



# OECD GUIDANCE DOCUMENTS

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Peter Kearns, Phd

OECD



## Working Group on Harmonisation of Regulatory Oversight in Biotechnology

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- Information (and methods) used in **environmental risk/safety assessment** of transgenic organisms are as similar as possible between countries.
  - Mutual understanding
  - Increase efficiency
  - Avoid duplication of effort
  - Reduce barriers to trade

Link with non-member countries





## Major Outputs

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- Publish science-based consensus documents (56)
  - Biology and trait
  - Microbes
  - Emerging issues
    - Molecular characterization
    - Low level presence
- Outreach and information dissemination
  - Biotrack online





## Working Group and Harmonization

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- **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
  - Adverse effects
  - Number of ministries involved in regulation (and in developing positions for international discussions)





# Working Group and Harmonization

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





# Environmental Risk/Safety Assessment in Plants - paradigm

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- **1986, Recombinant DNA Safety Considerations (*The Blue Book*)**, OECD, Paris.
  - Industrial, agricultural and environmental applications
  - Organism, Step-by-step, Case-by-case
- 1992, Safety Considerations for Biotechnology, OECD, Paris.
  - Confined Field tests
- **1993, Safety Considerations for Biotechnology: Scaleup of Crop Plants**, OECD, Paris.
  - Large-scale field tests
- Available electronically at <http://www.oecd.org/publications>





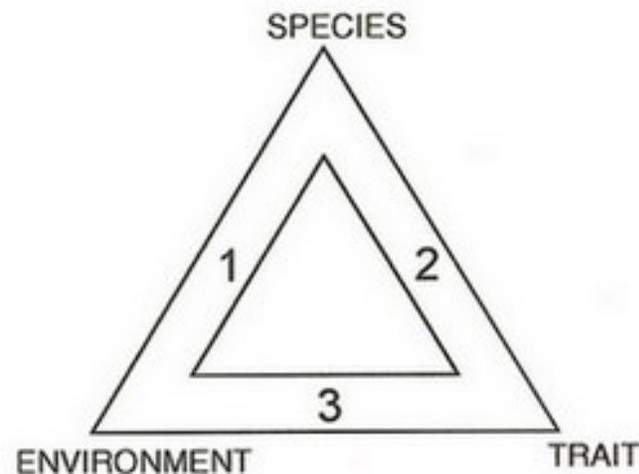
# Environmental Risk/Safety Assessment Plants-1993

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Concept of Familiarity (environmental safety) Basis of assessment

## **Risk/Safety Analysis**

- Hazard identification
- Risk assessment if a hazard identified.





## Terminology

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- rDNA (1986) safe development and use of rDNA organisms
  - Techniques used to produce organisms with novel genetic combinations
  - Represent an extension of conventional genetic procedures
  - Risks presented by organisms same in kind as those posed by any other organism.
  - Governed by same physical and biological laws.





## Definition of rDNA

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- No agreed upon definition in OECD texts.
- Reference country definitions
- Sometimes use “transgenic”
- GMOs
- LMOs
- GEOs.
  - Introduction of a trait.





## Conventional versus Molecular (1993)

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- Molecular techniques allow a greater diversity of genes to be introduced.
- Introduction of genetic material more precise
  - More thoroughly characterized organism
  - More predictable organism
- Plant.
  - Combination of techniques and traits.





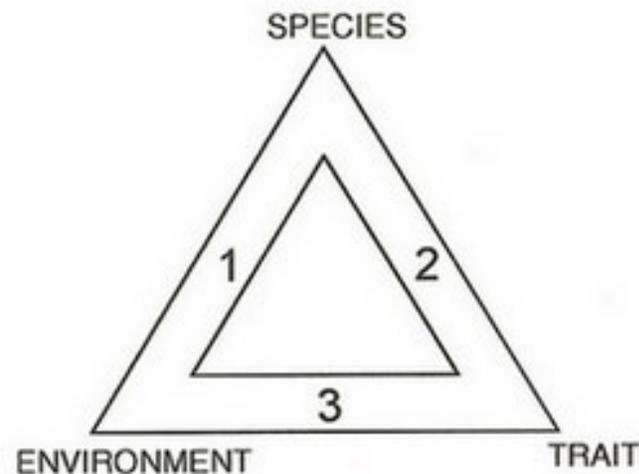
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## Biosafety Consensus Documents

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- Includes information for use in risk assessment on the ***biology*** of crops and traits (familiarity) agreed by authorities:
  - The use of the crop/ trait in agriculture practice
  - Taxonomy
  - Reproduction
  - Wild relatives – hybridisation
  - Centre of origin and diversity
  - Weediness





## Examples of published biosafety consensus documents

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- **Crops:** maize, soybean, potato, cotton, rice, bread wheat, sugar beet, sunflower, peppers, papaya, cucurbita, **brassicas**.
- **Traits:** tolerance to glyphosate herbicide, tolerance to phosphinothricin herbicides, virus resistant through coat protein gene-mediated protection, Bt resistance.
- **Trees:** Norway spruce, white spruce, poplars, Douglas fir, Sitka spruce, lodgepole pine, Eastern white pine, European white birch, larches.
- **Micro-organisms:** *Acinobacter*, *Pseudomonas*, baculoviruses, Taxonomy in Risk Assessment, Detection methods.





# Food/ Feed Safety: Risk Assessment

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Codex Guideline for the Conduct of Food  
Safety Assessment of Foods Derived from  
Recombinant-DNA

*Comparative Approach*  
*(Substantial equivalence)*





# Comparative Approach

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## Contents: Compositional analysis

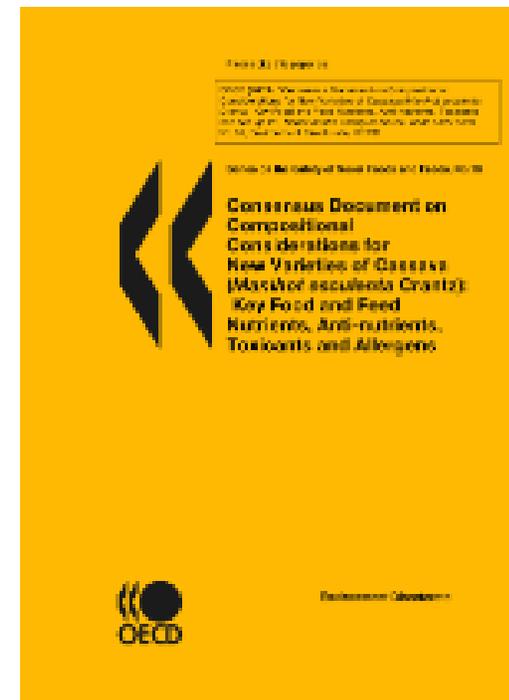
- Key nutrients
- Anti-nutrients
- Toxins
- Allergens





# Food/ Feed Safety Consensus Documents

Sugar beet, Potato, Rice,  
Maize, Rice, Wheat, **Cassava**,  
Sweet potato, Papaya, Low  
erucic acid rapeseed, Cotton,  
Barley, Tomato, Alfalfa, Soy  
bean, Sugarcane, Grain  
sorghum



## Complementary guidance

- Crop Plants
- Fruits
- Mushrooms
- Trees - only biosafety

<u>FRUITS</u>	<i>BIOSAFETY</i>	<i>FOOD/FEED</i>
Apple		<i>in progress</i>
Bananas		
Citrus	<i>in progress</i>	
Papaya		
Stone fruits (e.g. plum)		
<u>MUSHROOMS</u>	<i>BIOSAFETY</i>	<i>FOOD/FEED</i>
Cultivated mushroom		
Oyster mushroom		

<u>CROP PLANTS</u>	<i>BIOSAFETY FOOD/FEED</i>	
Alfalfa		
Barley		
Cassava	<i>in progress</i>	
Cowpea	<i>in progress</i>	
<b>Cotton</b>	<i>2008</i>	<i>2004, 2009</i>
Common bean	<i>proposal</i>	<i>in progress</i>
Grain sorghum	<i>in progress</i>	<i>2008</i>
<b>Maize</b>	<i>2003</i>	<i>2002</i>
<b>Oilseed rape</b>	<i>1997, 2012</i>	<i>2001, 2011</i>
Peppers		
Potato		
Rice		<i>under revision</i>
<b>Soybean</b>	<i>2001</i>	<i>2001, 2012</i>
Pumpkins		<i>in progress</i>
Sugar beet		
Sugarcane	<i>2013</i>	<i>2011</i>
Sunflower		
Sweet potato		
Tomato	<i>in progress</i>	
Wheat	<i>1999</i>	<i>2003</i>



# Final thoughts

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**Regulatory systems are not intrinsically bad;**

**They can work for NPBTs; whether they are in or out of the system;**

**The risk assessment tools we have for transgenics work equally well for NPBTs;**

**It is all about the efficiency (or goodwill) of implementation.**



# OECD's Work on Biosafety

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**Peter Kearns, Bertrand Dagallier, Ward Hermans,  
Takahiko Nikaido,  
Mika Hosokawa**

**OECD's Biosafety Team**

**<http://www.oecd.org/biotrack>**