行政院所屬各機關因公出國人員出國報告書

(出國類別：研究實習)

赴新加坡參加東南亞國協「農業基因改造生物產品之安全性與風險評估研習會」

行政院研考會/省(市)研考會編號欄

服務機關： 行政院衛生署

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職　　稱： 高級研究員

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報告名稱

參加農產基因改造生物之安全與風險評估訓練研習會

辦機關

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出國類別　考察

出國地區　新加坡

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關鍵詞　基因改造食品，生物技術，安全評估，食品安全，東南亞國協組織

內容摘要　基因改造食品近年來成爲全球所關切之食品衛生安全議題，世界各國陸續制訂有關法規或準則。我國主管基因改造食品之機構爲衛生署，由食品衛生處負責相關法規與政策之擬訂，於今(90)年2月22日已經公告基因改造黃豆及玉米的查驗登記與標示等相關規定。 東南亞國協組織有鑑於其會員國之基因改造食品管理規範仍然闕如，生物技術能力不足，特別舉辦訓練研習會。今年7月18~20日「農業基因改造生物產品之安全性與風險評估研習會」在新加坡首度舉行，研習重點爲基因改造食品之安全性評估方法及程序，邀請先進國家加拿大衛生部與澳洲/紐西蘭食品總署協助傳授實務經驗，藉以強化各國食品安全管理機制，並促進區域性管理規範之調合。 本屆研習有來自12個國家/地區八十餘位政府、學者與業界代表與會，以「耐嘉磷塞基因改造大豆」爲實際案例，進行二天半的安全性評估講習及模擬審查，使各國代表體會第一手經驗，借鏡先進國家採用之審查方式，並得以彼此交換意見，討論亞洲國家環境可能遭遇之特殊差異條件。本屆研習會，參加學員大致均獲得滿意的學習成果。

本文電子檔已上傳至出國報告資訊網

赴新加坡參加東南亞國協
「農業基因改造生物產品之安全性與風險評估研習會」

摘　　要

基因改造食品近年來成為全球所關切之食品衛生安全議題，世界各國陸續制訂有關法規或準則。我國主管基因改造食品之機構為衛生署，由食品衛生處負責相關法規與政策之擬訂，於今(90)年 2 月 22 日已經公告基因改造黃豆及玉米的查驗登記與標示等相關規定。

東南亞國協組織有鑑於其會員國之基因改造食品管理規範仍然闕如，生物技術能力不足，特別舉辦訓練研習會。今年 7 月 18~20 日「農業基因改造生物產品之安全性與風險評估研習會」在新加坡首度舉行，研習重點為基因改造食品之安全性評估方法及程序，邀請先進國家加拿大衛生部與澳洲/紐西蘭食品總署協助傳授實務經驗，藉以強化各國食品安全管理機制，並促進區域性管理規範之調合。

本屆研習有來自 12 個國家/地區八十餘位政府、學者與業界代表與會，以「耐嘉磷塞基因改造大豆」為實際案例，進行二天半的安全性評估講習及模擬審查，使各國代表體會第一手經驗，借鏡先進國家採用之審查方式，並得以彼此交換意見，討論亞洲國家環境可能遭遇之特殊差異條件。本屆研習會，參加學員大致均獲得滿意的學習成果。

目次：

英文缩寫：

ANZFA	Australian New Zealand Food Authority
ASEAN	Association of Southeast Asian Nations
AVA	Agri-food & Veterinary Authority of Singapore
CFIA	Canadian Food Inspection Agency
Codex	Codex Alimentarius Commission
ENV	Singapore's Ministry of Environment
FAO	Food and Agriculture Organization of the United Nations
GMO	Genetically Modified Organisms
GMAC	Genetic Modification Advisory Committee
ILSI	International Life Sciences Institute
IMA	Institute of Molecular Agrobiology, National University of Singapore
NParks	Singapore's National Parks Board
OECD	Organisation for Economic Co-operation and Development
USDA	United States Department of Agriculture
WHO	World Health Organization

壹、 源起與目的

基因改造食品近年來成為全球所關切之食品衛生安全議題，世界各國陸續制訂有關法規或準則。我國主管基因改造食品之機構為衛生署，由食品衛生處負責法規與政策之擬訂，於今(90)年 2 月 22 日已經公告基因改造之黃豆及玉米的查驗登記與標示等相關規定[1] 。

東南亞國協組織(ASEAN)有鑑於其會員國基因改造食品管理規範仍然闕如，生物技術能力普遍不足，經過部長級會決議，指定新加坡為主導國家(lead country) ，並特別舉辦三期系列訓練研習會，以建立國協會員國之管理能力(capacity building)，並促進區域性規範的調合性(harmonization)。

第一期訓練由新加坡主辦「農業基因改造生物產品之安全性與風險評估研習會」(ASEAN-ILSI Training Workshop on Safety and Risk Assessment of Agriculture Related GMOs)，於 7 月 18~20 日假星國濱華大酒店(Marina Mandarin of Singapore)舉行三天。研習重點為基因改造食品之安全性評估方法及程序，邀請加拿大衛生部(Health Canada)與澳洲/紐西蘭食品總署(ANZFA)協助傳授實務經驗，讓學員瞭解先進國家實際審查作業之方式。

研習課程主要是由加拿大衛生部生物技術食品處(Office of Food Biotechnology)規劃設計，由該處處長 Dr William Yan 主持並擔任講師，其他 3 位講師包括加國衛生部資深科技審查員 Mr Brian Harrison、加國食品政策統籌局(Bureau of Food Policy Integration, Health Canada)Ms Mireille Prud'homme 及澳紐食品總署生物技術經理 Dr Paul Brent。另外特別邀請雀巢公司亞洲研發中心經理 Dr Anthony Huggett 做專題演講。

本屆研習會共同參與主辦的單位有三個：東南亞國協組織、國際生物

[1] 行政院衛生署公報九十年三月十日第三十卷第十三號(總號第 709 號)。

科學研究院東南亞分部(International BioSciences Institute，ILSI Southeast Asia)、及新加坡農業食品暨獸醫局(Agri-food and Veterinary Authority Singapore，AVA)。會議執行秘書處由 ILSI 與 AVA 共同負責。

台灣並非東南亞國協會員，本案由美國在台協會 USDA 農業部代表主動代為邀請，徵得本署食品衛生處同意派員，透過美國駐新加坡大使館農業部協調，由 ILSI Southeast Asia 正式來電子函同意邀請，以觀察員身份與會(按：會員國報名費星幣 S$50，非會員國觀察員 S$350)。

參加研習報名計有來自 12 個國家及地區的學員計 89 人，地主國佔六成，學員主要是各國政府相關主管官員，少部分為學者與跨國食品生技業者，包括美國黃豆協會、雀巢、可口可樂及杜邦等駐星馬代表。不過，三天分組實務研習，參加者僅四十餘人，星國本地學員泰半未實際參與。

ASEAN-ILSI GMO Workshop Participants 參加學員統計 (人)

新加坡	54	泰國	9
馬來西亞	8	菲律賓	3
高棉	3	寮國	1
印尼	1	汶萊	2
美國	3	加拿大	3
澳洲	1	台灣	1

本案筆者得以順利成行首度代表台灣，與東南亞各國與加拿大、澳洲主管 GMO 事務政府官員相互交流，建立直接溝通管道，個人以為十分具有實質助益，例如這次見到了幾位新加坡、與泰國官員，有些過去電子信件連繫過，有些基於未來 APEC 生物技術業務將會有所接觸，經過本次研習會交宜，對於日後彼此工作需要上，相信都能比較容易交換訊息。在此對美國駐華與駐星農業組相關人員表示感謝之忱。

貳、 研習會程

七月十七日：起程

由中正機場搭乘華航 CI665 班機下午 13:25 起飛，經香港至新加坡樟宜機場已是晚間 19.55。抵星後搭乘計程車逕赴市中心落宿之濱華大酒店 (Marina Mandarin Singapore)，司機可操華語，一路暢行無阻順利到達，車行約 17 分鐘，花費 13 5 元星幣。由於 ASEAN-ILSI 秘書處已代預約訂房，研習會會場亦設在同一旅館會議廳，在旅館註冊登記後順便查明明天一早會議時程、地點，十分便利。

七月十八日：研習會第一天

大會 9:00 開始，首先由地主國 ILSI Southeast Asia 代表 Mrs Yeong Boon Yee 說明籌備經過以及報告大會秘書處相關事項，接著 AVA 首長 Dr Ngiam Tong Tau 致簡短歡迎詞。隨後交由 AVA 之 Dr Lee Yuen Tong 擔任主席主持上午共同會程。秘書處 Mrs Yeong 順便聲明，研習會注重務實，所以沒有敦請其他官員來做禮儀式致詞演講。

研習會開場，首先由加拿大衛生部 Dr William Yan 介紹研習的架構、目標，國際上相關活動過去的發展與未來的進度，最後說明本次三天研習將如何進行。

其次，加拿大衛生部資深科學審查員(Scientific Evaluator)Mr Brian Harrison 報告加拿大聯邦政府針對生物技術之規範現況。他的演講包含了加國管理生物技術的六大原則、三個相關部會的組織職掌(Health Canada, CFIA and Environment Canada)、新穎食品(novel food)定義、安全評估依據、

方式內容，未來將採取之科學專家群組，目前之生物技術顧問委員會組成任務，有關基因改造食品標示三項方針(guidelines)，國際組織 Codex 未來對標示規範的努力等。

第三位報告的是奧洲 ANZFA 產品標準處(Product Standards)生物技術經理 Dr Paul Brent。ANZFA 自 1991 年制定食品標準法案，由各州(state)負責執行。Dr Brent 很快的介紹了奧洲食品標準的目標、審查程序、風險分析架構、安全評估法律依據，相關數據型式，申請審查案件現況、基因改造食品安全評估要件，實質等同概念，同儕審議(peer review)方式，基因改造食品標示規定之沿革及內容。

Dr Yan 接下來報告「基因改造食品進行食品安全評估之概念與原則」。他首先說明傳統對於食品安全著看法；國際組織過去十年的討論過程，及其四點結論；有關比較評估的設計，如何應用實質等同概念，此一概念的爭議與限制，國際上的共識，美加、加澳的農業生技雙邊會談，Codex 生技食品臨時工作小組的任務，FAO/WHO 諮商會議，和 OECD 生技工作小組。

第五位報告的是 AVA Singapore 秘書 Sumita Thakurta 小姐。她主要說明東南亞國協的農業基因改造產物的風險評估指導方針。該指針係 1999 年部長級會議時制定，建立以科學為根據的風險評估程序，而標示、法律責任、賠償等社會經濟與宗教信仰因素之類議題則不包括在科學評估程序之內。Thakurta 隨後介紹新加坡政府相關主管部會(AVA, ENV, NParks and GMAC)及職掌，星國 GMO 農產品環境釋出的生物安全指針，申請登記、評估、核准之行政流程，最後檢討 ASEAN 未來面臨的挑戰。

大會綜合報告最後由加拿大衛生部 Ms Mireille Prud'homme 講解基因改造植物環境安全評估的概念與原則。加拿大之管理係以產品導向(product based)，管理範圍及於任何加國視為新穎特性之植物(例如對加拿大消費者新穎的奇異果)。對於田間試驗、作物處置、收穫後農地使用之限制均依不同物種有種種具體規定辦法。

大會經過半天六場密集的報告後已經接近午後一點，終於得以休會進行午餐。三天事後經驗證明，大會的時間、議程通常都有遲延或臨時狀況變更，不能準確遵守預定程序進行。好處說是有機動談性，缺點是顯現籌備規劃或許不夠周詳，所幸可以看見各單位人員之間仍然努力協調。

下午開始研習會的主戲--分組討論。Dr Yan 首先再度說明分組討論主旨是希望學員親身體會審查實務經驗，討論教材以孟山都公司申請查驗登記的「耐嘉磷塞基因改造大豆」(GTS 40-3-2 Roundup Soybean)為案例，就實際送審資料分成 10 章節，逐一研讀後，在講師指導下共同提出批評討論。使用的講義資料，係加拿大衛生部徵得孟山都公司同意，在不侵犯業務機密範圍之內，將部分資料原案摘錄，或綜合整理，所製作的教材。

七月十九日：研習會第二天

研習會第二天活動繼續昨日分組討論，進行研習安全評估教材的四個主要章節，重點內容包括：1)基因表達效應(Expression Material/Effect)；2)毒性試驗(Toxicity)； 3)過敏性試驗(Allergenecity)；和 4)營養數據(Nutrition Data)等四項。

下午原訂分組撰寫安全評估書面報告，該計畫取消。由於教材內容相當技術性，與會學員多為各國政府官員，缺乏分子生物、毒理、免疫、營

養等學科專長，討論尚且不容易，何況執筆撰寫評估報告。同樣理由，教材資料包括文字、科學數據，有上百頁，相當繁細，學員須要在幾十分鐘之內速讀，不易消化，雖然有講師導引討論，顯然有事倍功半之效。

本日活動結束之前，仍然舉行綜合討論。各組推派代表，將分組研討的心得做成結論提出分享。本組由印尼國立 Bogor 農業大學食品科技與人體營養系系主任 Dr Purwiyatno Hariyadi 代表報告。

綜合座談主席 Dr Yen 表示各小組在短促時間內，仍然能就現有數據資料提出看法，表示滿意。強調各國學員應該可以從模擬練習中吸取經驗，深入感受安全評估作業的內容實務，和所須要的專家資源。

七月二十日：研習會第三天

今天上午的課程活動主要是延續未竟討論章節，將分組討論做一結束，並進行全體綜合報告檢討，及專題講演。研習會的正式活動到達中午算是圓滿結束，聚餐後部分學員便搭機賦歸。下午，祕書處照預定計畫，安排其餘學員參觀國立新加坡大學附屬機構的分子農業生物學院 Institute of Molecular Agrobiology (IMA)。

專題講演邀請雀巢公司亞洲區品質管制經理(原歐洲總部品管經理) Dr Anthony Huggett 談「農業基因改造產品之食品安全評估以及未來挑戰—以食品產業的角度察」。

全體綜合討論時，Dr Yen 先對「基因改造食品的未來挑戰」也提出簡短結論報告，強調溝通策略(communication strategies)、能力建設(capacity building)、國際調合(international harmonization)的重要，並針對技術發展方面的分子農 (醫)藥業(molcular pharming/farming)、基改家畜漁牧業、機能性食品(functional foods)、過敏試驗、圖譜分析檢驗技術(profiling

technology)、原樣食品(whole foods)的安全評估、上市後監測體系(post market monitoring)、以及審查核准期限等議題也分別表達個人的看法。澳洲 Dr Paul Brent 補充說明國際合作，舉例加、澳二國之間交換審查經驗，研擬共同技術標準的可行性。Dr Yan 並且透露，美加目前合作訂定審查明細清單(check list)，做為科學性審案共同程序基準。

第三日下午由大會秘書處安排參觀新加坡大學校園內的分子農業生物學院。我們一行抵達時，發現學院門庭若市，樓上樓下擠滿了興奮的小學生，原來這幾天是一年一度實驗室開放日，全國各學校都安排學生來參觀教學。實驗室走廊上貼滿說明海報，有圖片、有模型、有實物顯微鏡，有遊戲，老師帶著一隊一隊學生過關玩遊戲，好不熱鬧。新加坡重視科學，相信引起學生學習動機，將來一定可以培養出色的科學人才。

由於人群太多，我們也只好分開來成三個小組，由學院派人分頭帶開參觀解說。我參加的一組由張建衛博士帶領，首先由溫室參觀起。張博士負責學院的智財權(知識產權部主任)，以及新-中生物技術合作。據瞭解，該學院的策略係開發上游生物的技術，取得智財權為主要目標，而不是著重個別產品基因轉殖作物為導向，對於下游作物，以與中國大陸為主要開發合作對象。目前分子農生院預算有三千萬星幣，此外，有若干跨國生技企業的合作投資案。該學院係 1995 年四月新成立的單位，現在擁有 22 個實驗室，據張博士說，仍然有許多空實驗室，將持續擴充。

七月二十一日：返國

返國搭乘華航早班機 8 10 由漳宜機場起飛。匆匆在旅館早餐後，7:00 有旅館預約安排的計程車直奔機場。新加坡日出比台北甚晚，7 點鐘天色才方明，適逢周末假日，街頭靜寂無人，所以車行順暢，到達機場也只花 13 分鐘，14 圓新加坡幣。華航經香港轉機，停留一小時，返抵桃園機場時已近下午三點。

參、心得及建議：

一、國際合作

本次參加東南亞國協舉辦之訓練研習會活動最大的意義與收穫在於體認國際合作的效益與功能。

首先，本活動係美國在台協會主動代為邀請，在報名截止最後一天火速獲得長官裁決，辦理手續參加，並透過美國農業部駐星官員推動，使得非國協會員之台灣能夠受邀。

其次，本次研習會是最好的國際合作榜樣。東南亞國協國家之間對於基因改造生物(GMO)及食品的管理規範，以集體合作方式為建立模式，並不各自獨立先進行規劃。當然，這種模式部分基於各國普遍能力、資源不足的問題，其次，大多數國家沒有顧著民意壓力的情形也值得注意。以民意壓力較突出的泰國為例，在國協中，政府的確有必要先行進行法規規劃。

加拿大衛生部出錢出力，積極參與世界各國能力建設的工作，傳授實務經驗，為各國留下深刻印象，與其政府寬列預算不無幫助，加強國際合作列為政府政策重要一環，對加國的產業、科技能力，建立國際聲望指標作用，加國為 GMO 主要生產及輸出國，保護並促進本國生技產業，其用意明顯。

新加坡對於發展生物科技十分積極，沒有反對 GMO 的民意。由 GMAC 主管政策擬訂，獎勵生技產業發展。由於星國地窄人少，多數生技產業以國際合作為目標，國內僅有少量有機農業、水耕農業。以 IMA 農業生物學院為例，據知識產權部主任劉建衛博士云，每年該院投資 30 百萬星幣

進行上游基礎先進技術研究，掌握專利權，並進行新-中生物技術合作，將技術轉移至中國大陸，做為下游產品開發。這種階層研發模式，藉國際合作施行境外研發，亦可以做為我國科技產業參考。

二、東南亞國協生物技術管理能力有待加強

就所接觸參加學員的一般印象，大多數東南亞國協派遣與會的官員對於 GMO 並不內行，欠缺專業素養，造成溝通討論上諸多困難，主辦單位被迫調整進行方式，不無原因。學員中表現較佳者為新加坡與泰國，多能提出適當問題，或代表小組作口頭報告。

新加坡公務人員普遍素質相當高，新加坡是多種族、多元文化開放社會，習於國際事務，經驗豐富。不過，可能缺乏反對 GMO 民意，一般官員承認，對 GMO 抱有積極樂觀的態度。曾經私下探詢三個 AVA 官員有關 StarLink 事件之意見，都表示不知道，甚至沒有聽過 StarLink 是什麼。

泰國代表團實力最強，不但有實務審查官員參加，也有留美學者(Texas A&M Univ.)。在分組討論，綜合座談會都能主動參與，提出有意義問題、發表個人見解，表現可圈可點。

綜合而觀，固然很難從片面接觸的表象，據以判斷各國的生物技術管理能力，但是從代表團的表現，可以大略顯示各國面臨的資源與執行運作能力。在本次研習會中，台灣常是新加坡及其他國家羨慕的對象，不過，未來對於 GMO 管理的國際協調，仍然必須要各國充分合作，有共同認識，才有溝通對話，解決紛紛，促進互惠繁榮的基礎。所以，有能力的國家，幫忙參與國際能力建設，應該不僅是國力展現，也有增進實質經濟的涵義。台灣以外貿導向為國家經濟基礎，應該努力朝此方向思考。

三、本次研習會的缺失

本次研習會大體進行得非常成功，多數學員都表示獲益良多，但也有少數缺失。

最常遭遇缺失是會程控制不佳。在會議秘書處方面，規劃協調不夠周延。有主持人不知道自己是該場主持的情形出現。會期時間掌握也不好，不能夠準時開始、結束，有拖延一個小時以上的狀況。晚餐也有嚴重誤點情況。相信一部分是出席人員的掌握，非常不確定，致使秘書處作業極為困難，半數以上本地星國參加人員並未全場參與，所以，分組也被迫機動調整，在第二天由四組合併為三組。與會加、澳講師與秘書處對課程規劃，學員反應，對進行方式也不斷檢討更改，希望獲得較佳效果，據悉，曾討論至午夜，其努力以赴的精神，值得敬佩學習。

研習會第二個缺失可能是節目設計有風險評估的題目，但缺少風險評估的內容。全程以 GM 食品安全評估為訓練教材，環境風險評估僅有一節演講。

以加拿大衛生部的立場，自我定位為科學技術單位，以人體健康安全為職掌，設計之課程程序並無不當，但是與會各國代表許多是關係農業植物安全、環境風險評估為目的，新加坡 AVA 眾多官員可能因此就半途放棄參加，從其他國家如菲律賓代表詢問的問題，也看出對食品安全並非注意重點。總之，研習會對於食品安全評估當做重點，加拿大衛生部(Health Canada)顯然將風險評估視為環境評估的一部分，略而不談。所以，針對研習會題目「農業基因改造生物產品之安全性與風險評估研習會」而來的多數學員便顯得失望。(按：環境風險評估是 CFIA 及 Environment Canada 的職掌。)

研習會的第三個缺失是課程設計過於技術性。這是兩難的問題，因為實務的審查本身便是非常技術性，要直接接觸科學文獻與實際數據。加拿大衛生部的專業人員熟悉程序，卻可能高估了第三世界國家的能力。

這也有能是加國衛生部本身的一個誤解，由於加拿大採取內審制度，接受案件之後，完全由衛生部內的不同專業的科技審查員審閱全部資料，然後將初審意見上陳，由不同層級主管複審彙整意見。其過程之中，只有少數狀況會有審查員徵詢部外專家學者意見的機會。這種行政與專業結合的作業方式，必須是主管機構內部已經擁有大量高素質的專家。這樣的模式與我們瞭解的日本政府作業也完全不同。日本厚生勞動省的審查作業完全委外，官方不做審查，交由獨立的專家、學者和消費者組成的委員會進行實質審查與裁決。相信，我國以及東南亞各國，將不可能採取加拿大政府之審查模式，毋寧將比較類似於日本的模式。以此而觀，本次研習會的的設計，顯然就有失焦點，學員能力無法配合，研習中學員反應相對困難，無法熱烈參與，原先計畫被迫變更。往後，類似研習應該以機制建設為討論重點，而非著重科學技術的實際，這方面可以讓各國瞭解如何尋找相關專家學者來處理。

總之，本屆活動係加拿大衛生部設計，針對 GMO 管理的複雜性，未來相關活動應可以邀請其他管理部會參與，或其他如歐盟國家的專家與會，以呈現全面互動的管理流程，給予對不同管理理念、模式充分表達意見的的機會，應該對促進彼此瞭解，解決國際調合性的可能產生的問題。

四、基因改造食品的安全評估因地區而有不同須要：

本次研習會最後綜合討論中，Dr Yan 曾經強調對於基因改造食品的安全審查資料，可能會有地域特殊性的考慮，比如過敏性試驗，東方人可能

會有與西方人種不同的反應。另外，營養成分也可能因人民攝食量，有不一樣安全風險。甚至作物在不同地區栽種，從溫帶到熱帶，其基因表現與成分組成不會完全一樣。各國應該考慮自己的因素，要求申請業者提供相關數據，以做為獨立審查判斷的參考。以上說明十分合理，一般學員都無異議。

不過，根據上述的原則，倘若加拿大經過安全評估，准許「耐嘉磷塞基因改造大豆」在本國生產、輸出，但對於在其他地區(比如菲律賓)栽種生產的「耐嘉磷塞基因改造大豆」，會不會禁止其輸入加拿大，或要求業者重新申請做安全評估呢？這個假設性問題提出後，與會者都譁然，加拿大代表也無法立即回答。

五、建立基因改造食品安全評估的科學程序：

衛生署今(90)年二月二十二日公告「基因改造之黃豆及玉米應向本署辦理查驗登記」規定包括了「基因改造食品安全評估之方法」附件，正式建立我國安全評估的科學方法與內容。

本次研習會在過敏性審查部分介紹了 FAO/WHO 和 ILSI 採取的安全評估「決策程序」(decision tree)(附件十一)。最後一天演講，雀巢經理 Dr Hugget 提醒學員注意，FAO/WHO 2001 年已經大幅修正該程序(附件十二)。

由此可觀，國際規範的趨勢，在某些安全評估的領域，將有採取嚴謹程序的共識，而不只是有適當的方法與內容。

隨科學技術進步，國際論壇逐漸進入實質討論，形成共識，我國的基因改造食品審查作業將要逐步調整，納入國際接受的安全評估內容與程序，以因應國際標準的檢驗，在國際調合的原則下，充分保障國人的健康和消費者權益。

肆、 附 件

一、東南亞國協會員國名單

東南亞國協 Association of Southeast Asian Nations

1. Brunei Darussalam
2. Cambodia
3. Indonesia
4. Laos
5. Malaysia
6. Myanmar
7. Philippines
8. Singapore
9. Thailand
10. Viet Nam

秘書處網址 http://www.aseansec.org/

二、研習結業證書


In collaboration with
Health Canada

CERTIFICATE OF PARTICIPATION

This is to certify that

Kao Wen Wen

has participated in the

ASEAN-ILSI Training Workshop on Safety and Risk Assessmert of Agriculture-related GMOs

from 18 to 20 July 2001
Singapore

Dr. Ngiam Tong Tau
Chief Executive Officer
Agri-food & Veterinary
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Mrs Yeong Boon Yee
Executive Director
International Life Sciences Institute
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四、第一次分組討論題綱

Health Canada Santé Canada

First Breakout Session

GTS 40-3-2 Herbicide Tolerant Soybean

- Host Organism
- Donor Organism
- Molecular Characterization
  - Modification Process
  - Characterization of Inserted DNA
  - Genetic Stability of the Inserted DNA

Novel Food Case Study

Health Canada Santé Canada

Host Organism

GTS 40-3-2 Herbicide Tolerant Soybean

- Knowledge of the host organism and the counterpart foods are used as the basis for comparison with the novel food
- Natural range and variation of key:
  - Nutrients
    - Vitamins, cofactors, essential amino acids
  - Toxicants
    - Glycoalkaloids, glucosinolates, cucurbiticin
  - Anti-nutrients
    - Soybean trypsin inhibitor
  - Allergens

Novel Food Case Study

Health Canada Santé Canada

GTS 40-3-2 Herbicide Tolerant Soybean

Novel Food Case Study

Donor Organism

- Potential allergenicity and/or pathogenicity of the donor organism
- Introduced proteins from known sources of allergens must be considered potential allergens until proven otherwise
- The donor genes – and in particular the protein products encoded by them

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GTS 40-3-2 Herbicide Tolerant Soybean

Novel Food Case Study

Molecular Characterization

- The transformation system
  - Microparticle bombardment
- Molecular characterization of the inserted DNA
  - Insert number
  - Insert composition
- Genetic stability of the introduced trait
  - Segregation analysis
  - Stability of the inserted DNA

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GTS 40-3-2
Herbicide
Tolerant
Soybean

Novel Food Case Study

Microparticle Bombardment

- Used to directly deliver DNA to the host genome
- Plasmid or linearized DNA fragments are fixed to tungsten or gold particles, which are accelerated into the host cell at high speed, penetrating the nucleus
- In the nucleus, DNA separates from the carrier particle and can become integrated into the host genome

Health Canada Santé Canada

GTS 40-3-2
Herbicide
Tolerant
Soybean

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Novel Food Case Study

Office of Food Biotechnology

Novel Food Case Study

五、第二次分組討論題綱

Health Canada Santé Canada

Second Breakout Session

GTS 40-3-2 Herbicide Tolerant Soybean

- Expressed Material/Effect
- Nutritional Data
- Toxicity
- Allergenicity

Novel Food Case Study

Health Canada Santé Canada

Expressed Material / Effect

GTS 40-3-2 Herbicide Tolerant Soybean

- Knowledge of which genes are expressed
- Characteristics, concentration and localization of expressed products
- Consequences of expression
- And, in cases where the modification results in the production of antisense mRNA, the consequences of altering the expression of an endogenous gene must be evaluated

Novel Food Case Study

Health Canada Santé Canada

Nutritional Assessment

GTS 40-3-2 Herbicide Tolerant Soybean

Novel Food Case Study

- All plant breeding methods, traditional and modern, have the potential to alter the nutritional value of the plant or lead to unexpected changes in the concentrations of various natural toxicants or anti-nutrients
- The safety assessment should consider the potential for any change in nutritional composition as well as the potential for any change in the bioavailability of key nutrients

Health Canada Santé Canada

Aim of Nutritional Assessment

GTS 40-3-2 Herbicide Tolerant Soybean

Novel Food Case Study

- For GM plants that were not developed to have intentionally altered nutritional value, the aim of the nutritional evaluation is to investigate whether there have been unintentional changes in levels of key nutrients, toxicants, allergens and anti-nutrients

Health Canada Santé Canada

Compositional Analysis

GTS 40-3-2 Herbicide Tolerant Soybean

- Protein
- Fat
- Fibre
- Starch
- Amino acid composition
- Fatty acid composition
- Ash
- Sugars
- Calcium
- Phosphorous

Novel Food Case Study

Health Canada Santé Canada

Toxicology and Food Safety

GTS 40-3-2 Herbicide Tolerant Soybean

- Very few foods consumed today have been subjected to rigorous toxicological assessment
- For the thousands of new foods placed on the market each year, it is generally assumed that if individual ingredients are safe, then new combinations of these are equally safe
- Consumption of large amounts of any single food would likely result in adverse effects

Novel Food Case Study

Health Canada Santé Canada

GTS 40-3-2
Herbicide
Tolerant
Soybean

Novel Food Case Study

Toxicological Considerations

- Introduced genes are often derived from microorganisms that do not have a history of <u>significant</u> consumption by humans
  - Bt proteins (Cry1Ab, Cry1Ac, Cry3A...) from *Bacillus thuringiensis*
  - PAT enzyme from *Streptomyces viridochromogenes, S. hygroscopicus*
  - EPSPS from *A. tumefaciens*
- However, in some cases the protein products of introduced genes have been consumed in significant amounts
  - Viral coat proteins from transgenic potatoes, papaya and squash
  - Isolated plant genes that have been modified by *in vitro* site-directed mutagenesis and re-inserted (*e.g.* mEPSPS in GA21 maize)

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GTS 40-3-2
Herbicide
Tolerant
Soybean

Novel Food Case Study

Unintended Effects

- A related issue is the possibility of unintentionally modifying metabolic pathways as a consequence of gene insertion, thus affecting concentrations of endogenous toxicants
- Since the toxic potential of endogenous toxins is already known, toxicological assessment is not required but determination of their levels is necessary as part of the compositional/nutritional analysis

Focus on the Defined Difference(s)

GTS 40-3-2 Herbicide Tolerant Soybean

- The principal focus of toxicity evaluation is/are the protein expression product(s) of the inserted gene(s)
- The inserted DNA, in itself, does not pose a food safety concern

Novel Food Case Study

Protein Toxins

GTS 40-3-2 Herbicide Tolerant Soybean

- Generally, novel proteins, like other dietary proteins, have a predictable metabolic fate upon ingestion – they are broken down to their constitutive amino acids under digestive conditions
- Proteins that behave this way, or are inactivated by heat (as in processing) are unlikely to exert adverse affects
- Protein toxins (and allergens) tend to be resistant to digestion – this is a necessary but not a sufficient condition, as in the absence of other toxicological evidence there is no consensus on resistant proteins being a higher risk

Novel Food Case Study

Health Canada Santé Canada

In Vitro Studies

GTS 40-3-2 Herbicide Tolerant Soybean

- Digestibility assays – incubating purified protein with simulated gastric and intestinal fluids and determining the extent of degradation over time
- Heat inactivation assays
- Amino acid sequence comparisons

Novel Food Case Study

Health Canada Santé Canada

Animal Studies

GTS 40-3-2 Herbicide Tolerant Soybean

- Commonly used for the safety assessment of many compounds, including pesticides, pharmaceuticals, industrial chemicals and food additives
  - Works well for substances of known purity, no nutritional value, low potential for human exposure – therefore easy to test at high multiples of anticipated exposure and determine no observed effect levels (NOELs) – and thus establish safe upper limits (*e.g.* acceptable daily intakes)
- Problematic with whole foods but can be used to investigate acute oral toxicity of purified proteins

Novel Food Case Study

Health Canada Santé Canada

Allergencity Assessment Strategy

GTS 40-3-2
Herbicide
Tolerant
Soybean

Novel Food Case Study

- Decision tree strategy
  - Gene source
  - Physiochemical properties (MW, heat and processing stability, digestive stability)
  - Immunologic analysis (RAST)
  - Amino acid sequence homology
  - Prevalence in foods
- Totality of assessments provides reasonable assurance that foods will not be rendered newly allergenic

Toxicology and Food Safety

- Very few foods consumed today have been subjected to rigorous toxicological assessment
- For the thousands of new foods placed on the market each year, it is generally assumed that if individual ingredients are safe, then new combinations of these are equally safe
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  - EPSPS from *A. tumefaciens*
- However, in some cases the protein products of introduced genes have been consumed in significant amounts
  - Viral coat proteins from transgenic potatoes, papaya and squash

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Focus on the Defined Difference(s)

- The principal focus of toxicity evaluation is/are the protein expression product(s) of the inserted gene(s)
- The inserted DNA, in itself, does not pose a food safety concern

QUESTIONS TO CONSIDER

•Is novel protein expressed in edible tissue of GM crop?;

•Expression levels in various plant tissues, particularly parts consumed, and

•What types of processing the food will be subjected to prior to consumption?

In Vitro Studies

- Digestibility assays – incubating purified protein with simulated gastric and intestinal fluids and determining the extent of degradation over time
- Heat inactivation assays
- Amino acid sequence comparisons

ANIMAL TOXICITY STUDIES

Acute Studies

- For newly expressed proteins in GM foods, few proteins in nature which exert toxic activity do so in acute timeframe (e g diptheria toxin, certain snake venoms),
- Acute studies not meant to be substitutes for long-term studies as misconstrued by many,
- Toxicity studies must be well designed and conducted according to internationally accepted guidelines – e g OECD guidelines,
- Most commonly used acute study is one very high dose by gavage followed by 14 day observation period including daily clinical observations, food and water consumption, weight measurements, post mortem examination

TOXICITY STUDIES

Pharmaceuticals, Ag/Vet chemicals, food additives.

- Well characterised, known purity, no nutritional value, human consumption low,
- Relatively easy to feed to animals at a range of doses (dose-response, several orders of magnitude above expected human exposure levels) to identify potential adverse effects,
- By determining the level of exposure at which no adverse effects occur, a safe level of exposure for humans can be established including appropriate safety factors

ANZFA
Australia New Zealand Food Authority

TOXICITY STUDIES

Foods.

•Foods complex mixtures characterised by wide variation in compositional and nutritional value,

•Due to bulk, fed to animals only at low multiples of amounts likely present in human diet,

•Dose-response not possible in most cases,

•Need to maintain nutritional value and balance of diet,

•Poorly balance diet will compromise interpretation feeding studies, small effects related to component will be confounded,

•Ethical considerations

ANZFA

Allergenicity Assessment Strategy

- Decision tree strategy
  - Gene source
  - Physiochemical properties (MW, heat and processing stability, digestive stability)
  - Immunologic analysis (RAST)
  - Amino acid sequence homology
  - Prevalence in foods
- Totality of assessments provides reasonable assurance that foods will not be rendered newly allergenic

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GTS 40-3-2: Soybean Toxicants, Antinutrients, and Allergens

GTS 40-3-2 Herbicide Tolerant Soybean

Novel Food Case Study

- Natural source of several antinutrients:
  - Trypsin inhibitors
  - Lectins (soybean hemagglutinin)
  - Phytoestrogens (genistein, daidzein and coumesterol_
  - Stachyose, raffinose
  - Phytic acid
- Known cause of food allergies
  - Although not completely characterized, proteins that are immunoreactive with the sera from sensitized individuals have been identified – number may be between 9 and 15 different proteins (as identified by immunoblotting techniques)

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Donor Organism

GTS 40-3-2 Herbicide Tolerant Soybean

Novel Food Case Study

- Potential allergenicity and/or pathogenicity of the donor organism
- Introduced proteins from known sources of allergens must be considered potential allergens until proven otherwise
- The donor genes – and in particular the protein products encoded by them

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GTS 40-3-2 Example Potentially Inserted Sequences

GTS 40-3-2 Herbicide Tolerant Soybean

Novel Food Case Study

Genetic Element	Size (kb)	Function
P-E35S	0 61	Duplicated/enhanced CaMV 35S promoter
CTP4	0.22	Chloroplast transit peptide signal sequence
CP4 EPSPS	1 36	C-terminal portion of EPSPS from *A. tumefaciens* strain CP4
NOS 3'	0.26	3' untranslated region from nopaline synthase gene (*A tumefaciens*)
KAN	1 32	Neomycin phosphotransferase II encoding gene from Tn5 transposon of *E coli*
Ori-pUC	0 65	*E. coli* origin of replication from plasmid pUC119
LAC	0.24	Partial *E coli* lacI coding sequence
P-MAS	0.42	Mannopine synthase promoter region
GUS	1 81	*E. coli* beta-glucuronidase encoding gene for use as scoreable marker
7S 3'	0.43	3' untranslated region from the soybean 7S storage protein alpha subunit
CMoVb	0.57	Figwort mosaic virus 35S promoter

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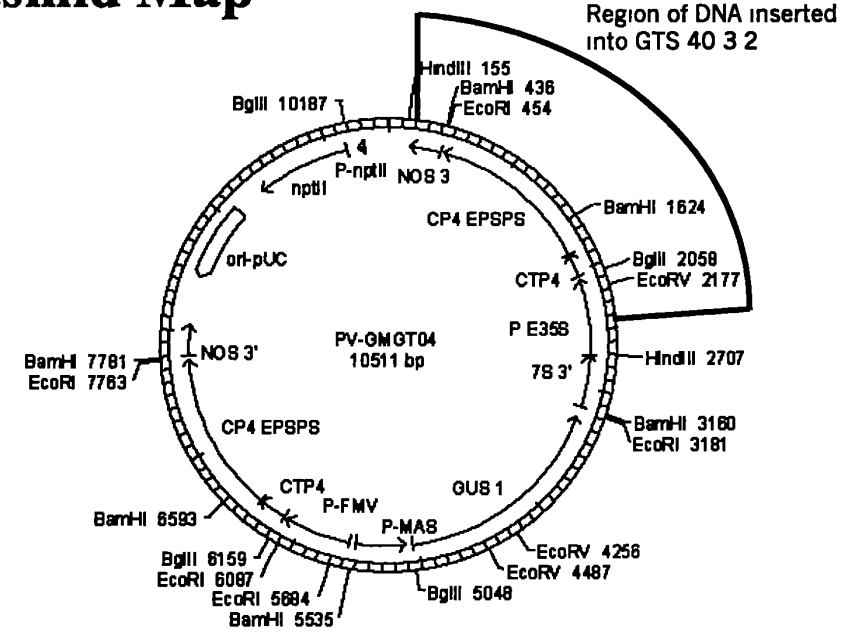
GTS 40-3-2 Example Plasmid Map

GTS 40-3-2 Herbicide Tolerant Soybean

Novel Food Case Study



The Inserted DNA - Insert Number

GTS 40-3-2
Herbicide
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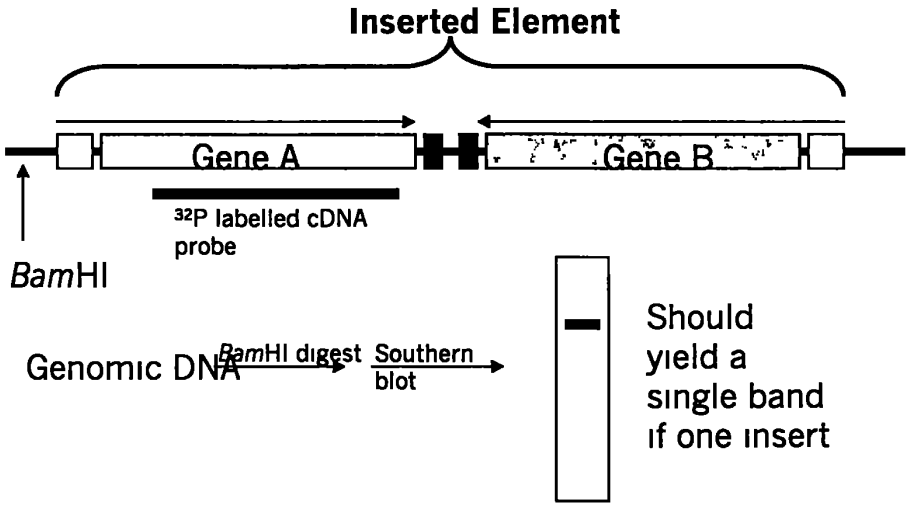

GTS 40-3-2 Example Insert Number

GTS 40-3-2
Herbicide
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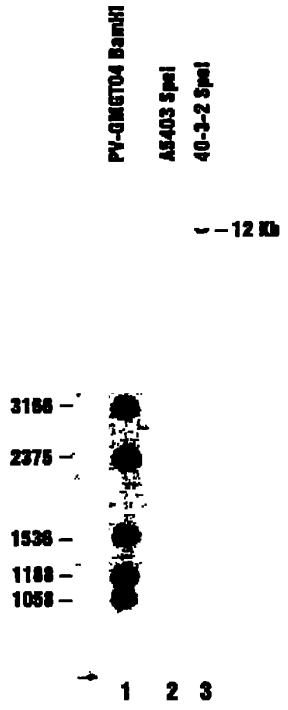
Novel Food Case Study

Southern blot analysis of genomic DNA from control (lane 2) and 40-3-2 (lane 1) lines. DNA was digested with *Spe*I and probed with ^{32}P-labelled PV-GMGT04 DNA. Positive control was plasmid DNA digested with *Bam*HI (lane 1).

Preliminary conclusion was that GTS 40-3-2 contained a single site of insertion of PV-GMGT04 DNA.



GTS 40-3-2 Example – Stability

GTS 40-3-2 Herbicide Tolerant Soybean

Novel Food Case Study

Southern blot of genomic DNA from GTS 40-3-2 R3 and R6 progeny generations digested with *HindIII* and probed with ^{32}P-labelled PV-GMGT04 DNA.

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Expressed Material / Effect

Office of Food Biotechnology

Food Safety
Assessment Workshop

Singapore, July 2001

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Hazard Identification Requires

GTS 40-3-2
Herbicide
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Soybean

Novel Food Case Study

- Knowledge of which genes are expressed
- Characteristics, concentration and localization of expressed products
- Consequences of expression
- And, in cases where the modification results in the production of antisense mRNA, the consequences of altering the expression of an endogenous gene must be evaluated

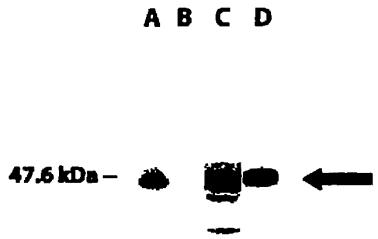
GTS 40-3-2 Example – Identity

GTS 40-3-2 Herbicide Tolerant Soybean

Novel Food Case Study

Western immunoblot detection of CP4 EPSPS protein in samples of GTS 40-3-2 soybean seed (lane C) or toasted meal prepared from GTS 40-3-2 soybean seed (lane D).

Purified CP4 EPSPS from an *E. coli* overexpression culture was included as a positive control (lane A), and a negative buffer control sample is shown in lane B.



GTS 40-3-2 Example - Amounts

GTS 40-3-2 Herbicide Tolerant Soybean

Novel Food Case Study

Quantitation of CP4 EPSPS protein in various tissues was determined by ELISA

No expression of GUS

Sample	No. of sites	Mean	Range
CP4 EPSPS		µg protein / mg fresh wt	
Leaf 1992	8	0 443	0.251-0 789
Leaf 1993	3	0 415	0.299-0 601
Seed 1992	9	0 288	0 186-0 395
Seed 1993	4	0 201	0 127-0 277
GUS			
Leaf 1992	8	ND	--
Seed 1992	9	ND	--

All samples were frozen immediately and shipped and stored frozen Means reported are of site means

ND Not detected

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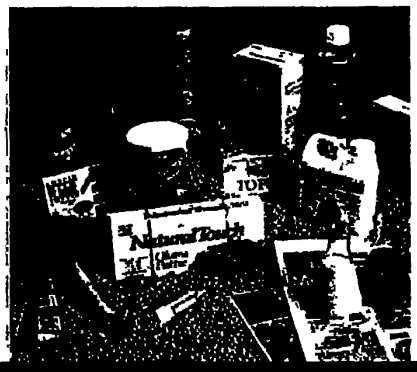
Nutritional Data

Office of Food Biotechnology



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Aim of Nutritional Assessment

GTS 40-3-2 Herbicide Tolerant Soybean

Novel Food Case Study

For GM plants that were not developed to have intentionally altered nutritional value, the aim of the nutritional evaluation is to investigate whether there have been unintentional changes in levels of key nutrients, toxicants, allergens and anti-nutrients

Health Canada Santé Canada

Compositional Analysis

GTS 40-3-2 Herbicide Tolerant Soybean

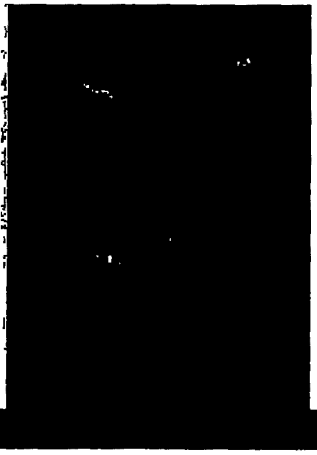
- Proximate analysis
- Fibre
- Protein
- Fat
- Ash
- Moisture
- Carbohydrates
- Amino acid composition
- Fatty acid composition
- Anti-nutritional components (trypsin inhibitors, lectin, isoflavone, stachyose, raffinose, phytic acid)

Novel Food Case Study

Health Canada Santé Canada

Toxicological Assessment

Office of Food Biotechnology



Food Safety Assessment Workshop

Singapore, July 2001

Toxicological Studies

GTS 40-3-2 Herbicide Tolerant Soybean

Novel Food Case Study

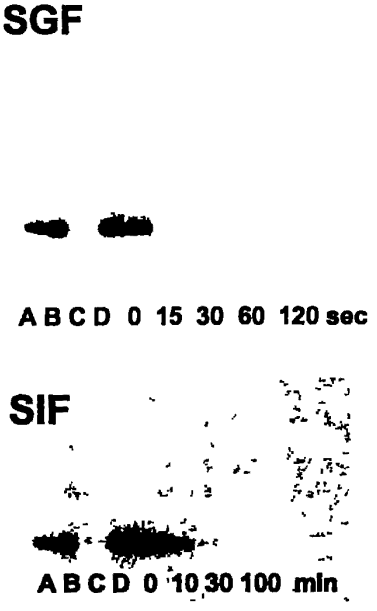
- Digestibility assays – incubating purified protein with simulated gastric and intestinal fluids and determining the extent of degradation over time
- Heat inactivation assays
- Acute toxicity study
- Amino acid sequence comparisons
  - Lack of homology with known toxins can be used as additional evidence for low potential for toxicity

GTS 40-3-2 Example – CP4 EPSPS Digest

GTS 40-3-2 Herbicide Tolerant Soybean

Novel Food Case Study

- Western immunoblot analysis of purified CP4 EPSPS protein following incubation with simulated gastric fluid (SGF) or simulated intestinal fluid (SIF)
- Purified CP4 EPSPS (5, 10 ng: lanes A, B), digestive fluid w/o CP4 EPSPS (C), and CP4 EPSPS in buffer control (D)



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Allergenicity

Office of Food Biotechnology

Food Safety Assessment Workshop

Singapore, July 2001

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GTS 40-3-2 Herbicide Tolerant Soybean

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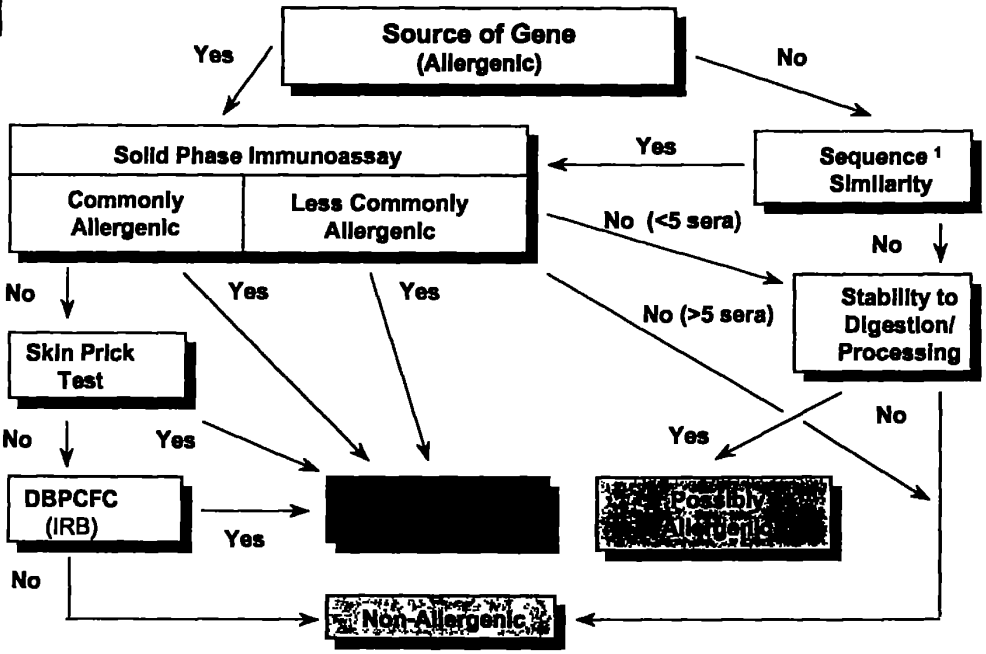
IFBC/ILSI Decision Tree



GTS 40-3-2 Example – CP4 EPSPS

Health Canada / Santé Canada

GTS 40-3-2 Herbicide Tolerant Soybean

Novel Food Case Study

- Amino acid sequence homology
  - Compared against sequences of 121 known allergens
  - No significant homology based on epitope size of 8 amino acids
- Degradation in simulated digestive fluids
  - Rapidly digested in simulated gastric fluid (T_{50} < 15sec)

Table 10 2 Characteristics of known protein allergens [1]

Characteristic	Allergens	CP4 EPSPS
Allergenic source of gene	yes	no
Mol wt 10-70 kDa	yes	yes
Glycosylated	yes[2]	no
Similar sequence to allergens	yes	no
Stable to digestion	yes	no
Stable to processing	yes	no
Prevalent protein in food	yes	no

1 As described in Taylor (1992) and Taylor *et al.* (1987).
2 Typically, but not absolutely.

九、基因改造食品安全評估未來面臨之挑戰

Future Challenges for GM Food Safety Assessment

William Yan

Paul Brent

Future Challenges:

- **Communication Strategies**
- **Capacity Building**
- **International Harmonization**

Future Challenges (cont'd)

- Molecular Farming/Pharming
- Genetically Modified Livestock and Fish
- Functional Foods

Future Challenges (cont'd)

- Allergenicity Assessment
- Profiling Techniques
- Safety Assessment of Whole Foods

Future Challenges (cont'd)

- **Post-Market Monitoring**
- **Time Limited Approvals**

十、基因改造食品安全評估未來面臨之挑戰-食品業的觀點

Future Challenges for Food Safety Assessment of Agriculture-Related GMOs

A Food Industry Perspective

Anthony C. Huggett
Quality Management, Nestlé

Key Issues for the Food Industry

- Safety Assessment
- Traceability
- Labelling

Food Safety Assessments - Concerns

- Media/Consumer concerns
  - "Long term effects"
  - Predictive tests for potential allergenicity
- 2nd & 3rd Generation products
  - Nutritionally improved GM crops
  - Genetically modified microorganisms

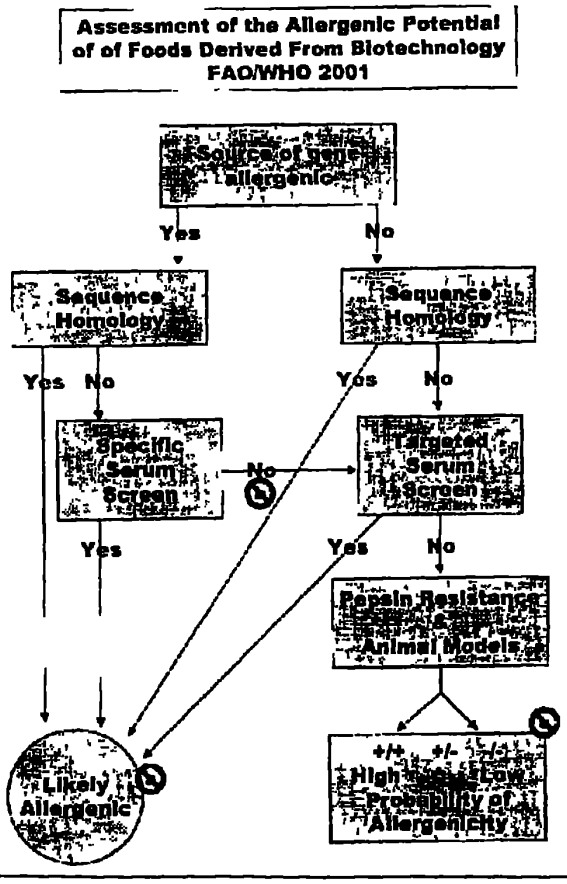
Long Term Effects

- Very little known about long term effects of consumption of any foods.
- Pre-marketing assessment already gives assurance that the food is as safe as the conventional counterpart.
- Possibility of long term effects being specifically attributable to genetically modified foods is highly unlikely.

Prediction of Allergenicity

- Allergenicity assessment starts with the premise that novel proteins are potentially important allergens and that any proteins derived from allergenic donors are allergens.
  - necessary to prove that they are innocuous
- FAO/WHO 2001 decision tree represents current state of knowledge
  - scientific base in this field is developing rapidly, database will be need to be updated
  - confidence that this approach provides high certainty of identifying allergens.

FAO/WHO 2001 Decision Tree



Transfer of an allergen to soybeans

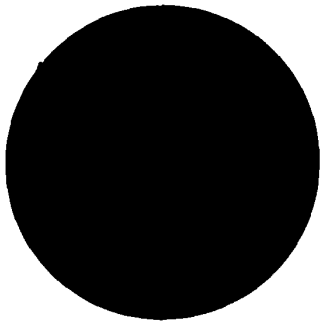
- Brazil nut 2S albumin storage protein is rich in methionine and cysteine
- Expressed in soybeans in order to improve nutritional quality of protein
- Brazil nut is a cause of allergenic reactions
- Tests demonstrated that transgenic soybeans contained proteins responsible for Brazil nut allergenicity
- Development of GM soybeans was stopped

Low probability that a new protein will be an important allergen

- food contains 100,000's different proteins
- relatively few foods responsible for food allergy
- chances that a completely new protein will be an important allergen is relatively small

- 8 foods responsible for >90% cases

  peanuts, soybeans, tree nuts, milk, eggs, fish, crustacea, wheat



Very small amounts of allergic proteins can cause a reaction

Incidents requiring medical treatment:

6 mg hazelnut in chocolate
50 mg corylin (hazelnut) in a cookie
10 mg casein (milk)
10-190 mg ovalbumin (egg)

Incident resulting in death (anaphylaxis):

60 mg casein (milk)

Scientifically controlled study (observable effect):

0.1 mg peanut protein

Hidden allergens

Most cases of severe food allergic reactions are due to hidden allergens (unlabelled).

Unexpected presence of an allergen in a food product:

- unusual ingredient (food service)
- presence of allergenic ingredient not indicated on ingredients list
- carry-over or cross-contamination during processing

HIDDEN ALLERGENS

Food Industry faces the allergen issue every day - unrelated to GMOs

- Initiatives must be taken during food processing to ensure the accurate labelling of finished products:

Allergy Prevention Plan (GMP/HACCP)

- Product formulation
- Ingredient control
- Rework
- System design and cleaning

Food Safety Assessments - Concerns

- Media/Consumer concerns
  - "Long term effects"
  - Predictive tests for potential allergenicity
- 2nd & 3rd Generation products
  - Nutritionally improved GM crops
  - Genetically modified microorganisms

2nd / 3rd Generation GM Products

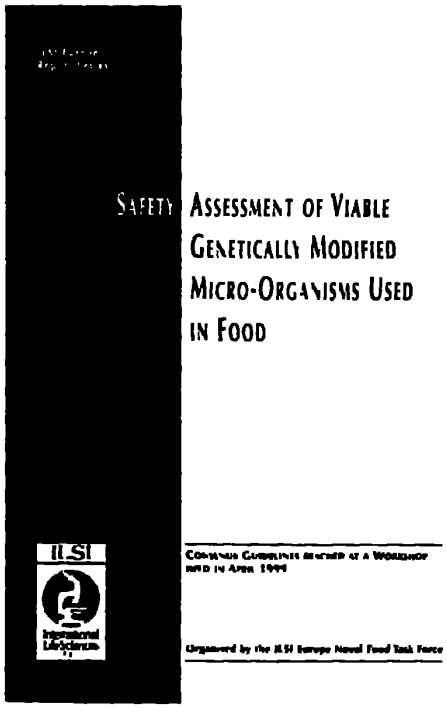
- Nutritionally improved GM crops (functional foods)
  - added nutritional or health value may lead to increased or unusual use of food product
    - adverse effects due to too high an exposure to active component (nutritional imbalance or toxicity)
    - unusually high exposure to traditional food components (e.g. anti-nutritional factors, toxicants)
    - need to consider overall impact of the food to the nutritional status of the population
    - different situations in different populations

2nd / 3rd Generation GM Products

- Food containing viable genetically modified microorganisms (GMMs)
  - limited experience of safety assessments
  - GMMs raise some special safety issues that are not relevant to genetically modified plants
    - pathogenicity
    - effects on gastrointestinal microflora
    - persistence/colonisation
    - reasonable to assume that gene transfer to organisms in GI tract will occur

2nd Generation GM Products

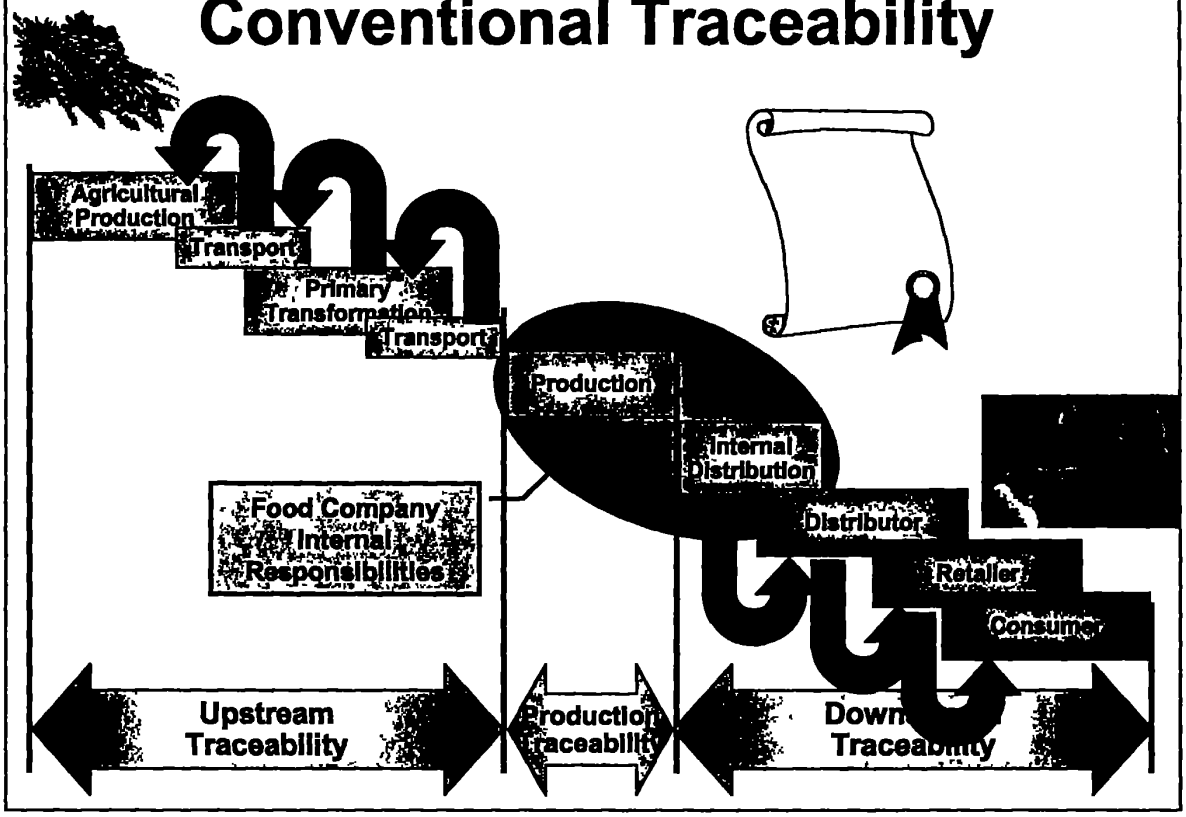
- Guidelines have been developed for the safety assessment of foods containing viable genetically modified microorganisms.



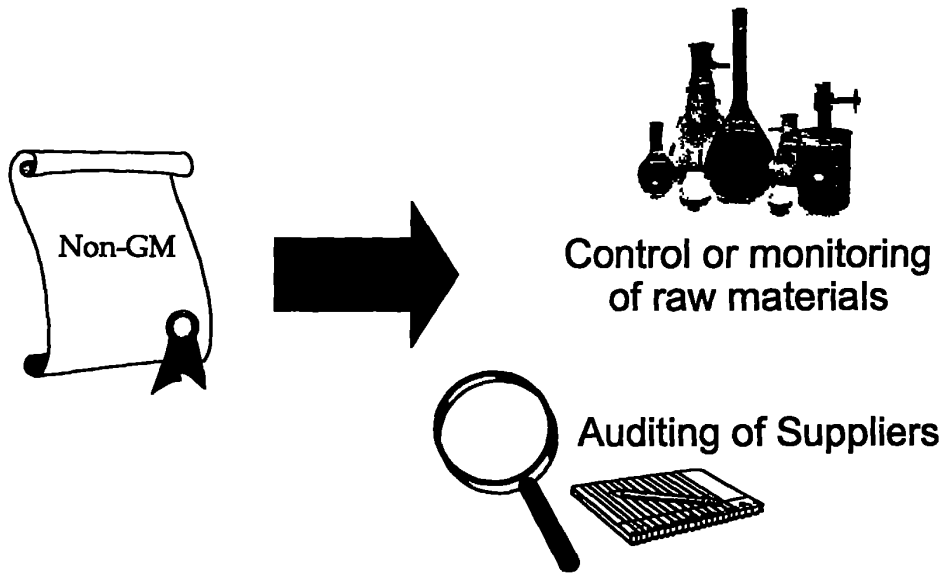
Traceability and Identity Preservation (IP) Systems

- Ensure that only approved GM foods are used
- Ensure compliance with mandatory (and voluntary) labelling requirements

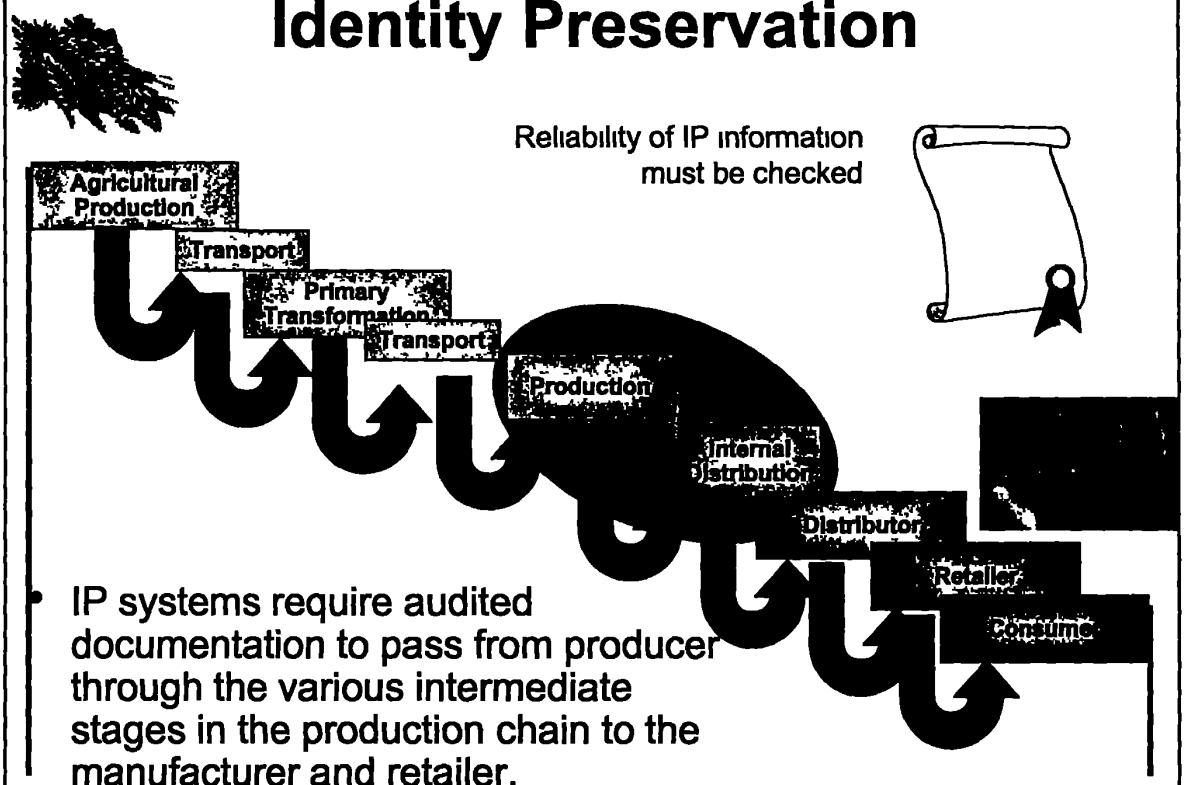
Conventional Traceability



Certification must be backed up by verification



Identity Preservation



- IP systems require audited documentation to pass from producer through the various intermediate stages in the production chain to the manufacturer and retailer.

Traceability

- Absence of unapproved varieties
  - approved in country of origin but not in country of food use
  - approved for feed use but not food use (e.g. Starlink case)
  - no approval - unauthorised release of material from field trials, etc.
- No methodology to test for unapproved varieties unless sequences are known

Applicability of Screening Method

CROP	NAME	COMPANY	GENETIC MODIFICATION	PRESENCE OF 35S-PROMOTER	PRESENCE OF NOS-TERMINATOR	PRESENCE OF npt II GENE
Maize 1	Maximizer, Bt-176	Ciba Seeds (Novartis)	Insect resistant	Yes	No	No
Maize		DeKalb	Herbicide tolerant	Yes	No	No
Maize[1]	T25, Liberty Link	Hoechst / AgrEvo	Herbicide tolerant	Yes	No	No
Maize[1]	Yield Gard MON810	Monsanto	Insect resistant	Yes	No*	Yes[2]
Maize	Nature Gard	Mycogen	Insect resistant	Yes	No	No
Maize[1]	Bt-11	Sandoz Seeds (Novartis)	Insect resistant	Yes	Yes	No
Maize	Seed Link	Plant Genetic Systems	Herbicide tolerant	Yes	Yes	No
Cotton	BXN Cotton	Calgene / Rhône Poulenc	Herbicide tolerant	Yes	No	Yes
Cotton		Du Pont	Herbicide tolerant	No	No	No
Cotton	Bollgard	Monsanto	Insect resistant	Yes	Yes	Yes
Cotton	Roundup Ready	Monsanto	Herbicide tolerant	Yes	Yes	Yes
Rapeseed		AgrEvo	Herbicide tolerant	Yes	No	Yes
Rapeseed	Laurical	Calgene	Altered fatty acid profile	Yes	No	Yes
Rapeseed	Roundup Ready	Monsanto	Herbicide tolerant	No	No	No
Rapeseed		Plant Genetic Systems	Herbicide tolerant	No	Yes	Yes
Papaya		Cornell University Hawaii University	Virus resistant	Yes	No	Yes

Applicability of Screening Method

CROP	NAME	COMPANY	GENETIC MODIFICATION	PRESENCE OF 35S-PROMOTER	PRESENCE OF NOS-TERMINATOR	PRESENCE OF npt II GENE
Potato[1]	Apron / Apropos	Avebe	Repressed amylose production, high amylopectin	Yes	Yes	Yes
Potato[1]	NewLeaf	Monsanto	Insect resistant	Yes	Yes	Yes
Potato[1]	NewLeaf Plus	Monsanto	Insect resistant leafroll virus resistant	No	Yes	(Yes)
Potato[1]	NewLeaf Y	Monsanto	Insect resistant Virus Y resistant	No	Yes	Yes
Soybean		Hoechst / AgrEvo	Herbicide tolerant	Yes	Yes	No
Soybean[1]	Roundup Ready	Monsanto	Herbicide tolerant	Yes	Yes	No
Squash		Asgrow	Virus resistant	Yes	No	Yes
Squash	Freedom B	Asgrow / Upjohn	Virus resistant	Yes	No	No
Cherry Tomato		Agrilope	Fruit ripening delayed	No	Yes	Yes
Tomato[1,3]	Flavr Savr	Calgene	Fruit ripening delayed	Yes	No	Yes
Tomato[3]	Endless Summer	DNA Plant Technology	Fruit ripening delayed	Yes	Yes	Yes
Tomato[3]		Monsanto	Fruit ripening delayed	Yes	Yes	Yes
Tomato[3]		Zeneca	Fruit ripening delayed / thicker skin	Yes	Yes	Yes
Chicory		Bejo Zaden BV	Herbicide tolerant	No	Yes	Yes

Labelling - Two Approaches

- Product based
  - labelling related to changes which impact safety & nutrition
  - e.g. USA, Canada
- Process based
  - unrelated to safety & nutrition
  - aimed at giving consumers information
  - e.g. Europe, Japan, Australia

GMO Labelling Regulation (1139/98, Sept 98)

Based on detection of GM DNA or protein

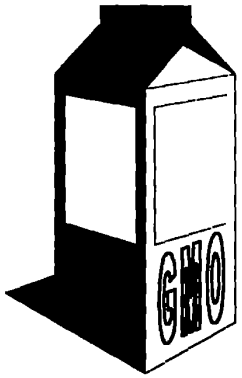
Example:

[redacted]

Other option:

[redacted]

GMO labelling in Europe



Global Regulations

(data provided by US GMA)

Country	Is labelling approval required?	Is GM food approval required?	Is labelling required for GM food?	Is there a required label?	Must processed foods be labelled?	Must animal feed be labelled?	Must GM food additives/ processing aids be labelled?	Must GM colours/flavourings be labelled?	Are retail GM service products labelled?
Argentina			[illegible]	[illegible]	[illegible]	NA	NA	NA	NA
Australia and New Zealand						NA			
Brazil			UD	D, A	UD	NA	E	NA	NA
Canada			UD	UD	UD	[illegible]	[illegible]	[illegible]	UD
Chile	NA	NA				NA	UD	UD	NA
China		UD	UD	UD	UD	NA	NA	NA	NA
Czech Republic				NA		NA	NA	NA	NA
Hong Kong	NA	NA	UD	UD	UD	NA	NA	NA	NA
India		NA	NA	NA	NA	NA	NA	NA	NA
Japan						UD	[illegible]	[illegible]	NA
Mexico	UD	NA	UD	D, A	UD	NA	NA	NA	NA
Norway	NA					NA	[illegible]	[illegible]	NA
Paraguay		[illegible]	[illegible]	NA	[illegible]	NA	NA	NA	NA
Russia	NA					NA	NA	NA	NA
Saudi Arabia	NA					NA	NA	NA	NA
South Korea						UD	NA	NA	
Sri Lanka	NA	NA	NA	NA	NA	NA	NA	NA	NA
Switzerland	NA					NA			
Taiwan	NA	UD	UD, E			NA	NA	NA	NA
United States			[illegible]	[illegible]	[illegible]	NA	[illegible]	[illegible]	NA
ASEAN									
Indonesia	NA		UD	UD, A	UD	NA	NA	NA	NA
Malaysia		UD	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	[illegible]	NA
Philippines	UD	UD	UD	UD, A	UD	NA	NA	NA	NA
Singapore	NA	UD	UD	NA	NA	NA	NA	NA	NA
Thailand			UD	NA	UD	[illegible]	[illegible]	[illegible]	NA
Vietnam	NA	NA		NA	NA	NA	NA	NA	NA
European Community						UD			NA
Codex	[illegible]	UD	UD	UD	NA	NA	NA	NA	NA

Global Regulations

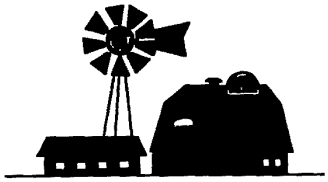
(data provided by US GMA)

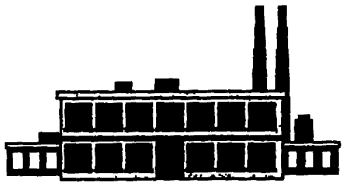
Country	Is planting approval required?	Is food approval required?	Is labelling required for GM food?	Is there a required label text?	Must processed foods be labelled?	Must animal feed be labelled?	Must GM food additives / processing aids be labelled?	Must GM colourings / flavourings be labelled?	Are retail / food service products labelled?
European Community						UD			NA
Austria						NA			NA
Belgium									NA
Denmark						NA			NA
France						NA			NA
Germany						NA			
Greece						NA			NA
Ireland						NA			NA
Italy						NA			NA
Luxembourg						NA			NA
Netherlands						NA			NA
Portugal						NA			NA
Sweden						NA			NA
Spain						NA			NA
U K						NA			

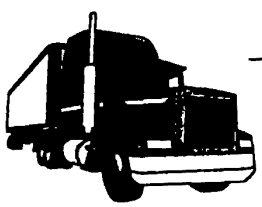
Cross-contamination Adventitious presence of GMO

- seeds
- harvest
- transport
- milling
- food processing

MAIZE / SOYA



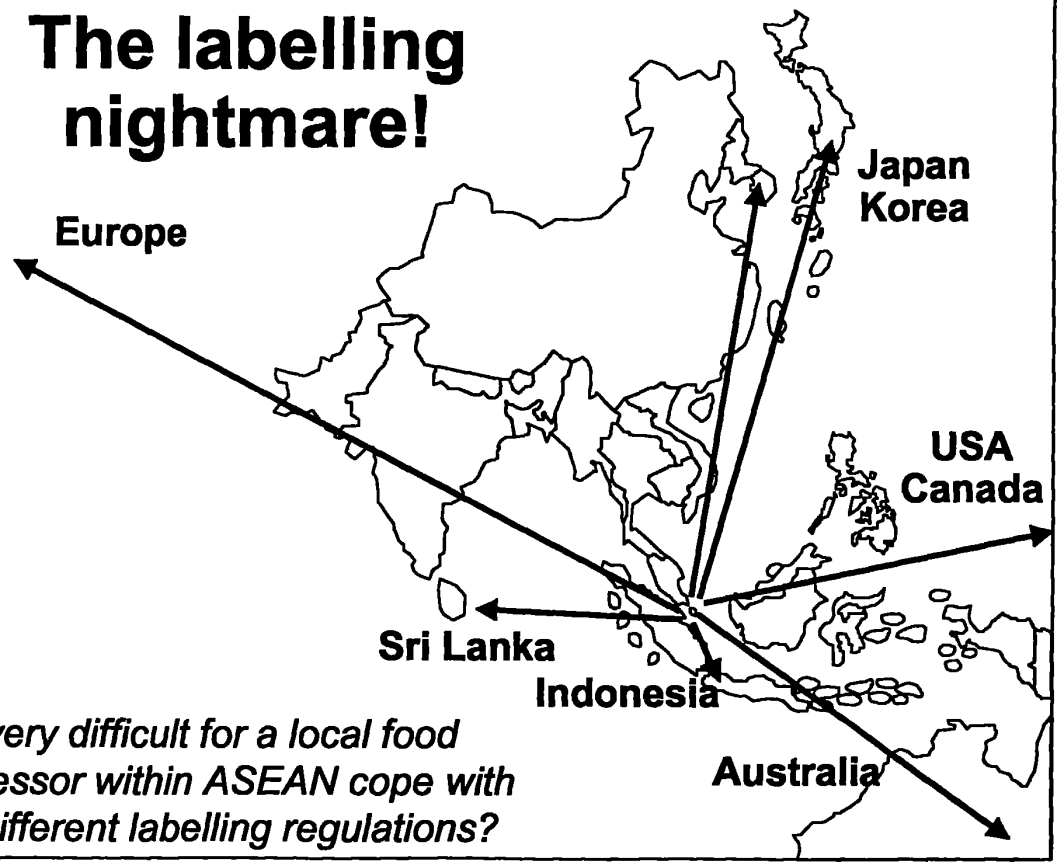




Thresholds for labelling

- Europe 1%
  - in UK includes food service (point of sale) products
- Australia 1%
- Japan 5% (only applies to top three ingredients in the food)
- Korea 5% (all ingredients)
- Others ???

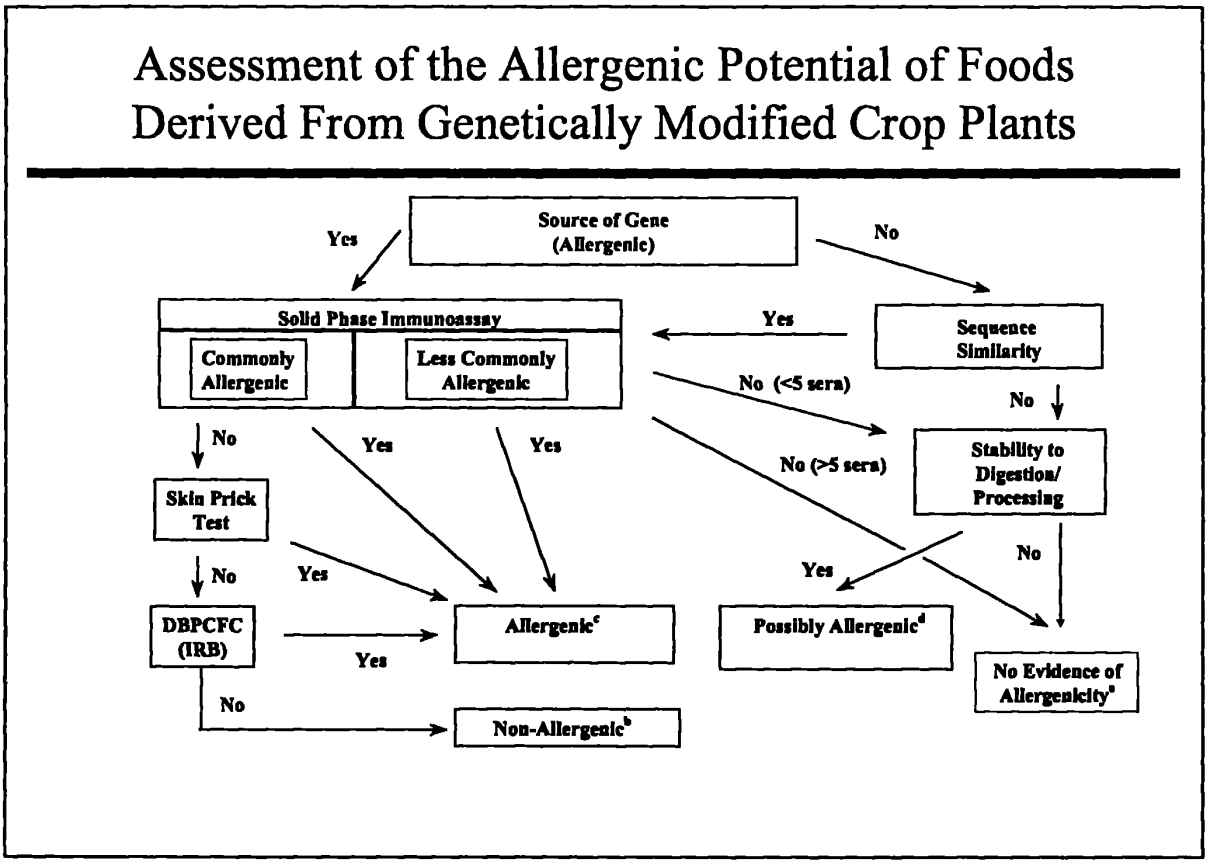
The labelling nightmare!



It is very difficult for a local food processor within ASEAN cope with the different labelling regulations?

Annex 3

FAO/WHO 2000 Decision Tree



Footnotes to Figure

(a) The figure was adapted from decision-tree approach developed by International Food Biotechnology Council and Allergy and Immunology Institute of the International Life Sciences Institute (Metcalfe *et al*, 1996)

(b) The combination of tests involving allergic human subjects or blood serum from such subjects would provide a high level of confidence that no major allergens were transferred The only remaining uncertainty would be the likelihood of a minor allergen affecting a small percentage of the population allergenic to the source material

(c) Any positive results obtained in tests involving allergenic human subjects or blood serum from such subjects would provide a high level of confidence that the novel protein was a potential allergen Foods containing such novel proteins would need to be labelled to protect allergic consumers

(d) A novel protein with either no sequence similarity to known allergens or derived from a less commonly allergenic source with no evidence of binding to IgE from the blood serum of a few allergic individuals (<5), but that is stable to digestion and processing should be considered a possible allergen Further evaluation would be necessary to address this uncertainty The nature of the tests would be determined on a case-by-case basis.

(e) A novel protein with no sequence similarity to known allergens and that was not stable to digestion and processing would have no evidence of allergenicity Similarly, a novel protein expressed by a gene obtained from a less commonly allergenic source and demonstrated to have no binding with IgE from the blood serum of a small number of allergic individuals (>5 but <14) provides no evidence of allergenicity Stability testing may be included in these cases. However, the level of confidence based on only two decision criteria is modest The Consultation suggested that other criteria should also be considered such as the level of expression of the novel protein

Annex 4

FAO/WHO 2001 Decision Tree