

International Issues on GM Foods 基因改造食品國際規範

The future challenges and missions for Codex
Biotech Task Force in the next four years
食品法典委員會未來四年的新任務與挑戰

行政院生物技術產業指導小組
基因改造產品跨部會工作小組委員

高文彥 博士

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Background

- 2003, 26th Codex Alimentarius Commission
 - considered proposal to establish a new Task Force
 - requested Japan to lead
 - to prepare a project document:
 - draft terms of reference
 - list of potential areas of work
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Background

- 2004, 27th Codex Alimentarius Commission
 - agreed to establish a new *Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology*
 - adopt the Terms of Reference
 - Delegate Japan to host
 - Final report to Commission in 2009
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Objectives

- To develop standards, guidelines or recommendations
 - on the basis of scientific evidence, risk analysis
 - and having regard to other factors relevant to the health of consumers
 - and the promotion of fair practices in the food trade.
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Time of frame

- Task Force shall complete its work within four years (2006-09).
 - Task Force shall submit a full report in 2009.
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Terms of Reference

- To elaborate standards, guidelines, or other principles,... taking account of the Principles for the Risk Analysis...
 - To coordinate and closely collaborate, with appropriate Codex Committees...
 - To take account of existing work carried out by national authorities, FAO, WHO, other international organizations...
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Principles for the Risk Analysis

CAC/GL 44-2003

Principles

- Risk Assessment
 - Risk Management
 - Risk Communication
 - Consistency
 - Capacity Building and Information Exchange
 - Review Processes
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Potential Areas of Work

- Foods derived from Animals
 - transgenic animals, including fish
 - cloned animals
 - Foods derived from plants
 - Plants expressing bioactive substances or nutritionally-enhanced plants
 - Plants with “stacked” genes (i.e. several genes conferring different traits in the same plant)
 - Biopharming
 - Plants expressing pharmaceutical or other non-food substance
 - Low level presence of unauthorized GM foods in authorized foods
 - Comparative food composition analysis
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Potential Areas of Work:

- Country proposals

**JOINT FAO/WHO FOOD STANDARDS
PROGRAMME**

**CODEX AD HOC INTERGOVERNMENTAL TASK
FORCE ON FOODS DERIVED FROM
BIOTECHNOLOGY**

Fifth Session

Chiba, Japan, 19-23 September 2005

European Community (EC)

EC proposes in a decreasing priority order:

1. Low level presence of **unauthorized GM material** in food
2. Food safety assessment of **GM animals** (including fish)
3. GM plants expressing **pharmaceutical** or non-food substances ("bioactive substances")
4. Food safety assessment of food derived from multiple recombinant-DNA plants (**stacked genes**)
5. Food safety issues specific to staple food crops for developing countries (**food composition**)
6. Food produced from **clone animals** and their offspring

EC on Stacked Gene Plants

- ❑ The Codex *Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant-DNA Plants* (CAC/GL 45-2003) does not address the case.
- ❑ More and more stacked gene plants are on the market and under development
- ❑ Needs a guidance as to identify specific food safety issues and how to assess and manage these issues

Reference: CX/FBT 05/5/4-Add.1 (June 2005)

EC on Stacked Gene Plants

- ❑ Relevance to Codex Strategic Objectives
 - Promotion of consumer protection
 - Promotion of the application of scientific principles and risk analysis
 - Facilitation of trade of food

Reference: CX/FBT 05/5/4-Add.1 (June 2005)

Japan

- Suggests 3 items in priority:
 1. Foods derived from plants with 'stacked' genes
 2. Foods derived from 'nutritionally-enhanced' plants
 3. If GM animals to be discussed, priority should be given to GM fish
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Stacks in Japan

As of 5 Sept 2005

- **MHLW (厚生労働省) approved:**

- **Corn**

1. MON863 x NK603
2. GA21 x MON810
3. T25 x MON810
4. TC1507 x NK603
5. MON810 x MON863
6. Mon863 x MON810 x NK603

- **Cotton**

1. 1445 x 531
2. 15985 x 1445
3. MON88913 x 15985

- **MHLW under Evaluation**

- **Corn** MON88017 x MON810
- **Alfalfa** J101 x J163
- **Cotton** 281 x 3006

United States

US proposes:

1. Food Safety Issues Specific to staple food crops for developing countries (Food composition)
2. Low-level presence in food of plant material derived from recombinant-DNA plants

Reference: CX/FBT 0/5/4 (May 2005)

United States

□ US says 'No' to:

1. Transgenic animals
 2. Cloned animals
 3. Plants expressing bioactive substances or nutritionally-enhanced plants
 4. Plants with 'stacked' genes
 5. Biopharming/plants expressing pharmaceutical or other non-food substances
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Australia

- High Priority work
 - Foods derived from transgenic animals
 - Foods derived from cloned animals
 - Comparative food composition
 - Plants expressing bioactive substances or nutritionally enhanced plants
 - Low Priority Work
 - Plants with “stacked” genes
 - Low level presence of unauthorised GE foods in authorised foods
 - Work outside the scope of the Task Force
 - Biopharming
 - Plants expressing pharmaceutical or other non-food substances
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Biotechnology Industry Organization

- Guidelines/Principles for the assessment of the inadvertent, intermittent low-level presence of proteins(s) in food/food ingredients for
 - Approved/authorized within a country/countries that follow Codex risk assessment
 - Unapproved/unauthorized traits
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Issues Related to Taiwan

Codex Issues = Taiwan's GMF problems

Taiwan: Transgenic & Cloned Animals



由台灣動物科技研究所研究成功的複製豬「酷比三號」，八日在第三屆台灣國際生物科技大展記者會中亮相。

「酷比三號」是全球第一例雙基因轉殖複製豬。

(中央社記者鄭傑文攝91.8.8)

Taiwan: Biopharming



Tg gilt No. 8-3



Tg gilt No. 8-5

**Tg pigs harboring both transgenes of
*α*LA- pLF & *α*LA- hFIX genes**

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Taiwan: Bioactive substances

Field Trials in progress at TARI in 2003~

GM Plants	Transgene	Applicants
rice	Phytase gene	Academia Sinica
rice	Phytase gene	InGene
rice	Amylopullulanase gene	Academia Sinica
rice	Lactoferrin gene	Nat'l Chung Hsing Univ
potato	Phytase gene	Academia Sinica
broccoli	IPT (isopentenyl transferase)	Academia Sinica

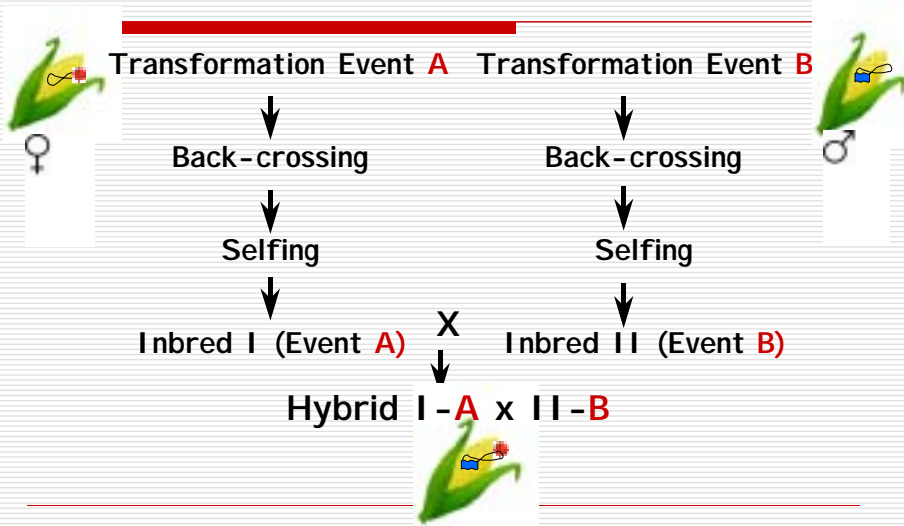
TARI: Taiwan Agricultural Research Institute

Taiwan: Stacks (混合型基因改造玉米)

□ Problems faced

- Registration
 - Risk assessment
 - Detection Methods
 - Threshold to labeling
-

何謂混合型 (stacked traits hybrid)?



Taiwan: stacks at DOH(衛生署)

□ Corn

- MON810 x T25
- MON810 x GA21 (台灣檢出)
- MON810 x NK603 (台灣檢出)
- MON810 x MON863 (台灣檢出)
- MON863 x NK603 (台灣檢出)
- MON810 x MON863 x NK603 (台灣檢出)
- TC1507 x NK603

□ Alfalfa

- J101 x J163
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Taiwan: Low level of unauthorized GMF

國際統一編號	種類	品名	轉殖品系	申請者	核准日期	備註
DKB-89614-9	玉米	抗蟲及耐固殺草基因改造玉米	DBT418	孟山都	92.10.16	有效日期至94.10.16
DKB-89790-5	玉米	耐固殺草基因改造玉米	DLL25	孟山都	92.10.20	有效日期至94.10.20
--	玉米	抗蟲及耐固殺草基因改造玉米	Bt10	先正達	--	審查中
--	玉米	抗蟲基因改造玉米	CBH351	安萬特	--	(StarLink)

Other unknown? (GM papaya, GM rice...)

Taiwan: Food Composition

- DOH “Guidance of GM Food Safety Assessment” (基因改造食品安全性評估方法, 2001) – to be updated
 - To identify key component, e.g. nutrients, anti-nutrients and toxins.
 - Adoption of OECD Consensus Documents*?
 - e.g.:
Consensus Document on Compositional Considerations for New Varieties of Maize (Zea Mays): key food and feed nutrients, anti-nutrients and secondary plants metabolites.

* http://www.oecd.org/document/51/0,2340,en_2649_34391_1889395_1_1_1_1,00.html

Convention on Biological Diversity

- Terms of Reference
 - To take account of existing work carried out by national authorities, FAO, WHO, other international organizations...
- Risk Assessment & Risk Management
 - *Ad Hoc Technical Expert Group on Risk Assessment under the Cartagena Protocol on Biosafety*
Italy, 15 - 18 November 2005
 - Reference:
 - UNEP/CBD/BS/COP-MOP/2/INF/2 (country positions)
 - UNEP/CBD/BS/COP-MOP/2/9 (excellent overview)

CONCLUSIONS

- Capacity Building
 - Infra-structure for safety assessment
 - New Guidelines for safety management
- Implementation of Codex Risk Analysis
- New Issues



Figure 1. Basic elements providing for implementation of biosafety regulations

Reference: McLean, *et al.* A conceptual framework for implementing biosafety: Linking policy, capacity & regulation. ISNAR Briefing paper No.47, 2002.

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THANK YOU

Wen-Yen Kao, Ph.D.
wenyen.kao@syngenta.com