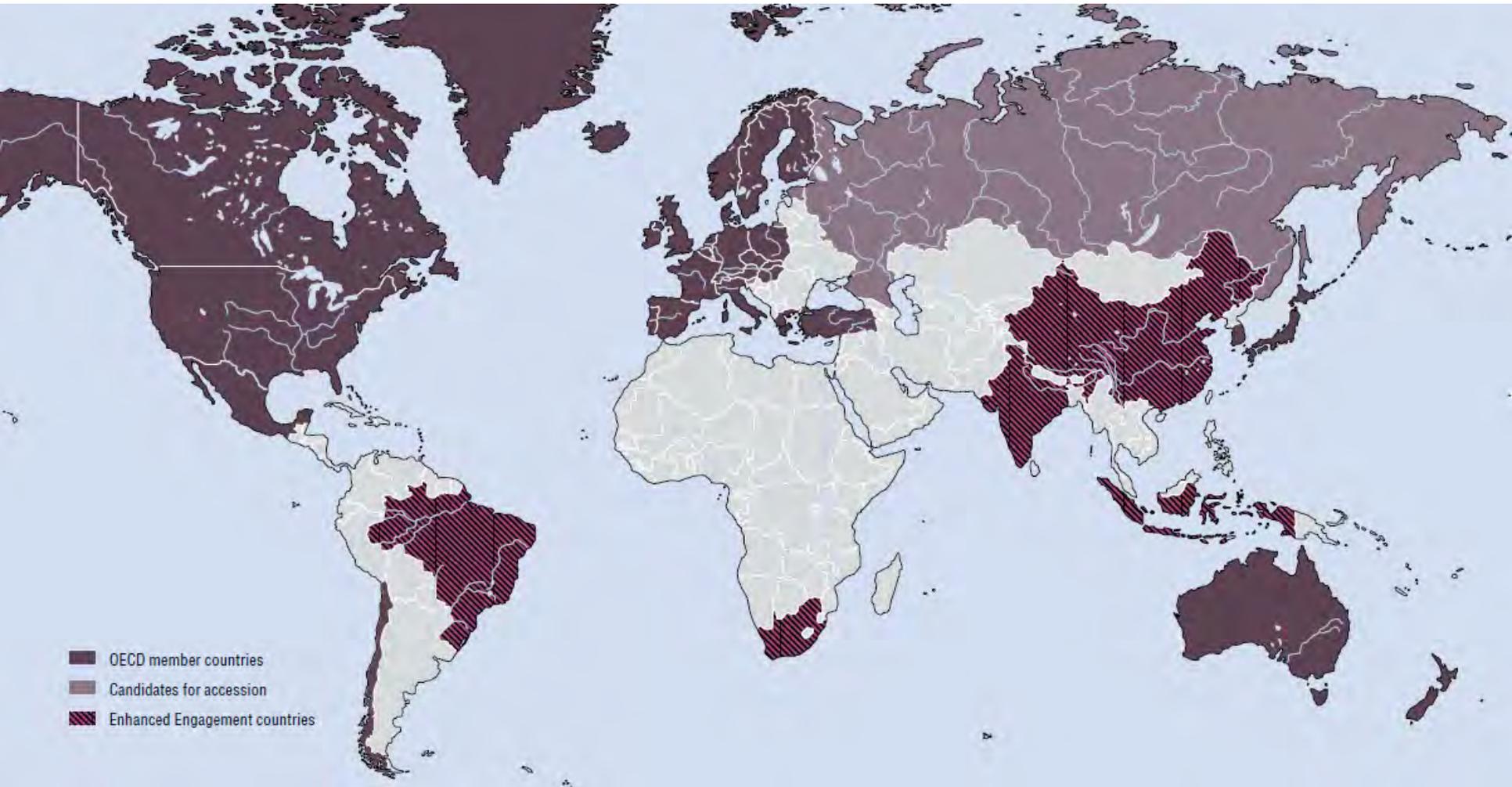




Risk/Safety Assessment of Modern Biotechnology Products

**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*



*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)*

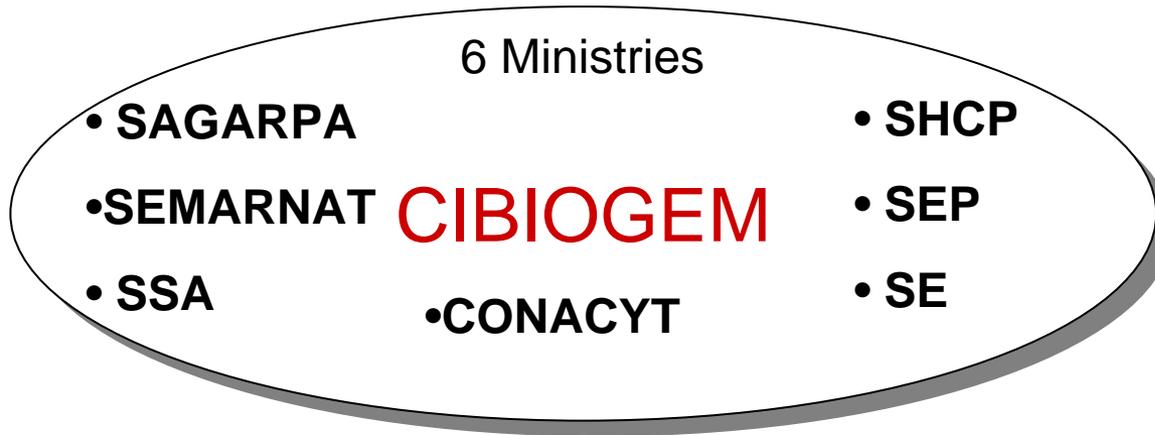
MEXICO and the OECD Biosafety Work



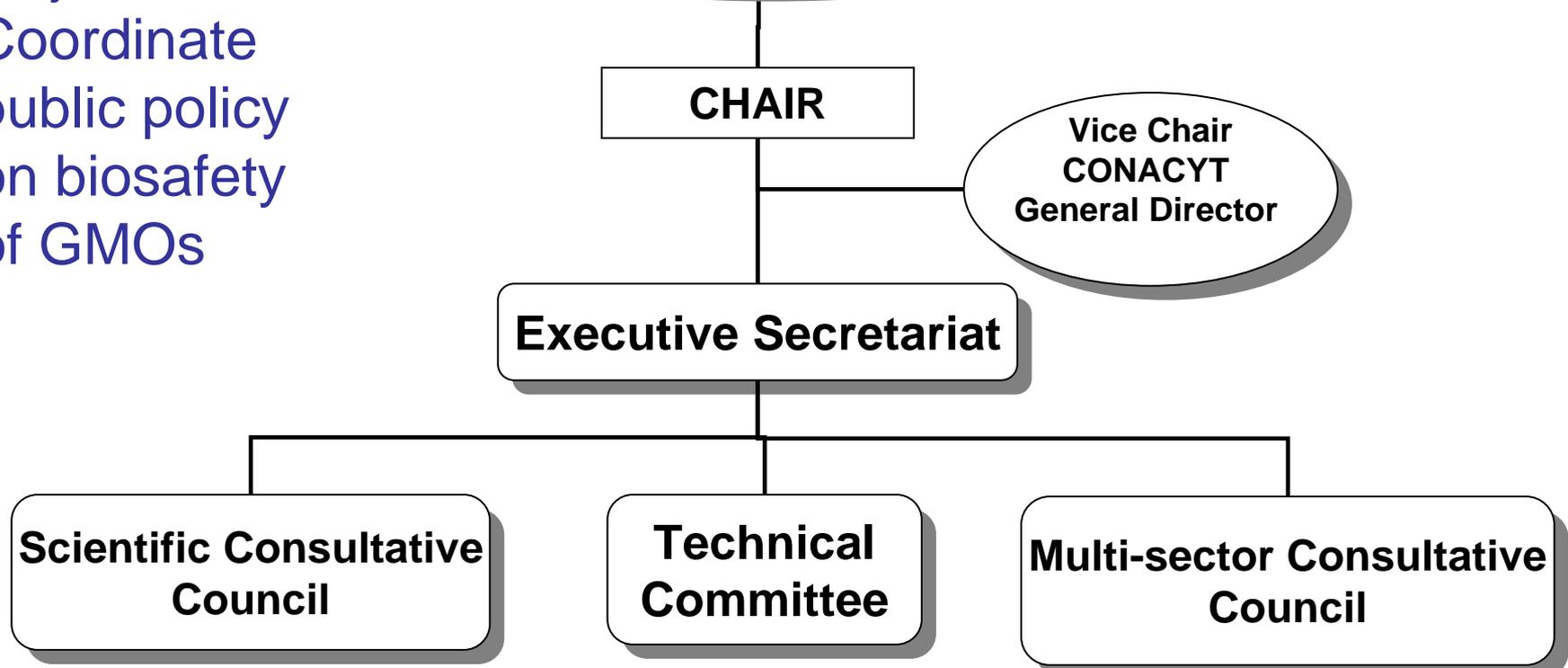
SOME BENEFITS from MEXICO's participation in the elaboration of OECD biosafety documents:

- 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

COORDINATED FRAMEWORK



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

Generating “ OECD Food/ Feed Safety Consensus Document “

The CASSAVA Story a Team Work approach!



2006 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

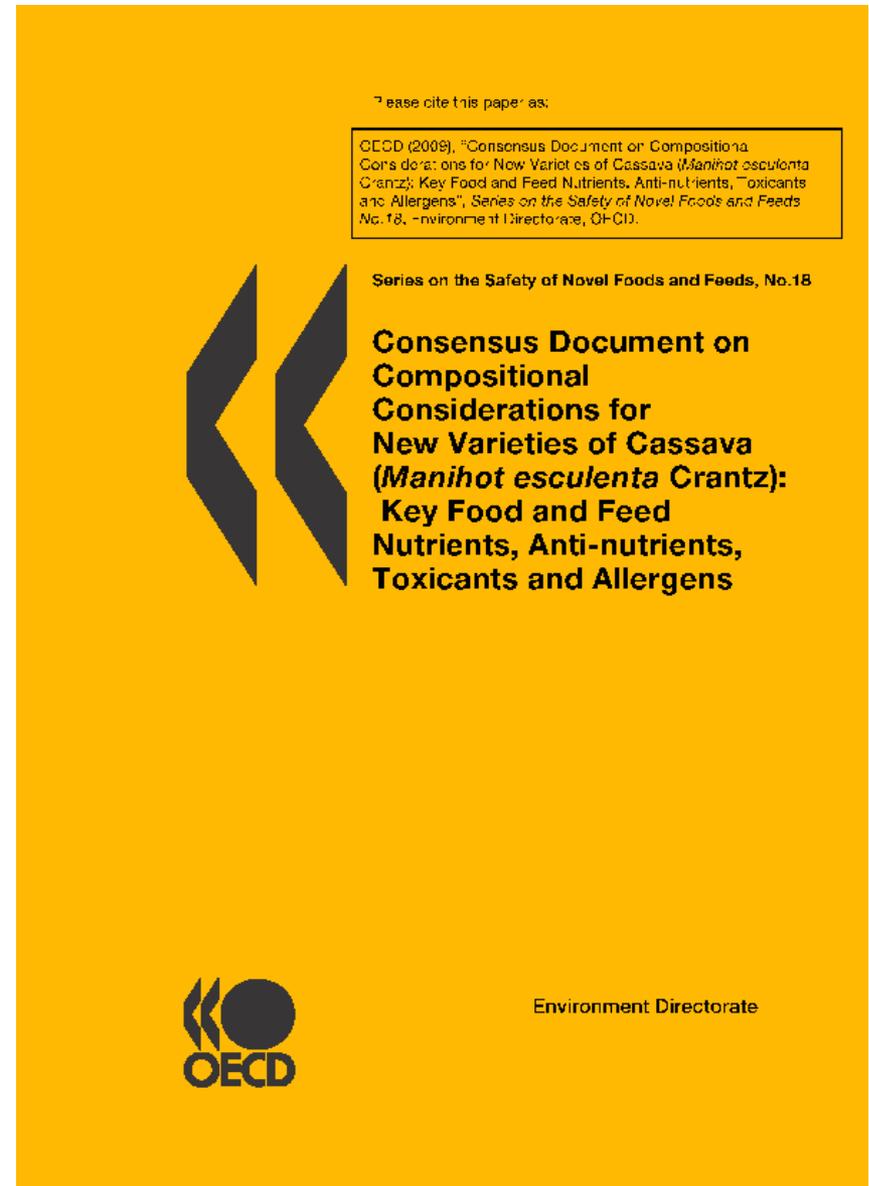
ACRONYMS

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



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

Please cite this paper as:

OECD (2009), "Consensus Document on Compositional Considerations for New Varieties of Cassava (*Manihot esculenta* Crantz): Key Food and Feed Nutrients, Anti-nutrients, Toxicants and Allergens", Series on the Safety of Novel Foods and Feeds No. 18, Environment Directorate, OECD.

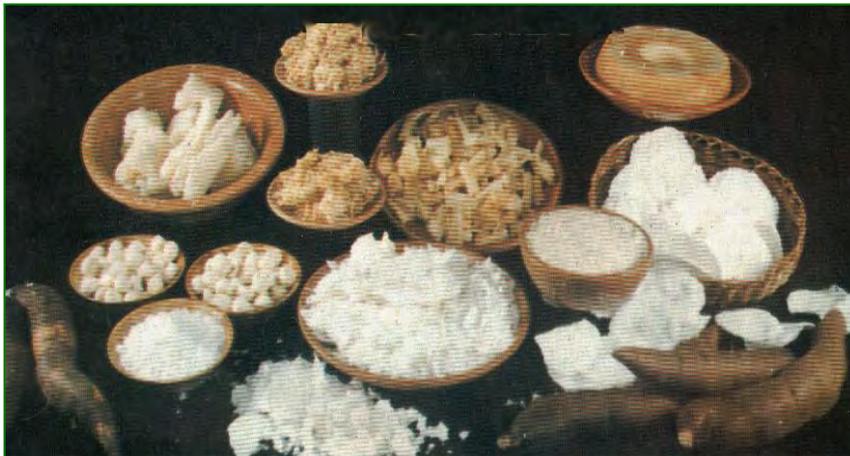
Series on the Safety of Novel Foods and Feeds, No.18



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

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 except 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>

biosafety@oecd.org

