

# Regulatory Implications for Advanced Breeding Technologies: OECD Biosafety Considerations

## ASSAF NPBTs Workshop

Dr Dean Oelofse

[doelofse@arc.agric.za](mailto:doelofse@arc.agric.za)

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# The Organisation for Economic Co-operation and Development (OECD)

- The OECD provides a forum in which governments can work together to share experiences and seek solutions to common problems.
- Today, 34 OECD member countries worldwide regularly turn to one another to identify problems, discuss and analyse them, and promote policies to solve them.

Australia	France	Korea	Slovenia
Austria	Germany	Luxembourg	Spain
Belgium	Greece	Mexico	Sweden
Canada	Hungary	Netherlands	Switzerland
Chile	Iceland	New Zealand	Turkey
Czech Republic	Ireland	Norway	United Kingdom
Denmark	Israël	Poland	United States
Estonia	Italy	Portugal	
Finland	Japan	Slovak Republic	

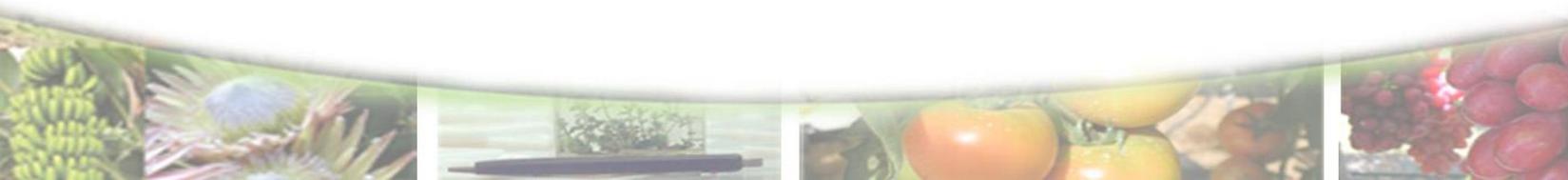
# OECD Key Partners

- These **Key Partners** (non-member countries) contribute to the OECD's work in a sustained and comprehensive manner.
  - Brazil (always present)
  - India
  - Indonesia
  - China
  - South Africa (always present)



# Biosafety Working Groups

- To increase the efficiency of the risk/safety assessment process, as well as reducing duplicative effort, OECD countries have recognised the value of working together to harmonise approaches and share information used in safety assessments of GM products.
- Two closely related programs of work at the OECD has resulted in the establishment of:
  1. The Working Group on Harmonisation of Regulatory Oversight in Biotechnology which addresses aspects of the environmental risk/safety assessment of GM plants, fish and micro-organisms.
  2. The Working Group for the Safety of Novel Foods and Feeds which addresses aspects of the safety assessment of foods and feeds derived from GM crops.



# OECD Participation: Dr D Oelofse

- As from March 2012, a non-OECD member country committee member of the:
  - OECD Working Group for the Safety of Novel Foods and Feeds.
  - OECD Working Group on Harmonisation of Regulatory Oversight in Biotechnology.
- As from April 2015, a Bureau member (vice chair) of the OECD Working Group for the Safety of Novel Foods and Feeds. (*First non-OECD country member to be appointed into this position*)



# Biosafety Working Groups

- The main objective is to ensure that the types of information and data used in the risk/safety assessments, as well as methods used, are as similar as possible amongst countries.
- Both programs identify a common base of scientific information that can be useful in assessing the safety of specific products regarding human food, animal feed and the environment.
- The main output of the work are the “Consensus Documents”, which are practical tools in which key information on major crops are compiled (traits and other products), agreed upon by consensus which countries believe to be relevant to risk/safety assessment when new (genetically engineered) products are compared to conventional ones.



# Working Group on Harmonisation of Regulatory Oversight in Biotechnology

- This working group develops Consensus Documents on aspects of the biology of major crop species and trees, introduced traits, as well as micro-organisms that are of relevance to the risk/safety assessment.
- The documents addressing biology include a short natural history of the plant, its major uses, agronomic practices, and if relevant, the potential for out-crossing within crop species and among related species.
- There are also documents addressing traits inserted in plants derived using modern biotechnology.



# Working Group on Harmonisation of Regulatory Oversight in Biotechnology

Consensus Documents on the Biology of Plants	Year
<a href="#"><u>Cassava (<i>Manihot esculenta</i> Crantz) *</u></a>	2014
<a href="#"><u>Sugarcane *</u></a>	2013
<a href="#"><u>Brassica Crops (<i>Brassica</i> spp.) *</u></a>	2012
<a href="#"><u>Cucurbita L. (Squashes, Pumpkins, Zucchini and Gourds)</u></a>	2012
<a href="#"><u>Bananas &amp; Plantains (<i>Musa</i> spp.)</u></a>	2009
<a href="#"><u>Cotton (<i>Gossypium</i> spp.) *</u></a>	2008
<a href="#"><u>Chili, Hot &amp; Sweet Peppers (<i>Capsicum annum</i>)</u></a>	2006
<a href="#"><u>Papaya (<i>Carica papaya</i>) *</u></a>	2005
<a href="#"><u>Sunflower (<i>Helianthus annus</i>) *</u></a>	2004
<a href="#"><u>Maize (<i>Zea mays</i> subs. <i>ays</i>) *</u></a>	2003
<a href="#"><u>Sugar Beet (<i>Beta vulgaris</i>)</u></a>	2001
<a href="#"><u>Soybean (<i>Glyxine max</i>) *</u></a>	2000
<a href="#"><u>Rice (<i>Oryza sativa</i>) *</u></a>	1999
<a href="#"><u>Wheat (<i>Triticum aestivum</i>) *</u></a>	1999
<a href="#"><u>Potato (<i>Solanum tuberosum</i> subsp. <i>Tuberosum</i>) *</u></a>	1997

(\* ) Complementary document on food/feed safety (Compositional Considerations) is available for the species at [Food/Feed Safety Series](#)



# Working Group on Harmonisation of Regulatory Oversight in Biotechnology

Consensus Document on the Biology of Trees	Year
<i>Trees</i>	
<a href="#"><u>Eucalyptus spp.</u></a>	2014
<a href="#"><u>Black Spruce (<i>Picea mariana</i>)</u></a>	2010
<a href="#"><u>Lodgepole Pine (<i>Pinus contorta</i>)</u></a>	2008
<a href="#"><u>Douglas-Fir (<i>Pseudotsuga menziesii</i>)</u></a>	2008
<a href="#"><u>Western White Pine (<i>Pinus monticola</i>)</u></a>	2008
<a href="#"><u>North American Larches (<i>Larix lyalli</i>, <i>L. occidentalis</i>, <i>L. laricina</i>)</u></a>	2007
<a href="#"><u>Jack Pine (<i>Pinus banksiana</i>)</u></a>	2006
<a href="#"><u>European White Birch (<i>Betula pendula</i>)</u></a>	2003
<a href="#"><u>Eastern White Pine (<i>Pinus strobus</i>)</u></a>	2002
<a href="#"><u>Stika Spruce (<i>Picea sitchensis</i>)</u></a>	2002
<a href="#"><u>Poplars (<i>Populus spp.</i>)</u></a>	2000
<a href="#"><u>White Spruce (<i>Picea glauca</i>)</u></a>	1999
<a href="#"><u>Norway Spruce (<i>Picea abies</i>)</u></a>	1999
<i>Fruit Trees</i>	
<a href="#"><u>Bananas &amp; Plantains</u></a> [Listed in "Crops"]	2009
<a href="#"><u>Papaya</u></a> [Listed in "Crops"]	2005
<a href="#"><u>Stone Fruits (<i>Prunus spp.</i>)</u></a>	2002

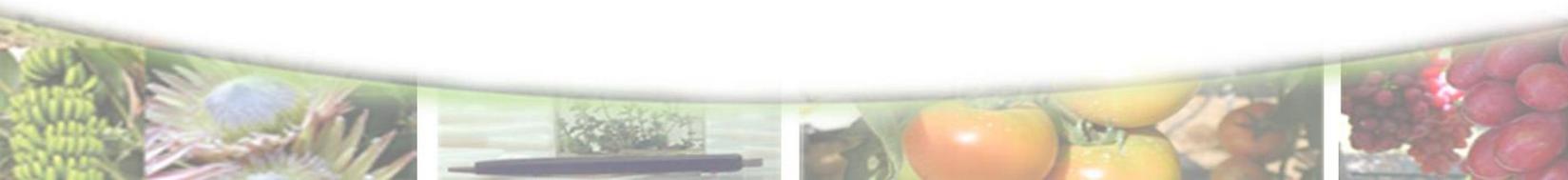
# Working Group on Harmonisation of Regulatory Oversight in Biotechnology

Consensus Documents on Micro-organisms	Year
<i>Micro-organisms</i>	
<a href="#">Acinetobacter</a>	2008
<a href="#">Acidithiobacillus</a>	2006
<a href="#">Baculovirus</a>	2002
<a href="#">Pseudomonas</a>	1997
<i>Biosafety Aspects of Bacteria</i>	
<a href="#">Pathogenicity Factors in Assessing the Potential Adverse Health Effects of Micro-Organisms: Bacteria</a>	2011
<a href="#">Horizontal Gene Transfer Between Bacteria</a>	2010
<a href="#">Methods for Detection of Micro-organisms Introduced into the Environment: Bacteria</a>	2004
<a href="#">Use of Taxonomy in Risk Assessment of Micro-organisms: Bacteria</a>	2003



# Working Group on Harmonisation of Regulatory Oversight in Biotechnology

Consensus Document on Traits	Year
<a href="#"><u>Plants Expressing <i>Bacillus thuringiensis</i> (Bt) - Derived Insect Control Protein</u></a>	2007
<a href="#"><u>Herbicide Metabolism and the Residues in Glufosinate-Ammonium (Phosphinothricin) -Tolerant Transgenic Plants</u></a>	2002
<a href="#"><u>Genes and their Enzymes that Confer Tolerance to Phosphinothricin Herbicide</u></a>	1999
<a href="#"><u>Genes and their Enzymes that Confer Tolerance to Glyphosate Herbicide</u></a>	1999
<a href="#"><u>Crop Plants Made Virus Resistant through Coat Protein Gene-Mediated Protection</u></a>	1996



# Working Group on Harmonisation of Regulatory Oversight in Biotechnology

Consensus Documents for Facilitating Harmonisation	Year
<a href="#"><u>Low Level Presence of Transgenic Plants in Seed and Grain Commodities</u></a>	2013
<a href="#"><u>Molecular Characterisation of Plants Derived from Modern Biotechnology</u></a>	2010
<a href="#"><u>Designation of a Unique Identifier for Transgenic Plants (Revised Version) (Guidance Document)</u></a>	2006
<a href="#"><u>Points to Consider for Consensus Documents on Biotechnology of Cultivated Plants</u></a>	2006
<a href="#"><u>Introduction to the OECD Biosafety Consensus Documents</u></a>	2005



# Working Group for the Safety of Novel Foods and Feeds

- Food and feed safety assessments are addressed in this WGs Consensus Documents.
- They contain information on the major components of specific crop plants, such as key nutrients, toxicants, anti-nutrients and allergens at time of harvest (fresh), as well as after processing for use as food and feed.
- This information is of value in the safety assessment of new GM varieties for the comparison of these components of the new variety to those of the traditional varieties.



# Working Group for the Safety of Novel Foods and Feeds

Consensus Document	Year
<a href="#"><u>Soybean (<i>Glycine max</i>)*</u></a>	2012
<a href="#"><u>Low Erucic Acid Rapeseed (Canola)*</u></a>	2011
<a href="#"><u>Sugarcane (<i>Saccharum</i> spp. hybrids)*</u></a>	2011
<a href="#"><u>Papaya (<i>Carica papaya</i>)*</u></a>	2010
<a href="#"><u>Sweet Potato (<i>Ipomoea batatas</i>)</u></a>	2010
<a href="#"><u>Grain Sorghum (<i>Sorghum bicolor</i>)</u></a>	2010
<a href="#"><u>Cassava (<i>Manihot esculenta</i>)*</u></a>	2009
<a href="#"><u>Tomato (<i>Lycopersicon esculentum</i>)</u></a>	2008
<a href="#"><u>Sunflower (<i>Helianthus annus</i>)*</u></a>	2007
<a href="#"><u>Alfalfa (<i>Medicago sativa</i>) and other temperate forage legumes</u></a>	2005
<a href="#"><u>Barley (<i>Hordeum vulgare</i>)</u></a>	2004
<a href="#"><u>Cotton (<i>Gossypium hirsutum</i> and <i>G. barbadense</i>)*</u></a>	2004
<a href="#"><u>Rice (<i>Oryza sativa</i>)*</u></a>	2004
<a href="#"><u>Wheat (<i>Triticum aestivum</i>)*</u></a>	2003
<a href="#"><u>Maize (<i>Zea mays</i>)*</u></a>	2002
<a href="#"><u>Potato (<i>Solanum tuberosum</i> subsp. <i>tuberosum</i>)*</u></a>	2002
<a href="#"><u>Sugar Beet (<i>Beta vulgaris</i>)*</u></a>	2002

(\*) Complementary document on environmental safety (Biosafety) is available for the species at [Biosafety Series](#)

# Working Group for the Safety of Novel Foods and Feeds

<b>Consensus Document for Facilitating Harmonisation in Food/Feed Safety Assessment</b>	<b>Year</b>
<a href="#"><u>Molecular Characterisation of Plants Derived from Modern Biotechnology</u></a>	2010
<a href="#"><u>An Introduction to the Food/Feed Safety Consensus Documents of the Task Force</u></a>	2006
<a href="#"><u>Considerations for the Safety Assessment of Animal Feedstuffs derived from Genetically Modified Plants</u></a>	2003



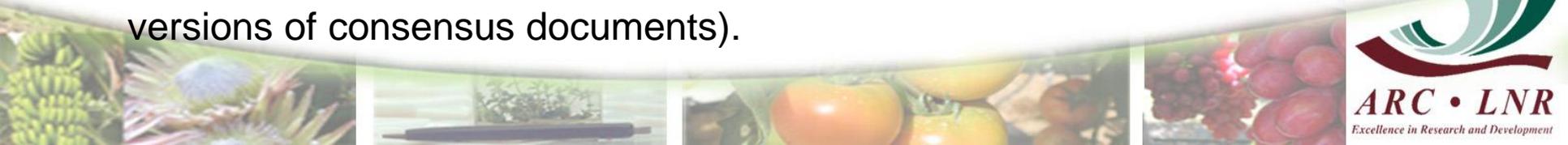
# ***Tour de Table***

- The “*Tour de Table*” gives the delegations (countries, observer organizations) the opportunity to briefly present their developments relating to their environmental safety activities at the Working Group meetings since the last meetings.
- This exercise is an informal update, supported by short written statements sent in advance, enabling for information sharing.
- *Contains links to relevant and important documents and publications of relevance to the research being performed in South Africa.*



# *Tour de Table*

- The “*Tour de Table*” includes information on:
  - GM crop production figures,
  - new general release additions since last meeting,
  - new commodity clearance additions since last meeting,
  - **products from new plant breeding techniques (NPBTs) and safety assessments,**
  - survey of products developed by the OECD Working Group for the Safety of Novel Foods and Feeds,
  - LLP update,
  - usefulness of the OECD Consensus documents,
  - labelling of foods with any GM content,
  - **changes in legislation (important for SA to note, can affect trade),**
  - update of progress of consensus documents,
  - **new topics/technologies of possible relevance to the Working Groups,**
  - proposals of new projects (develop new consensus documents or revise older versions of consensus documents).



# Importance to the ARC/South Africa

- The presence of multiple differences between the GM crop and the untransformed counterpart requires rigorous safety assessments to determine the impact of these unintended and unexpected alterations of the intended enhancement of the GM crop.
- Thus, it is very important that the ARC and South Africa ensures that the types of information and data used in the risk/safety assessments (including those produced using NPBTs), as well as methods used, are as similar as possible amongst countries, as indicated in the developed consensus documents.
- Ensures that we comply to the required international legislation requirements, and that we note possible changes in legislation as it can/will affect trade/export.



# OECD BioTrack Product Database

- OECD public database allows regulatory officials and other interested stakeholders to easily share basic information on products derived from the use of modern biotechnology, as well as some products with novel traits acquired by the use of conventional breeding or mutagenesis, that have been approved for commercial application in at least one country, in terms of food, feed or environmental safety.
- This database accommodates **Unique Identifiers**, which are intended to be used as "keys" to access information of each transgenic product in this database.



# OECD BioTrack Product Database

- This database is updated using information provided on a voluntary basis by authorities in OECD member/non-member countries and certain institutions that developed these products.
- Dr Oelofse has, with the assistance from DAFF, provided the OECD Secretariat with all relevant information needed in order to enter all of the approved GMO events in South Africa into the OECD BioTrack database, dating back to 1997.
- It is the first time that the South African information has been entered into the OECD BioTrack database. There are 21 general release entries and 75 commodity clearance entries.
- Dr Oelofse will ensure that the approved GMO events in South Africa will be entered into the OECD BioTrack database on a regular basis, as they are approved, with the assistance from DAFF.
- The entries can be viewed at: <http://www2.oecd.org/biotech/default.aspx>



# New Genetic Engineering Technologies

- Recent scientific progress has enabled the development of a new generation of techniques to be applied to plant breeding which are often referred to as *New Plant Breeding Techniques* (NPBTs).
- By applying these the latest methods, plant breeders can make the same desired changes with greater precision and in a much shorter time than was possible with earlier.
- Because these new methods are efficient and economical, they are accessible to public and commercial plant breeders in developed and developing countries and can be used across all agriculturally important crops, including field, vegetables and specialty crops.
- It was agreed that delegations will continue the information-sharing on NPBTs at following meetings, and will include in the written “*Tour de Table*” their experiences on NPBTs. Thus it is of importance for me to attend these workshops in South Africa.



# New Genetic Engineering Technologies

- There are no regulatory developments on NBTs in the European Union.
- Concerning the legal status of NPBTs, EU countries are waiting for a interpretation of NPBTs by the European Commission and the Opinion of the Scientific Advice Mechanism which is expected to be disclosed some time in 2017.
- In addition, the French administrative court addressed a request for a preliminary ruling to the European Court of Justice, which will be answered before April 2018.
  - In the context of a case brought by several organizations to the Conseil d'Etat (the highest administrative Court in France) on **herbicide tolerant varieties derived from mutagenesis**, the Conseil d'Etat asked questions to the Court of Justice of the European Union (CJEU) for a preliminary ruling. **These questions relate in particular to the inclusion or not of the organisms obtained by the new mutagenesis techniques within the scope of Directive 2001/18/EC on GMOs and on the validity of this Directive in the light of the precautionary principle taking into account the evolution of techniques.**
- According to the outcomes of the above deliberations the discussion may be finally resolved whether the respective methods will be subject to the EU GMO-regulations or not – will impact on South Africa.



# New Genetic Engineering Technologies

- In view of the rapid progress in agricultural biotechnologies, the Commission in September 2016 submitted a scoping paper to the High Level Group of the Scientific Advice Mechanism (SAM) (adopted in November 2016).
- The following questions on new techniques of agricultural biotechnology were proposed:
  1. key characteristics of the various new techniques
  2. comparison with established techniques
  3. scientific needs and gaps
  4. forward-looking investigation.
- The scoping paper is available on SAM's website:  
[https://ec.europa.eu/research/sam/pdf/meetings/hlg\\_sam\\_052016\\_scoping\\_paper\\_agribiotechnology.pdf](https://ec.europa.eu/research/sam/pdf/meetings/hlg_sam_052016_scoping_paper_agribiotechnology.pdf)
- SAM agreed to provide an explanatory note on the first two questions. The explanatory note was published on 28 April 2017 and is available on SAM's website:  
[https://ec.europa.eu/research/sam/pdf/topics/explanatory\\_note\\_new\\_techniques\\_agricultural\\_biotechnology.pdf](https://ec.europa.eu/research/sam/pdf/topics/explanatory_note_new_techniques_agricultural_biotechnology.pdf)



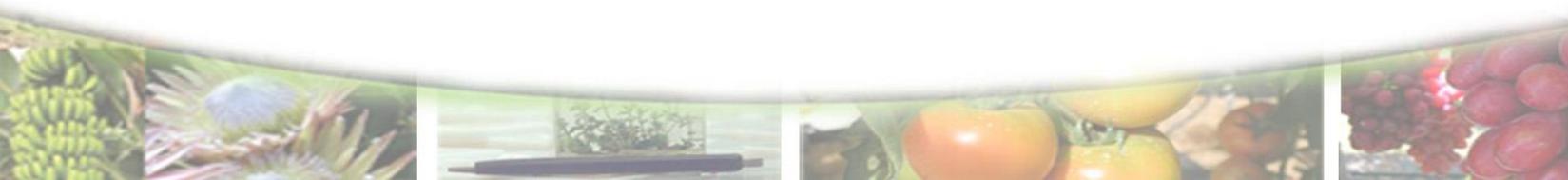
# New Genetic Engineering Technologies

- In addition, the European Commission intends to launch a public debate on how the EU can benefit from modern biotechnologies and responsible innovation in the food and agricultural sector while maintaining high safety standards.
- The EU Commissioner for Health and Food Safety will hold a high level conference on modern biotechnologies and innovation in sustainable agriculture on 28 September 2017 in Brussels.
- The objective is to gather input from, and foster constructive debate between a wide range of stakeholders.
- The conference intends to be EU-focused, however non-EU countries may participate.
- Information and outcomes from the debate will be of relevance to South Africa and should be noted.



# Health and Environmental Safety in Genome Editing Applications

- Genome editing is a new form of genetic engineering that is raising major policy implications for governments in biomedicine, agricultural applications, industrial biotechnology and sectors that are related to the bio-economy or otherwise involve the use of living systems to develop goods or services.
- It will have major implications for innovation across these sectors, whilst raising significant ethical issues, questions related to intellectual property rights, as well as human health and environmental safety concerns.
- These concerns have to be considered if the benefits of innovation are to be realized.



# Health and Environmental Safety in Genome Editing Applications

- Genome editing refers to techniques in which specialized enzymes which have been modified, can insert, replace, or remove DNA from a genome with a high degree of specificity.
- One of the most discussed of these techniques is the CRISPR/Cas9 system.
- Amongst the reasons for interest in CRISPR/Cas9 is the ease of use of this technique, as well as its low cost as compared with other techniques.
- Even modestly equipped labs are able to work with CRISPR.
- It has been successfully used with organisms of commercial importance such as crop plants and farm animals raising the possibility of new methods for the control of pests and diseases, as well as improving the efficiency of plant and animal breeding.



# Health and Environmental Safety in Genome Editing Applications

- The use of CRISPR and other gene editing techniques raises a number of policy challenges which governments will be asked to address.
- The use of this technique in agricultural crops and animals raises human health and environmental safety issues which need to be addressed.
- It will be important to consider, on the one hand, whether existing regulatory structures designed to protect health and safety will apply to genome editing.
- On the other hand, it will be important to consider whether they will be adequate enough to deal with risk assessment.
- If not, it might be necessary to update or adapt existing regulatory measures and their approach to regulatory science.
- Currently, a number of administrations are considering how best to address this topic.



# Health and Environmental Safety in Genome Editing Applications

- The OECD Council agreed to a proposal to allocate EUR 45 000 to host a workshop *Health and Environmental Safety in Genome Editing Applications* from the Secretary General's Central Priority Fund (CPF).
- Funding from the CPF is given to issues or topics which have a multi-disciplinary component and, in OECD terms, are relevant to a number of OECD programmes and committees.
- Council noted that this proposal would contribute to OECD work on: science and technology policies, including the innovation strategy; food and agricultural policies, as well as environment, health and safety. The workshop is of relevance to South Africa and South Africa must note the outcomes of the workshop.
- The workshop is proposed to be held in 2018 in conjunction with the WG HROB and WG SNFF meetings to address genome editing issues.



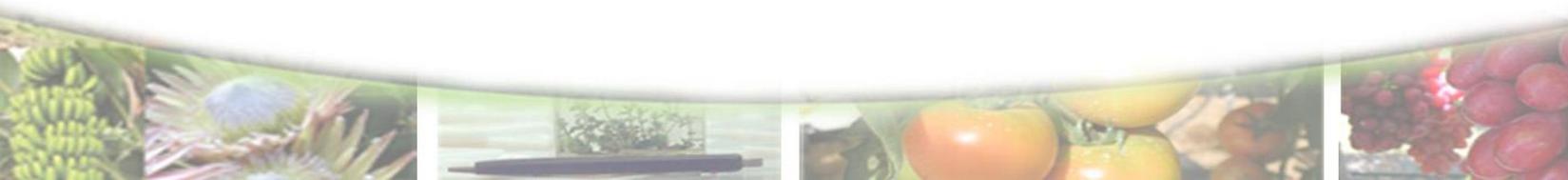
# Health and Environmental Safety in Genome Editing Applications

- This CPF project will build on existing projects underway in a number of programmes of work at OECD.
- The main programmes include:
  - harmonisation of regulatory oversight in biotechnology;
  - the safety of novel foods and feeds;
  - emerging issues in biotechnology, nanotechnology and converging technologies (Science, Technology and Innovation (STI); Science and Technology Policy (STP));
  - considerations of ethics;
  - responsibility and inclusivity of innovation;
  - biological resources in agriculture (Trade and Agricultural Directive (TAD)); and
  - schemes for the varietal certification of seed moving in international trade (TAD/COD).
- Gene editing is relevant to each of these activities and policy issues related to genetic engineering and have been or are being addressed in their programmes of work.



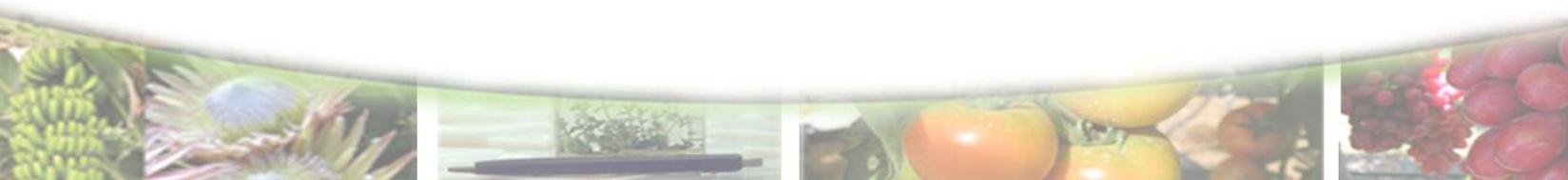
# Health and Environmental Safety in Genome Editing Applications

- The CPF will focus on the health and safety assessment issues.
- The main activity will be the organisation of the conference which will bring together:
  - policy makers working on the topic,
  - academia,
  - innovators, and
  - other stakeholders, such as the Business and Industry Advisory Committee to the OECD (BIAC), the Trade Union Advisory Committee to the OECD (TUAC) and other relevant NGOs.
- This event will:
  - identify the extent to which genome editing is raising novel safety concerns across the range of sectors known to be affected,
  - whether or not existing frameworks for risk analysis are equipped to produce necessary evidence for policy makers, and
  - what the implications are for regulation, ethics, and agricultural innovation.



# Health and Environmental Safety in Genome Editing Applications

- The main deliverable will be a final report (including the proceedings of the conference) which will:
  - identify and analyse any specific safety concerns and their implications for regulatory systems and innovation,
  - their uncertainties, and
  - potential policy remedies.
- Council recognised the following three benefits/outcomes to the project:
  1. A clearer understanding of the regulatory challenges raised by genome editing across a range of sectors;
  2. The identification of the policy responses needed to address these challenges, especially in the respective OECD Committees: Committee on Agriculture (COAG), Committee for Science and Technology Policy (CSTP), Chemicals Committee and the Environment Policy (EPOC); and
  3. A coherent policy approach to facilitate innovation involving genome editing.



# Genome editing: scientific opportunities, public interests and policy options in the European Union (March 2017)

EASAC – the **European Academies' Science Advisory Council** – is formed by the national science academies of the

EU Member States to enable them to collaborate with each other in giving advice to European policy-makers. It thus provides a means for the collective voice of European science to be heard.

EASAC was founded in 2001 at the Royal Swedish Academy of Sciences.



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