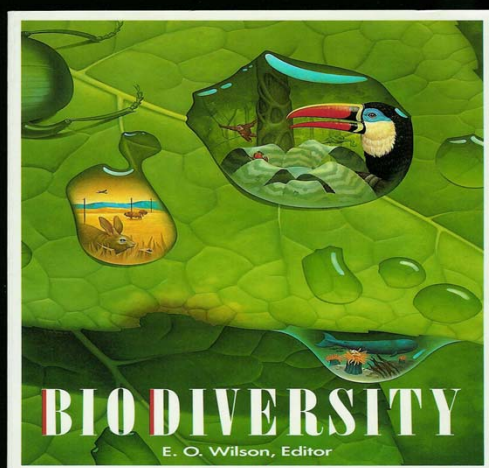


LMO Biosafety Practice: Case in Japan

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“...It is the foundation upon which human civilizations have been built. Its conservation is a prerequisite for sustainable development and, as such, constitutes one of the greatest challenges of the modern era.”



Genetically Engineered Organisms (LMOs) are concerns of global communities

However, the use of LMOs have been recognized in international forums with legal bindings

- Transboundary movements (CPB-CBD, IPPC, WTO)
- International Standardization of risk assessment methods on environmental biosafety (WTO -> ISO)
- Standardization on food safety (FAO/WHO CODEX)

Historical landmarks

- Genetic engineering enabled: 1973, Cohen & Boyer
- Ashilomar Conference: 1975, Paul Berg etc
- First commercial product thereof (insulin) by Genentech, 1982
- Booms in R&D for specific pharmaceutical purposes, 1980-mid 1990's, and subsequent commercialization
- Transgenic crop field testing, since late 1980's
- Commercialization of GM tomato: 1994
- OECD guideline on GMO, 1994
- Jakarta mandate by CBD, 1995
- Cartagena Protocol on Biosafety agreed, Jan., 2000
- Cartagena Protocol entered into force, Sept. 11, 2003

Cartagena protocol on Biosafety for Convention on Biological Diversity

- Article 8: AIA for deliberate release of LMOs to environment and RA on potential adverse effects to the environments
- 103 Parties signed
- It entered into force in September 11, 2003
- 160 countries : contracting parties (Oct., 11)
- COPMOP-1 in March 24-27, 2004 @ Kula Lumpur
- COPMOP-2 at Montreal May to June, 2005
- COPMOP-3 at Brazil in March, 2006: major discussion in implementation
- COPMOP-4 at Bonn
- COPMOP-5 at Nagoya, 2010 : A27 Liability & Redress
- COPMOP-6 at India on October, 2012
- Many EU and non-EU European countries ratified. GM crop exporting countries are slow in ratification process
- Many LDCs do not have instrumental function yet to implement

Risk assessment under CPB

- In Article 15 and ANNEX III
- MOP-4 decision on May, 2008: RA AHTEG meeting formed with participatory discussion and feedback by on-line forums
- Frequent e-discussions
- Face to face meetings (2009, 2010 and 2011: one week session for each meeting)
- But limited specialty of members and biased to non-scientific discussion rather than technical and fact-base document integration
- Weak in feedback from the users

Debate on GM Food

- Species barriers are crossed and unknown effects
- Impact on the environment
- Can we test the safety of GM-foods adequately
- Are test procedures strict enough/uniformly applied
- Traceability, labelling and GM-free foods
- Contribution to a sustainable agriculture
- Whose interest



Concern on GM Soybean with BT in Japan in late 1990's.
Bugs die, we die, too!! Awas!!!



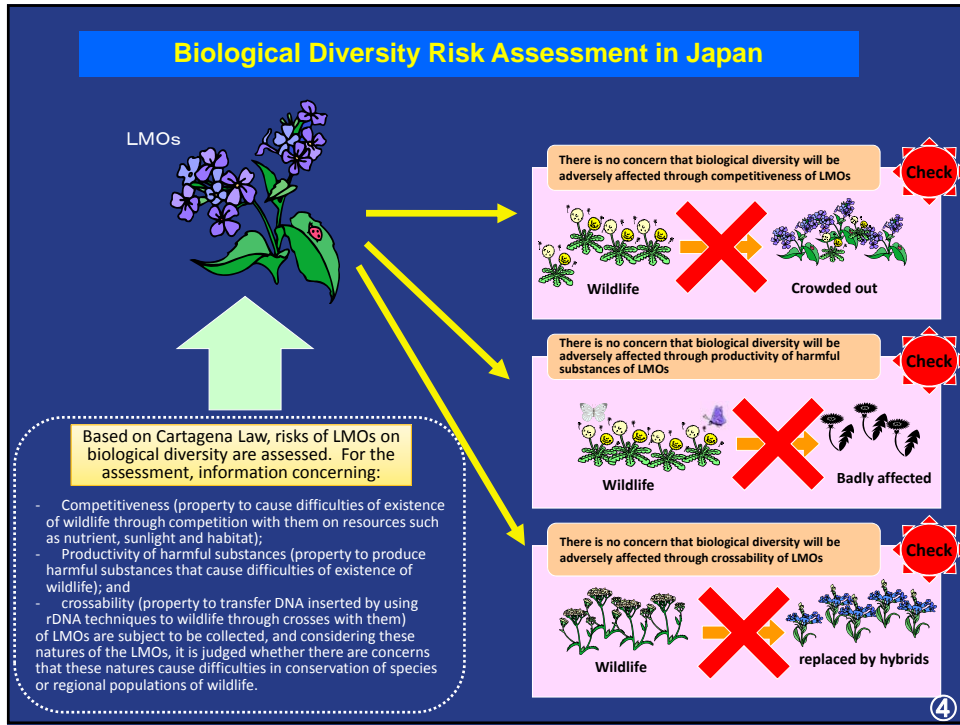
**Risk Assessment, Management and
Communication on LMOs**

Risk

- Not hazard, not danger, it is probability
- Level, exposure, time and management to cope with risk
- Likelihood measurement

Risk assessments

- Precautionary approach
- Step-by-step
- Case by case (host by transgene by environment)
- De-regulation upon cases and monitoring
- Environmental risk and food safety are separate issues



Risk management and monitoring

- Case By Case
- Revision may be needed for further caution or deregulation
- Risk communication shall be in the part of risk management, public awareness addressed in the Protocol

CPB Scope: environmental safety (Human health and food safety handled at WHO-FAO Codex Alimentarius, while consideration stays for human health on CPB)

Contained Use for R&D Article 18	Environmental Release for R&D Articles 8, (11) and 18
Contained Use for Sales / markets E.g.: fermentation w/GMM Pharmaceutical uses Articles (11), 18	Use in open environments: Agriculture, Forestry, Fisheries, Bioremediation Articles 8, (11) and 18

FFPs?

- FFP approval is independent from EB
- FFP purposes also are examined on EB
- FFP bulk shipments can have spill over in transportation, and imports should be tested on EBR

Japanese experiences on commercialization (As of Dec., 2011)

http://www.bch.biodic.go.jp/english/e_index.html
<http://www.cbijapan.com/other/crops.php>

Crop	FFP Approval	EB Approval
Alfalfa	3	3
Carnation	---	10
Soybean	7	21
Sugar beet	1	1
Canola	10	13
Maize	47	65
Cotton	11	17
Rose	---	4

Japanese experiences on field testing (As of Dec, 2011)

http://www.bch.biodic.go.jp/english/e_index.html

<http://www.cbijapan.com/other/crops.php>

Crop	EB Approval
Poplar	2
Eucalypts	7
(one approvals with multiple events)	
Papaya	1
Rice	23
Creeping Bent Grass	1

Debates

- Genetic engineering and products thereof are hazardous and should be eliminated
- Religion, creed and individual thoughts are the highest priority, S&T less value or no value
- No option
- Deny participation
- Scientific risk assessment and management furnished and proven to be safe
- Balanced benefit for societies with potential risk
- Leave options for choice
- Allow participatory approach