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Developments in Delegations on the Safety Assessment of Novel Foods and Feeds, April 2020 – March 2021

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of Novel Foods and Feeds, April 2020 – March 2021**

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ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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

- [No. 1, Consensus Document on Key Nutrients and Key Toxicants in Low Erucic Acid Rapeseed (Canola) (2001) – ***REPLACED with revised consensus document No. 24 (2011)***]
- [No. 2, Consensus Document on Compositional Considerations for New Varieties of Soybean: Key Food and Feed Nutrients and Anti-nutrients (2001) – ***REPLACED with revised consensus document No. 25 (2012)***]
- No. 3, Consensus Document on Compositional Considerations for New Varieties of Sugar Beet: Key Food and Feed Nutrients and Anti-nutrients (2002)
- No. 4, Consensus Document on Compositional Considerations for New Varieties of Potatoes: Key Food and Feed Nutrients, Anti-nutrients and Toxicants (2002) – ***REPLACED with revised consensus document No. 33 (2020)***]
- No. 5, Report of the OECD Workshop on the Nutritional Assessment of Novel Foods and Feeds, Ottawa, Canada, February 2001 (2002)
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- No. 17, Consensus Document on Compositional Considerations for New Varieties of Tomato: Key Food and Feed Nutrients, Anti-nutrients, Toxicants and Allergens (2008)
- No. 18, Consensus Document on Compositional Considerations for New Varieties of Cassava (Manihot esculenta Crantz): Key Food and Feed Nutrients, Anti-nutrients, Toxicants and Allergens (2009)
- No. 19, Consensus Document on Compositional Considerations for New Varieties of Grain Sorghum [Sorghum bicolor (L.) Moench]: Key Food and Feed Nutrients and Anti-nutrients (2010)
- No. 20, Consensus Document on Compositional Considerations for New Varieties of Sweet Potato [Ipomoea batatas (L.) Lam.]: Key Food and Feed Nutrients, Anti-nutrients, Toxicants and Allergens (2010)

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- No. 21, Consensus Document on Compositional Considerations for New Varieties of Papaya (*Carica papaya* L.): Key Food and Feed Nutrients, Anti-nutrients, Toxicants and Allergens (2010)
- No. 22, Consensus Document on Molecular Characterisation of Plants Derived from Modern Biotechnology (2010)
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- No. 24, Revised Consensus Document on Compositional Considerations for New Varieties of Low Erucic Acid Rapeseed (Canola): Key Food and Feed Nutrients, Anti-nutrients and Toxicants (2011)
- No. 25, Revised Consensus Document on Compositional Considerations for New Varieties of Soybean [*Glycine max* (L.) Merr.]: Key Food and Feed Nutrients, Anti-nutrients, Toxicants and Allergens (2012)
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- No. 30, Consensus Document on Compositional Considerations for New Varieties of Cowpea (*Vigna unguiculata*): Key Food and Feed Nutrients, Anti-nutrients and Other Constituents (2018)
- No. 31, Consensus Document on Compositional Considerations for New Cultivars of Apple (*Malus × domestica* Borkh.): Key Food and Feed Nutrients, Allergens, Toxicants and Other Metabolites (2019)
- No.32, Developments in Delegations on the Safety Assessment of Novel Foods and Feeds, April 2019 - March 2020 (2020)
- No.33, Revised Consensus Document on Compositional Considerations for New Varieties of Potato (*Solanum tuberosum*): Key Food and Feed Nutrients, Toxicants, Allergens, Anti-nutrients and Other Plant Metabolites (2020)

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 groups 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 groups 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 Novel Foods and Feeds publications, consult the OECD's World Wide Web site
[\(www.oecd.org/env/ehs/biotrack/\)](http://www.oecd.org/env/ehs/biotrack/)

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FOREWORD

The Working Party for the Safety of Novel Foods and Feeds (WP-SNFF) is a subsidiary body of the Chemicals and Biotechnology Committee of the OECD.

The WP-SNFF aims to assist countries in evaluating the potential risks of novel foods and feeds derived from genetically-engineered organisms, foster communication and mutual understanding of relevant regulations in countries, and facilitate harmonisation in risk/safety assessment of products from modern biotechnology. This programme encourages information sharing, promotes harmonised practices and contributes to prevent duplication of efforts among countries, while consolidating high food and feed safety standards. The WP-SNFF's activities and outputs are complementary to those of the Working Party on the Harmonisation of Regulatory Oversight in Biotechnology, which deals with environmental safety (biosafety) of genetically-engineered organisms.

The WP-SNFF main outputs are the science-based *consensus documents* on compositional considerations, which are mutually acceptable among member countries and partners. These practical tools contain information for use during the regulatory safety assessment of a particular food/feed product. Already covering 22 different crop species, the consensus documents provide key elements on the nutrients, anti-nutrients or toxicants of the considered product, information of its use as a food/feed and other relevant information. Additional guidance documents are also published by the WP-SNFF, available together with the consensus documents at www.oecd.org/env/ehs/biotrack/.

Of different content, this information document compiles elements provided by delegations on the occasion of the 28th WP-SNFF meeting (3-5 March 2021). It aims at summarising relevant information on activities related to the safety assessment of novel foods and feeds 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-SNFF 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 THE SAFETY ASSESSMENT OF NOVEL FOODS AND FEEDS, 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 trials

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> ppm		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).
- the 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. GM food regulation in Australia

Food Standards Australia New Zealand (FSANZ; www.foodstandards.gov.au) is an Australian Government agency responsible for developing food standards for Australia and New Zealand.

GM foods are regulated under Standard 1.5.2 – Food produced using Gene Technology of the *Australia New Zealand Food Standards Code* (the Code), which is a joint standard with New Zealand. Approved GM foods are listed in Schedule 26 of the Code. The approvals listed in Schedule 26 apply in both Australia and New Zealand. To obtain a GM food approval, an application must be lodged with FSANZ seeking an amendment to Schedule 26 of Code to include a new food.

- Standard 1.5.2 is available here: <https://www.legislation.gov.au/Details/F2018C00169>.
- Schedule 26 is available here: <https://www.legislation.gov.au/Details/F2021C00093>.

2. GM food assessments and approvals in Australia

A full list of the GM foods that have been assessed by FSANZ, as well as links to relevant assessment reports, are available from the FSANZ website at

<https://www.foodstandards.gov.au/consumer/gmfood/applications/Pages/default.aspx>

Recent assessments undertaken by FSANZ include:

Application	Current Status
<i>Foods derived from fermentation of a GM microorganism:</i>	
Soy leghaemoglobin in meat analogue products (A1186)	Approved
<i>GM plant foods:</i>	
Food derived from herbicide-tolerant corn line MON87429 (A1192)	Approved
Food derived from nematode-protected and herbicide-tolerant soybean line GMB151 (A1196)	Approved
Food derived from enhanced yield and herbicide-tolerant corn line DP202216 (A1198)	Approved
Food derived from Innate potato lines V11 & Z6 (A1199)	Approved
Food derived from herbicide-tolerant and insect-protected corn line DP23211	Approved
Food derived from herbicide-tolerant canola line MON94100	Under assessment

3. GM food safety assessment sharing with Health Canada

Work on this collaboration between FSANZ and Health Canada (the agencies) commenced in 2013. The aim of the collaboration was to explore opportunities for improving the efficiency of GM food safety assessment by streamlining the assessment process through safety assessment sharing.

Under the arrangement, where approval for a GM food is being sought from both FSANZ and Health Canada, companies may request to have their product assessed under a safety assessment sharing arrangement. See also: <https://www.foodstandards.gov.au/science/international/Pages/gm-food-safety.aspx>

Under this arrangement, and in line with agreed protocols, an application is submitted to both agencies, but only one food safety assessment is prepared (either by FSANZ or Health Canada). The assessment is then referred to the other agency for review and input to ensure it meets the requirements of both agencies. The joint food safety assessment is then used by both FSANZ and Health Canada for their own separate and independent decision-making process.

The first product to be assessed under the new arrangement is herbicide tolerant canola-line MON94100. For this first shared safety assessment it was agreed Health Canada would prepare the safety assessment and FSANZ would review it.

An application for the approval of food derived from MON94100 was submitted to Health Canada first with the application to FSANZ being lodged once the Health Canada process had been completed. FSANZ's subsequent assessment of the application, which included the joint food safety assessment prepared by Health Canada, was released for public comment between 18 February – 1 March 2021. FSANZ is now in the final stages of completing its decision process.

By using a safety assessment prepared by Health Canada, it is anticipated the FSANZ assessment and approval process can be shortened by four months. This is a significant time and cost saving for both FSANZ and the developer.

Once the first shared safety assessment is completed, FSANZ and Health Canada will then finalise their guidance for product developers.

4. New breeding techniques

4.1. FSANZ review of food derived using new breeding techniques

FSANZ commenced a review of food derived using new breeding techniques (NBTs) in June 2017. Its purpose was to consider how the *Australia New Zealand Food Standards Code* (the Code) applies to the food products of new breeding techniques (NBT foods).

The objectives of the review were to consider whether the definitions for ‘*food produced using gene technology*’ and ‘*gene technology*’ remain fit for purpose in the context of new and emerging technologies and to determine whether there is justification on a risk basis for requiring NBT foods to undergo pre-market safety assessment before entering the food supply.

FSANZ released its final report in December 2019. A copy of the final report is available at:

<http://www.foodstandards.gov.au/consumer/gmfood/Pages/Review-of-new-breeding-technologies-.aspx>

The key finding of the review was that the definitions in the Code lack clarity, are outdated and do not reflect the diversity of techniques now in use. As a result of this finding FSANZ has initiated a process to revise and modernise the definitions (see below).

4.2. Proposal P1055 – Definitions for gene technology and new breeding techniques

On 20 February 2020, FSANZ commenced a new proposal to amend the definitions in the Code for ‘*food produced using gene technology*’ and ‘*gene technology*’. The objectives for amending the definitions are to:

- improve clarity about what foods are subject to pre-market assessment (reduce uncertainty)
- better accommodate new and emerging genetic technologies (future proofing)
- regulate NBT foods in a manner that is commensurate with the risks they pose (proportionality).

FSANZ has been engaging with an Expert Advisory Group and is also undertaking consumer research to strengthen the evidence base for the proposal. A consultation paper is planned for release in mid-2021.

Details about the new proposal are available at:

<https://www.foodstandards.gov.au/code/proposals/Pages/p1055-definitions-for-gene-technology-and-new-breeding-techniques.aspx>

BELGIUM

1. Notifications for commercialisation

Belgium remains actively involved in the European Food Safety Authority (EFSA) consultation for placing on the market of genetically modified organisms (GMOs). Input in the risk assessment is provided through the Biosafety Advisory Council, which besides food and feed aspects also evaluates environmental impacts of GMOs. The Service Biosafety and Biotechnology (SBB) of Sciensano (formerly Scientific Institute of Public Health) ensures the secretariat of the Biosafety Advisory Council and provides permanent scientific support to its activities. Assessment reports and relevant documents can be consulted on <https://www.bio-council.be> and <https://www.biosafety.be>.

The OECD consensus documents on compositional considerations for new varieties of crops (the series on the safety of Novel Foods and Feeds) are used as reference documents during the evaluations.

2. GMO detection in Belgium

Detection, identification and quantification of GMOs present in food and feed is conducted by the service “Transversal activities in Applied Genomics” (TAG) of Sciensano. TAG is part of the Belgian “National Reference Laboratory for Genetically Modified Organisms” (NRL-GMO) established in the frame of Regulation (EC) 1829/2003 on GM Food and Feed and Regulation (EC) 1830/2003 on labelling and traceability of GMO. The NRL-GMO is involved in all the enforcement actions implemented by the Belgian Federal Agency for the Safety of the Food/Feed Chain and the Federal Public Service Public Health, Food Chain Safety and Environment.

The GMOLab of TAG has ISO17025 flexible scope of accreditation for detection of GMOs (plant, microorganisms, etc.). In 2020, the GMOLab extended the flexible scope to other PCR methods e.g. digital droplet PCR. TAG is also involved in several research projects.

Follow-up of the activities:

- Development of a Next Generation Sequencing-based approach to characterize unauthorized GMOs. This can be applied in isolated GMO or complex matrices using enrichment steps for targeted DNA by DNA walking.
- Detection of Genetically modified microorganisms (GMM) in food enzyme (FE) preparations: Since 01/12/2017, TAG is coordinating a national project, SPECENZYM (RT17/5), on the purity of food enzyme (FE). In this project, workflows for identification of the producer organism and recombinant DNA are developed. It also aims at studying the purity of FE for the development of general purity criteria, in the context of the implementation of Regulation (EC) 1332/2008. There was currently no strategy for an efficient and accurate control and monitoring of contaminants in FE and FE preparations. This project has collected information related to FE and available methods existing in Belgian enforcement laboratories to detect FE impurities including GMM and recombinant DNA. Evidence based results were provided on the contamination present in 50 FE preparations. In particular living GMM or DNA were present in several samples. This has led to several RASFF (EU Rapid Alert System for Food and Feed). The end of the project is foreseen in 2021 and the evidence-based results will be used to propose recommendations to competent authorities to help them take the appropriate actions in order to guarantee the safe use of FE in the food chain. In the frame of this project a strategy to detect GMM in food and feed fermentation products has been developed and applied for enforcement purposes.

In parallel another research project (AMRSEQ) financed by Sciensano is on-going on the characterisation of plasmids. Plasmids are elements that are often present in GMM and may carry antibiotic resistance genes. The plasmids are particularly difficult to characterize. Therefore in this project, the specific abilities of different NGS platforms are combined, such as aligning high-quality short reads generated by the Illumina® technology to substitutes for reference sequences created by the long reads generated by the Pacific Biosciences® and/or Oxford Nanopore® technologies.

- A research project focusing on metagenomics approaches (sequencing the whole sample) was also initiated in order to strengthen the current genetically modified organism (GMO) detection system for unauthorized GMO (UGM) as well the feasibility to integrate the MinION Next-Generation-Sequencing (NGS).
- Development and evaluation of approaches for detection of organisms modified by new genome editing techniques (GenEdit): Belgian federal project on development of novel approaches and strategies for detection of GE plants in food and feed products.
- Networking: TAG coordinates a networking project with ICAR-National Bureau of Plant Genetic Resources in India, focused on UGM events and novel analytical tools for their detection (e.g. NGS).

Peer-reviewed publications:

- Fraiture M.-A., Laure J., Vandermassen E. , Delvoye M. , Van Geel D., Michelet J-Y., Van Hoeck E., De Jaeger N., Papazova N. and Roosens NHC (2020) Retrospective survey of unauthorized genetically modified bacteria harbouring antimicrobial resistance genes in feed additive vitamin B2 commercialized in Belgium: Challenges and solutions. *Food control*, 119: 107476.
- Fraiture M.-A, Deckers M., Papazova N., Roosens. N.H.C. (2020) Are antimicrobial resistance genes key targets to detect genetically modified microorganisms in fermentation products? *International Journal of Food Microbiology* 331, 108749.
- Fraiture M.-A., Deckers M, Papazova N. Roosens NHC (2020) Strategy to Detect Genetically Modified Bacteria Carrying Tetracycline Resistance Gene in Fermentation Products. *Food Analytical Methods*; <https://doi.org/10.1007/s12161-020-01803-6>.
- Deckers, M., Vanneste, K., Winand, R., Hendrickx, M., Becker, P., De Keersmaecker, S.C.J., Deforce, D., Fraiture M.-A., Roosens, N.H.C. (2020) Screening strategy targeting the presence of food enzyme-producing fungi in food enzyme preparations. *Food Control*, 117. DOI: 10.1016/j.foodcont.2020.107295.
- Deckers, M., Deforce, D., Fraiture, M.-A, Roosens, N.H.C. (2020) Genetically Modified Micro-Organisms for Industrial Food Enzyme Production: An Overview. *Foods*, 9 (3). DOI: 10.3390/foods9030326.
- Fraiture, M.-A., Bogaerts, B., Winand, R., Deckers, M., Papazova, N., Vanneste, K., De Keersmaecker, S.C.J., Roosens, N.H.C. (2020) Identification of an Unauthorized Genetically Modified Bacteria in Food Enzyme Through Whole-Genome Sequencing. *Scientific Reports* 10 (1). DOI: 10.1038/s41598-020-63987-5 .

- Berbers, B., Saltykova, A., Garcia-Graells, C., Philipp, P., Arella, F., Marchal, K., Winand, R., Vanneste, K., Roosens, N.H.C., De Keersmaecker, S.C.J. (2020) Combining Short and Long Read Sequencing to Characterize Antimicrobial Resistance Genes on Plasmids Applied to an Unauthorized Genetically Modified *Bacillus*. *Scientific Reports*. 10(1). DOI 10.1038/s41598-020-61158-0.
- Deckers, M., Vanneste, K., Winand, R., Keersmaecker, S.C.J.D., Denayer, S., Heyndrickx, M., Deforce, D., Fraiture, M.-A., Roosens, N.H.C. (2020) Strategy for the identification of micro-organisms producing food and feed products: Bacteria producing food enzymes as study case. *Food Chemistry* 305. DOI: 10.1016/j.foodchem.2019.125431.
- Fraiture, M.-A., Deckers, M., Papazova, N., Roosens, N.H.C. (2020) Detection strategy targeting a chloramphenicol resistance gene from genetically modified bacteria in food and feed product. *Food Control*, 108. DOI: 10.1016/j.foodcont.2019.106873.

3. New Techniques

Prior to the ruling of the European Court of Justice of 25 July 2018, it was considered that genome 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, although a case-by-case approach was applied. 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. No field trial with genome-edited plants were initiated since the last WP meeting.

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 alphavelmanase, 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 nº 24, published in January 7th 2020: rules for commercial release/use and monitoring of GMOs and their derivatives;
- Normative Resolution CTNBio nº 26, published in May 25th 2020: transport procedures and rules for GMOs and their derivatives;
- Normative Resolution CTNBio nº 27, published in August 11th 2020: modification of Normative Resolution nº 22, published in July 31st 2019;
- Normative Resolution CTNBio nº 29, published in September 12th 2020;
- Normative Resolution CTNBio nº 30, published in September 16th 2020: establishing the isolation conditions for genetically modified citrus field release liberation;
- Normative Resolution CTNBio nº 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

1. Approvals of Novel Foods and Feeds

Novel Food Approvals

To date, Health Canada (HC) has permitted 225 novel foods to be sold in the Canadian marketplace. Since April 2020, the following novel foods have been authorized:

- LactoSpore®

- Highly refined oil rich in DHA derived from canola – NS-B50027-4
- Herbicide tolerant MON 87429
- Simplot Innate □ Potato Event Gen2-Z6
- Enhanced yield and herbicide tolerant maize DP-202216-6

A list of authorized novel foods, each summarized by a decision document, can be found at <https://www.canada.ca/en/health-canada/services/food-nutrition/genetically-modified-foods-other-novel-foods/approved-products.html>

Novel Feed Approvals

The Canadian Food Inspection Agency (CFIA) is responsible for the pre-market assessment of novel feeds, in accordance with the *Feeds Act and Regulations*. To date, the CFIA has approved over 120 novel feeds derived from plants sources and over 15 novel feeds from microbial sources.

Since the last Task Force meeting in March 2020, three novel feeds from plant sources have been authorized. These include:

- Highly refined oil rich in DHA derived from canola event NS-B50027-4
- Herbicide tolerant MON 87429
- Enhanced yield and herbicide tolerant maize DP202216

A complete list of approved novel feeds from plants sources is available at: <http://www.inspection.gc.ca/english/plaveg/bio/dde.shtml>

2. Genome Editing Techniques

In Canada, the approach to regulatory oversight of plant products is under review. Canada’s regulatory approach is based on the characteristics of the product and not the means of development. Novel products subject to Part V of the *Seeds Regulations*, the *Feed Regulations*, and/or the *Food and Drug Regulations* may be the result of mutagenesis, recombinant DNA techniques or other methods of plant breeding such as gene 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 transparent, consistent, and predictable. Canadian regulators are working cooperatively with developers to provide greater clarity regarding our regulatory programs (i.e., environment, feed, and food) as they apply to gene editing and other plant breeding innovations. Guidance is being drafted and will be subject to public consultation in the near future.

The CFIA and Health Canada have published a joint webpage describing Canada’s regulatory framework for the environmental release of Plants with Novel Traits (PNTs), novel feeds, novel foods, and how products derived from gene editing techniques may or may not be considered novel. This webpage is available on CFIA’s website: <https://www.inspection.gc.ca/plant-health/plants-with-novel-traits/gene-editing-techniques/eng/1541800629219/1541800629556>.

3. 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.

4. Feed Regulatory Renewal Project

During 2020/21, the CFIA has continued to make progress on its comprehensive feed regulatory renewal project and anticipates publishing the proposed regulations in Canada Gazette Part 1 for public consultation in Spring 2021. In the fall of 2020 the CFIA held an additional consultation which summarized all of the proposed changes and was the final consultation step before we're able to publish the proposed regulations in the Canada Gazette. The CFIA is finalizing the package for Canada Gazette I, which includes the proposed regulatory text, a Cost/Benefit Analysis, and a Regulatory Impact Analysis Statement. The completion of this package is a priority for 2021. In addition, a suite of guidance materials and stakeholder information sessions are anticipated to accompany the Canada Gazette consultation period. These will be aimed at helping stakeholders provide meaningful feedback on the proposed regulatory text.

Other feed related information.

- In the fall 2020, the CFIA consulted on acid based products which are used to adjust the pH of feeds. These often fall between the feed and therapeutic purpose so this consultation helped to provide some clarity on how these products may be used in feeds.
- The CFIA has announced our intent to work with Health Canada on a pilot project for allowing some veterinary health products to be used in feeds. This pilot will be limited to certain organic acids and essential oils and is anticipated to start in March 2021, with these products available in the market by this summer. Providing the pilot goes well, we'll also look to further expand the VHP products that can be used in feeds.

5. Nanotechnology (no update since last meeting)

Currently, Health Canada is using existing legislative frameworks to regulate applications of nanotechnology. However, it recognizes that new approaches may be necessary in the future to keep pace with the advances in this area. Potential risks/benefits of nanotechnology-based products are examined on a case-by-case approach, as it is still a new field of applications and research. In 2011, the Department adopted the Policy Statement on Health Canada's Working Definition for Nanomaterial. This Working Definition provides Health Canada with a consistent approach across its diverse regulatory program areas to identify regulated products and substances that may be or may contain nanomaterials (NMs). The definition also helps further the development of policy, guidance and programs applicable to nanomaterials. Given the range of nanomaterial-related regulatory responsibilities at Health Canada, the working definition is intentionally broad and applies more specifically in each regulatory program area.

Health Canada's Food Directorate completed research projects on nanoparticle immunotoxicology and continues to take part in various initiatives to strengthen its analytical and regulatory capacity. For instance, the Food Directorate collaborated with the Canadian Food Inspection Agency (CFIA) in developing the Government of Canada - Nanotechnology Technical Network (NTN). This forum facilitates a Community of Practice across federal departments, allowing discussions, presentations and collaborative activities between federal nanotechnology laboratories.

COSTA RICA

Costa Rican Legislative Framework on Safety of Novel Foods and Feeds

No substantial change since the last meeting: the Ministry of Health and the National Service for Animal Health presented, a few years ago, a draft of the national legal framework on the safety of novel foods and feeds. This regulatory framework will establish the procedures to import produce and sell food and feed produced from LMOs. However, the stakeholder have not yet reached a consensus, therefore the document is still under discussion. In other words, in Costa Rica there is no regulatory framework that regulates the safety of novel foods and feeds.

CZECH REPUBLIC

1. Legislative Framework

As the Czech Republic is part of the European Union, there is no substantial change in GMO legislation since the last meeting. (GMOs are not part of the Novel Food Regulation in the EU).

Concerning Novel Foods, there has been a change to the list of third countries and regions thereof authorised for the entry into the European Union of insects intended for human consumption. Thailand was added to the list, so there are four countries on the list: Canada, Switzerland, South Korea and Thailand.

By decision of the European Court of Justice in case C-663/18, CBD extracted from the *Cannabis sativa* plant in its entirety and not solely from its fibre and seeds does not fall under Schedules I and II of the Single Convention on Narcotic Drugs, which means it can be classified as food.

2. 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.

3. Commercial cultivation

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

4. Information for the public

Information on legislation, 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.

5. New breeding techniques

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.

FINLAND

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

1. GM food and feed

The situation in Finland regarding GM products on the market remains unchanged. There are very few or sporadic GM foods on the market. GM soy continues to be used as a feed protein. According to the EU legislation, GM products have mandatory labelling requirements stating genetic modification. A voluntary “GM free” marketing claim is approved for use in Finland, and the Finnish Food Authority has given guidance on the conditions of its use (<https://www.ruokavirasto.fi/en/companies/food-sector/production/common-requirements-for-composition/genetically-modified-food/gmo-free-marketing-claim/>, available in Finnish, Swedish and English). Some “GM free” labelled foods are on the market.

No unauthorised use of GM has been detected in Finland since the last meeting.

2. Cultivation and field trials

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

3. New genomic techniques

According to the European Court of Justice ruling (case C-528/16, 25 July 2018), the Directive 2001/18/EC also covers new mutagenesis techniques. Finland as well as other Member States have given the Commission information relevant to the implementation of the Court ruling (potential applications, field trials, experience etc.) and answered the Commission questionnaire on new genomic techniques via EU survey before 30 April 2020. The discussion continues at the EU level and a need for amending GMO Directives 2001/18/EC and 2009/41/EC to adapt them to the ongoing technical progress has been expressed.

There is an ongoing joint government study on the utilization of new genomic engineering techniques in Finland. The purpose of this study is to provide information to support decision-making, knowledge management and operational practices.

4. Non-GM novel foods

Consumers and enterprises in Finland have shown great interest in the cultivation and utilization of hemp and hemp-derived products (such as cannabinoids) as food. According to the European Court of Justice ruling (case C-663/18, 19 November 2020), cannabidiol (CBD) should not be considered as a “drug” as it does not have any psychotropic effects. The Commission therefore considers that CBD extracted from any part of the hemp plant can be qualified as food, provided that also the other conditions of Article 2 of Regulation (EC) No 178/2002 are met. Cannabinoids are considered as novel foods and thus they require a novel food authorization before entering the market in EU. Due to the ECJ ruling, the Commission has resumed the assessments for authorisation of hemp-derived products, notably CBD, under the novel food Regulation. Finland follows the ECJ ruling and any interpretations regarding hemp-derived products commonly agreed in the EU.

Interest in rearing and utilising insects as a food or feed has diminished in Finland, but some farmers and manufacturers still remain on the market. According to the European Court of Justice ruling (case C-526/19, 1 October 2020), whole animals, in particular whole insects intended for human consumption, did not fall within the scope of the old novel food Regulation (EC) No 258/97. As a result of this, the transitional measures laid down in Article 35(2) of Regulation (EU) 2015/2283 may apply to whole insects. During the transition period 8 different insect species can be used as food in Finland as well as imported to Finland for food purposes from those countries

which are listed in the Commission Implementing Regulation (EU) 2019/1981 (South Korea, Switzerland, Canada). The transition period continues until the decisions on novel food authorizations are finalized. The Finnish Food Authority has drawn up guidelines for the food business on the rearing, sale and preparation of insects (https://www.ruokavirasto.fi/globalassets/tietoa-meista/asiointi/oppaat-ja-lomakkeet/yriitykset/elintarvikeala/alkutuotanto/hyonteisohje_10588_3_fi.pdf, updated version available only in Finnish). In the feed sector the growing and use of insects is also possible as long as applicable rules are followed.

GERMANY

1. Genetically modified organisms (GMO)

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). 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.

2. New Plant Breeding Techniques (NPBTs)

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

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

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

- 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 Hochegger 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

IRELAND

As part of the European Union, Ireland is bound by EU legislation on GMOs and there is nothing new to report in that area.

In other developments the issue of insects as a food source is coming to the fore with a number of insect-related novel food applications expected to reach a conclusion in 2021. Also under novel food legislation, the issue of foods and ingredients derived from the cannabis plant (*Cannabis sativa*) are the subject of regular discussion. Plant-derived and synthetic cannabidiol (CBD) products are in the novel food authorisation process, but none are expected to be authorised in 2021.

ITALY

1. Genetically modified organisms (GMO)

As a member of the European Union, EU regulations on biotech products also apply to Italy. The status of GM products remains unchanged. GM crops are not grown and there has been no deliberate release of GMOs for field trials.

Italy has a strong history in plant breeding and plant genomics, but plant biotechnology has suffered the limitation in field trials due to the lack or incorrect implementation of the regulatory framework on GMOs. Indeed, the Ministerial Decree of 19 January 2005 for the assessment of the risk for agrobiodiversity, agricultural systems and the agri-food chain, relating to the activities of deliberate release into the environment of GMOs for any purpose other than placing on the market, in order to carry out a field trial, requires that the local governments (regions) identify public sites suitable for experimentation in open field, and the National Competent Authority (Ministry of Agriculture, Food and Forestry Policies) publishes specific experimental protocols: both of these necessary actions were never been implemented.

2. New Plant Breeding Techniques (NPBTs)

Over the last three years, before and after the ruling of the European Court, there have been several positions taken on this topic also by Italian scientific societies, federations of societies (e.g. Italian Federation of Life Sciences, FISV) and academies. The Italian Society of Agricultural Genetics (SIGA) and the farmer association Coldiretti signed an agreement on June 2020 called "Camici e trattori" (Lab coat and tractors) to support initiatives aimed at overcoming the current legislative restrictions on GMOs, pushing for the restarting of field trials and funding research activities.

3. Research activities on genetic improvement and NBTs

1) To support the assessment of NBTs' potential for Italy, Italian Ministry of Agricultural (MIPAAF) approved a three-year sustainable agriculture research plan 'BIOTECH' coordinated by the Italian Council for Agricultural Research and the Analysis of Agrarian Economy (CREA) started in 2018 and extended for another year through 2022. This is the first national plant biotechnology project since '90. It aims to apply cisgenesis and genome editing in crop plants to acquire knowledge on gene functions, to develop new genotypes and to promote the diffusion of new breeding techniques in the Italian scientific community.

The focus of BIOTECH is on improving fruit qualitative traits, resistance to biotic and abiotic stress, and plant architecture of 16 main crops, such as rice, wheat, barley, tomato, eggplant, basil, artichoke, grape, orange, peach,

apple, olive and poplar representing most of Italian cereal, fruit and horticultural agrifood production. A specific task of BIOTECH is also to evaluate the socio-economic impact of the application of new breeding technologies to crops typical of the Italian agri-food sector and to actively promote a science-based awareness for modern plant breeding in the society. (<https://www.politicheagricole.it/flex/cm/pages/ServeBLOB.php/L/IT/IDPagina/9613>)

2) The Department of Genomics and Biology of Fruit Plants (DGBPF) of the Edmund Mach Foundation (FEM, private foundation with public capital) mainly carries out research and genetic improvement activities on the fruit trees of greatest interest for Trentino: grapevine, apple and small fruits (raspberry, blueberry, strawberry).

Four new vine varieties tolerant to downy mildew and powdery mildew have just been registered in the National Register of Vine Varieties and are therefore ready to be cultivated in Trentino and in the rest of Italy.

At FEM, NBTs are used in research projects aimed at identifying the function of a gene in a plant, and to obtain grapevine more tolerant to biotic and abiotic stresses. Examples of these ongoing projects in the DGBPF are the application of genome editing for (i) the "correction" of the genes of susceptibility to powdery mildew and downy mildew in grapevine to obtain clones that are more tolerant to these fungi and therefore require a smaller number of pesticide treatments and (ii) the "correction" of the genes of susceptibility to powdery mildew and fire blight in apple varieties. As regards abiotic stresses, an ongoing project concerns (iii) the editing of genes that regulate stomatal density in order to improve water use efficiency (WUE) performance in grapevine.

Another NBT that has been applied in this institute is cisgenesis in apple aiming to obtain apple varieties such as Golden and Gala that are more tolerant to scab thanks to the presence of a resistance gene transferred from a wild apple genotype.

Latest Publications

- “The Arabidopsis pattern recognition receptor EFR enhances fire blight resistance in apple”. Piazza S., Campa M., Pompili V., Dalla Costa L., Salvagnin U. e Nekrasov V. bioRxiv preprint, <https://doi.org/10.1101/2021.01.22.427734>.
 - “Strategies to produce T-DNA free CRISPRed fruit trees via *Agrobacterium tumefaciens* stable gene transfer”. Dalla Costa, L., Piazza, S., Pompili, V. et al. Sci Rep 10, 20155 (2020). <https://doi.org/10.1038/s41598-020-77110-1>.
- 3) Italian national Agency for New technologies, Energy, and Sustainable Development (ENEA) has been involved in the genetic improvement of species of agricultural interest since the late 1950s. Currently different research groups continue to do so using innovative biotechnology:
- Transgene-free tetraploid potato plants (cv. Desiree) have been generated in which the eIF4E-1 gene, responsible for interaction with the potyvirus VpG protein, has been inactivated by Cas9. They are currently testing these plants for resistance to several potyviruses.
- 4) Several Italian research groups (Universities, ENEA, The National Research Council (CNR) actively participate in the COST action iPlanta program:
- University of Ancona is working on interfering RNA in fruit-culture for disease control.
 - CNR of Turin is working on the use of RNAi for virus control.
 - The University of Bologna is working on disease control in fruit species using biotechnology, including RNAi.
 - ENEA is mainly involved in biosafety of biotechnologies. They are currently performing RNAi bioassays on beneficial insects (i.e. *Chrysoperla carnea* and honeybees). They are also synthesizing new dsRNAs to be used against Mediterranean pests.

Latest Publications

- “Factors affecting the regeneration, via organogenesis, and the selection of transgenic calli in the peach rootstock Hansen 536 (*Prunus persica* × *Prunus amygdalus*) to express an RNAi construct against PPV virus”. Sabbadini, S., Ricci, A., Limeria, C., Baldoni, D., Capriotti, L., & Mezzetti, B. (2019). *Plants*, 8(6), 178.
- “The Induction of an Effective dsRNA-Mediated Resistance Against Tomato Spotted Wilt Virus by Exogenous Application of Double-Stranded RNA Largely Depends on the Selection of the Viral RNA Target Region”. Tabein, S., Jansen, M., Noris, E., Vaira, A. M., Marian, D., Behjatnia, S. A. A., & Miozzi, L. (2020). *Frontiers in plant science*, 11.

- “In silico analysis of fungal small RNA accumulation reveals putative plant mRNA targets in the symbiosis between an arbuscular mycorrhizal fungus and its host plant” Silvestri, A., Fiorilli, V., Miozzi, L., Accotto, G. P., Turina, M., & Lanfranco, L. (2019). *BMC genomics*, 20(1), 1-18.
- “Transcriptome profiles of strawberry (*Fragaria vesca*) fruit interacting with *Botrytis cinerea* at different ripening stages”. Haile, Z. M., Guzman, N. D., Grace, E., Moretto, M., Sonogo, P., Engelen, K., & Baraldi, E. (2019). *Frontiers in plant science*, 10, 1131.
- “Biotechnological Approaches: Gene Overexpression, Gene Silencing, and Genome Editing to Control Fungal and Oomycete Diseases in Grapevine”. Capriotti, L., Baraldi, E., Mezzetti, B., Limer, C., & Sabbadini, S. (2020). *International Journal of Molecular Sciences*, 21(16), 5701.
- “Biosafety of GM crop plants expressing dsRNA: data requirements and EU regulatory considerations”. S. Arpaia, O. Christiaens, K. Giddings, H. Jones, B. Mezzetti, F. Moronta-Barrios, J.N. Perry, J.B. Sweet, C.N.T. Taning, G. Smagghe, A. Dietz-Pfeilstetter (2020). *Frontiers in Plant Science* 11:940.
- “Biosafety of bee pollinators in genetically modified agro-ecosystems: Current approach and further development in the EU”. S. Arpaia, G. Smagghe, J.B. Sweet. (2021) *Pest Management Science*, DOI: 10.1002/(ISSN)1526-4998.

JAPAN

1. Introduction: Regulations related to GM Foods and Feeds in Japan:

- i. The Food Sanitation Act (The regulation for GM foods and food additives)
- ii. The Law Concerning Safety Assurance and Quality Improvement of Feeds (The regulation for GM feeds and feed additives)
- iii. The Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms (The regulation to prevent adverse effects on Biological Diversity Caused by the Use of Living Modified Organisms)

2. Update information of safety assessment for GM Foods and Food Additives

The safety assessment of GM foods and food additives is mandatory under the Food Sanitation Act. The Ministry of Health, Labour and Welfare (MHLW) receives application and the Food Safety Commission (FSC) evaluates their risks of using them as foods.

As of February 2021, 323 GM foods (10 potatoes; 28 soybeans; 3 sugar beets; 206 corns; 22 oilseed rapes; 48 cottons; 5 alfalfas; and 1 papaya) and 49 GM food additives have been approved; 1 food and 5 food additives are newly approved since the last meeting in April 2020.

3. Update information of safety assessment for GM Feeds and Feed Additives

The safety assessment of GM feeds and feed additives is mandatory under the Law Concerning Safety Assurance and Quality Improvement of Feeds. The Ministry of Agriculture, Forestry and Fisheries (MAFF) receives application. The Agricultural Materials Council evaluates risks of feeding them to livestock and the FSC evaluates risks of using animal products derived from livestock fed with them as foods.

As of February 2021, 94 GM feeds (18 oilseed rapes; 29 corns; 18 soybeans; 21 cottons; 3 sugar beets; 3 alfalfas; and 2 potatoes) and 18 feed additives have been approved; 0 feeds and 0 feed additives are newly approved since the last meeting in April 2020.

4. Food hygiene handling procedures for food and food additives derived from genome editing technology

In October 2019, MHLW started food hygiene handling procedures for food and food additives derived from genome editing technology. MHLW has introduced guideline requesting developers and users to notify their foods or food

additives derived from genome editing technology. Foods or food additives obtained through recombinant DNA technology are not subject to the notification.

For crossbred progeny obtained through a traditional breeding technique between a conventional breed etc.* and a breed made known to the public as a product notified to the MHLW as a food derived from genome editing technology, the developer etc. concerned is not required to consult with the MHLW in advance and to notify the MHLW of the obtained product (amended in December 2020).

* *A conventional breed etc. means: (i) a conventional breed, (ii) a breed made known to the public as a product notified to the MHLW as a food derived from genome editing technology, or (iii) a breed made known to the public as a product evaluated to be safe as a food derived from recombinant DNA technology.*

Details for the guideline is available on the MHLW's web site.

https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/shokuhin/bio/genomed/index_00012.html

5. A product notified to the MHLW as a food derived from genome editing technology

In December 2020, a tomato, in which γ -aminobutyric acid (GABA) content is increased by a mutation in a GABA synthetic enzyme gene using genome editing technology. The tomato with high GABA content became the first case of the notification of the food derived from genome editing technology to the MHLW.

6. Feed safety guideline for feed and feed additives derived from genome editing technology

In February 2020, MAFF started Feed safety guideline for feed and feed additives derived from genome editing technology. MAFF has introduced guideline requesting developers and users to notify their feed or feed additives derived from genome editing technology. Feed or feed additives obtained through recombinant DNA technology are not subject to the notification.

Detailed information will be available in MAFF web site. https://www.maff.go.jp/e/policies/ap_health/petfood/

7. A product notified to the MAFF as a feed derived from genome editing technology

In December 2020, a tomato, in which γ -aminobutyric acid (GABA) content is increased by a mutation in a GABA synthetic enzyme gene using genome editing technology. The tomato with high GABA content became the first case of the notification of the feed derived from genome editing technology to the MAFF.

KENYA

1. Background information on Biosafety regulatory framework

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

To achieve this mandate, the Authority has developed the following biosafety regulations which are now fully operational;

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

2. Status of GM approvals in Kenya

Since its inception the Authority has approved a number of projects including; 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

3. 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.

4. 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).

5. 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

1.1. Risk assessment/regulatory decisions

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

In accordance with the adopted “National Biosafety Systems development plan for 2020.-2026”, Latvia improves the National Biosafety System, ensuring a safe circulation of GMOs, preventing adverse effects on the environment, human, animal health and preserving of biodiversity. These measures are also included in GMO Scientific Risk Assessment at the national level and additional tests of GMO on the market.

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.

There is a special program adopted every year for supervision and control of GMO in food/feed and as well as to control GMO on the border in imported products from third countries. Control is performed by the Food and

Veterinary Service on the presence of GMO in approved and non-approved GMO foods, and feeds in accordance with Regulation No [2017/625](#).

1.2. 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

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

On January 26th, 2001 the Members of the European Parliament Jessica Polfjård (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.

3. Developments related to new breeding techniques (NBTs)

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

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.

3.2. 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”.

NETHERLANDS

1. General

The Netherlands, as a European Union (EU) member state, follows and implements the EU’s policy and legislation on biotechnology, respectively.

There are currently various national initiatives through which the Dutch government pursues enhanced communication about biotechnology, and greater involvement of stakeholders and the public at large in policy formulation. An example thereof is a recently published report on communication on genetically modified organisms, which can be retrieved from the following webpage on the Dutch government’s website:

<https://www.rijksoverheid.nl/onderwerpen/biotechnologie/documenten/rapporten/2020/07/28/informatie-over-ggo-wet--en-regelgeving-onder-de-microscoop> (language: Dutch, 26 pages).

2. New Plant Breeding Techniques

As a European Union (EU) member state, The Netherlands implements the EU’s legislation on biotechnology, including that on gene editing and other forms of new plant breeding techniques.

PARAGUAY

1. Developments related to implementation of national biosafety framework

1. Risk assessment/regulatory decisions

i. Events for confined field trails

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 Nº 334
MON87427 x NK603 x MON87419	Monsanto Paraguay S.A.	Maize	Tolerance to glufosinate-ammonium, dicamba and glyphosate.	30 April 2020	Resolución MAG Nº 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 assessed¹. 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 1030² and 1071³, 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

¹ 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.

² 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>

³ 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>

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

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

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. POLICY

Current Policy Regime

In 2016, Philippine regulators issued a new policy framework (DOST-DA-DENR-DOH-DILG Joint Department Circular No. 1, series of 2016 or JDC1) that would govern the research, handling and use, transboundary movement, release into the environment and management of plants and plant products of biotechnology. The JDC 1 delineates the functions of each regulatory agency, considers socio-economic issues, and puts in place a systematic process of risk assessment as the basis for decision-making. Pursuant to the JDC 1, all applications for any use covering field testing, propagation, and food and feed will undergo risk assessment by the DA, DOH, DENR, DOST and the STRP, and subject to the consultative requirements of the DILG.

Five years after its implementation, the JDC1 is currently undergoing review to address policy gaps and other issues encountered by regulators.

Under development

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.

Other relevant policies

In 2013, RA No. 10611 otherwise known as the Food Safety Act of 2013 was signed into law. The law primarily aims to strengthen the food safety regulatory system in the country by ensuring that food will not cause harm, and that human health is protected and market access of locally-produced foods and food products is facilitated. Under the Food Safety Act, *food* refers to any substance or product whether processed, partially processed or unprocessed that is intended for human consumption.

2. REGULATORY APPROVALS

Pursuant to the JDC 1, biosafety permits are being issued to regulated articles that have been determined safe to human and animal health, and the environment based on the result of risk assessments. Since March 2020, the Philippines, through the Bureau of Plant Industry, has issued biosafety permits for regulated articles intended for direct use as food and feed or for processing (8) and for commercial propagation (4). Under the Philippine regulation, the total number of processing days for applications is 85 days. Biosafety permits are valid for five years and may be renewed six months prior to its expiration.

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

SLOVAK REPUBLIC

Due to the restrictions in 2020 caused by the pandemic of coronavirus, there was not much action regarding the new breeding techniques (NBTs) coming from scientists, academics or plant breeders and suppliers in the Slovak Republic - they generally support the use of NBTs; the situation was therefore unchanged.

The Slovak Republic as part of the European Union is obliged to respect and follow the EU legislation related to the GMO and NBTs, supporting rather conservative and careful attitudes, that are also approved by the most food/feed producers and consumers in the State.

Ministry of Agriculture and Rural Development of the Slovak Republic, in cooperation with the European Commission and EFSA, offers to GMO producers a possibility to apply for new GM product to be approved for food or feed production and placing on the EU market. In 2020 there was no such application submitted.

In 2020 some specific NBTs were approved for academic and research projects at Universities and the Slovak National Academy of Sciences. Each of them was critically checked by the experts and control bodies and will be strictly controlled during duration of the project. There was confirmed no threat of a release to the environment. In charge of the supervision is the Ministry of the Environment of the Slovak Republic.

No new NBT was developed in the area of the Slovak Republic in 2020.

SLOVENIA

The Republic of Slovenia is the member of the European Union and shares the common European legislation. All preparations of legal acts are taking place at the EU level, including policy decisions and approval procedures except for contained use of GMOs. All acts concerning GMOs in food and feed are directly applicable in Slovenia.

1. GMOs in food and feed

The Competent Authority for GMOs in food and in feed is The Administration of the Republic of Slovenia for Food Safety, Veterinary Sector and Plant Protection, which is the body within the Ministry of Agriculture, Forestry and Food. Slovenia has no commercial cultivation of GMOs, neither field trials. On an annual monitoring basis on GMOs in food and feed, we are establishing that feed consisting of or containing GMO is often on the Slovenian market, but we can rarely find the food consisting of or containing GMOs. Occasionally we detected the presence of EU-approved GMOs in sports food produced from third countries. In 2020, we tested samples of feed and food. In 2021, Slovenia is continuing the testing of the presence of GMOs in food, feed and plants.

2. Monitoring of GMOs in seed

In the framework to ensure safety in the use of products of modern biotechnology the Competent Authority for contained use, deliberate release and placing GMOs on the market is in Slovenia Ministry of the Environment and Spatial Planning. In that respect, it is also responsible for monitoring of GMOs presence in seed which is taking place in Slovenia for many years. In 2020, 23 samples of seeds of maize, rapeseed and soybean were analysed. Among them, 15 samples of maize seed, 5 samples of rapeseed and 3 samples of soybean were tested for the presence of GMOs. All maize and rapeseed samples were first, subject to screening analysis with the five-target method for the presence of genetic elements: CaMV 35S promoter, NOS terminator, bar, pat and CTP2-CP4-EPSPS and

determination of the reference gene (presence of DNA, maize or rapeseed). In case of maize additionally DAS40278 was tested, because it is not covered by five-target method. All 3 soybean samples were tested with pre-spotted plates that cover presence of 16 GM soybeans. All the samples tested were negative for the presence of GM elements.

3. GMOs in cultivation

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

In 2020, 12 samples of plants were planned for testing the presence of GMOs under the law on the coexistence of crops with genetically modified plants, but the sampling and testing was not conducted due to COVID-19 epidemic. We are planning to collect approximately 10 samples in 2021.

4. Laboratory's Capacity for GMOs detection

National Institute of Biology (NIB) is nominated as National Reference Laboratory for detection of genetically modified organisms in food, feed and seed, for development of methods and other tasks related to GM control by Ministry of Agriculture, Forestry and Food and Ministry of Environment and Spatial Planning of the Republic of Slovenia. NIB is testing samples of food, feed, plants and seeds for official control. NIB is a holder of the national measurement standard in the category of amount of substances/bioanalysis of nucleic acids, especially in the field of GMOs and microorganisms.

At the moment Department of Biotechnology and Systems biology at NIB has 75 qPCR accredited methods for qualitative and quantitative testing of genetically modified organisms in foodstuffs and agricultural products of plant origin and further methods are yearly in the process of verification, and 3 methods for quantification by dPCR. Digital PCR is the most recent PCR-based approach that enables absolute quantification of nucleic acids. NIB continued on research of digital PCR (dPCR) for GMO analyses (MILAVEC, Mojca, DOBNIK, David, BOGOŽALEC KOŠIR, Alexandra, ŽEL, Jana. Metrology of DNA approaches. V: BURNS, Malcolm (ur.), FOSTER, Lucy (ur.), WALKER, Michael (ur.). *DNA techniques to verify food authenticity: applications in food fraud*. Cambridge: Royal Society of Chemistry, 2020. Str. 147-153. Food Chemistry, Function and Analysis, 16. ISBN 978-1-78801-602-5, ISBN 1-78801-602-5. <http://dx.doi.org/10.1039/9781788016025>. [COBISS.SI-ID 5204559]).

NIB also contributed to the general MIQE guidelines for dPCR (Alexandra S Whale, Ward De Spiegelaere, Wim Trypsteen, Afif Abdel Nour, Young-Kyung Bae, Vladimir Benes, Daniel Burke, Megan Cleveland, Philippe Corbisier, Alison S Devonshire, Lianhua Dong, Daniela Drandi, Carole A Foy, Jeremy A Garson, Hua-Jun He, Jan Hellemans, Mikael Kubista, Antoon Lievens, Mike G Makrigiorgos, Mojca Milavec, Reinhold D Mueller, Tania Nolan, Denise M O'Sullivan, Michael W Pfaffl, Stefan Rödiger, Erica L Romsos, Gregory L Shipley, Valerie Taly, Andreas Untergasser, Carl T Wittwer, Stephen A Bustin, Jo Vandesompele, Huggett JF. *The Digital MIQE Guidelines Update: Minimum Information for Publication of Quantitative Digital PCR Experiments for 2020*. Clin Chem. 2020 Aug 1;66(8):1012-1029. doi: 10.1093/clinchem/hvaa125) .Digital PCR is used also during routine analyses especially during verification of methods.

NIB cooperates intensively within European network of GMO laboratories (ENGL) and their working groups and additionally with Directorate – F of JRC on studies of reference materials. The Institute is also providing scientific and technical support to authorities. NIB is also a member of the Network of Laboratories for the Detection and Identification of GMOs operating under the Cartagena Protocol on Biosafety and play an active role in preparing documents for the network.

5. New breeding techniques

NIB is following the developments in Genome editing in Plants as a member of COST Action CA18111 Genome Editing in Plants (<https://plantgenomeediting.eu/>).

NIB is also a member of European Initiative for Sustainable Agriculture through Genome Editing (EU-SAGE; <https://www.eu-sage.eu/>). EU-SAGE is a network representing 131 European plant science institutes and societies that have joined forces to provide information about genome editing and promote the development of European and EU member state policies that enable the use of genome editing for sustainable agriculture and food production.

In 2020 NIB participated in public consultation on NBT by answering a questionnaire prepared and distributed by

European Commission.

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

6. Nanotechnologies in Food and Feed

Slovenia participated in teleconference meeting of EFSA scientific network on Nanotechnologies in Food and Feed held on 21st and 22nd October 2020.

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 tolerant	Du Pont Pioneer	2016
DAS81910-7	Cotton	Herbicide tolerant	DowAgroSciences	2016
DAS-24236-5 x DAS-21023-5	Cotton	Insect resistant	DowAgroSciences	2016
MON89034 x TC1507 x MON88017 x DAS-591227 x DAS-40278-9	Maize	Insect resistant Herbicide tolerant	DowAgroSciences	2016
MON89034 x TC1507 x NK603 x DAS-40278-9	Maize	Insect resistant Herbicide tolerant	DowAgroSciences	2016
DP4114	Maize	Insect resistant Herbicide tolerant	Du Pont Pioneer	2016
NK603 x T25	Maize	Herbicide tolerant	Monsanto	2016
MZHG0JG	Maize	Herbicide tolerant	Syngenta	2016
DP73496	Canola	Herbicide tolerance	Du Pont Pioneer	2016

Table 2. General release approved for importation/exportation, commercial planting, and for food and/or feed in South Africa 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

2. 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 recombination 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 to reduced BBTV titers and symptoms may lead to 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*.

3. 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.

4. 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>

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>

SWITZERLAND

1. Novel Food and Feed control

- Food control 2019

Foods derived from genetically modified plants (GMPs) are not imported on a large scale. The authorities responsible for food control test food samples with respect to the presence of food materials derived from GMPs. The results of the analyses of 2019 have been published in November 2020 by the Federal Food Safety and Veterinary Office.

year	2019	2018	2017	2016	2015
total samples	336	244	493	377	303
negative	305 (91%)	228 (93%)	434 (88%)	335 (89%)	276 (91%)
positive	31 (9%)	16 (7%)	59 (12%)	42 (11%)	27 (9%)

In 12 of the 31 samples tested positive in 2019, the presence of GMP derived material was at a level below 0.1%, in 2 samples, the level was between 0.1 and 1%, whereas in 1 sample, the level was above 1%. In the other samples, traces of GM material were detected, but could not be assigned to a specific GMP event.

As sampling may focus on specific product categories, and may be based on the likelihood of the materials to contain traces of GMP derived materials, the results should not be considered as being representative of the Swiss food market.

The report is available (in French) under <https://www.blv.admin.ch/blv/en/home/lebensmittel-und-ernaehrung/publikationen-und-forschung/statistik-und-berichte-lebensmittelsicherheit.html>

- Feed control 2019

Feed materials derived from GMPs for farm animals have not been imported in 2019, according to the Agricultural Report 2019 published by the Federal Office for Agriculture in 2020. Actually, no such imports have been reported since 2008.

The report is available (in French) under <https://www.agrarbericht.ch/fr> (Rapport agricole 2019>Production> OGM dans les aliments pour animaux importés).

2. Moratorium on commercial cultivation of GM plants

Since 2005 and until the end of 2021, a transitional period (i.e., moratorium) for putting GMOs into circulation for agricultural, horticultural or forestry purposes is in place. In November 2020, upon the parliamentary motion 19.4225, the Federal council (government) proposed to continue the moratorium for four more years and change the Gene Technology Act accordingly. This proposal is under public consultation until 25 February 2021. See also Mo 19.4225: <https://www.parlament.ch/en/ratsbetrieb/suche-curia-vista/geschaefte?AffairId=20194225> Gene Technology Act: <https://www.fedlex.admin.ch/eli/cc/2003/705/en>

3. Field trials with GM crop plants

In 2014, a three-hectare test field in Zurich equipped to counter the threat of violence ('Protected Site'), financed by the Federal budget, has been set up in order to conduct experimental field trials with GM plants safe from vandalism. Field trials with GMPs are ongoing since then. See also <https://www.agroscope.admin.ch/agroscope/en/home/topics/environment-resources/biosafety/gv-pflanzen/protected-site.html>

According to Swiss regulation, announcement, risk assessment documents, field trials authorisations and reports regarding GMOs are publicly available and may be submitted upon request. See also <https://www.bafu.admin.ch/bafu/en/home/themen/thema-biotechnologie/biotechnologie--daten--indikatoren-und-karten/biotechnologie--indikatoren/indikator-biotechnologie.pt.html/aHR0cHM6Ly93d3cuaW5kaWthdG9yZW4uYWwRtaW4uY2gvUHViG/jL0FibURldGFpbD9pbmQ9QlQwMTgmbG5nPWVuJlN1Ymo9Tg%3d%3d.html>

Three trials are currently running:

- A multi-year field trial with GM spring wheat with increased resistance to the fungal disease powdery mildew (*Blumeria ex Erysiphe graminis*), using genetic material from wheat and rye (alleles of *Pm3*, *Pm8*, and *Pm17* genes and combinations of these alleles) and conducted by the University of Zurich and Agroscope, is currently under way (field release code: B18001). These lines were sown in 2019 for the first time. The trial will be continued until 2023. The trial is a follow-up to the earlier multi-year field trial conducted between 2014 and 2018 (B13001) which has ended, with post-trial monitoring ongoing.
- Multi-year field trials with GM maize and GM barley, both with increased resistance to fungal diseases, using the *Lr34* gene from wheat, are being conducted by the University of Zurich (B18003 and B18004, respectively). The plant lines have been sown in 2020 for the first year. The trials will be continued until 2023.

Three other trials have come to an end:

- A multi-year field trial with GM (cisgenic) potatoes has been conducted by Agroscope between 2015 and 2019 (B14001). The potatoes had been produced at the Wageningen University (NL) using genetic material from wild potato species (*Solanum* spp.) leading to an increased resistance to the fungal disease late blight (*Phytophthora infestans*). The trial has ended. Monitoring after the trial is ongoing.
- A multi-year field trial with GM (cisgenic) apple trees has been conducted by Agroscope between 2017 and 2020 (B15001). The plants contain genetic material from a crab apple species (*Malus × robusta*) leading to an increased resistance to the bacterial disease fire blight (*Erwinia amylovora*). The trial was scheduled until 2021, but trees have been cleared in November 2020 as all the necessary material and data have been generated. Post-trial monitoring is now in place for at least two years.

- A multi-year field trial with GM winter wheat has been conducted by Agroscope after authorisation was granted in October 2016 (B16001). The plants expressed a saccharose transporter gene from barley and show increased yields in greenhouse experiments. The plant lines have been produced by the Leibniz Institut für Pflanzengenetik und Kulturpflanzenforschung (IPK) in Gatersleben (DE). Plants were not grown in 2020, and the trial has effectively ended. Post-trial monitoring is now in place for at least two years.

Further information is available under <https://www.agroscope.admin.ch/agroscope/en/home/topics/environment-resources/biosafety/gv-pflanzen/protectedsite/projects.html> and <https://www.bafu.admin.ch/bafu/en/home/topics/biotechnology/info-specialists/experimental-releases/experimental-releases-of-genetically-modified-organisms--gmos-.html>

4. New techniques in biotechnology

The Federal Council confirmed, in a response to an interpellation in parliament, that genome edited organisms fall under the definition of genetically modified organisms according to the Gene Technology Act. Genome editing techniques are therefore considered as techniques of genetic modification from a technical as well as a legal viewpoint. See also <https://www.admin.ch/gov/fr/accueil/documentation/communiqués.msg-id-73173.html>

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, small and medium enterprises, 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/>

UNITED STATES

U.S. Food and Drug Administration Regulatory Update

Agricultural Biotechnology Education and Outreach Initiative

On September 29, 2020, the U.S. Food and Drug Administration (FDA) has posted additional “[Feed Your Mind](#)” consumer education materials. Developed in partnership with the U.S. Department of Agriculture and the Environmental Protection Agency and [launched earlier](#) this year, “Feed Your Mind” is a consumer education initiative to provide science-based information on genetically engineered foods, commonly called GMOs or genetically modified organisms. The new materials include: two videos, four fact sheets and Spanish translation of the fact sheets and infographics.

As part of the initiative, the [Science and Our Food Supply: Exploring Food Agriculture and Biotechnology](#) high school middle school curricula are now available. These supplementary curricula include science-based lesson plans to introduce an in-depth understanding of the science behind genetically engineered plants.

Plant Biotechnology

Since the last meeting of OECD Working Group for the Safety of Novel Foods and Feeds in March 2020, the Food and Drug Administration (FDA) completed consultations on the following new plant varieties:

Raw and refined sugar derived from insect resistant, herbicide tolerant sugarcane CTC91087-6 from Centro de Tecnologia Canavieira is the subject of a completed consultation with FDA. CTC91087-6 sugarcane was genetically engineered to express Cry1Ac from *Bacillus thuringiensis* and phosphinothricin N-acetyltransferase from *Streptomyces hygroscopicus*. Sugar from CTC175-A is intended for use in human and animal food.

Additional information regarding FDA consultations on new plant varieties is available at

<https://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon>.

Animal Biotechnology

On December 14, 2020, the U.S. Food and Drug Administration approved a first-of-its-kind intentional genomic alteration (IGA) in a line of domestic pigs, referred to as GalSafe pigs. This is the first IGA in an animal that the FDA has approved for both human food consumption and as a source for potential therapeutic uses. The IGA in GalSafe pigs results in no detectable levels of alpha-gal sugar on the surface of the pigs' cells. People with Alpha-gal syndrome (AGS) may have mild to severe allergic reactions to alpha-gal sugar found in red meat (e.g., beef, pork, and lamb) and other products containing mammalian-derived substances, including medicines. Pending further approval, GalSafe pigs may also potentially provide a source of porcine-based materials to produce human medical products that are free of detectable alpha-gal sugar. Tissues and organs from GalSafe pigs could also potentially address the issue of immune rejection in patients receiving xenotransplants, as alpha-gal sugar is believed to be a cause of rejection in patients.

FDA's role in this approval was to determine if the intentional genomic alteration (IGA), the pPL657 rDNA construct in GalSafe pigs, when used according to the conditions stipulated in the approved application, is safe and effective in the disruption of the GGTA1 gene, resulting in undetectable endogenous galactose- α 1,3-galactose sugar (alpha-gal). FDA also reviewed safety data (toxicology and microbial food safety) and determined that food from GalSafe pigs is safe for consumption by the general population. It should be noted that FDA's safety evaluation was not specific to those who have alpha-gal syndrome. USDA has oversight over the slaughter, processing, and labeling of the food products from GalSafe pigs, including any special labeling claims regarding the absence of alpha-gal sugar.

Revivicor, the developer of the IGA and owner of the GalSafe lineage, participated in FDA's Veterinary Innovation Program, which facilitates advancements in the development of innovative animal products by providing greater certainty in the regulatory process, encouraging development and research, and supporting an efficient and predictable pathway to approval for IGAs in animals.

For more information about the approval, please see the FDA webpage: <https://www.fda.gov/news-events/press-announcements/fda-approves-first-its-kind-intentional-genomic-alteration-line-domestic-pigs-both-human-food>.

<p>Policy and Regulatory Update for the U.S. EPA - Office of Pesticide Programs, Biopesticides and Pollution Prevention Division (OPP/BPPD) 2020/2021</p>
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EPA proposal on plant-incorporated protectants (PIP): Proposed Exemption for “Plant-incorporated protectants based on sexually compatible plants created through biotechnology”

On October 09, 2020 EPA published a proposed rule that would exempt certain PIPs, called “PIPs based on sexually compatible plants created through biotechnology,” from regulation under FIFRA and FFDCA. Associated with this action was a 60-day public comment period. EPA's proposed rule would allow these PIPs to be exempt under existing regulations in cases where they: 1) pose no greater risk than PIPs that EPA has already concluded meet safety requirements, and 2) could have otherwise been created through conventional breeding. On September 28, 2020, EPA held a webinar (website link: <https://www.youtube.com/watch?v=8cj34z8d9Gw&feature=youtu.be&app=desktop>) 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 (website link: <https://beta.regulations.gov/document/EPA-HQ-OPP-2019-0508-0002>).

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 6/11/2020.
- ❖ 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 1/15/2021 in response to petitions from Hangzhou Ruifeng Biosciences Co., Ltd. of Hangzhou, China.

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 TM	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 TM	HT	Rohm and Haas
DAS-444Ø6-6	20/9/2019	Soybean	Enlist E3	HT	Rohm and Haas
DAS-4Ø278-9	20/9/2019	Maize	Enlist TM	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 TM 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	Mãïe	SmartStax Pro	IR&HT	Dekalb VN
LL Cotton 25	14/9/2020	Cotton	Liberty Link	HT	Bayer VN
KK179	16/12/2020	Alfalfa	HarvXtra TM 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 GM Food and Feed

1.1. 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-SNFF 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).

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

The Transparency Regulation⁴ 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.

⁴ 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)

In this context, EFSA has published a statement, and further work on protein safety assessment is ongoing:

- *Statement on in vitro protein digestibility tests in allergenicity and protein safety assessment of genetically modified plants*, available at: <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2021.6350>

1.3 **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>

1.4 **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>

2. Further developments related to novel foods and feeds

2.1. **Risk assessment/regulatory decisions**

As of 1 January 2018, Regulation (EU) 2015/2283 on novel foods became applicable. The Regulation improves conditions so that food businesses can easily bring new and innovative foods to the EU market, while maintaining a high level of food safety for European consumers. The authorisation procedure has been centralised and simplified and a faster and structured notification system for traditional foods from non-EU countries have been established.

The European Commission has received, to date, 370 requests for authorisation (309 applications and 61 notifications for traditional foods from third countries) since the regulation became applicable. The Union list of novel foods has been amended 50 times, including the authorisation of five traditional foods.

2.2. **New and emerging regulatory challenge(s) for Novel food / feed**

The use of alternative feed sources and circular economy on the integrity of the food / feed chain: the feed sector is considering the use of alternative feed sources (e.g. insects, former food products, algae) and products of food/feed production technologies of increasing relevance (e.g. biofuel by-products). The implementation of more sustainable agro-zootechnical and food/feed policies, such as the circular economy, also give an important input in this direction. As highlighted in the FAO report on Hazards associated with animal feed (FAO 2019), there is a need to better target the risk assessment for these new products (e.g. insects, former food products, biofuel by-products, aquatic products of animal or plant origin).

2.3. **Public engagement and outreach activities**

The role of circular economy as a driver for emerging risks of novel feed were discussed in 2020 at the 23rd Emerging Risks Exchange Network (EREN) meeting and dedicated stakeholder meetings. Further discussion is ongoing.

2.4. **Research projects on novel food / feed; relevant publications**

Ongoing procurement on food and feed safety vulnerabilities in circular economy, including aspects related to novel feeds. The overall objective of this procurement is to critically review available literature and monitor on-going research projects with the aim to gather information and evaluate the evidence for vulnerabilities of circular economy for food/feed safety, plant, animal and human health and the environment. As a new driver, implementation of circular economy might bring about a set of emerging risks, understood as risks resulting from a newly identified hazard to which significant exposure may occur, or from an unexpected new or increased significant exposure and/or susceptibility to a known hazard.

3. Developments related to new breeding techniques (NBTs)

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

In November 2019, the Council of the European Union requested⁵ 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>

⁵ 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)

3.2. **Public engagement and outreach activities**

Consultations of the public was carried out after the adoption of each scientific opinion on new genomic techniques. The outcome of the public consultations is available on the webpages of the individual scientific opinions under “supported information”.

3.3. **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.

Business at OECD (BIAC)

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.

The Agriculture & Food Systems Institute (AFSI)

1. About the Agriculture & Food Systems Institute

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

2. Updates regarding international activities

Capacity building

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:

- 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.

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.

Webinar series on Microbial Biotechnology

AFSI is developing a series of seminars and workshops focused on bringing increased attention to the development, use, and safety assessment process for microbial biotechnology. The goal is to help countries implement informed policies that meet the need for governments, producers, and consumers to assess and access products produced using microbial biotechnologies. The [Microbial Biotechnology for Novel Foods Webinar Series](#) was a rescheduling of the workshop that was initially planned to be hosted at OECD headquarters immediately following the 2020 meeting of the WP-SNFF. Taking place over four, non-consecutive days between July 9-17th 2020, the webinars included a keynote presentation, and three technical sessions dealing with the science of microbial products, industry, and consumer perspectives and trade. The webinars attracted 330 registered participants, from 43 countries including China, EU Member States and both developed and developing countries.

New activities in 2021 will include a series of international and regional workshops combining online and in-person programming if travel restrictions ease.

3. Developments related to new breeding techniques (NBTs)

Webinar series on gene editing for Korean Scientists

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-April of 2021 is intended to convene Korean stakeholders

to engage in sessions centred 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

Publications

[Genetic Biocontrol for Invasive Species](#) Teem JL, Alphey L, Descamps S *et al.* *Frontiers in Bioengineering and Biotechnology*. May 25, 2020. This publication provides an overview of the state of genetic biocontrol and covers four different approaches to genetic biocontrol for invasive species: sterile-release, YY males, trojan female technique, and gene drive. This review was co-authored by Dr. Andrew Roberts, CEO, AFSI and Dr. Rachel Melnick, Senior Manager, Scientific Programs.

[Sublethal Endpoints in Non-Target Organism Testing for Insect-Active GE Crops](#) Roberts A, Boeckman CJ, Mühl M *et al.* *Frontiers in Bioengineering and Biotechnology*. June 9, 2020. This review presents the current status and history of sublethal endpoint use in insect-active GE crops and evaluates the future use of sublethal endpoints for new and emerging technologies. Dr. Andrew Roberts is the lead author and Dr. Rachel Melnick is a co-author of this review.

Resources

Crop Composition Database

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

[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.

eLearning courses

Self-paced, interactive eLearning courses developed by AFSI serve as a complementary resource to in-person training workshops and are being used to support capacity building programs we conduct in collaboration with our partners. All courses are peer-reviewed and are available in English. Additionally, some courses are available in Spanish and Chinese. Presently AFSI offers the following eLearning courses: Concepts in the Safety Assessment of Novel Food and Feed, Application of Problem Formulation to Food and Feed Safety Assessments, Understanding Low Level Presence in Agricultural Biotechnology, Application of Problem Formulation to the Environmental Risk Assessment of Genetically Engineered Crops and Confined Field Trials of Genetically Engineered Plants.

AFSI is in the process of releasing three new eLearning modules.

- *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 is in the final production stage.

- 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.
- *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.

Health and Environmental Sciences Institute (HESI)

1. Overview

About HESI: The [Health and Environmental Sciences Institute \(HESI\)](#) is a non-profit institution whose mission is to collaboratively identify and help to resolve global health and environmental challenges through the engagement of scientists from academia, government, industry, NGOs, and other strategic partners. Since its creation in 1989, HESI has produced scientific research that informs applied health protection decision making around the globe. Today, HESI’s team of 12 scientific staff provides leadership to more than fifty scientific projects and programs that benefit human and environmental health. HESI is based in Washington D.C., USA, but operates globally.

HESI PATB: The [Protein Allergens, Toxins and Bioinformatics \(PATB\) committee](#) is the new designation adopted in 2018 for the longstanding HESI committee formerly known as “Protein Allergenicity Technical Committee” (PATC), the only committee at HESI focusing *exclusively* on scientific research relating to food safety. The new designation was adopted to embrace a broader scope, expertise, interests, and collaborators in the fields of bioinformatics and protein toxins, while strengthening the core focus of the committee in allergenicity.

PATB’s Mission: The committee’s mission is to advance the scientific understanding of the relevant parameters defining allergenic proteins and protein toxins in foods and feeds by: (i) encouraging the development of reliable and accurate methodologies for characterizing the allergenic potential and “toxicity” potential of novel sources of proteins, and (ii) leveraging the power of bioinformatics approaches in accomplishing these efforts.

To fulfill its mission, the committee brings together expertise from public and private sector scientists, with participants from the US FDA, US EPA, expert academics and clinicians from the University of Amsterdam’s Academic Medical Center (Netherlands), the Copenhagen University Hospital at Gentofte (Denmark), the Children’s Hospital of Philadelphia [(CHOP), USA], Zhejiang University (China), the Joint Institute for Food Safety and Applied Nutrition (JIFSAN) – a joint venture between the University of Maryland and the US FDA – as well as molecular biologists, toxicologists and bioinformaticians from agricultural biotechnology companies who share real world experiences and common challenges.

2. 2020 Updates

2.1. Experimental research

The committee has concluded the experimental work of two projects (items a. and b., below), as part of a multi-year collaboration with the University of Amsterdam’s Academic Medical Center (Netherlands), and is starting a new research project (c.) in collaboration with the Copenhagen University Hospital at Gentofte (Denmark).

- Food Matrix project:** This research project was undertaken to study the impact of food matrices on the digestibility of proteins and complements previous committee completed work on *in-vitro* digestibility models ([Akkerdaas et al., 2018](#)) by testing whether protocols that take matrices into account would provide a better discrimination of allergens and non-allergens than protocols focusing on purified proteins in solution. Two pairs of “allergens vs. non- (or weak) allergens” in presence of one of three food matrices were tested in

both gastric and duodenal digestion conditions. Results are being analyzed and the committee plans to share the outcomes of this study via publication in the peer-review literature.

- b. **Allergen Rebuild project:** This project aims to evaluate the impact of amino acid (aa) replacement (at a single dominant epitope level) on IgE-binding to the epitope, as part of using an intact, full-length major protein allergen. The impact of the aa substitution was also evaluated at the structural level with NMR and computational modeling. Results are being analyzed and the committee plans to share the outcomes of this study via publication in the peer-review literature. It is anticipated that this study will contribute to the understanding of the biology of allergen IgE-binding.
- c. **Immunogenicity of allergens vs. non-allergen proteins:** This project aims to detect if allergens have an inherent type of immunogenicity compared to non-allergens from the same protein family, based on a defined *in-vitro* protocol for identification of specific T cells and antibodies from allergic patients and non-allergic individuals.

2.2. Scientific resources and assessment tools

COMPARE Allergen Database, www.comparedatabase.org (fifth iteration released Jan. 2021): This HESI program is a collaborative public-private effort, in partnership with the Joint Institute for Food Safety and Nutrition at the University of Maryland (<http://jifsan.umd.edu>), which provides programmatic support. The initiative was launched in 2016 in response to the widespread use of genomic sequencing technology and the need to develop a process implementing a cutting-edge and high-throughput bioinformatic pipeline to identify a meaningful subset of “candidate sequences” for scientific review by an independent panel of experts. Since its first release in 2017, the database is updated annually using a transparent process (documented in the database website and in a publication - *submitted*) that employs computer-based methods to identify candidate sequences that are subsequently reviewed and approved by an independent international panel of academic and clinical allergy experts. Improvements incorporated in the database since 2019 are described in the “database” tab under the hyperlink “documentation”. COMPARE 2021 comprises 2,348 protein sequences and associated metadata.

COMPASS Tool: “COMPASS” (COMPare Analysis of Sequences with Software) is the COMPARE database companion tool, released in July 2019. It is equipped with a comparative sequence search software allowing users to conduct website-based, real-time searches in the COMPARE database to produce amino acid sequence alignments (between two or more amino acid sequences). The intended use of the built-in COMPASS tool is to provide users the possibility of assessing the degree of shared sequence similarity between an amino acid sequence of interest (“query sequence”) and allergen sequences within the COMPARE database. To this end, the user can perform three different types of sequence searches, informed by internationally recognized guidelines [FAO/WHO (2001)⁶ and CODEX Alimentarius (2003⁷,2009⁸): full length sequence search; 80-mer sliding window FASTA search; and 8-mer FASTA search. In July 2020, the tool was upgraded with the addition of a visualization option to view results in a color-coded graphic display.

2.3. International Outreach: workshops and publications

Recent PATB organized workshop: “From Protein Toxins to Applied Toxicological Testing”

October 21st -23rd, 2020 (online event)

In collaboration with the Society of Toxicology (SOT) Food Safety Specialty Section

Full program details and presentations available in the event page:

<https://hesiglobal.org/event/patb-committee-protein-toxins-workshop/>

⁶ FAO/WHO. (2001) Evaluation of Allergenicity of Genetically Modified Foods. Report of a Joint FAO/WHO Expert Consultation on Allergenicity of Foods Derived From Biotechnology. Food and Agriculture Organization of the United Nations, January 22–25, 2001, Rome, Italy.

⁷ Codex Alimentarius Commission. (2003) Appendix III (Guideline for the conduct of food safety assessment of foods derived from recombinant-DNA plants) and Appendix IV (Annex on the assessment of possible allergenicity). In (eds.), Alinorm 03/34: Joint FAO/WHO Food Standard Programme, Codex Alimentarius Commission, Twenty-Fifth Session, Rome, 30 June–5 July, 2003. Codex Alimentarius Commission, Rome, Italy, pp. 47–60.

⁸ Codex Alimentarius Commission (2009). Codex Alimentarius: Foods Derived from Modern Biotechnology. 2nd ed. Joint FAO/WHO Food Standards Programme. Rome: World Health Organization. pp. 1-85. ISBN 978-92-5-105914-2.

This workshop was organized as part of the PATB Protein Toxins Task Force activities, following up previous work completed on the topic ([Negi et al., 2017](#)). The program was designed to serve two key purposes: 1) learning about the advances in protein toxin research presented by recognized international academic experts in the field and 2) assessing the translation of knowledge into practical applications (e.g., into weight-of-evidence approaches for the safety assessment of biotechnology products; relevance, applicability, and/or limitations of existing protein toxin databases and tools for risk assessment).

Additional PATB outreach events in 2020:

- Presentation at the Chinese Society of Allergy 2020 Annual Meeting (September 2020, virtual): Committee member, Dr. Gao Zhong-Shan, presented the COMPARE database as part of the Translational Allergy Session.

A complete list of past events and publications of the PATB Committee can be found in the committee public webpage: <https://hesiglobal.org/protein-allergens-toxins-and-bioinformatics-committee-patb/>. The 2020 Committee Fact Sheet is also available on the same page.

3. Open to new collaborators

The PATB is welcoming new public and private sector participants with relevant technical expertise. All geographic areas welcomed.

Solving complex challenges in food and feed safety and sustainability requires dialogue, collaboration, and innovation. HESI's PATB committee has over 20 years of history, from the early days of agricultural biotechnology product development to present, with a strong track record as a neutral convener, to facilitate interactions across sectors and help address new scientific needs through collaboration.

With the emergence of new biotechnologies (*e.g.*, gene editing, microbial protein production) and the growing use of proteins from novel food sources in food production, PATB recognizes the need to include these new topic areas in its activities. To learn about how to get involved, please contact Dr. Lucilia Mouriès (lmouries@hesiglobal.org), HESI's Senior Scientific Program manager for the PATB Committee and COMPARE database.