



# IRGC-OECD-Duke University Improving Risk Regulation Paris, 13-14 October 2014

## OECD work on Innovation and Risk Regulation

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## Two strands of OECD work on biotechnology and nanotechnology

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- **Committee for Scientific and Technological Policy** (Directorate for Science, Technology and Innovation):
  - Working Party on Biotechnology
  - Working Party on Nanotechnology
- **Chemicals Committee** (Environment Directorate):
  - Working Party on Manufactured Nanomaterials
  - Joint Meeting of Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology



# Risk/ Safety Assessment of Products of Modern Biotechnology (GMOs)

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- OECD has two programmes related to the harmonisation of risk/ safety assessment of transgenic organisms (GMOs) mainly those crops which are major trading commodities
- They are managed by the Chemicals Committee
- The **first** addresses environmental risk assessment
- The **second** addresses food/ feed safety assessment of products derived from transgenic products
- There are many differences between countries on their approach to such products
- More importantly, there are similarities including a common approach to **science-based risk assessment**

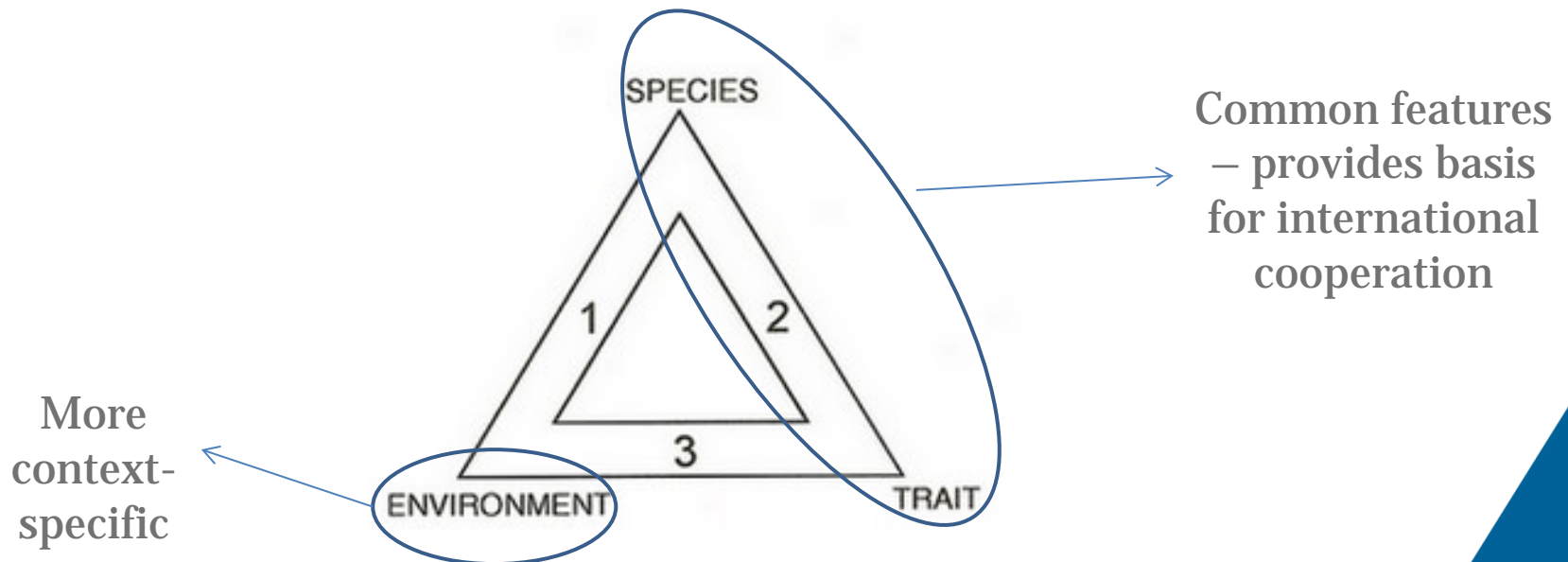


# Environmental Risk/Safety Assessment Plants-1993

Concept of Familiarity (environmental safety)  
Basis of assessment

## **Risk/Safety Analysis**

- Hazard identification
- Risk assessment if a hazard identified.





# Working Group and Task Force

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- **Similarities between countries**
  - Risk assessment systems
    - Biology + trait + environment X interaction
    - Use of familiarity (well-known products)
    - Comparative (based on existing knowledge)
    - Step-by-step, case-by-case (specific, not general)



## Published Guidance

- Crop Plants
- Fruits
- Mushrooms

<u>FRUITS</u>	<i>BIOSAFETY</i>	<i>FOOD/FEED</i>
Apple		<i>in progress</i>
Bananas		
Citrus	<i>in progress</i>	
<b>Papaya</b>		
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>	
<b>Alfalfa</b>		
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		
<b>Potato</b>		
<b>Rice</b>		<i>under revision</i>
<b>Soybean</b>	<i>2001</i>	<i>2001, 2012</i>
Pumpkins		<i>in progress</i>
<b>Sugar beet</b>		
Sugarcane	<i>2013</i>	<i>2011</i>
Sunflower		
Sweet potato		
<b>Tomato</b>	<i>in progress</i>	
Wheat	<i>1999</i>	<i>2003</i>



# Work on Manufactured Nanomaterials: Evaluation in 2006

- A key statement:
- *“the approaches for the testing and assessment of traditional chemicals are in general appropriate for assessing the safety of nanomaterials, but may have to be adapted to the specificities of nanomaterials.”*

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT



**SIX YEARS OF OECD WORK ON THE SAFETY OF MANUFACTURED NANOMATERIALS:**  
**Achievements and Future Opportunities**

For more than 40 years OECD has had a key role in the safe use of chemicals and the protection of human health and the environment.

As part of its response to emerging issues, OECD identified the need to analyse the potential safety concerns caused by manufactured nanomaterials. As nanomaterials started to be used in commercial applications, OECD launched a programme of work in 2006 to ensure that the approaches for hazard, exposure and risk assessment for manufactured nanomaterials are of a high quality, science-based and internationally harmonised.

After six years of work, the OECD and its member countries have come to the conclusion that the approaches for the testing and assessment of traditional chemicals are in general appropriate for assessing the safety of nanomaterials, but may have to be adapted to the specificities of nanomaterials. As with other chemicals, it is clear that each nanomaterial may pose specific challenges, but in most instances, they can be addressed with existing test methods and assessment approaches. In some cases, it might be necessary to adapt methods of sample preparation and dosimetry for safety testing. Similarly, adaptations may be needed for certain Test Guidelines. But it will not be necessary to develop completely new approaches for nanomaterials. OECD continues to review all existing methodologies to identify and implement the necessary changes needed for their application to nanomaterials.

**Manufactured Nanomaterials and their potential applications**

Manufactured nanomaterials have been and are being developed to exhibit new characteristics in contrast to the same material without nanoscale features. Such characteristics can include increased strength of the material, its chemical reactivity or conductivity. These novel features offer possibilities for new applications in a broad range of sectors such as in; medicine (e.g. detection of genetic sequences using DNA-tagged gold nanoparticles); environment (e.g. waste-water treatment with carbon nanotube filters); and energy production (e.g. solar cells using silicon nanocrystals). At the same time, the use of manufactured nanomaterials in a number of commercial applications raises questions regarding potential unintended risks to humans and the environment.

Much research on new uses for nanomaterials is underway and, while currently the production volumes are not very large compared to chemicals that are not at the nanoscale, many other applications are foreseen in the near future and production volumes are expected to increase significantly over the coming decade.

Manufactured nanomaterials are chemicals at the nano-scale (1-100 nm typically, most from top-down materials with novel properties developed from old materials (carbon fibres; rubber and plastics products)  
→ new materials (fullerenes; molecular threads)  
→ existing materials (TiO<sub>2</sub>; photodegradation of polystyrene)



# OECD Council Recommendation

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Endorsed by the OECD Council, December 2013,  
recommends that:

- “Members, in the testing of manufactured nanomaterials, apply the OECD Test Guidelines for Chemical safety testing, adapted as appropriate to take into account the specific properties of manufactured nanomaterials; and the OECD Principles of Good Laboratory Practice”
- This clears the way for the safety testing of nanomaterials to be part of the OECD system of Mutual Acceptance of Data
- It is open to non-members.





## 1981 “Mutual Acceptance of Data” Council Decision

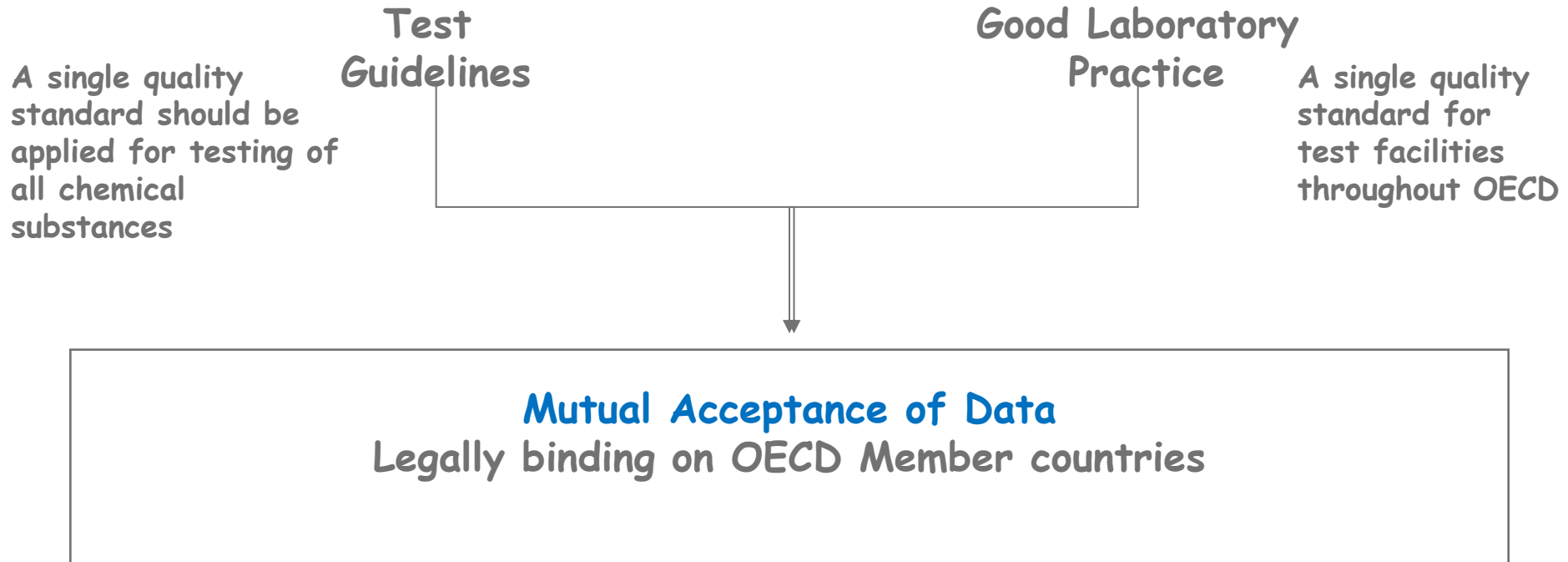
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### ***OECD Council Decision on Mutual Acceptance of Data in an Assessment of Chemicals C(81)30(Final)***

*“Decides that the data generated in the testing of chemicals in an OECD Member country in accordance with OECD Test Guidelines and OECD Principles of Good Laboratory Practice shall be accepted in other Member countries for purposes of assessment and other uses relating to the protection of man and the environment.”*



# Mutual Acceptance of Data (MAD)



- Avoids duplication of testing: around Euros 150 million saved each year
- Reduces use of animals
- Reduces trade barriers



# General lessons from the OECD's work on biotechnology and nanotechnology (1)

- Need for common language and a common understanding between stakeholders.
- Need for open, transparent and effective participatory processes.
- Challenge of dealing with diversity of technologies and applications. Not possible to generalise across uses and situations. Guidance and actions must be specific and fit for purpose, e.g. work on nanotechnology and tyres.





## General lessons from the OECD's work on biotechnology and nanotechnology (2)

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- Importance of international co-ordination in risk governance, regulation, testing and other implementation areas.
- Role of the OECD is to develop suitable environments for both policy and its implementation.
- Data and scientific evidence are central to risk assessment.
- Complementarity of voluntary and mandatory measures, the former being for practitioners to decide and governments to facilitate.



## And other areas of work on regulation and innovation

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Work on digital technologies, e.g.

- Recommendations on protection of privacy on-line (already in 1980, amended in 2013).
- Work on cybersecurity
- Principles on Internet Policy Making (2011)

Life sciences:

- Recommendation on governance of clinical trials (2013)
- Etc.



# Thank you

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