5 HT Maize, 3) SUNY ESF Blight Tolerant Chestnut, and 4) ArborGen Freeze Tolerant Eucalyptus.

Weblink for petition documents: https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/petitions/petition-status

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

On April 5, 2021, all applicants for APHIS BRS permits were required to apply using APHIS eFile. Consistent with the revised regulations found at 7 CRF part 340, APHIS BRS discontinued accepting applications for notifications after April 4, 2021.

In Fiscal Year (FY) 2021 (10/1/2020 through 09/30/2021), APHIS received 1125 applications for import, interstate movement, and environmental release. Of those, APHIS issued 565 permits and acknowledged 246 notifications. In addition, 2 applications are pending, 310 were withdrawn, and 2 were denied for reasons unrelated to risk (e.g., applicant needed to apply for a permit instead of a notification or the application was not deemed complete prior to the regulatory deadline). During the portion of FY 2022 that has currently elapsed (10/1/2021 through 04/20/2022), APHIS received 621 applications. Of those, APHIS issued 334 permits. In addition, 188 applications are pending and 99 were withdrawn.

❖ ***Compliance and oversight.***

From October 1, 2020, through April 20, 2022, USDA-APHIS and its state partners completed 878 inspections (708 in FY 2021, and 170 thus far in FY 2022) to meet compliance and oversight goals for the regulation of field trials involving plants and organisms developed using genetic engineering. In March 2020, USDA-APHIS began conducting inspections virtually due to COVID-19 travel restrictions. A limited number of in-person inspections have been conducted since May 2021, with a goal of increasing the number of in-person inspections in the coming months.

❖ ***2021 USDA-APHIS BRS Stakeholder Meeting.***

On November 18, 2021, USDA-APHIS Biotechnology Regulatory Services (BRS) held its annual stakeholder meeting. The meeting was open to stakeholders and the public to foster engagement and transparency in BRS regulatory activities. BRS provided updates on the current fiscal year program activities and initiatives, including the implementation of the revised regulations; USDA-APHIS eFile (the new electronic submission system for permits); and compliance, regulatory, and policy activities. BRS also held an optional session on APHIS eFile that included a demo of APHIS eFile's Permitting Assistant, an overview of enhancements coming in 2022, and location requirements. The meeting provided an opportunity for questions and discussion in a group setting and one-on-one interactions with BRS staff. The agenda, a written recording of the proceedings, and copies of handouts and presentations can be found at the USDA-APHIS-BRS website under "Meetings."

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

Updates for the United States Environmental Protection Agency (EPA)

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

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

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

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

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

Weblink for the webinar:
https://www.youtube.com/watch?v=8cj34z8d9Gw&feature=youtu.be&app=desktop
Weblink for the docket:
https://www.regulations.gov/docket?D=EPA-HQ-OPP-2019-0508
https://beta.regulations.gov/document/EPA-HQ-OPP-2019-0508-0002

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

On November 23, 2021 EPA published a response to public comments and revised framework to improve lepidopteran resistance management strategies for pests of *Bacillus thuringiensis* (Bt) corn and cotton PIPs to prolong the durability these genetically modified crops. In response to increasing reports of lepidopteran pest resistance to Bt PIP crops, EPA convened a FIFRA Scientific Advisory Panel in 2018. Based on the panel's report and recommendations, EPA in 2020 proposed improvements to resistance monitoring, actionable definitions for insect resistance to Bt PIPs, enhanced mitigation measures for resistant pest populations, an increase in refuge size, strengthened refuge compliance measures, and a phase-down of at-risk single trait and pyramided PIP products. EPA took public comment on these proposals and after reviewing the comments, revised the resistance management framework accordingly. The response to comments and revised framework document is available in Docket# EPA-HQ-OPP-2019-0682.

Weblink for the webinar (held September 28, 2020 for the original proposal):
https://www.youtube.com/watch?v=-Cf7ZorPo84&feature=youtu.be
Weblink for the docket:
https://www.regulations.gov/docket?D=EPA-HQ-OPP-2019-0682.

❖ ***Regulatory Update for Plant-Incorporated Protectants***

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

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

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

  Weblink for the docket:

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

Office of Pollution Prevention and Toxics (OPPT)

❖ **Reviewed Biotechnology Submissions**

- In the last fiscal year, FY21 (Oct. 1, 2020 to Sept. 30, 2021), the U.S. EPA/OPPT reviewed 32 genetically engineered microbial strains submitted in 14 Microbial Commercial Activity Notices (MCANs) used in closed systems. The identity of some of these microorganisms were claimed as confidential. Of the non-confidential microorganisms, many were *Saccharomyces cerevisiae* for production of chemical substances, biofuel, or ethanol. Seven genetically engineered strains of *Escherichia coli* were reviewed. These were modified with genetically stable plasmid-borne DNA for production of enzymes or plasmid-borne DNA. Fourteen strains of microorganisms were submitted in three TSCA Experimental Release Applications (TERAs), the submissions needed for environmental introduction of genetically engineered microorganisms for commercial research and development purposes. The strains reviewed included several strains with a bioluminescent marker protein for investigating microbial colonization of plants, several strains of bacilli to affect nitrogen production, and several strains of green microalgae tested in open ponds. A determination of "not likely to present an unreasonable risk to health or the environment" was made for all these genetically engineered strains.

❖ **Microalgae Consensus Document**

- U.S. EPA/OPPT and Canada (New Substances Program – Environment and Climate Change Canada and Health Canada) as co-leads have responded to the comments received by the sub-working group (SWG) on Microorganisms members from Canada, The Netherlands, Germany, Australia, and Business at OECD (BIAC) on the Draft Operational Plan and the OECD Consensus Document on Microalgae. Comments on the Draft Operational Plan were to be submitted by April 30, 2021. Since no comments were received, the Draft Operational Plan was considered final. The Secretariat requested assistance from other SWG members to address specific sections of the Microalgae Consensus Document. The U.S. and Canada authored numerous sections of the document, including the "*Chlorella* chapter", and other sections applying to microalgae in general such as growth characteristics, dispersal mechanisms, geographical distribution, interactions in the environment, horizontal gene transfer, and risk assessment of genetically engineered algae. The Secretariat compiled text developed by the United States, Canada, and other SWG members to develop a Draft OECD Consensus Document on Microalgae to be distributed to the entire WP-HROB prior to the 36th WP-HROB Meeting May 18 - 20, 2022.

❖ **Assessment Tools for Biotechnology Products**

- In 2021, EPA's Office of Research and Development awarded $3,041,583 in funding to five institutions to develop science-based approaches to evaluate the potential human health and environmental impacts of new biotechnology products. The Request for Applications (RFA) closed at the end of the summer in 2020. In FY21 applications were reviewed externally for their scientific merit and then by EPA/OPPT and EPA/OPP and for their relevancy to program office research needs. The five awards (made by ORD beginning in July 2021) were for the following research topics: A Comprehensive Methodology to Track Genetically Recoded Organisms and Assess Their Impacts on Freshwater Microbial Communities; Development of a Data-Driven Model for Assessing Benefits and Risks of the pgSIT Approach for *Aedes aegypti* Eradication in Hawaii; Developing Microbial Biocontainment Strategies and Their Assessment Methods; Microbial Community Models for Measuring Survival and Persistence of SynBio Microbes in Soil; EcoGenoRisk : Identifying Potential Ecological Risks Posed by a Novel Genome. An EPA/ORD workshop was held July 28-29, 2021 to further discuss the research needs of the two program offices for synbio products, and to hear presentations by the STAR Grant awardees on their funded research.

II. International Activities

Updates for the United States Department of Agriculture (USDA)

***Technical Trilateral Working Group (TTWG)*.** The TTWG is a technical working group for biotechnology between the United States, Canada, and Mexico. The TTWG met for the annual meeting September 27-28, 2021. The TTWG also conducts quarterly calls throughout the year.

III. Developments in New Breeding Techniques (NBT)

Updates for the United States Department of Agriculture

Am I Regulated. USDA-APHIS has had practical experience fielding questions from developers regarding the regulatory status of new plants and plant products, including those developed with a variety of techniques. USDA-APHIS launched a voluntary "Am I Regulated" (AIR) process in 2011. On June 16, 2020, USDA-APHIS retired the AIR process as it transitioned to implementation of the revised biotechnology regulations. In total, USDA-APHIS responded to 166 AIR requests and posted responses to the website.

***Weblink for USDA-APHIS-BRS AIR process*:**

https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated

Confirmation Requests. On August 17, 2020, exemptions from the SECURE rule became effective, as did a process for developers to request confirmation from USDA-APHIS that a modified plant meets the criteria for exemption from the biotechnology regulations in 7 CFR part 340.

Specifically, the regulations in 7 CFR part 340 do not apply to plants that have been modified such that they contain either a single modification of a type listed in paragraphs (b)(1) through (3) of § 340.1, or additional modifications as determined by the Administrator, and described in paragraph (b)(4) of § 340.1.

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

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

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

(4) The Administrator may propose to exempt plants with additional modifications, based on what could be achieved through conventional breeding. Such proposals may be Agency-initiated, and follow the process in paragraph (b)(4)(i) of this section, or in response to a request made in accordance with paragraph (b)(4)(ii) of this section.

Over time, USDA-APHIS expects new plant breeding innovations to evolve with advances in science and technology, along with further developments of scientific information related to conventional plant breeding. To ensure they keep pace with these advances and developments, the biotechnology regulations include a process by which the Administrator can identify additional modifications that plants can contain and be exempt from the regulations, based on what could be achieved through conventional breeding. A guidance document is available that describes the process members of the public may use to prepare and submit proposals to exempt plants with additional modifications from regulation.

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

EUROPEAN UNION

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

i. Risk assessment

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

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

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

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

New authorisations:

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

Renewals:

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

More applications for authorisations are in the pipeline.

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

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

- Statement on in vitro protein digestibility tests in allergenicity and protein safety assessment of genetically modified plants, available at: https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2021.6350
- Adopted a scientific opinion on development needs for the allergenicity and protein safety assessment of food and feed products derived from biotechnology, available at: https://doi.org/10.2903/j.efsa.2022.7044

EFSA has published two scientific opinions on synthetic biology:

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

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

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

3. **Risk management measures**

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

4. **Public engagement and outreach activities**

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

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

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

2. Developments related to new breeding techniques (NBTs)

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

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

The study[31] was published on 29 April 2021 and identified limitations to the capacity of the legislation to keep pace with scientific developments; these cause implementation challenges and legal uncertainties. The study demonstrated that there are strong indications that the applicable legislation is not fit for purpose for some NGTs and their products, and that it needs to be adapted to scientific and technological progress. It may not be justified to apply different levels of regulatory oversight to similar products with similar levels of risk, as is the case for plants conventionally bred and obtained from certain NGTs. The study further confirmed that NGT products have the potential to contribute to sustainable agri-food systems in line with the objectives of the European Green Deal and Farm to Fork Strategy.

Based on the outcome of the study, the Commission has initiated a policy initiative on plants produced by targeted mutagenesis and cisgenesis. The initiative aims for a proportionate regulatory oversight for the concerned plant products, ensuring a high level of protection of human and animal health and the environment, and enabling

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

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

innovation and the contribution of safe new genomic techniques to the objectives of the European Green Deal and the Farm to Fork Strategy. An inception impact assessment was published on 24 September 2021[32].

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

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

- hosted a high-level event "New genomic techniques – way forward for safe and sustainable innovation in the agri-food sector" on 29 November 2021, with 855 registered participants from over 50 countries representing Members of the European Parliament, the Council Presidency, Member States, EFSA, researchers and academia, breeders, farmers, organic and GM-free sector and environmental NGOs.
- Organised a 4-week public consultation on inception impact assessment. During this consultation, over 70.000 contributions were received from citizens, economic operators along the agri-food chain, academia and research institutions, NGOs and environmental and consumer organisations, public authorities. Contributions originated from 91 countries (27 EU-Member States and 64 non-EU countries).
- Currently has a public consultation[33] ongoing. This consultation remains open for comments until 22 July 2022.

EFSA has published a scientific opinion

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

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

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

As regards EFSA's public engagement and outreach, on 16 May 2022, EFSA launched a 6-week public consultation on the draft opinion on plants developed through cisgenesis and intragenesis endorsed on 4 May 2022. This draft opinion is an update of the 2012 EFSA opinion on cisgenesis/intragenesis. It takes into account the recent developments of new genomic techniques to produce cisgenic and intragenic plants. This consultation is accessible at: https://connect.efsa.europa.eu/RM/s/publicconsultation2/a0l7U0000011Zb2/pc0176

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

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

BIAC (BUSINESS AT OECD)

1. Developments related to biosafety activities

1. CropLife International shares regulatory harmonization project

Industry has continued the conversation on science-based regulatory harmonisation, building on the publication of several articles in the Journal of Regulatory Science in early 2021. Those publications included science-based recommendations for food/feed assessments, environmental risk assessment, and stacked trait products. Throughout

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

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

2021, CropLife International engaged with the broader scientific community, presenting on the modernised regulatory approach described in these papers at several virtual scientific conferences including Plant science for Climate Emergency, Plant Biology 2021, and the American Chemical Society – AGRO Division Meeting. In addition, CropLife International presented on regulatory harmonization at a webinar organised by the International Consortium on Applied Bioeconomy Research (ICABR) and CropLife International. The webinar drew on experts from Europe, North America, and South America, providing participants with insights about the importance of both trans-Atlantic and globally compatible regulatory frameworks. Other related outreach activities included presentations during CropLife Canada's 2021 Spring Dialogue days, joining a panel at the APEC High-Level Policy Dialogue on Agricultural Biotechnology, and presenting at a workshop organised by Kenya's National Biosafety Authority.

2. Time-and-Cost to Market Study

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

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

3. Additional publications, reports, and resources

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

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

4. Emphasis on Sustainability

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

5. Global Communications Resources on GMOs

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

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

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

Other communications resources available on the CropLife website include:

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

2. Updates regarding international activities

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

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

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

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

3. Developments related to new breeding techniques (NBTs)

1. Industry Recognises Progress Related to Plant Breeding Innovation

The global seed industry (represented through the International Seed Federation and CropLife International) maintains its science-based position that plant varieties developed through the latest plant breeding methods, such as genome editing, should not be differentially regulated if they are similar or indistinguishable from varieties that could have been produced through conventional plant breeding methods34. Further, we encourage the processes used to determine whether products fall in or out of scope of genetically modified organism (GMO) regulations to be transparent, time-efficient, and considering already existing regulatory mechanisms for new plant varieties (such as, for example, plant variety registration, national seed laws, or general food safety laws). The adoption of common approaches across countries can be facilitated through alignment of definitions, standardisation of information requirements in support of a regulatory status determination, adoption of predictable and efficient assessment

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

timelines, and recognition of other countries' determinations on regulatory status. These common approaches are essential to maintain a functional trading system that facilitates food security enabled by innovative products including those derived from genome editing.

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

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

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

The seed industry continues to recognise the importance of timely information sharing around plant breeding tools, both at the international and national levels. We support initiatives that provide relevant information to governments, the value chain, and consumers, provided such efforts are both achievable by all users of genome editing in all jurisdictions and that information is not arbitrarily discriminatory toward certain plant breeding approaches versus others. We further note that the content and appropriate systems to share such information are driven, in part, by local context (e.g. national laws) and believe that there is unlikely to be a global "one size fits all" solution but rather a collection of reliable information sources.

2. Global Communications Resources Genome Editing

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

AUDA NEPAD-ABNE (African Biosafety Network of Expertise)

1. AUDA-NEPAD and its biosafety programme

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

environment, human and animal health.

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

2. Overall focus and delivery during the reporting period

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

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

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

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

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

3. Progress in functionality of biosafety systems in Africa and emerging challenges

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

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

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

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

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

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

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

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

Participation in OECD events

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

Country status update

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

Nigeria

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

Eswatini

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

Ethiopia

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

Malawi

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

Kenya

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

Sudan

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

AFSI (Agricultural and Food Systems Institute)

About the Agriculture & Food Systems Institute

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

1. Developments related to biosafety activities

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

AFSI has convened an Expert Working Group (EWG) with experts from Bangladesh, Bhutan, India, and Sri Lanka that is working towards Regional Harmonization for the Safety Assessment of Foods Derived from GE Plants. The EWG members, who are working in an individual capacity, have met virtually multiple times since September of 2020. The EWG recognises the similarities among the respective national guidelines as all are based on Codex and agreed to develop a mechanism to harmonise the process for safety assessment. To this end a guidance document entitled "***Towards a harmonised approach to Food Safety Assessment of Genetically Engineered plants in South Asia***" that describes a consensus approach to the safety assessment of foods derived from GE crops for application across the participating countries has been finalised after multiple rounds of discussion. AFSI is working on stakeholder engagement with plans tailored towards each of the participating countries' needs for the adoption and operationalization of the regional guidance. This will include in-person training opportunities for relevant stakeholders in the four participating countries.

IBO Training Program

In partnership with the Ministry of Agriculture, Government of Bangladesh and under the auspices of the South Asia Biosafety Program, AFSI is hosting a series of workshops targeting Institutional Biosafety Officers (IBOs) and Committees (IBCs) at research institutions engaged in biotechnology research and development in Bangladesh. The purpose of the workshop series is to ensure that institutions in Bangladesh are aware of their obligations under the biosafety regulatory system and are empowered to work with researchers to meet these obligations while continuing their research.

The *introductory workshop*, a by-invitation only, in-person event, was held in December 2021. This interactive activity provided a platform for discussion of the fundamentals of laboratory safety, with presentations on concepts of biosafety in the context of genetically engineered organisms. The *second workshop* was held virtually in February 2022 with a focus on biosafety compliance while working with GE plant material in laboratories and greenhouses. The *third IBO workshop* was an in-person event held in March 2022 and focused on capacity building exercises for IBOs and IBCs, covering topics including the development of standard operating procedures for greenhouse work, key considerations for containment of GE crops, and key components for record keeping, handling, storage, transfer, shipment, and disposal of GE plant material. Compliance for import, exchange, and research involving GM crops was also discussed. Three more workshops will be held in this series.

2. Updates regarding international activities

Webinar series on Microbial Biotechnology

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

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

Collaboration with the Inter-American Institute for Cooperation on Agriculture

On March 10, 2021, AFSI and the Inter-American Institute for Cooperation on Agriculture (IICA) signed a technical cooperation agreement recognising their shared commitment to improving understanding of agricultural technologies, responsible use, and capacity building in order to promote sustainable development and enhance the well-being of rural populations in the Americas. Under this framework, the two organisations have committed to work on a joint virtual course to provide training to support the preparation for new regulators in Guatemala, Honduras, and El Salvador. The joint program aims to strengthen the relationship between the members of national technical committees on biosafety from the three countries, as well as foster the importance of simplified and science-based procedures in the framework of the *Trilateral Customs Agreement*. The introductory session for the training course took place on February 23, 2022, which focused on AFSI's e-learning resources, risk assessment, and biosafety

regulatory frameworks in Guatemala and Honduras. The second session, which focused on problem formulation was held on April 6, 2022. An additional joint capacity building activity with IICA is planned for May 25, 2022, which will focus on ERA for GE crops.

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

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

AFSI is currently working with several U.S. agencies to put together an agenda for a meeting on *Agricultural Biotechnology: Operationalizing Resource Sharing, Communication Strategies, and Lessons Learned* with the intent that this virtual workshop will be hosted in August 2022. The project is still under consideration by the APEC secretariat. We intend on having OECD's BioTrack database presented as a valuable resource at this workshop.

3. Developments related to new breeding techniques (NBTs)

Webinars and Workshops on gene editing for Korean Scientists

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

4. Additional Information – AFSI Resources

eLearning courses

Self-paced, interactive eLearning courses developed by AFSI serve as a complementary resource to in-person training workshops and are being used to support capacity building programs we conduct in collaboration with our partners. All courses are peer-reviewed and are available in English. Additionally, some courses are available in Chinese. All courses will be available in Spanish at the end of Q4.

AFSI offers the following eLearning courses:

- **NEW** ***Food Safety of Genetically Engineered Animal Products***: This course covers the safety measures employed to evaluate the risk of genetically engineered animal products and how genetically engineered animal products are evaluated against non-genetically modified products. It discusses the safety measures employed to evaluate the risk of genetically engineered animal products. *(Being translated into French, Spanish and Portuguese)*.
- **NEW** ***Genetic Variability in Crops***: This course discusses genetic variability in crops, providing a basic review of genetics and plant breeding, an overview of modern breeding technologies, and a discussion of how new plant cultivars are released.

- **NEW** ***Environmental Risk Assessment of Non-Target Organisms for GE Crops***: This course discusses when, why, and how environmental risk assessments for GE crops are informed by testing of non-target organisms.
- **NEW** ***Genetic Engineering in Livestock Production***: This course covers advancements in genetic engineering in animals that have been demonstrated in laboratory settings and their application in livestock production. The course provides an overview on conventional livestock breeding as well as presents techniques that can be used to delete or alter existing genes or introduce new genetic sequences into livestock. The course also highlights obstacles in genetic improvement in animals and discusses opportunities for improved production for genetically engineered and gene edited livestock. *(Being translated into French, Spanish and Portuguese)*.
- ***Concepts in the Safety Assessment of Novel Food and Feed***: This course discusses how people use information about foods to make basic decisions regarding food safety and how government regulators use similar information to address the safety of novel foods that may be introduced into their country's food supply.
- ***Application of Problem Formulation to Food and Feed Safety Assessments***: This course teaches how to apply problem formulation to the food and feed safety assessment of GE crops.
- ***Understanding Low Level Presence in Agricultural Biotechnology***: This course teaches what low level presence is and how associated environmental risks can be assessed.
- ***Application of Problem Formulation to the Environmental Risk Assessment of Genetically Engineered Crops***: This course introduces the key concepts of problem formulation for the environmental risk assessment of genetically engineered crops.
- ***Confined Field Trials of Genetically Engineered Plants***: This course provides a comprehensive discussion of risk management methods for confined field trials of genetically engineered plants and how those methods may be incorporated into a regulatory framework.

The following eLearning courses are under development:

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