OECD and Biosafety Considerations

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

- The OECD was established in 1961.
- Headquarters: Paris, France.
- The OECD provides a forum in which governments can work together to share experiences and seek solutions to common problems.

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OECD Member Countries

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	

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OECD Key Partners

- These Key Partners contribute to the OECD's work in a sustained and comprehensive manner.
    - Brazil
    - India
    - Indonesia
    - China
    - South Africa

OECD Participation

- As from March 2012, a non-OECD member country committee member of the:
  - OECD Task Force for Novel Foods and Feeds.
  - OECD Working Group on Harmonisation of Regulatory Oversight in Biotechnology.

- As from April 2015, a Bureau member of the OECD Task Force for Novel Foods and Feeds.

Task Force (TF) and Working Group (WG)

- One of the challenging issues facing countries is the safety assessment of products derived from biotechnology, especially seeing that there is a worldwide increase in the cultivation of genetically engineered crops.
- These products are rigorously assessed by governments to ensure that they meet the standards that ensure human food, animal feed and environmental safety.
- In order 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.

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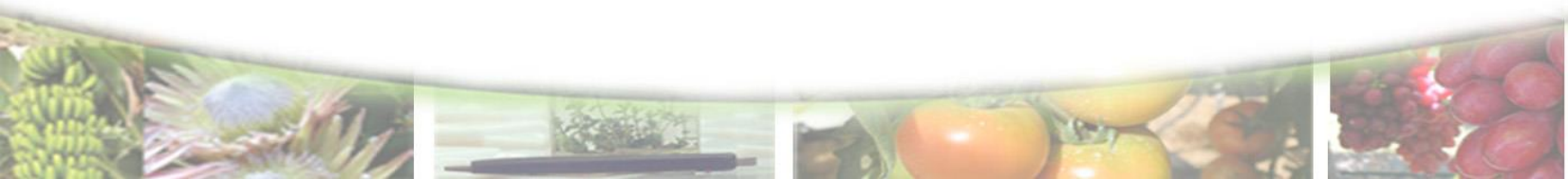
Task Force (TF) and Working Group (WG)

- Two closely related programs of work at the OECD has resulted in the establishment of:
  - The Working Group on Harmonisation of Regulatory Oversight in Biotechnology.
  - The Task Force for the Safety of Novel Foods and Feeds.

Task Force (TF) and Working Group (WG)

- The Working Group on Harmonisation of Regulatory Oversight in Biotechnology addresses aspects of the environmental risk/safety assessment of GM plants, fish and micro-organisms.

- The Task Force for the Safety of Novel Foods and Feeds addresses aspects of the safety assessment of foods and feeds derived from GM crops.



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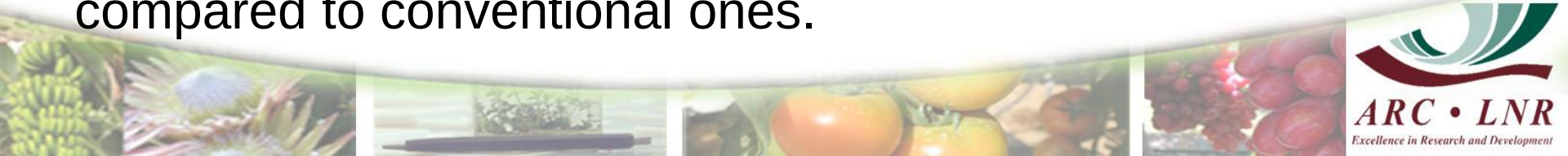
Task Force (TF) and Working Group (WG)

- 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.



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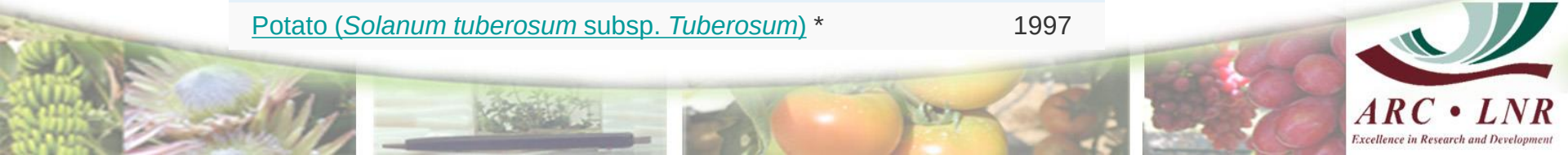
The Working Group on Harmonisation of Regulatory Oversight in Biotechnology

- The 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.

The Working Group on Harmonisation of Regulatory Oversight in Biotechnology

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

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



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The Working Group on Harmonisation of Regulatory Oversight in Biotechnology

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

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The Working Group on Harmonisation of Regulatory Oversight in Biotechnology

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

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The Working Group on Harmonisation of Regulatory Oversight in Biotechnology

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

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The Working Group on Harmonisation of Regulatory Oversight in Biotechnology

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

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The Task Force for the Safety of Novel Foods and Feeds

- Food and feed safety assessments are addressed in the TF 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.

The Task Force for the Safety of Novel Foods and Feeds

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

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

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The Task Force for the Safety of Novel Foods and Feeds

Consensus Documentfor Facilitating Harmonisation in Food/Feed Safety Assessment	Year
Molecular Characterisation of Plants Derived from Modern Biotechnology	2010
An Introduction to the Food/Feed Safety Consensus Documents of the Task Force	2006
Considerations for the Safety Assessment of Animal Feedstuffs derived from Genetically Modified Plants	2003

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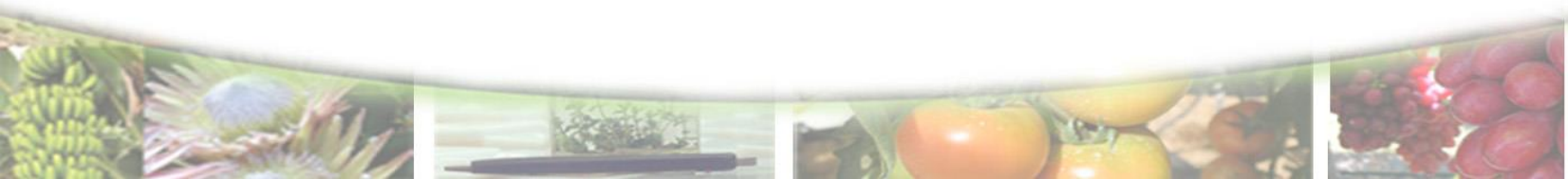
OECD BioTrack Product Database

- 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.



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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.
- This database accommodates **Unique Identifiers**, which are intended to be used as "keys" to access information of each transgenic product in this database.

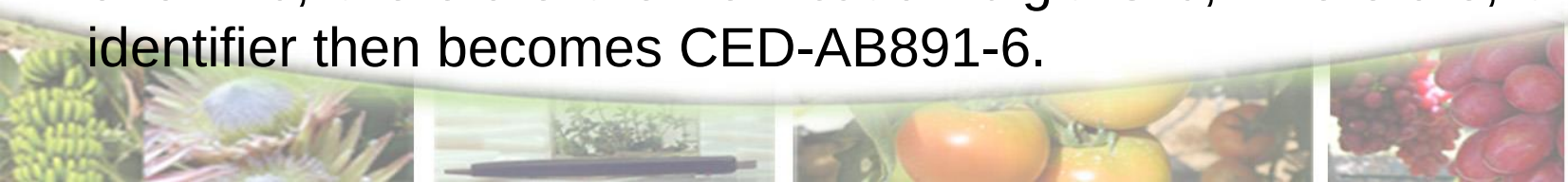
OECD BioTrack Product Database

- **Unique Identifier** is a code of a fixed length of 9 alphanumeric digits for a product derived from recombinant DNA techniques.
- It is composed of three elements separated by dashes:
  - 2 or 3 alphanumerical digits to designate the applicant;
  - 5 or 6 alphanumerical digits to designate the "transformation event"; and
  - One numerical digit as a verification. The verification digit is intended to reduce errors by ensuring the integrity of the alphanumeric code, entered by the users of the database.

OECD BioTrack Product Database

- Unique Identifier example:

  – C E D – A B 8 9 1 – 6 or C E – A B C 8 9 1 – 5
- The verification digit is calculated by adding together the numerical values of each of the alphanumerical digits in the unique identifier.
- The numerical value of each of the digits is from Ø to 9 for the numerical digits (Ø to 9) and 1 to 26 for the alphabetical digits (A to Z)
- The total sum will be calculated by adding the remaining digits together using the same rule until the final sum is a single numerical digit.
- For example, the verification digit for the code CED-AB891 is calculated as follows: Step one: 3+5+4+1+2+8+9+1 = 33; Step two: 3+3 = 6; therefore the verification digit is 6; Therefore, this unique identifier then becomes CED-AB891-6.



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New Plant Breeding Techniques (NPBT)

- Science is continuously developing new techniques for advancing plant breeding.
- It is important to begin to understand whether and how countries are contemplating regulation and environmental risk/safety assessment of the emerging plant products and the biotechnologies used to develop them.
- Certain these new techniques have been identified by some as New Plant Breeding Techniques (NPBT, Lusser *et al,* 2012).

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New Plant Breeding Techniques (NPBT)

NPBT after Lusser *et al.* (2011)

Agro-infiltration	Genetic material, so-called T-DNA, is inserted in a plant to express transiently by vector such as *A. tumefaciens*.
Cisgenesis/Intragenesis	Genes derived from cross-compatible species are inserted into a plant genome.
Grafting on GM rootstock on wild-type Scion	GM rootstock is grafted to non-GM scion without possessing transgenic elements in the leaves or fruits.
Oligonucleotide Directed Mutagenesis (ODM)	Specific mutation is introduced in a defined place in a plant genome by introducing synthetic oligonucleotides as a target to homologous genes.
Reverse Breeding	Homozygous parental plant is generated from selected heterozygous plant by the suppression of meiotic recombination by RNA interference.
RNA-directed DNA methylation (RdDM)	Methylation of promoter region is induced by the introduction of RNA fragments, which results in silencing of the downstream gene.
Site Directed Nucleases (SDN)	Targeted mutagenesis of genes or targeted insertions/deletions of genetic material are achieved by some protein complexes.

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New Plant Breeding Techniques (NPBT)

- A questionnaire was developed to obtain an understanding of the types of plants under development, the phenotypic changes being introduced and the new technologies deployed to develop them.
- Some countries reported knowledge of plants being developed by NPBT.
- The techniques that were mentioned most frequently include Oligonucleotide Directed Mutagenesis (ODM) and cisgenesis.

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New Plant Breeding Techniques (NPBT)

- The traits mentioned most frequently were pathogen resistance (e.g. late blight, fire blight or scab resistance) or herbicide tolerance.
- The crops mentioned as most frequently being developed by the application of NPBT were food crops (e.g. apple, potato and maize), although most of them are still in the research phase and not yet approaching commercial use.

New Plant Breeding Techniques (NPBT)

- Some countries mentioned that they were informed of the perspective of the public and private sector on plants developed using NPBT, many of which advocate following a science-based evaluation in which new characteristics of the product, i.e. phenotype, should determine if an ER/SA is required and not whether the plant is obtained by a NPBT.
- If this approach was followed, some plants obtained by NPB might be exempted from regulation and ER/SA procedures, since many NPBT produce plants that resemble conventional breeding methods that have an established history of safe use (e.g. chemical mutation breeding) or natural crossing techniques.

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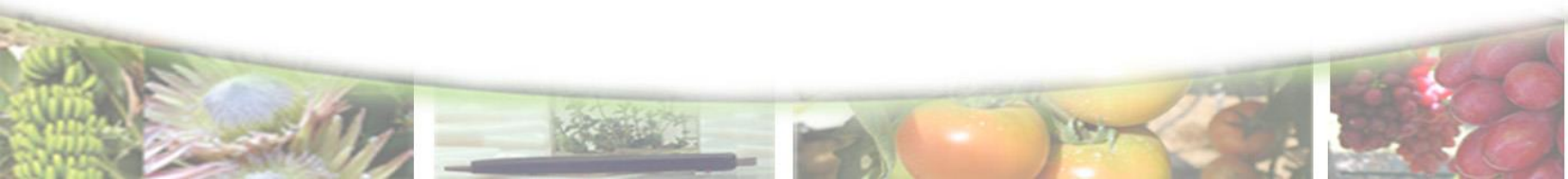
New Plant Breeding Techniques (NPBT)

- Indeed, plants that are developed by these techniques are often indistinguishable from conventional bred varieties.
- It was also noted that such an approach would be dependent on the requirements of each country's regulatory framework.
- Lowering the regulatory burden could stimulate innovation since it enables also small and medium enterprises (SMEs) to develop plants with NPBT.

New Plant Breeding Techniques (NPBT)

- Most countries indicated that, to date, they do not have practical experience in performing an ER/SA for a plants developed through techniques considered to be NPBT.
- A few countries indicated that they have performed an ER/SA for plants developed by NPBT because the techniques and/or plants are subject to regulation through existing regulatory frameworks.
- In these cases no new safety issues were identified and according to these countries current guidance tools for ER/SA were considered adequate.



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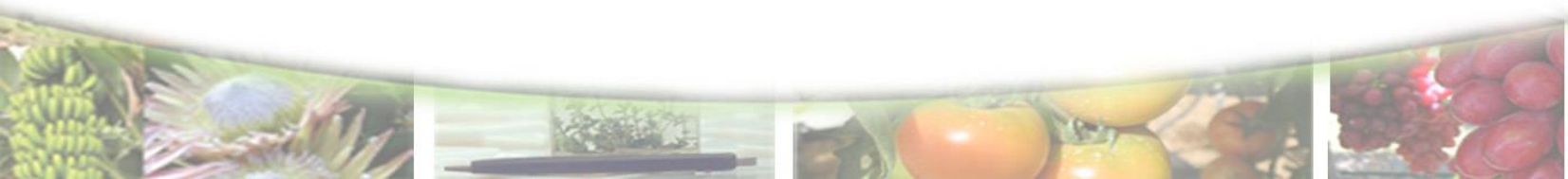
New Plant Breeding Techniques (NPBT)

- The discussion and the different presentations brought up many different perspectives, experiences and considerations.
- However, consensus existed among participants that to date, current guidance and tools for ER/SA of transgenic plants are applicable to plants developed using NPBT, where ER/SA of such plants is required.
- The workshop participants also acknowledged that the application of NPBT in plant development will remain topical because it also raises a range of other issues including policy, legal and trade, and that these were beyond the scope of the workshop.

OECD questionnaire on environmental risk/safety assessment of plants developed with New Plant Breeding Techniques (NPBT)

- ***Note:*** *I am not the authorised focal point to speak on the matter, but this is my understanding of the local situation based on the responses received from the role players in South Africa that completed the OECD questionnaire.*
- Questionnaire sent to about 20 role players in South Africa, with the Department of Science and Technology (DST) providing contact details of a number of the role players in South Africa.
- Nine provided inputs (of note being the Department of Agriculture, Forestry and Fisheries (DAFF), BioSafety South Africa, Syngenta South Africa, Pioneer, the ARC Biotechnology Platform and a number of Universities).



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Question I: Does South Africa consider NPBT? Which techniques does your country consider as NPBT?

- Yes, we would, but only to the extent that the product generated by an NPBT adheres to the definition of a genetically modified organism as per the GMO Act.
- A number of NPBTs are being developed at a research level, however, there is no specific guidance as yet as to what constitutes an NPBT.
- We would view the JRC list as NBPTs.

Question II: Is South Africa seeing any plants developed with NPBT in the private or public sector (industry and/or academia)?

- No application has been received under the GMO Act which involves NPBTs. We do not have access to other non-regulated research developments (which may include the use of NPBTs).
- None of the currently used GM crops have been developed in South Africa, only evaluated. Most of the “new” GM crops are generated by conventional breeding techniques using approved GM crops, and also require approval before planting and distribution.
- No imminent applications that we are aware of as most activities are early stage research and development work.

Question III: Does South Africa have any practical experience in performing an environmental risk/safety assessment on plants developed with NPBT?

- No
- The regulatory procedure which must be followed will depend on a large degree on whether the NPBT is classified as a GMO or not. This definition has not changed since the GMO Act was first passed.
- The GMO Act has been drafted in a way that enables the Executive Council (EC) to implement a case-by-case risk assessment approach for new technologies. The EC is expected to deal with this on a case-by-case basis as they are empowered to so by law.

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Question III: Does South Africa have any practical experience in performing an environmental risk/safety assessment on plants developed with NPBT?

- No environmental risk/safety assessments for plants developed with NPBTs have been made available to the public because none done to date, thus no relevant reports, guidance documents and links available for South Africa.

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Do you expect plants developed using NPBT will give rise to new issues in environmental risk/safety assessment and, if so, what are those issues?

- It may be possible, in South Africa we apply a case-by-case approach, implying that not all NPBTs would give rise to the same concern.
- No new issues or new risks.
- The current environmental risk assessment process being followed in the country will be able to cover NPBTs. Furthermore, the EC has the authority to request additional risk assessment data if required.
- The requirements of the existing field trial application forms require ERA for all GMOs that will be released to the environment.

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Question IV: Have the public or private sector (academia and/or industry) provided their perspective regarding environmental risk/safety assessment of plants developed with NPBT?

- No formal engagement focussing on NPBTs has occurred between academia/ industry and regulators that we are aware of. This has been done on an informal basis.
- Various organizations have submitted inputs to the authorities independently. Details are not available.

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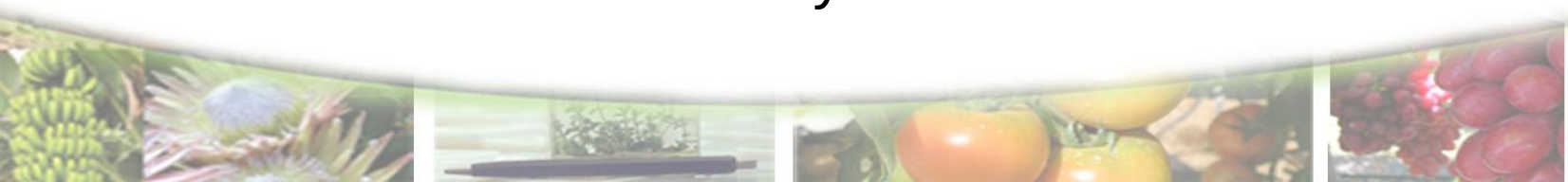
Question V: Are there other questions on NPBTs you consider to be of importance in South Africa?

- No, we're still assessing the potential implications of NPBTs on our current Risk Assessment approach.
- Regulatory uncertainty and potentially prohibitive costs for risk assessments if crops made from these techniques are classified as GMOs may restrict their development.
- It would be of prime importance if regulatory hurdles, which make it difficult to implement beneficial technologies for the poor, could be removed or weakened to a meaningful extent.
- Food production improvement is very important for South Africa and the rest of the African continent – while we pursue increased food production – we need to pay equal attention to issues related to food safety.



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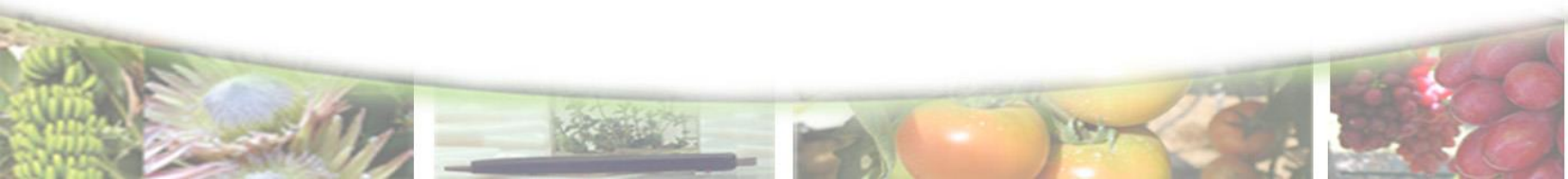
Question V: Are there other questions on NPBTs you consider to be of importance in South Africa?

- In principal the products of NPBTs should be covered within a biosafety framework, but for South Africa this is primarily the GMO Act.
- It would be very undesirable to extend the regulatory space, but at the same time, there needs to be a reasonable process in terms of decisions about what risk assessment is required or desirable.
- Also it is important that we do not get a moratorium on the implementation of NPBTs, it would be better to consider them under existing regulation, until there are developments in that legal environment.



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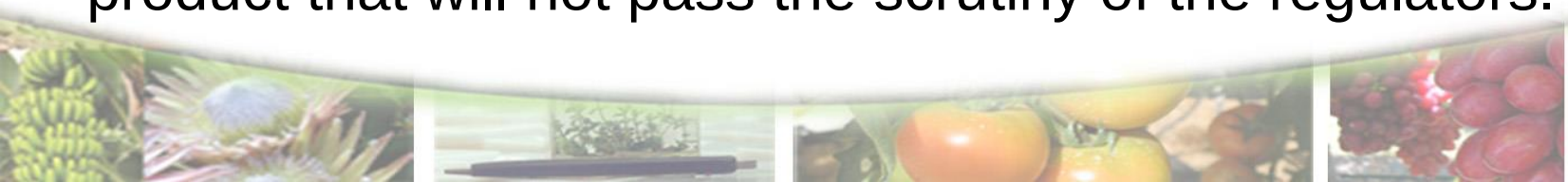
Question VI: What do you consider to be important objectives and outcomes for the OECD workshop? Are there NPBT that are of particular interest to South Africa?

- All of the emerging NPBTs are important for Africa and should be utilized to develop low-input/high yielding crops.
- An important outcome would be to produce a guidance document for the environmental risk assessment of NPBTs.
- A clear policy/advisory document detailed enough to be informative to specialists, as well as simple enough to be understood by consumers and the rest of the society. Scientists need to be trained and empowered so that they can approach their scientific experiments with the end user in mind. After all, no one wants to work for many years on developing a product that will not pass the scrutiny of the regulators.



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Question VI: What do you consider to be important objectives and outcomes for the OECD workshop? Are there NPBT that are of particular interest to South Africa?

- Consideration needs to be given to whether the regulation should be around the technology, or the phenotypic changes that are introduced. For example, we have both transgenic and mutation based tolerance to herbicides; but the regulation and risk assessment of the GM version is not the same as for the non-GM version, although they are exactly the same phenotypic trait with the same risks.

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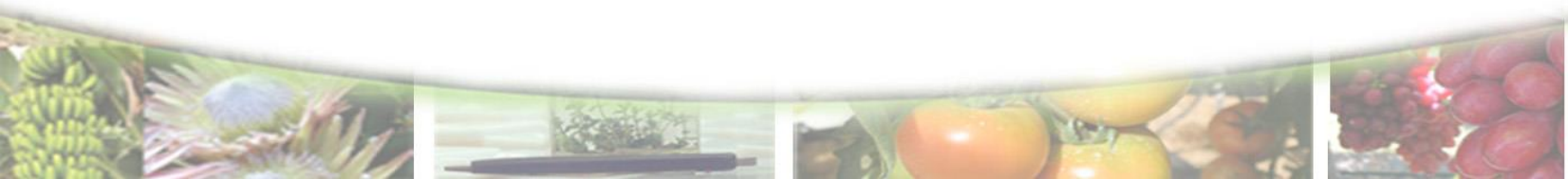
Question VI: What do you consider to be important objectives and outcomes for the OECD workshop? Are there NPBT that are of particular interest to South Africa?

- How do we avoid increasing entrance barriers for NBTs (especially for public institutions and small start-up Biotech companies that may have limited budgets to conduct comprehensive ERA research? Is it possible to consider benefits as well, and not only assess the risks so that there is a balanced outcome of the process?)



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Joint Reviews on Novel Foods and Feeds Safety Assessments

- A joint review is defined as the formal process where the review is done by two or more countries.
- The OECD provides a forum for regulatory collaboration via the Working Group on Pesticides and Registration Steering Committee.
- The OECD Guidance Document on Planning and Implementation of Pesticide Joint Reviews is available to guide the process.
- It was highlighted that joint reviews are strongly driven by only a limited number of countries, ie the USA, Canada and Australia.
-

Joint Reviews on Novel Foods and Feeds Safety Assessments

- Important to note for joint reviews are:
  - Early contact between collaborating countries is essential.
  - One country takes the lead.
  - A project plan must be developed.
  - The work is split between the countries involved.
  - Timelines are essential, ie dates of key milestones and deliverables.

Joint Reviews on Novel Foods and Feeds Safety Assessments

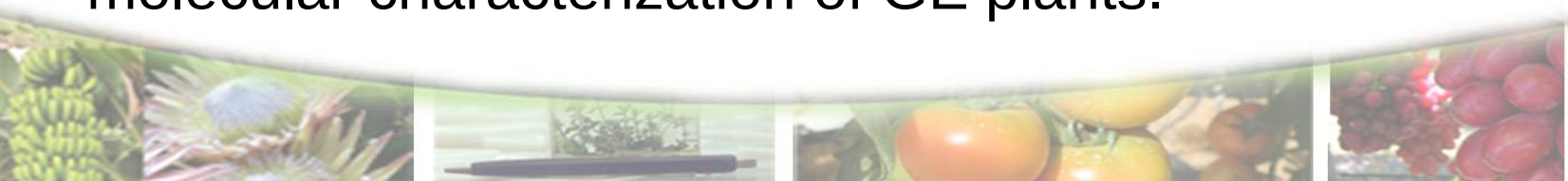
- The benefits of joint reviews are:
  - Strengthens the review process.
  - Increases the efficiency of the process.
  - Facilitates simultaneous evaluation in different jurisdictions, thus different climatic zones.
  - Joint reviews contribute to capacity building in countries lacking in experience.

Joint Reviews on Novel Foods and Feeds Safety Assessments

- The USA commented that the exercise was useful to learn about the counterparts regulatory systems. However, simultaneous evaluation of the submission did not make the process more efficient, the result of co-ordination issues.
- If felt appropriate, elements for future activities to be developed in the TF framework could be identified during the discussion. However, delegations felt premature to undertake such activity in the framework of the Task Force. The subject of Joint Reviews can be informally discussed at the next Task Force meeting.

High Throughput DNA Sequencing in the Safety Assessment of GE Plants

- Proposes to hold a ‘Seminar/Workshop’ for exchanging information and explore the matter, back-to-back with the next meetings of the Task Force and the Working Group in 2016.
- The background information will explain the central role molecular characterization, including that of inserted DNA and products of transcription and translation (RNA, proteins), has in the safety assessment of GE plants.
- Provide attendees with a general overview of genome sequencing so that attendees can generally understand the new methods of DNA sequencing that may be used in the molecular characterization of GE plants.



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High Throughput DNA Sequencing in the Safety Assessment of GE Plants

- **Canadian experiences and insights**
  - This presentation will highlight the outcomes of a workshop that was held to engage various stakeholders, including experts in Next Generation Sequencing (NGS) technology and bioinformatics. Progress on drafting guidance and training for scientific evaluators on NGS data interpretation and critical assessment in the context of GM food submissions will be shared.

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- **Belgian experiences and insights**
  - On the utility of NGS for characterization of GMOs, the Biosafety & Biotechnology Unit (SBB) hosted a workshop end 2013 jointly with the Biotechnology and Molecular Biology Platform (PBB), both Units of the Scientific Institute of Public health (WIV-ISP). Feedback, partly obtained from the organized workshop, and the analysis of the WIV-ISP on the utility of NGS for the purpose of molecular characterization of GMOs is provided.

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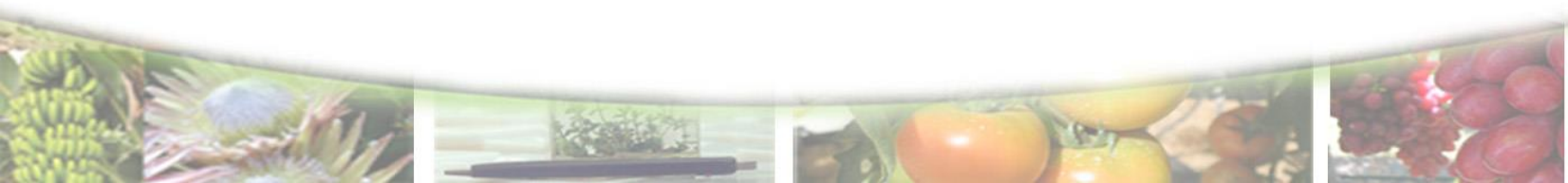
- **U.S. experiences and insights**
  - This presentation will focus on how the U.S. FDA's experience considering genome sequence data as part of consultations on the safety assessment of foods derived from GE plants. The U.S. FDA has completed several consultations where genome sequence data derived from newer DNA sequencing methods has been considered. Part of this presentation will focus on how the U.S. has managed these data in a regulatory dossier.



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- **Development of a short proceedings document .**
  - Feedback from the workshop, including a summary of the presentations and discussions, will be briefly presented at the ensuing meeting of the OECD Task Force for the Safety of Novel Foods and Feeds.
  - The workshop organizing committee intends to publish (i.e., declassify) a short proceedings document describing the talks presented during the session.
  - The paper will have no conclusions or recommendations.

THANK YOU FOR YOUR ATTENTION