

Unclassified**English - Or. English****27 July 2020****ENVIRONMENT DIRECTORATE
JOINT MEETING OF THE CHEMICALS COMMITTEE AND THE WORKING
PARTY ON CHEMICALS, PESTICIDES AND BIOTECHNOLOGY****Developments in OECD Delegations on the Safety Assessment of Novel Foods
and Feeds, April 2019 – March 2020****Series on the Safety of Novel Foods and Feeds
No. 32****JT03464259**

OECD Environment, Health and Safety Publications

Series on the Safety of Novel Foods and Feeds

No. 32

**Developments in OECD Delegations on the
Safety Assessment of Novel Foods and Feeds,
April 2019 – March 2020**

Environment Directorate

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

Paris 2020

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)
- No. 5, Report of the OECD Workshop on the Nutritional Assessment of Novel Foods and Feeds, Ottawa, Canada, February 2001 (2002)
- No. 6, Consensus Document on Compositional Considerations for New Varieties of Maize (Zea mays): Key Food and Feed Nutrients, Anti-nutrients and Secondary Plant Metabolites (2002)
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- No. 9, Considerations for the Safety Assessment of Animal Feedstuffs Derived from Genetically Modified Plants (2003)
- [No. 10, Consensus Document on Compositional Considerations for New Varieties of Rice (Oryza sativa): Key Food and Feed Nutrients and Anti-nutrients (2004) ***REPLACED with revised consensus document No. 28 (2016)***]
- No. 11, Consensus Document on Compositional Considerations for New Varieties of Cotton (Gossypium hirsutum and Gossypium barbadense): Key Food and Feed Nutrients and Anti-nutrients (2004)
- No. 12, Consensus Document on Compositional Considerations for New Varieties of Barley (Hordeum vulgare L.): Key Food and Feed Nutrients and Anti-nutrients (2004)
- No. 13, Consensus Document on Compositional Considerations for New Varieties of Alfalfa and Other Temperate Forage Legumes: Key Feed Nutrients, Anti-nutrients and Secondary Plant Metabolites (2005)
- No. 14, An Introduction to the Food/Feed Safety Consensus Documents of the Task Force for the Safety of Novel Foods and Feeds (2006)
- No. 15, Consensus Document on Compositional Considerations for New Varieties of the Cultivated Mushroom Agaricus Bisporus: Key Food and Feed Nutrients, Anti-nutrients and Toxicants (2007)
- No. 16, Consensus Document on Compositional Considerations for New Varieties of Sunflower: Key Food and Feed Nutrients, Anti-nutrients and Toxicants (2007)
- 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)

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- 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)
- 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)
- No. 23, Consensus Document on Compositional Considerations for New Varieties of Sugarcane (*Saccharum* spp. hybrids.): Key Food and Feed Nutrients, Anti-nutrients and Toxicants (2011)
- 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)
- No. 26, Consensus Document on Compositional Considerations for New Varieties of Oyster Mushroom (*Pleurotus ostreatus*): Key Food and Feed Nutrients, Anti-nutrients and Toxicants (2013)
- No. 27, Consensus Document on Compositional Considerations for New Varieties of Common Bean (*Phaseolus vulgaris* L.): Key Food and Feed Nutrients, Anti-nutrients and Other Constituents (2015)
- No. 28, Revised Consensus Document on Compositional Considerations for New Varieties of Rice (*Oryza sativa*): Key Food and Feed Nutrients, Anti-nutrients and Other Constituents (2016)
- No. 29, High-throughput DNA Sequencing in the Safety Assessment of Genetically Engineered Plants: Proceedings of the OECD Workshop held in April 2016 (2016)
- 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)

ABOUT THE OECD

The Organisation for Economic Co-operation and Development (OECD) is an intergovernmental organisation in which representatives of 37 industrialised 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/)

or contact:

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

E-mail: ehscont@oecd.org

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FOREWORD

The Working Group for the Safety of Novel Foods and Feeds (WG-SNFF) is a subsidiary body of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology of the OECD.

The WG-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 WG-SNFF's activities and outputs are complementary to those of the Working Group on the Harmonisation of Regulatory Oversight in Biotechnology, which deals with environmental safety (biosafety) of genetically-engineered organisms.

The WG-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 WG-SNFF, available together with the consensus documents at www.oecd.org/env/ehs/biotrack/.

Of different content, this information document compiles information provided by delegations on the occasion of the 27th WG-SNFF meeting (23-24 March 2020). It aims at summarising relevant information on activities related to the safety assessment of novel foods and feeds since the previous meeting (April 2019) at the international level, by collating individual contributions from OECD Members, partner countries and observer organisations participating in the work.

The Working Group for the Safety of Novel Foods and Feeds endorsed this document, which is published under the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology of the OECD.

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DEVELOPMENTS IN OECD DELEGATIONS ON THE SAFETY ASSESSMENT OF NOVEL FOODS AND FEEDS, April 2019-March 2020

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 <http://www.bio-council.be> and <http://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

Since June 2006 the National Reference Laboratory for Genetically Modified Organisms (NRL-GMO) is fully operational and has been involved in all the enforcement actions implemented by the Belgian Federal Agency for the Safety of the Food/Feed Chain. This task is entrusted to the service “Transversal activities in Applied Genomics” (TAG) of Sciensano. The GMOLab of TAG has ISO17025 flexible scope of accreditation for detection of GMOs (plant, microorganisms, etc.). In 2019, the TAG lab started validation of Droplet Digital PCR (ddPCR) methods for detection of transgenic sequences in view of extension of that accreditation.

TAG is also involved in several research projects.

Follow-up of the activities:

- The current focus remains on the development of a Next Generation Sequencing-based approach to characterise unauthorised GMOs coupled with the DNA walking approach. In this context, a PhD thesis is ongoing with the goal to construct a GMO database including sequences and NGS data analysis.
- Detection of GMMs in food enzyme (FE) preparations: Since 01/12/2017, TAG is coordinating a national project, SPECENZYM, on the purity of food enzyme. 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 is currently no strategy for an efficient and accurate control and monitoring of contaminants in FE and FE preparations. This project will collect information related to FE and available methods existing in Belgian enforcement laboratories to detect FE impurities including GMM and recombinant DNA. 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 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 characterise. 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.

- An internally financed research project was developed in order to strengthen the current genetically modified organism (GMO) detection system for unauthorised GMO (UGM) and the feasibility to integrate the MinION Next-Generation-Sequencing (NGS).
- 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). In 2019 2 scientists from ICAR-NBPGR visited the GMOLab of TAG for training on the use of DNA walking combined with MinIon technology for characterisation of UGM.

Peer-reviewed publications:

M.-A. Fraiture, G. Ujhelyi, J. Ovesná, D. Van Geel, S. De Keersmaecker, A. Saltykova, N. Papazova, N. HC Roosens. MinION sequencing technology to characterise unauthorised GM petunia plants circulating on the European Union market, *Nature, Scientific Reports* (2019) 9: 71-41, <https://doi.org/10.1038/s41598-019-43463-5>.

M.-A. Fraiture, M. Deckers, N. Papazova, N. HC Roosens. (2020). Chloramphenicol resistance gene detection in food and feed products, *Food Control*, 108. <https://doi.org/10.1016/j.foodcont.2019.106873>.

Deckers et al. 2019. Strategy for the identification of micro-organisms producing food and feed products: Bacteria producing food enzymes as study case. *Food Chemistry*. <https://doi.org/10.1016/j.foodchem.2019.125431>.

M.-A. Fraiture et al. (2019) Are antimicrobial resistance genes key targets to detect genetically modified microorganisms in fermentation products? *International Journal of Food Microbiology*, submitted

M.-A. Fraiture et al. (2019) Next-generation sequencing: a key tool to identify unauthorised genetically modified microorganism in food enzyme and to develop event-specific real-time methods. *Nature Scientific Report*, submitted

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. One field trial involving maize modified with CRISPR/Cas9 was ongoing at the time of the ruling and has been brought into regulatory compliance according to this interpretation of the ECJ. An application for field trials with maize modified through CRISPR mutagenesis has been submitted in January 2019 to the Belgian authorities in accordance with Part B of Directive 2001/18/EC, and authorised in April 2019.

Publication:

AJ Bogdanove, DM Donovan, E Elorriaga, J Kuzma, K Pauwels, SH Strauss, DF Voytas (2018) *Genome Editing in Agriculture: Methods, Applications, and Governance*. A paper in the series on *The Need for Agricultural Innovation to Sustainably Feed the World by 2050*. Council for Agricultural Science and Technology (CAST), Issue Paper 60. CAST, Ames, Iowa.

BRAZIL**1. Regulatory Framework**

In 2019 there were concluded and updated 3 GMO Biosafety regulations by the National Biosafety Technical Commission - CTNBio:

- Normative Resolution N° 24, January 07th 2020: Commercial approval of genetically modified organisms and derivatives and post-Commercial approval monitoring of genetically modified organisms;
- Normative Resolution N° 23, October 03rd 2019: GMO events that had already been field liberated previously;
- Normative Resolution N° 22, July 31st 2019: GMO eucalyptus field release liberation.

There are some reviews in progress related with GMO Biosafety regulations by the National Biosafety Technical Commission - CTNBio:

- Normative Instruction N° 04, December 19th 1996: Transport of GMO;
- Normative Resolution N° 10, October 03rd 2013: GMO sweet orange (*Citrus Sinesis* (L.) OSBECK) field release liberation.

2. Commercial Approvals

Since last Meeting 16 new GM events were approved for commercial release in Brazil in 2019 (<http://ctnbio.mctic.gov.br/deliberacoes>):

- *Saccharomyces cerevisiae* microorganism (GICC03435 and GICC03486): industrial application for ethanol production.(Danisco Brasil Ltda);
- MIR162 × MON 89034 × GA21; Bt11 × MON89034; MON89034 × GA21: herbicide tolerant and insect resistance maize (Syngenta Seeds Ltda);
- Bt11 × MIR162 × MIR604 × TC1507 × 5307; Bt11 × MIR162 × MIR604 × TC1507; Bt11 × MIR162 × MIR604; Bt11 × TC1507; Bt11 × 5307; MIR162 × MIR604 × TC1507 × 5307 × GA21; MIR162 × MIR604 × TC1507 × 5307; MIR162 × MIR604 × TC1507; MIR162 × MIR60 (subcombinations): herbicide tolerant and insect resistance maize (Syngenta Seeds Ltda);
- *Corynebacterium glutamicum* cepa DM24.60 and its derivatives: GM microorganism for use in industrial fermentation and its derivative for use in animal feed as additive (Evonik Degussa do Brasil);
- *Saccharomyces cerevisiae* microorganism (SCY011): industrial application (Novozymes Latin America Ltda);
- *Saccharomyces cerevisiae* microorganism (Y47220): industrial application (Amyris);
- *Saccharomyces cerevisiae* microorganism (GICC03506): industrial application (Danisco Brasil Ltda.);
- Subtilisina (GICC 03528): derivative from GM microorganism – Subtilisina (Danisco Brasil Ltda.);
- Treonina: derivative from GM microorganism – Grainy Treonina THR Pro (L-Treonina 75%) (CJ do Brasil Indústria e Comércio de Produtos Alimentícios Ltda.);
- HB4 and HB-4 × RR: herbicide tolerant and drought tolerant soybean (Tropical Melhoramento Genético - TMG);
- MON-87427-7 × MON-89034-3 × DAS-01507-1 × MON-87411-9 × DAS-59122-7 × DAS-40278-9: herbicide tolerant and insect resistance maize (Dow Agrosience Industrial);
- MON 87427 × MON 87419 × NK603: herbicide tolerant maize (Monsanto);
- MON 87427 × MON 89034 × MIR162 × NK603 (and subcombinations): herbicide tolerant and insect resistance maize (Monsanto);
- GHB811 × T-304-40 × GHB119 × COT102 × COT102: herbicide tolerant and insect resistance cotton (BASF);
- DAS-21023-5 × DAS-24236-5 × SYN-IR102-7 × DAS-81910-7: herbicide tolerant and insect resistance cotton (Dow Agrosience Industrial);
- CTC93209-4: insect resistance sugarcane (Centro de Tecnologia Canavieira - CTC);

The total number of commercial approvals of GMOs in Brazil are: 94 genetically modified plants (50 maize, 22 cotton, 17 soybeans, 3 sugar cane, 1 eucalyptus and 1 common bean), 39 recombinant vaccines, 1 genetically modified mosquito and 25 genetically modified microorganisms, and derivatives. Further information can be accessed at <http://ctnbio.mctic.gov.br/liberacao-comercial#/liberacao-comercial/consultar-processo>

3. GMO Research

In Brazil in 2019 there were 61 field trials approved, with different plant species, including maize, soybean, cotton, sugarcane, eucalyptus, rice and citrus. The characteristics of the biotech crops included insect resistance, herbicide tolerance, disease resistance, drought tolerance, increased yield, reduced lignin content, increased growth and fibre quality. There are currently 9 field trials in the CTNBio agenda under analysis (March/2020).

In 2018 there was a total number of 449 private and public institutions registered and approved by CTNBio to conduct research with GMOs under containment, according to CTNBio website.

4. GM Crops production

According to the private sector estimative (Celeres Consulting, <http://celeres.com.br>) in 2017/18 the total area reached about 53.1 million hectares cultivated with GM crops (soybean, maize and cotton). The data shows an area around 35.1 million hectares cultivated with GM soybean, representing 97,1% of the cultivated area; 16.8 million hectares with GM maize, representing 91,4% of the cultivated area and 1.16 million hectares cultivated with GM cotton., representing 83,9% of the cultivated area.

5. 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 314 inspections in field trials and commercial use of GMOs to check the biosafety requirements.

6. Participation in Biotechnology and Biosafety forums:

- ✓ Working Group on Harmonisation of Regulatory Oversight in Biotechnology / OECD
- ✓ Working Group for the Safety of Novel Foods and Feeds / 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)
- ✓ Nagoya Protocol: “Digital Sequence Information” (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
- ✓ Brazil-Argentina Bilateral Dialogue on Biotech
- ✓ CAS – Southern Agricultural Council
- ✓ GLI – Global Low Level Presence Initiative
- ✓ MERCOSUL – SGT-8 Agricultural Biotechnology Commission

7. GM Data Bank

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

8. New Breeding Techniques

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 ten consultations since NR16 approval. Five microorganism lines (*Saccharomyces cerevisiae*) for bioethanol production, a hornless cow for dairy cow management), a tilapia for improved meat production, a waxy corn for starch quality, a vaccine for canine parvovirus control and a RNAi for topical application used in mosquito control. According to the provisions RN16, all those products, except the hornless cow, were considered by CTNBio to attend the characteristics established in the Normative and were not considered to fall under the scope of the Law 11.105/2005 that regulates genetically modified organisms in Brazil.

CANADA

1. Novel Food Approvals

To date, Health Canada (HC) has permitted 218 novel foods to be sold in the Canadian marketplace. Since April 2019, the following novel foods have been authorised:

- Imidazolinone Herbicide Tolerant Rice RTC1
- Insect-resistant sugarcane CTC91087-6

- EPA+DHA Herbicide Tolerant Canola Event LBFLFK
- Soy leghemoglobin (LegH) preparation as an ingredient in a simulated meat product (e.g., The Impossible™ Burger) and other ground beef analogues

A list of authorised 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>

2. 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 April 2019, two novel feeds from plant sources have been authorised. These include:

- EPA+DHA Herbicide Tolerant Canola Event LBFLFK (BASF)
- Imidazolinone Herbicide Tolerant Rice RTC1

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

3. Genome Editing Techniques

In Canada, the approach to regulatory oversight 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 recognise 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.

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>.

4. Low Level Presence Update

In 2012, the Government of Canada initiated the Global Low Level Presence Initiative (GLI), a group of 15 importing and exporting countries^[1] committed to working collaboratively to develop international approaches that facilitate the management of Low Level Presence (LLP). To date, the GLI has had 6 face-to-face meetings (Canada 2012, Argentina 2012, South Africa 2013, Rome 2016 and 2017, Brazil 2018).

The Government of Canada is currently planning the next face-to-face meeting of the GLI, which will take place in Indonesia, the week of June 8, 2020. The Government of Indonesia will co-chair the event with Canada.

^[1] Australia, Argentina, Brazil, Canada, Colombia, Costa Rica, Indonesia, Mexico, Paraguay, Philippines, Russia, South Africa, United States, Uruguay, Vietnam

The objective of the next GLI will be to advance the discussion on asynchronous approvals, the underlying cause of LLP, and explore ongoing best regulatory practices to prevent and manage LLP. The agenda will include topics such as domestic case studies, regulatory collaboration, communications and international engagement.

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 address farming productivity, GLI members participate in international and regional discussions to raise awareness of asynchronous approvals, and best practices to mitigate trade implications.

Since March 2019, work has been done to raise awareness of WTO members on this topic, through information sharing, a side event on LLP and a thematic session on approval procedures.

The FAO has also been engaging on this topic, through its GM Food Platform initiative. In September 2019, the FAO brought together officials from over 70 countries to explore how the Platform could be better utilized to help inform domestic decision-making related to approvals of products of biotechnology, as well as potential areas of cooperation between members.

As the number and complexity of genetically modified crops developed and cultivated worldwide increases, Canada, and GLI members, will continue to 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 Secretariat is led by Agriculture and Agri-Food Canada and can be contacted at AAFC.GlobalLLPInitiative-InitiativeGlobalesurlaPFC.AAC@CANADA.CA

5. Feed Regulatory Renewal Project

During 2019/20, 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 2020. 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 the remainder of 2020. 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.

6. Nanotechnology *(no update since last meeting)*

Currently, Health Canada is using existing legislative frameworks to regulate applications of nanotechnology. However, it recognises 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. Basically, this regulatory framework will establish the procedures to import, produce and sell food and feed produced from LMOs. However, the parties 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 feed.

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 is new Commission Implementing Regulation (EU) 2019/1981 in force with a list of third countries and regions thereof authorised for the entry into the European Union of insects intended for human consumption. There are three countries on the list: Canada, Switzerland and South Korea.

2. Field trials

Only 3 field trials were carried on in the growing season 2019, all for research purposes. Total area of the trials was only few hundred m².

- Plum trees with a modification conferring virus-resistance (resistance to plum pox), notified by the Crop Research Institute, Prague;
- Soy with gene LTB (scientific project, a few plants), notified by Institute of Experimental Botany, Czech Academy of Science, Prague;
- 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.

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

Organisms produced by new breeding techniques (gene editing) are used in contained space only – in laboratories, greenhouses, breeding facilities, industrial premises. Research projects with gene edited laboratory animals, plants and microorganisms are 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 soya 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” labelling scheme is approved for use in Finland, and the Finnish Food Authority has given guidance on the conditions of its use (https://www.ruokavirasto.fi/globalassets/tietoa-meista/asiointi/oppaat-ja-lomakkeet/yritykset/gm-tuotteet/gmo-vapaa-ohje_06032017_en.pdf, available in Finnish, Swedish and English). Some “GM free” labelled foods are on the market.

No unauthorised GM control cases have 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 is one field trial with hybrid aspen ongoing. The trees are conventional transgenic GMOs. All the currently ongoing clinical trials with GMMs have been considered as contained use, not deliberate release, and the organisms used in the clinical trials have all been conventional transgenic GMOs. The number of clinical trials with GMOs is still rising in Finland.

A national act on restriction of the cultivation of GMOs (445/2019) came into force 1st January 2020. This act provides for national arrangements for amending Directive 2001/18/EC as regards the possibility for Member States to restrict or prohibit the cultivation of GMOs in its territory under the provisions of Directive (EU) 2015/412.

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.). In addition, Finland will answer the Commission questionnaire on new genomic techniques via EU survey before 30 April 2020. The discussion continues at the EU level and the need for amending GMO Directives 2001/18/EC and 2009/41/EC to adapt them to the ongoing technical progress has been expressed.

The Committee for the Future of the Parliament of Finland has after the publication on Gene technology (2/2018) continued following the topic and made a further statement on the development of gene technology 2018-2020 in different fields of importance. There is also a joint governmental study starting on 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 a great interest in cultivation and utilization of hemp and hemp derived products (such as cannabinoids) as food. The historical use of hemp and the use of different parts of the plant as food are currently being clarified and discussed in working groups of the EU Commission. Finland follows the interpretations agreed commonly in the EU and written down in the Commission Novel Food Catalogue (https://ec.europa.eu/food/safety/novel_food/catalogue_en). Extracts containing cannabinoids such as cannabidiol have been considered as unauthorised novel foods and such products have been withdrawn from the Finnish market.

Interest in rearing and utilising insects as a food or feed has continued in Finland. The novel food status of insects is clear in the new novel food Regulation (EU) 2015/2283. 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 authorisations are finalised. 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/yritykset/elintarvikeala/alkutuotanto/eviran_ohje_10588_2_uk.pdf, available in Finnish, Swedish and English). In the feed sector growing and using insects is also possible as long as applicable rules are followed.

GERMANY

1. Genetically modified organisms (GMO)

The situation in Germany regarding GM products remains unchanged. GM crops are not cultivated and there was no deliberate release of GMOs for field trials. Since there is only a low level of acceptance of GM food in Germany, only very few foodstuffs labelled as genetically modified are sold on the market. There is a voluntary labelling “Ohne Gentechnik” (“GM free”) that can for example be used for food derived from animals that are fed feedstuff not labelled as “genetically modified” during a certain time of their lifespans (feeding periods).

2. New Plant Breeding Techniques (NPBTs)

The topic of NPBTs, especially Genome Editing, is discussed controversially in Germany. Up to now there is to the knowledge of the Federal Ministry of Food and Agriculture no cultivation of NPBT-crops and no deliberate release of NPBT-plants for field trials in Germany.

According to the ruling of the Court of Justice of the European Union (ECJ) of 25th July 2018 organisms obtained by mutagenesis techniques are GMOs, fall within the scope of Directive 2001/18/EC and are thus subject to the obligations laid down by that directive. However, the GMO Directive does not apply to organisms obtained by mutagenesis techniques which have conventionally been used in a number of applications and have a long safety record (basically conventional mutagenesis).

3. Research Activities

The German government funds several research projects related to NBTs and NPBTs. Funding is furthermore provided for fundamental research in this area and projects on analytical aspects.

One of the projects is “ELSA-GEA (Ethical, Legal and Socio-economic Aspects of Genome Editing in Agriculture)” funded by the German Federal Ministry of Education and Research. – Within this project, a comprehensive and transdisciplinary approach is applied to broadly address the aspects of genome editing in the agricultural context. Ethical, legal, socio-economic and communicative as well as risk assessment issues are considered in a systematic process for crop plants. Based on a broad spectrum of results from the different disciplines, structured information will be provided to enable a rational societal dialogue on genome editing in agriculture. Publications addressing policy makers and professional stakeholders on the one hand and a broader public on the other hand will support an informed public debate. The final report is expected by end of April 2020.

Publications:

- Beyond risk considerations: Where and how can a debate about non-safety related issues of genome editing in agriculture take place? 2018. <https://doi.org/10.3389/fpls.2018.01724>
- Which organisms and technologies fall under the mutagenesis exemption of the European GMO-Directive? 2018. <https://doi.org/10.1007/s00003-018-1166-9> (published before the ECJ judgement)
- Roads Forward for European GMO Policy—Uncertainties in Wake of ECJ Judgment have to be Mitigated by Regulatory Reform. 2019. <https://doi.org/10.3389/fbioe.2019.00132> (published after the ECJ judgement)
- Socioeconomic Impact of Genome Editing on Agricultural Value Chains: The Case of Fungal-Resistant and Coeliac-Safe Wheat. 2019. <https://doi.org/10.3390/su11226421>
- What is the available evidence for the application of genome editing as a new tool for plant trait modification and the potential occurrence of associated off-target effects: a systematic map protocol. 2018. <https://doi.org/10.1186/s13750-018-0130-6>
- What is the available evidence for the range of applications of genome-editing as a new tool for plant trait modification and the potential occurrence of associated off-target effects: a systematic map. 2019. <https://doi.org/10.1186/s13750-019-0171-5>
- Regulation of GM Organisms for Invasive Species Control. 2020. <https://doi.org/10.3389/fbioe.2019.00454>

Another ongoing R&D project deals with “New technologies in genetic engineering law: European and national regulatory options”. Within this project, two legal opinions have already been published, which are available on the website of the Federal Agency for Nature Conservation:

- Memorandum on the question of the applicability of the statements of the European Court of Justice in case C- 528/16 to the area of regulation of Directive 2009/41/EC on the contained use of genetically modified micro- organisms.
(https://www.bfn.de/fileadmin/BfN/recht/Dokumente/Spranger_Dir_2009_41_EC_contained_use_C_528_16.pdf)
- Memorandum on the international trade law implications of the judgment of the European Court of Justice in case C-528/16. (https://www.bfn.de/fileadmin/BfN/recht/Dokumente/Spranger_int_trade_law_implications_C528_16.pdf)

4. Outreach and communication

In addition, the German government funds outreach and public communication projects and events.

The German Federal Ministry of Food and Agriculture hosted for example a dialog event (“Forum NBT 2019”) in June 2019. With about 110 attendees, we discussed consequences of the ECJ judgement and the question what could be an adequate legislation framework for NBTs that respects economic, ecological and social aspects. (Further information: https://www.bmel.de/DE/Landwirtschaft/Pflanzenbau/Gentechnik/_Texte/Bericht-Forum-NMT.html, German only.)

Another example is the “Consumer Conference on Genome Editing in the Field of Nutrition and Human Health” hosted by the German Federal Institute for Risk Assessment in autumn 2019. The conference aimed at obtaining nuanced viewpoints from informed consumers on the application of genome editing in the fields of nutrition and human health in form of a consumer vote.

- Consumer vote: <https://www.bfr.bund.de/cm/349/consumer-vote-genome-editing.pdf>
- BfR Communication: <https://www.bfr.bund.de/cm/349/the-bfr-genome-editing-in-the-field-of-nutrition-and-human-health-consumer-conference-startson-10th-august-2019.pdf>

ITALY

1. Legislative framework and GMOs

As a member of the EU, generally EU regulations on biotech products also apply to Italy. Since July 2013, Italy has been banning the cultivation of GM crops, even for GM seed production

Therefore, public and private research funding on GM products has gradually been cut to zero and currently no GM field trials are being conducted in Italy.

Regarding GM animals and clones, GM in Italy is focused on genomic selection to improve animal breeding and is primarily used for medical or pharmaceutical applications. Italy does not produce cloned animals for commercial purposes. There is, however, one genetic research centre, Avantea Ltd., located in Cremona (CR).

Avantea Srl is a laboratory of advanced technologies for animal reproduction and biotechnology research. Here a list of selected publications in internationally reviewed journals in 2019: <https://www.avantea.it/en/avantea/research-publications/>

2. New Plant Breeding Techniques/ Innovative Biotechnologies

On July 25, 2018, the European Court of Justice ruled that organisms created through newer genome-editing techniques are to be regulated as “GMOs” in the EU. Italian reaction to the ruling was mixed, with some farmers’ and consumers’ association warmly welcoming the decision, while others farmers’ associations and the agri-food industry describing it as a setback for and innovation and cutting-edge science. Despite Italy’s strong opposition to GE products, a growing number of Italian farmers, agri-food industry players, and scientists have come forward in favour of innovative biotechnologies, such as cisgenesis and genome editing.

On May 18, 2018, MIPAAF (Italian Ministry of Agricultural, Food, and Forestry Policies) approved a three-year sustainable agriculture research plan ‘BIOTECH’ (€6 million in Italy’s budget) coordinated by the Italian Council for Agricultural Research and the Analysis of Agrarian Economy (CREA – in Italian). The research focuses on genome editing and cisgenesis for grapevine, olive, apple, citrus fruit, apricot, peach, cherry, strawberry, kiwifruit, eggplant, tomato, basil, artichoke, wheat, rice, and poplar trees. This is the first national plant biotechnology project

since '90. It promotes the diffusion on new breeding techniques in Italian scientific community (Italy has a strong history in plant breeding and plant genomics, but plant biotechnology was limited after the GMO ban). The project has been prepared on the current legislation: it does not carry out field trial for genome edited or cisgenic plants. In 2021, when the project will close, a decision will be taken about the plant generated by BIOTECH, based on the legislation in force at that time.

The National Agency for New Technologies, Energy and Sustainable Economic Development (ENEA, public body) has been involved in the genetic improvement of species of agricultural interest since the late 1950s. Currently two different research groups continue to do so using innovative biotechnology:

- 1) Introducing Potato virus Y (PVY) resistance in potato through a transgene-free genome editing approach.
- 2) Genome editing for the modulation of tomato nutritional (carotenoids and apocarotenoids) and anti nutritional (Glycoalkaloids and allergens) attributes.
- 3) Crispr-Cas9 tomato plants (currently under omics multi-level characterisation (at phenomics, transcriptomics and metabolomics level) in which the levels of glycoalkaloids and the allergen Sol t 4 were reduced by the knocking out of corresponding synthetic genes.
- 4) production of pro-nutritional compounds in the carotenoid pathway, in order to increase the levels of lycopene and β -carotene in edited fruits.

An agreement is coming soon that will open a new perspective for the Italian world of biotechnology in agriculture: Coldiretti and the Italian Society of Agricultural Genetics (Siga) will soon sign a collaboration agreement on new genetic engineering techniques

Recently, the European Council requested the Commission to conduct a study presenting an overview of the state of the art of NBT potential challenges and possible ways of implementing the judgment of the Court of Justice of the European Union in case C-528/16. The study will be conducted directly by the Commission and the results should be ready by April 2021. The Commission intends to respond to the Council's request by working together with the Member States (MS). The Commission will analyse and evaluate the responses received and may request further clarification.

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. Updated information on 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 March 2020, 322 GM foods (10 potatoes; 28 soybeans; 3 sugar beets ; 206 corns; 22 oilseed rapes; 47 cottons; 5 alfalfas; and 1 papaya) and 44 GM food additives have been approved ; 2 foods and 4 food additives are newly approved since the last meeting in April 2019.

3. Updated information on 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 March 2020, 93 GM feeds (18 oilseed rapes; 29 corns; 18 soybeans; 21 cottons; 3 sugar beets; 3 alfalfas; and 1 potato) and 12 feed additives have been approved; 1 feeds and 2 feed additive are newly approved since the last meeting in April 2019.

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.

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. 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/index.html>

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; 32 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 commercialisation in January, 2020. A third application for environmental release of genetically modified Gypsophila was rejected. Details of these decisions are available through our website www.biosafetykenya.go.ke/.

In the intervening period since the last OECD meeting in 2019, the following decisions have been made:

i) Environmental release

The two approvals for limited environmental release include Bt-maize (MO810) and Bt cotton (MON15985) which were both approved in 2016 for National Performance Trials. Since then, the National Performance Trials for

Bt- cotton commenced with planting initiated in seven sites within the country. The first and second season of NPTs were concluded in January and October, 2019, respectively. The results from the NPT trials led to approval of four Bt cotton varieties by Kenya Plant Inspectorate Services (KEPHIS). The approval for release of the four Bt cotton varieties was based on superior performance in comparison to a local check variety.

Due to GMO import ban imposed in 2012, the Bt cotton issue was tabled to Cabinet for direction. Following the Cabinet meeting held on 19th December 2019, the Government approved the commercialisation of Bt cotton varieties in Kenya and other crops to be considered on case by case basis. Following the cabinet decision the National Biosafety Authority issued approval document to the Applicant (Monsanto Kenya Ltd, now Bayer East Africa) for MON 15985 Bt cotton to allow for full commercialisation in Kenya on 28th January, 2020. The approval is for an initial period of 10 years which is renewable.

Following the approval of Bt cotton for environmental release, the developer has embarked on a country wide demonstration farms within the cotton growing regions of the country. It is envisaged that Bt cotton seeds will be made available to the farmers for planting during the short rainy period in October-November period.

The Bt maize has also proceeded to the first National Performance Trials while, the third application for environment release and placing in the market of genetically modified cut flower, Gypsophila was reviewed during the intervening period. The final decision was to reject the application on the grounds that approval would have disrupted the huge floriculture market, specifically in the European Union where the modified flower is not approved.

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
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.

iii) Contained use approvals

The Authority has so far approved 32 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, three 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 reviewing the following documents in preparation for possible commercialisation of GMOs into the country. The documents include; i) Post Release Monitoring Manual, ii) Coexistence Policy and iii) LLP and AP Guidelines. The process of development of the above documents include a survey 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 finalised by the end 2020.

4. Regulation of products derived from New Plant Breeding techniques

Kenya at the moment does not guidelines on regulation of products derived from New Plant Breeding Techniques. It is anticipated that within the next two years, guidelines on how to regulate search products will be developed.

The OECD organised meeting on Genome Editing in 2018 could not therefore have come at a better time as Kenya prepares to develop guidelines. The first brain storming meeting on development of guidelines for regulations of products developed through genome editing was held in April, 2019. A second Stakeholders validation workshop was held on 28-29th November, 2019. The document awaits final approval by Board of Management.

In the meantime, Kenya has proceed to review applications using the New Plant Breeding Techniques with five of such projects already approved as contained use projects under BSLII laboratory containment facilities. The approved projects include use of CRIPR/Cas9 (**development of virus resistant banana and virus resistant and vit A enhanced yam**); 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 National Biosafety Conference is scheduled for 18th - 21st August, 2020. This is one of the forum through which the Authority raises awareness on Biosafety matters to a wide spectrum of stakeholders. It is also an opportunity to show-case the various developments in the country and in the global arena. The first two days (18th-19th August, 2020) will be dedicated to pre-conference course on Genome Editing. The target group for the pre-conference courses are post graduate students and young researchers. The main conference (20- 21st August, 2020) will have key note addresses and presentation from the submitted abstracts.

KOREA

1. Regulatory framework

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

Since the last update in Oct 2019, the Rural Development Administration (RDA) and the Ministry of Food and Drug Safety (MFDS) have approved 5 new LMOs for food, feed and processing use, but none for environmental release or cultivation as follows:

- a. RDA (164 events): Soybean (29), Corn (85), Cotton (31), Canola (14), Alfalfa (5)
- b. MFDS (177 events): Soybean (29), Corn (88), Cotton (29), Canola (15), Alfalfa (5), Sugar beet (1), Potato (4), Microorganism (6)

Further information is available at <http://www.biosafety.or.kr>.

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

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

The Ministry of Agriculture, Food and Rural Affairs has revised the Feed Control Act to indicate that imported LMOs have been used as feedstuffs in packaging materials and containers manufactured and processed using LMO as a raw material.

2. Biosafety Issues

a. Social consultation related to genetically modified food labelling system

Consumers and NGOs criticized that the revised regulation does not satisfied the consumers' demand to know not only the information after processing but also the information about the crops that were used. The petition from March 2018 demanded that the government revise the GMO regulation to meet international standards. The Petition group has been demanding that i) label the use of GMOs without exception, ii) prohibit the use of GMOs in public school meals. It also called for a revision of the Ministry of Food and Drug Safety's law that prevents food products from having "Non-GMO" on labels.

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

b. Unauthorised genetically modified canola

In May 2017, genetically modified canola which was not approved for agricultural use was found for the first time at a flower festival site. The government had conducted an environmental impact assessment for two years, it was considered until now there is no impact on natural ecosystems.

3. New Breeding Techniques

Korean government faces a strong demand from researchers and companies to clarify the regulatory status of organisms developed through the use of genome editing techniques. The ministry of Trade, Industry and Energy has hosted working group meetings with related interagency regulators and open meeting about possible future regulation of the New Breeding Techniques. The Working Group is discussing the direction of regulation of new breeding technologies and will decide the direction of regulation within the year through stakeholder public hearings.

LATVIA

1. Novel food/feed safety issues in general

As part of the European Union, Latvia has the same legal framework on GMOs as other Member States of the Union.

Latvia has adopted amendments to the Law on Circulation of Genetically Modified Organisms (the Law) in 2019. The amendments to the Law to clarify administrative penalties for GMO circulations violations, requirements for control of GM seeds and animals, responsibilities of competent authorities.

There has not been any application submitted to the Competent Authority of Latvia in respect to a deliberate release or placing on the market of GMOs. However, GM food and feed that have been approved for marketing in the EU are found on Latvian market

GM crops are not cultivated in Latvia. However, the animal feed sector is very dependent on imported protein, which includes GM soya and maize ingredients.

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.

Latvia has been involved in the European Food Safety Authority (EFSA) consultation for placing on the market of GMOs. Input in the risk assessment is provided through the Scientific Expert Commission, which, besides food and feed aspects, also evaluates environmental impacts of GMOs. The State Scientific Institute "Institute of Food Safety, Animal Health and Environment "BIOR"" (BIOR)) ensures the secretariat functions of the Scientific Expert Commission and provides permanent scientific support to its activities., The risk assessment was carried out on GM soybean, rapeseed, maize and cotton in 2019.

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.

2. New Breeding Techniques (NBTs) and new technologies

Latvia has not received any applications for approval of varieties for cultivation or field trials of plants produced by new plant breeding techniques.

There are also no registered varieties with new mutagenesis techniques in Latvian national catalogue of varieties.

According to the decision of the European Council of November 8th 2019, the Commission is supposed 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” by April 30th 2021. At the same time, it is requested to submit “a proposal, if appropriate in view of the outcomes of the study”, or otherwise inform the Council of necessary action required following the study. The MS and selected EU-level stakeholder organisations to support the Commission study, by participating in the survey on new genomic techniques to contribute to the study requested by the Council.

Since the Decision of the European Court of Justice (ECJ) ruling, Latvia 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.

According to the Decision of the EJC, the National Reference GMO laboratory of Latvia needs more workshops and training for detection and identification of a genome-edited product. Therefore, the Ministry of Agriculture supports research activities in the area of NBTs. Scientists from the BIOR and the Latvian University participate in the project ““Detection of food, feed and food additives obtained by NBTs and scientific risk assessment of such products”. The main objective of the project is to evaluate of diagnostic methods and potential risks of food, feed and their additives obtained by NBTs in Latvia.

There has also been regional cooperation on NBTsNordic/Baltic project workshop on "Ecological and socio-economic impacts of gene drive organisms" held in Tallin, Estonia, 24 – 25 October 2019. The main aim of the workshop was to facilitate the dialogue and knowledge-exchange between the GMO-authorities in the Nordic and Baltic countries, to learn more about the scientific developments of gene drive organisms, and to provide productive discussions on crucial issues of environmental risk assessment management, socio-economic considerations and regulatory frameworks of gene drive organisms. This in turn can provide valuable input from the Nordic and Baltic countries into the current processes on gene drive organisms regionally and internationally.

The Nordic/Baltic GMO meeting “We cannot detect it – what is the way forward? – The European Court of Justice decision on mutagenesis and its implications for GMO control” was held in Roskilde, Denmark, 30. September - 2 October, 2019. The colleagues from the competent authorities (CA) responsible for GMO (food, feed and seed) discussed the challenges and implementation measures after the European Court of Justice’s ruling on the interpretation of the Directive 2001/18/EC on deliberate release and new mutagenesis techniques.

NETHERLANDS

General

As a member of the European Union (EU), The Netherlands implement EU community-level decisions and regulations on genetically modified foods and feeds at the national level.

1. New Plant Breeding Techniques:

In The Netherlands (as an EU member state), plants obtained through gene editing and other new breeding techniques are subject to EU legislation (which is implemented at the national level).

The National Commission on Genetic Modification (COGEM) hosted an international conference on the topic of “Gene edited crops: Global Perspectives and Regulations” in autumn 2019. The conference report is available in PDF format at the following website: <https://cogem.net/app/uploads/2020/01/200115-01-COGEM-symposium-gene-edited-crops-global-perspectives-regulation.pdf>

SLOVAK REPUBLIC

Current developments since the last meeting

Current developments on novel foods/feeds safety assessment in the Slovak Republic since the last meeting are mainly focused on NBT, what is a new and highly discussed topic. In the area of the Slovak Republic, NBT have not been developed recently, but there are many questions coming from the science sector, agricultural sector and state authorities responsible for legislation and control that need to be answered. The Slovak Republic as the member of the European Union has unified rules of legislation approach and methodological principles with all other member states. In nowadays, there are intensive discussions at the EU level and in the spring of 2021 there should be „clear rules“. The Slovak Republic is in favour to support scientific development and, at the same time, to protect environment and to ensure human and animal health. Slovak people are in favour of novel foods and feeds, and prefer those without GMO.

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.

In 2019 we tested samples of feed and food. In 2020, Slovenia is continuing the testing of the presence of GMOs in food and feed.

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 2019, 23 samples of seeds of maize, rapeseed and soybean were analysed. Among them, 15 samples of maize seed, 4 samples of rapeseed and 4 samples of soybean were tested for the presence of GMOs. All 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 or maize, rapeseed or soya). In case of soybean additionally MON 87701 (MON-87701-2), MON87769 (MON-87769-7), DP305423 (DP-305423-1), MON87708 (MON-87708-9), CV127 (BPS-CV127-9), were tested, because they are not covered by five-target method. 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 2019, we did not sample agricultural plants for the presence of GMOs under the law on the coexistence of crops with genetically modified plants. We are planning to collect 12 samples for 2020.

3. Laboratory's Capacity for GMOs detection

The 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 78 qPCR accredited methods for qualitative and quantitative testing of genetically modified organisms in foodstuffs and agricultural products of plant origin and further methods are in the process of verification and some on dPCR. Digital PCR is the most recent approach in PCR 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](#)])). 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.

4. 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/>).

Within a national project »Procedures for ensuring safety and social acceptability of new techniques and applications of synthetic biology and modern biotechnology« the applicability of existing approaches for risk assessment of products of modern biotechnology and synthetic biology was assessed with a view to ensure high level of biosafety. Appropriate amendments to the existing biosafety framework were proposed where needed. In addition, a set of socio-economic factors associated with wide use of new techniques was defined. Results of the project will be important for deciding on the necessity of adjustment or upgrading the existing biosafety system in Slovenia.

(https://www.sicris.si/public/jqm/prj.aspx?lang=eng&opdescr=search&opt=2&subopt=400&code1=cmn&code2=auto&psize=1&hits=1&page=1&count=&search_term=šuštar vozlič&id=10371&slng=&order_by=).

SOUTH AFRICA

1. GM crop production in South Africa update

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

In the field of biotechnology, South Africa is the leader in Africa. No updated figures for 2019/2020 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).

It is estimated that the economic gains from biotech crops for South Africa for the period 1998 to 2016 was about US\$2.3 billion and US\$330 million for 2016 alone (ISAAA brief 53 of 2017).

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

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

Application of the Act

This Act shall apply to:

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

Executive Council

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

Functions of Advisory Committee

(1) The Advisory Committee (AC) shall:

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

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

Appointment of registrar

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

The registrar:

- a. is charged with the administration of this Act;

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

Functions of registrar

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

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

3. Department of Agriculture Forestry and Fisheries (DAFF) (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 Department of Agriculture Forestry and Fisheries (Directorate Genetic Resources) is the recognised Competent National Authority for South Africa and is responsible for ensuring that all provisions and obligations relating to the Protocol are met.

4. New GM approvals in South Africa

The new commodity clearance approvals since the last meeting are presented in Table 1 and are indicated in bold text (*added to the list after the 2019 bio/food safety meetings held in Paris*).

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

Event	Crop	Trait	Company	Year approved
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

The new general release approval since the last meeting is presented in Table 2 and is indicated in bold text (*added to the list after the 2019 bio/food safety meetings held in Paris*).

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

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

Event	Crop	Trait	Company	Year approved
MON89034 x TC1507 x NK603	Maize	Insect resistance Herbicide tolerance	DowAgroSciences	2018
Innovcax-ND	Vaccine	-	Intervet	2015
Vectormune HVT NDT & Ripens	Vaccine	-	Ceva Animal Health	2015
MON87460	Maize	Drought tolerant Antibiotic resistant	Monsanto	2015

5. Genome editing research and activities in South Africa

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

Genome editing workshop

The African Centre for Gene Technologies (ACGT) is an initiative that involves the Council for Scientific and Industrial Research CSIR, the University of Pretoria, the University of the Witwatersrand (WITS), the University of Johannesburg (UJ) and the Agricultural Research Council (ARC). The aim is to create a collaborative network of excellence in advanced biotechnology, with specific focus on the “-omics”.

The ACGT and the ARC hosted a plant genome editing workshop between the 3rd and the 5th of September 2019 at the ARC’s Biotechnology Platform. Scientists from the Karlsruhe Institute of Technology, Germany (KIT) presented a “starter kit” for model plant CRISPR-related work in South Africa.

The three-day workshop included both theory and practical sessions during which the participants were introduced to gene targeting in plants by using the CRISPR/Cas9-system.

The plant genome editing community in South Africa is a small, but growing one. The workshop provided an opportunity for scientists in the field to be aware what other institutions in the region are doing in the plant genome editing space. The ACGT facilitated the process by creating a CRISPR list server and subsequently a Genome Editing Interest Group. The participant feedback indicated that both the extensive theoretical overview of the different technologies, combined with the KIT CRISPR experts’ practical experience, provided key insights into the technology during the practical sessions, with details often not provided in laboratory protocols or papers.

CRISPR/Cas9 research at the ARC Biotechnology Platform

Project Title: 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 homologues repair that is part of the CRISPR/Cas9 technology. They are also investigating different delivery systems for the CRISPR construct and donor templates, including *Agrobacterium* transformation.

CRISPR/Cas9 research at the CSIR and UP

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/Cas9 research at the University of the Witwatersrand

Project Title: CRISPR gene editing to improve the crop cassava.

Objective: To improve resistance to cassava mosaic disease.

Aim: To identify natural resistance in cassava by identifying genes or proteins involved in susceptibility and tolerance/resistance in cassava germplasm.

Project approach: The project has identified putative genes involved in effector triggered resistance (ETI) and basal resistance (RNA silencing) and they are knocking them out using the CRISPR/Cas9 system of editing. They have developed a high throughput system of screening using cassava protoplasts. They also have developed vectors for knocking out candidate genes in cassava in planta.

Long term objective: Should candidate genes be identified, CRISPR/Cas9 gene editing could be used to edit cassava for greenhouse and field trials to screen for virus resistance.

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

Project Title: Functional genetic analysis of cellulose and xylan related genes affecting woody biomass processing

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

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

When Dr D Oelofse (ARC) requested information from some of the stakeholders on research being performed using NPBTs in South Africa, they all expressed their interest in receiving the information on NPBTs contained in the OECD *Tour de Table*, as submitted by the delegations attending the OECD Working Group on the Harmonisation of Regulatory Oversight in Biotechnology (WG-HROB) and the OECD Working Group on the Safety of Novel Foods and Feeds (WG-SNFF) meetings. This includes research institutions, universities, Biosafety South Africa, the Department of Agriculture Forestry and Fisheries (DAFF), the Department of Science and Innovation (DSI), and the Technology and Innovation Agency (TIA). Biosafety South Africa and the DSI/TIA unit for promoting biosafety in South Africa, 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 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 WG- HROB and the OECD WG-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.

6. Usefulness of the OECD Biology documents

Biosafety South Africa is a platform within the national Technology Innovation Agency, which is an initiative of the national Department of Science and Technology. 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 comprehensive list of published biology consensus documents on commercially released GM crops, as well as those GM crops with potential for commercialisation in South Africa.

Cassava	- http://biovisionestafrica.com/publications/Cassava%20biology%20document.pdf
Cotton	- http://www.oecd.org/olis/2008doc.nsf/LinkTo/NT0000794A/\$FILE/JT03257
Maize/ Corn	- http://www.inspection.gc.ca/english/plaveg/bio/dir/dir9411e.pdf - http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/650f3e0dfb990fca25692100069854/330c90ca0496618fa2574d0001d4dd6/\$FILE/biologymaize08.pdf - http://www.oecd.org/olis/2003doc.nsf/LinkTo/NT0000426E/\$FILE/JT00147699.PDF
Potato	- http://www.oecd.org/dataoecd/25/62/27854542.pdf
Soybean	- http://www.inspection.gc.ca/english/plaveg/bio/dir/t11096e.pdf - http://www.oecd.org/olis/2000doc.nsf/LinkTo/NT00002C3A/\$FILE/00085953.PDF
Sugar Beet	- http://www.oecd.org/olis/2001doc.nsf/LinkTo/NT0000096E/\$FILE/JT00118011.PDF
Sugar Cane	- http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/sugarcane-3/\$FILE/biologysugarcane.pdf
Sunflower	- http://www.oecd.org/olis/2004doc.nsf/LinkTo/NT000092F2/\$FILE/JT00177388.PDF
Wheat	- http://www.ogtr.gov.au/internet/ogtr/publishing.nsf/Content/wheat-3/\$FILE/biologywheat08.pdf - http://www.oecd.org/olis/1999doc.nsf/LinkTo/NT00002B2A/\$FILE/04E94444.PDF

SWITZERLAND

1. Food control 2018

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 2018 have been published in August 2019 by the Federal Food Safety and Veterinary Office.

Year	2018	2017	2016	2015	2014
total samples	244	493	377	303	506
negative	228 (93%)	434 (88%)	335 (89%)	276 (91%)	480 (95%)
positive	16 (7%)	59 (12%)	42 (11%)	27 (9%)	26 (5%)

In 10 of the 16 samples tested positive in 2018, 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 4 samples, the level was above 1%.

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> (Statistics and reports: Food safety>Foreign substances and components in foodstuffs>GMO products in foodstuffs)

2. Feed control 2018

Feed materials derived from GMPs for farm animals have not been imported in 2018, according to the Agricultural Report 2019 published by the Federal Office for Agriculture in 2019. Actually, no such imports have been reported since 2008.

In 2018, 370 samples of imported feedstuffs for farm animals were tested for the adventitious presence of material derived from GMPs. All the materials tested met the pertinent legal requirements.

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

3. Moratorium on commercial cultivation of GM plants

A moratorium on the use of GMPs in agriculture, horticulture and forestry, laid down in the Gene Technology Act as of 1 January, 2018, is in effect until the end of 2021.

4. Field trials with GM crop plants

Field trials with GMPs are ongoing since 2014 on a three hectare test field in Zurich equipped to counter the threat of violence ('Protected Site') and run by the Swiss federal research institute for the agri-food sector, Agroscope.

A multi-year field trial with GM spring wheat with increased resistance to the fungal disease powdery mildew (*Blumeria ex Erysiphe graminis*) conducted by the University of Zurich and Agroscope ended with the 2018 season. Surveillance after the trial is ongoing.

A multi-year field trial with GM potatoes has been conducted by Agroscope between 2015 and 2019. 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*).

A multi-year field trial with GM apple trees is being conducted by Agroscope after authorisation was granted in April 2016. The plants have been produced by Agroscope using genetic material from a crab apple species (*Malus ×robusta*) leading to an increased resistance to the bacterial disease fire blight (*Erwinia amylovora*). The trees have been planted in 2016. The trial will be continued until 2021.

A multi-year field trial with GM winter wheat is being conducted by Agroscope after authorisation was granted in October 2016. The plants express 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). The wheat has been sown in October 2018 for the third year. The trial will be continued until 2022.

A follow-up multi-year field trial with new GM spring wheat lines with increased resistance to powdery mildew has been authorised. The wheat has been sown in 2019 for the first year. The trial will be continued until 2023.

Authorisations for two multi-year field trials with GM maize and GM barley, respectively, both with increased resistance to fungal diseases, have been granted to the University of Zurich. The trials are planned to start in 2020.

Further information is available under <https://www.agroscope.admin.ch/agroscope/en/home/topics/environment-resources/biosafety/gv-pflanzen/protectedsite.html>

5. New techniques in biotechnology

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

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

Meanwhile, the Federal Council has confirmed in a response to 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.

6. Nanotechnology

'InfoNano' is the Swiss federal authorities central information hub for nanotechnology. It provides information on the opportunities and risks associated with nanomaterials, illustrates where nanomaterials are used and describes the goals and milestones of the 'Action plan for synthetic nanomaterials'. Key topics include guidelines on safe use, promotion of public dialogue, key research and regulatory updates.

Further information is available under

<https://www.nanopartikel.info/en/switzerland/1021-infonano-2>

UNITED STATES

1. Modernising the Regulatory Framework for Agricultural Biotechnology Products

On June 11, 2019, President Donald J. Trump signed the Executive Order on Modernizing the Regulatory Framework for Agricultural Biotechnology Products. This executive order calls for, among other things, regulatory streamlining in order to facilitate the innovation of agricultural biotechnology to the market efficiently, consistently, and safely under a predictable, consistent, transparent, and science-based regulatory framework. The Executive Order can be accessed at <https://www.whitehouse.gov/presidential-actions/executive-order-modernizing-regulatory-framework-agricultural-biotechnology-products/>.

2. Unified Website for Biotechnology Regulation

On January 9, 2020, the U.S. Food and Drug Administration, the Department of Agriculture and the Environmental Protection Agency launched a Unified Website for Biotechnology Regulation. The website streamlines information about the three regulatory agencies charged with overseeing agriculture biotechnology products and is part of President Donald J. Trump's Executive Order on Modernizing the Regulatory Framework for Agricultural Biotechnology Products. The Unified Website for Biotechnology Regulation describes the federal review process for certain biotechnology products and allows users to submit questions to the three agencies. The goals of this website are to provide enhanced customer service to innovators and developers, while ensuring Americans continue to enjoy the safest and most affordable food supply in the world and can learn more about the safe use of biotechnology innovations. The Unified Website for Biotechnology Regulation can be accessed at <https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/home/>.

3. U.S. Food and Drug Administration Regulatory Update

Plant Biotechnology

Since the last meeting of OECD Working Group for the Safety of Novel Foods and Feeds in April 2019, the Food and Drug Administration (FDA) completed consultations on the following new plant varieties:

TAM66274 cotton from Texas A&M AgriLife Research, genetically engineered to have reduced levels of gossypol in seed while maintaining normal gossypol levels in the rest of the plant. TAM66274 cotton was engineered with inverted repeat nucleotide sequences of the *delta cadinene synthase* gene from *Gossypium hirsutum* under control of a seed specific promoter and the *neomycin phosphotransferase type II* gene from *Escherichia coli* transposon Tn5. Texas A&M's intended uses for TAM66274 in human food include general uses customary for conventional cotton and uses authorised for glandless cottonseed in 21 CFR §172.894. Texas A&M's intended uses for TAM66274 in animal food include general uses customary for conventional cotton (including hulls, meal, and other cotton plant byproducts in ruminant diets and low gossypol cottonseed meal in animal diets).

Fuji apple variety OKA-NB003-1 intended to reduce enzymatic browning and bruising, from Okanagan Specialty Fruits, Inc., expressing gene segments from four polyphenol oxidase genes from *Malus x domestica* and the neomycin phosphotransferase type II (NPTII) protein from *Escherichia coli* transposon Tn5.

Additional information regarding FDA consultations on new plant varieties is available at <https://www.accessdata.fda.gov/scripts/fdcc/?set=Biocon>.

Animal Biotechnology

FDA’s Center for Veterinary Medicine (CVM) is planning to hold a series of six animal biotechnology stakeholder outreach meetings in agricultural regions of the country and in the Washington, D.C. area directed towards various stakeholder audiences (farmers, producers, academia, industry, professional organisations, etc.). Timing for the meetings is dependent on lifting of restrictions associated with the Corona virus pandemic. The goal of these meetings will be to collect feedback on ways to enhance predictability, transparency, and efficiency of the review process for intentional genomic alterations in animals and to incorporate these ideas as enhancements to the Veterinary Innovation Program. We will also be presenting case studies with information about CVM’s risk assessment process as well as data requirements for approval. This information will help developers understand the data requirements for specific product types and intended uses prior to investing in the development of a new product.

Agricultural Biotechnology Education and Outreach Initiative

On March 4, 2020, the U.S. Food and Drug Administration, in collaboration with the U.S. Environmental Protection Agency and the U.S. Department of Agriculture, launched a new initiative to help consumers better understand foods created through genetic engineering, commonly called GMOs or genetically modified organisms.

The initiative, “Feed Your Mind,” aims to answer the most common questions that consumers have about GMOs, including what GMOs are, how and why they are made, how they are regulated and to address health and safety questions that consumers may have about these products.

The “Feed Your Mind” initiative is launching in phases. The materials released today include a new website, as well as a selection of fact sheets, infographics and videos. Additional materials—including a supplementary science curriculum for high schools, resources for health professionals and additional consumer materials—will be released later in 2020 and 2021.

To guide development of the “Feed Your Mind” initiative, the three government agencies formed a steering committee and several working groups consisting of agency leaders and subject matter experts; sought input from stakeholders through two public meetings; opened a docket to receive public comments; examined the latest science and research related to consumer understanding of genetically engineered foods; and conducted extensive formative research. Funding for “Feed Your Mind” was provided by Congress in the Consolidated Appropriations Act of 2017 as the Agricultural Biotechnology Education and Outreach Initiative.

You can follow the “Feed Your Mind” initiative at the website:
<https://www.fda.gov/food/consumers/agricultural-biotechnology>.

Global Regulatory Workshop on Plant and Animal Biotechnology Innovation

FDA hosted a Global Regulatory Workshop on Plant and Animal Biotechnology Innovation on September 19-20, 2020, in Brussels. About 50 biotechnology experts from 25 regulatory agencies across the world exchanged experiences in plant and animal genome editing and discussed challenges and opportunities in this area. FDA participants included representatives from the Center for Food Safety and Nutrition, the Center for Veterinary Medicine, the Office of Policy, and our Europe and Latin America Offices. Representatives from the U.S. Department of Agriculture, the Environmental Protection Agency, and the State Department joined FDA to provide the U.S. government regulatory perspective.

4. Policy and Regulatory Update for the United States Environmental Protection Agency (EPA)

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

Scientific Advisory Panel on Resistance in Lepidopteran Pests to Bt Plant-Incorporated Protectants

As reported at the last 2019 WG-HROB and WG-SNFF OECD meetings, EPA held a Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel meeting (FIFRA SAP) on July 17-20, 2018. The meeting was held to receive guidance on recent resistance cases to four Lepidopteran pests of Bt corn and Bt cotton and on how to improve the IRM program for Lepidopteran target pests. EPA is continuing to work through the SAP’s recommendations. The panel’s report was delivered to EPA on October 17, 2018 and is available on-line at <https://www.epa.gov/sap/meeting-materials-july-17-20-2018-scientific-advisory-panel>. Additional information on this FIFRA SAP can be found on the web in the following docket: <https://www.regulations.gov/docket?D=EPA-HQ-OPP-2017-0617>

Policy

In 2016, as part of its activities to update its approach to the regulation of biotechnology products (Coordinated Framework for Regulation of Biotechnology), the United States published a National Strategy for Modernizing the Regulatory System for Biotechnology, <https://www.epa.gov/regulation-biotechnology-under-tsca-and-fifra/national-strategy-modernizing-regulatory-system>. As mentioned last year, among a number of the initiatives, two are of particular note in this forum. First, EPA OPP committed to working with FDA and USDA to better align regulatory responsibilities over genetically engineered insects consistent with their traditional oversight roles. Second, EPA OPP indicated its intention to clarify its approach to pesticidal products derived from genome-editing techniques.

- US EPA continues in its commitment to work with FDA and USDA to better align regulatory responsibilities over genetically engineered insects.
- On June 11, 2019, US President Trump issued Executive Order 13874 on Modernizing the Regulatory Framework for Agricultural Biotechnology Products, <https://www.whitehouse.gov/presidential-actions/executive-order-modernizing-regulatory-framework-agricultural-biotechnology-products/>. Section 4(b) of this Executive Order directs the US EPA Administrator to use existing statutory authority, as appropriate, to exempt low-risk products of agricultural biotechnology from undue regulation to the extent consistent with law and the principles set forth in section 3 of the Executive order.

US EPA currently regulates all PIPs except those created through conventional breeding as exempted by regulation at US Code of Federal Regulations 40 CFR 174.25 and 174.508, https://www.ecfr.gov/cgi-bin/text-idx?SID=58a69c740bb1d12b05ef19001dcefb53&pid=20180719&tpl=/ecfrbrowse/Title40/40cfr174_main_02.tpl.

Due to recent technological advances, EPA is considering proposing to update the existing exemptions for certain PIPs. This update would be to accommodate those PIPs that are formed when genetic material is transferred using bioengineering technology between plants that could otherwise transfer the genetic material by natural interbreeding. This action fulfils the requirement in Section 4(b) of the US Executive Order on Biotechnology mentioned above.

Section 5 of the 2019 US Executive Order on Biotechnology requires the development of a Unified Biotechnology Web-based Platform. In fulfilment of this, in January 2020, the three U.S. Agencies responsible for the regulation of biotechnology, the Food and Drug Administration (FDA), the Department of Agriculture (USDA) and the Environmental Protection Agency (EPA) launched a unified web site to provide information on biotechnology regulation. The website provides an overview of the Coordinated Framework, the roles and responsibilities of each Agency, and resources for technology developers and the public. There is also a convenient “contact us” feature that allows visitors to pose questions to each Agency (or all three Agencies). The web site can be found at: <https://usbiotechnologyregulation.mrp.usda.gov/biotechnologygov/home/>

Registrations and Experimental Use Permits for Plant-Incorporated Protectants

No experimental use permits or registrations have been issued since the 2019 WG-HROB and WG-SNFF OECD meetings. The following existing experimental use permit was extended:

- Spinach defensin (SoD) in citrus against citrus greening; extended 04/2019

5. New Plant Breeding Techniques: The United States Environmental Protection Agency

Office of Pesticide Programs (OPP)/BPPD

On June 11, 2019, US President Trump issued Executive Order 13874 on Modernizing the Regulatory Framework for Agricultural Biotechnology Products, <https://www.whitehouse.gov/presidential-actions/executive-order-modernizing-regulatory-framework-agricultural-biotechnology-products/>. Section 4(b) of this Executive Order directs the US EPA Administrator to use existing statutory authority, as appropriate, to exempt low-risk products of agricultural biotechnology from undue regulation to the extent consistent with law and the principles set forth in section 3 of the Executive order.

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EUROPEAN COMMISSION

1. GM food and feed

Overview of products

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 the products that may be placed on the market are in the Community Register of GM food and feed: http://ec.europa.eu/food/dyna/gm_register/index_en.cfm

Since the last WG-SNFF meeting, the European Commission has authorised 65 GM food and feed (including 54 sub-combinations) and has renewed 6 authorisations.

1. maize 5307
2. maize MON 87403
3. maize 4114
4. maize MON 87411
5. maize MZHG0JG
6. maize Bt11 x MIR162 x 1507 x GA21 (and 3 sub-combinations)
7. maize MON 89034 x 1507 x NK603 x DAS-40278-9 (and 3 sub-combinations)
8. maize MON 89034 x 1507 x MON 88017 x 59122 x DAS-40278-9 (and 14 sub-combinations)
9. maize Bt11 x MIR162 x MIR604 x 1507 x 5307 x GA21 (and 34 sub-combinations)
10. soybean MON87751
11. cotton GHB614 x LLCotton25 x MON1598

Renewals

1. oilseed rape Ms8 x Rf3 for feed
2. maize 1507 x NK603
3. soybean MON 89788
4. soybean A2704-12
5. cotton LLCotton25
6. oilseed rape T45

The tolerance period (up to 0,1%) of the GM hybrid oilseed rape Ms1×Rf1, Ms1×Rf2 and Topas 19/2, and their derived products, has been extended until 31 December 2022.

More authorisations are in the pipeline.

The European Food Safety Authority (EFSA) has since April 2019 published 8 new scientific opinions, of which 3 renewal applications:

1. soybean SYHT0H-02
2. soybean MON 87751 x MON 87701 x MON 87708 x MON 89788
3. maize MON 87427 x MON 87460 x MON 89034 x MIR162 x NK603
4. soybean MON 87708 x MON 89788 x A5547-127
5. maize MON 87427 x MON 89034 x MIR162 x MON 87411
6. maize MIR604 (renewal)
7. maize MON 88017 (renewal)
8. maize MON89034 (renewal)

EFSA also published a statement complementing its scientific opinion on maize 3272.

The opinions of EFSA on GMO applications as well as information on applications currently undergoing safety assessment are available on the website of EFSA:

<http://registerofquestions.efsa.europa.eu/rqFrontend/ListOfQuestionsNoLogin?6>

Guidance documents

Since April 2019, EFSA adopted the following guidance documents and reports relevant to the risk assessment of GM food and feed:

- [Administrative guidance on the submission of applications for renewal of authorisation of genetically modified food and feed under Articles 11 and 23 of Regulation \(EC\) No 1829/2003](#) (published on 24 June 2019).
- [Human dietary exposure to GMO food](#) (published 31 July 2019).
- [Animal dietary exposure: overview of current approaches used at EFSA](#) (published 15 November 2019)

In addition to the above, EFSA is continuing its work on:

- Allergenicity assessment, as a follow-up of previous EFSA guidance document on allergenicity¹ a dedicated Working Group will be set up to discuss: i) the relevance of the new experimental data produced on *in vitro* digestion². The outcome of such a work opens up new opportunities for the allergenicity and the overall protein safety assessment; and ii) the formulation of recommendations for future development in terms of specific research needs for allergenicity assessment and protein safety (*in silico*, *in vitro* and *in vivo* testing). In such context, the organisation of an EFSA workshop will be a key step and will involve the collaboration with international partners and stakeholders. The date of the event will be confirmed later.
- Four other mandates in the field of biotechnology with potential implications for future GMO applications in the EU are also ongoing. In the context of these mandates EFSA has been requested by the European Commission to produce:
 1. A scientific opinion assessing whether its existing guidelines for the risk assessment of genetically modified animals are adequate for the molecular characterisation and environmental risk assessment of genetically modified insects with synthetically engineered gene drives and in particular of gene drive modified disease-spreading mosquitoes and agricultural insect pests for deliberate release into the environment. The document also discusses whether there is a need for updated guidance in relation to the existing risk assessment guidelines. EFSA launched an open consultation on this GMO Panel scientific opinion on 17 February 2020 and is due to end on 17 April 2020 (duration of eight weeks). Following the evaluation of the received comments, the scientific opinion will be finalised by the end of 2020. Considering the current societal debate on the gene drive technology, EFSA organised another consultation in the shape of an open workshop that took place early in the development process to discuss with stakeholders the potential environmental risks associated with the deliberate release into the environment of gene drive modified insects.³
 2. Two scientific opinions assessing whether its existing risk assessment guidelines are adequate for the molecular/microbial characterisation and environmental risk assessment of (i) genetically modified plants (GMPs) or (ii) genetically modified microorganisms (GMMs) developed through synthetic biology (SynBio) technologies. In line with the mandate, both scientific opinions were produced through a case study approach taking into account SynBio developments for agri-food use that could reach the EU market in the near future (within the next decade)⁴ and assessing if the use of synthetic biology is expected to constitute potential risks and hazards upon deliberate release of SynBio GMPs or SynBio GMMs into the environment. These opinions also discuss whether updated guidance in specific areas may be needed.

¹ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms). Guidance on allergenicity assessment of genetically modified plants. EFSA Journal 2017; 15 (5):4862. <https://doi.org/10.2903/j.efsa.2017.4862>

² Mackie A, Dupont D, Torcello-Gómez A, Jardin J, Deglaire A, 2019. Report on EFSA project “In vitro protein digestibility” (Allergestion). EFSA supporting publication 2019:EN-1765. <https://doi.org/10.2903/sp.efsa.2019.EN-1765>

³ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2020.EN-1819>

⁴ <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2020.EN-1687>
<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2020.EN-1664>

- EFSA launched an open consultation for the GMO Panel scientific opinion on SynBio GMPs on 31 March 2020 and is due to end on 26 May 2020 (duration of eight weeks). Following the evaluation of the received comments, the scientific opinion will be finalised by the end of 2020.
 - EFSA launched an open consultation for the EFSA Scientific Committee scientific opinion on SynBio GMMs on 31 March 2020 and is due to end on 26 May 2020 (duration of eight weeks). Following the evaluation of the received comments, the scientific opinion will be finalised by the end of 2020.
3. A scientific opinion on plant genome editing assessing whether the risk assessment considerations for plants developed via site directed nucleases type-3 (SDN-3) as described in a previously published scientific opinion⁵ are valid for plants developed via other genome editing approaches, namely SDN-1, SDN-2, and oligonucleotide-directed mutagenesis (ODM). In delivering this opinion, the GMO Panel compared the hazards associated with plants produced via SDN-1, SDN-2 and ODM with those associated with plants obtained via both SDN-3 and conventional breeding focusing on the types of genetic modification associated with these techniques (i.e. insertion of exogenous DNA such as a transgene or modification of plant endogenous genomic sequences). In line with the mandate, this scientific opinion also discusses the applicability/sufficiency of EFSA's existing guidelines for the GM plant food/feed and environmental risk assessment for plants generated via SDN-1, SDN-2 and ODM. EFSA launched an open consultation on this GMO Panel scientific opinion on 15 April 2020 and is due to end on 27 May 2020 (duration of six weeks). Following the evaluation of the received comments, the scientific opinion will be finalised by the end of October 2020.
 4. A scientific opinion providing an overview on the risk assessment of plants developed through new genomic techniques (NGTs) such as cisgenesis and intragenesis, SDN-1, SDN-2 and SDN-3. The opinion will review EFSA's previous and current work on NGTs, as well as that carried out at national level by EU Competent Authorities and national institutions since 2012.⁶ In the context of this opinion the following definition of NGTs applies: "*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*". This scientific opinion will support the European Commission with the delivery of a study requested by the Council of the European Union, regarding the status of NGTs under Union law, in light of the Court of Justice's judgment in Case C-528/16. This scientific opinion will be finalised by the end of October 2020.

The guidance documents and notes can be found on the EFSA website:
www.efsa.europa.eu/en/applications/gmo/regulationsandguidance

2. Novel Foods

As of 1 January 2018, the new Regulation (EU) 2015/2283 on novel foods became applicable. The new 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 since the last WG SNFF meeting, through the e-submission system, 98 requests (87 applications and 11 traditional foods from third countries) for authorisation under the new Regulation. The Union list of novel foods has been amended 14 times, including the authorisation of one traditional food.

⁵ EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms). Scientific opinion addressing the safety assessment of plants developed using Zinc Finger Nuclease 3 and other Site-Directed Nucleases with similar function. EFSA Journal 2012;10(10):2943. <https://doi.org/10.2903/j.efsa.2012.2943>

⁶ <http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2020-0010>

3. Summary of policy work

Transparency and sustainability of the EU risk assessment in the food chain

Since the last meeting of the WG SNFF, the [General Food Law Regulation](#)⁷ has been amended by [a new Regulation on the transparency and sustainability of the EU risk assessment in the food chain](#) (Transparency Regulation). It aims at increasing the transparency of the EU risk assessment in the food chain, strengthening the reliability, objectivity and independence of the studies used by [European Food Safety Authority](#) (EFSA), and revisiting the governance of EFSA in order to ensure its long-term sustainability.

The new Transparency Regulation was published in the Official Journal on 6 September 2019. It entered into force 20 days after publication and **will become applicable on 27 March 2021**.

A key feature of the Transparency Regulation is the proactive **disclosure of all studies** supporting requests for scientific opinion, including authorisations, **early on in the risk assessment process** – when an application is deemed valid/admissible –, with the exception of duly justified confidential information. Confidentiality may only be claimed based on closed lists of confidential items and if the applicant demonstrates that public disclosure would potentially harm its interests to a significant degree. The new law also makes clear that intellectual property rights (IPRs), data exclusivity rules and protection of personal data remain unaffected. It also provides that **clear undertakings or signed** statements are to be given by those accessing the relevant documents, prior to their public disclosure, specifying that such disclosure would not constitute a permission for further use or exploitation. The provision of such undertakings/statements should not jeopardise the proactive character of public disclosure and the easy access to the disclosed information.

In addition, the new Regulation foresees a series of measures to strengthen the reliability of industry studies, including, **pre-submission advice, notification of commissioned studies** at pre-submission phase, public consultation of planned and submitted studies, **fact-finding missions** to laboratories and testing facilities and the possibility for the Commission to ask EFSA to commission **verification studies** in exceptional circumstances.

Risk communication will be also further strengthened through the definition of objectives and principles of risk communication and the future development of a general plan on risk communication. The Commission and the European Food Safety Authority (EFSA) are closely cooperating to ensure the proper implementation of the new Regulation.

New developments in novel foods and feeds – new breeding techniques

In **November 2019**, The Council of the European Union requested the Commission ([Council Decision \(EU\) 2019/1904](#)) 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.

⁷ Adopted in 2002, the General Food Law sets out a comprehensive harmonised legal framework, addressed to EU institutions, Member States and business operators. It covers the entire food chain, including feed and imports. It established the European Food Safety Authority (EFSA), which provides scientific advice in the area of food and feed safety, animal health and welfare, plant health, nutrition and Genetically Modified Organisms (GMOs).

- 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).

More details on the study can be found [here](#).

Business at OECD (BIAC)

1. Plant Biotech Industry Aligns on Technical Rationale for Regulatory Harmonisation

CropLife International, its members and the CropLife network have continued their work encouraging predictable, science-based regulatory frameworks to enable farmers with new agricultural innovations without compromising the safety of food, feed, and the environment.

Given the more than 25 years of safe use and numerous benefits to farmers, consumers and the environment, CropLife International believes it is time to review and streamline the safety assessment process for GM crops. Building on the Codex standard which states that “*where appropriate, the results of a risk assessment undertaken by other regulatory authorities may be used to [...] avoid the duplication of work*” CropLife International has continued to advocate the sharing of science and safety assessments across geographies to encourage harmonise global regulations and data requirements.

CropLife International recognises that industry has a pivotal role to play in facilitating this information sharing for regulatory authorities and as such, has recently submitted five papers for peer-review clearly outlining industry’s view of which studies should comprise a science-based safety assessment given the 25 years of regulatory and cultivation experience. The publication of these papers is anticipated for Q1 2019 and in the interim, CropLife International has produced a series of infographics and fact sheets that provide more detail on the compelling story for regulatory harmonisation, the benefits for all stakeholders and more detail on the recommended studies. Work will now begin building case studies to illustrate what these recommendations could look like in practice.

2. Industry Recognises Multilateral Progress Related to Plant Breeding Innovation

The international seeds industry maintains its position that plant varieties developed through the latest plant breeding methods, like 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 and regulations to facilitate the commercialisation of plant breeding innovations. The adoption of common approaches across countries can be facilitated through alignment of definitions, standard information requests needed to make determinations, timelines and recognition of other countries’ determinations on regulatory status.

The international seeds industry recognises the ongoing development and recent finaliation of certain policies around genome edited products in Japan, Australia, Paraguay, Honduras and Guatemala, specifically noting the approach of these governments in identifying certain products that could be developed using conventional breeding and excluding these products from premarket approval processes associated with plant biotechnology products. These regulatory developments contribute to a strong bloc of countries who recognise the value of genome editing and appreciate the need to enact rationale policy.

In Europe, the international seeds industry notes the planned European Commission study to evaluate new genomic techniques, technological advancements, and implementation of GMO legislation around products developed using said new genomic techniques. Through this process, industry hopes the study will identify areas in which the current GMO directive is not fit for purpose for the varied applications of genome editing and other new genomic techniques, and develop recommendations under which the European agriculture sector is able to fully utilize new tools of plant breeding.

The international seeds industry also notes the ongoing discussion about information sharing around products developed using plant breeding tools such as genome editing. Industry supports efforts to provide useful and informative information to consumers and the value chain provided these efforts are achievable by all users of genome

editing and provides information that is not arbitrarily discriminatory toward certain plant breeding approaches versus others.

3. The International Seeds Industry Publishes New Gene Editing Resources

A series of case studies were developed that explore the gene editing work being done across various crops and can be accessed at the links below:

- [Beans and Gene Editing: Breeding a Better Bean](#)
- [Wheat and Gene Editing: Breeding for Better Bread](#)
- [Rice and Gene Editing: Defending Against Rice Blast Disease](#)
- [Lettuce and Gene Editing: Increasing Heat Resistance to Combat Changing Climate](#)
- [Oranges and Gene Editing: Innovating to Save the Citrus Industry](#)
- [Cassava and Gene Editing: Eliminating Toxins in Cassava to Unlock its Potential](#)

The lettuce, oranges, and wheat studies go hand-in-hand with the Plant Breeding & Innovation video series produced with the [American Seed Trade Association](#):

- Wheat: <https://youtu.be/4kuockyMGOW>
- Oranges: <https://youtu.be/qkws7jvEj3A>
- Lettuce: https://youtu.be/B_BNMqiAHWI

A new video is currently under production which will address gene editing work that has the potential to improve the health of rural African populations by eliminating the cyanide-producing qualities of undercooked cassava.

Additionally, National Association of Plant Breeders (NAPB) with support from the American Seed Trade Association (ASTA) ran a symposium focused on plant breeding science and applications focused on updating government officials as to the latest approaches used to develop new varieties. The content and presentations from the symposium are available through this [link](#).

4. Plant Science Industry continues to be engaged in the ongoing discussions on 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, Cartagena Protocol on Biosafety and 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 focuses its work on the primary implementation issues relevant to the plant science industry, 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. Importantly, the GIC has established a new workgroup to lead industry input into the Post-2020 Global Biodiversity Framework (GBF) negotiations. The GIC remains actively engaged in this work program: completing a detailed submission to the Convention Secretariat on synthetic biology, socio-economic considerations, environmental risk assessment focused on gene drives and living modified fish; participating in online fora on synthetic biology, socio-economic considerations, detection methods and environmental risk assessment; representing the plant science industry at the Liaison Group on Biosafety, the ad hoc technical expert group on synthetic biology, the ad hoc technical expert group on socio-economic considerations, the meetings of the Open-ended workgroup on the Post2020 GBF, and the meetings of the Subsidiary Body on Scientific, Technical and Technological Advice. CropLife International will continue to advocate for a clear 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 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 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 Biodiversity Convention in October 2020 to ensure the ongoing discussions are advised by a broad perspective

of stakeholders. Progress made in these venues will help ensure that the transboundary movement of LMOs continues to protect biological diversity, while maintaining uninterrupted international trade and ensuring farmers have access to sustainable agricultural innovations. CropLife International and members of the GIC and plant biotech industry will continue to participate in the intersessional meetings scheduled by the Parties prior to 2020 Biodiversity Convention to take place in October 2020 in Kunming, China, and expects to have 40 GIC participants, representing over 20 countries, present at that meeting.

AUDA-NEPAD – African Biosafety Network of Expertise (ABNE)

<http://www.nepadbiosafety.net/>, March 2020

1. About ABNE

The African Biosafety Network of Expertise (ABNE) of the African Union Development Agency (AUDA – NEPAD) continues to assist African Union member states build their biosafety regulatory systems. Areas of intervention include information sharing, training on various aspects of biosafety, facilitation of policy dialogue, consultancy support, technical assistance, networking and regulatory study tours. Moreover, ABNE because of the trust it has continued to muster from AU member states, has continued to play significant role in unifying AU member states to form a common position on modern biotechnology in international negotiation forums such as the Conference of Parties of the Convention on Biological Diversity and the Meeting of Parties of the Cartagena Protocol to the Convention on Biological Diversity (COP-MOP).

In its Implementation phase II, which ended by 31 December 2019 ABNE had been able to achieve 80% of its target in terms of helping five countries each to approve biotech crops for CFTs and environmental release.

The four ABNE focus countries that granted approvals for CFTs or multi-locational trials (MLTs) of GM crops of their priority interest were Ethiopia, eSwatini, Mozambique and Tanzania. The four countries that granted approval for environmental release were Ethiopia, eSwatini, Kenya, Malawi and Nigeria. Continued support was provided to other countries - Burkina Faso and Sudan- that have already commercialised GM crops in order to avoid backtracking; and several emerging countries including Togo, Senegal, Namibia, Mali, Côte d'Ivoire, Rwanda and Niger.

During the year 2019, progress was made in several countries including Burkina Faso, Ghana, Malawi, Niger and Nigeria as evident in the various approvals issued on GM mosquitoes and GM crops, as well as passage of regulatory instruments such as laws and implementing regulations. Nevertheless, few focus countries witnessed varying degree of setbacks such as the case of Uganda, where the President declined assent to the Bill. All hands are on deck in deploying key strategies towards addressing this challenge.

ABNE has sustained efforts in joining the global community for consultations on emerging technologies including genome editing and gene drives applications and their regulatory requirements. Such consultations have led to the development of an Integrated Vector Management Programme, which encompasses the provisions for regulatory strengthening for Gene Drive technology, governance structure, training curriculum, guidelines and platform for regional dialogue. The development of the guidelines identified as priority have progressed significantly and reaching advanced draft stage.

2. Country updates

BURKINA FASO: Approval for small scale release of GM mosquitoes was granted. The release was successfully conducted in July 2019. A national biosafety laboratory was commissioned. This is one of the deliverables of West Africa regional biosafety program started in 2008 with funding by the World Bank. Also established is a centre of excellence for biotechnology application in health at the Health Research Institute in Bobo-Dioulasso (IRSS). Field trials of Bt cowpea are ongoing.

ETHIOPIA: In the year 2019, Ethiopia has continued to make progress by growing more than 500 hectares of Bt cotton in Gambela Regional State of Ethiopia. Findings indicated that the technology is effective in containing bollworm and in guarding yield that would have been lost to attack by the insect. Ethiopia is also conducting confined field trials of insect resistant and drought tolerant maize and is close to reviewing biosafety dossier for environmental release approval.

eSWATINI: Approval for commercial release of Bt cotton hybrids was granted and production of more than 250 ha of Bt cotton had materialized in 2019.

GHANA: The Biosafety Regulations was passed on June 28, 2019 and now publicly available and on the international BCH. The National Biosafety Authority (NBA) now has the full legal regime to receive and process all applications including that for environmental release. ABNE also provided support for the development of model application forms for event registration and import/export of GMOs for FFPs to assist streamlining of processes for regulatory compliance. The NBA received support as well, in the ongoing lawsuit to ensure they were abreast with new developments and had access to requisite technical and legal resources. Progress has been made on the Food and Drugs Authority (FDA) draft guidelines on GM labelling with respect to improved language in line with international best practices and obligations.

KENYA: Capacity building effort was extended to stakeholders in cotton growing counties, where decision making regarding adoption of technologies is taking place, to strengthen capacity and create public awareness on Kenya National Biosafety Regulatory Framework. National performance trials for Bt cotton has been conducted and approval granted for variety registration in December 2019. However, environmental impact assessment needs to be completed before embarking on commercial production.

MALAWI: Approval for variety registration and commercial release of four Bt cotton hybrids has been granted. Moreover, confined field trials of GM banana for bunchy top virus disease resistance is on-going. Confined multi-location trials for Bt cowpea are expected.

MALI: Noticeable progress has been made in the field of biotechnology applications for malaria vector control, including approval of contained use of Genetically Modified male sterile mosquitoes granted to the Malaria Research and Training Centre (MRTC) at the University of Bamako.

MOZAMBIQUE: Confined field trials of WEMA maize has been successfully conducted and in the process of starting Bt cotton activities.

NIGER: Biosafety Law was enacted by the Parliament at its plenary session on October 17, 2019. This is considered a breakthrough achievement for the country as the enactment of the law was awaited since the country ratified the Cartagena protocol in 2004. Also, a draft national strategy document was endorsed by stakeholders for policy direction to the government in its effort to ensure food and nutrition security as well as a safer environment through the prevention of biological risks. The endorsed strategy is awaiting government's approval for final adoption.

NIGERIA: Approval for variety registration of Bt cowpea varieties was granted in December 2019. Other confined field trials are on-going. National Biosafety Management Agency (NBMA) amendment bill was initiated by the House of Representatives in 2018 and was passed by the 8th National Assembly into law in 2019. The amendment broadened the scope of regulation to include synthetic biology, genome editing, gene drive and biosecurity. Additional milestone was a training workshop that was organised on genome editing and steps initiated to develop a policy on how genome edited crops would be regulated in Nigeria. A draft guideline, adopting a science-based approach in regulating genome edited products, is currently being reviewed by stakeholders.

RWANDA: Final drafts of the legal instruments (Biosafety Policy and Biosafety Law) were validated by all relevant stakeholders and being subject to processes preceding the approval of the policy and enactment of the Law. An application for approval to conduct confined field trial of GM cassava variety resistant to CBSD and CMD was received by the Rwanda Environment Management Agency (REMA) and was reviewed by the National Biosafety Committee, which made recommendations for approval of the activity to REMA in February 2020.

TANZANIA: Confined field trials of insect resistant and drought tolerant maize have successfully conducted. However, there have been challenges of predictability in political buy-in which confronted the smooth running of the process.

UGANDA: Uganda has been conducting CFTs of an array of biotech crops. However, environmental release approval continues to be a challenge because of failure to sign the biosafety bill into law. Thus, ABNE continues to provide support to have the bill signed into law and towards the development of the implementing Regulations.

3. Networking Activities for Partnership Building and Policy Advocacy

UN Biodiversity Conference (COP-MOP): The Conference of the Parties at its fifteenth meeting in October 2020, is expected to consider for adoption the post-2020 global biodiversity framework which is being developed through

a preparatory process agreed upon during COP 14, COP-MOP 9, and COP-MOP 3 in Sharm El-Sheikh, Egypt in November 2018. To ensure that the African Group of Negotiators actively contribute to the process, several activities were undertaken by AUDA-NEPAD and AU-HRST in 2019. AUDA-NEPAD collaborated with the CBD Secretariat and the African Union Commission to organise a regional consultation on the post-2020 global biodiversity framework for the Africa Region in April 2019 in Addis Ababa. Participants identified priorities for the continent and proposed the scope and content of the post-2020 global biodiversity framework. Upon request from AU member states, a training on genome editing was organised for 60 biosafety regulators and policy makers from 31 AU member states in June 2019 in Addis Ababa. Member States improved their understanding on the applications of genome editing in the various sectors of the bioeconomy and discussed key considerations for policy formulation and regulation of genome editing. Member states requested that the High-Level African Panel on Emerging Technologies should provide guidance on genome editing with support from AUDA-NEPAD as the Secretariat. A review of the UN Biodiversity Conference 2018 was also held during this June 2019 meeting.

A major outcome from the June meeting was the establishment of the *African Union Biosafety Regulators Forum (AU-BRF)*. AU-BRF is a specialized platform of the African Union expected to serve as a catalyst for coherent biosafety regulatory oversight on the continent. Member states endorsed the establishment of an interim steering committee composed with sub-regional representation to provide leadership to the African Group of Negotiator's during the intercessional period. AUDA-NEPAD also assisted in organising daily meetings for the African Group of Negotiators (AGN) present at the first meeting of the open-ended working group on the post-2020 global biodiversity framework in August 2019 in Nairobi. Consequently, AGN members were able to strategize and advance Africa's position and interests during this meeting. Support was also provided to the AGN on the fringes of the 17th session of AMCEN. AMCEN reaffirmed Africa's priorities as adopted at the Africa Biodiversity Summit in Egypt during the 2018 UN Biodiversity Conference and endorsed a proposed coordination mechanism for the AGN on biodiversity matters. There were also online engagements with members of the AGN on COP MOP agenda issues during the year under review. Relevant information documents and updates were shared with African Parties and there is currently ongoing support for AU Member States attending the 23rd meeting of Subsidiary Body on Scientific, Technological and Technical Advice (SBSTTA) towards the inclusion of the continental priorities for biodiversity and biosafety in the post-2020 global biodiversity framework.

ECOWAS - West Africa Regional Harmonization Biosafety Programme: Following a meeting of ECOWAS, UEMOA and CILSS member states' sectoral ministers held to present the draft harmonised biosafety framework, as validated by technical experts, ECOWAS, UEMOA and CILSS member states agreed to refer the draft Regional Regulation on biosafety to their various ministers of Justice to ensure conformity with national legal system after inclusion of recommended texts before its adoption by the ECOWAS council of Ministers, as recommended.

Policy dialogue on labelling of foods derived from modern biotechnology: AUDA-NEPAD/ABNE organised a policy dialogue on labelling of foods derived from modern biotechnology in August 2019 with participants from Ghana, Kenya, Malawi, Namibia and Nigeria. The dialogue empowered participants with knowledge that enables adoption of best practices in establishing and implementing labelling regulations for foods derived from modern biotechnology.

Study Tour: ABNE's 2020 Study Tour Program focused on the regulatory and commercialisation experiences of Bt Cotton in India. The program was implemented at three locations in India (New Delhi, Jalna/Aurangabad and Hyderabad) in collaboration with Michigan State University and partners in India. High level government officials, policy makers/regulators, and other representatives from Cote d'Ivoire, Ethiopia, Kenya, Mali and Togo attended the program. The group interacted with the Biosafety Service Unit of Government of India and visited 3 seed companies (Beej Sheetal/Kalash Seed Company, JK Seeds and Mahyco) that are actively engaged in Biotechnology Research and Development, as well as developing joint ventures with Africa. Visits were made to ICRISAT and Nucleome Genomics & Informatics Company as well. The participants also met with smallholder farmers that have been growing Bt cotton for over 13 years.

Strengthening Seed Systems for Smallholder Farmers - On-Farm Economic Analysis of Cotton Production Practices in Ethiopia: A four-member team representing Michigan State University, AUDA-NEPAD Agency, and a private consultant from Ethiopia conducted an assessment of cotton production economics and production practices of small-scale farmers in Ethiopia in April 2019. The team visited 26 farmers in four of the seven main cotton growing regions of Ethiopia. The participating farmers were in the Afar, Gambella, SNNPR and Tigray Regions of Ethiopia. The information collected has guided the deployment strategies for Bt cotton seed delivery systems for smallholder farmers in Ethiopia.

Training of African Regulators/Stakeholders through Biotechnology and Biosafety Short Course at Michigan State University, USA: A total of 10 African regulators, policy makers, and relevant stakeholders from Senegal, Nigeria, Burkina Faso, Niger, Kenya, Ethiopia, Rwanda, Namibia, and Uganda attended the international short course on Biotechnology and Biosafety organised by Michigan State University in August 2019. Two new components of science and regulation of genome-edited crops and biotechnology product stewardship were included in this comprehensive training course.

ILSI Research Foundation (now AFISI)

1. About the ILSI Research Foundation⁸

The ILSI Research Foundation is a non-profit, scientific organisation that advances and disseminates science for public benefit. We convene scientists from public, academic, non-profit and private sectors to address scientific issues that are relevant to human health and environmental sustainability. The results of those discussions are disseminated through open access publication, capacity building, education, and stakeholder engagement.

2. Updates Pertinent to the Work of the WG-SNFF

Capacity building

Technical Workshop on Safety Assessment of Foods and Feeds Derived from Genetically Engineered (GE) Plants

Training for Chinese Scientists

In 2019, the ILSI Research Foundation convened a two-part training program for Chinese scientists engaged in GE food safety assessment, entitled *Safety Assessment of Foods and Feeds Derived from Genetically Engineered Plants*. Phase I of the program took place March 5-7 in Langfang, China, and Phase II took place June 17-21 in Washington DC and at Charles River Laboratories in Ashland. Immediate feedback from participants was very positive, with many recommending that the program be repeated next year for additional Chinese participants. In a survey conducted three months after the Phase I training, all participants indicated that they were able to apply what they learned in their work, with examples including the application of problem formulation in the safety assessment of a Bt corn line, incorporating resources presented during the training in classes taught to graduate students, and designing animal tests for the safety assessment of a GE food. 80% of participants had shared training materials with colleagues, and half of them had led discussions using information presented during the training.

<https://ilsirf.org/event/china-phase1/>

<https://ilsirf.org/event/china-phase2/>

Training for Indonesian Scientists

Planning is underway for a technical training workshop for Indonesian scientists engaged in the safety assessment of GE foods and feeds. The workshop scheduled to be held April 15-16, 2020, is being co-organised with the National Agency of Drug and Food Control (BPOM) and the Indonesian Center for Agricultural Biotechnology and Genetic Resources Research and Development (ICABIOGRAD). This will be a follow-on activity to technical training held in 2017 in Bogor, Indonesia. At the request of BPOM and ICABIOGRAD, April's workshop will focus on stacked events regulation.

Symposium and Workshop on Risk Assessment and Regulation of Gene Edited Plants

The ILSI Research Foundation co-organised the *Symposium on Risk Assessment of Plants Developed Using New Breeding Technologies* with the Bureau of Plant Industry, Department of Agriculture on October 8-9, 2019 in Manila, Philippines. The symposium provided an opportunity for Filipino scientists, risk assessors, and regulators to learn about the science of gene editing, as well as how risk assessment and regulation of products of new plant breeding technologies are being considered in key countries, such as Australia, Germany, Japan, and the United States. Risk assessors from Malaysia, Vietnam, and Thailand also attended. The two-day symposium concluded with a discussion

⁸ On 1 May 2020, the ILSI Research Foundation became the Agriculture and Food Systems Institute (AFSI), along with a new website: <https://foodsystems.org>

about considerations for the regulation of genome edited plants in the Philippines and was followed by an invitation-only *Workshop on Risk Assessment and Regulation of Genome Edited Plants*. The workshop was open to members of the four competent national authorities Biosafety Committees, with participation by 31 individuals. The participants worked through a series of four case studies prepared by Dr. Bhavneet Bajaj, ILSI Research Foundation, followed by rich plenary discussions.

<https://ilsirf.org/event/nbt/>

Resources

Crop Composition Database

The ILSI Research Foundation's Crop Composition Database (CCDB) is a curated, open resource that provides data on the natural variability in the nutritional composition (e.g., nutrients, anti-nutrients, and secondary metabolites) of key conventionally bred crop species. These 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 7.0 of the CCDB was released in January 2019 and includes over 1.24 million data points with inclusion of data for apple.

Compositional data for brown rice has been received from the National Institute of Agricultural Sciences, Rural Development Administration, South Korea and processed for inclusion into the CCDB. Discussions are underway for inclusion of sugarcane and sugar beet data as well.

Development of a new CCDB website is underway and is expected to be completed by August 2020. The new website will be more user-friendly, intuitive and will have data visualization capabilities amongst other enhancements.

www.cropcomposition.org