



Harmonisation of Regulatory Oversight in Biotechnology: The OECD Perspective

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**OECD's Working Group for the Harmonisation of
Regulatory Oversight in Biotechnology
(*Environmental safety of transgenic organisms*)**

**OECD's Task Force for the Safety of Novel Foods
and Feeds**

| | | | | | |
|---|-------------|---|----------------|---|-----------------|
|  | Australia |  | Austria |  | Belgium |
|  | Canada |  | Czech Republic |  | Denmark |
|  | Finland |  | France |  | Germany |
|  | Greece |  | Hungary |  | Iceland |
|  | Ireland |  | Italy |  | Japan |
|  | Korea |  | Luxembourg |  | Mexico |
|  | Netherlands |  | NZ |  | Norway |
|  | Poland |  | Portugal |  | Slovak Republic |
|  | Spain |  | Sweden |  | Switzerland |
|  | Turkey |  | UK |  | US |



Non-member economies who participate

- ◆ Argentina
- ◆ Brazil
- ◆ Cameroon
- ◆ China
- ◆ Chile
- ◆ India
- ◆ Latvia
- ◆ Philippines
- ◆ Russian Federation
- ◆ Slovenia
- ◆ South Africa
- ◆ Thailand



Who attends?

- ◆ **Working Group:** delegates from ministries/ agencies responsible for environmental risk assessment of transgenic organisms (competent authorities);
 - Observers and invited experts: UNEP, CBD Secretariat, UNIDO, other stakeholders.

- ◆ **Task Force:** delegates from ministries/ agencies responsible for risk assessment of novel foods and feeds (competent authorities);
 - Observers and invited experts: FAO, WHO, Codex secretariat, other stakeholders.



What are the objectives of the work?

- ◆ To protect consumer and animal livestock health;
- ◆ To protect the environment;
- ◆ To promote harmonisation; while
- ◆ Reducing unnecessary barriers to trade.



Outputs of the work

- Exchange of views amongst delegations on regulatory issues related to GMOs
- Tools/ instruments/ databases which assist member states in the safety/ risk assessment of GMOs
 - What does this have to do with the topic of this Coexistence Conference, which is a separate issue?
 - I will give some examples



Study for the G8 Heads of State and Government, Okinawa - 2000

"In light of the increasing importance of issues concerning food safety we invite the OECD *Working Group on Harmonization of Regulatory Oversight of Biotechnology* and the OECD Task Force for the Safety of Novel Foods and Feeds to undertake a study of the implications of biotechnology and other aspects of food safety. We invite OECD experts to discuss their findings with our personal representatives. We ask the latter to report to us by the next Summit on possible ways to improve our approach to these issues through international and other institutions, taking into account the reflections underway in other fora."

Cologne communiqué, June 1999



BioTrack Online

(Information exchange)

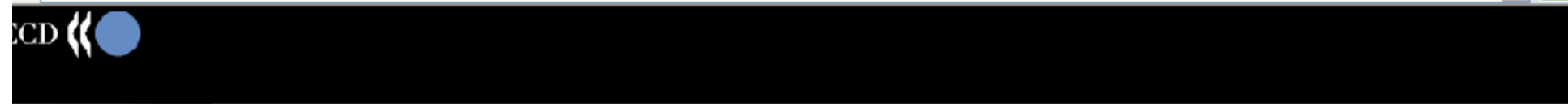
(<http://www.oecd.org/biotrack/>)

- ◆ Database of commercialised (GM) products: shows which products are on the market
- ◆ Database of field trials of genetically modified organisms: shows which products are in development.
- ◆ Regulatory contacts in OECD countries
- ◆ Outputs of OECD's Work
- ◆ Co-ordination with the Secretariat of the Convention on Biological Diversity (Cartagena Protocol)



Examples of Commercialised Products

| Unique Identifier | Transformation Event, Line | Crop | Developer |
|-------------------|----------------------------|-----------|--------------|
| ACS-ZMØØ1-9 | MS3 | Maize | Bayer |
| CGN-89564-2 | FLAVR SAVR | Tomato | Monsanto |
| DAS-Ø15Ø7-1 | 1507 | Maize | Dow, Pioneer |
| DD-Ø1951A-7 | 19-51a | Cotton | DuPont |
| FLO-ØØØØ4-9 | 4 | Carnation | Florigene |
| MON-ØØ531-6 | 531 | Cotton | Monsanto |
| PH-MON8Ø9-2 | MON809 | Maize | Pioneer |
| SYN-BTØ11-1 | Bt 11 | Maize | Syngenta |



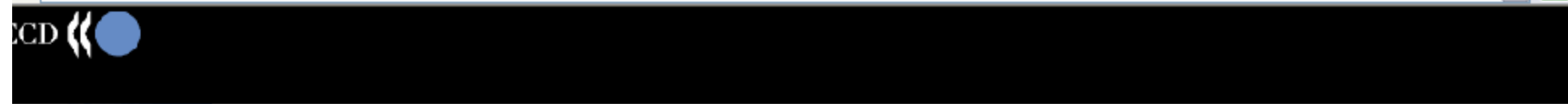
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| MON-00810-6 | |
|--------------------------------|---|
| Transformation Event | MON 810 |
| Trade Name | Yieldgard™ insect protected corn |
| Applicant | Monsanto Show |
| Organism Common Name | Corn / Maize |
| Organism Scientific Name | Zea mays |
| Centre of Origin and Diversity | Biology Consensus Document on Maize |
| Food and Feed Safety Issues | Food/ Feed Consensus Document on Maize |
| Methods for safe handling | |
| Additional Information | Show |

| Trait(s) | Gene(s) |
|------------------------|---------|
| Lepidoptera resistance | cry1Ab |

| Australia | | | | |
|-------------------|-------------|---|----------------------|--------------------|
| Date | Type of Use | Authority | Decision(s) | Risk(s) Assessment |
| November 24, 2000 | Food | Food Standard Australia New Zealand | A346 | |

Canada



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Australia

| Date | Type of Use | Authority | Decision(s) | Risk(s) Assessment |
|-------------------|-------------|---|----------------------|--------------------|
| November 24, 2000 | Food | Food Standard Australia New Zealand | A346 | |

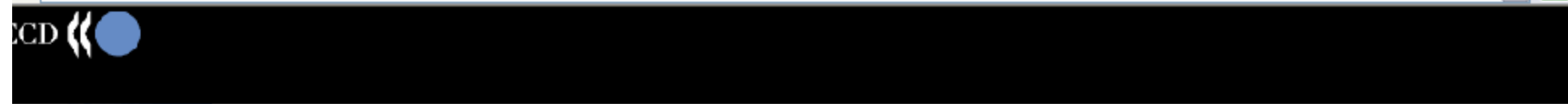

Canada

| Date | Type of Use | Authority | Decision(s) | Risk(s) Assessment |
|-------------------|---------------------|--|------------------------------|--------------------|
| January 22, 1997 | Feed | Canadian Food Inspection Agency - Feed Section | DD97-19 | |
| February 17, 1997 | Food | Health Canada - GM Foods and Other Novel Foods | FD/OFB-97-07 | |
| January 22, 1997 | Unconfined Planting | Canadian Food Inspection Agency - Plant Biosafety Office | DD97-19 | |

European Community

| Date | Type of Use | Authority | Decision(s) | Risk(s) Assessment |
|-------------------|---------------------|---------------------|---------------------------|--------------------|
| April 22, 1998 | Feed | European Commission | 98/294/EC | |
| December 10, 1997 | Food | European Commission | | |
| April 22, 1998 | Unconfined Planting | European Commission | 98/294/EC | |

Japan

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New Zealand

| Date | Type of Use | Authority | Decision(s) | Risk(s) Assessment |
|-------------------|-------------|---|-------------|--------------------|
| November 24, 2000 | Food | Food Standard Australia New Zealand | | |

Switzerland

| Date | Type of Use | Authority | Decision(s) | Risk(s) Assessment |
|---------------|-------------|---|---------------------------------------|--------------------|
| July 27, 2000 | Feed | Swiss Federal Office of Agriculture | 916.307.11 (French) | |
| July 27, 2000 | Food | Swiss Federal Office of Public Health | SWI food 810 (German) | |

United States of America

| Date | Type of Use | Authority | Decision(s) | Risk(s) Assessment |
|--------------------|---------------------|--|-----------------------|--------------------|
| September 25, 1996 | Feed | Food and Drug Administration (USFDA) | BNF34 | |
| September 25, 1996 | Food | Food and Drug Administration (USFDA) | BNF34 | |
| March 15, 1996 | Unconfined Planting | Department of Agriculture (USDA) | | |



OECD's Unique identification system for transgenic crops was developed because:

- It was widely recognised as a “key” to access information on products in databases
- Unique identifiers are referenced in the Cartagena Protocol on Biosafety (e.g. article 18, 2(a)).
- The establishment of a U.I system is called for under REGULATION (EC) No 1830/2003, “concerning the traceability and labelling of GMOs, etc”.



OECD's Unique identification system

COMMISSION REGULATION (EC) No 65/2004

OF 14 January 2004

establishing a system for the development and assignment of unique
identifiers for genetically modified organism



Examples of Commercialised Products

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Working Group Biosafety Consensus Documents

- ◆ Include a wealth of information (for use in risk assessment) on the **biology** (also crucial to coexistence) of crops and traits:
 - The use of the crop/ trait in agriculture practice
 - Taxonomy
 - Reproduction
 - Wild relatives – hybridisation
 - Centre of origin and diversity
 - Weediness



Some Published Biosafety Consensus Documents



- ◆ **Crops:** maize, oilseed rape, potato, bread wheat, rice, soybean, sugar beet, sunflower, papaya, etc.
- ◆ **Traits:** tolerance to glyphosate herbicide, tolerance to phosphinothricin herbicides, virus resistant through coat protein gene-mediated protection, etc.
- ◆ **Trees:** Norway spruce, white spruce, poplars, sitka spruce, eastern white pine, European white birch, etc.
- ◆ **Micro-organisms:** *Pseudomonas*, baculoviruses, Taxonomy in Risk Assessment, Detection methods, etc.



**Biosafety for
Agriculture and
the Environment**

OECD CONSENSUS DOCUMENTS
VOLUME 1

PRELIMINARY VERSION

OECD  

The cover features a white top half and a green bottom half. The title and subtitle are in black text. A box containing 'PRELIMINARY VERSION' is centered below the subtitle. The bottom left corner has the OECD logo. The green section contains faint, repeating text in white, which is a watermark or bleed-through from the reverse side of the page.



Other Working Group Projects

- ◆ Transgenic Fish
- ◆ Molecular Characterisation
- ◆ Environmental Safety Criteria



Food/ Feed Safety Consensus Documents

- ◆ Include information (for use in food/ feed safety risk assessment of new varieties) on key:
 - Nutrients
 - Anti-Nutrients
 - Toxicants
 - Allergens
 - Secondary metabolites



Food/ Feed Safety Consensus Documents

- ◆ Some Published documents

- Soybean
- Canola/Oilseed Rape
- Potato
- Sugar Beet
- Maize
- Bread Wheat
- (Considerations for safety of animal feeds)
- Rice
- Cotton
- Barley



Thank You

**OECD's Biosafety Team
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