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Developments in Delegations on Biosafety Issues, April 2020 – March 2021

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No. 69

**Developments in Delegations on Biosafety Issues,
April 2020 – March 2021**

Environment Directorate

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Paris 2021

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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
[\(www.oecd.org/env/ehs/biotrack/\)](http://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 35th WP-HROB meeting (1-3 March 2021). It aims at summarising relevant information on activities related to biosafety issues since the previous meeting (March 2020) 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 2020–March 2021

ARGENTINA

1. New legislations in the regulatory framework

There were some reviews related with GMO Biosafety and NBTs regulations by National Advisory Commission on Agricultural Biotechnology:

2019

National regulations were simplified and updated for GMOs:

- a. Res. SABI N° 36/2019 s / Scope of the regulatory framework and procedures for the analysis of commercial authorization of plant GMOs.
- b. Res SABI 44/2019 s / Procedures for contained or confined activities.
- c. Res. SABI 52/2019 on commercial use of genetically modified microorganisms; Res. SABI 63/2019 s / Scope of the regulatory framework and procedures for the analysis of commercial authorization of animal GMOs.
- d. NBTs regulations: In 2019, the resolution of animal NBT and microorganisms was officially published, both contemplated under their respective commercial authorization regulations. In addition, this year the NBTs regulations for plants were updated.
- e. MERCOSUR Regulations: Res. GMC 23/19 s / Mechanism to reduce the occurrence of LLP.

2020

- a. Provision on Isolation and postharvest for confined trials.
- b. Guideline for the Risk Assessment of Genetically Modified Organisms.
- c. Updating and drafting of the new regulations on Contents and Containers.
- d. Update of I.4 of resolution 36/19 and Provision 3/19 related to stacked events.
- e. New provision for Management of Insect Resistance (IRM).

2021

- a. In 2020 the Biosafety Commission worked on updating the regulations for products obtained by new breeding techniques. This resolution became official.
The access link in Spanish is <https://www.boletinoficial.gob.ar/detalleAviso/primera/240526/20210208>
- b. Resolution N° 19/2021: Establish the "REFERENCE PARAMETERS FOR ACTIVITIES CONFINED WITH VEGETABLE GMOs"
The access link in Spanish is: <https://www.boletinoficial.gob.ar/detalleAviso/primera/240360/20210203>

2. Events for confined field trails

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

2019: 59 authorisations were granted for different crops:

	FIELD TRAILS	PRODUCTION	GREENHOUSE
QUANTITY	47	9	3
CROP			
Potato	0	0	1
Corn	11	4	0
Soy	22	4	0
Sugar cane	3	0	0
Cotton	4	0	1
Alfalfa	1	0	1
Lolium	1	0	0
Rice	2	0	0
Beet	1	0	0
Wheat	2	1	0

Organism	Phenotype	Institution	Activity
<i>Mycobacterium Avium</i>	Paratuberculosis	INTA	field trials
<i>Brucella Melitensis</i> pm		University of San Martin	Animal test

2020: 70 authorisations were granted for different crops:

	FIELD TRAILS	PRODUCTION	GREENHOUSE
QUANTITY	41	18	11
CROP			
Wheat	1	1	1
Corn	12	11	2
Sugar cane	2	0	0
<i>Lolium</i>	1	0	0
Soy	18	6	4
Cotton	2	0	0
Tobacco	1	0	0
Beet	1	0	0
Rice	1	0	0
Safflower	1	0	1
Alfalfa	1	0	0
Sorghum	0	0	1
Lettuce	0	0	2

Organism	Phenotype	Institution	Activity
<i>Escherichia coli</i>	Ev. B41	INTA	field trials

3. Events for Commercial Approvals

Genetically modified events were approved for commercial release in Argentina in 2019 and 2020:

Unique Identifier	Applicant	Common Names	Traits	Type of use	Date of approval	Decision name
BCS-GH811-4	Basf Agricultural Solutions	Cotton	Tolerance to glyphosate and HPPD inhibitor herbicides	Cultivation, Food and Feed	5/2/2019	AR10
MON-89034-3 X DAS-01507-1 X MON-00603-6 X SYN-IR162-4 X DAS-40278-9	Dow AgroSciences Argentina	Maize	Tolerance to herbicides formulated based on products of the aryloxyphenoxy family and 2,4-D, glufosinate-ammonium and glyphosate, and resistance to Lepidoptera.	Cultivation, Food and Feed	13/3/2019	AR20
BCS-GH002-5 X BCS-GH004-7 X BCS-GH005-8 X SYN-IR102-7, BCS-GH004-7, BCS-GH005-8	Basf Agricultural Solutions	Cotton	tolerance to glufosinate ammonium, glyphosate and resistance to Lepidoptera.	Cultivation, Food and Feed	11/6/2019	AR31
MON-89034-3 X DAS-01507-1 X MON-88017-3 X DAS-59122-7	Monsanto Argentina, Dow AgroSciences Argentina and Pioneer Argentina	Maize	Resistance to Lepidoptera and Coleoptera, and tolerance to glufosinate-ammonium and glyphosate.	Cultivation, Food and Feed	9/8/2019	AR59-2019
MON-87427-7 X MON-89034-3 X DAS-01507-1 X MON-88017-3 X DAS-59122-7	Monsanto Argentina	Maize	Resistance to Lepidoptera and Coleoptera, and tolerance to glufosinate-ammonium and glyphosate.	Cultivation, Food and Feed	9/8/2019	AR60-2019
MON-87427-7 X MON-89034-3 X MON-00603-6	Monsanto Argentina	Maize	Resistance to Lepidoptera and Coleoptera, and tolerance to glufosinate-ammonium and glyphosate.	Cultivation, Food and Feed	9/8/2019	AR61-2019
MON-87427-7 X MON-89034-3 X SYN-IR162-4 X MON-00603-6	Monsanto Argentina	Maize	With Protection against Lepidoptera and tolerance to glyphosate	Cultivation, Food and Feed	30/9/2019	AR103-2019
SYN-IR102-7	Syngenta Agro	Cotton	Protection against Lepidopteran insects	Cultivation, Food and Feed	17/10/2019	AR117
IND-00410-5	INDEAR	Soybean	Drought resistance and glufosinate tolerance	Cultivation, Food and Feed	1/10/2015	AR397
IND-10003-4, IND-10015-7, IND-10003-4 X IND-10015-7	INDEAR	Safflower	With expression of bovine pro-chymosin in seed	Cultivation, Food and Feed	7/12/2017	AR103-2017
TIC-AR233-5	Tecnoplant	Potato	Virus resistance	Cultivation, Food and Feed	5/8/2018	AR65
DBN-09004-6	INDEAR	Soybean	Glyphosate and glufosinate tolerance	Cultivation, Food and Feed	26/2/2019	AR17
IND-00412-7	INDEAR	Wheat	Tolerance to drought and tolerance to the herbicide glufosinate ammonium	Cultivation, Food and Feed	7/10/2020	AR41-2020

4. New Breeding Techniques

There were 12 consultations for plants, animals, and microorganisms. Those products were considered by CONABIA to attend the characteristics established on the NBTs Normative and not considered to fall under the scope of the Law 763/11 that regulates genetically modified organisms.

Finally, we can mention that since 2015 until now, around 20 ICPs have been carried out for the different organisms.

5. Participation in International Activities

2019

- 5 high-level bilateral or regional meetings:
 - a. VIII Meeting of the China-Argentina Working Group on Agricultural Biotechnology.
 - b. I Meeting of the Joint Working Group on Agricultural Biotechnology and Biosafety between Argentina and the Russian Federation.
 - c. VI Argentina-EU Bilateral Dialogue on issues related to the application of Biotechnology to Agriculture.
 - d. IV Meeting of the Agricultural Biotechnology Commission of the SGT No. 8 "Agriculture" of MERCOSUR.
 - e. GT5 meeting "Public policies in biotechnology" of the Southern Agricultural Council (CAS).
- The Agreement was renewed with the FAO (Food and Agriculture Organization of the United Nations) by which CONABIA acts as a Reference Center for the Biosecurity of GMOs.
- 3 interventions in specialized intergovernmental meetings (multilateral) organized by OECD, FAO and APEC.
- 2 high-level dissertations in international conferences on Bioeconomy:
 - a. XXIII International Congress of Applied Bioeconomy (Italy) and
 - b. II African Congress of Bioeconomy (South Africa).
- Other international activities in 2019:
 - a. Working Group on Harmonisation of Regulatory Oversight in Biotechnology / OECD.
 - b. Working Group for the Safety of Novel Foods and Feeds / OECD.
 - c. Global Consultation Workshop on the Post-2020 Global Biodiversity Framework, Biosafety and the Cartagena Protocol.
 - d. First meeting of the Open-Ended Working Group on the Post-2020 Global Biodiversity Framework.
 - e. Foro Online Consideraciones Socioeconómicas (Artículo 26 Protocolo de Cartagena).
 - f. Thirteenth meeting of the Liaison Group on the Cartagena Protocol on Biosafety.
 - g. Twenty-third meeting of the Subsidiary Body on Scientific, Technical and Technological Advice.
 - h. Meeting of the Ad-hoc Technical Expert Group on Socioeconomic Considerations (Article 26 of the Cartagena Protocol).
 - i. Workshop FAO "Towards effective risk-based GM food safety assessment and regulatory management".
 - j. Conference "12th TRANSGENIC ANIMAL RESEARCH CONFERENCE" organized by the University of California Davis.

2020

- 4 bilateral or regional high-level meetings:
 - a. VI Meeting of the Agricultural Biotechnology Commission of SGT No. 8 "Agriculture" of MERCOSUR.
 - b. VII Meeting of the Commission for Agricultural Biotechnology of SGT No. 8 "Agriculture" of MERCOSUR.
 - c. VII Argentina-EU Bilateral Dialogue on issues related to the application of Biotechnology to Agriculture.
 - d. Meeting GT5 "Public policies in biotechnology" of the Southern Agricultural Council (CAS)
- Interventions in specialized intergovernmental and multilateral meetings to discuss the negotiation of the SPS chapter and on Biotechnology and LLP in the MERCOSUR - CANADA Agreement.
- High-level dissertation at international conference on Bioeconomy: XXIV International Congress of Applied Bioeconomy (Argentina).
- Contribution or organization of capacity building actions in Biotechnology regulation in third countries: Training for Panamanian officials in biosafety in the framework of a GEF Project (Global Environment Facility) and CONABIA as a reference center of FAO, Virtual exchange South-South.
- IV, V, VI, VII, VIII IICA Virtual Sessions on Biotechnology and Biosafety of the Convention on Biological Diversity and preliminary sessions of the Cartagena Protocol.
- Virtual 7th Meeting of the Global Low Level Presence Initiative (GLI)

- High-level dissertation at 2020 Gene Editing Seminar organized by Korea and named “Global trends in the policy for gene edited crops” aimed to appeal Korean authorities to establish science-based policy.
- Training for Panamanian officials on biosafety in the framework of a GEF (Global Environment Facility) Project and CONABIA as a reference center for FAO, South-South Virtual Exchange, Argentina-Panama. NBTs, regulations for Argentina.
- Virtual Conference: Wheat production systems and breeding technologies –Argentina- Tunéz, 19 de November.
- 24th ICABR Bioeconomy CONFERENCE, held from October 12 to 15. We participate in the organization and contribute to the bioproducts panel.
- Active participation in WTO SPS Working Group on Approval Procedures.
- International Virtual Workshop Series on Regulatory Approaches for Animal Biotechnology.
- 2nd International Congress of Biotechnology - Bolivia Innova and in the Seminar: Introduction to Genomic Editing by CRISPR / Cas.
- Mini course carried out within the framework of the activities for the 10 years of the Degree in Biotechnology at FACEN-UNA. Paraguay.
- One CGIAR Global Webinar Series- Regulation and Genome Edited Plants. Webinar 4: Regulation and Genome Edited Plants. Primer Congreso de Argentino de semillas “germinando nuevas ideas” hablando de Sistema Regulatorio de las especies mejoradas por métodos biotecnológicos. ALAP.
- ERB & CAI Seminar - National Biosafety System - Uruguay. Experiences in Gene editing in Argentina.
- Annual Congress of Entomology. (Entomological society of America). "The use of the portability of data from field studies in Argentina".

6. Communication and education

2019

- 6 contributions or organization of actions to capacity building in biotechnology regulation in third countries, including Cuba, Ecuador, Chile, Mexico, Turkey, and the Netherlands.
- 6 trainings to agricultural schools in different provinces.

2020

During 2020, a training on agricultural biotechnology was carried out at an agro-technical school.

7. Products derived from agriculture

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 fibers); 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.
- 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.)

- 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.

AUSTRALIA

1. Developments related to implementation of national biosafety framework

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

1. Risk assessment/regulatory decisions

ENVIRONMENTAL RELEASE APPROVALS:

GMO REGISTER

In July 2020, **three GM carnations** were placed on the GMO Register, following preparation of a risk assessment and risk management plan (RARMP). The GM carnations, modified to have altered (blue) flower colour, were previously authorised (for import as cut flowers) under a licence (DIR 134).

Placing a GMO on the GMO Register means there is no longer a requirement for there to be a licence holder for that GMO, and anyone can conduct dealings with the GMO (subject to any conditions placed on the registration). The authorised dealings with the GM carnations as cut flowers are import, transport and disposal.

Details of GMOs placed on the GMO Register, including RARMPs, are available at:

<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/gmoregister-1>

LICENCES FOR ENVIRONMENTAL RELEASE since March 2020 (at 13 April 2021)

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:

<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/ir-1>

Commercial release approvals – GM plants - one approval:

- **GM cotton** (*Gossypium hirsutum*) – herbicide tolerance traits (dicamba and glufosinate ammonium). (DIR 173)

Commercial release approvals – GMO therapeutics - two approvals (note that approvals from the Therapeutic Goods Administration are also required):

- **Vaccine against COVID-19** (ChAdOx1), GMO is a replication defective chimpanzee adenovirus expressing SARS-COV-2 spike protein. (DIR 180)
- **Vaccine against cholera** (Vaxchora®), GMO is an attenuated strain of *Vibrio cholera*, genetically modified to prevent cholera toxin expression. (DIR 174)

Field Trial approvals - ‘limited and controlled’ releases - one new field trial approved since March 2020:

- **white clover** genetically modified for increased condensed tannins (DIR 176)

Clinical Trials approvals - ‘limited and controlled’ releases - three trials with live GMOs:

- **Solid cancerous tumour treatment** – GMO is *Vaccinia virus* (vaccine strain) expressing immunomodulatory genes (DIR 179)
- **Bladder cancer treatment**, GMO is an attenuated adenovirus expressing a gene stimulating anti-tumour response (DIR 177)
- **Vaccine against influenza**, GMO is an attenuated, replication incompetent influenza virus (DIR 171)

APPLICATIONS UNDER ASSESSMENT (at 23 February 2021)

Commercial release GM plants - two applications currently under assessment:

- **GM canola** (*Brassica napus*) – herbicide tolerance (glufosinate ammonium) and hybrid breeding system (MS11 line) (DIR 175)
- **GM canola** (*Brassica napus*) – herbicide tolerance (glufosinate ammonium, glyphosate) and hybrid breeding system (RF3xMS11, RF3xMS11xMON88302) (DIR 178)

Commercial release GMO therapeutics - one application currently under assessment:

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

Field trials of GM plants

At 14 April 2021, there are no applications for limited & controlled release of GM plants under assessment.

Clinical trials of GMO therapeutics - three applications currently under assessment:

- **Cystic fibrosis treatment** – GMO is a replication defective *Herpes simplex virus* expressing the human cystic fibrosis transmembrane conductance regulator (CFTR) gene (DIR 181)
- **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)
- **Vaccine against Covid 19**. GMO (SC-Ad6-1) is replication defective human adenovirus expressing SARS-COV-2 spike protein (DIR 184)

Risk assessment guidance documents

Two revised biology documents have been published since March 2020:

- The Biology of *Trifolium repens* L. (**White Clover**).
- The Biology of *Triticum aestivum* L. (**Bread Wheat**)

OGTR Biology documents are modelled on the OECD concept and are available at:

<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/biology-documents-1>

Modernisation of application processes – online forms

As part of the ongoing development of digital service delivery, OGTR has released a number of online application forms. A number of other online forms are planned or under development. Information on the online forms project is available at: <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/online-forms-help-htm>

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

AMENDMENTS TO LEGISLATION

The primary biosafety legislation, the *Gene Technology Act 2000*, has not been amended since the 34th WG-HROB meeting in March 2020.

Some amendments to the Gene Technology Regulations 2001 commenced (i.e. came into force) on 1 July and 8 October 2020. These amendments were agreed in 2019 and resulted from the 2016 Technical Review of the Regulations. Most amendments commenced on October 2019.

Details of all the amendments is available at:

<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/amendments%20to%20the%20regs%202019>

- Amendments commenced on 1 July 2020: Minor changes to recording and reporting for Notifiable Low Risk Dealings (contained work)
- Amendments commenced on 8 October 2020: Repeal of Item 1 of Schedule 1.

Schedule 1 of the GT Regulations, Organisms that are not GMOs, lists types of organisms and the changes made to them that are not considered to be GMOs and that are excluded from regulation under the GT Act.

The now repealed Item 1 was a source of ambiguity for stakeholders and the OGTR: “A mutant organism in which the mutational event did not involve the introduction of any foreign nucleic acid (that is, non-homologous DNA, usually from another species).” The delayed commencement of this repeal was to enable time for anyone working with organisms that might have been excluded from regulation by Item 1 to apply for necessary authorisations.

ONGOING POLICY REVIEW ACTIVITIES

A public consultation process is currently underway (14 December 2020 – 17 March 2021) on possible options for updating Australia’s Gene Technology regulatory scheme. Submissions closed on Wednesday 17 March 2021. This policy work is being undertaken by the Department of Health on behalf of the Legislative & Governance Forum on Gene Technology (comprised of all Australian jurisdictions).

Options for possible changes to the scheme are set out in a **Consultation Regulation Impact Statement (CRIS)** – ‘*Modernising and future proofing the National Gene Technology Scheme: Proposed regulatory framework to support implementation of the Third Review of the Scheme*’ supported by an Explanatory Paper.

The focus of the CRIS is to explore options to make the regulatory scheme more risk proportionate and more responsive to changes in technology and its applications. A series of webinars has been held to provide information to interested stakeholders on the options and process.

The CRIS and explanatory paper and information on how to make submissions are available at:

<https://consultations.health.gov.au/best-practice-regulation/gene-technology-scheme-cris/>

The options have been developed as part of the implementation of the recommendations of the Third Review of the National Gene Technology Regulatory Scheme which was commenced in 2017. Information on the Review is at: <https://www1.health.gov.au/internet/main/publishing.nsf/Content/Gene+Technology-2>

3. Risk management activities

OGTR continued to undertake monitoring and compliance activities throughout 2020. However due to the COVID-19 pandemic and border restrictions across Australian states and territories the ability to undertake ‘on site’ inspections was reduced. Significant effort was therefore put into ‘desk top’ reviews and regular communication with regulated stakeholders.

4. Public engagement and outreach activities

Fact sheets

OGTR publishes Fact Sheets to provide information to the public on operation of the regulatory scheme. Fact Sheets revised since March 2020 include:

- Genetically Modified (GM) Cotton in Australia
- Genetically Modified (GM) Carnations in Australia
- Who needs to apply to import or use (deal with) a GMO?

OGTR Fact Sheets are available at: <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/factsheets>

2. Updates regarding international activities

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

In September-October 2020, OGTR participated in an online webinar series organised by CGIAR (formerly the Consultative Group for International Agricultural Research) – ‘One CGIAR Global Webinar Series on Genome Editing in Agriculture: Innovations for Sustainable Production and Food Systems’. Dr Peter Thygesen presented in the final webinar on regulation and genome editing in Australia and provided an update on OECD NPBT activities. Information about the webinar series is available at: <https://www.icrisat.org/event/one-cgiar-global-webinar-series-on-genome-editing-in-agriculture/>

OGTR also participated in several other online international meetings:

- International Society of Cell and Gene Therapy 2020 virtual meeting, May 2020
- 2020 Innovations Dialogue: Life Sciences, International Security and Disarmament, August 2020
- 4th International Workshop on Regulatory Approaches for Animal Biotechnology, , September-November 2020.
- International Conference on Precision Crop Breeding, October 2020
- APEC High Level Policy Dialogue on Agricultural Biotechnology, October 2020
- Global Low Level Presence Initiative, October and December 2020
- International Society of Cell and Gene Therapy, Australia & New Zealand regional meeting, Febr. 2021

3. Developments related to new breeding techniques (NBTs)

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

OGTR and GMO regulation

There have been no new developments specific to new breeding techniques or genome editing since the 2019 amendments to the Gene Technology Regulations. Those amendments excluded organisms resulting from site directed nuclease-1 (SDN-1) type modifications without any introduced nucleic acid template to guide genome repair from regulation.

OGTR has published general guidance for researchers and potential applicants regarding regulatory coverage of genome editing - <http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/newtechnologies-htm>. Researchers and developers are encouraged to contact OGTR to discuss specific genome editing applications of genome-edited organisms to clarify regulatory requirements.

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. A proposal (P1055 Definitions for gene technology and new breeding techniques) for amending the Food Standards Code was published in February 2020. This work has been delayed due to the Covid-19 pandemic. It is anticipated that comments from the community, government, industry and other interested parties will be sought in mid-2021. 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

Appointments to expert advisory committees

The new memberships of the Gene Technology Technical Advisory Committee (GTTAC) and the Gene Technology Ethics & Community Consultative Committee (GTECCC) were announced in March 2020 –

<http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/committees-index-1>

The Gene Technology Regulator receives expert advice from the two statutory committees, GTTAC and GTECCC. GTTAC provides advice on all environmental release assessments.

AUSTRIA

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

1) During the current reporting period (April 2020–March 2021), 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 participated in the risk assessment procedure conducted by EFSA for notifications of GM-products for EU-wide authorisation for import/processing/food and feed use.

2) As notified in our last report a legislative amendment to the Austrian Release Ordinance (Freisetzungsverordnung, BGBl. II Nr. 260/2005) was enacted on April 30th 2020 with the joint consent of all five competent federal ministries to transpose Commission Directive (EU) 2018/350 of 8 March 2018 amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms, in particular the risk assessment of GM higher plants. The text of the amendment (BGBl. II - 30. April 2020 - 193. Verordnung des Bundesministers für Soziales, Gesundheit, Pflege und Konsumentenschutz, mit der die Freisetzungsverordnung 2005 geändert wird) is available (in German language only) at: https://www.ris.bka.gv.at/Dokumente/BgblAuth/BGBLA_2020_II_193/BGBLA_2020_II_193.pdf

The national Gene Technology Act is currently reviewed for amendment with a view to the upcoming deadline for implementation of Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (“the Transparency Regulation”).

3) 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) The lead Austrian competent authority (BMSGPK) and Environment Agency Austria submitted an opinion to the European Commission in support of further activities coordinated and conducted by EFSA to develop a risk assessment guidance document for applications of GM organisms with gene drive.

5) The following reports, scientific papers or other documents addressing issues related to biosafety were published (since April 2020):

- Frieß, J. L., Breckling, B., Pascher, K., and Schröder, W. (2020a). “Case Study 2: Oilseed Rape (*Brassica napus* L.)” In Gene drives at tipping points: Precautionary technology assessment and governance of new approaches to genetically modify animal and plant populations, ed. A. von Gleich and W. Schröder (Cham, Switzerland: Springer), 103–45.
- Frieß, J. L., Otto, M., Simon, S., Giese, B., and Liebert, W. (2020b). Umbruch in der Biotechnologie: Sprung aus dem Labor in die Natur. *Natur und Landschaft* 95 (5). doi: 10.17433/5.2020.50153799.209-214.

- Giese, B., Gleich, A. von, and Frieß, J. L. (2020). “Alternative Techniques and Options for Risk Reduction of Gene Drives.” In *Gene drives at tipping points: Precautionary technology assessment and governance of new approaches to genetically modify animal and plant populations*, ed. A. von Gleich and W. Schröder (Cham, Switzerland: Springer), 167–85.
- Ladics, G. S., Fan, L., Sewalt, V. J., and Spök, A. (2021). “Chapter Eight - Safety assessment and regulation of food enzymes.” In *Enzymes*, ed. S. Kermasha and M. N.A. Eskin (San Diego: Academic Press), 203–58.

2. Updates regarding international activities

- 1) 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).
- 2) 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.
- 3) Participation in informal 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).
- 4) Support for further implementation of the Standards for GMO-free production in the Danube region in Central and Eastern Europe.

3. Developments related to new breeding techniques (NBTs)

- 1) Austria is awaiting the publication of the study conducted by the European Commission concerning the status of applications of new breeding techniques (nGT products) which is due to be published by April 2021. The Austrian competent authorities and national institutions involved in risk assessment and management of GM products submitted a coordinated response to a questionnaire directed to EU Member States by the European Commission.
- 2) 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 will apply for these products.
- 3) 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. The results of an Ethical-Delphi survey commissioned by the Federal Ministry of Social Affairs and Health (BMSGPK) addressing ethical value concepts and socio-economic aspects concerning the possible use of nGTs in agriculture or other fields was published as a scientific paper (Dürnberger et al. 2020):
 - Dürnberger, C., Kallhoff, A., and Grimm, H. (2020). Getrennt durch die Zukunft? Österreichische Stakeholder(innen) beurteilen „Neue Pflanzenzüchtungsverfahren“. *Gaia - Ecological Perspectives for Science and Society* 29 (2). doi: 10.14512/gaia.29.2.9.
- 4) The following reports, scientific papers or other documents addressing issues related to nGTs are available (since April 2020):
 - Eckerstorfer, M., Dolezel, M., Greiter, A., Heissenberger, A., Miklau M., Steinbrecher, R.A. (2020). Risk Assessment of Plants developed by new Genetic Modification Techniques (nGMs): Biosafety Considerations for Plants Developed by Genome Editing and Other New Genetic Modification Techniques (nGMs) and consequences for their regulation. BfN-Skripten 592, DOI: 10.19217/skr592. Available at: https://www.researchgate.net/publication/349607487_Risk_Assessment_of_Plants_developed_by_new_Genetic_Modification_Techniques_nGMs_Biosafety_Considerations_for_Plants_developed_by_Genome_Editing_and_other_new_Genetic_Modification_Techniques_nGMs_and_C and <https://www.bfn.de/fileadmin/BfN/service/Dokumente/skripten/Skript592.pdf>
 - Eckerstorfer, M., Anita Greiter, A., Heissenberger, A. (2020). Risk Assessment of Plants developed by new Genetic Modification Techniques (nGMs) - Comparison of existing Regulation Frameworks in non-EU Countries with a Focus on the respective Requirements for Risk Assessment. BfN-Skripten 598, Federal Agency for Nature Conservation, Bonn, Germany. DOI 10.19217/skr598. Available at:

https://www.researchgate.net/publication/349947736_Risk_Assessment_of_Plants_developed_by_new_Genetic_Modification_Techniques_nGMs_Comparison_of_existing_Regulation_Frameworks_in_non-EU_Countries_with_a_Focus_on_the_respective_Requirements_for_Risk_Assessment and <https://www.bfn.de/fileadmin/BfN/service/Dokumente/skripten/Skript598.pdf>

- Ribarits, A., Eckerstorfer, M., Simon, S., and Stepanek, W. (2021a). Genome-Edited Plants: Opportunities and Challenges for an Anticipatory Detection and Identification Framework. *Foods* 10 (2). doi: 10.3390/foods10020430.
- Ribarits, A., Narendja, F., Stepanek, W., and Hochegger, R. (2021b). Detection Methods Fit-for-Purpose in Enforcement Control of Genetically Modified Plants Produced with Novel Genomic Techniques (NGTs). *Agronomy* 11 (1). doi: 10.3390/agronomy11010061.

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 is available at the Belgian Biosafety Server (<https://www.biosafety.be/content/field-trials-gm-plants-database>). A field trial with GM maize with modified growth characteristics is still ongoing.

Field trial (1) notified since March 2020

- Field trial with GM 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)

Further, two clinical trials have been notified and one clinical trial with GM micro-organisms for clinical purposes has 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 trial (2) notified since March 2020

- Immunotherapy of vaccine against skin and lung cancer types (B/BE/20/BVW5)
- Gene therapy of Duchenne Muscular Dystrophy (B/BE/20/BVW4)

Clinical trials (1) approved since March 2020

- Therapy of (sub)cutaneous lesions (B/BE/20/BVW3)

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 will introduce changes to the procedures for approval of placing on the European market of GMOs as or in products, including notifications handed in in Belgium under the Directive 2001/18/EC. Belgium is currently participating in the discussions on the practical implementation of this Transparency Regulation.

3. Research projects on biosafety, relevant publications

Belgium supported the following activities:

- Adequacy and sufficiency evaluation of existing EFSA guidelines for the molecular characterisation, environmental risk assessment and post-market environmental monitoring of **genetically modified insect** containing engineered gene drives. EFSA Journal 2020;18(11):6297. DOI: 10.2903/j.efsa.2020.6297

2. Updates regarding international activities

1. 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 COP-MOP meetings and the CBD and Protocol activities such as the expert online forums on LMOs containing gene drives.

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 a field trial 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 has been issued asking for a study on the status of New Genomic Techniques (<https://eur-lex.europa.eu/eli/dec/2019/1904/oj>), which is expected to be finalised by April 30, 2021.

2. Specific cases of application, assessment and decision

No field trials with genome-edited plants were initiated since the last WP meeting.

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

Belgium supported in the following activities:

- Applicability of the EFSA opinion on site-directed nucleases type 3 for the safety assessment of plants developed using site-directed nuclease type 1 and 2 (SDN-1 & SDN-2) or oligonucleotide directed mutagenesis (ODM). EFSA Journal 2020;18(11):6299. DOI: 10.2903/j.efsa.2020.6299.
- Evaluation of existing guidelines for their adequacy for the microbial characterisation and environmental risk assessment of microorganisms obtained through synthetic biology. EFSA Journal 2020;18(10):6263. DOI: 10.2903/j.efsa.2020.6263.
- Evaluation of existing guidelines for their adequacy for the molecular characterisation and environmental risk assessment of genetically modified plants obtained through synthetic biology. EFSA Journal 2021;19(2):6301. DOI: 10.2903/j.efsa.2021.6301.

4. Any other information related to NBTs.

Belgian scientists were involved in the following publication:

- Van de Meer *et al.* (2021). The status under EU law of organisms developed through novel genomic techniques. European Journal of Risk Regulation, p.1-20. DOI: <https://doi.org/10.1017/err.2020.105>

BRAZIL

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

Since last OECD meeting, 25 new GM events were approved for commercial release in Brazil in 2020 (<http://ctnbio.mctic.gov.br/liberacao-comercial#/liberacao-comercial/consultar-processo>):

GM Plants:

- ✓ NK603 x T25 x DAS-40278: herbicide-tolerant maize (DuPont/Corteva);
- ✓ MON-89034-3 x DAS-01507-] x SYN-IR162-4 x MON-00630-6 x DAS40278-9 (and subcombinations): herbicide-tolerant and insect-resistant maize (Dow Agrosciences);
- ✓ MON 95379: insect-resistant maize (Monsanto/Bayer);
- ✓ CTC75064-3: insect-resistant sugarcane (Centro de Tecnologia Canavieira - CTC);
- ✓ CTC79005-2: insect-resistant sugarcane Centro de Tecnologia Canavieira - CTC);
- ✓ MON 87701: insect-resistant soybean (Monsanto);
- ✓ MON 89788: herbicide-tolerant soybean (Monsanto).

GM Microorganisms:

- ✓ Granulated Tryptophan TRP Pro: industrial application (CJ do Brasil Indústria e Comércio de Produtos Alimentícios Ltda.);
- ✓ *Saccharomyces cerevisiae* microorganism (Y63348): industrial application (Amyris);
- ✓ Derivative from GM *Corynebacterium glutamicum*: use in animal feed as additive (CJ do Brasil Indústria e Comércio de Produtos Alimentícios Ltda.);
- ✓ Derivative from microorganism alpha-amylase enzyme (GICC03556): industrial application (Danisco Brasil Ltda.);
- ✓ *Saccharomyces cerevisiae* microorganism (M15419): industrial application (Lallemand Brasil Ltda.);
- ✓ Soybean Leg-hemoglobin produced from GM *Picchia pastoris* microorganism (Leg-hemoglobine): human food consum (Jomakol Representações e Serviços Ltda.);
- ✓ MGM L-Lysine (BestAminoTM): additive for animal feed (CJ do Brasil Indústria e Comércio de Produtos Alimentícios Ltda.);
- ✓ *Prototheca moriformis* strain S9120: microorganism for industrial application (Corbion Produtos Renováveis Ltda.);
- ✓ Alpha-amylase enzyme (GICC03561): industrial application (Danisco do Brasil Ltda.)

Vaccines:

- ✓ LUXTURNA (voretigene neparvovec): gene therapy indicated for the treatment of adult and pediatric patients with vision loss due to hereditary retinal dystrophy by biallelic mutation of RPE65 gene (Novartis Biociências S.A.);
- ✓ MHYOSPHERE PCV ID: inactivated vaccine. Recombinant strain of *Mycoplasma hyopneumoniae* (Hipra Saúde Animal Ltda.);
- ✓ (INNOVAX ND-ILT): Vaccine against Marek Disease, Newcastle Disease and Infectious laryngotracheitis. Merck Infecçiosa, derivated from de GMO INNOVAX ND-ILT (Merck Sharp & Dohme Saúde Animal Ltda.);
- ✓ Zolgesma: gene therapy for the treatment of pediatric patients with spinal muscular atrophy (Novartis Biociências S.A.);
- ✓ Avian Recombinant vaccine: vaccine to prevent Marek Disease, Newcastle Disease and Gumboro Disease (Ceva Saúde Animal Ltda.);
- ✓ Lamzede: commercial name of the active component alphasialosidase, with is a human recombinant alpha-mannosidase, indicated for the treatment of adult and pediatric patients suffering from the deficiency of the lysosomal enzyme alpha-mannosidase (Chiesi Farmacêutica Ltda.);
- ✓ CIRCO/MYCOGARD: recombinant vaccine against Circovirus and Swine *eMycoplasma hyopneumoniae* (Eco Animal Health do Brasil, Comércio de Produtos Veterinários Ltda.);

- ✓ Poulvac Procerta HV-ND: recombinant vaccine against Marek e Newcastle (Zoetis Indústria de Produtos Veterinários Ltda).

GM Insects

- ✓ Mosquito *Aedes aegypti*, strain OX5034, (Oxitec do Brasil Ltda.)

The total number of commercial approvals of GMOs in Brazil are: 99 genetically modified plants (53 maize, 22 cotton, 17 soybeans, 5 sugar cane, 1 eucalyptus and 1 common bean), 47 recombinant vaccines, 1 genetically modified mosquito and 34 genetically modified microorganisms, and derivatives. Further information can be accessed at <http://ctnbio.mctic.gov.br/liberacao-comercial#/liberacao-comercial/consultar-processo>

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

- Normative Resolution CTNBio n° 24, published in January 7th 2020: rules for commercial release/use and monitoring of GMOs and their derivatives;
- Normative Resolution CTNBio n° 26, published in May 25th 2020: transport procedures and rules for GMOs and their derivatives;
- Normative Resolution CTNBio n° 27, published in August 11th 2020: modification of Normative Resolution n° 22, published in July 31st 2019;
- Normative Resolution CTNBio n° 29, published in September 12th 2020;
- Normative Resolution CTNBio n° 30, published in September 16th 2020: establishing the isolation conditions for genetically modified citrus field release liberation;
- Normative Resolution CTNBio n° 31, published in November 20th 2020: establishing the registration of institutions with Biosafety Quality Certificate - CQB in the Biosafety Information System - SIB.

2. Updates regarding international activities

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

3. Developments related to new breeding techniques (NBTs)

The Normative Resolution No 16 (NR16) was published on January 15th, 2018 and has the technical requirements for a consultation process, analysed case-by-case by CTNBio on the use of Precision Breeding Innovative Techniques, or also known as New Breeding Technologies. There were 7 consultations in 2020.

For genome edition, three microorganism lines of *Saccharomyces cerevisiae* and two microorganism lines of *Klebsiella variicola*, 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.

CTNBio had also a consultation regarding the use of dsRNA for topical application under the scope of NR16. The dsRNA would be used to silence genes in *Spodoptera frugiperda* and *Helicoverpa armigera*, insects that attack cultivated crops. The consultation is still under analysis.

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 2020 related to field trials and commercial use of GMOs to check the biosafety requirements.

GMO Research

In 2020 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 fiber quality.

In 2020 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.

Priority performance for analysis of projects related to SARS-CoV-2 (COVID-19)

- ✓ Analysis of 16 projects from institutions that used GMOs for development of new vaccines and diagnostic kits;
- ✓ 40 requests for new Biosafety Quality Certificates – CQBs;
- ✓ CQB extensions to work with coronavirus-related projects;
- ✓ 16 research projects under containment and new diagnostic tests and vaccines for SARS-CoV-2 and two consultations on products intended for coping with COVID-19;
- ✓ 07 Extraordinary Plenary Meetings to decide on requests with the required speed.

CANADA

CANADIAN FOOD INSPECTION AGENCY AND HEALTH CANADA (NOVEL FOODS)

Confined Field Trials of Plants with Novel Traits

The Canadian Food Inspection Agency authorized 213 confined field trials for plants with novel traits in the 2020 growing season that were conducted at 24 locations across Canada. We saw an increased number of field trials for canola and corn trials. However, we saw a decrease in interest in soybean and camelina improvement and no trials for wheat. Other trials included barley, borage, white mustard, sugar beet and poplar. The CFIA has not yet received applications for confined field trials for the 2021 growing season but expects to receive a similar number of applications and crop types as in 2020 trials.

Authorizations 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 authorized 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: <http://www.inspection.gc.ca/english/plaveg/bio/dde.shtml>.

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 2020, Canada has authorized 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) corn event MON 87429, genetically modified to be tolerant to the herbicides dicamba, 2,4-D / quizalofop and glufosinate, and to have male sterility inducible by glyphosate.
- Pioneer Hi-Bred Canada Company corn event DP202216, genetically modified to be tolerant to the herbicide glufosinate and have enhanced grain yield potential.
- Advanta Seeds DMCC sorghum event ADV-IMI-R, developed through conventional breeding and EMS mutagenesis of the endogenous sorghum acetohydroxy acid synthase protein (sbAHAS), is tolerant to imazethapyr and imidazolinone herbicides.
- NuSeed DHA canola event NS-B5ØØ27-4, developed through the introduction of microalgae and yeast genes in the docosahexaenoic acid (DHA) biosynthetic pathway to convert canola oleic acid to DHA, an omega-3 long chain polyunsaturated fatty acid.
- J.R. Simplot potato event SPS-ØØZ6-5, developed through introduction of the *Solanum venturii* VNT1 resistance protein that confers late blight resistance, into the previously authorized Gen-V11 background that exhibits reduced accumulation of asparagine and reducing sugars and decreased polyphenol oxidase expression. Since this event is substantially equivalent to three previously authorized second-generation potato events, it fulfils the requirements of the CFIA's retransformation policy.

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 2020 Canada has received Notices of Submission for the following plant products:

- Canola (MON94100) which has been genetically modified to be tolerant of the herbicide dicamba.
- Corn (MON95379) which has been genetically modified for insect resistance.
- Soybean (GMB151) developed by BASF Canada Inc. which has been genetically modified to be nematode resistant and herbicide tolerant.

Nine additional plant products are currently undergoing feed, food and/or environmental assessments, however the developers opted not to subscribe to the voluntary Notices of Submission process.

Clarification Regarding the Development Method of Cibus Canada Inc.'s Canola (*Brassica napus* L.) Event 5715

In recent years, the CFIA has received many inquiries regarding the development method of Cibus Canada Inc.'s Canola (*Brassica napus* L.) Event 5715. The confusion originated because, although an oligonucleotide-directed mutagenesis (ODM) approach was used within the developer's Rapid Trait Development System™ (RTDS™), the mutation used in Event 5715 arose independently through spontaneous somaclonal variation. The RTDS approach includes the application of tissue culture techniques that generated plant cells more receptive to mutagenesis. Following ODM treatment of the parental canola line, a canola event known as BnALS-57 was isolated. Sequencing confirmed that the mutated gene (BnAHAS1) of BnALS-57 contains a single nucleotide mutation, which confers tolerance to AHAS-inhibiting herbicides such as the sulfonylureas and imidazolinones. Although BnALS-57 was isolated following ODM treatment of cells, the mutation in BnALS-57 was created as a result of a spontaneous somaclonal variation that occurred during the tissue culture process, rather than due to the oligonucleotide used in the ODM which targeted a different mutation at a different position in the gene.

The CFIA publishes Decision Documents for each authorized plant with a novel trait and in July 2020, the CFIA edited the Canola Event 5715 Decision Document to add clarity as to how this trait was introduced. The following sentence was added to provide clarity:

The mutation in BnALS-57 has been created as a result of a spontaneous somaclonal variation that occurred during the tissue culture process.

It should be noted, that all of the information required to make this Decision Document edit was included in the original data submission to the CFIA. The Decision Document edit was introduced simply to respond to the many inquiries by clarifying this detail.

The full Decision Document *DD 2013-100: Determination of the Safety of Cibus Canada Inc.'s Canola (Brassica napus L.) Event 5715* can be found at the following web address:

<https://www.inspection.gc.ca/plant-varieties/plants-with-novel-traits/approved-under-review/decision-documents/dd-2013-100/eng/1427383332253/1427383674669>

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 editing. Canada views gene editing techniques as additional tools for plant breeders. As with conventional breeding and recombinant DNA techniques, gene editing techniques have the potential to develop both novel and non-novel products. In Canada, only those gene-edited products that are deemed novel require a pre-market assessment.

By allowing for risk-appropriate decision making and focusing on outcomes, Canada's regulatory system can accommodate new developments in biotechnology techniques.

The CFIA and Health Canada recognize the need of product developers to accurately determine the regulatory status of gene edited products in Canada, and for regulatory decisions to be 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. Guidance is being drafted and will be subject to public consultation in the near future.

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

New Substances Notifications

The New Substances Program (NSP) for living organisms continues to be responsive to advances in biotechnology (including gene editing) because it focuses on the resulting organism and not the technology used to create it. The Program continues to receive new notifications for micro-organisms and animals. Since March 2020, Environment and Climate Change Canada (ECCC)/Health Canada (HC) completed 57 new living organism assessments under the *Canadian Environmental Protection Act, 1999* (CEPA). Of this number, 26 were for various environmental or industrial uses, while 31 were for food and drugs uses (including genetic therapies and vaccines) of which 19 were for cell and gene therapies, 3 for flu vaccines and 9 for COVID-19 vaccines. The types of organisms that were assessed ranged from bacteria, to virus, virus-like particles, animal cells, and fungi.

On 18 July 2020, a Significant New Activity notice was published for the production and grow-out of the AquAdvantage Salmon at a second facility in Prince Edward Island with the result of requiring the continuing application of strict containment measures at the facility to prevent releases of the salmon into the environment

The CEPA assessment of a line of dairy cattle derived through Somatic Cell Nuclear Transfer cloning technology (SCNT) was completed in April 2020 with the conclusion of no risk to the environment or human health.

The NSP continues to publish summaries of some of its risk assessments as part of the voluntary public engagement initiative.

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 NSP 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. Responses to comments received during the public consultation period

may be taken into account in the risk assessment and made public after the end of the statutory assessment period. Since 2018, the NSP established 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](#).

Risk Assessment Decision Summaries

Summaries of selected risk assessment decisions for new living organisms assessed under CEPA can be found on the following webpage:

<https://www.canada.ca/en/environment-climate-change/services/managing-pollution/evaluating-new-substances/biotechnology-living-organisms/risk-assessment-decisions.html>

Regulatory Reviews

The Government of Canada is involved in several initiatives to modernize and align our regulatory oversight for products derived from 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. In addition to a regulatory review pertaining to higher organisms and micro-organisms, an analysis is being conducted by the NSP to identify potential areas for modernization based on experience and lessons learned from administration of the *New Substances Notification Regulations (Organisms)* (NSNR (O)) over the last 20 years.

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

The NSP is conducting 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 modernization of policies and regulations (NSNR (O)) related to the CEPA assessment of micro-organisms.

Publication of an Advisory Note on Virus-like Particles (VLPs) and Sub-viral Particles (SVPs)

The NSP published an advisory note to communicate its interpretation of the terms VLPs and SVPs in paragraph (b) of the definition “micro-organism” described in subsection 1(1) of the NSNR (O). The purpose of the advisory note is to clarify that engineered VLPs that contain genome-free (“empty”) viral capsids or viral envelopes and that are incapable of replication **are not considered to be animate**, and are thus not notifiable under the NSNR (O) (they may however be notifiable as a biochemical under the *New Substances Notification Regulations (Chemicals and Polymers)*).

Supplementary 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)*

The NSP has developed a supplementary 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.

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 has been developed to help shift towards a semi-qualitative-quantitative estimation of human health burden and environmental risk posed by the micro-organisms.

Micro-algae Consensus Document

The NSP in partnership with the U.S. EPA/OPPT have evaluated the comments and feedback provided by Micro-organisms Sub Working Group members from Canada, The Netherlands, Germany, Australia, and Business and Industry Advisory Committee to the OECD (BIAC) on the Draft Operational Plan of the OECD Consensus Document on Micro-algae. 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 is to serve as a model for the drafting of additional chapters on other micro-algae species by other member countries. BIAC provided text on cyanobacteria to be incorporated into the document. The Working Party on Biotechnology, Nanotechnology and Converging Technologies (BNCT) was contacted regarding their availability to contribute to the sustainability and

commercialization sections of the micro-algae document. Based on the comments received on the Draft Operational Plan and the Draft OECD Consensus Document on Micro-algae in late summer of 2020, both documents have been revised for discussion at the 35th WP-HROB meeting in March 2021. In January 2021, HC initiated a literature review on *Schizochytrium* for a future chapter in the consensus document.

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 Indonesia co-hosted the 7th meeting of the GLI virtually, in October and December 2020. The virtual sessions were structured to advance the global discussion on asynchronous approvals, the underlying cause of LLP, and to highlight ongoing best regulatory practices to prevent and manage LLP. Real-life examples illustrated recent progress made on collaboration, such as, the Mercosur intra-regional arrangement to prevent LLP-related impacts; Paraguay's approach of recognizing foreign food safety assessments; the U.S. Secure Rule that builds on familiarity with a product's mode of action to facilitate approvals; Canada-Australia-New Zealand collaboration on food safety assessments; and, the recent agricultural biotechnology provisions in the United-States-Mexico-Canada Agreement. The topic of communications was also a key feature of the meeting, with the release of industry videos on LLP and an overview of the imminent FAO communications package on food biotechnology.

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

The GLI now has its own website: <https://llp-gli.org>. This public interface features useful resources and tools to inform practices to minimize asynchronous approvals and practically manage LLP. It includes background information on factors leading to LLP, their impacts, and best management practices; an overview of potential approaches for governments and technology developers to consider to minimize occurrences of asynchronous authorizations; as well as key principles to data sharing and collaboration to facilitate the management of LLP. The GLI Secretariat is led by Agriculture and Agri-Food Canada and can be contacted at GLI-IMP@canada.ca.

COLOMBIA

1. Developments related to implementation of national biosafety framework

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

Please note that this is not an official statement from the Colombian Government, this is the information provided from the authorized Institute (ICA) that regulates on the matter.

New authorizations granted in 2020 by the Instituto Colombiano Agropecuario - ICA:

Decision	Organism	LMO Name	Trait	Authorized for
61761	Maize	MON87427 x MON89034 x MON87419 x NK603	Insect resistance Herbicide tolerance	Feed
61762	Maize	MON89034 x TC1507 x MIR162 x NK603	Insect resistance Herbicide tolerance	Cultivation
72112	Cotton	GHB811	Herbicide tolerance	Feed

Decision	Organism	LMO Name	Trait	Authorized for
72113	Soybean	GTS 40-3-2	Herbicide tolerance	Field Trials
72130	Rose	Colour-modified Rose	Changes in quality and/or metabolite content: Pigmentation / Coloration Flavonoids (e.g. anthocyanin)	Field Trials
82350	Wheat	IND-ØØ412-7	Tolerance to abiotic stress Herbicide tolerance	Feed
82351	Soybean	GTS 40-3-2	Herbicide tolerance	Cultivation
82352	Soybean	GTS 40-3-2	Herbicide tolerance	Cultivation
82353	Soybean	GTS 40-3-2	Herbicide tolerance	Feed
82354	Maize	TC1507	Insect resistance Herbicide tolerance	Feed
82355	Maize	NK603 x T25 x DAS40278	Herbicide tolerance	Feed
82356	Maize	MON87427 x MON89034 x MIR162 x MON87411	Insect resistance Herbicide tolerance	Cultivation
82357	Maize	MON87427 x MON89034 x MIR162 x MON87419 x NK603	Insect resistance Herbicide tolerance	Feed
82358	Maize	MON87427 x MON87419 x NK603	Insect resistance Herbicide tolerance	Feed
82359	Maize	DP202216	Changes in physiology and / or production Herbicide tolerance	Feed
82360	Chrysanthemum	Colour-modified Chrysanthemum	Changes in quality and/or metabolite content Pigmentation / Coloration Flavonoids (e.g. anthocyanin)	Cultivation
82361	Sugar Cane	Not available	Changes in physiology and / or production Tolerance to abiotic stress	Field Trials
82362	Cotton	MON88702	Insect resistance	Feed
82363	Cotton	T-304-40 x GHB119 x COT102	Insect resistance Herbicide tolerance	Feed
82364	Cotton	Glytol x TwinLink (GHB614 x (T304-40 x GHB119))	Insect resistance Herbicide tolerance	Cultivation (Extended authorization)
82365	Cotton	COT102	Insect resistance	Cultivation

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

Starting in 2019, 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 Biosafety and Monitoring plan for genetically modified crops. As a result, ICA granted the Resolution No. 72221 (28/07/2020), “by which the biosafety and monitoring plan is implemented to commercial plantings of genetically modified crops with resistance to target pests of the technology and / or tolerance to herbicide application”.

In Addition, the Working Group mentioned before cooperated to modify and update the regulatory framework that regulates the authorizations of Living Modified Organisms (LMOs) in Colombia, exclusively for agricultural, livestock, fishing, commercial forest plantations and agro-industry purposes. At present, this regulation draft was recently approved by the General Manager of ICA to be published and enforced in the next days.

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

2. Updates regarding international activities

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

- Second Virtual Session on Biotechnology and Biosafety 2020
- Third Virtual Session on Biotechnology and Biosafety 2020
- Fourth Virtual Session on Biotechnology and Biosafety 2020
- Fifth Virtual Session on Biotechnology and Biosafety 2020
- Sixth Virtual Session on Biotechnology and Biosafety 2020
- Seventh Virtual Session on Biotechnology and Biosafety 2020
- Eight Virtual Session on Biotechnology and Biosafety 2020

These meetings were coordinated by the Inter-American Institute for Cooperation on Agriculture (IICA); These virtual sessions aim to foster the continuous exchange of technical information on issues relevant to countries' biosafety performance and to facilitate dialogue on national biosafety approaches and on activities under the Convention on Biological Diversity and its protocols.

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

As ICA, we have required the BioTrack Database to consult Decisions and Risk Assessments from other countries to study and analyse our own authorizations and decisions. Additionally, ICA has been developing a virtual platform for LMOs applications and has required a review of the BioTrack database to reinforce our tool draft in search of the efficiency and agility of authorization procedures.

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*".

2. Specific cases of application, assessment and decision

Organism	Trait	Decisión
Maize	Waxy Corn	Not considered LMO
Rice	Increases the bioavailability of Fe	Pending - Concept tests
Rice	Resistance to bacterial blight <i>Xanthomonas oryzae</i> pv. <i>oryzae</i> (Xoo)	Not considered LMO

COSTA RICA

1. Developments related to implementation of national biosafety framework

Regarding genetically modified plants, Costa Rica approved in the last year the planting of 182 hectares of Genetically Modified (GM) cotton and 115 of GM pineapple. During 2020, no new genetically modified crop events were approved.

2. Developments related to new breeding techniques (NBTs)

In Costa Rica, we have robust regulatory framework for transgenic plants and successful record of accomplishment in science-based risk assessment and post-release management of transgenic plants. Nevertheless, with respect to New Plant Breeding Technologies (NPBTs), Costa Rican government considered its regulatory status to establish suitable risk and safety assessment, without representing an obstacle to the commercialization of products derived from NPBTs. However, important in this context is to determine if products derived from NPBT represent new risks compare to products of traditional plant breeding or Live Modified Organism (LMO).

In February 2020, the State Phytosanitary Service presented a 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).

Unfortunately, due to the difficulties that have arisen due to the COVID-19 Pandemic, we have not been able to advance with most of the objectives set in the area of LMOs and NBTs. However, the regulatory project is expected to be published in the first quarter of 2022.

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”. In general, the analysis under the scope of the NBT Draft Regulatory is concentrated on the interrogation whether a novel combination of genetic material has happened. 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, which could not occur through conventional breeding or not found in nature”. Therefore, the regulatory framework will provide the procedures to distinguish between a genetic engineer product and genome editing product that can be considered as conventional.

The National Technical Biosafety Commission, (CTNBio), advisory body of the State Phytosanitary Service on biosecurity of the Genetically Modified Crop Plants, will be responsible for analyzing within 60 days, on a case-by-case basis the information supplied by the developer.

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 the CTNBio consider necessary.

The general process for determining whether a product derived from new breeding technologies should be considered as LMO or not is shown in the Fig. 1. An interesting feature to be highlighted in this regulatory framework is that developers can consult the CTNBio about the status of a putative product that is still in the design phase. According to the regulatory draft, all products derived from NPBTs that resort to modern biotechnology must be submitted to prior consultation, or otherwise are considered a LMO.

Briefly, if there is a new combination of genetic material in the genome, the product is considered a LMO. On the other hand, if there is not a new combination of genetic material but the development of the NBT product uses a transgene temporarily, and the final product is not free of transgene, it is also considered LMO. Contrary, if the product does not contain a new combination of genetic material in the genome, the product does not fall under the LMO regulation.

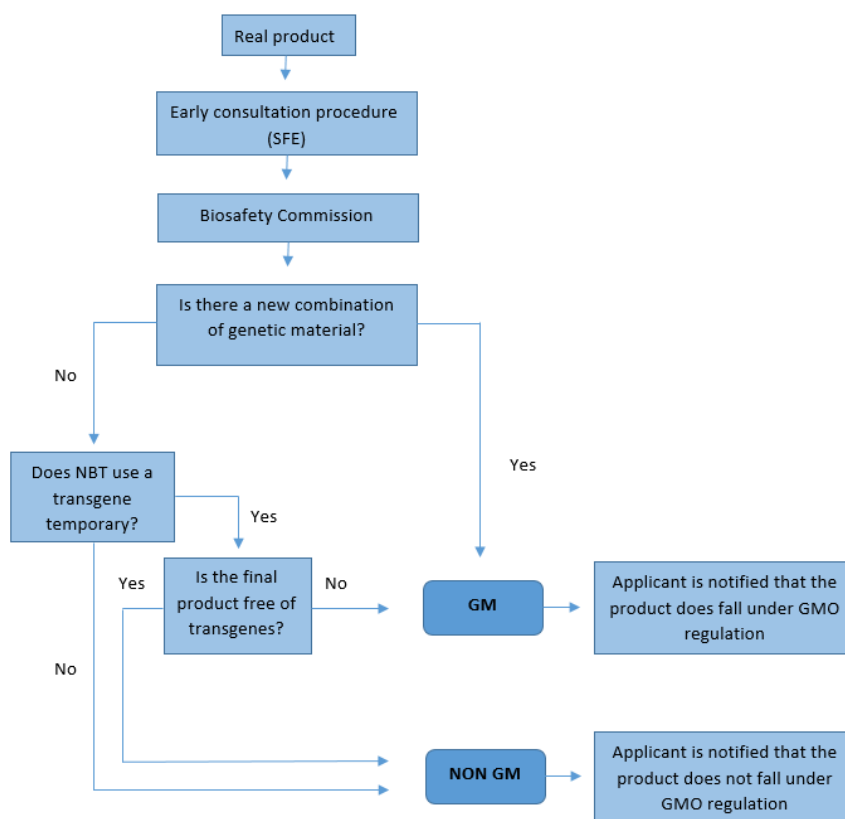


Fig. 1. General procedure for determining if a product derived from new breeding technologies should be consider as LMO in Costa Rica

CZECH REPUBLIC

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

Maize MON810, the only GM crop authorised for cultivation in EU, has not been grown in the Czech Republic since 2017.

Field trials: No new field trial was authorised in 2020. Only two trials were carried on, with the total area 840 m²:

- Plum trees with a modification conferring virus-resistance (resistance to the plum pox virus), notified by the Crop Research Institute, Prague (640 m² without buffer zones);
- Barley producing peptide LL-37, research project of the Palacky University in Olomouc, the cultivation carried out and therefore notified by the company Usovsko, region Olomouc (200 m² without buffer zones).

The number of premises notified for contained use of GMOs stayed approximately constant – over 100 subjects. Only 3 laboratories were classified in BSL 3, the others were BSL 1 or 2. Three clinical trials with medical products containing GM cells or viruses were authorised.

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

Post release monitoring was carried out on the sites where field trials had been conducted in previous years. The period of monitoring had 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*)

Regulatory challenges for our country emerge from notifications of clinical trials and compassionate use (i.e. use without the pertinent marketing authorisation) of medical products containing GM microorganisms. Regulations for medical products and the legislative on GMOs differ in some aspects of the authorisation processes.

There were also discussions on application of some recombinant DNA/RNA particles, whether the resulting organisms fall under the scope of GMO regulations.

5. Public engagement and outreach activities

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

Due to the Covid-19 pandemic, outreach activities were limited.

2. Updates regarding international activities

The Czech Republic has been participating in EU preparatory process for the upcoming Third meeting of the Supplementary Body on Implementation of the Convention of the Biological Diversity and its Protocols as well as the Twenty-fourth meeting of the Subsidiary Body on Scientific, Technical and Technological Advice. Topics related to biosafety are on the agenda of both meetings, especially the Post-2020 Global Biodiversity Framework, Implementation Plan of the Cartagena Protocol on Biosafety and the Action Plan for Capacity Building for the period 2020-2030, Risk assessment and Risk management and Synthetic biology. Up to date, only informal virtual sessions of both meetings have been conducted due to the ongoing Covid-19 pandemic. Dates of formal sessions resulting in formal recommendations for the Conference of Parties to the Cartagena Protocol on Biosafety have not been officially set yet.

3. Developments related to new breeding techniques (NBTs)

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

Organisms produced by new breeding techniques (gene editing) were used in contained space only – in laboratories, greenhouses, breeding facilities, industrial premises. Research projects with gene edited laboratory animals, plants and microorganisms were carried out in contained use.

DENMARK

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions (e.g. organisms assessed, type of use, introduced traits/genes);
 - i. The situation in Denmark regarding deliberate release of GMO's into the environment remains unchanged.
 - ii. No GM crops are cultivated and there has been no deliberate release of GMO's for field trials.

2. Additional Information

Control measures in 2020 in Denmark.

The planned GMO control of seeds in 2020 has focused on imports of Alfalfa (*Medicago sativa*), Danish production of Oilseed rape (*Brassica napus*) certified seed and Maize (*Zea mays*) seed.

No GMO's have been found.

Unsolicited seed

In Denmark, we have confiscated approximately 17.000 of unsolicited seed packages, which were sent primarily from China. We chose to test a subset of these seed packages for GMO content. A subset of 141 packages were tested in an initial rough screening (pooled PCR). Out of these, 12 packages were positive for the kanamycin resistance gene (nptII). A second PCR test of these 12 packages individually confirmed the GMO presence. We sent the seed to our experts for germination and identification. Unfortunately – or maybe luckily – the seed did not germinate. We were therefore not successful in identifying the species and the exact GM event.

Fortunately, the seed therefore does not pose a threat to nature and agriculture. We have not pursued the matter further.

ESTONIA

1. Developments related to implementation of national biosafety framework

Estonia is involved in the European Food Safety Authority (EFSA) consultations for placing on the market of genetically modified organisms.

During the intersessional period, Estonia has been transposing the regulation 2019/1381¹ into our national law. There were government level discussions whether to transpose the directive 2015/412² to our national legislation or not.

There has been no application submitted to the Competent Authority of Estonia concerning a deliberate release of GMO for field or clinical trials. There was one new premises applying for contained use of GMOs and two premises that renewed their applications.

2. Updates regarding international activities

Estonia is participating in the discussions under the Cartagena protocol and synthetic biology discussions under the CBD.

3. Developments related to new breeding techniques (NBTs)

Estonia is waiting for the results of the European Commission's study³. Currently, all research in Estonia with NBTs has been done in contained use.

¹ Regulation (EU) 2019/1381 of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC

² Directive 2015/412 of the European Parliament and of the Council 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

³ 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

There has been no applications for field trials. In contained use, the inspections do not depend on the methods used in the lab, therefore the inspection practices do not need adaptations. For other controls, we have not adapted the inspection practices for the products produced by new mutagenesis technologies, as we do not know about reliable, cost-effective identification methods.

There have been no applications or registrations on NBT plant varieties into our national catalogues.

FRANCE

[English version follows]

1. Développements relatifs à la mise en œuvre du cadre national de biosécurité

1. Évaluation des risques/décisions réglementaires (ex. organismes évalués, destination, traits/gènes introduits):

Mise sur le marché

Dans le cadre du règlement européen (CE) n°1829/2003, l'Autorité européenne de sécurité des aliments (EFSA) consulte les États membres sur les dossiers de demande d'autorisation. En France, l'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (Anses, <https://www.anses.fr>) et le Haut conseil des biotechnologies (HCB, <http://www.hautconseildesbiotechnologies.fr>) sont chargés de l'évaluation des dossiers. Leurs commentaires relatifs à l'évaluation des risques pour la santé ou l'environnement sont transmis à l'EFSA.

Dans ce cadre, les évaluations suivantes ont été réalisées depuis le 1^{er} janvier 2020 :

Maïs 3272 : <https://www.anses.fr/fr/system/files/BIOT2019SA0181.pdf>

Colza LBFLFK : <https://www.anses.fr/fr/system/files/BIOT2019SA0201.pdf>

Soja A5547-127 : <https://www.anses.fr/fr/system/files/BIOT2019SA0159.pdf>

Maïs MON87429 : <https://www.anses.fr/fr/system/files/BIOT2020SA0014.pdf>

Maïs DP23211 : <https://www.anses.fr/fr/system/files/BIOT2020SA0060.pdf>

Maïs MZIR098 : <https://www.anses.fr/fr/system/files/BIOT2020SA0100.pdf>

Maïs DAS-40278-9 : <https://www.anses.fr/fr/system/files/BIOT2020SA0052.pdf>

Coton GHB6014 : <https://www.anses.fr/fr/system/files/BIOT2020SA0116.pdf>

Moutarde brune RF3

Les décisions d'autorisation de mise sur le marché des OGM sont prises au niveau européen.

Expérimentation en milieu ouvert

Aucune demande d'autorisation pour l'expérimentation d'OGM en milieu ouvert n'a été déposée en France depuis le 1^{er} janvier 2020.

Utilisations d'OGM en milieu confiné (en laboratoire)

Environ 1500 dossiers d'utilisation d'OGM en milieu confiné sont examinés chaque année en France.

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. Développement/examen/amendement des stratégies, règles et lignes directrices nationales

Décision du Conseil d'État du 7 février 2020 sur la mutagenèse

En 2015, neuf associations ont déposé un recours au Conseil d'État sur les variétés tolérantes aux herbicides issues de mutagenèse demandant, notamment, l'abrogation de l'article D.531-2 du code de l'environnement en ce qu'il exempte les variétés obtenues par mutagenèse 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 mutagenèse 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 mutagenèse aléatoire *in vitro* soumettant des cellules de plantes à des agents mutagènes chimiques ou physiques, ainsi que les techniques de mutagenèse 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 réglementation 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 :

- Le projet de décret vise à modifier la disposition du code de l'environnement qui liste les techniques de mutagenèse exemptées de la réglementation relative aux organismes génétiquement modifiés (OGM), afin de la mettre en conformité avec la décision du Conseil d'État.
- Les projets d'arrêté visent à lister les variétés qui seront interdites à la commercialisation et à la mise en culture en France faute d'avoir été évaluées et autorisées au titre de la réglementation relative aux OGM et à annuler l'inscription, au catalogue officiel des espèces et variétés de plantes cultivées en France, des variétés obtenues par une technique relevant désormais de la réglementation sur les OGM. Il s'agit de variétés de colza tolérantes aux herbicides.

Conformément au code de l'environnement, ces projets de textes ont été soumis au Haut conseil des biotechnologies qui a publié son avis le 15 juillet 2020 (<http://www.hautconseildesbiotechnologies.fr/fr/avis/avis-hcb-sur-projet-decret-modifiant-larticle-d531-2-code-lenvironnement>).

Les projets ont également été notifiés à la Commission européenne en application de la directive (UE) 2015/1535:

<https://ec.europa.eu/growth/tools-databases/tris/fr/search/?trisaction=search.detail&year=2020&num=280>
<https://ec.europa.eu/growth/tools-databases/tris/fr/search/?trisaction=search.detail&year=2020&num=281>
<https://ec.europa.eu/growth/tools-databases/tris/fr/search/?trisaction=search.detail&year=2020&num=282>.

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.

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. Il devrait se prononcer sur ce recours courant 2021.

3. Projets de recherche sur la sécurité environnementale; publications

Recherches sur la détection des OGM

Des recherches ont été menées par un des laboratoires nationaux de référence sur les OGM sur :

- la détection d'OGM inconnus par des méthodes de séquençage haut-débit et d'analyse statistique. La méthode développée a été testée sur des bactéries. Elle pourrait faire l'objet de travaux ultérieurs pour être adaptée aux OGM végétaux et animaux.

Publication : 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>

- l'identification d'un OGM détecté par criblage mais inconnu. Une méthode simple et rapide a été développée pour obtenir la séquence d'un transgène dans le cas où seule une séquence de criblage est connue.

Publication : 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>

2. Developments related to new breeding techniques (NBTs)

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

Décision du Conseil d'État du 7 février 2020 sur la mutagenèse : voir point 1.2.

Étude au niveau européen sur les nouvelles techniques génomiques

Le Conseil de l'UE a demandé à la Commission européenne de conduire une étude, d'ici fin avril 2021, sur le statut des nouvelles techniques génomiques dans le droit de l'UE, à la lumière de l'arrêt de la Cour de Justice de l'Union Européenne du 25 juillet 2018 sur la mutagenèse. En fonction des résultats, la Commission pourrait être amenée à présenter une proposition législative ou à proposer d'autres mesures.

La France a transmis une contribution à la Commission européenne en réponse à la consultation des Etats membres dans le cadre de l'étude.

[English translation]

1. Developments related to implementation of national biosafety framework (for countries)

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

Placing on the market

Under European Regulation (EC) No 1829/2003, the European Food Safety Authority (EFSA) consults Member States on authorization applications. In France, the French Agency for Food, Environmental and Occupational Health and Safety (Anses, <https://www.anses.fr>) and the High Council for Biotechnologies (HCB, <http://www.hautconseildesbiotechnologies.fr>) are responsible for evaluating the dossiers. Their comments relating to the assessment of the risks to health or the environment are forwarded to EFSA.

In this context, the following evaluations have been carried out since January 1, 2020 :

Maize 3272 : <https://www.anses.fr/fr/system/files/BIOT2019SA0181.pdf>

Oilseed rape LBFLFK : <https://www.anses.fr/fr/system/files/BIOT2019SA0201.pdf>

Soybean A5547-127 : <https://www.anses.fr/fr/system/files/BIOT2019SA0159.pdf>

Maize MON87429 : <https://www.anses.fr/fr/system/files/BIOT2020SA0014.pdf>

Maize DP23211 : <https://www.anses.fr/fr/system/files/BIOT2020SA0060.pdf>

Maize MZIR098 : <https://www.anses.fr/fr/system/files/BIOT2020SA0100.pdf>

Maize DAS-40278-9 : <https://www.anses.fr/fr/system/files/BIOT2020SA0052.pdf>

Cotton GHB6014 : <https://www.anses.fr/fr/system/files/BIOT2020SA0116.pdf>

Brassica juncea Rf3

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

Experimentation in the environment

No authorization application for experimentation of GMOs in an open environment has been filed in France since January 1, 2020.

Contained use of GMOs (in laboratory)

Around 1,500 dossiers for contained use of GMOs are examined each year in France.

GMO cultivation

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

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

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

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 "*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*" are excluded from the scope of that directive.

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 that now fall in the scope of this legislation, according to its analysis.

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).

The Government has prepared a draft decree and two Minister's Orders in order to answer to the injunctions of the Conseil d'État:

- The draft decree aims to modify the provision of the Environmental Code which lists the mutagenesis techniques that are exempted from the regulations relating to genetically modified organisms (GMOs), in order to bring it into line with the decision of the Conseil d'État.
- The Minister's Orders aim to list the varieties which will be prohibited for marketing and cultivation in France for lack of having been assessed and authorized under the regulations on GMOs and to cancel the registration, in the Official French Catalogue of species and varieties of cultivated crops, of varieties obtained by a technique now covered by the regulations on GMOs. These are herbicide tolerant rapeseed varieties.

In accordance with the Environmental Code, these draft texts were submitted to the High Council for Biotechnology which published its opinion on July 15, 2020 (<http://www.hautconseilbiotechnologies.fr/fr/avis/avis-hcb-sur-projet-decret-modifiant-l'article-d531-2-code-lenvironnement>)

The projects have also been notified to the European Commission in application of Directive (EU) 2015/1535:

<https://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2020&num=280>

<https://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2020&num=281>

<https://ec.europa.eu/growth/tools-databases/tris/en/search/?trisaction=search.detail&year=2020&num=282>

The European Commission, as well as five EU Member States, have issued detailed opinions challenging the legal compatibility of the draft texts with EU law.

The Conseil d'État has received, by the organizations behind the initial litigation, a new appeal aiming at obtaining the execution of the injunctions of the decision of February 7, 2020. It should rule on this appeal during 2021.

3. Research projects on biosafety; relevant publications.

Research projects on GMO detection

Research has been carried out by one of the national reference laboratories on GMOs on:

- the detection of unknown GMOs by high-throughput sequencing and statistical analysis methods. The developed method has been tested on bacteria. It could be the subject of further work to be adapted to GM plant and animal.

Publication : 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>

- the identification of a GMO detected by screening but unknown. A simple and rapid method has been developed to obtain the sequence of a transgene in the case where only a screening sequence is known.

Publication : 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>

2. Developments related to new breeding techniques (NBTs)

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

Decision of the Conseil d'Etat of February 7, 2020 on mutagenesis : voir point 1.2.

European study on new genomic techniques

The Council of the EU has asked the European Commission to conduct a study, by the end of April 2021, on the status of new genomic techniques in EU law, in the light of the judgment of the Court of Justice of the European Union of July 25, 2018 on mutagenesis. Depending on the outcomes, the Commission may present a legislative proposal or propose other measures.

France sent a contribution to the European Commission in response to the consultation of Member States in the framework of the study.

GERMANY

1. Developments related to implementation of national biosafety framework

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

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

All products that are authorised for placing on the EU market can be found in the EU Register of GM food and feed (https://ec.europa.eu/food/plant/gmo/eu_register_en).

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 advise 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 2020 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 market, harmonized procedures for risk assessment and authorisation, labelling requirements and ensures traceability of GMOs placed on the market.

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

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

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

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

4. Research projects on biosafety; relevant publications:

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

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

- EU COST Action **Modifying plants to produce interfering RNA**
- Publication: RNAi for Plant Improvement and Protection. Edited by: Mezzetti B, Sweet J, Burgos L, March 2021, ISBN 9781789248890

- Dolezel M, Simon S, Otto M, Engelhard M, Züghart W (2020): Gene Drive Organisms. Implications for the Environment and Nature Conservation. The joint technical report of the EPA/ENCA Interest Group on Risk Assessment and Monitoring of GMOs (ISBN 978-3-99004-524-4)
- Lang A, Dolek M, Lee MS, Freese-Hager A, Otto M (2020): Selection of non-target Lepidoptera species to test Bt maize effects in the laboratory: which species and how to breed them? *BioRisk* 15: 45–65. <https://doi.org/10.3897/biorisk.15.59823>
- Pott, A., Bundschuh, M., Bundschuh, R., Otto, M. & Schulz, R. (2020): Effect of Bt toxin Cry1Ab on two freshwater caddisfly shredders - an attempt to establish dose-effect relationships through food-spiking. *Scientific Reports*, 10, 5262
- Zanatta, C.B., Benevenuto, R.F., Nodari, R.O. & Agapito-Tenfen, S.Z. (2020): Stacked genetically modified soybean harboring herbicide resistance and insecticide rCry1Ac shows strong defense and redox homeostasis disturbance after glyphosate-based herbicide application. *Environmental Sciences Europe*, 32.

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.

- Genome Editing in Europe: New Agenda or New Disputes? - German National Academy of Sciences Leopoldina, International virtual conference on scientific advice to policy-makers and society (1-2 Oct 2020)
- Plant and Animal Genome XXVIII Conference (11-15 Jan 2020); hosting the workshop: “New breeding technologies: Prospects and regulatory hurdles”

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

The German BVL and the Dutch WFSR host and maintain EUGenius, 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. EUGenius’ 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 (e.g. Consensus Documents, other guidance materials, BioTrack Product Database...):

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

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

3. Developments related to new breeding techniques (NBTs)

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

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

2. Specific cases of application, assessment and decision:

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

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

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

- The project **Nachweismethoden für genomeditierte und klassische GV-Pflanzen**, commissioned by the German Federal Agency for Nature Conservation, reviewed available and upcoming analytical methods in enforcement laboratories for their ability to detect genome-edited plants (Ribarits *et al.* 2021).
- Menz J, Modrzejewski D, Hartung F, Wilhelm R and Sprink T (2020). Genome Edited Crops Touch the Market: A View on the Global Development and Regulatory Environment. *Front. Plant Sci.* 11:586027. doi: 10.3389/fpls.2020.586027
- Unkel, K., Krause, D., Sprink, T., Hartung, F., & Wilhelm, R. (2020). Mapping of plant SynBio developments in the agri-food sector. *EFSA Supporting Publications*, 17(3), 1687E
- Schiemann J, Robiński J, Schleissing S, Spök A, Sprink T and Wilhelm RA (2020). Editorial: Plant Genome Editing – Policies and Governance. *Front. Plant Sci.* 11:284. doi: 10.3389/fpls.2020.00284
- Bartsch D, Ehlers U, Hartung F, Kahrman J, Leggewie G, Sprink T and Wilhelm R (2020). Questions Regarding the Implementation of EU Mutagenesis Ruling in France. *Front. Plant Sci.* 11:584485. doi: 10.3389/fpls.2020.584485
- Modrzejewski D, Hartung F, Lehnert H, Sprink T, Kohl C, Keilwagen J and Wilhelm R (2020). Which Factors Affect the Occurrence of Off-Target Effects Caused by the Use of CRISPR/Cas: A Systematic Review in Plants. *Front. Plant Sci.* 11:574959. doi: 10.3389/fpls.2020.574959
- Ribarits A, Narendja F, Stepanek W and Hohegger R (2021). Detection Methods Fit-for-Purpose in Enforcement Control of Genetically Modified Plants Produced with Novel Genomic Techniques (NGTs). *Agronomy*. 11(1):61. doi: 10.3390/agronomy11010061

HUNGARY

1. Developments related to implementation of national biosafety framework

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

Cultivation of GMOs: The only GM crop authorised for commercial cultivation in the EU is maize MON810. In the course of 2020 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): Four decisions have been published in the course of 2020. Two trials have been carried out in order to evaluate the safety and efficacy of R062 vaccine (live genetically modified HVT vaccine strain containing ND and AIV H9 inserts) in broiler chickens. Two other clinical trials have also been carried out where in one case the purpose of the release is to evaluate the efficacy, safety and tolerability of the IV administration of the GMO (VB-111) in combination with paclitaxel compared to placebo and paclitaxel in patients with platinum resistant ovarian cancer. In the other case the ShigE_{TEC} vaccine has been used in a first-in-human study with the primary objective to establish product safety (tolerability) in healthy adult volunteers. The secondary objective was to determine its immunogenicity by measuring vaccine specific antibodies.

Contained use activities: In the course of 2020 two new class 1 and eight new class 2 premises received authorisations for contained use activities. Altogether 14 contained use activities in class 2 had been authorised mainly with GMMs.

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

The National Biodiversity Strategy for 2021-2030 is under development which will also include a biosafety target with the respective goals, measures and indicators.

3. Research projects on biosafety; relevant publications.

The Hungarian gene technology authority contributed to Springer's recently published book, *GMOs: Implications for Biodiversity Conservation and Ecological Processes*.

Andorkó R., Kőrösi L. (2020) Hungary—Hungary's GMO-Free Policy and Its Legal Background. In: Chaurasia A., Hawksworth D.L., Pessoa de Miranda M. (eds) *GMOs. Topics in Biodiversity and Conservation*, vol 19. Springer, Cham. https://doi.org/10.1007/978-3-030-53183-6_39

2. Updates regarding international activities

1. 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 COP-MOP meetings and also in the expert meetings (i.e. Liaison Group on the Cartagena Protocol on Biosafety) during the intersessional periods.

3. Developments related to new breeding techniques (NBTs)

1. Specific cases of application, assessment and decision;

As we have already reported on the last reporting period, in 2020 we have provided national input to the request of the European Commission in relation to the preparation of the study in light of the Court of Justice's judgement in Case C-528/16 regarding the status of novel genomic techniques under Union law.

No new developments in this field have been occurred.

2. Any other information related to NBTs.

Cultivation/deliberate release: In the course of 2020 neither cultivation of GM crops produced by new techniques nor deliberate release of GMOs produced by new techniques for field trials and for clinical trials occurred in Hungary.

4. Additional Information

Keeping agriculture free from genetically modified organisms (GMOs) is continuously among the top priorities of the Hungarian Government. Hungary is one of the strongest opponents of agricultural gene technology in the European Union (EU), and this policy has not been changed.

JAPAN

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

Latest Situation of Approval for Releasing of LMOs

In accordance with the Cartagena Act (Japanese national law to implement the Cartagena Protocol on the Biosafety to Convention on Biological Diversity), one cotton and one corn event have been newly approved for commercial use since the last WG-HROB meeting held in March 2020.

The number of LM plants approved for commercial use at the end of January 2021 are described in the Table. Decision documents and summary reports of environmental risk/safety assessments are available*¹ at Japan Biosafety Clearing House (J-BCH) (URL; <https://www.biodic.go.jp/bch/english/lmo.html>).

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

Table: LM plants approved for commercial use

Plant Species	Event Number	Plant Species	Event Number
Alfalfa	5	Papaya	1
Oilseed Rape	16* ²	Rose	2
Carnation	8	Soybean	30* ²
Corn/Maize	89* ²	Sugar Beet	1
Cotton	36* ²		

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

2. Developments related to new breeding techniques (NBTs)

Specific cases of application, assessment and decision

Genome editing technology

In October 2019, the Ministry of Agriculture, Forestry and Fisheries of Japan (MAFF) published a notification regarding specific procedures for providing information to the MAFF regarding organisms obtained through genome editing technology, which falls under administrative jurisdiction of the MAFF. The key components of the procedure are as follows:

- Any person intending to use organisms obtained through genome editing provides information to the MAFF regarding the characteristics of the organisms and the views of their possible adverse effects on biological diversity, prior to the use of the organisms.
- A first draft of the information form needs to be submitted to the MAFF by the person for “Prior Consultation”.
- The MAFF asks opinions, as needed, from academic experts and requests the person to provide additional information if any question arises concerning its potential effects on biological diversity.
- After the completion of the prior consultation with the MAFF, the person finalizes the information form and submits it to the MAFF.
- The information form is published on the MAFF website, except for one that may cause any unfair advantages or disadvantages to specific persons, if it is disclosed.
- The MAFF also request the person to take appropriate measures if the use of the organism demonstrates a possibility of potential effect on biological diversity.

As the first case to have gone through this procedure, in December 2020, the MAFF accepted the finalized information form of the tomato with a mutation in a γ -Aminobutyric acid (GABA) synthetic enzyme gene using genome editing technology. The tomato is containing about five times the GABA of normal one.

At the same time, the information form* was released on the MAFF website. ***Only in Japanese.**

Any other information related to NBTs

Research and Development (R&D) related to NBTs

Since 2014 in the Cross-ministerial Strategic Innovation Promotion Program (SIP), new or upgraded genome editing tools and genome-edited crops has been developed. They include several crops with commercial traits, such as high-GABA tomatoes, solanine-less potatoes, and high-yield rice. Since 2019, another research program is running to develop genome-edited crops funded by a MAFF-commissioned project. In the SIP project, researches to improve ways of providing information, including development of communication tools are also studied.

Science Communication Activities

MAFF continuously conducts a science communication project focusing biotechnology. In FY 2020, the outbreak of Covid-19 forced the project to cancel several communication events. Even so, 30 science communication events such as public lectures aimed at consumers, food companies, and so on, were held in the project, and careful science communications were ensured. As a new initiative, tours for research institutes developing products using genome editing technique were held.

KENYA

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

A) Status of GM approvals in Kenya

Since its inception the Authority has approved a number of projects including; 34 laboratory/green house projects, 14 confined field trials, 28 import/transit of GM derived products. One projects for limited environmental release to allow for National Performance Trials and Bt cotton approved for commercialization in January, 2020. In February 2020, the Authority also received an application for Cassava, which is currently awaiting the Board decision. A fourth application for environmental release of genetically modified *Gypsophila* was rejected. Details of these decisions are available on our website; (www.biosafetykenya.go.ke).

In the intervening period since the last OECD meeting in 2020, the following decisions have been made;

i) Environmental release

The Bt cotton MON 15985 (BollGuard II) was approved for commercialization in January 2020. Following this approval, the developer, Monsanto Ltd/Bayer has embarked on country wide demonstration farms within the cotton growing regions of the country. These demonstration plots have had a positive impact with pioneer farmers in the management of cotton bollworm. It is envisaged that Bt cotton seeds will be made available to farmers for open cultivation during the April-May 2021 long rains period.

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. These trials alongside DUS Tests are still on-going and are expected to conclude by 2021/20222 year.

The Authority is currently reviewing an application for cassava modified for cassava brown streak disease (CBSD) that is utilizing the RNAi technology (Cassava Event 4046). Kenya is indeed the first country to consider an environmental release application involving cassava. A decision is yet to be made.

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 <i>Xanthomonas</i> 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 34 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

B) Development of Biosafety regulatory manuals/guidelines

The Authority is currently in the final stages of concluding the development of key guidelines crucial for commercialization of GMOs into the country. The documents include; i) Post Release Monitoring Manual, ii) Coexistence Policy, iii) LLP and AP Guidelines and iv) Guidelines for regulation of genetically modified animals under containment and confinement. The process of development of the above documents include a gap analysis of existing documents, drafting, followed by a series of stakeholder consultations before approval by the Board of Management. The approval of these guidance documents will most likely be finalized in 2021.

C) Regulation of products derived from New Plant Breeding techniques

Kenya has already conducted stakeholder consultations and public participation of genome editing guidelines which have already been developed. The guidelines await final consideration and approval by NBA Board of Management which has now been appointed by the Government.

In the meantime, Kenya has proceed to 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 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).

D) 9th Annual Biosafety Conference

The 9th Annual Biosafety Conference whose theme was “Functional Biosafety Systems towards Commercialization of Agricultural Biotechnologies for Economic Development in Kenya” was held virtually from 10th – 13th November 2020. This was necessitated by the on-going COVID19 pandemic that did not permit face to face interactions as has been the case during previous conferences. The conference provided a platform for scientists, regulators, students and technology developers to deliberate on new breeding techniques such as genome editing and the progress of commercialization of Bt cotton in Kenya. Resource speakers and participants were drawn from different parts of the globe.

LATVIA

1. Developments related to implementation of national biosafety framework

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

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 2020 the State Scientific Institute “Institute of Food Safety, Animal Health and Environment “BIOR”” took part regularly at centralized GMO risk assessment procedure. BIOR provided opinion on 8 applications in respect of GMO placing on the EU market.

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

Draft on regulations of the Cabinet of Ministers on GMO deliberate release is elaborated to fulfil requirements resulting from Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain. The Transparency Regulation amends, among others, Regulation (EC) No 178/2002, (General Food Law) as well as Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms.

2. Updates regarding international activities

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

- 1.1. On January 26th, 2001 the Members of the European Parliament Jessica Polfj rd (SE, EPP) and Erik Bergkvist (SE, S&D) hosted a webinar on “Genome editing and the Farm to Fork strategy”. The webinar discussed the potential of genome editing to contribute to the F2F objectives, the current regulatory landscape for GMOs, and future governance options.
- 1.2. On November 26th, 2020 the online Conference: Technical Potential and Risks of Genome Editing was hosted by Institute for Independent Impact Assessment of Biotechnology “Testbiotech”, Germany. The conference aimed to inform policy makers of scientific facts and arguments relevant to the regulation and application of New Genetic Engineering, with a focus on genome-edited plants.

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 started in 2020. The main objective of the project is evaluating of diagnostic methods and potential risks of food, feed and additives obtained with help of NBTs. This is two-year project. The main tasks done in 2020 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.

Any other information related to NBTs.

On November 3rd, 2020 in connection with the above-mentioned project The State Scientific Institute “Institute of Food Safety, Animal Health and Environment “BIOR”” organized webinar “GMOs and organisms obtained with the help of NBTs: use and risk assessment”.

LITHUANIA

1. Developments related to implementation of national biosafety framework

Lithuanian legislation framework is compatible with the provisions of the Cartagena Protocol on Biosafety (was ratified in 2003) and European Union legislation.

Lithuania has been transposing the regulation 2019/1381⁴ into our national law. In 2020 was adopted amendment of GMO Law and the legislative procedure to adopt an amendment that transposes “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 be finished⁵.

Field trials and Commercial cultivation. In 2020 there was no cultivation of GM crops and no deliberate release of GMOs for field trials in Lithuania.

Contained use. In 2020 the Ministry of Environment received 3 new notifications on new contained use activities with GMMs and GMOs of Class 1 with no or negligible risk. So, due to date there are 15 institutions for contained use (Directive 2009/41/EC) registered in Lithuania.

2. Updates regarding international activities

An international virtual conference on scientific advice to policy-makers and society “Genome Editing in Europe: New Agenda or New Disputes?” was organized by German National Academy of Sciences Leopoldina on the 1st - 2nd of October 2020.

Implementing the European Green Deal and Digital Transformation “Baltic cluster Christmas forum 2020” was organized by Lithuanian Agency for Science, Innovation and Technology (MITA) on the 10th of December, 2020.

3. Developments related to new breeding techniques (NBTs)

In 2020 there was no application received of GMO developed by the new plant breeding techniques.

Currently, The European Commission is preparing the outcomes of the study on the status of new genomic techniques which will be available at the end of April 2021.

4. Additional Information

The project on GMO Environmental Risk Assessment was ongoing in 2019-2020. The aim of the project is to examine the requirements of legal acts regulating the use of GMOs, experiences of other countries, assess the current situation of possible GM oilseed rapes in Lithuania and to prepare a study on the environmental impact assessment of GMOs with conclusions and recommendations on further actions to strengthen the management of the environmental impact assessment of GMOs.

NETHERLANDS

1. Developments related to implementation of national biosafety framework

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

Notifications for field trials and clinical trials in the Netherlands

The Dutch authorities received several new applications for deliberate release into the environment under directive 2001/18/EC part B. General information about genetically modified organisms that have been approved in

⁴ Directive 2015/412 of the European Parliament and of the Council 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

⁵ Regulation (EU) 2019/1381 of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/E

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>).

Last year the Netherlands reported it had issued a permit for the production of organic acids with cyanobacteria (*Synechocystis* spp) under semi-confined conditions. Recently we published a draft decision on a follow-up application with the same parent organism. We expect the final decision to be issued in the course of the year.

Over the last period Netherlands issued 21 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).

Recently permits were issued for phase I/II clinical trials with live genetically attenuated malaria parasites (*Plasmodium falciparum*). The objective of this clinical trial is to expose test subjects to the sporozoites of genetically attenuated *P. falciparum* (Pf) malaria parasites (GAP) to test safety and in subsequent studies to determine the immunogenicity and preliminary protective immunity of repeated exposure to GAP against an infection with wild type (WT) Pf malaria parasites. The overall aim is to: i) Determine the safety of a novel late-arresting GAP (LA-GAP) including attenuation phenotype, ii) compare the immunogenicity of the LA-GAP with an existing early-arresting GAP (EA-GAP; authorized in 2015) and iii) determine the preliminary protective immunity of the LA-GAP.

Over the last period no new notifications for field trials with GM plants were received

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

Amendment of the Dutch GMO Decree for a simplified procedure for applications for clinical studies with designated categories of GMOs

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 standardized environmental risk assessment (ERA) is available. The amendment also introduces the first two categories:

- 1) adeno-associated viral vectors (AAV) without harmful sequences as transgenes
- 2) human cells genetically modified by means of retro/lentiviral vectors where there is no or negligible risk of formation of replication competent virus, and residual infectious retro/lentiviral vector particles have been reduced to negligible concentrations in the finished product

The structure of the amendment is such that it is considered to act as a so-called learning or modular system where new categories can be included relatively fast.

Applicants who demonstrate that their GMO complies with a standardized ERA, as published by the Dutch government, no longer need to perform an ERA themselves and can refer to this standardized ERA in their permit application. In this way the procedural term is reduced to a maximum of 56 days or even 28 days in specific cases.

National temporary emergency regulation related to license applications for clinical trials to cure or prevent COVID-19

On March 31, 2020 The Ministry of Infrastructure and the Environment adapted the application procedure for clinical trials with GMOs aimed at COVID-19 related therapies or vaccines to make an urgency procedure possible. To this effect, new legislation was created to make it possible to obtain a permit to work with GMOs for COVID-19 related clinical trials within 28 days. Seeing how urgently the world needs a vaccine or therapy for COVID-19, it was felt necessary to develop such a fast procedure. In addition, the Dutch Parliament issued a resolution that called for the development of such an urgency procedure.

Under this emergency regulation an application was processed that covered a phase 2 clinical trial with an Ad26COVS1 clinical vector developed by Janssen Vaccines & Prevention. This vaccine is intended to be used for prophylactic immunization against coronavirus disease 2019 (COVID-19). To this aim, a synthetic sequence is designed based on antigen(s) of the severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) and inserted in the replication-incompetent Ad26 vector. The permit was issued within 11 days.

In July 2020 this temporary emergency regulation was repealed due to the EU Regulation 2020/1043.

Regulation (EU) 2020/1043 on the conduct of clinical trials with and supply of medicinal products for human use containing or consisting of GMOs intended to treat or prevent coronavirus disease (COVID-19)

On July 17, 2020 the European Commission published a temporary regulation that a day later, on 2020, July 18 took effect. Because of this Regulation 2020/1043 parts of the national GMO Decree are derogated in case of clinical trials for COVID-19. As a result a GMO permit will no longer be required for clinical research into curative or preventive treatment of COVID-19. As a consequence of Regulation 2020/1043, the earlier Dutch temporary emergency regulation related to license applications for gene therapy to cure or prevent COVID-19 has been repealed.

2. Updates regarding international activities

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

The Netherlands is a party to the CBD and to the Cartagena Protocol, and has actively participated in the COP-MOP meetings and the CBD and Protocol activities such as the expert online forums on LMOs containing gene drives.

3. Developments related to new breeding techniques (NBTs)

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

Currently the European Commission is conducting a study as a response to the Council's request for a study on the status of new genomic techniques. The scope of the study concerns techniques, which have been developed after 2001, for which the Council seeks clarification. To this end the Commission sent out a questionnaire on new genomic techniques to contribute to the study as requested by the Council. The outcome of the study by the European Commission is expected to be available at the end of April 2021.

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.

NEW ZEALAND

1. Developments related to implementation of national biosafety framework

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

The 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. A genetically modified vaccine IMOJEV® for Japanese encephalitis virus (JEV) was approved for import and release with its use subject to the Medicines Act 1981. (EPA press release 30 April 2019)
<https://www.epa.govt.nz/news-and-alerts/latest-news/application-to-import-gmo-vaccine-approved/>
- ii. Genetically modified human cells developed for use in CAR-T cell therapy. Release from containment of GMO cells and may only be released for use in a clinical trial at Wellington Hospital. The approval expires upon the conclusion of the trial. (EPA press release 27 September 2019)
<https://www.epa.govt.nz/news-and-alerts/latest-news/next-step-for-cancer-treatment-trial/>
- iii. Two ongoing field trials of GMOs in 2020.
<https://www.epa.govt.nz/industry-areas/new-organisms/gm-field-tests/>
- iv. The pharmaceutical company, Pfizer, applied to the EPA for a statutory determination of whether its COVID-19 vaccine is considered a new organism under the Hazardous Substances and New Organisms Act 1996.

An EPA decision-making committee has determined that the Pfizer COVID-19 vaccine is not a new organism. (EPA press release 11 February 2021)

<https://www.epa.govt.nz/news-and-alerts/latest-news/determination-on-pfizer-covid-19-vaccine/>

- v. Numerous approvals for import and development of GMOs in containment. More information can be found at the EPA HSNO register 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 Rauhi 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 principle 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

The EPA developed the He Whetū Mārama (HWM) framework to guide the EPA in undertaking its statutory and other obligations to Māori including regulatory processes for new organisms. The HWM framework is based on four principles of Te Tiriti o Waitangi/Treaty of Waitangi (Te Tiriti):

- Waka hourua: Partnership
- Tiakitanga: Protection
- Whai wāhi: Participation
- Pito mata: Potential

Through the application of Te Tiriti principles, EPA decision making is informed by Māori perspectives and contributes towards a shared understanding of Te Tiriti.

In July 2020 the EPA has launched its Mātauranga Framework which aims to help decision makers and EPA staff incorporate Māori perspectives and mātauranga evidence into decision-making.

Mātauranga is the pursuit of knowledge and understanding of te taiao – the natural environment. It includes knowledge or lore about a landscape or an element within the landscape, such as how a river has behaved over time. It follows a systematic methodology based on evidence, and incorporates culture, values, and Māori worldview.

By weaving this knowledge alongside conventional science, our decision makers will be able to better understand mātauranga as a form of evidence. A waka hourua, or double-hulled canoe, symbolises our approach to mātauranga. The two hulls represent two knowledge systems – mātauranga and science – moving together in the same direction. The interwoven sails represent the information, evidence, advice, and risk assessment that inform our decisions.

The primary goals of the mātauranga programme are to:

- Enable well-informed decision-making.
- Ensure the EPA understands the issues and implications of mātauranga for its decision-making processes.
- Increase the understanding of mātauranga across the EPA.

More information can be found at the following links:

<https://www.epa.govt.nz/about-us/what-we-do/>

<https://www.epa.govt.nz/news-and-alerts/latest-news/new-epa-matauranga-framework-a-first-of-its-kind/>

<https://www.epa.govt.nz/applications-and-permits/engaging-with-maori/incorporating-maori-perspectives/>

<https://www.epa.govt.nz/about-us/annual-report-2020/>

3. Public engagement and outreach activities;

Wai Tūwhera o te Taiao – Open Waters Aotearoa, uses eDNA data gathered from waterways, including lakes, rivers, streams and estuaries to provide a picture of what species are present in the environment.

More information can be found at the following links:

<https://www.epa.govt.nz/news-and-alerts/latest-news/testing-the-waters-with-environmental-dna-edna/>

<https://www.epa.govt.nz/community-involvement/open-waters-aotearoa/>

2. Updates regarding international activities

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

Activities under the Cartagena Protocol on Biosafety included

- leading the preparation and submission of the quadrennial 4th National Report on New Zealand's activities under the Cartagena Protocol on Biosafety, as the National Focal Point for the Biosafety Clearing House under the Cartagena Protocol
- providing expertise to the 13th meeting of the Liaison group of the Cartagena Protocol, the Open-Ended working group meetings on the Post-2020 Global Biodiversity Framework, and multiple reports resulting from Risk Assessment/ Risk Management Decisions made at the Conference of Parties/ Meeting of the Parties
- membership in the Informal Advisory Committee on the Biosafety Clearing House

3. Developments related to new breeding techniques (NBTs)

1. Any other information related to NBTs.

No new organisms developed utilising NBTs have been assessed by the New Zealand EPA for potential environmental release. New gene editing technologies are regulated as GMOs under the HSNO Act.

PARAGUAY

1. Developments related to implementation of national biosafety framework

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

i. Events for confined field trials

Event	Applicant	Common Names	Traits	Date of approval	Decision document
MON87427 x MON95379 x MON87411 x MON87419	Monsanto Paraguay S.A.	Maize	Resistance to Lepidoptera and Coleoptera, and tolerance to glufosinate-ammonium, dicamba and glyphosate.	30 April 2020	Resolución MAG N° 334
MON87427 x NK603 x MON87419	Monsanto Paraguay S.A.	Maize	Tolerance to glufosinate-ammonium, dicamba and glyphosate.	30 April 2020	Resolución MAG N° 334

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

i. **Simplified Approval Procedure**

In 2019, Paraguay's National Agricultural and Forestry Biosafety Commission proposed the introduction of a simplified approval procedure for events that have been assessed by sound and experienced regulatory systems, thus maintaining the regular procedure for those GE crops that have not been previously assessed⁶. The simplified procedure applies to commercial approvals hence including both food and feed and environmental evaluations. This implies the acceptance of scientific opinion by the regulatory authority in the country where the GE crop has been approved but only when several criteria have been taken into consideration in the risk assessment performed by those regulatory authorities.

Through the Paraguayan Ministry of Agriculture's Resolutions 1030⁷ and 1071⁸, a differentiated treatment was established for the commercial release of novel GE crops and for GE crops that have been approved in third countries, whose scientific, technical and safety characteristics are well-founded. Paraguay usually receives submissions to assess events that have been in the market for a while and have thus been submitted to the evaluation of regulatory systems that are sound and experienced. In addition, those countries usually share Paraguay's protection goals.

The aforementioned Resolutions authorize the consideration of decision documents from third countries with regard to both human and animal food safety in the cases where these evaluations have been based on Codex Alimentarius, such as the Guidelines for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants and carried out in countries with time-tested regulatory systems and transparent procedures.

Concerning environmental safety, assessments are accepted for GE crops that besides having been authorized for commercial planting in countries with sound regulatory systems, include in the decision documents considerations as follows: that the GE crop under review has been studied under different environmental conditions, behaving in the same way as the conventional non-GE counterpart; that it will be managed in an agronomic manner similar to any GE or conventional hybrid/variety of the species; another aspect is that Paraguay is not center of origin of that crop, and finally two relevant characteristics are that there are no related weeds in Paraguay with which the GE crop could cross-breed and that the main target pests and the main non-target arthropod species present in Paraguay have been taken into account in the GE risk assessment carried out in those countries.

During 2019, in the period immediately following the adoption of the simplified procedure for events with commercial authorizations in third countries, thirteen events were approved; most of them with herbicide tolerance and/or Lepidoptera resistance, traits for which there is an extensive body of literature and experience with the safety of the novel proteins involved.

3. Research projects on biosafety; relevant publications.

Benítez Candia N, Fernández Ríos D and Vicién C (2020) Paraguay's Path Toward the Simplification of Procedures in the Approval of GE Crops. *Front. Bioeng. Biotechnol.* 8:1023. <https://doi.org/10.3389/fbioe.2020.01023>

2. **Updates regarding international activities**

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

i. **Virtual Session on Biotechnology and Biosafety 2020**

⁶ MAG. (2015). Resolución No 27: Por la cual se aprueban los documentos Formulario 1: Ensayos Regulados, 2: Liberación Comercial y la Guía para Formulario 2: Liberación Comercial. Ministerio de Agricultura y Ganadería.

⁷ MAG. (2019). Resolución 1030: Por la cual se amplía el Inc. C) del Artículo 31 de la Resolución MAG No 1348 Por la cual se reglamenta el Decreto No 9699 del 19 de Setiembre de 2012 «Que crea la Comisión Nacional de Bioseguridad Agropecuaria y Forestal (CONBIO)». Ministerio de Agricultura y Ganadería. [Online] Available from <https://conbio.mag.gov.py/media/ckfinder/files/RES.N1030%20DE%2023%20DE%20AGOSTO%20DE%202019Liberacion%20Comercial.pdf>

⁸ MAG. (2019b). Resolución 1071: Por la cual se amplía el Inc. C) del Artículo 31 de la Resolución MAG No 1348 Por la cual se reglamenta el Decreto No 699 del 19 de Setiembre de 2012 «Que crea la Comisión Nacional de Bioseguridad Agropecuaria y Forestal (CONBIO)». Ministerio de Agricultura y Ganadería. [Online] Available from <https://conbio.mag.gov.py/media/ckfinder/files/RES.N1071%203%20DE%20SETIEMBRE%20Aprobaciones%20ComercialDE%202019.pdf>

These meetings were coordinated by the Inter-American Institute for Cooperation on Agriculture (IICA); these virtual sessions aim to foster the continuous exchange of technical information on issues relevant to countries' biosafety performance and to facilitate dialogue on national biosafety approaches and activities under the Convention on Biological Diversity and its protocols.

<https://sites.google.com/iica.int/biotecnologia-y-bioseguridad/actividades-t%C3%A9cnicas/seminarios-virtuales/feed-your-mind>

ii. International Virtual Workshop Series on Regulatory Approaches for Animal Biotechnology

These virtual activities are being planned and carried out by the international organizing committee for the Fourth International Workshop on Regulatory Approaches for Animal Biotechnology, the in-person event has been postponed until 2021. The objectives of the international workshop and these supporting virtual activities include: exchanging information on regulatory approaches, sharing regulatory experiences, and enhancing regulatory cooperation. The focus is on agricultural and food/feed applications of animals created via genetic engineering/modification and via genome editing.

<https://sites.google.com/a/vt.edu/animalbiotechresources/2020-online-workshops>

iii. 7th Virtual GLI Meeting

The Global LLP Initiative (GLI) is an inter-governmental initiative that grew out of a meeting hosted by the Government of Canada for like-minded, interested countries to work collaboratively on the issue of low level presence. Paraguay made a presentation at the webinar on Synchronization of Biotech Approvals: Challenges and Best Practices, as part of a session on Country Experiences on Asynchronous Approvals and Managing LLP Incidents. <https://llp-gli.org/>

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

Benítez Candia N, Fernández Ríos D and Vicién C (2020) Paraguay's Path Toward the Simplification of Procedures in the Approval of GE Crops. *Front. Bioeng. Biotechnol.* 8:1023. <https://doi.org/10.3389/fbioe.2020.01023>

Reports on the amount of approved GE events may vary depending on whether the parental lines and intermediate combinations approved through a single legal instrument are counted. **For this work, we used the Biotrack Product Database (OECD) entry on Paraguay** along with Decision documents from the Paraguayan government.

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 2020, the Bureau of Plant Industry has approved 8 events for direct use as food and feed, or for processing, and 4 events for commercial propagation (see Table below). Under the Philippine regulation, the total number of processing days for applications is 85 days.

Transformation Event	Type of Use	Trait
1. CORN MON89034 X TC1507 X NK603	For Direct Use	Insect Resistance and Herbicide Tolerance
2. COTTON GHB811	For Direct Use	Herbicide Tolerance
3. CORN GA21 X T25	For Direct Use	Herbicide Tolerance
4. CORN 5307	For Direct Use	Insect Resistance
5. CORN TC1507 X MON810 X MIR162 X NK603	For Direct Use	Insect Resistance and Herbicide Tolerance
6. SOYBEAN FG72	For Direct Use	Herbicide Tolerance
7. COTTON COT102	For Direct Use	Insect Resistance and Antibiotic Resistance
8. SOYBEAN DAS 81419-2 X DAS 44406-6	For Direct Use	Insect Resistance and Herbicide Tolerance

9. CORN NK603	For commercial propagation	Herbicide Tolerance
10. CORN 89034 X TC1507 X NK603	For commercial propagation	Insect Resistance and Herbicide Tolerance
11. CORN BT11	For commercial propagation	Insect Resistance
12. CORN BT11 X TC1507 X GA21	For commercial propagation	Insect Resistance and Herbicide Tolerance

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

The Philippines policy framework on the regulation of plant and plant products derived from the use of modern biotechnology or the Joint Department Circular No. 1 series of 2016 is currently undergoing a review.

3. Public engagement and outreach activities;

On August 18, 2020, the Bureau of Plant Industry- Biotechnology Office has organized a webinar entitled “Biotech Regulations in the Philippines” which targeted personnel from the local government in the region. The main purpose of this activity is to raise awareness and brief DA Regional counterparts, Provincial and Municipal Agriculture Officers (PAO/MAO), Corn Coordinators, BPI-Plant Quarantine Officers and other concerned/interested government agency on how biotechnology crops are regulated in the Philippines.

2. **Updates regarding international activities**

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

a. **ASEAN GENETICALLY MODIFIED FOOD TESTING NETWORK (GMFNET)**

Staff of the Biotech Office have participated to the 17th Meeting of the ASEAN Genetically Modified Food Testing Network (GMFNET) held on July 16, 2020 which was hosted by the Department of Agriculture (DOA) and Department of Medical Sciences (DMSc) of Thailand. The objective of this meeting was to report the developments of countries’ commitments to GMFNET and to discuss ASEAN GMFNET Plan of Action 2018-2025.

b. **CGIAR GLOBAL WEBINAR SERIES - "REGULATION AND GENOME EDITED PLANTS"**

- **Webinar 1:** Genome Editing in Agriculture: Innovations for Sustainable Production and Food Systems – 22 Sept 2020
- **Webinar 2:** Applications of Genome Editing in Agriculture: CGIAR Focus on Crop Improvement – 29 Sept 2020
- **Webinar 3:** Applications of Genome Editing in Agriculture: CGIAR Focus on Livestock and Aquaculture – 6 Oc 2020
- **Webinar 4:** Regulation and Genome Edited Plants – 13 Oct 2020
- **Webinar 5:** Path to Commercialization for Genome Edited Crops – 20 Oct 2020

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

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

Recognizing the emergence of new technologies in the field of plant breeding, the Department of Agriculture through its Biotech Program Office spearheaded the review of regulatory landscape governing products developed using plant breeding innovations (PBIs) or new plant breeding techniques (NBTs), including applicable domestic laws and policies, and current capabilities of public R&D institutions on NBTs. The output of the said review was a technical study, which the National Committee on Biosafety of the Philippines (NCBP) reviewed and approved. To provide clarity on the regulatory regime that would govern PBIs/NBTs, a Resolution, which contains regulatory classification criteria that would distinguish whether or not a product of an NBT would be categorized as a GMO, was proposed. The said Resolution is expected to be published within the year, and thereafter the Department of Agriculture will formulate relevant rules and regulations.

RUSSIAN FEDERATION

1. Developments related to implementation of national biosafety framework

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

To date, Russia is actively working to improve the legislation in the field of state regulation of genetic engineering and genetic technologies.

Under consideration is the issue of introducing amendments and changes to **Federal Law No. 86-FZ dated July 5, 1996, “On State Regulation in the Field of Genetic Engineering Activity”**.

On December 30, 2020, **Federal Law No. 492-FZ “On Biological Safety in the Russian Federation”** came into force. The Law establishes the state regulation basis for ensuring biological safety of the Russian Federation and defines a set of measures aimed at protecting the population and conserving the environment from the effects of hazardous biological factors, preventing biological threats, and creating and developing a biological risks monitoring system.

“*The Russian State Center for Animal Feed and Drug Standardization and Quality*” (VGNKI), which is subordinate to ROSSELKHOZNADZOR, conducts research on grain, feed, feed additives and food products for the presence of GMOs or products made of them in order to assess potential risks of their use.

In this connection a number of methodologies have been developed to reduce the risks associated with the spread of unregistered GMO lines, prevent the import into the Russian Federation of feed and food products containing new genetic lines and rule out the masking of unregistered GMO lines by the presence of registered ones.

The following methods were developed and approved by Orders of the Russian Ministry of Agriculture:

- **Order of the Russian Ministry of Agriculture No 126 dated from March 22, 2019**, “On approval of the Methods of conducting molecular genetic study of genetically engineered and modified organisms used for the production of feed and feed additives for animals, as well as feed and feed additives for animals obtained by using such organisms or containing such organisms”.
- **Order of the Ministry of Agriculture of the Russian Federation No. 92** “On Approval of Methodology for Examinations (Studies) of Biological Safety of Genetically Engineered/Modified Organisms Used for Production of Medicinal Products for Veterinary Use” dated February 28, 2020.
- **Order of the Ministry of Agriculture of the Russian Federation No. 160** ‘On Approval of Methodology for Examinations (Studies) of Biological Safety of Genetically Engineered/Modified Organisms Used for Production of Feed and Feed Additives for Animals” dated March 27, 2020.

In addition, it is planned to enact the following in the near future:

- **Order of the Russian Ministry of Agriculture No 655 dated from October 30, 2020**, “On approval of the Methods of conducting molecular genetic research of genetically engineered and modified agricultural microorganisms used for breeding and/or growing in the Russian Federation, the Methods of carrying out examinations (studies) of biological safety of genetically engineered and modified agricultural microorganisms used for breeding and/or growing in the Russian Federation”.
- **Order of the Russian Ministry of Agriculture No. 650 dated October 30, 2020**, “On approval of the Methods for conducting molecular genetic studies of genetically engineered and modified animals used for breeding and/or raising in the Russian Federation, the Methods for conducting examinations (studies) of biological safety of genetically engineered and modified animals used for breeding and (or) raising in the Russian Federation”.
- **Order of the Ministry of Agriculture of the Russian Federation No. 716** “On Approval of Methodology for Molecular Genetic Study of Genetically Engineered/Modified Plants Used for Breeding and (or) Cultivation in the Territory of the Russian Federation, Methodology for Examinations (Studies) of Genetically Engineered/Modified Plants Used for Breeding and (or) Cultivation in the Territory of the Russian Federation” dated November 30, 2020.

A number of methodological documents have been developed to carry out the above activities, such as the Method for examining genetically engineered and modified microorganisms using whole-genome sequencing technology on the MiSeq (Illumina) platform.

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

New Federal Law No. 492-FZ “On Biological Safety in the Russian Federation” which entered into force on December 30, 2020, provides for organization of a state information system in the field of biological safety, established with the purpose of managing and monitoring biological risks, as well as developments in the field of genetically modified products.

3. Public engagement and outreach activities

Nowadays, biosafety is widely discussed in the Russian media. Television broadcasts meetings of high-level Scientific Councils discussing the priorities of fundamental science. The Russian Academy of Sciences has updated its infrastructure with two Scientific Councils addressing biosafety: the RAS Council on Genetic Engineering under the RAS Presidium (2019) and the RAS Scientific Council on Biotechnology (2020).

2. Updates regarding international activities

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

On May 23, 2019 - The high-level bilateral I Meeting of the Joint Working Group on Agricultural Biotechnology and Biosafety between Argentina and the Russian Federation (at the Ministry of Agriculture of the Russian Federation).

At the meeting of the Committee of the Codex Alimentarius Commission (Codex Committee on Food Additives, CCFA), on the initiative of the Russian Federation, food additives used as preservatives/antibiotics of microbial origin, nisin and natamycin, were included in the priority list of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). The highest (1) JECFA Risk Assessment Priority Index has been established for the use of these preservatives in the food industry, WHO (CCFA Report 51 – <http://www.fao.org/fao-who-codexalimentarius/meetings/en/>).

Risk assessments of antibiotics permitted for use in the food industry as preservatives, nisin (INS 234) and natamycin (INS 235), have been prepared and sent to the Secretariat of the Codex Alimentarius Commission, CCFA and JECFA.

On August 28, 2019, the RF Government adopted **Ordinance No. 1906-r** “On the Plan of Measures for Implementing the Basic Principles of the RF State Policy in the Field of Chemical and Biological Security for the Period up to 2025 and Further on”.

According to the approved plan, the Russian Federation is to join, prior to 2023, the Cartagena Protocol on Biosafety to the Convention on Biological Diversity, as well as the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity, the Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety.

In this regard, it is necessary to harmonize the basic concepts with these protocols, set up a national coordination center and carry out other administrative and organizational activities for its implementation.

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

Application of the OECD documents to develop a concept for formation of a national bioresource center (BRC) network in Russia. The network formation includes standardization of microbial biological resources for biotechnological purposes to ensure safe use and control over the spread of microbial biological resources, including genetically engineered/modified resources.

- OECD. Best practice guidelines for Biological resources centers, 2007.
- OECD. Guidance for the operation of biological resources centers, 2008.

The information regularly submitted to Russia by the Organisation for Economic Cooperation and Development covering the regulatory considerations of biosafety in different countries, on product- and process-oriented concepts of regulation in the field of genetic technologies, on the development of basic biosafety documents allows using the experience of other countries, valuable for updating the Russian legislation stimulated by the emergence of breakthrough biotechnologies.

An obligatory element in assessing toxicity and hazard of chemicals and their mixtures for human health is analyzing their mutagenic and carcinogenic activity. Methodological recommendations for the principle tests are provided in the documents of the Organization for Economic Cooperation (OECD) and are included in the majority of national and international regulations.

For the purposes of technical regulation, the Federal State Unitary Enterprise “*Russian Scientific and Technical Center for Information on Standardization, Metrology and Conformity Assessment*” (FSUE STANDARTINFORM), based on its own translation of the OECD Guidelines from English into Russian, prepared a series of interstate standards for genetic toxicology and carcinogenic activity assessment.

The interstate standard GOST 34659-2020 “Methods of Testing the Impact of Chemical Products on Human Body. Assessment of chromosomal aberrations in mammalian bone marrow cells” has been harmonized with the international document (OECD Guideline No. 475:2016).

This standard is aimed at aligning the requirements for studies to assess the mutagenic effect in mammals in vivo when exposed to chemicals and their mixtures (including pesticides and industrial chemicals) potentially capable of inducing neoplasms in the body.

The interstate standard GOST 34661-2020 “Methods of Testing the Impact of Chemical Products on Human Body. Tests to Evaluate Carcinogenic Activity” has been harmonized with the international document (OECD Guideline No. 451:2018).

This standard is aimed at establishing uniform requirements for conducting studies to assess the carcinogenic activity of chemicals and their mixtures (including pesticides and industrial chemicals), to determine target organs, as well as the possibility of accumulation, to assess the level of adverse effects, and to define safety criteria for human exposure.

These standards are applicable for state registration of chemicals, newly introduced into production and previously unused, and medicinal products manufactured on their basis, potentially hazardous to humans; certain types of products potentially hazardous to humans; certain types of products newly imported to the Russian Federation as part of a systematic study of marketed chemicals, their mixtures and products based on them; during hygienic certification, certification of certain types of products potentially hazardous to humans, as well as in the formation of a state information system – the Federal Register of Potentially Hazardous Chemical and Biological Substances, in the practical implementation of the EAEU Technical Regulations “On Safety of Chemical Products” (TR EAEU 041/2017).

These standards are intended for specialists from testing centers (laboratories) of the Federal Service for Surveillance on Consumer Rights Protection and Human Wellbeing, the Ministry of Health of the Russian Federation, the Federal Medical and Biological Agency and research organizations of other agencies certified under the established order, whose activities are related to conducting non-clinical laboratory studies of chemicals and their mixtures in accordance with the principles of Good Laboratory Practice, their assessment and classification of hazards.

3. Developments related to new breeding techniques (NBTs)

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

In 2020, projects on NBT products biosafety, as well as research in the field of genetic technologies in general, were carried out as part of the **Federal Scientific and Technical Program for the Development of Genetic Technologies for 2019-2027**. The program is mainly aimed at comprehensive solution of the problems regarding accelerated development of genetic technologies, including genetic editing technologies. The leading participants of the Program are the World-Class Genomics Research Center for Biological Safety and Technological Independence; Kurchatov Genomics Center; Center for Precision Genome Editing and Genetic Technologies for Biomedicine. Their work ranges from biosafety and technological independence, genetic technologies of agriculture to genetic technologies for medicine and industrial microbiology.

Using genetic editing technologies, it is planned to develop plant and animal lines including aquaculture that are in demand in the real sector of the economy.

A proper regulatory framework should be put in place to facilitate research and subsequent active implementation of the results of genetic technology development in Russia to ensure an effective and safe use of genome editing. In this respect, the issue of genome editing regulation is being examined for incorporation into the current legislation.

Works on accelerated selection of high-yielding and resistant varieties and hybrids of plants with specified quality characteristics are also carried out in the World-Class Centers for Scientific and Technological Development (WCNC) – consortia within the framework of the national project “Science”.

4. Additional Information

Russian recombinant two-vector Sputnik V COVID-19 vaccine was developed in the National N.F. Gamaleya Research Center for Epidemiology and Microbiology and after successful clinical trials was registered on August 11, 2020. It was approved for use in Russia and some other countries. At present, a large-scale Covid-19 vaccination of the population is taking place in the Russian Federation.

SLOVAK REPUBLIC

1. Developments related to implementation of national biosafety framework

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

Last year, there was a trend to request the revocation of the consents approving the premises for contained use, where any contained use had been carried out. One user submitted an application for approval of premises for activities in risk classes 1, 2 and 3.

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

The legislative procedure to adopt an amendment that transposes “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” will be finished this year.

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

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

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

Gene drive technology. Some researchers made attempts to implement gene drive technology in contained use, but without success.

2. Updates regarding international activities

In the last year we have participated only in virtual conferences of European bodies where it was obligatory.

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. Developments related to implementation of national biosafety framework

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 2020/2021 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). 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.

3. 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.

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

Biosafety:

Mission

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

Functions

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

Role as the Competent National Authority

The Cartagena Protocol on Biosafety, which is an international agreement that aims to ensure an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms (LMOs) resulting

from modern biotechnology, was established under the Convention of Biological Diversity. South Africa acceded to the Cartagena Protocol on Biosafety on August 14, 2003. In terms of the Protocol the DALRRD (Directorate Genetic Resources) is the recognized Competent National Authority for South Africa and is responsible for ensuring that all provisions and obligations relating to the Protocol are met.

5. **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 approval since the last meeting is presented in Table 2 and is indicated in bold text.

Table 1. Commodity clearance imports approved for food and feed in South Africa in 2016/2020.

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

Event	Crop	Trait	Company	Year approved
MON89034 x TC1507 x MIR162 x NK603 x DAS-40278-9	Maize	Insect resistance Herbicide tolerance	Pioneer Hi-Bred RSA (Pty) Ltd	2020
MON87427 x MON89034 x MON810 x MIR162 x MON87411 x MON87419	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2020
MON87427 x MON89034 x MIR162 x MON87419 x NK603	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2020
MON87427 x MON87419 x NK603	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2020
MON87427 x MON89034 x MON87419 x NK603	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2018
MON87427 x MON89034 x TC1507 x MON87411 x DAS 59122-7 x MON87419	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2018
MON87751 x MON87701 x MON87708 x MON89788	Soybean	Insect resistance Herbicide tolerance	Monsanto SA	2018
FG72 x A5547-127	Soybean	Herbicide tolerance	Bayer	2018
MON89034 x TC1507 x MIR162 x NK603	Maize	Insect resistance Herbicide tolerance	DowAgroSciences	2018
BT11 x MIR162 x MIMR604 x MON89034 x 5307 x GA21	Maize	Insect resistance Herbicide tolerance	Syngenta SA	2018
MON87705 x MON87708 x MON89788	Soybean	Herbicide tolerance	Monsanto SA	2018
MON87427 x MON87460 x MON89034 x TC1507 x MON87411 x DAS-59122-7	Maize	Insect resistance Herbicide tolerance Drought or water tolerance	Monsanto SA	2018
MON87427 x MON89034 x MIR162 x MON87411	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2018
MON87427 x MON89034 x TC1507 x MON87411 x DAS-59122-7	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2018
MON87427 x MON87460 x MON89034 x MIR162 x NK603	Maize	Insect resistance Herbicide tolerance Drought or water tolerance	Monsanto SA	2018
MON87708 x MON89788 x A5547-127	Soybean	Herbicide tolerance	Monsanto SA	2018
BT11 x MIR162 x MON89034	Maize	Insect resistance Herbicide tolerance	Syngenta SA	2018
MON87427 x MON89034 x MON88017	Maize	Insect resistance Herbicide tolerance	Monsanto SA	2017
MON89034 x MIR162	Maize	Insect resistance	Monsanto SA	2017
BT11 x MIR162 x MON89034 x GA21	Maize	Insect resistance Herbicide tolerance	Syngenta	2017
DP114 x MON810 x MIR604 x NK603	Maize	Insect resistance Herbicide tolerance	Du Pont Pioneer	2017
TC1507 x MON810 x MIR162 x NK603	Maize	Insect resistant Herbicide tolerant	Du Pont Pioneer	2016
TC1507 x MIR604 x NK603	Maize	Insect resistant Herbicide tolerant	Du Pont Pioneer	2016
TC1507 x MON810 x MIR604 x NK603	Maize	Insect resistant Herbicide tolerant	Du Pont Pioneer	2016
TC1507 x 59122 x MON810 x NK603	Maize	Insect resistant Herbicide tolerant	Du Pont Pioneer	2016
TC1507 X 59122 X MON810 x MIR604 x NK603	Maize	Insect resistant Herbicide	Du Pont Pioneer	2016

		tolerant		
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 in 2015-2020. Source: <http://www.dalrrd.gov.za/>

Event	Crop	Trait	Company	Year approved
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
Innovax-ND	Vaccine	-	Intervet	2015
Vectormune HVT NDT & Ripens	Vaccine	-	Ceva Animal Health	2015
MON87460	Maize	Drought tolerant Antibiotic resistant	Monsanto	2015

6. Genome editing research and activities in South Africa

South Africa realizes 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 on sunflower: Developing a haploid inducer system for sunflower.

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

Project on banana: 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. We conducted an RNASeq study to identify genes differentially expressed in response to BBTV. We are 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.

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

Project on tobacco: 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.

CRISPR research in the Vitis Lab at Stellenbosch University

Projects on grapevine: 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 using CRISPR/Cas13 which targets RNA and the model plant *N. benthamiana*. They 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.

Projects on wheat: 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.

CRISPR/Cas9 research at the Forestry and Agricultural Biotechnology Institute (FABI), University of Pretoria

Projects on biomass: Functional genetic analysis of cellulose and xylan related genes affecting woody biomass processing

Aim: To enhance the industrial processing of woody biomass, particularly chemical cellulose extraction, using advanced biotechnology approaches such as genetic engineering and gene editing, while improving our understanding of the molecular genetics of wood formation with a special focus on xylan biosynthesis in *Eucalyptus*.

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 expressed their 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 (WP-HROB) and the OECD Working Party on the Safety of Novel Foods and Feeds (WP-SNFF) meetings. This includes research institutions, universities, Biosafety South Africa, the Department of Agriculture, Land Reform and Rural Development (DALRRD), the Department of Science and Innovation (DSI), and the Technology and Innovation Agency (TIA). Biosafety South Africa and the DSI/TIA units are promoting biosafety in South Africa, and are intimately involved in advancing regulation in genome editing and other NPBTs.

DSI indicated that the information would be most useful to the regulators in South Africa, in particular the Advisory Committee (AC) and the Executive Council (EC).

South African database on genome editing

Biosafety South Africa has again expressed an interest in developing a South African database on people who are working on genome editing, together with Dr D Oelofse, 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 from various sources (including OECD) as well as those GM crops with potential for commercialisation in South Africa.

Cassava

- [http://www.oecd.org/officialdocuments/displaydocument/?cote=env/jm/mono\(2014\)13&doclanguage=en](http://www.oecd.org/officialdocuments/displaydocument/?cote=env/jm/mono(2014)13&doclanguage=en)

Cotton

- <https://www.oecd.org/env/ehs/biotrack/46815918.pdf>

Maize/ Corn

- <https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/applicants/directive-94-08/biology-documents/zea-mays-l-maize-eng/1330985739405/1330985818367>
- [http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/5DCF28AD2F3779C4CA257D4E001819B9/\\$File/The%20Biology%20of%20Zea%20mays%20L.%20ssp%20mays%20\(maize%20or%20corn\).pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/5DCF28AD2F3779C4CA257D4E001819B9/$File/The%20Biology%20of%20Zea%20mays%20L.%20ssp%20mays%20(maize%20or%20corn).pdf)
- <https://www.oecd.org/env/ehs/biotrack/46815758.pdf>

Potato

- <https://www.oecd.org/env/ehs/biotrack/46815598.pdf>

Soybean

- <https://inspection.canada.ca/plant-varieties/plants-with-novel-traits/applicants/directive-94-08/biology->

- [documents/glycine-max-l-merr-/eng/1330975306785/1330975382668](https://www.oecd.org/env/ehs/biotrack/46815668.pdf)
 - <https://www.oecd.org/env/ehs/biotrack/46815668.pdf>
- Sugar Beet**
- <https://www.oecd.org/env/ehs/biotrack/46815688.pdf>
- Sugar Cane**
- [http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/5DCF28AD2F3779C4CA257D4E001819B9/\\$File/The%20Biology%20of%20the%20Sugarcane.pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/5DCF28AD2F3779C4CA257D4E001819B9/$File/The%20Biology%20of%20the%20Sugarcane.pdf)
- Sunflower**
- <https://www.oecd.org/env/ehs/biotrack/46815798.pdf>
- Wheat**
- [http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/5DCF28AD2F3779C4CA257D4E001819B9/\\$File/The%20Biology%20of%20Triticum%20aestivum%20L.%20\(bread%20wheat\).pdf](http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/5DCF28AD2F3779C4CA257D4E001819B9/$File/The%20Biology%20of%20Triticum%20aestivum%20L.%20(bread%20wheat).pdf)
 - <https://www.oecd.org/env/ehs/biotrack/46815608.pdf>

SPAIN

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

General information about activities with GMOs which have been approved in Spain as contained use or deliberate release into the environment and relevant reports are available from the Ministry for Ecological Transition Web Page: <https://www.miteco.gob.es/es/calidad-y-evaluacion-ambiental/temas/biotecnologia/organismos-modificados-geneticamente-omg-/>

a) Contained use activities

Since the last meeting in March 2020, forty-one (41) new facilities for different contained use activities have been notified in Spain and assessed by the National Biosafety Commission (21 BSL1; 19 BSL2 and only one BSL3).

96 different activities have been notified to be carried out in these facilities: 25 are classified as risk 1 (BSL 1); 61 as risk 2 (BSL2) and 10 as biological level of risk 3 activities (BSL3).

Some of the genetically modified organisms used during this period are bacteria (*E. coli*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Shigella flexneri*, *Salmonella*, *S. cerevisiae*, *C. necátor*, *Trypanosoma cruzi*, *Xylella fastidiosa*, *Salmonella enterica*, *Brucella melitensis* 16M, *Brucella melitensis* Rev1 and *M. tuberculosis*, etc.), and viruses (Moloney murine leukemia virus, African Swine Fever Virus, Chimpanzee Adenovirus Type Ox1, Betanodavirus), viral vectors (adenovirus, lentivirus, retrovirus, vaccinia), and many cell lines (human and murine lines).

There are genetically modified animals (lab mice, rats, *D. melanogaster*) and plants (strawberry, *Arabidopsis thaliana*), which are being used under physical confined conditions.

Twenty-one (21) research activities have been performed with SARS-CoV-2, MERS-CoV virus, vaccinia virus, vesicular stomatitis virus, human coronavirus 229E, cell lines, baculovirus, etc. in order to obtain vaccines against COVID-19.

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

b) Experimental deliberate release into the environment

From July 2018, sixteen (16) applications for deliberate release trials have been evaluated:

- Three (3) with plants: field trials with a genetically modified tobacco which is used as a biofactory.

- Thirteen (13) clinical trials in humans with different viruses (adeno-associated virus (AAV and AAV-2), gorilla adenovirus, lentiviral vector modified autologous T lymphocytes, Newcastle disease virus, herpes simplex virus type 1 (HSV-1), HAd5 oncolytic adenovirus,) or with genetically modified cells (mainly CAR-T human autologous T lymphocytes, other CAR-T cells) for the treatment of different diseases.

For detailed information:

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

c) Placing on the market

In 2019, the growing surface of Bt maize (MON10) in Spain was 98.151,58 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.

On the other hand, an article on the presence of teosinte in Europe has recently been published, in which the introgression of genes from maize varieties grown in the EU into teosinte plants, responsible, for example, for flowering has been observed or resistance to herbicides, which could have an impact on the persistence of teosinte in the environment. In this study, the results show that the adaptive introgression of wild-grown maize has triggered both a rapid adaptation to a new climate niche and the acquisition of herbicide resistance, thus promoting the establishment of an emerging noxious weed.

National Commission on Biosafety sent a report requested by the Spanish Competent Authority contributing with information on the following issues: 1) Suitability of teosinte and its progeny as a host plant for the agents responsible for the borer pest, 2) Suitability of teosinte and its progeny as a host plant for non-target lepidoptera; 3) Presence of the Cry1Ab protein in teosinte and its progeny in Spain; and 4) Expression levels of the Cry1Ab protein in teosinte and its progeny in Spain.

https://www.miteco.gob.es/es/calidad-y-evaluacion-ambiental/temas/biotecnologia/informe_cnb_teosinte_pnas_2020_tcm30-522343.pdf

For detailed information on facilities and activities performed in Spain with GMOs:

- <https://www.miteco.gob.es/es/calidad-y-evaluacion-ambiental/temas/biotecnologia/organismos-modificados-geneticamente-omg-notificaciones-y-autorizaciones/comercializacion.aspx>
- <https://www.miteco.gob.es/es/calidad-y-evaluacion-ambiental/temas/biotecnologia/organismos-modificados-geneticamente-omg-consejo-interministerial-de-ogms/superficie.aspx>
- <http://www.mapa.gob.es/es/estadistica/temas/estadisticas-agrarias/agricultura/esyrce/>

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

The Interministerial Council of GMOs depending on Ministry of Agriculture, Fisheries and Food is reviewing of the Spanish Royal Decree 178/2004, of 30 January, which establishes the legal regime of the contained use, deliberate release and commercialization of genetically modified organisms. The aim of this review is to introduce the provision included in the Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (Text with EEA relevance.)

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

The Ministry of Agriculture, Fisheries and Food has established a Working Group with the Autonomous Communities to develop a national program to control the deliberate release of GMOs for food and feed purposes. The program has been included in the Multiannual National Control Plan for the Food Chain.

4. Public engagement and outreach activities;

The Ministry of Agriculture, Fisheries and Food has included a new section on its web with information on NBTs, including a “Questions and answers” document to follow the developments, the legal framework and reports on this technologies.

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

2. Updates regarding international activities

The CNB uses the OECD consensus documents regularly mainly for the risk assessment of genetically modified plants.

3. Developments related to new breeding techniques (NBTs)

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

As work following the European Court of Justice ruling of 25th July 2018, National Commission on Biosafety (CNB) has delivered two reports:

- Report of CNB on the directed mutagenesis (“genome editing”), where finally concludes that EU GMO legislation needs to be improved to make it clear, evidence-based, enforceable, proportionate and flexible enough to deal with future advances in science and technology in this area. To achieve this, it was recommend reviewing the current GMO Directive to reflect current knowledge and scientific evidence, in particular on gene editing and established genetic modification techniques. This must be done in relation to other relevant legislation for food safety and environmental protection".
- Report of the CNB on Random *in vitro* mutagenesis in plant cell cultures, in February 2020, the French Conseil d'Etat asked the French government to reconsider the list of genetic modification techniques and derived products (plant varieties), which have been used conventionally and have a long safety record. Following this “reconsideration” analysis carried out, the French government has made a proposal to change its legislation on genetically modified organisms (GMOs) which was notified to the European Commission. This proposal led to the situation that plants regenerated from *in vitro* cultured cells that have been subjected to the application of physical or chemical mutagens would be, as requested by the French government from the European Commission, subjected to the provisions of the French legislation on GMOs. "Mutagenesis" is excluded from the scope of the GMO regulations in the 2001 Directive (Annex IB) and previous regulations. The 2012 EFSA opinion on ZFN3 and other targeted nucleases describes mutagenesis technologies without making a distinction, in terms of risks, depending on whether it is *in vivo* or *in vitro*. Compared with *in vivo* mutagenesis, *in vitro* mutagenesis treatment is more uniform, the ability to regenerate plants from one or a few cells is increased, there is a greater ease of segregation of chimeras when they are formed, the conditions are very controlled, and the costs of physical and chemical treatments are reduced (greater number of individuals per unit of area). Finally, the CNB considers that, in both types of mutagenesis, the main health risks would be toxicity and allergenicity problems. However, these techniques were used before 2001 and it has been scientifically proven that they do not pose risks to health or the environment.
(https://www.miteco.gob.es/es/calidad-y-evaluacion-ambiental/temas/biotecnologia/organismos-modificados-geneticamente-omg/-comision-nacional-bioseguridad/informes_cnb.aspx).

2. Any other information related to NBTs.

The Ministry of Agriculture, Fisheries and Food has included a new section on its web with information on NBTs, including a “Questions and answers” document to follow the developments, the legal framework and reports on this technologies.

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

SWITZERLAND

1. Biotechnology activities

• **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.^{9,10,11}

- **Approval of gene and cell therapy**

Since the 34th WG-HROB meeting, two new gene therapy has been authorised:

- Gentherapy product, m AVXS-101, Zolgensma, Behandlung von spinaler Muskulärer Atrophie
- Abecma with new active substances (NAS) Idecabtagene vicleucel (ide-cel), Immuntherapy product for patients suffering from Myeloma (MM; Plasmazellmyelom) VSV-ZEBOV

- **Approval of COVID-19 vaccine**

- Moderna mRNA vaccine against SARS-CoV-2
- Pfizer / BioNTech mRNA vaccine against SARS-CoV-2

- **Approval of gene and cell therapy**

In 2020, six clinical trials have been reported (compared to six in 2018).

- **GMO cultivation**

Since 2005 and until End of 2021, a transitional period (i.e., moratorium) for putting GMO into circulation for agricultural, horticultural or forestry purposes is in place. In November 2020, the Federal Council (government) proposed to continue the moratorium in the Gene technology Act¹² for four more years. This proposal is under public consultation until 25 of February..¹³

- **GMO Food and Feed**

No new authorization have been granted since 2015. Currently, there are 5 authorizations for GMO food and feed products:^{14,15}

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

However, there is no import of these authorized commodities.

- **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.¹⁶ According to Swiss regulation, announcement, risk assessment documents, field trials authorizations and reports regarding GMO are publicly available and may be submitted upon request.¹⁷

Three trials are currently running:¹⁸

- 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 tag¹⁹
- Genetically modified maize strains with improved resistance against phytopathogenic fungi is running from 2019 to 2023 (resistance against phytopathogenic: Lr34 from wheat) is

⁹ <https://www.bafu.admin.ch/bafu/en/home/topics/biotechnology/state/indicators.html>

¹⁰ <https://www.ecogen.admin.ch/public/#/dossiers>

¹¹ According to the Federal Coordination Centre for Biotechnology and Swiss biotech report 2020: [20200421-Swiss-Biotech-Report.pdf](#)

¹² [SR 814.91 - Federal Act of 21 March 2003 on Non-Human Gene Technology \(Gene Technology Act, GTA\) \(admin.ch\)](#)

¹³ <https://www.parlament.ch/en/ratsbetrieb/suche-curia-vista/geschaeft?AffairId=20194225>

¹⁴ <https://www.blv.admin.ch/dam/blv/fr/dokumente/lebensmittel-und-ernaehrung/rechts-und-vollzugsgrundlagen/gvo-bewilligungsliste.pdf.download.pdf/f-gvo-bewilligungsliste.pdf>

¹⁵ <https://www.blw.admin.ch/dam/blw/fr/dokumente/Nachhaltige%20Produktion/Pflanzliche%20Produktion/Getreide%20und%20Futtermittel/Zugelassene%20und%20tolerierete%20GVO%20als%20Futtermittel.pdf.download.pdf/GVO%20Futtermittel%202020%20fr.pdf>

¹⁶ www.protectedsite.ch

¹⁷ <https://www.bafu.admin.ch/bafu/en/home/themen/thema-biotechnologie/biotechnologie--daten--indikatoren-und-karten/biotechnologie--indikatoren/indikator-biotechnologie.pt.html/aHR0cHM6Ly93d3cuaW5kaWtdG9yZW4uYWRtaW4uY2gvUHViG/1jL0FlbURldGFpbD9pbmQ9QlQwMTgmbG5nPWVuJlNlYmo9Tg%3d%3d.html>

¹⁸ <https://www.agroscope.admin.ch/agroscope/en/home/topics/environment-resources/biosafety/gv-pflanzen/protectedsite/projects.html>

¹⁹ [B/CH/18/01 \(B18001\): Application to release genetically modified wheat strains with improved mildew resistance for experimental purposes \(admin.ch\)](#)

- Genetically modified barley strains with improved resistance against phytopathogenic fungi is running from 2019 to 2023.²⁰

Since the 34th WG-HROB meeting, two field trials on the protected came to an end, but a post-trial monitoring is now in place for at least two years.¹⁴

- Cisgenic Potatoes with Improved Late Blight Resistance
- Cisgenic Apple Trees with Improved Fire Blight Resistance
- genetically modified wheat strains with increased yield potential

2. Regulatory activities

New breeding techniques (*new techniques in biotechnology, genome editing*)

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),²¹ 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.²²

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

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

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

GMO monitoring

The presence of unauthorized GMO plants in the environment is monitored since 2011. The results show that GMO are present in the environment in low quantities.¹⁷ 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,²³ indicating that the GMO plants accidentally released into the environment originate from domestic transport of imported food and feed (adventitious presence threshold). As these GMO plants are not authorized, the competent authorities in the cantons are in charge of their elimination.

3. 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

²⁰ [B/CH/18/04 \(B18004\): Application to release genetically modified barley strains with improved resistance against phytopathogenic fungi for experimental purposes \(admin.ch\)](https://www.admin.ch/opc/en/classified-compilation/19996136/index.html)

²¹ <https://www.admin.ch/opc/en/classified-compilation/19996136/index.html>

²² <https://www.parlament.ch/en/ratsbetrieb/suche-curia-vista/geschaeft?AffairId=20194050>

²³ <https://www.blw.admin.ch/blw/fr/home/services/medienmitteilungen.msg-id-69124.html>

genetically modified seeds present in the soil. Since the 34th 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^{24,25}

4. **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.

5. **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/>

6. **Relevant Documents published by Switzerland:**

- 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.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.pdf](#)
- Current situation regarding research, and licensing of NBT products:
<https://www.bafu.admin.ch/dam/bafu/de/dokumente/biotechnologie/externe-studien-berichte/endbericht-semnar-gelinsky.pdf.download.pdf/endbericht-semnar-gelinsky.pdf>
- Technical report on NBT: https://www.bafu.admin.ch/dam/bafu/de/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
- 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

²⁴ [ig-gmo-2020-IG GMO technical report on gene drives.pdf](#)

²⁵ [IG GMO \(admin.ch\)](#)

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 trials of vaccines and other investigational medical products based on such vectors are regulated under contained use. This meant that the Adenovirus-based COVID-19 vaccine developed by the Oxford Vaccines group/AstraZeneca was trialled under the contained use regulations and not as a deliberate release. The regulatory process for the COVID-19 vaccine trial approval was thus much faster, as the duty holder classed this GMO vaccine as containment class level 1 (CL1), which the Competent Authorities (CAs) did not disagree with. This meant that if the medical trial facilities were already notified to the CA through a CL1 premises notification, further notification to the CAs was not necessary.

During 2020, the EU brought in regulation 2020/1043 which provided a derogation from the GMO requirements for clinical trials of investigational medical products for the treatment of COVID-19 that contain or consist of GMOs. This was intended to expedite such trials, particularly those carried out across more than one EU member state, especially since there are differences in how the GMO directives are implemented across the EU. Our incorporation of 'biological containment' as a regulatory criterion in the UK is an example of such a difference between Member States. However, the EU derogation 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.

Although the UK officially left the EU at the end of 2020, all the relevant EU directives and regulations are 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 is that organisms produced by GE or by other genetic technologies should not be regulated as GMOs if they could have been produced by traditional breeding methods. Leaving the EU provides an opportunity to consult on the implications of addressing this issue. We recognise there is a spectrum of opinions on these topics, and we are consulting to provide an opportunity for all views to be shared.

We began a 10-week consultation of the regulation of genetic technologies sought 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 will be published within 3 months of it closing.

Questions that we asked in the consultation were framed around the following:

- Do organisms produced by GE pose a similar, lesser or greater risk of harm to human health or the environment compared with their traditionally bred counterparts? Then we ask for evidence to support this response.

- What criteria should be used to determine whether an organism produced by GE or other genetic technologies could have been produced by traditional breeding or not? Again, we then ask the respondent to provide evidence to support this response.

The UK Government also 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.

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

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. To illustrate this there were 104 such notifications (covering both research, commercial activities and clinical trials) for the first 6 months of 2020 (9 of these were for COVID-19 work; and 6 of which were for clinical trials).

Ongoing Deliberate Release field trials

There are currently only three 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.
- 19/R52/01 Gm wheat trials- This wheat was genetically modified to produce increased iron levels in the endosperm tissue, to produce biofortified wheat grain. The deliberate release of this GMO investigates the effect of this under field conditions.

Completed and new deliberate release clinical trials

- SNEAS- streptococcus pneumoniae Nasopharyngeal Experimental challenge study of attenuated strains- 18/R51/01- This was a trial of an experimental human pneumococcal challenge model and was completed in 2019.
- *Salmonella typhi* bottlenecks study- 18/R48/01 – This clinical trial made use of an attenuated GM strain of *S. typhi* to test the bottleneck theory in a phase I trial. The trial completed in 2019.
- 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 has not started due to the current pandemic.

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>

3. GMO marketing applications

No marketing applications for GMOs have been received in 2020.

UNITED STATES

I. Developments related to implementation of national biosafety framework

A) 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.

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.

Developers can 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. On August 17, 2020, the exemptions and confirmation process replaced the preexisting “Am I Regulated?” (AIR) process (see below). Previous AIR responses indicating nonregulated status of organisms are still considered valid under the revised regulations for the particular requestor and specific plant(s).

Weblink for additional information: <https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/permits-notifications-petitions/confirmations/confirmation-process>

Regulatory Status Review (RSR). Under the revised regulations, developers have the option of requesting a permit and/or a regulatory status review 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 will be implemented for certain crops on April 5, 2021 and fully implemented on October 1, 2021.

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.federalregister.gov/documents/2020/05/18/2020-10638/movement-of-certain-genetically-engineered-organisms>

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 are due on February 26, 2021.

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

The following updates occurred under USDA-APHIS's legacy regulations at 7 CFR part 340.

Petitions for non-regulated status. Since March 2020, USDA-APHIS has made determinations of non-regulated status for four products. Determinations for non-regulated status were made for Simplot potato that has protection against late blight protection, low acrylamide potential, lowered reducing sugars, and reduced black spot (August 28, 2020); Pioneer maize with enhanced yield potential, and glufosinate-ammonium herbicide resistance (December 21, 2020); Westhoff A1-DFR petunias that produce orange flowers (January 12, 2021); and Monsanto cotton that is resistant to certain insects, primarily tarnished plant bugs (*Lygus* species) (January 19, 2021).

Currently there are seven products pending review: 1) Pioneer Insect Resistant and Herbicide Tolerant Corn, 2) Pioneer SPTA Maize (extension), 3) BASF Nematode-Protected Soybean, 4) Bayer 5 HT Maize, 5) SUNY ESF Blight Tolerant Chestnut, 6) Agrivida Phytase Corn, 7) 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. From October 1, 2019 through February 4, 2021, USDA-APHIS received 2,111 applications for import, interstate movement, and environmental release. Of those, USDA-APHIS issued 1,106 permits and acknowledged 534 notifications. In addition, 99 permit applications are pending and 159 were withdrawn, while 16 notification applications are pending, 194 were withdrawn, and 3 were denied.

Compliance and oversight. From October 1, 2019 through February 4, 2021, USDA-APHIS and its state partners completed 664 inspections to meet compliance and oversight goals for the regulation of field trials involving plants and organisms developed using genetic engineering. Since March 2020, USDA-APHIS has been conducting inspections virtually due to COVID-19 travel restrictions.

2020 USDA-APHIS BRS Stakeholder Meeting. On December 9, 2020, 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. 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>

B) 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 FFDC. Associated with this action was a 60-day public comment period. EPA’s proposed rule would allow these PIPs to be exempt under existing regulations in cases where they: 1) pose no greater risk than PIPs that EPA has already concluded meet safety requirements, and 2) could have otherwise been created through conventional breeding.

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

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 September 8, 2020 EPA published a draft proposal to improve lepidopteran resistance management strategies for pests of *Bacillus thuringiensis* (Bt) corn and cotton PIPs to prolong the durability these genetically modified crops. EPA has proposed improvements to resistance monitoring, actionable definitions for insect resistance to Bt PIPs, and enhanced mitigation measures for resistant pest populations. The draft proposal also includes more complex resistance management options for refuge size, refuge compliance, and a phase-down of at-risk single trait and pyramided PIP products. EPA did not take a position in its proposal on these complex options; rather, the Agency sought comment from stakeholder groups. On September 28, 2020, EPA held a webinar to present an overview of the proposal. The draft proposal is available in Docket# EPA-HQ-OPP-2019-0682.

Weblink for the webinar: <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*

- New PIP registration and tolerance exemption: Event GMB151 (Cry14Ab-1) in soybean for control of soybean cyst nematode. A seed increase/breeding registration and tolerance exemption were issued to BASF on June 11, 2020.
- First commercial use PIP product: Event MON 88702 (mCry51Aa2) in cotton for control of lygus and thrips. A commercial use registration for the stacked PIP product MON 88702 x MON 15985 x COT102

(mCry51Aa2 x Cry1Ac x Cry2Ab2 x Vip3Aa19) was issued to Bayer on May 10, 2020. Previous approvals of mCry51Aa2 were limited to seed increase/breeding.

- U.S. import PIP tolerance exemptions: Cry1Ab/Cry2Aj (PIP active ingredient) and G10evo-EPSPS (PIP inert ingredient/marker) in corn. Tolerance exemptions were finalized for these traits on January 15, 2021 in response to petitions from Hangzhou Ruifeng Biosciences Co., Ltd. of Hangzhou, China.

❖ **Regulatory Update for genetically engineered mosquitoes**

In April 2020, EPA granted a two-year Experimental Use Permit for a genetically engineered *Ae. aegypti* mosquito to test for its efficacy to suppress *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 Texas. 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 past fiscal year (FY20), October 1, 2019 to September 30, 2020, the U.S. EPA/OPPT received 10 Microbial Commercial Activity Notices (MCANs) consisting of 29 genetically engineered microbial strains for closed system fermentation. Some of these MCANs were for *Saccharomyces cerevisiae*, and one was for *Escherichia coli*. The other microorganism identities were claimed as confidential by the developers. U.S. EPA/OPPT received two TSCA Experimental Release Applications (TERAs) in FY20. One was for an Alphaproteobacteria with a trace marker, and the other was for open pond testing of multiple genetically engineered strains of a micro-algae species.

❖ **Micro-algae Consensus Document**

U.S. EPA/OPPT and Canada (New Substances Program – Environment and Climate Change Canada and Health Canada) as co-leads have evaluated the comments received by Working Party for the Harmonisation of Regulatory Oversight in Biotechnology's (WP-HROB) Micro-Organism Sub-Working Group members from Canada, The Netherlands, Germany, Australia, and Business at OECD (BIAC) on the Draft Operational Plan and the OECD Consensus Document on Micro-algae.

Earlier the U.S. EPA/OPPT developed extensive text in the document on *Chlorella sorokiniana*, which is being called the “*Chlorella* chapter”. The *Chlorella* chapter is to serve as a model for the drafting of additional chapters on other micro-algae species by other member countries. BIAC submitted a write-up on cyanobacteria for incorporation into the document. The OECD Working Party on Biotechnology, Nanotechnology and Converging Technologies was contacted regarding their availability to contribute to the sustainability and commercialization sections of the micro-algae document. Based upon the comments received on the Draft Operational Plan and the Draft OECD Consensus Document on Micro-algae in late summer of 2020, both documents have been revised for discussion at the 35th WP-HROB Meeting in March 2021.

❖ **Algae Supplement Document**

U.S. EPA/OPPT has finalized the “Algae Supplement” to the “Points to Consider in the Preparation of TSCA Biotechnology Submissions for Microorganisms,” which is guidance to submitters of Microbial Commercial Activity Notices (MCANs) or TSCA Experimental Release Applications (TERAs) for genetically engineered micro-algae. U.S. EPA/OPPT posted the “Algae Supplement” was posted on its website under Filing a Biotechnology Submission, along with the “Agency Response to Comments” from a 2016 workshop, and “Public Meeting and Opportunity for Public Comment on EPA's Draft Algae Guidance for the Preparation of TSCA Biotechnology Submissions.”

Weblink for the “Algae Supplement” document: <https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/guidance-documents-filing-biotechnology-submission>

II. Updates regarding 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 23-24, 2020. The TTWG also conducts quarterly calls throughout the year.

III. Developments in New Breeding Techniques (NBT)

Updates for the United States Department of Agriculture (USDA)

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>

VIET NAM

1. Regulation framework

In 2020, Viet Nam Government and its authority ministries (Ministry of Natural Resources and Environment, Ministry of Agriculture and Rural Development) have amended and supplemented the government Decrees 69/2010/ND-CP on the biosafety of GMOs and GMO products. This included:

- The clarification of definition of transformation events, include single and stack transformation events;
- Adding information requirements for stack event in the risk assessment report;
- Clarifying the contents of field trials for environment risk assessment of GMO;
- Revising the responsibility of Ministry of Agriculture and Rural Development for the field trials on environment risk assessment of GMO, including the accreditation of field trial conductor; field trial certification, Scientific Council for field trials and certification of field trial results;
- Revising the responsibility of Ministry of Natural Resources and Environment for the *Biosafety Certification* on biodiversity and environment;
- Revising the responsibility of Ministry of Agriculture and Rural Development for the *Food and Feed safety Certification* of GMO products.

2. Commercial approval for GM food and feed

From 2018 to 2020, Viet Nam approved 27 events of GM maize, soybean, cotton, rapeseed, sugar beet, alfalfa for food and feed as follows:

Event	Approval date	Crop	Trade name	Traits	Applicant
DP- 305423-01	25/10/2018	Soybean	Plennish™	oleic acid enhancement	Pioneer hi-breed VN
DAS-59122-7	25/10/2018	Maize	Herculex RW	IR	Pioneer hi-breed VN
3272	25/02/2019	Maize	-	AMY797E	Syngenta VN
SYHT0H2	25/02/2019	Soybean	Enogen®	HT	Syngenta VN
CV 127	25/02/2019	Soybean	Cultivance®	HT	BASF VN
J101	20/9/2019	Alfalfa	Roundup ready Alfalfa	HT	Dekalb VN
J163	20/9/2019	Alfalfa	Roundup ready Alfalfa	HT	Syngenta VN
DAS-68416-4	20/9/2019	Soybean	Enlist™	HT	Rohm and Haas
DAS-44406-6	20/9/2019	Soybean	Enlist E3	HT	Rohm and Haas
DAS-40278-9	20/9/2019	Maize	Enlist™	HT	Rohm and Haas
MS8	21/01/2020	Alfalfa	-	HT	Bayer VN
MON 88913	21/01/2020	Cotton	Roundup Ready® Flex	HT	Dekalb VN
MON 15985	21/01/2020	Cotton	BollGard II	IR	Dekalb VN
RT73	19/02/2020	Rapeseed	-	HT	Dekalb VN
MON 88302	19/02/2020	Rapeseed	Truflex roundup Ready	HT	Dekalb VN
H7-1	19/02/2020	Sugar beet	Roundup ready	HT	Dekalb VN
FG72	19/02/2020	Soybean	Balance™ GT	HT	Bayer VN
RF3	19/02/2020	Rapeseed	-	HT	Bayer VN
MON 87751	15/3/2020	Soybean	Intacta	IR	Dekalb VN
COT102	15/7/2020	Cotton	VIPCOT Cotton	IR	Syngenta VN
GHB 614	15/7/2020	Cotton	GlyTol	HT	Bayer VN
T304-40	14/9/2020	Cotton	LibertyLink ^R	IR&HT	Bayer VN
MON 87411	14/9/2020	Mãie	SmartStax Pro	IR&HT	Dekalb VN
LL Cotton 25	14/9/2020	Cotton	Liberty Link	HT	Bayer VN
KK179	16/12/2020	Alfalfa	HarvXtra™ Reduced Lignin Alfalfa	Lignin content reduction	Dekalb VN
MON 88701	16/12/2020	Cotton	Dicamba & glufosinate tolerant cotton	HT	Bayer VN
GHB 119	16/12/2020	Cotton	-	HT	Bayer VN

Notes: - Trade name not registered

Details of information on GMO regulations and approval status can be seen at the website <http://antoansinhhoc.vn/>.

3. GM Data Bank

Relevant information about GMOs approved in Viet Nam are being registered at the BCH, FAO GM FOODS PLATFORM and OECD BIOTRACK.

4. New Breeding Techniques

The Viet Nam Government funds several research projects related to NBTs to evaluate the application of genome editing technique for creating new rice and cassava variety resistance to plant pathogen. Four of such projects are already approved as contained use under laboratory containment facilities. Viet Nam, at the moment, does not have guidelines on regulation of products derived from New Plant Breeding Techniques.

EUROPEAN COMMISSION

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

i. 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 (https://webgate.ec.europa.eu/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 (http://gmoinfo.jrc.ec.europa.eu/gmc_browse.aspx).

Since the last WG-HROB meeting, the European Commission has authorised 32 GM food and feed (including 26 sub-combinations) and has renewed 3 authorisations:

New authorisations:

- soybean MON 87708 x MON 89788 x A5547-127
- soybean MON 87751 x MON 87701 x MON 87708 x MON 89788
- soybean SYHT0H2
- maize MON 87427 x MON 89034 x MIR162 x NK603 (and 6 sub-combinations)
- maize MON 87427 x MON 87460 x MON 89034 x MIR162 x NK603 (and 14 sub-combinations)
- maize MON 87427 x MON 89034 x MIR162 x MON 87411 (and 6 sub-combinations)

Renewals:

- maize MIR162
- maize MON 88017
- maize MON 89034

More authorisations are in the pipeline.

ii. Risk assessments

Since March 2020, the European Food Safety Authority (EFSA) has adopted 11 new scientific opinions (10 published), of which 4 renewal applications:

- EFSA-GMO-NL-2015-126 (soybean MON 87705 x MON 87708 x MON 89788)
- EFSA-GMO-NL-2015-127 (maize 1507 x MIR162 x MON 810 x NK603 and its sub-combinations)
- EFSA-GMO-NL-2016-132 (soybean DAS-81419-2 x DAS-44406-6)
- EFSA-GMO-BE-2016-138 (*Brassica napus* MS11)
- EFSA-GMO-NL-2017-139 (maize MON 87427 x MON 87460 x MON 89034 x 1507 x MON 87411 x 59122 and its sub-combinations)
- EFSA-GMO-DE-2017-142 (maize MZIR098)
- EFSA-GMO-NL-2018-153 (GMB151 soybean)- publication in progress
- RX-002 (oilseed rape GT73)
- RX-014 (maize MON 88017)
- RX-016 (maize Bt-11)
- RX-017 (maize MON 88017 x MON 810)

EFSA also published a statement complementing its scientific opinion on oilseed rape MS8 x RF3 x GT73 and sub-combinations not authorised previously (i.e. MS8 x GT73 and RF3 x GT73).

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

The Transparency Regulation²⁶ aiming at more transparency, more reliability and independence of studies, better governance and more effective risk communication, will come into force on 27 March 2021. The main elements of the Regulation aim at:

- **Ensuring more transparency**: Citizens will have automatic access to all studies and information submitted by industry in the risk assessment process. Stakeholders and the general public will also be consulted on submitted studies. At the same time, the Regulation will guarantee confidentiality, in duly justified circumstances, by setting out the type of information that may be considered significantly harmful for commercial interests and therefore cannot be disclosed
- **Increasing the independence of studies**: The European Food Safety Authority will be notified of all commissioned studies to guarantee that companies applying for authorisations submit all relevant information and do not hold back unfavourable studies. The Authority will also provide general advice to applicants, in particular SMEs, prior to the submission of the dossier. Commission may ask the Authority to commission additional studies for verification purposes and may perform fact-finding missions to verify the compliance of laboratories/studies with standards
- **Strengthening the governance and the scientific cooperation**: Member States, civil society and European Parliament will be involved in the governance of the Authority by being duly represented in its Management Board. Member States will foster the Authority's scientific capacity and engage the best independent experts into its work
- **Developing comprehensive risk communication**: A general plan for risk communication will be adopted and will ensure a coherent risk communication strategy throughout the risk analysis process, combined with open dialogue amongst all interested parties.

3. **Risk management measures**

Since the previous meeting, EFSA assessed the 2018 post-market environmental monitoring report on the cultivation of the Cry1Ab-expressing maize event MON 810. EFSA's statement on this report is available at <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2020.6245>

4. **Public engagement and outreach activities**

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

EFSA has published two technical reports:

- technical report “Scientific advice on the Testbiotech's requests for internal review of Commission Implementing Decisions (EU) No 2019/2083 and 2019/2084 on soybean MON 89788 and soybean A2704-12 (applications EFSA-GMO-RX-011 and EFSA-GMO-RX-009)”, available at <https://doi.org/10.2903/sp.efsa.2020.EN-1805>
- technical report “Assessment of the outcomes of the project “Risk Assessment of Genetically Engineered Organisms in the EU and Switzerland (RAGES)”, available at <https://www.efsa.europa.eu/en/supporting/pub/en-1890>

²⁶ Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC (OJ L 231, 6.9.2019, p. 1–28)

2. Developments related to new breeding techniques (NBTs)

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

In November 2019, the Council of the European Union requested²⁷ 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”. For this study, NGTs are defined as techniques capable to change the genetic material of an organism and that have emerged or have been developed since 2001, when the existing GMO legislation was adopted. The study will deal with:

- A state-of-play on the implementation and enforcement of the GMO legislation, as regards NGTs, based on 1) contributions from targeted consultations of the Member States and stakeholders; 2) work of the European Union Reference Laboratory, together with the European Network of GMO Laboratories, on the detection of products obtained by new mutagenesis techniques.
- Information on the status and use of NGTs in plants, animals and micro-organisms for agri-food, industrial and pharmaceutical applications.
- An overview on the risk assessment of plants developed through new genomic techniques, prepared by the European Food Safety Authority (EFSA), based on its own previous and ongoing work and on work carried out at national level.
- An overview of current and future scientific and technological developments in new genomic techniques as well as of new products that are, or are expected to be marketed, prepared by DG Joint Research Centre (JRC).

In addition, EFSA has published four scientific opinions and further work on synthetic biology is ongoing:

- 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>
- Scientific opinion on the adequacy and sufficiency evaluation of existing EFSA guidelines for the molecular characterisation, environmental risk assessment and post-market environmental monitoring of genetically modified insects containing engineered gene drives, available at <https://efsa.onlinelibrary.wiley.com/doi/10.2903/j.efsa.2020.6297>
- 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>

2. Specific cases of application, assessment and decision

One application using CRIPR-Cas9 for targeted insertion was submitted to the EU and that the application is currently under validation before the risk assessment.

²⁷ 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)

BIAC (Business at OECD)

1. Developments related to biosafety activities

CropLife International publishes recommendations to modernize the regulation of GM crops

CropLife International recently published seven papers in a special issue of the *Journal of Regulatory Science* [2021: Vol 9, No. 1] detailing recommendations to modernize the regulation of GM crops:

1. [Recommendations for Science-Based Safety Assessment of Genetically Modified \(GM\) Plants for Food and Feed Uses](#)
2. [Core and Supplementary Studies to Assess the Safety of Genetically Modified \(GM\) Plants Used for Food and Feed](#)
3. [Allergy Risk Assessment for Newly Expressed Proteins \(NEPs\) in Genetically Modified \(GM\) Plants](#)
4. [Toxicological Assessment of Newly Expressed Proteins \(NEPs\) in Genetically Modified \(GM\) Plants](#)
5. [Streamlining Data Requirements for the Environmental Risk Assessment of Genetically Modified \(GM\) Crops for Cultivation Approvals](#)
6. [Data Transportability for Studies Performed to Support an Environmental Risk Assessment for Genetically Modified \(GM\) Crops](#)
7. [Stacked Trait Products Are As Safe As Non-Genetically Modified \(GM\) Products Developed By Conventional Breeding Practices](#)

The publications include recommendations for food/feed assessment, environmental risk assessment and assessment of stacked trait products. They represent the work of over 50 scientists from the private sector to build alignment and develop recommendations for a risk-based safety assessment of GM crops incorporating our familiarity and experience with the development, cultivation and regulation of these crops over the last 25+ years. We believe that it is now time to re-examine how GM crops are regulated and reviewed by incorporating these learnings, experience, and knowledge into the regulatory process to enable further innovation.

Global Communications Resources on GMOs

CropLife International has also developed new resources on its website, with a new page dedicated to information on regulatory harmonization: [Regulatory Harmonization | CropLife International](#). This page provides access to a range of information and resources, including position papers, factsheets and infographics related to the papers listed above.

Over the last year the GMO Answers website (www.gmoanswers.com) has been updated with more global resources on GMOs. GMO Answers resources in 11 languages were added to the site, including infographics and articles. The translated resources can be found at [Translated Content | GMO Answers](#).

In celebration of 2021 marking 25 years of GM crop cultivation, CropLife International launched a Biotech #FoodHeroes program that spotlighted individuals who have worked to advance the adoption and acceptance of plant biotechnology worldwide. The Biotech #FoodHeroes can be found at [Your Biotech #FoodHeroes | CropLife International](#).

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 the Global Industry Coalition's (GIC) engagement in the implementation negotiations of the Convention on Biological Diversity, and its subsidiary agreements, the Cartagena Protocol on Biosafety and its Supplementary Protocol on Liability and Redress, and the Nagoya Protocol on Access and Benefit-sharing. The GIC receives input and direction from trade associations and companies from all over the world engaged in a variety of industrial sectors such as plant science, seeds, agricultural biotechnology, food production, animal agriculture, human and animal health care, and the environment.

The GIC's main focus of work is on the implementation issues of relevance to its members, including those relating to synthetic biology, environmental risk assessment, unintentional transboundary movements of LMOs, digital sequence information within the context of access and benefit-sharing, and the role of socio-economic considerations in decision-making. Since 2019 the GIC has also focused on the negotiations on the Post-2020 Global Biodiversity Framework (GBF) and has established a leadership role in coordinating input from the plant science industry into the GBF negotiations. The GIC remains an engaged and strong contributor to this work program, responding to all CBD Secretariat submission requests and participating in all intersessional meetings, expert groups, and liaison groups. CropLife International will continue to advocate for a clear recognition of the important role of scientific and technological innovations towards the transformative ambitions of the global biodiversity framework.

The GIC is also closely coordinating with the International Chamber of Commerce (ICC), which continues to closely monitor the ongoing discussions on digital sequence information (DSI) in the context of the CBD and the Nagoya Protocol. The ICC has prepared a submission on the concept of digital sequence information on genetic resources and the benefit sharing arrangements from commercial and non-commercial use of digital sequence information, and has recently issued an overall policy position on ABS "[Towards a New Implementation Strategy for Access and Benefit Sharing](#)". The ICC also participated in the second Ad Hoc Technical Expert Group on DSI and continues to engage directly in the discussions, including in conversations with OECD members.

The GIC encourages Parties and observers to take an active role in the intersessional meetings leading up to the 2021 Biodiversity Convention to ensure the ongoing discussions on implementation of the agreements are informed by a broad perspective of stakeholders. Our efforts are coordinated with other business sector groups, such as Business for Nature and One Planet Business for Biodiversity to ensure that the business sector contributes to achieving the goals of the Post-2020 Global Biodiversity Framework. Progress made in these venues will help ensure that the transboundary movement of LMOs continues without adverse impacts on biological diversity, while ensuring uninterrupted international trade of agricultural commodities and access for farmers to sustainable and innovative seed products. CropLife International and members of the GIC and plant biotech industry will continue to participate in the intersessional meetings in the lead up to the 2021 Biodiversity Convention, supporting a large global delegation to this meeting to provide further support for positive and productive negotiation outcomes.

3. Developments related to new breeding techniques (NBTs)

Industry Recognizes Progress Related to Plant Breeding Innovation

The global seed industry (represented through the International Seed Federation and CropLife International) maintains their 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 earlier plant breeding methods. Further, we encourage processes used to determine whether products fall in or out of scope of genetically modified organism (GMO) regulations to be predictable and timely and consider existing regulatory mechanisms for improved plant varieties (such as variety registration and national seed laws). The adoption of common approaches across countries can be facilitated through alignment of definitions, standardization of information requirements in support of a market status determination, adoption of appropriate predictable and efficient assessment timelines and recognition of other countries' determinations on regulatory status. These common approaches are essential to maintain a functional trading system that facilitates food security.

Surveying recent R&D developments, ISF and CLI recommend specific attention be paid by governments to the full range of applications of genome editing tools. The tools are not only very important for the improvement of specific traits and characteristics but also for the acceleration of breeding programs. For example, editing can be used to guide genetic recombination and facilitate efficient development of hybrid crop seeds. Further, applications like base-editing continue to be refined and are expected to become broadly applied. The seed industry also recognizes ongoing challenges related to the availability of genomic information and tools for minor crops, and value in ongoing efforts to address this paucity.

The seed industry recognizes the continued development and finalization of policies around genome edited varieties in Nigeria and Japan, and ongoing stakeholder consultation processes in India, Singapore, the Philippines, Europe, Canada, the United States, the United Kingdom, Kenya, and many other countries. We support and encourage continued government-to-government dialogue during policy development to enable aligned definitions and regulatory processes.

The seed industry also recognizes the importance of information sharing around plant breeding tools, both at the international and national levels. We support initiatives for sharing useful and 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 provide information that is not arbitrarily discriminatory toward certain plant breeding approaches versus others.

Lastly, we recognize the increasing global interest in the sustainability and resilience of the food system, and that this has been amplified by the COVID-19 pandemic. We look forward to working with governments and other stakeholders to showcase the significant, evidence-based, and scale neutral effects that plant breeding has on sustainable food systems – effects that the use of plant breeding innovations have the potential to greatly amplify.

Global Communications Resources Genome Editing

This past year, CropLife International and the American Seed Trade Association launched *Repairing the Root of the Problem*, the fourth in a series of videos that looks at public sector research leveraging genome editing. This new video features the research of the Innovative Genomics Institute at the University of California at

Berkeley to reduce the cyanide content in undercooked cassava to improve food safety and the health of rural African populations. The video can be found online at [Repairing the Root of the Problem - YouTube](#).

Further, in February of this year a broad group of Canadian agricultural stakeholders from across the value chain launched a public transparency and communication initiative called [Nature Nurtured](#) (microsite and social media presence) which endeavours to make the science of genome editing accessible to the public and highlight the safety, benefits and applications of genome editing in plant agriculture.

AFSI (Agriculture and Food Systems Institute)

1. Developments related to biosafety activities

Public Engagement and Outreach

Online Training on Safety Assessment of Foods and Feeds Derived from Genetically Engineered (GE) Plants for Indonesian Scientists

AFSI hosted [Phase III](#) of the multi-phased training program on safety assessment of foods and feeds derived from GE plants for Indonesian scientists virtually in 2020 including training on evaluation of stacked traits. The multi-phase program began in 2017 and was supported by a grant from the USDA Emerging Markets Program:

- Phase I was conducted in Bogor, Indonesia in 2017 on concepts in GE food and feed safety assessment in the form of lectures, case studies and exercises.
- This was followed by Phase II in 2017 in the United States comprising of tours of a facility conducting animal feeding studies, laboratory demonstrations, and in-depth study of toxicology reports.
- Phase III was conducted online due to travel restrictions resulting from the pandemic. Phase III was designed as an interactive online training course during which participants reviewed the concepts covered in earlier phases. In addition, modules on stacked events regulation were offered. This self-paced course was offered with ten video-based modules followed by a combination of graded assignments and self-assessments. The program concluded with an online session in December 2020 during which 22 participants who are members of the Food and Feed Safety Technical Teams from Indonesian National Agency of Drug and Food Control, BPOM and Indonesian Center for Agricultural Biotechnology and Genetic Resources Research and Development, ICABIOGRAD, interacted with international experts and AFSI staff who served as faculty during the training.

eLearning

AFSI maintains a series of e-learning modules that have been developed to provide baseline understanding of biosafety considerations relevant to the use of GE crop plants in food and in the environment

(<https://foodsystems.org/resources/elearning/>). In light of the global pandemic and associated travel restrictions, these resources are increasingly recognized as a critical component for expansion and development of capacity building programs. AFSI is in the process of releasing three new eLearning modules related to GE crops:

- *Environmental Risk Assessment of Non-Target Organisms for GE Crops* presents when, why, and how environmental risk assessments for GE crops are informed by assessments and testing of non-target organisms (NTOs). The course presents what is an NTO, the important role of problem formulation in identifying what needs to be protected, the development of testable risk hypotheses, and the selection of NTOs and surrogate species for testing. Upon completing this course, students should have a better understanding of the importance of carefully designed NTO testing to inform the regulatory risk assessment of GE crops. This course will be released in April 2021.
- With the growing importance of gene editing and other new technologies, together with advances in understanding of genetic variability in crops, the course on *Genetic Variability in Crops* explains how genetic variability associated with plant breeding using novel technologies can be considered in the context of natural variability and the variability associated with conventional breeding to rationalize regulatory requirements and the collection of data around “off target” mutations. This course is in the final production stage. This course will be released in April 2021
- *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. This course is under development.

AFSI is in the process of developing a series of eLearning modules addressing animal biotechnology that we anticipate being available this fall. This will include an introductory module on the history and use of genetic diversity in animals. Additional modules will focus on problem formulation related to risk assessment for livestock intended for human consumption, as well as GE animals intended to be released into the environment.

AFSI is in the process of developing a companion set of modules that will similarly address the technical basis needed to understand microbial biotechnology in food production, as well as problem formulation for the use of GE microorganisms in foods that will build upon the previous webinar we have hosted for microbial biotechnology

Relevant publications:

Teem, JL, L. Alphey, S. Descamps, MP Edgington, O. Edwards, N. Gemmill, T. Harvey-Samuel, RL Melnick, KP Oh, AJ Piaggio, JR Saah, D Schill, P Thomas, T Smith, A Roberts Andrew (2020), Genetic Biocontrol for Invasive Species. *Frontiers in Bioengineering and Biotechnology*, 8. 452
<https://www.frontiersin.org/article/10.3389/fbioe.2020.00452>

Roberts A, CJ Boeckman, M Mühl, J Romeis, JL Teem, FH Valicente, JK Brown, MG Edwards, SL Levine, RL Melnick, TB Rodrigues, AM Vélez, X Zhou, RL Hellmich (2020), Sublethal Endpoints in Non-target Organism Testing for Insect-Active GE Crops. *Frontiers in Bioengineering and Biotechnology*. 9, 556. doi: 10.3389/fbioe.2020.00556.

2. Updates regarding international 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 recognizes the similarities among the respective national guidelines as all are based on Codex and agreed to develop a mechanism to harmonize the process for safety assessment. To this end a guidance document that describes a consensus approach to the safety assessment of foods derived from GE crops for application across the participating countries has been drafted. The document is being developed progressively with multiple rounds of discussion. The next steps will involve discussion and a potential plan for

the adoption and operationalization of the regional guidance. Once travel restrictions ease, AFSI will also begin planning for in-person training opportunities for the EWG and engagement with other stakeholders in the four countries.

3. Developments related to new breeding techniques (NBTs)

AFSI is preparing to organize online and in-person activities on gene editing for Korean scientists, regulators, and academics. This series of activities that will begin in March of 2021 is intended to bring together Korean stakeholders to engage in sessions centered around the technology of gene editing and the regulatory landscape for the products of gene editing. We envision that the workshops will also improve dialogue between Korean government officials, scientists and other stakeholders and enable effective communication on issues related to new plant breeding technologies.

4. Additional Information

Crop Composition Database

The Agriculture & Food Systems Institute's [Crop Composition Database](#) (CCDB) is a curated, open access resource that provides compositional data on the natural variability in nutrients, anti-nutrients, and secondary metabolites of some conventionally bred crop species that form the world's food and feed supply. The data can be applied to improve overall knowledge of human nutrition, inform the development of diets that promote the healthy growth of livestock, and improve global datasets related to food security and nutrition modelling.

[Version 8.0 of the CCDB](#) was released on October 14, 2020 and includes all data from the previous version, with significant changes to the database platform and the data import process. Sugar beet became the 10th crop, the compositional data for which was added to the new version. In addition to an entirely new website, the user experience was optimized with new data visualization capabilities.

Compositional data for brown rice, received from the National Institute of Agricultural Sciences, Rural Development Administration, South Korea and for sugarcane from Sugarcane Research Centre (CTC), Brazil will be included in the next version of CCDB expected to be released in March-April 2021. Data for new crops including strawberry, cassava and cowpea are in the pipeline.