# OECD and Harmonization

Organization for Economic Cooperation and Development
Working Group on Harmonization of Regulatory Oversight in Biotechnology

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Chair

## 3rd International Workshop for Regulation of Animal Biotechnology

# 35 Member Countries of OECD

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

# Regulatory Harmonization in Biotechnology

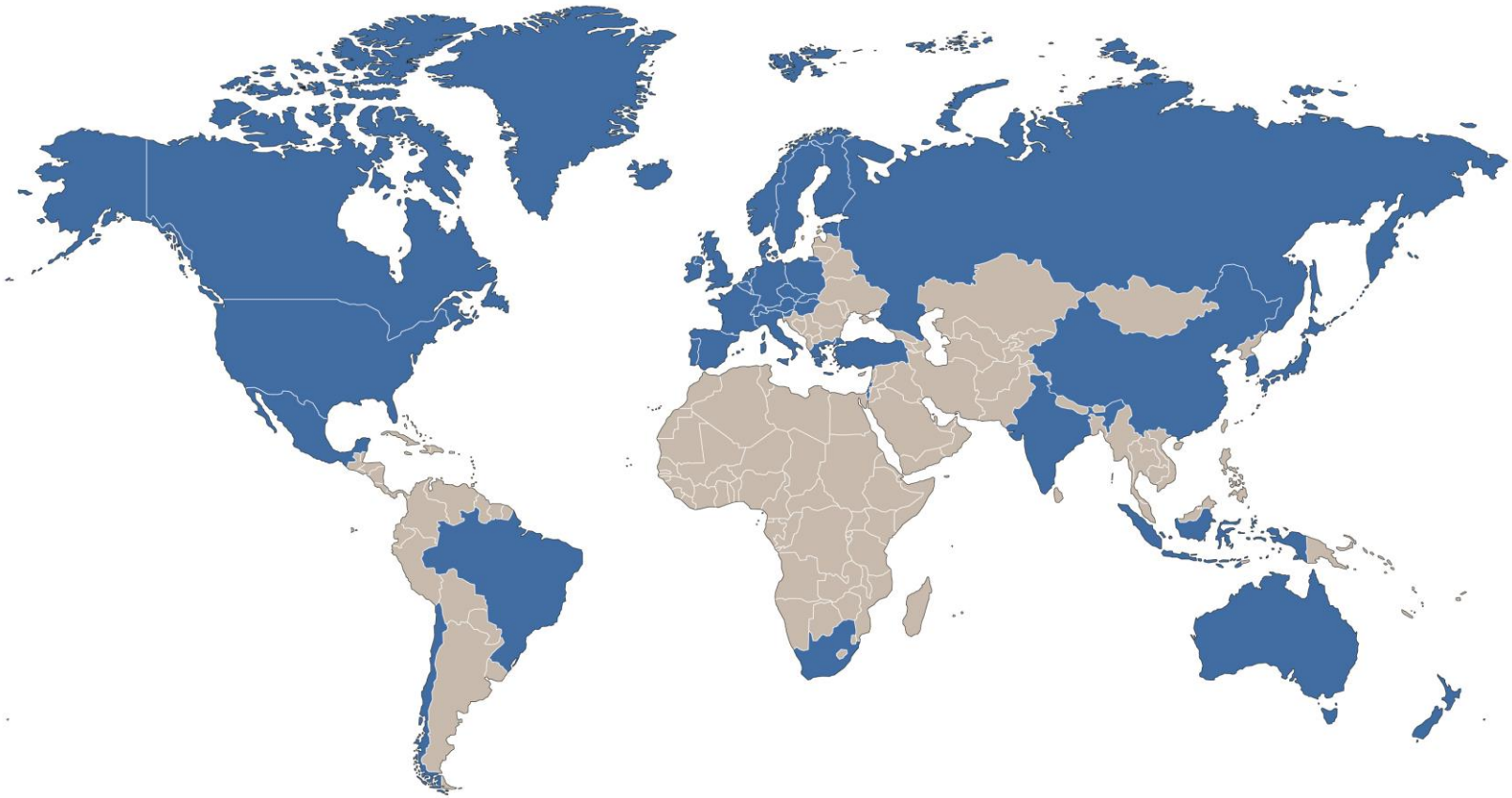
- Working Group for the Harmonization of Regulatory Oversight in Biotechnology
  - Environmental
- Working Group for the Safety of Novel Foods and Feeds
  - Food and Feed

# Enhanced Engagement and Observers

- Argentina
- Bangladesh
- Brazil
- China
- India
- Indonesia
- Kenya
- Lithuania
- Paraguay
- Philippines
- Russian Federation
- South Africa
- Thailand
- Vietnam

- OECD Business and Industry Advisory Committee

# Importance of Global Collaboration



# Other Working Group Observers

- CBD Secretariat
- FAO
- ILSI RF
- NEPAD-ABNE
- PRRI
- UNEP
- UNIDO

# HARMONIZATION-WG

- Goals of Harmonization
  - Develop a common way of thinking for regulators and safety assessors
  - Technical documents that support risk assessment for environmental release
  - Capacity Building
  - Link with Non-Member Countries
- Mutual recognition of or acceptance of data

# Working Group and Harmonization

- Differences between countries
  - New Laws or not
  - Regulation endpoints based upon adverse effects or defined risks
  - Combined or separate environmental or food/feed safety reviews
  - Triggers- novelty, GE/GMO, combination
  - Protection goals vary
  - Number of ministries involved in regulation (and in developing positions for international discussions)

# Working Group and Harmonization

- Similarities between countries
  - Risk assessment paradigm
    - Biology + trait + environment X interaction
    - Use of familiarity
    - Comparative
    - Step-by-step, case-by-case

# Assessment Paradigms

Established in OECD - 1993

- Concept of Familiarity (environmental safety)-Basis of assessment
  - *Safety Considerations for Biotechnology: Scale-up of Crop Plants*, OECD, Paris.
    - Biology X Trait X Environment + Interaction
    - Hazard identification and safety assessment

# Terms of Reference 2017-2020

- Promote harmonization in assessment and regulation of organisms produced through modern biotechnology
- Information (and methods) used in environmental risk/safety assessment of organisms are as similar as possible between countries.
  - Mutual understanding (common thinking)
  - Increase efficiency
  - Avoid duplication of effort
  - Reduce barriers to trade
  - Link with non-member countries

# Criteria

- Science Basis for approaches to environmental assessment
- Leverage collective expertise in environmental assessment of biotechnology products
- Economies of scale

# Working Process

- Bureau (AUS, BE, CAN, FIN, USA)
- Lead country/countries
  - Proposal
  - Drafting outline and text
  - E.g. cotton, *Brassica*
- Steering group – 5-8 countries
  - Other interested countries
  - Provide comments
  - Conference calls
  - Must agree before goes to entire Working Group

# Programme of Work

# Program of Work 2017-2020

I. Consensus Documents – biology and trait

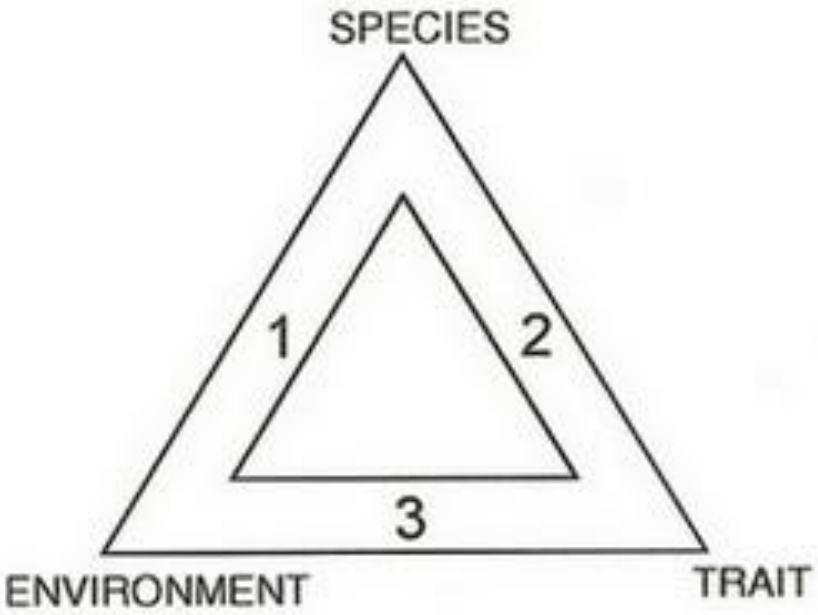
II. Information Dissemination and Outreach

III.Facilitating Harmonization: Emerging Issues

# Organisms in the Environment

- Plants
- Micro-organisms
- Animals

# Environmental Risk Assessment Plants



# I. Consensus Documents- Biology of Crop Plants (34)

- *Zea mays* (Maize)
- *Beta vulgaris* L. (Sugar Beet)
- *Glycine max* (L.) Merr. (Soybean)
- *Oryza sativa* (Rice)
- *Triticum aestivum* (Bread Wheat)
- *Solanum tuberosum* subsp. tuberosum (Potato)
- *Brassica napus* L. (Oilseed rape)
- *Carica papaya* (Papaya)
- *Capsicum annuum* complex
- *Helianthus annus* (sunflower)
-

# Consensus Documents-Traits

- Virus Resistance (coat protein)
- Glyphosate Herbicide Tolerance
- Phosphinothricin Herbicide Tolerance
- Herbicide Metabolism and the Residues in Glufosinate-Ammonium (Phosphinothricin)-Tolerant Transgenic Plants
- *Bacillus thuringiensis* (2007)- Trait

# Guidance for Development of Biology Documents

- Introduction to Biosafety Consensus Documents (2005)
- Points to Consider (2006)
- Guidance for Authors (2008)
  - Lead country
  - Lead authors
  - Working Group review
  - Secretariat

# Points-to-Consider

- Points to Consider for Consensus Documents on the Biology of Cultivated Plants
  - Aid to revising and developing documents
  - Rationales
    - Why relevant
    - Not how used in risk/safety assessment
  - Examples – OECD consensus documents

# Points-to-Consider

- Points to Consider for Consensus Documents on the Biology of Cultivated Plants
  - Guide to revising documents
  - Guide to developing new documents
- Descriptions of sections and sub-sections e.g.
  - Taxonomy
  - Related and sexually compatible species
  - Cultural practices
- Rationales
  - Why relevant
  - Not how used in risk/safety assessment
- Examples – OECD consensus documents

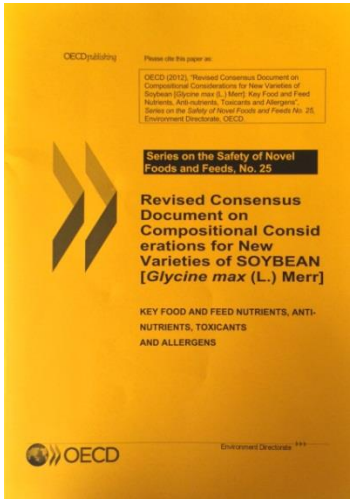
# Animal Biology Documents

- Consensus Document on the Biology of Atlantic salmon (*Salmo salar*)
  - May, 2017
  - Norway, Finland, United States (FGR)
- Drafting
  - *Aedes aegypti*
    - Mexico, Brazil, ILSI RF
  - *Anopheles gambiae*
    - NEPAD-ABNE, ILSI RF

# Working Group SNFF Consensus Documents – Food & Feed Safety

- Considerations for the Safety Assessment of Animal Feedstuffs Derived from Genetically Modified Plants

- Compositional Considerations: Key Food and Feed Nutrients, Anti-Nutrients and Toxicants (22)
  - Bread Wheat (*Triticum aestivum)*
  - Maize (*Zea Mays)*
  - Potatoes
  - Sugar Beet
  - Soybean
  - Low Erucic Acid Rapeseed (Canola)
  - Papaya



# rDNA Animals WG-SNFF

- Initial discussions on animal composition

# CODEX ALIMENTARIUS

- PRINCIPLES FOR THE RISK ANALYSIS OF FOODS DERIVED FROM MODERN BIOTECHNOLOGY 1 CAC/GL 44-2003
- GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA PLANTS 7 CAC/GL 45-2003
- GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS PRODUCED USING RECOMBINANT-DNA MICRO-ORGANISMS 35 CAC/GL 46-2003
- **GUIDELINE FOR THE CONDUCT OF FOOD SAFETY ASSESSMENT OF FOODS DERIVED FROM RECOMBINANT-DNA ANIMALS 57** CAC/GL 68-2008

# Use of Consensus Documents

- By applicants for submissions
- By regulators for assessments
  - LLP/AP
- By public for understanding

# II. Outreach Activities

- Biotrack Online www.OECD.org/biotrack
  - OECD Publications-finalized 'consensus documents'
  - Links to Member Country Websites
  - Product database
    - CBD BioSafety Clearinghouse – UID Registry
    - CODEX/FAO LLP database
- Unique Identifiers – plants (2003), stacked genes (2007)
- International Symposia for Biosafety of GMOs – 3 Workshops (Korea, New Zealand and Argentina)

# III. Facilitating Harmonization

- Molecular characterization-Consensus Document on Molecular Characterisation of Plants Derived from Modern Biotechnology (2010)
- Low Level Presence of Transgenic Plants in Seed and Grain Commodities: Environmental Risk/Safety Assessment, and Availability and Use of Information (2013)

# Facilitating Harmonization

- Environmental Considerations
- New Plant Breeding Techniques
  - 2018 Workshop on Health and Environmental Safety of Genome Editing Applications
    - Agriculture
    - Animals and plants
  - Tour de Table

# Environmental Considerations

- Problem Formulation
  - Hazard Identification depending on organism, phenotype and environment
  - Pathways to harm
  - Hypothesis and hypothesis testing
  - Information elements relevant to hypothesis.

# THANK YOU!