Risk/Safety Assessment of Modern Biotechnology Products

OECD’s harmonized approach and tools for biosafety

FAO International Technical Conference on Agricultural Biotechnologies in Developing Countries (ABDC-10) Guadalajara, Mexico, 1-4 March 2010
Organisation for Economic Co-operation and Development

31 Members (including Chile 1st half of 2010) + 4 Candidates for accession + 5 Enhanced Engagement countries

Other countries involved in **OECD biosafety work** (global collaboration): Argentina, Cameroon, Latvia, Philippines, Thailand, and observers: FAO...
OECD Biosafety Work Basic Principles

Purposes:

- Assist countries to evaluate potential risks of modern biotech products for human-animal health and environment, and ensure high standards of safety
- Limit duplicative efforts: mutual understanding and acceptable data
- Reduce the potential for non-tariff barriers to trade

Means:

- Harmonisation of approaches and regulatory frameworks
- Share/disseminate common base of scientific information
OECD Biosafety Work Main Outputs

“Consensus” and Guidance Documents
- to help assessment and decision process
- practical tools for comparing conventional and “GE” products (comparative approach) – available online

“Is this new crop-organism/new food-feed as safe as its conventional counterpart?”

Exchange/cooperation between biosafety Authorities on current and new issues

Database on transgenic products

Workshops, other events
OECD Biosafety Work

organised in two programmes:

1) **Environmental safety of transgenic organisms**
   Working Group for the Harmonisation of Regulatory Oversight in Biotechnology

2) **Foods/feeds derived from transgenic organisms**
   Task Force for the Safety of Novel Foods and Feeds
Environmental Safety Consensus Documents

**Biology of crops and traits:** use in agriculture or forestry, taxonomy, centre of origin/diversity, reproduction, wild relatives/hybridisation etc.

- *e.g. crops:* rice, cotton, peppers, papaya, bananas & plantains, oyster mushroom... *(future: cassava, sugarcane)*
- *e.g. trees:* stone fruits, poplars, spruces, pines,... *(future: eucalyptus)*
- *e.g. traits:* virus resistance, herbicide toler., pest resist. (Bt)...  

**Micro-organisms:** *pseudomonas*, *baculoviruses*, *acinobacter*...

Detection methods, bacteria taxonomy *(future: fusarium, bacteria pathogenicity factors..)*

**Future:** *Fish* - Atlantic salmon

**Guidance documents:** Unique identifier: used in databases (OECD, CBD, FAO-IPFSAPH, industry, others)

*(Future guidance docs: Environmental Considerations, Low level presence, Molecular characterisation)*
Food/ Feed Safety Consensus Documents

Include information for use in food/ feed safety assessment of new varieties on key Nutrients, Anti-nutrients, Toxicants, Allergens

Some published docs.:

- on compositional considerations of soybean; canola (under review), potato, maize, cotton, rice, cultivated mushroom (Agaric b.), tomato, ...

(future docs: sweet potato, papaya, grain sorghum, sugarcane)

- Safety assessment of animal feedstuffs
Generating “Consensus Documents” relevant for environmental assessment and decision making process: a Mexican perspective

**Mexico’s Use of OECD Documents**

*Guidance documents:* The *Unique Identifier* for G.E. plants is required by the Mexican Legislation, and the OECD system is the most commonly used in national databases.

*Biology of crops and traits documents:* Used for complementing base line information for the risk assessment and decision making process: *Cotton, Maize, Herbicide tolerance, Pest resistance (Bt)*
MEXICO and the OECD Biosafety Work

**SOME BENEFITS** from MEXICO’s participation in the elaboration of OECD biosafety documents:

- Providing inputs to documents in progress
- Leading country for *maize* (issue 2007) and *cucurbits* (to be issued mid-2010) biology consensus documents
- Participating in steering committees
Objective: Coordinate public policy on biosafety of GMOs
MEXICO and the OECD Biosafety Work

Providing Inputs to Documents in Progress

1. Identify national experts on specific subjects:  
   Enforces national networking, and awareness

2. Contact experts and ask for reviews and comments:  
   Contributes to international networking and information exchange

3. Follow-up integration of received comments, and provide inputs:  
   Supply to enrich the process, identify relevant information and improve the outcome
MEXICO: Leading country for OECD biology documents on maize and cucurbits

1. Identifying national experts on these crops, promoting coordination and common goals:
   Contributes to expand dialogue between national academic groups, integration of information

2. Generate draft and consider inputs from all experts from OECD and other involved countries:
   Contributes to international networking and info. exchange, identifying general relevant information

3. The exercise can also lead to generating national information on these crops: *Cucurbita* doc. generated the integration of information for this cultivated family that will also result in a publication with a local approach
MEXICO’s Participation in OECD Steering Committees: “Environmental Considerations” project

1. Involvement of national government officials:
   Contributes to harmonization and common understanding on Risk Assessment

2. Coordination with competent authorities to analyzed science-based information and compare/refine approaches:
   Keeps on the relevant national experts/consulting bodies with the “State of the Art”

3. Capacity building at local level:
   Contributes to understanding of regional differences and to elaborate solutions fulfilling local challenges
The OECD Task Force identified the need to produce a Cassava document. South Africa proposed as leader, co-chaired by Brazil (both non OECD members = “observer countries”) and Canada.

2007 Expert Group meeting in Pretoria (ZA) in order to
• Identify the specific needs due to cassava particularities;
• Compose a working team with experts from Colombia, Nigeria, USA, Sweden, Canada, South Africa and Brazil, under coordination of South Africa/Witwatersrand University expert, with strong leadership of senior partner in Food Safety FoodNCropBio, and support by OECD Secretariat
• Distribute tasks by expertise: breeding, biology, food composition, food processing, toxicology (among others)

Challenge for the group: produce an OECD document!
A new crop ... for developing countries ....
With not very much information available in English.
The CASSAVA Story ... ... a Team Work approach!

2008 First draft ‘Consensus Document’ presented to the OECD Task Force, Challenges:
◊ Introduce cassava to delegates who have never tasted or seen it!
◊ Get support and obtain necessary information from other OECD members and observers
Subsequent revisions circulated for discussion, suggestions and re-draft. **Challenge**: get reliable scientific references for all information needed.

2009 Final version agreed by the Task Force, for declassification:
First consensus document coordinated by an observer country at the OECD Task Force, for a crop that is mainly for subsistence.

**Cassava Producing Countries** such as Nigeria, RD Congo, Brazil, Kenya, South Africa, Colombia... can now use the document in support to their national legislation.

R&D centers in USA which are developing GM cassava varieties, might use the document as a reference as well!
ABOUT THE OECD
FOREWORD
PREAMBLE
THE ROLE OF COMPARATIVE APPROACH AS PART OF A SAFETY ASSESSMENT
ACRONYMS
SECTION I – BACKGROUND
1. General description of cassava
2. Production ..... 
3. Processing and Use 
3.1 General human and animal consumption
3.2 Human food processing 
3.3 Animal feed processing
3.4 Range of industrial food products
3.5 Ethanol production and animal feed by-products
4. Appropriate comparators for testing new varieties
5. Breeding characteristics screened by developers ..
SECTION II – NUTRIENTS
1. Unprocessed roots and leaves .
   1.1 Proximate composition

Consensus Document on Compositional Considerations for New Varieties of Cassava (Manihot esculenta Crantz): Key Food and Feed Nutrients, Anti-nutrients, Toxicants and Allergens

1.2 Carbohydrates
1.3 True protein (amino acids)
1.4 Lipids
1.5 Minerals
1.6 Vitamins
2. Processed cassava products

SECTION III – OTHER CONSTITUENTS
1. Anti-nutrients
1.1 Tannins
1.2 Phytic Acid
1.3 Oxalate, Nitrate, Polyphenol, Saponin, Trypsin inhibitor
2. Toxicants
3. Allergens

SECTION IV- SUGGESTED CONSTITUENTS TO BE ANALYZED RELATED TO FOOD USE
1. Food uses and products
2. Suggested analysis for food use

SECTION V - SUGGESTED CONSTITUENTS TO BE ANALYZED RELATED TO FEED USE
1. Livestock feed uses
2. Suggested analysis for feed use

SECTION VI – REFERENCES
CASSAVA FOOD HABITS IN LATIN AMERICA

Paraguay ◊ 100 % of population in rural areas; 80 % of population in urban areas: boiled, fried, food preparations
Brazil ◊ North-East and North areas: cassava flour, boiled, fried, bakery products, food preparations
Colombia ◊ Bakery products, fried products, food preparations
Mexico ◊ Not a food habit, almost not consumed
Argentina ◊ Not a food habit, almost not consumed expect by small farmers (border with Paraguay), family-based agriculture, boiled and fried
Chile ◊ Not a food habit, almost not consumed
Peru ◊ Bakery products, fried products, food preparations.
Costa Rica ◊ Food preparations with meat, potato and plantain (olla de carne)
Cuba ◊ Fried, food preparations
Thank You!

OECD Biosafety Consensus Documents online:

http://www.oecd.org/biotrack

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