行政院及所屬各機關出國報告書
出國類別：開會

赴加拿大參加
第 3 屆全球少量作物高峰論壇
出國報告

服務機關：行政院農業委員會動植物防疫檢疫局
出國人員：黃鈺婷科長
洪裕堂技正
出國期間：106 年 9 月 29 日至 10 月 7 日
報告日期：107 年 1 月 8 日

提要表

系統識別號：	C10603173
相關專案：	無
計畫名稱：	赴加拿大參加第3屆全球少量作物高峰論壇
報告名稱：	赴加拿大參加第3屆全球少量作物高峰論壇出國報告
計畫主辦機關：	行政院農業委員會動植物防疫檢疫局
出國人員：	姓名 / 服務機關 / 服務單位 / 職稱 / 官職等 / E-MAIL 信箱 黃鈺婷 / 行政院農業委員會動植物防疫檢疫局 / 植物防疫組 / 科長 / 薦任(派) 洪裕堂 / 行政院農業委員會動植物防疫檢疫局 / 植物防疫組 / 技正 / 薦任(派) / 聯絡人 hungyt@mail.baphiq.gov.tw
前往地區：	加拿大
參訪機關：	加拿大農業及農業食品部田間試驗中心(AAFC Saint-Jean-sur-Richelieu Research and Development Centre)
出國類別：	開會
實際使用經費：	年度 / 經費種類 / 來源機關 / 金額 106年度 / 其他經費 / 行政院國家科學技術發展基金 / 244,250元
出國計畫預算：	年度 / 經費種類 / 來源機關 / 金額 106年度 / 其他經費 / 行政院國家科學技術發展基金管理會 / 261,246元
出國期間：	民國106年09月29日 至 民國106年10月07日
報告日期：	民國107年01月08日
關鍵詞：	農藥，少量作物，農藥殘留
報告書頁數：	25頁
報告內容摘要：	為解決全球少量作物用藥問題，美國農業部、美國環保署與IR-4計畫自2007年起，每4-5年舉辦1次「全球少量作物高峰會議」。邀請各國政府機關、農業研究單位、農企業及跨國農藥公司等人員，進行研討及交換心得。俾使全球各國及各組織對於「少量作物」能有共同的認識，並討論國際間農藥殘留試驗法規要件及相關資料取得之調和、國際上對於少量作物之殘留安全容許量資料之訂定程序及共享途徑，及依取食風險訂立作物分群的方式，並支援各國發展及建立更進一步的殘留量訂定計畫。本局曾參與2007年於義大利羅馬舉辦之第1屆會議。本次「第3屆全球少量作物高峰會議」(The Third Global Minor Use Summit，GMUS-3)會議係由加拿大衛生部有害生物管理局(Health Canada Pest Management Regulatory Agency)主辦，並與美國農業部、美國環保署與IR-4計畫合作，於2017年10月1日至5日在加拿大魁北克省蒙特婁市辦理。藉由本局參與此次會議，可瞭解國際間農藥使用、農藥殘留安全容許量標準及國際調和之情形，並與與會專家學者交換意見及收集資料，俾供作為我國農藥管理制度及實務運作之參考，並健全我國農藥產業之發展，及強化我國農產品之農藥使用安全。
報告建議事項：	建議事項 / 狀態 / 說明 推動解決少量作物用藥問題，辦理作物群組化及農藥延伸使用工作 / 已採行 / 持續關注各國對於少量作物用藥需求之處理模式及解決方案 / 已採行 / 依循 Codex 所訂之農藥殘留的相關規範 / 未採行 / 我國有足夠的智識可自行建立農藥殘留的相關規範，也有能力可執行相關農藥殘留檢測工作
電子全文檔：	C10603173_01.pdf
出國報告審核表：	C10603173_A.pdf
限閱與否：	否
專責人員姓名：	
專責人員電話：	

摘　　要

為解決全球少量作物用藥問題，美國農業部、美國環保署與 IR-4 計畫自 2007 年起，每 4-5 年舉辦 1 次「全球少量作物高峰會議」。邀請各國政府機關、農業研究單位、農企業及跨國農藥公司等人員，進行研討及交換心得。俾使全球各國及各組織對於「少量作物」能有共同的認識，並討論國際間農藥殘留試驗法規要件及相關資料取得之調和、國際上對於少量作物之殘留安全容許量資料之訂定程序及共享途徑，及依取食風險訂立作物分群的方式，並支援各國發展及建立更進一步的殘留量訂定計畫。本次「第 3 屆全球少量作物高峰會議」 (The Third Global Minor Use Summit，GMUS-3) 會議係由加拿大衛生部有害生物管理局 (Health Canada Pest Management Regulatory Agency) 主辦，並與美國農業部、美國環保署與 IR-4 計畫合作，於 2017 年 10 月 1 日至 5 日在加拿大魁北克省蒙特婁市辦理。藉由本局參與此次會議，可瞭解國際間農藥使用、農藥殘留安全容許量標準及國際調和之情形，並與與會專家學者交換意見及收集資料，俾供作為我國農藥管理制度及實務運作之參考，並健全我國農藥產業之發展，及強化我國農產品之農藥使用安全。

目　　次

壹、前言

臺灣作物種類多樣化，病蟲害種類複雜，以往採一種藥劑對應一種作物及一種有害生物方式之農藥登記制度，已不敷現行多樣化的農業生產使用。而「少量作物」，在國際上是指非主要作物或種植面積較小的作物，因該類作物經濟重要性低，致發生病蟲害時農藥業者基於市場考量，申請登記意願不高，造成核准登記藥劑不足，致使農民施用農藥時面臨無藥可用，或自行使用未登記之農藥，既違反農藥使用規定，也影響農產品食用安全。1963 年美國州立農業研究所 (SAES) 創立 IR-4 (Inter-Regional Research Project Number 4) 計畫，提供美國農業部 (USDA) 解決「少量作物用藥問題」之方法。

此外，為確保農產品衛生安全，國際間對國產及進口農產品之農藥殘留均依法訂有安全容許量而進行管制。由於各國間不同之作物病蟲害與登記農藥種類、地理環境及國民飲食習慣等，致使國與國之間農藥殘留安全標準有所差異，並進而影響國際間雙方農產品貿易之進行。又因我國非聯合國或世界衛生組織之會員國，故 WHO/FAO 之 CODEX 之容許量訂定過程中我國無法全程參與，適時提出與我國切身相關之藥劑及取食量高之國產農產品種類之殘留標準訂定案，故現行許多 Codex 之容許量標準無法涵蓋我國之需求。但各國對於「少量作物」定義及作物的分群有不同的標準，而此「少量作物」在農藥的使用登記制度及殘留安全容許量 (MRLs) 的訂定上亦有不同的策略。為使各國可以共同解決前述的問題，聯合國糧農組織、美國農部及美國環保署前於 2007 年 12 月 3 日至 7 日在義大利羅馬舉辦「第 1 屆全球少量作物論壇」，希望可以藉由研討會的方式，邀請各國政府機關、農業研究單位、

農企業及跨國農藥公司等人員，進行研討，交換心得，本局亦有派員參與，並有效獲取許多有關少量作物及作物分群的寶貴經驗，並應用於後續農藥管理相關法規之制定。

針對此問題，農委會動植物防疫檢疫局 (以下簡稱本局) 改變過去每年均以公務預算進行田間藥劑篩選試驗，而於 2008 年起即開始著手研擬合理化擴大農藥之延伸使用範圍措施，研擬以作物類群方式擴大農藥使用方法來增加推薦藥劑，並於 2009 年 3 月 31 日發布修正「農藥田間試驗準則」，以及公告「農藥延伸使用範圍之群組化作物或有害生物種類、代表性使用範圍及其實施方式」規定。由於此項制度之推動，不僅可同時兼顧植物保護需求及農產品衛生安全，更可有效解決農民無藥可用的難題。惟田間疫情管理與農藥使用，關係到作物取食量、農藥使用與藥劑安全性等問題，在在與我國植物防疫檢疫施政，甚至國際貿易息息相關。

「第 2 屆全球少量作物高峰會議」於 2012 年同樣於義大利羅馬 FAO 舉辦，惟該次會議因受時任 FAO 秘書處之中國大陸以技術性干擾，故臺灣代表無法出席，僅能從會後與網路上之資料追蹤該次會議之辦理情形及相關決議。而本局 2014 年則已派員至 IR-4 計畫之總部研習，藉由實際參與美國 IR-4 計畫，加入其工作團隊，實習相關田間試驗規劃、作物分群架構，瞭解其組織架構、內部運作機制及與國際組織之溝通聯繫技巧，並吸取 IR-4 計畫操作之經驗，參與該計畫有關少量作物之管理，以及如何在農民-農藥生產業者-政府組織等三方間取得協調等經驗，作為我國植物防疫作為及消費者食品安全保護之參考。

本次「第 3 屆全球少量作物高峰會議」 (The Third Global Minor Use

Summit，GMUS-3) 係由加拿大衛生部有害生物管理局 (Health Canada Pest Management Regulatory Agency) 主辦，並與美國農業部、美國環保署與 IR-4 計畫合作，於 2017 年 10 月 1 日至 5 日在加拿大魁北克省蒙特婁市辦理 (包含 1 天參訪加拿大園藝作物的田間生產行程)。討論內容則包含了盤點近 5 年來各國針對少量作物的解決方案、農藥殘留標準之訂定情形、對農藥業者的鼓勵措施、各國間的相互合作等，並將著重於政策制定上，幫助世界各地的少量作物種植者獲得更安全和現代的工具來生產作物，並促進國家間的貿易。

貳、行程

一、期間：106 年 9 月 29 日至 106 年 10 月 7 日，共計 9 天。

二、行程概要如下：

時　間	行　程　內　容
09 月 29 日- 09 月 30 日	**啟程 (台北→加拿大蒙特婁市)** 自桃園國際機場搭乘長榮航空公司班機 (BR 10)，經加拿大溫哥華 (Vancouver) 轉乘加拿大航空公司班機 (AC 308) 至加拿大蒙特婁市 (Montreal)，並自行前往旅館。
10 月 01 日- 10 月 04 日	**加拿大蒙特婁市** 參加第 3 屆全球少量作物高峰論壇-正式會議。
10 月 05 日	**加拿大蒙特婁市** 參加第 3 屆全球少量作物高峰論壇-田間參訪。
10 月 06 日	**返程 (加拿大蒙特婁市→台北)** 自加拿大蒙特婁市搭乘加拿大航空公司班機 (AC 311)，經加拿大溫哥華轉乘長榮航空班機 (BR 9) 返回台北。

時　間	行　程　內　容
10 月 07 日	返抵桃園國際機場。

參、議程及內容

本次會議於加拿大蒙特婁市伊莉莎白皇后飯店 (Hotel The Queen Elizabeth) 舉辦 (圖 1)，包含 4 天正式會議及 1 天田間參訪行程，詳細議程請參考附件 1，參加人員約有 230 名來自各國政府農藥主管機關、植物保護業者及農民生產團體等 (圖 2、圖 3、圖 4，名單詳如附件 2)，並有 3 次分組討論，重要議題及內容簡述如下：

◎**會前附帶活動**－少量作物與國際間短期攝食評估研析 (The IESTI Equations and Minor Crops)：International Estimated Short Term Intake (IESTI) (附件 3)

為利本項會議於正式進行前能凝聚與會者之共識，主辦單位於會前亦邀集工作坊介紹少量作物之國際間短期攝食估算 (International Estimated Short-Term Intake，簡稱 IESTI E)。由於在農藥殘留的風險評估上，從早期側重慢性毒性漸漸移轉加入對於短期急性中毒的評估，特別是針對敏感族群。急性參考劑量 (Acute Reference Dose，ARfD)，係為在較短時間內，通過食品而攝入的農藥量不致引起健康損害的劑量。ARfD 值通常大於 ADI 值。CCPR 爰建議在進行農藥的攝食暴露風險評估時要以 ADI 評估農藥的慢性毒性；也要以 ARfD 來併同考量急性毒性。而過去認為安全的的農藥，經過其他所累積數據的重新評估，可能產生新的疑慮，進而需進行汰除機制。

會中並由 CCPR 電子工作小組介紹 Codex MRLs 訂定之依據與流程：該工作小組主要任務為決定評估清單供 JMPR 後續收集相關資料、評估並作成報告，評估結果經徵詢無意見後，CCPR 即依據 JMPR 風險評估結果，提供風險管理建議予 CAC，所面臨之挑戰為每年持續增加評估數量及需求。JMPR (Joint Meeting of Pesticides Residue 簡稱 JMPR) 為 FAO 及 WHO 自 1963 年成立之專家委員會，其組成的均為 FAO 及 WHO 邀請的有關農藥毒理及殘留評估之專家，該等專家雲端或電話會議進行獨立審查。WHO 分組將所評估之毒理資料每日可接受攝入量 (ADI) 及急性參考劑量 (ARfD)；FAO 分組負責審查農藥使用方法、物理化學特性、環境影響、動植物代謝、田間殘留消退試驗、殘留分析方法及加工試驗資料，並據以評估殘留定義 (MRLs 及膳食評估)、MRLs 與短期及長期攝食風險，所評估之 MRLs 係依據可反應農業操作規範之田間殘留消退試驗數據，運用 OECD MRL 計算工具，並確保提出 MRLs 所致暴露量低於 ADI 及 ARfD。

◎開幕致詞：

- Pest Management Centre (PMC，加拿大有害生物管理中心) Executive Director – Marcos Alvarez
- Agriculture and Agri-Food Canada (AAFC，加拿大農業及農業食品部) –Christiane Deslauriers, Director General, Coastal Region, Science and Technology Branch
- United States Department of Agriculture (美國農業部) – Robert Macke, Deputy Administrator, Office of Agreements and Scientific Affairs, Foreign Agricultural Services (USDA-FAS)

- CropLife Canada/CropLife International –Pierre Petelle
- FAO Opening Remarks – Baogen Gu (顧寶根，前中國大陸農藥檢定所所長)
- IR-4 Opening Remarks – Jerry Baron

◎**回顧第 2 屆會議之工作計畫及本屆會議之工作重點** – Dan Kunkel、Marcos Alvarez (附件 4)

◎**第 2 屆會議後的能力建構** –Jason Sandahl (USDA-ARS) / Michael Braverman (IR-4) (附件 5-1、5-2)：

- 三項由標準暨貿易發展機構基金 (STDF) 所贊助計畫的進展和產出 (Progress and outputs from the three Standards Trade Development Facility (STDF) capacity building projects)：
  - ASEAN – Ngan Chai Keong – Malaysia (附件 5-3)
  - Latin America – Adriana Castañeda –Colombia (附件 5-4)
  - Africa - Paul Osei-Fosu – Ghana (附件 5-5)

【註：STDF 係由世界貿易組織 (WTO)、聯合國糧農組織 (FAO)、世界衛生組織 (WHO)、世界動物衛生組織 (OIE) 及世界銀行 (WB) 於 2002 年共同倡議成立之夥伴關係及財務機制，旨在透過其設置之動植物防疫檢疫措施 (Sanitary and Phytosanitary Measures, SPS)資源分享平台，協調並監督 SPS 相關之技術及財務援助，強化低度開發國家及開發中國家之貿易能力。】

◎**Minor Use 計畫及其他地區 Minor Use 計畫之開發 (包括建立此類計畫的模式和資金)：**

- 已建立的 Minor Use 計畫 – 我們如何達成的?

- 北美視角 – Jerry Baron (IR-4) / Marcos Alvarez (AAFC) (附件 6-1)
- 歐盟視角- Jeroen Meeussen (EU Minor Uses Coordination Facility) (附件 6-2)

- 新興 Minor Use 計畫 – Which paths are being taken?
  - Minor Uses 在巴西 – Carlos Alexander Gomes (Brazilian Health Regulatory Agency) (附件 6-3)
  - 澳洲 Minor Use – Kevin Bodnaruk (Grains Research & Development Corporation) (附件 6-4)

◎**全球調和成果** – Dan Kunkel (IR-4)

- Codex 及 OECD 現況更新 – Xavier Sarda (電子工作小組主席 (electric Working Group，eWG)) (附件 7-1)
  - 農藥殘留專家工作小組簡要概述2015年食品法典委員會農藥殘留委員會 (Codex Committee on Pesticide Residue，CCPR) 於 Minor Use 之最終報告
  - OECD 農藥殘留專家工作小組指導文件之更新與進展
- 農藥殘留專家會議 (Joint FAO/WHO Meeting of Pesticide Residue，JMPR) 工作計畫 – Ian Reichstein (Australian Government Department of Agriculture) (附件 7-2)
- Codex 作物分群現況 – Bill Barney (IR-4) (附件 7-3)
- WTO SPS 委員會於農藥殘留容許量標準之最新工作 – Julia Doherty (USTR for Agricultural Affairs) (附件 7-4)
- 國際農產品-食品網路對於農藥殘留容許量標準之努力 – Gord Kurbis (Market Access and Trade Policy, Pulse Canada) (附件 7-5)

◎**區域視角：法規的現狀與未來**– Janet Collins and Rebecca Lee

- 歐盟: Klaus Berend (Health and Food Safety, European Commission) and Jeroen Meeussen (EU Minor Uses Coordination Facility) (附件 8-1)
- 北美: Peter Chan and Rick Keigwin (PMRA Health Canada) (附件 8-2)
- 亞洲: Panpilad Saikaew (National Bureau of Agricultural Commodity and Food Standards, Thailand) (附件 8-3)
- 非洲: Lucy Namu (Kenya Plant Health Inspectorate Service) (附件 8-4)
- 拉丁美洲: Daniel Mazzarella (National Animal Health and Agri-food Quality Service, Argentina) (附件 8-5)

◎**植物保護業者視角：成功，挑戰和機遇** – Luc Peeters and Alan Norden

- 從 GMUS-2 到 GMUS-3 – Philip Brindle (CropLife International) (附件 9-1)
- 業界於少量作物之登記概況 – Jessica Christiansen (CropLife International) (附件 9-2)
- 東非共同體於調和農藥法規體系上之努力：區域解決方案的模式方法 - Jason Sandahl (USDA-FAS) (附件 9-3)
- 農藥製造業者的能力建構經驗 – Carmen Tiu (Dow AgroScience) (附件 9-4)
- 生物農藥：法規障礙和常見誤解 – Nina Wilson (Biological Products Industry Alliance，BPIA) (附件 9-5)
- 快速發展中的生物農藥產業和相關貿易的動態– David Cary (International Biocontrol Manufactures Association，IBMA) (附件 9-5)
- 少量使用：以區域的視角來看全球觀點 – David Wright (EngageAgro)

(附件 9-6)

◎區域種植業者所面臨的挑戰和參與：實現當前和未來的機遇 – Peter Chan and Javier Fernández

- North America: Jim Cranney (California Citrus Quality Council) / Rebecca Lee (Canadian Horticultural Council) (附件 10-1、10-2)
- Asia: Amy Nguyen (Dragonberry Produce) (附件 10-3)
- Europe: Luc Peeters (COPA-COGECA, BelOrta) (附件 10-4)
- Africa: Kelvin Remen Swai (Tanzania Horticultural Association，TAHA) (附件 10-5)
- Latin America: Chilean Grower perspectives – Eduardo Aylwin (Chilean Food Safety and Quality Agency) (附件 10-6)
- Oceania: Jodi Pedrana (Hort Innovation Australia) (附件 10-7)
- Grower consultants perspective: How Growers Face the MRL Challenge – Matt Lantz (Bryant Christie INC.) / Caroline Harris (Exponent International Ltd.) (附件 10-8)

◎分組討論：(由大會將參加者預先區分為 6 個小組，每個小組討論不同的主題，並由大會彙整相關結論) (圖 5)

- 第 1 次討論重點 (以法規管理的角度來看)：

  關鍵政策、全球化農藥殘留量資料、業者及調和工作的激勵措施與溝通、在法規審查面需要合作的關鍵技術和政策、法規管理者、業者及試驗單位的能力需求為何?

- 第 2 次討論重點 (以農藥業者的角度來看)：

  考慮推動更多的全球化農藥殘留量資料、其他對於產業投注

於少量使用的激勵措施、全球化農藥殘留量資料試驗的能力建構。

- 第 3 次討論重點 (以生產者的角度來看)：

  數據資料庫，種植者的挑戰，農藥殘留容許量標準與病蟲害防治產品之使用，相互溝通

- 分組討論所提出的建議如下：

範疇	建議事項
相互合作	1. 廣邀來自各地區 Minor Use 夥伴，參與年度會議和研討會，並於全球性的活動和即將舉行的活動中交流。 2. 在本屆會議中要確定各種作物田間試驗的優先以達到延伸使用及少量使用的需求： (1) 促進國家法規主管部門的同步審查。 (2) 共享國家之間的數據和研究評論，以促進相互承。 (3) 業界可以針對延伸使用及少量使用進行同時申請。
農藥殘留容許量標準 (MRLs)	1. 審查並公佈免除 MRLs 的物質清單 (如生物農藥和無毒物質的化合物)。 2. 推動全球採用 APEC 程序，以建立包括 Codex 在內的 MRLs。
鼓勵措施	收集現有對註冊於少量作物的獎勵措施，並鼓勵其他國家進一步採用或擴大實施。
作物分群	請 FAO 針對糧食和動物飼料的分類，以及作物分群的代表作物及延伸使用提出指引，以作為國際標準。
相互溝通	1. 尋求全球 MRL 數據庫可供公開獲取的機制。 2. 通過社交媒體等機制探索和拓展交流工具。 3. 藉由擴大 EU Minor Use 數據庫 (EUMUDA)，以維護優先清單，數據持有者以及各國登記者。

	4. 建立 Minor Use 協調委員會。 5. 增加每年面對面的機會 (如擴大全球性會議及活動)。
能力建構	根據 GMUS 3 會議中所確定的項目，制定一份關於能力建構需求的白皮書。
法規評估	1. 善用 OECD 的指導文件並探詢 FAO 的採用情況。 2. 針對非糧食作物的藥效及殘留試驗數據，開發國際性作物分群方案。 3. 請 OECD 農藥殘留化學專家小組 (Expert Group on. Pesticide Residue Chemistry，RCEG) 考慮將作物分群的田間試驗的原則納入歐盟田間試驗指南。 4. 檢視小宗作物的各種定義，並確定共同點和差異。

◎**研擬及報告「前進 «Going Forward»」工作計畫** – Marcos Alvarez, Dan Kunkel

◎**全球少量使用農藥殘留標準試驗優先順序設定 workshop** – Jim Chaput

◎**參訪加拿大魁北克省農業生產** - Luc Urbain

- Ferme hotte et van winden inc. (農場)
  - 大規模釋放玉米螟卵寄生蜂之防治工作：

    加拿大推廣以天敵進行防治工作，有業者生產玉米螟卵寄生蜂之卵片，可供農民手動懸掛於玉米田 (與臺灣類似作法)。另因應許多玉米田的面積廣大且植株高度難以進入，亦研發以無人載具投放含有玉米螟卵寄生蜂卵粒的白色球體，以省工省時，該球體為環保材質，可於田間自然分解，避免污染 (圖 6、圖 7)。
  - 大規模釋放不孕性洋蔥地種蠅 (*Delia antiqua*) 之防治工作：

    洋蔥地種蠅為加拿大魁北克地區重要的洋蔥害蟲，以往

多以農藥陶斯松來防治，但因會污染該地區的地表水及作物生產，所以研發以不孕性的技術來防治洋蔥地種蠅 (圖 8、圖 9)，施放方式與臺灣早期釋放不孕性東方果實蠅類似，將不孕個體置於紙袋內，以人工的方式灑佈於田間。此項技術經由 7 年的研發，於 2011 年開始釋放，迄今 6 年期間，防治面積由 140 公頃增加至 630 公頃，每年釋放約 1-2 千萬隻的個體。而近 5 年來因為野生族群密度的降低，不孕性個體釋放的數量已減少了 90%，且也減少陶斯松污染水體的情形 (從 2006 年水體中檢出最大濃度為 2.2 μg/L 降至 2014 年 0.05 μg/L)。

- 利用收集空中孢子來偵察區域性空氣傳播植物病害：

以往田間植物病害多以直接觀察田間發病密度及狀態，來預測期流行病學，但往往會受到田間病害發生的空間及分布情形而有所限制。業者於 15 年前研發了區域性空氣傳播病害決策支援系統 (Decision Support System，DSS)，來改善由 *Botrytis squamosa* 所引起的洋蔥灰黴病。藉由收集空中病原菌孢子的密度，預測病害發生並減少殺菌劑使用約 25%，並可推廣至防治其他洋蔥病害使用 (如露菌病及 stemphylium leaf blight) (圖 10)。

- 參訪結球萵苣現場採收工作：

參訪時已為結球萵苣的採收末期，結球萵苣係以人工採收，剝除下位葉及有損傷的部位後，經藥劑初步處理 (應為保鮮劑) 再自動化包裝上市 (圖 11、圖 12)。

- AAFC Saint-Jean-sur-Richelieu Research and Development Centre (加拿

大農業及農業食品部 Saint-Jean-sur-Richelieu 田間試驗中心)：

- 介紹 IR-4 GLP 田間試驗流程及設備

  加拿大農業及農業食品部所屬之 Saint-Jean-sur-Richelieu 田間試驗中心研究與發展中心係於 1912 年在魁北克省成立，面積達 245 公頃，除協助加拿大園藝作物之植物保護工作，也參與 Minor Use 計畫，是其田間試驗的重要基地之一，相關試驗均符合良好實驗室操作 (Good Laboratory Practice，GLP) 規範。(圖 13)

- IRDA - Research Center De Saint-Bruno (IRDA 研究中心)：

  IRDA 為一家非營利研究公司，於 1988 年由 the Ministère de l'Agriculture, des Pêcheries et de l'Alimentation (MAPAQ)、the Union of Agricultural Producers (UPA – L'Union des producteurs agricoles)、the Ministère du Développement durable, de l' Environnement et de la Lutte aux changements climatiques (MDDELCC) 及 the ministère de l'Économie, de l'Innovation et des Exportations (MEIE) 等 4 個單位共同資助設立。其使命是從可持續發展的角度參與農業環境研究，開發和推廣活動以促進農業創新。IRDA 每年與眾多的農業社區和研究合作夥伴進行約 100 個研究項目。(圖 14)

  - 介紹以網罩方式減少蘋果病蟲害之研究：

    研發不同材質的網罩可以有效減少蘋果各項病害及蟲害的發生，且不會影響植株的生長及果實的品質。(圖 15)

  - 介紹改善噴藥器具以改善防治效果並減少農藥使用與飄散：

    藉由改善傳統施藥器械，可減少農藥使用以及降低農藥

飄散，且因為提高藥劑均勻分佈，也可以提高蟲害的防治效果。(圖 16)

肆、 心得與建議

一、 10 年前，赴 FAO 參加第 1 屆的全球少量作物高峰論壇 (GMUS)) 時，少量作物的問題尚處於啟蒙階段，雖然美國的 IR-4 計畫已經執行多年，但許多國家則指示提出需求，但還沒有明確的解決方案。在這 10 年間，我國自 2009 年起推動「農藥延伸使用範圍」制度後，在有限的經費下已逐步的解決部分少量作物所面臨無防治藥劑的問題。而其他許多國家亦逐步訂定相關的法規，不論是採用國際標準或以類似作物群組的方式延伸相關標準 (東協或中南美洲國家)，都已經可以稍稍解決少量作物的問題，此外，亦有陸續成立相關的組織或機構，以全球性或區域性的方案來找出解決之道。

二、 相較於美洲部分，由美國 IR-4 主導，並由加拿大 AAFC、PMRA 等單位共同參與執行之 Minor Use 計畫，歐盟自第 2 次全球少量作物高峰論壇 (GMUS-2) 之後，於 2014 年建立由歐盟委員會共同出資的 Minor Use 獨立協調機構。由歐洲和地中海植物保護組織 (European and Mediterranean Plant Protection Organization，EPPO) 主辦，由歐盟和法國，德國和荷蘭政府共同資助，開始先為期 3 年，由於許多會員國表示 Minor Use 的問題不可能在 3 年之內解決，所以也已規劃了未來 5-10 年的計畫，目前已成立 7 個專家小組，包括蔬果、觀賞作物、菸草、稻米、啤酒花、種子及菇蕈等。另該機構也成立網站及資料庫 (http://www.eumuda.eu/)。由於歐盟也是我

國主要的農產品出口國之一，我們可以持續關注其發展。

三、 世界各主要農產品出口國，為順暢其農產品出口，除了植物檢疫相關問題之外，無不花費心思於農藥殘留標準事宜，致力於全球的國際調和，業者除協助推動 Minor Use 外，也不斷強調要葛國政府參考 Codex 標準，以減少非關稅貿易障礙。STDF 甚至與美國及許多國際農藥業者合作，在世界各地推動熱帶水果的全球農藥殘留計畫，以分工的方式建立 Codex 標準。而由於其合作的國家多為未開發、開發中國家或採用 Codex 標準的國家，計畫的推動除有助於在該國建立符合 GLP 規範的田間及實驗室操作，也有助於其相關農產品的貿易。我國有足夠的智識可自行建立農藥殘留的相關規範，並推動農藥延伸使用制度，也有能力可執行相關農藥殘留檢測等工作，可依據我國人的飲食習慣，用藥策略等訂定適合我國國情的相關標準，尚不需依循 Codex 所訂之標準。

四、 現行我國在增修農藥殘留容許量標準事宜上，係由行政院農業委員會及衛生福利部 (以下簡稱衛福部) 各依業務職掌及權責分工辦理，農方依據農藥管理法核准登記農藥及延伸使用範圍；衛福部依食品安全衛生管理法制訂農藥殘留容許量標準，並辦理該標準增修訂公告等事宜，兩部會在案件審理之面向與重點雖不盡相同，但遵循既定之審議流程，並建置有溝通聯繫機制，部會間各依權責分工辦理。其優點係為可增加評估層面，使標準研訂過程更為嚴謹：本會基於農業使用需求，針對農藥之藥效、藥害、殘留等田間試驗及環境、動物毒理等各種資料進行藥劑使用評估，核准合理農藥使用方法及建議殘留容許量草案。衛福部則著重消

費者取食風險及健康影響，進行容許量標準之評估，兩部會依據不同面向進行評估，除避免球員兼裁判之疑慮外，多一層把關亦可加深評估層面，並納入更多專家不同角度之意見，使標準制定更為嚴謹。

五、 韓國食品醫藥品安全處 (Ministry of Food and Drog Safety, MFDS) 宣佈自 2017 年 1 月 1 日起優先針對堅果種子類及熱帶水果類作物，實施農殘留農藥容許量正面表列制度 (PLS)，並預計於 2019 年 1 月 1 日起擴大實施 PLS 於所有農產品後，許多韓國的小宗作物已面臨缺乏農藥殘留標準的情形，其農村振興廳亦曾派員來臺，詢問我國對於少量作物的農藥登記及管理政策，顯見少量作物問題的重要性。惟本次會議參與人員中，亞洲地區除臺灣外，僅有中國大陸、馬來西亞、泰國、印度及新加坡有派員出席，以往均有出席的日本及南韓本次並無參加，詢問主辦單位及其他參與人員亦不知原因，或許他們已有相應的對策。

六、 少量作物病蟲害防治用藥缺乏為世界各國共同面臨之問題，為兼顧病蟲害防治需求及農產品食用安全，先進國家均基於科學原理，採取彈性原則，以解決其登記、許可以及後續農藥 MRL 訂定之相關問題。我國雖有推行延伸使用範圍之群組化作物或有害生物種類、代表性使用範圍來解決相關問題，但由於作物及病蟲害種類繁多，並無法有效解決極少量及特殊之情況，加上誘因不足，業者亦不願投入相關試驗，致延伸的範圍有限。未來建議我國延伸使用的設計要政策引導業者參與，以及農民所集合之農民團體，共同提出需求，和政府密切合作，共同處理少量作物或新興作物

缺乏藥劑的問題，保障農業生產，並進一步順暢農產品貿易。

七、 事實上我國對於本項工作歐美日等已開發國家之實施方法及評估流程一致，相較於開發中國家之管理方式尚未到位之現況相去甚遠，未來建議我國可持續該等議題之國際能見度發揮影響力，對於專業人才應持續進行能力建構等事宜，除可進一步健全國內農藥管理外，並保護國人飲食衛生安全，順暢國際農產品貿易。

伍、附件

附件 1　詳細議程

3rd GLOBAL MINOR USE SUMMIT

The Fairmont Queen Elizabeth Hotel
Montreal, Quebec, Canada
October 1-4, 2017

PROGRAMME
Filling the Tool Box for Growers:
Developing Strategies for Specialty Crop and Minor Use Programs and Harmonization

GMUS-3
SMUM-3
CMUM-3

September 30th, 2017

16:00 – 18:00 Registration

DAY 1 - Sunday, October 1st, 2017

8:00 - 17:00 Registration

8:30 – 11:00 Pre-meeting on IESTI – Av. Van-Horne Room

11:30 – 12:45 Lunch (buffet) – Square Dorchester Room

13:00 – 14:10 Place du Canada Boardroom

Welcome and Opening Remarks by the following:

CHAIR: **Marcos Alvarez**

- Pest Management Centre (PMC) Executive Director – Marcos Alvarez
- Agriculture and Agri-Food Canada (AAFC) – Christiane Deslauriers, Director General, Coastal Region, Science and Technology Branch
- United States Department of Agriculture – Robert Macke, Deputy Administrator, Office of Agreements and Scientific Affairs, Foreign Agricultural Services (USDA-FAS)
- CropLife Canada/CropLife International – Pierre Petelle
- FAO Opening Remarks – Baogen Gu
- IR-4 Opening Remarks – Jerry Baron

14:10 – 14:15 Overview of the GMUS-2 work plan – Dan Kunkel

14:15 – 14:20 Purpose of the GMUS-3 and Objectives – Marcos Alvarez

14:20 – 14:45 Capacity Building Updates since the GMUS-2

MODERATORS: **Jason Sandahl / Michael Braverman**

Progress and outputs from the three Standards Trade Development Facility (STDF) capacity building projects

- ASEAN – Ngan Chai Keong – Malaysia
- Latin America – Adriana Castañeda - Colombia
- Africa - Paul Osei-Fosu – Ghana

14:45 – 15:15 Minor Use Programs, Development of dedicated minor use programs (including models & funding to establish such programs)

MODERATOR: **Marcos Alvarez**

Established Minor Use Programs – How did we get here?

- North American Perspective – Jerry Baron
- EU Coordination Facility - Jeroen Meeussen

Emerging Minor Use Programs – Which paths are being taken?

- Brazil – Carlos Alexander Gomes
- Australia – Kevin Bodnaruk

15:15 – 15:45 Health Break

15:45 – 17:30 Global Harmonization Efforts

MODERATOR: **Dan Kunkel**

15:45 – 16:15 Codex and OECD updates – Xavier Sarda (Chair of eWG)

- Brief overview of the Committee on Pesticide Residues eWG on Minor Uses final report from 2015 CCPR
- OECD Residue Expert WG Update including Guidance documents, new and updated

Link to Day 1 Presentations

16:15 – 16:30 JMPR work plan – Ian Reichstein

16:30 – 16:45 Codex Crop Group Update Bill Barney

16:45 – 17:00 WTO SPS Committee: Recent work on Pesticides MRLs – Julia Doherty

17:00 – 17:15 International Agri-Food Network's MRL efforts – Gord Kurbis

17:15 – 17:30 Wrap-up Day 1 and Review Day 2 Schedule – Dan Kunkel

18:00 – 20:00 Reception offered by Crop Life Canada and CropLife International – Terrace or Square Victoria Room

DAY 2 – Monday, October 2nd, 2017
Place du Canada Boardroom

MODERATORS: **Janet Collins and Rebecca Lee**

08:30 – 10:00 **A Regional Look at the Regulatory Landscape: Enabling Current and Future Opportunities**

08:30 – 09:00 Europe: Klaus Berend and Jeroen Meeussen

09:00 – 09:15 North America: Peter Chan and Rick Keigwin

09:15 – 09:30 Asia: Panpilad Saikaew

09:30 – 09:45 Africa : Lucy Namu

09:45 – 10:00 Latin America : Daniel Mazzarella

- Brief Information on BOGs: Moderators

10:00 – 10:30 Health Break

10:30 – 12:00 Breakout session #1 to discuss:

Key policy considerations, global data sets, incentives for industry and harmonization, communication. What are some of the key science and policy considerations of working cooperatively on regulatory reviews? Capacity needs for Regulatory, Industry and other data generators.

Breakout Group Meeting rooms: Rue McGill, Rue Sherbrooke, Rue Mansfield, Rue Saint-Denis, Rue Notre-Dame, Rue Sainte-Catherine

Leads for the Breakout Groups

Kevin Bodnaruk (AU)
Lois Rossi (US)
Jeroen Meeussen (EU)
Carlos Alexander Gomes (BR)
Sheridawn Schoeman (UK)
Magda Gonzalez Arroyo (LA)

12:00 – 13:30 Lunch Break – Square Dorchester Room

MODERATORS: **Luc Peeters and Alan Norden**

13:30 – 15:00 **Plant Protection Industry Perspective: Successes, Challenges and Enabling Opportunities**

13:30 – 13:35 Introduction: From GMUS-2 to GMUS-3 – Philip Brindle

Link to Day 2 Presentations

13:35 – 13:55 Overview of Industry Considerations for Minor Crop Registrations – Jessica Christiansen

East African Community Efforts to Harmonize Pesticide Regulatory Systems: A Model Approach for Regional Solutions - Jason Sandahl

13:55 – 14:15 A Manufacturer's experience with Capacity Building – Carmen Tiu

14:15 – 14:35 Biopesticides: Regulatory Hurdles and Common Misperceptions – Nina Wilson

Dynamics of a Rapidly growing BioProducts Industry and Trade Association – David Cary

14:35 – 14:45 Minor Uses: A regional perspective. A global View – David Wright, Engage Agro

14:45 – 15:00 Questions and Answers

15:00 – 15:30 Health Break

15:30 – 17:00 Breakout session #2 to discuss:

Considerations for greater implementation of global data sets, other incentives for industry that add value to minor uses. Global data generation and capacity building for prospects for global data generation hubs.

Breakout Group Meeting rooms: Rue McGill, Rue Sherbrooke, Rue Mansfield, Rue Saint-Denis, Rue Notre-Dame, Rue Sainte-Catherine

Leads for the Breakout Groups:

Andreza Fantine Martinez (BR)
Patty Vandierendonck (CND)
Eduardo Aylwin (Chile)
Sheridawn Schoeman /Angel Saavedra (UK / MX)
Michael Braverman (US)
David Cary (BPG-IBMA)

17:00 – 17:30 Report back of Breakout sessions #1 – BOG Leads

17:30 – 18:00 Report back of Breakout sessions #2 – BOG Leads

18:00 - 18:15 Wrap-up of Day 2 – Moderators

DAY 3 – Tuesday, October 3rd, 2017
Place du Canada Boardroom

MODERATORS: **Peter Chan and Javier Fernández**

08:00 – 10:00 **A Regional Look at Grower Challenges and Engagement: Enabling Current and Future Opportunities**

08:00 – 08:25 North America: Jim Cranney / Rebecca Lee

08:25 – 08:40 Asia: Amy Nguyen, Dragonberry Produce

08:40 – 09:00 Europe: Luc Peeters, COPA-COGECA, BelOrta

09:00 – 09:15 Africa: Kelvin Remen Swai, TAHA, Tanzania

Link to Day 3 Presentations

09:15 – 09:30 Latin America: Eduardo Aylwin – Chilean Grower perspectives

09:30 – 09:45 Oceania: Jodi Pedrana, Hort Innovation Australia

09:45 – 10:00 Grower consultants perspective: Matt Lantz / Caroline Harris

10:00 – 10:30 Health Break

10:30 – 12:00 Breakout session #3 to discuss:

Databases, grower challenges, MRLs and access to pest control products, secondary standards, communication

Breakout Group Meeting rooms: Rue McGill, Rue Sherbrooke, Rue Mansfield, Rue Saint-Denis, Rue Notre-Dame, Rue Sainte-Catherine

Leads for the Breakout Groups:

Rebecca Fisher (NZ)
Cary Gates (CND)
Kevin Bodnaruk (AU)
Tom Prado (BR)
Matt Lantz (US)
Vivian Powell (UK)

12:00 – 13:30 Lunch Break – Square Dorchester Room

13:30 – 14:00 Report back from Breakout session #3: BOG Leads

14:00 – 17:30

***MODERATORS*: Lois Rossi, Alan Norden**

Overview of the Recommendations from the Breakout Sessions

- Discuss and refine conclusions and recommendations with breakout groups
- Circulation of each group's draft conclusions to all participants

Identification of key actions items from all Breakout sessions

15:30 – 16:00 Health Break

16:00 – 17:30 Development of the "Going Forward" Work-plan

17:30 Wrap-up of Day 3 and Review of Day 4 Schedule

DAY 4 – Wednesday, October 4th, 2017
Place du Canada Boardroom

***MODERATORS:* Co-chairs of the Summit (Marcos Alvarez, Dan Kunkel)**

08:30 – 09:15 Presentation on the «Going Forward» Work-plan

- Wrap-up of Conclusions and Recommendations

Global Minor Use Priority Setting Workshop

***MODERATOR:* Jim Chaput**

09:15 – 10:00

- Introduction to the 2nd Global Minor Use Priority Setting Workshop – Jim Chaput

Link to Workshop Presentations

- Introductions – ALL
- Priorities from the first Global Minor Use Priority Setting Workshop and progress to date – Dan Kunkel
- Guidelines and process for the 2nd Workshop – Jim Chaput / Mario Wick
- Update of Global minor use priority database; explaining how we narrow down the list – Mario Wick / Jim Chaput

10:00 – 10:30	Health Break
10:30 – 12:00	Discussion and refinement of priorities
12:00 – 13:30	Lunch Break – Square Dorchester Room
13:30 – 15:30	Final discussions, refinement of priorities (as required), next steps and wrap-up – Jim Chaput / ALL
15:30 – 15:45	Heath Break
15:45 – 16: 15	Closure of the Second Global Minor Use Priority Closure of the Third Global Minor Use Summit – Marcos Alvarez and Dan Kunkel

Information for the Field Tour participants - Luc Urbain

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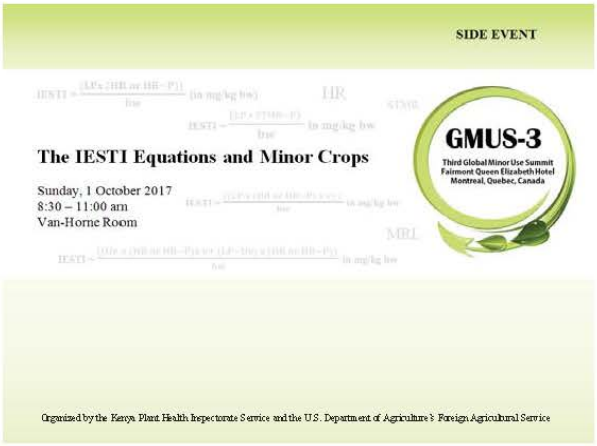
附件 3

The IESTI Equations and Minor Crops



What are the IESTI equations?

- International Estimated Short-Term Intake
- A set of equations used to estimate one-day exposures to pesticides
- Individual commodity basis, not designed to assess multi-commodity exposure
- Intended to generate conservative/protective acute dietary exposure estimates

Why do the IESTI equations matter?

- Used by national and international bodies to determine if an MRL can be established

IESTI ≤ aRfD → Exposure is acceptable; MRL can be established

IESTI > aRfD → Exposure is unacceptable; MRL may not be able to be established

Why do the IESTI equations matter?

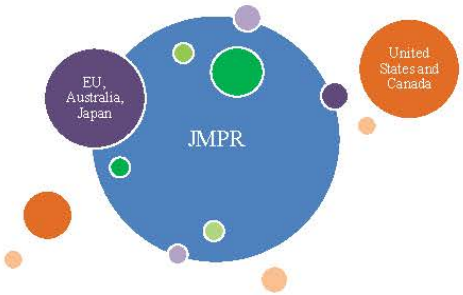
- Used by national and international bodies to determine if an MRL can be established

IESTI ≤ aRfD → Exposure is acceptable; MRL can be established

IESTI > aRfD → Exposure is unacceptable; MRL may not be able to be established

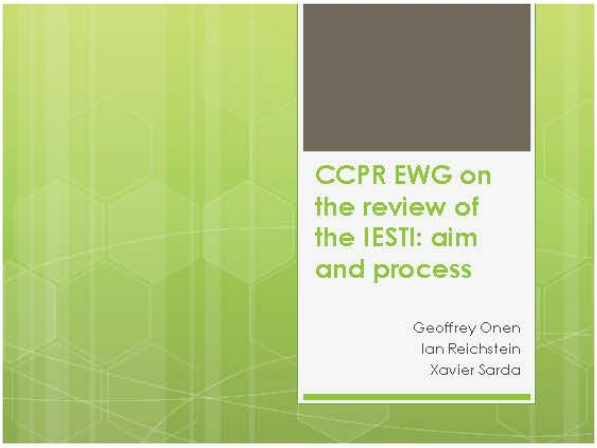
→ Direct and indirect implications for pesticide risk management, agricultural production, and international trade

Who uses the IESTI equations?



Today's Session

CCPR EWG on the review of the IESTI equations: aim and process	Geoffrey, Ian, and Xavier
Relevance of IESTI to minor crops: a developing country perspective	Lucy
Proposed review of the IESTI equations and potential impact to minor crops	Cheryl
Group discussion and sharing of views	All



Codex Committee on Pesticide Residues- CCPR

History of IESTI



- 1997 FAO/WHO Geneva Consultation
- 1998 York International Conference on Pesticide Residues Variability and Acute Dietary Risk Assessment (PSD, UK)
- *ad hoc* Expert Meeting held before the 1999 CCPR (Annex V in JMPR 1999 report)
- JMPR meetings 1999, 2000, 2002, 2003, 2005, 2006
- changes consolidated at FAO/WHO 'Annapolis' workshop (WHO, 2008 = EHC 240)

Reviewing the IESTI

- Proposal by JMPR (2006, 2007, 2010). JMPR recommended organising an international consultation, including all relevant stakeholders.
- In response: September 2015 2-day **Scientific Workshop in Geneva**, organized by the European Food Safety Authority (EFSA) and the Dutch WHO Collaborating Centre on Chemical Food Safety (@RIVM). FAO and WHO co-sponsored this event.

Reasons for reviewing IESTI

- Check against current science and practicalities after 15 years of use
- Communicating that the legal standards (MRLs) are assessed may contribute to building trust among the general audience
- Amongst other factors, harmonizing the IESTI methodology may increase the acceptability of Codex MRLs and in turn help contribute to a level playing field in international trade.

Reasons for reviewing IESTI-2

- Use of OECD MRL calculator and harmonised MRL classes:
  - MRLs are derived in the same way everywhere
  - using the MRL instead of the HR will no longer lead to different conclusions in different countries
- HR is based on a small dataset.
  - In reality, residue levels may vary outside the dataset. The 'OECD – MRL calculation unrounded' is a statistically more reliable estimate of the highest residue. The OECD – MRL calculation in many cases results in a level at approximately 2x the HR

2015 Geneva Workshop main recommendations

- Replace the HR and STMR by the MRL in all cases of the IESTI equation
- Use a a default variability factor of 3
- Derive the P97.5 large portion from the distribution of consumption values expressed as g/kg body weight
- Proposal to remove the unit weight from the IESTI equations
- applicable to both MRL setting for individual commodities and enforcement purposes

2015 Geneva Workshop main re...

- Rep... ...all co...
- U...
- D... ...d c... as...
- Prop... ...the IESTI e...
- applicable... ...individual commodities and enforcement purposes

Recommendations; not world-wide consensus!

2016 CCPR

- 2 side events on IESTI, from Europe and from CropLife
- Discussion paper by EU + Australia
- EWG (chair NL, co-chair AUS) with ToR:
  'To identify advantages and challenges that might arise from the possible revision of the current IESTI equations and the impact on risk management, risk communication, consumer protection goals, and trade. The recommendations of the international EFSA/RIVM workshop cosponsored by FAO and WHO and the discussions in CCPR48 should be taken into account.'

2017 CCPR

- In-session WG meeting
- the EWG could not fully accomplish its work because of the divergent views on the need to revise the IESTI equations
- JMPR Secretariat: the periodic review of scientific methodologies is a normal process

CCPR 2017 – 2

ToR (chair NL, co-chairs AUS + Uganda)

I. To provide information on the history, background and use of the IESTI equations.
II. To review and provide illustrative comments on advantages and challenges that arise from the current IESTI equations and their impact on risk management, risk communication, consumer protection goals and trade.
III. To gather relevant information on bulking and blending, as well as other information or data as outlined in Table 3 Appendix 2 of CX/PR 17/49/12 in order to feed into the risk assessors work through the JMPR Secretariat.
IV. On the basis of the above considerations develop a discussion paper providing recommendations for consideration at CCPR 50.

CCPR 2017 - 3

Request to FAO/WHO risk assessors:

I. To review the basis and the parameters of the IESTI equations;
II. To benchmark the outcomes of IESTI equations to a probabilistic distribution of actual exposures; and
III. To present the outcome to CCPR.

CCPR 2018 - preview

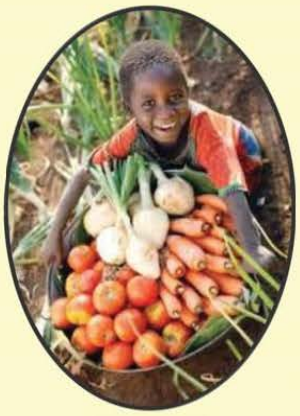
- Two groups working in parallel: EWG and FAO/WHO working group
- CCPR 2018 will discuss the results from both groups and decide on a way forward

Review of IESTI & minor crops

- The review is ongoing and no decision has been made yet on whether to revise the IESTI equations and if yes, how.
- **Therefore, the impact on minor crop MRLs is yet unknown.**
- N.B. minor crops are defined by CCPR based on low consumption both world-wide and local. Large Portion will be small. Because of reduced number of trials, MRL may be relatively high. Trade-off in IESTI result?

Thank you for your attention!

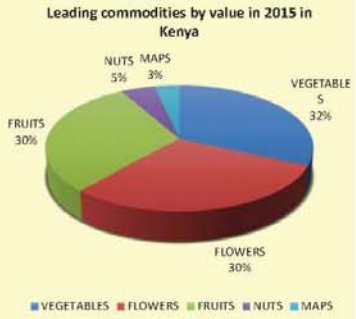
Understanding the relevance of the IESTI equations to minor crops: A developing country perspective



Lucy Namu
KENYA

Importance of minor / specialty crops

- Changing consumer demands → product diversification
- Minor / specialty crops grown by developing countries
  - High value / R.O.I percapita



Minor / specialty crops

Tropical Fruits (large)

Spices & Herbs

Tropical Fruits (small)

Fruiting / Legume veg.

Progress in CCPR(49) – Vegetable groups

- Group 09 Bulb vegetables,
- Group 012 Fruiting vegetables, other than cucurbits
- Group 18: Edible fungi
- Group 10: Brassica vegetables (except Brassica leafy vegetables)
- Group 13: Leafy vegetables
- Group 17: Stalk and stem vegetables
- Group 16: Roots and Tubers
- Group 15: Pulses
- Group 11: Fruiting vegetables, cucurbits
- Group 14: Legume vegetables

Others adopted

- Tropical and subtropical fruits (Edible / inedible peel)
  - Large
  - Medium
  - Small

Concerns

1. Limited MRLs on minor / specialty crops
2. IESTI equations used, however different parameters used (residues, variability factors, unit weights, large portions); hence different outcomes

Initial Proposals:

- Replaces data in current (HR and STMR) with MRL as exposure
- Vf = 3, introduce new CF to use with MRL
- Projects use of LPbw data not yet available

Concerns.../2

- Some MRLs established earlier have RL whose short term dietary exposures > ARfD.
- **Careful** Examination of
  - Trade impact
  - Variability factor, blending / bulking

Using IESTI
Case 1
- $U_{(RAC)} \leq 25g$

$$IESTI = \frac{LP \times HR}{bw}$$ (or HR-P)

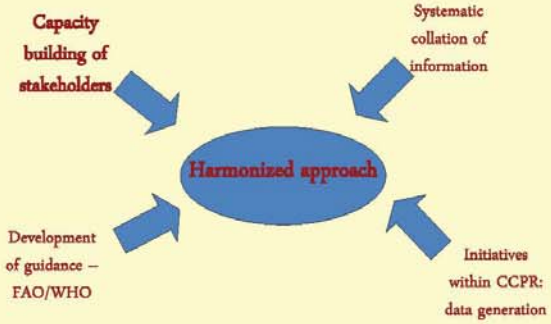
Case 3
- Bulked /blended

$$IESTI = \frac{LP \times STMR}{bw}$$ (or STMR-P)

Ongoing initiatives

- The TDS methodology is useful to assess dietary exposure to chemical contaminants.
  - Benin, Cameroon, Mali, Nigeria (STDF/PG/303)
  - Project still underway, pilot in region
- Regional harmonization in EAC

Tools that aid review



CropLife INTERNATIONAL

IESTI Perspectives

October 2017

Cheryl Cleveland, Ph.D.
via CropLife International

2

Cheryl B. Cleveland, Ph.D.

- Global Consumer Safety
  - 4 years at BASF
  - 27 years in industry
- Chair of CLA Dietary Assessment Work Group
- CARES NG Technical Working Group
- CLI focal point for CCPR IESTI eWG

2

3

Outline of talk

- MRL and IESTI
- Basics of Dietary Risk Assessment
- Benchmarking

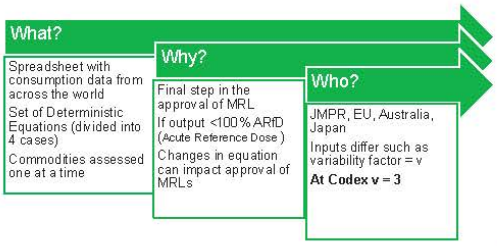
3

MRL= Maximum legal limit of a residue
(US Tolerance, CODEX CXL)

What it is	*What it is not*
From residue studies of maximized use pattern to set upper bound for local enforcement of GAP using **OECD calculator**	Stand alone value, divorced from supporting data.
Upper bound to check compliance with labeled use	An inherent property of active ingredient, it is dependent on use.
Set in context of acceptable dietary risk/safety assessment	Stand-alone health standard; it is not a safety threshold.
Conservative Screening exposure input in dietary safety assessment	**Realistic measure of typical exposure**

4

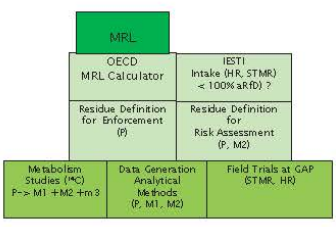
IESTI – International Estimate of Short Term Intake



Used in acute risk assessments - 70% of newer AIs get an ARfD

5

Foundations of an MRL



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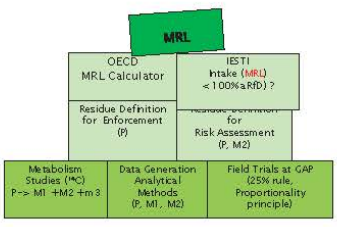
Proposed Change for Future MRL



7

What is the IESTI Issue?

Many concerned that proposed change to the IESTI equation may **lead to a loss of CODEX MRLs** without international justification.

There is also concern the proposal leads to **inflated dietary estimates for all commodities at international level.**

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IESTI Equations:
Proposal from EFSA / WHO workshop, 2015

Dietary exposure = consumption X residues

The proposal . . .
- Replaces all field data (HR and STMR) with MRL as exposure
- Keeps variability factor 3, but applies it to the MRL
- Removes unit weight from Case 2a
- Introduces new CF in order to use MRL
- Projects use of LP_{bw} data not yet available

9

IESTI Equations:
Proposal from EFSA / WHO workshop, 2015

Dietary exposure = consumption X residues

Case	Current IESTI (mg/kg bw)	Proposed IESTI (mg/kg bw)
1	$\frac{(LPx\ (HR\ or\ HR-P))}{bw}$	$LP_{bw} \times MRL \times CF \times PF$
2a	$\frac{((Ue\ x\ (HR\ or\ HR-P)x\ v+\ (LP-Ue)\ x\ (HR\ or\ HR-P))}{bw}$	$LP_{bw} \times MRL \times v \times CF \times PF$
2b	$\frac{((LP\ x\ (HR\ or\ HR-P)\ x\ v)\ )}{bw}$	$LP_{bw} \times MRL \times v \times CF \times PF$
3	$\frac{(LP * STMR-P)}{bw}$	$LP_{bw} \times MRL \times CF \times PF$

The proposal . . .
- Replaces all field data (HR and STMR) with MRL as exposure
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10

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2b	$\frac{((LP\ x\ (HR\ or\ HR-P)\ x\ v)\ )}{bw}$	$LP_{bw} \times MRL \times v \times CF \times PF$
3	$\frac{(LP * STMR-P)}{bw}$	$LP_{bw} \times MRL \times CF \times PF$

The proposal . . .
- Replaces all field data (HR and STMR) with MRL as exposure
- Keeps variability factor v= 3, but applies it to the MRL
- Removes unit weight from Case 2a
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11

IESTI Equations:
Proposal from EFSA / WHO workshop, 2015

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2b	$\frac{((LP\ x\ (HR\ or\ HR-P)\ x\ v)\ )}{bw}$	$LP_{bw} \times MRL \times v \times CF \times PF$
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The proposal . . .
- Replaces all field data (HR and STMR) with MRL as exposure
- Keeps variability factor v= 3, but applies it to the MRL
- Removes unit weight from Case 2a
- Introduces new CF in order to use MRL
- Projects use of LP_{bw} data not yet available

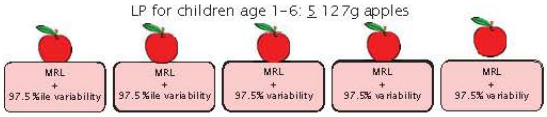
12

The Variability Factor
Is V=3 appropriate when used with the MRL?

Case 2a - apples and oranges

IESTI = MRL x **V** x LP

LP for children age 1-6: 5 127g apples



In the proposed IESTI equation EACH apple in the large portion consumption has BOTH an MRL-level residue AND p-97.5 level unit variability.

Smaller case 2a commodities like apricots, kiwi, fig, garlic, carrot, mandarin are even more affected by this compounded conservatism.

→ **The variability factor is SIGNIFICANTLY over conservative for case 2a commodities**

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Preliminary impact assessment - Revision of the IESTI equation

Case	Crops / commodities	Increase of Calculated exposure
1	**Meal portion < 0.025 kg** *including meat, eggs*	1.7X
2a	**Meal portion > 0.025 kg** Ue<LP *Use of 3 x MRL for all food*	3.5X
2b	Ue>LP	2.3X
3	**Bulked and blended**	5.2X

→ **Prior to change: Investigations on the use of variability factor recommended**
→ **Prior to revision: Investigations on blending procedures recommended**

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Conversion Factors

To account for difference in residue definition between MRL for enforcement and risk assessment residue definition

- MRL is the marker for use (and any misuse) for compliance
- Definition for risk assessment may contain additional metabolites (based on metabolism and field data)
  - Currently field data on measured metabolites are added into exposure
  - Proposal projected to add in a conservative worst case CF from metabolism regardless of appearance

→ **A survey of Codex residue definitions reveals that 20% of commodities have differing residue definitions for enforcement and risk assessment**

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6

Part 2

Basics of Dietary Risk Assessment

16

7

Risk assessment – General principle

Hazard + Exposure ≠> Risk

<<<

=> High!

>>>

=> Low!

The risk to any hazard is a function of the exposure!
Exposure to plant protection product residues is estimated via IESTI equation.

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Dietary Risk Assessment for Pesticides

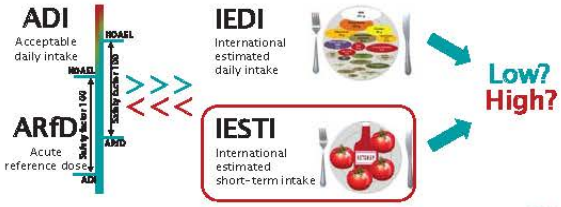
Risk = f (Exposure, Hazard->safety threshold)
Exposure = Consumption X Residue in Food
Hazard = f(Toxicological Endpoint, Residue Definition)

18

9

Risk assessment – Plant protection residues

Hazard + Exposure => Risk?



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What do we know about Dietary Exposure?

- The MRL is not a good measure of ACTUAL dietary exposure because . . .
  - *not all commodities are treated at the critical GAP and a variety of timings and actives are used*
  - *residue levels decline significantly between harvest and transportation to consumers*
  - *reduction of residues typically occurs in household preparation, cooking or industrial processing*
- Most global dietary models use field data (HR/STMR) - initial refinement in dietary exposure
- Dietary Monitoring data allows a *reality check* on models

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Overview – Exposure Components and Acute Dietary Model OPTIONS

Level	Consumption	Residue Estimates	Model
Unrefined Less Resources	• Food Balance Sheets	• MRL and 100% Crop Treated	• Deterministic (single values) • Single foods assessments
Intermediate	• House Hold Surveys • Recipes for RACs	• Field Trial (HR and STMR) • *Worst Case Variability for HR* • AI-specific processing	• Probabilistic consumption with deterministic residue estimates
Refined Data intensive	• Individual Diet Surveys • Recipes for RACs and processed products	• Percent Crop Treated • Dietary Monitoring Data • Washing and Cooking Factors • *Duplicate Dinner Plates*	• Probabilistic consumption with residue distributions for individual foods

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Acute CODEX process

Level	Consumption WHO	Residue Estimates	Model IESTI
Unrefined Less Resources		• 100% Crop Treated	• Deterministic (single values) • Single foods assessments
Intermediate	• Recipes for RACs	• Field Trial (HR and STMR) • *Variability for HR* • *vF = 3* • AI-specific processing	
Refined Data intensive	• Individual Diet Surveys *(or 5* % or 14 separate countries)* • Recipes for RACs and processed products	• Percent Crop Treated • Dietary Monitoring Data • Washing and Cooking Factors • *(Case by Case)*	

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Acute US Processes (with Tiered Residue Estimates)

Level	Consumption WWEIA	Residue Tiered Estimates	Model DEEM FCID
Unrefined Less Resources		• MRL and 100% CT	
Intermediate		• Field Trial (HAFT and averages) • AI-specific processing	• Probabilistic consumption with deterministic residue estimates (95%th)
Refined Data intensive	• Individual Diet Surveys • Recipes for RACs and processed products	• Percent Crop Treated (BEAD) • Dietary Monitoring Data (USDA PDP) • Washing and Cooking Factors	• Probabilistic consumption with residue distributions for individual foods (99.9%th)

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4

Outline of talk

Benchmarking

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Why Benchmarking?

From Official 2017 Report REP17/PR of CCPR

The Committee agree to request FAO/WHO:

- To review the basis and the parameters of the IESTI equations;
- To benchmark the outcomes of IESTI equations to a probabilistic distribution of actual exposures; and
- To present the outcome to CCPR.

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Why Benchmarking?

General IESTI and IEDI spreadsheets are valuable

- enabled the adoption of many new Codex MRLs (CXL) each year

Probabilistic Models envisioned as a calibration

- aid for risk communication discussions,
- not replacement for routine assessments

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Dietary Risk Assessment Options

Deterministic

- Inputs are single value point estimates
  - Pesticide Residue in Food
  - Quantity of Food Consumed
- Risk estimate is single outcome
  - High end estimate
  - No context of variability
- Example: IESTI Spreadsheets

Probabilistic

- Takes distributions of input (residues and consumption patterns)
- Risk Estimates Outpu- distribution with probabilities assigned
  - Monte Carlo technique combines thousands of random samplings of input distributions to build final output exposure distribution
- Examples: CARES NG, US EPA DEEM

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Apple Case Study for Benchmarking

Step 1: Active Ingredient Selection

CODEX MRL	ARfD	USDA PDP
• apple • pome	• Children • General population	• 2014-15 • >5% detects

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Quote: California EPA Guidance on Dietary Risk Assessment March 2009

"When an **actual** measured residue value is needed for the exposure assessment, the **ideal residue data** set would be one with the pesticide concentration measured in many samples (*e.g.*, **more than one hundred**) and different food forms, during the years which **reflect actual range** of weather and pest conditions and current use practices, from representative **samples collected at the consumer level**. In practice, the residue data from multiple sources are often used due to the inherent limitations in each data set. The following considerations can be used to select one value or one set of values. **Overall, the USDA PDP is the preferred source** because it is designed to provide pesticide residue data for dietary exposure assessment . . . ."

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What is Dietary Monitoring?

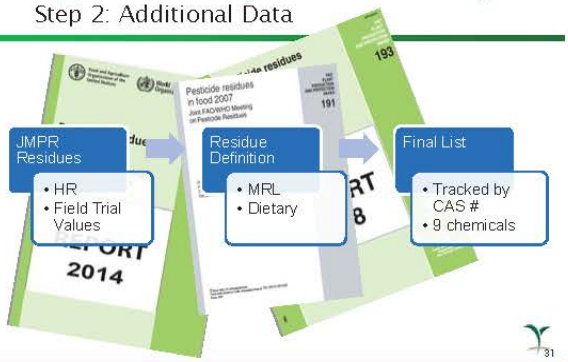
Commodity	Sample Preparation Steps
Apples	Wash and drain. Do not peel. Remove the stem. Remove the core using a commercially available apple corer, or cut each apple in half or quarters and remove the core portion.
Bananas	If necessary, banana samples may be stored in a secure location at room temperature for up to 72 hours for ripening purposes. Peel each fruit.
Blueberries, Cultivated	Wash by the handful or by using a colander and drain.
Broccoli	Visually examine and discard any damaged portion or wilted florets. Trim away inedible portions of stems. Wash and drain.
Carrots	If carrots have any visible dirt, hold each carrot under cold running tap water and gently scrub the entire surface with a clean vegetable brush to remove any loose soil and grit. Wash and drain. Remove stem cap portion from each carrot.
Celery	Using a clean, dry knife, remove the inedible portion of the stalk to allow stems to separate. Wash and drain.
Cherries	Remove the stem from each cherry. Wash and drain. Remove the pit, being careful to remove as little of the meat as possible.
Frozen Product Blueberries, Cherries, Green Beans, Sweet Corn	The samples may be chopped while frozen, or to prevent damage to the chopper/homogenizer blades, the sample may be thawed in a refrigerator or in a room temperature water bath. Open the containers and pour the entire contents into the chopper/homogenizer.

- From 2014 USDA PDP annual report

30

Apple Case Study for Benchmarking

Step 2: Additional Data



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Apple Case Study for Benchmarking
Step 3: Run Calculations

Deterministic
- IESTI
  - Current HR
  - Proposed MRL
  - 97.5th consumption

Quasi-Probabilistic
- MRL
- Consumption distribution

Probabilistic
- Field Distribution
- Monitoring Distribution

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Probabilistic Models Used

- Dietary Exposure Evaluation Model (**DEEM-FCID**) is current US EPA model estimates dietary exposures arising from the use pesticides.
  - **Publicly available** for download since June 2012
- The Cumulative and Aggregate Risk Evaluation System - Next Generation (**CARES NG**) software updated but similar approach to calculate dietary exposures.
  - Cloud based with web interface; **public release** planned in late 2017
- Both use National Health and Nutrition Examination Survey/"What We Eat in America" (**NHANES/WWEIA**) survey to derive the consumption part of the exposure estimation.

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Apple Case Study: Short Term Intakes (ug/kg bw/day)

Active Ingredient	IESTI Deterministic	IESTI Deterministic	Quasi Probabilistic	Probabilistic	Probabilistic
	Current	*Proposed*	*Acute w/MRL* 97.5th %ile user Only	*Field Trial Data* 95th %ile Per Capita	*PDP Data* 99.9th %ile Per Capita
A	33.4	60 (+ 1.8x)	13 (- 2.6x)	1.7 (- 20.2x)	1.3 (- 25.5x)
B	50.9	225 (+ 4.4x)	48.9 (- 1x)	4.5 (- 11.3x)	0.9 (- 54.4x)
C	5.66	15 (+ 2.7x)	3.3 (- 1.7x)	0.6 (- 8.7x)	0.2 (- 34.9x)
D	13.6	22.5 (+ 1.7x)	4.9 (- 2.8x)	0.4 (- 30.8x)	0.2 (- 69.7x)
E	13.0	37 (+ 2.8x)	8.1 (- 1.6x)	0.7 (- 18.2x)	0.2 (- 74.3x)
F	413	750 (+ 1.8x)	163 (- 2.5x)	26 (- 15.9x)	1.6 (- 256x)
G	16.4	37.5 (+ 2.3x)	8.2 (- 2x)	1 (- 16.6x)	0.6 (- 26.2x)
H	113	225 (+ 2x)	48.9 (- 2.3x)	14.8 (- 7.6x)	23.2 (- 4.9x)
J	21.5	52.5 (+ 2.4x)	11.4 (- 1.9x)	1 (- 20.6x)	0.2 (- 128.7x)

Comparison with Current IESTI Intake (Fold Increase+/Decrease-)

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All Case Study Benchmarks are not yet reflecting Probability of Percent Crop Treated - a more formal study will need to consider this aspect

Apple Case Study: Short Term Intakes (ug/kg bw/day)

Active Ingredient	IESTI Deterministic	IESTI Deterministic	Quasi Probabilistic	Probabilistic	Probabilistic
	Current	*Proposed*	*Acute w/MRL* 97.5th %ile user Only	*Field Trial Data* 95th %ile Per Capita	*PDP Data* 99.9th %ile Per Capita
A	33.4	60 (+ 1.8x)	13 (- 2.6x)	1.7 (- 20.2x)	1.3 (- 25.5x)
B	50.9	225 (+ 4.4x)	48.9 (- 1x)	4.5 (- 11.3x)	0.9 (- 54.4x)
C	5.66	15 (+ 2.7x)	3.3 (- 1.7x)	0.6 (- 8.7x)	0.2 (- 34.9x)
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Comparison with Current IESTI Intake (Fold Increase+/Decrease-)

35

My Learnings from Case Study

- Case Studies are labor intensive!
- A public Codex Database of final residues used to established MRLs could be useful
- Current IESTI consumption for children populations age groupings are inconsistent and summed commodities open to country interpretations
- Difficult to depict overview in a single chart between deterministic and probabilistic outcomes.
- The current IESTI tool is considerably more conservative than EPA's P99.9 (or P95) criteria for MRLs (Chemical-Crop combinations)

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Considerations for Benchmarking

- Dietary Benchmarking should be distinct from risk assessment.
  - Probabilistic sampling of worst case field data is not fully benchmarking.
- In risk assessment when you are missing data, you default to a conservative assumption
  - in benchmarking how do you ensure realistic assumptions?
  - Will incomplete data sets be rejected?

.

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Benchmarking Questions?

- Monitoring data as close to the consumer level as possible provides most refined assessment
  - Are worst case GAP field trials useful?
  - How will monitoring data gathered from various countries be QAed?
- Percent Crop Treated is an important refinement
  - how will global market share data be used?
- Exposure Percentiles for comparison?
  - Need discussion of Level of Protection
    - What are agreed %tiles for exposure?

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Final Thoughts

- **Proposed changes to IESTI lead to larger projected dietary intakes, which could prevent the approval of some MRLs unnecessarily.**
- Risk communication is not solved by promotion of the MRL from a trading standard to a health standard.
- Details of the FAO workgroup procedures for the benchmarking exercise should be transparent to all.
- The quality of the new FAO technical group benchmarking exercise will depend on the quality of the food consumption info and the dietary exposure data used.
- 2017 CCPR IESTI eWG needs renewed participation to: a) address technical challenges to proposed equation and b) thoughtfully and globally consider protection goals related to benchmarking.

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Acknowledgements

Special Thanks to Bruce Young (Bayer Crop Science) for Co-development of Apple Benchmarking Case Study and implementation of CARES NG

Thanks to Jane Stewart, Monika Richter (BASF) and Carrie Fleming (DowDuPont) for technical discussions

US EPA provided consultation on content – Benchmarking exercise reflects EPA tiered approaches for dietary risk assessment

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Web References

- IESTI spreadsheet Version 16, August 2017: http://www.who.int/foodsafety/areas_work/chemical-risks/gems-food/en/
- WHO IESTI Guidance: http://www.who.int/foodsafety/areas_work/chemical-risks/Guidance_IESTI_2014.pdf?ua=1
- USDA PDP Monitoring Data: https://www.ams.usda.gov/datasets/pdp
- CARES NG: http://caresng.org/
- CODEX MRL Pesticide Data Base: http://www.fao.org/fao-who-codexalimentarius/standards/pestres/pesticides/en/
- JMPR Acute Reference Doses: http://apps.who.int/pesticide-residues-jmpr-database

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3

Quotes from Final eWG IESTI Discussion Document

Any change to the IESTI equations needs careful consideration and deliberation. It is clear from the complexity of the issue, from the comments of delegations at CCPR 2016 and the variety of viewpoints expressed by the current eWG that the discussion on a ***possible revision of the IESTI equations will require continuous work over several years.***

. . . based on preliminary assessments the implementation of all recommendations made by the 2015 Geneva workshop could lead to a loss of Codex MRLs. The actual number of Codex MRLs that may be lost if the recommendations from the Geneva Workshop are implemented is unknown and ***simple counts of MRLs that may be lost do not necessarily appropriately reflect the trade value****. . .*

Although the level of conservativeness of the current IESTI is not clearly defined, it is well accepted world-wide. Therefore, ***it is proposed that changes to the IESTI should not lead to substantial changes in the level of conservativeness.***

FAO/WHO technical working group should be requested to develop a suitable approach to quantify the differences between the current and proposed IESTI, e.g. to ***benchmark the outcome of the current and the newly proposed IESTI to a suitable probabilistic distribution of actual exposures***

附件 4

Overview of the GMUS-2 work plan / Purpose of the GMUS-3 and Objectives

Main Themes

1. Coordination & Collaboration
2. Communication
3. Incentives
4. Capacity Development
5. Registration of Minor Uses and MRL setting

1 – Coordination & Collaboration

- 1.4 GMU Steering Committee
  - Establish membership*
  - http://www.gmup.org/GMUWorkinggroupsfinal5_30_14.xlsx

Steering Committee

25 members/15 countries and 3 organizations

- **Provides**
  - **coordination and oversight of activities**
  - **communication of activities to working groups**
  - **communication to other stakeholders and should serve as a link to decision makers (regulators, government etc.)**
  - **focus on the 5 year work plan and timelines**
  - **assistance to other workgroups in completing their task**
  - **Initially had quarterly teleconferences.**

White paper topics…

1. **Support the Joint Meeting on Pesticide Residues (JMPR/Codex) process**
2. **Awareness regarding how Import Maximum Residue Levels affect commodities in trade.**
3. **Impact of how secondary standards affect trade and choice of products for the growers.**
4. **Need for training and equipment is critical to properly monitor pesticide residues and for data generation.**
5. **Incentives to support minor uses and to encourage greater use of these incentives among all countries**

Started draft 2014…..

CLA – Industry White paper…

- Challenges to Establishing Harmonized Maximum Residue Levels (MRLs) for Facilitating Global Trade
  - Reviews the challenges faced by the agrochemical industry and its stakeholders in the food value chain in establishing harmonized MRLs to support the global trade of agricultural commodities. Addressing these challenges is critical to continue feeding our growing global population in the future.
  - Covers many of the same topics: awareness, secondary standards, misconceptions etc…
  - http://gmup.org/MRLWhitePaperAugust2014.pdf

Book: Declining International Cooperation on Pesticide Regulation, Frittering Away Food Security

- May T. Yeung et al…
  - Investigates barriers to international agricultural trade caused by a lack of standardized maximum residue levels (MRL) for pesticides.
  - A understanding of the reasons for the decline in international cooperation, the trade impacts, and potential solutions is critical.
  - An analysis of the economics of MRL regulatory harmonization, select case studies, and a look at incentives and disincentives for government agencies and regulators..
  - The Canola Council of Canada sponsored the work
  - http://www.palgrave.com/gp/book/9783319605517#otherversion=9783319605524

White paper topics…

1. **Support the Joint Meeting on Pesticide Residues (JMPR/Codex) process**
2. **Awareness regarding how Import Maximum Residue Levels affect commodities in trade.**
3. **Impact of how secondary standards affect trade and choice of products for the growers.**
4. **Need for training and equipment is critical to properly monitor pesticide residues and for data generation.**
5. **Incentives to support minor uses and to encourage greater use of these incentives among all countries**

1 – Coordination & Collaboration

- 1.1 Global priority setting process for minor uses
  - 2015 Global Workshop, Chicago, IL.
    - Update on Wednesday
- 1.2 Databases
  - Established Global Database for 2015 Workshop…
  - Updated in 2017 and will be added to the EU MU database.

  Workshop on Wednesday

2– Communication

- 2.1 Enhancement of the GMU Portal
- 2.2 Risk communication
- 2.3 Benefit communication
- 2.4 Establish list of (and networks of) existing working groups

3 – Incentives – that add value to Minor Uses

- **Monitor implementation and uptake of regulatory incentives**
- **Promote and implement new incentives as they are developed**
  1. Program Funding, waivers
  2. Address Import MRLs
  3. Authorization procedures and requirements – data protection
  4. Economic
  5. Liability

4 – Capacity Development

1. National and regional capacity
   - Disseminate information on pest management tools
   - Strengthen/establishment regional expert working groups
2. Engage policy makers to implement regulatory initiatives
3. Establish national minor use programs
4. Encourage greater participation in data generation
5. Provide guidance on Codex processes

Resource Document

- Program booklet
- Papers on related subjects
  - **Minor Use Programs**
  - **Codex/JMPR minor use activities**
  - **Incentives**
  - **Databases**
  - **Crop groups**
- **http://www.gmup.org/GMUS2_webversion.pdf**

5 – Registration of Minor Uses and MRL setting

1. Harmonized data requirement and submission documents
2. Crop Grouping (residue and efficacy) Also provides guidance for data generators
3. JMPR capacity building
   - Funding sources for JMPR
   - Expanding JMPR expert panel
4. Transparency in registration decisions
5. Working towards common MRLs
   - Side meetings at CCPR, Urge regulatory bodies to utilize Codex standards including Codex Crop groups

5 – Registration of Minor Uses and MRL setting

Working towards common MRLs

- Proposals …
  - Side meetings at CCPR to discuss barriers to harmonization
  - Support and involvement for Crop grouping at CCPR and representative crops*
  - Develop questionnaire through the electronic Working Group on Minor Uses/CCPR on import MRL setting by national authorities
  - Urge regulatory bodies to utilize Codex standards

Thank you!

GMUS-3
SMUM-3
CMUM-3
2017 2017

Global Minor Use Summit (GMUS) – 3 Purpose and Objectives

Developing Strategies for Specialty Crop and Minor Use Programs and Harmonization: Filling the Tool Box for Growers

GMUS-3
SMUM-3
CMUM-3
2017 2017

Update on the action items and 5-year work plan from the first two summits and from the first Global Minor Use Priority Setting Workshop

- Progress and outputs from the three Standards Trade Development Facility (STDF) capacity building efforts
- The Codex Committee on Pesticide Residues and JMPR
- Priorities from the first Global Minor Use Priority Setting Workshop and progress to date

Technical and cooperative areas:

- Overview of working groups – Global needs, Capacity development and Communication.
- Approaches and examples for international data sharing and research collaboration
- A focus on limiting duplication of efforts, robust data sets, data review.
- Data exchangeability
- Enhanced involvement of all stakeholders, especially specialty crop grower's/commodity associations in identifying needs and facilitating solutions to the minor use problems.
- Re-evaluate capacity building via updates and strengthen working groups and networks to more efficiently address specialty crop grower needs. Considerations for a "Phase 2" of capacity building.
- Review and Refine Industry partnerships in collaborative research efforts that address minor uses.
- Review, discuss and implement guidance on crop groups and extrapolation.

Policy considerations:

- Approaches to enhance involvement of policy makers who can help in facilitating solutions to the minor use problems.
- Advance the topic of international harmonization through cooperation and transparency in establishment of MRLs and risk assessment by regulators
- Promote acceptability to exchange field trial sites for residue and efficacy studies
- Share and implement criteria standards that define and recognize minor uses.
- Develop a timeline for implementation of new policies for minor uses.
- Discuss policy aspects to enhance the registration of minor uses

STRUCTURE OF THE SUMMIT

- **The Third Summit will have a plenary session, group discussions and a "needs" workshop.**
- The **plenary** session will provide updates from various minor use and government agencies regarding progress of the key action items identified in the past Summits and provide an overview of the objectives for this summit.
- The breakout sessions will focus on the key areas of interest involving the Regulatory, Industry and Grower sectors.
- The last day will be a follow-up global workshop to further discuss and refine priorities of grower needs identified from the First Global Minor Use Priority Setting Workshop.

附件 5-1

Capacity Building Updates since the GMUS-2

Capacity Building: Updates since GMUS2

Progress and outputs from the three Standards Trade Development Facility (STDF) capacity building projects

Jason Sandahl, PhD
Food Safety Technical Advisor
Office of Capacity Building and Development
USDA Foreign Agriculture Service

USDA UNITED STATES DEPARTMENT OF AGRICULTURE

GMUS-2: Theme 4 Capacity Development

Tasks:

4.1 National and regional capacity
- Disseminate information on existing pesticide and pest management tools (e.g., extrapolation methods, crop grouping, IPM)
- Facilitate the strengthening or establishment of new regional expert working groups that support minor use issues
- Develop and implementation new tools and guidance
- Establish sustainably operating regional expert working groups for minor uses

4.2 Engage policy makers to implement regulatory initiatives
- Include decision makers at technical meetings or workshops to demonstrate importance of implementation of technical inputs

4.3 Establish national minor use programs
- Provide guidance to national authorities on design and implementation of minor use programs

4.4 Encourage greater participation in data generation
- Initiate collaborative projects to better participate in Codex processes (e.g., crop grouping, data submissions, MRL setting process)
- Implementation of collaborative projects
- Stakeholder engagement in data generation and other areas to support minor uses

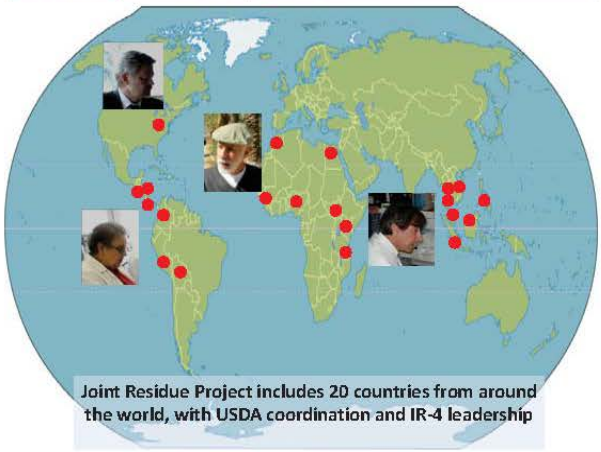
4.5 Provide guidance on Codex processes

Global Residue Project for Tropical Fruits

Goal: Develop process for generating residue data to establish Codex MRLs (and/or other national MRLs) through collaborative projects.

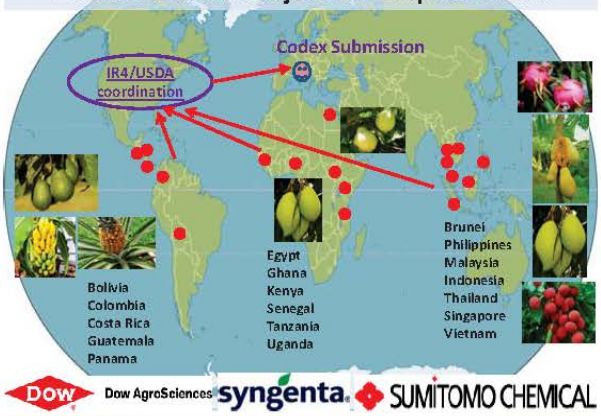
Vision: Establish global network of residue research teams to collaborate in generating data for MRLs (work-sharing and cost-sharing) and to coordinate minor use programs.

USDA IR-4 Project STDF FAO ASSOCIATION OF SOUTHEAST ASIAN NATIONS IICA



Joint Residue Project includes 20 countries from around the world, with USDA coordination and IR-4 leadership

Global Residue Project for Tropical Fruits



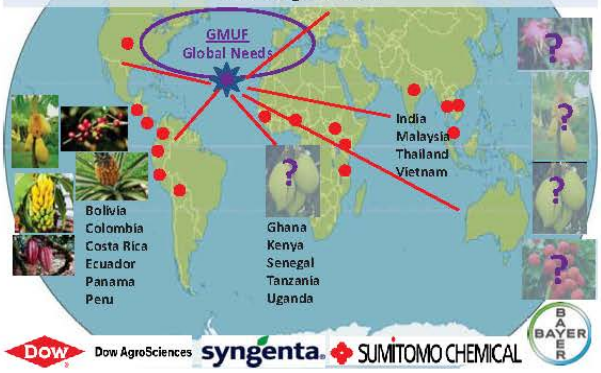
Dow Dow AgroSciences syngenta SUMITOMO CHEMICAL

Global Minor Use Fund: "Phase 2"

Identifying Regional/Global Priorities: Solutions for - MRLs, Crops, Pests

Global Minor Use Fund: "Phase 2"

In Progress....



Dow Dow AgroSciences syngenta SUMITOMO CHEMICAL BAYER

附件 5-2

GLP Field Residue Studies Global Capacity Building

GLP Field Residue Studies Global Capacity Building

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IR-4 Headquarters, Rutgers, The State University of New Jersey,
500 College Road East, Suite 201 W, Princeton, NJ 08540.
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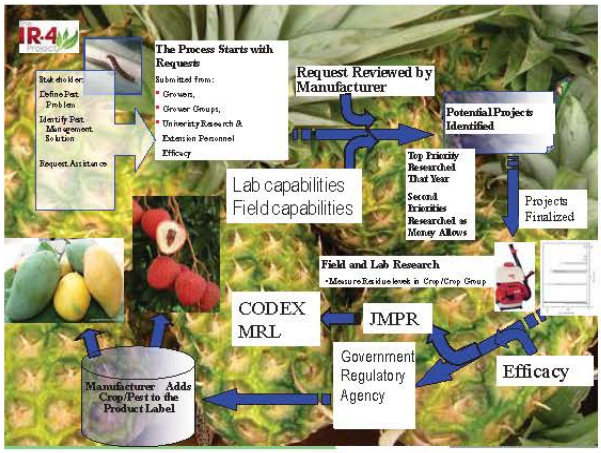

Asia

- Malaysia- Field and Lab
- Singapore- Lab
- Thailand- Field and Lab
- Philippines- Field and Lab
- Indonesia- Field and Lab
- Vietnam- Field
- Brunei- Field

Africa

- Ghana- Field
- Kenya- Field
- Senegal- Field
- Tanzania- Field
- Uganda- Field

Latin America

- Bolivia - Field
- Colombia - Field and Lab
- Costa Rica- Field and Lab
- Guatemala - Field
- Panama - Field and Lab

GROUP TRAINING

GROUP TRAINING

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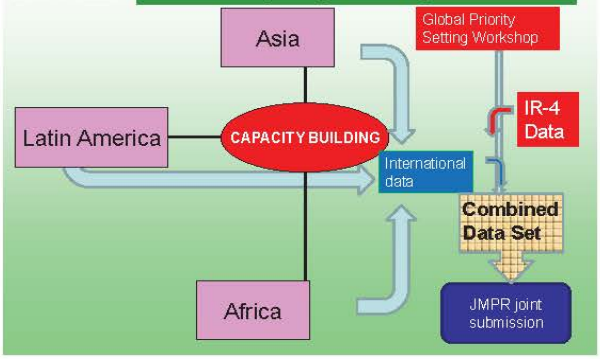
STDF-Capacity Building



COOPERATIVE AGREEMENTS

附件 5-3

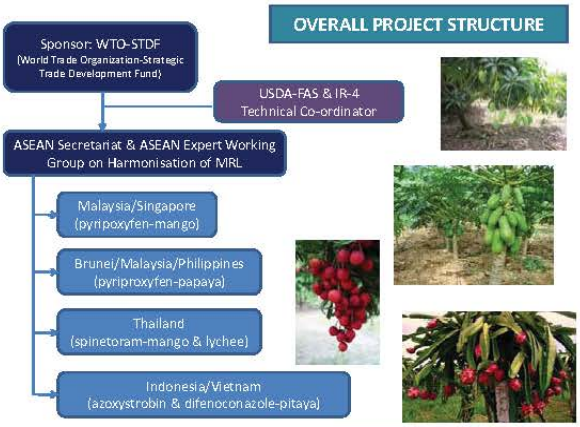
ASEAN countries' experience in collaboration with IR-4 & USDA

ASEAN countries' experience in collaboration with IR-4 & USDA

Ngan Chai Keong

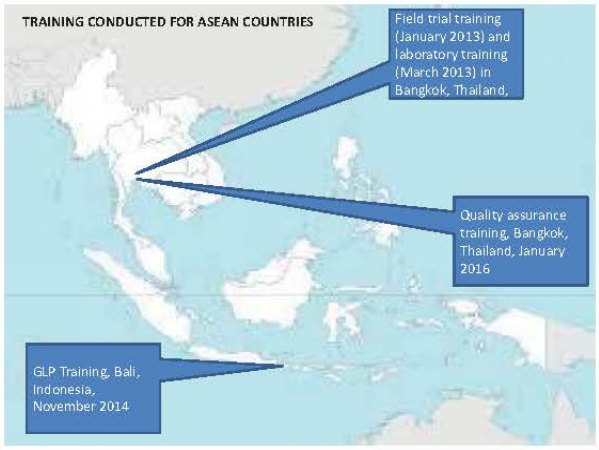
Introduction

- In 2009, USDA approached ASEAN countries for collaboration on global residue data generation project.
- Following few meetings with the *Expert Working Group on Harmonisation of MRLs of Pesticides among ASEAN Countries* within 2010-2012, project started in December 2012.
- Project completed by end of 2015.



Capacity Building & Residue Data Generation

- Onsite field & laboratory training in each participating countries.
- Field & laboratory training courses/workshops for all ASEAN countries.
- ASEAN countries not involved in the residue data generation project also sent representatives to the training course.



Challenges

- Multi agencies collaborating within one pesticide-crop residue data generation project.
- Communication between project counterparts from different countries.
- Trans-border or trans-island sample shipments.
  - Ensure sample integrity upon arrival at laboratory.
- Trial failure (crop loss due to theft).

Benefits & Beyond

- Good exposure to GLP residue study.
- Strengthen capability in residue data generation.
- Learning curve in team work, problem solving.
- Establish international networking.
- Future collaboration with global players:
  - Coordination of residue trial worldwide.

THANK YOU

附件 5-4

Colombian experiences in IR4 participation Spinetoram/ avocado

Colombian experiences in IR4 participation Spinetoram/avocado

ADRIANA CASTAÑEDA, PhD
Scientific director of analysis and diagnosis
Colombian Agriculture Institute

Edwin Barbosa, René Castro, Hugo Rodriguez, Javier Soriano, Julián Ayala, Rosana Brochado

Jacqueline Guevara, Yohana Velandia

Strenghts

- Team work comitment
- Personnel proficienty
- Training and coaching
- Laboratory facilities
- Growers support

Setbacks

- Not easy to start
- Personnel change (directive and executors)
- Laboratory (equipment, power supply, air conditioning)
- Limited funding
- High level government
- Projecto perception

Accomplishment

- Project finished and accepted
- Completed entirely by Colombia
- GLP team set up
- Future projects-continuity
- Trained personnel
- New institutions involved
- International recognition

Leasons learned

- Planning
- Personnel comitment
- Two people per rol
- Problem solving decision
- Communication
- Changes adapting

Recommendations

- Budget increase
- Keep training
- Involve high level government

Future work

- Involve other institutions (Corpoica, National Universities, Industry)
- Next projects in :

Cacao

Pinneaple

Banana

Acknowledgment

Edith, Milena, Amy, Jason, Daniel Dow

STDF, IR4, American embassy, ICA, IICA

附件 5-5

Update of the STDF capacity building project in Africa (Ghana, Kenya, Senegal, Tanzania & Uganda)

Update of the Standards Trade Development Facility (STDF) capacity building project in Africa (Ghana, Kenya, Senegal, Tanzania & Uganda)

PAUL OSEI-FOSU (PhD)
GHANA STANDARDS AUTHORITY
(Presenting on behalf of the team)

1

ACTIVITIES

- Increased technical capacity that will support the facilitation of new registrations and improved national pesticide monitoring programs,
- Generation of actual residue data (mango/sulfoxaflor)
- Submit data to JMPR for establishment of Codex MRLs.
- Crop/pesticide priority list for the participating African nations will be developed for future collaborations and for establishing a regional strategy for addressing identified priorities

2

ACCOMPLISHMENTS

- Project preparation
- Good Laboratory Practise (GLP) trainings for laboratory analysis and field trials
- Facility Inspection
- Protocol finalisation
- Study implementation(supervised residue field trials completed-Mango/Sulfoxaflor)
- Quality assurance and notebook reviews
- Registration preparation of mango/sulfoxaflor in participating countries

CAPACITY BUILDING

- **Project preparation**

This item was originally completed in December 2015, but due to changes in the crop/pesticide combination (**Mango/Sulfoxaflor**) this was completed in July 2016.

- **GLP training**

A 5 days GLP field research training was organised in 2014 in Ghana for all the participating countries

A 5 days GLP laboratory analysis training was organised in Ghana in March 2017 for all the participating countries.

Good Laboratory Practice (GLP) training in Ghana

5

- **Facility Inspection**

From February to June 2016, the IR-4 and USDA technical team visited both field and laboratory sites in Ghana, Kenya, Senegal, Tanzania and Uganda to carry out facility inspection

- **Study implementation**

Five supervised residue studies for sulfoxaflor in mango have been completed by Ghana (2), Kenya (2), Senegal (1), Tanzania (1) and Uganda (1). All these studies were completed before January 2017. All samples have been stored in deep freezers awaiting shipment and analysis in the UK laboratory.

- **Quality assurance and notebook reviews**

All the participating countries undertook a laboratory and quality assurance training which was held in June 2016 in Kenya.

All countries have submitted their field notebooks to the study director to conduct quality assurance review of the documents.

6

Laboratory and quality assurance training in Kenya

7

Laboratory and quality assurance training in Kenya

8

FUTURE DEVELOPMENTS

- Priority could be given to fruit fly and that spinetoram/mango combination was an important area where a project could be initiated considering the growing importance of fruit fly in Africa.
- Priority list of commodities which had been prepared during the conception of the project should form the basis for selection of commodities for future work.

Country	Crops identified
Kenya	Avocado, mango, passion fruit, pineapple
Uganda	Banana, passion fruit, pineapple
Tanzania	Guava, avocado, banana, mango, pineapple, passion fruit
Ghana	Banana, papaya, mango, pineapple
Senegal	Mango, pineapple, papaya, banana

9

ACKNOWLEDGEMENT

- Dow Agroscience-test material
- STDF-funds
- AU-IBAR -supervisory role
- IR-4 -Technical advisors
- USDA-FAS- advisors

Thank You!

10

附件 6-1

Established Minor Use Programs: North American Perspective

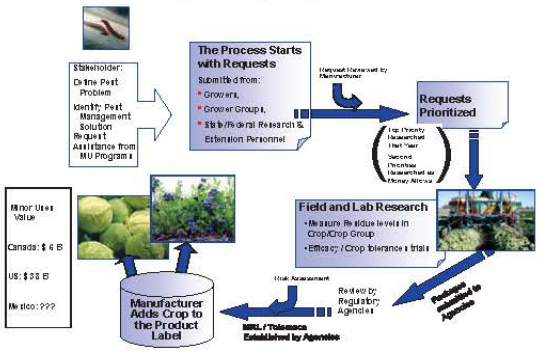
Established Minor Use Programs: North American Perspective

Dr. Jerry Baron
IR-4 Project
&
Dr. Marcos Alvarez
Pest Management Centre-AAFC

The IR-4 Project

Facilitating the regulatory approval of sustainable pest management technology for specialty crops and specialty uses to promote public well-being

The Regulatory Registration Process



Canada - US Partnership Model

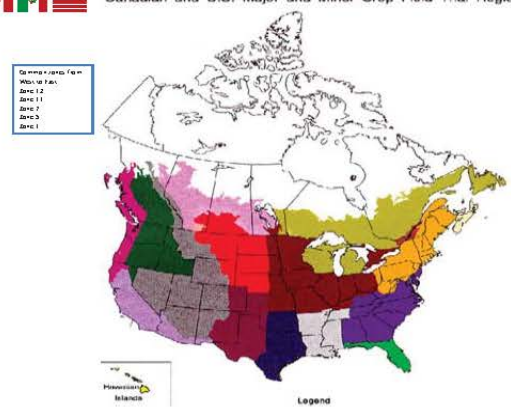
PMC

- AAFC funded including MU Program for PMRA
- Consultations with Prov. Minor Use Coordinators, Grower Groups and Manufacturers
- MU Pesticides Priority Setting Workshop (March)
- Biopesticides Priority Setting Workshop (March
- Planning Meeting (January)
- Field Trials at 7 GLP AAFC Research Centers and private contractors and Universities
- Located in 4 Regions
  - Western (2)
  - Prairies (1)
  - Central (3)
  - Atlantic (1)
- AAFC-PMC lab
- Over 1,800 new uses registered for growers

IR-4

- USDA and Industry Funding
- Consultations with Regional Field Coordinators, Grower Groups and Manufacturers
- Food Use Workshop (September)
- Biopesticides Workshop (September)
- Ornamental Workshop (October)
- Research Planning Meeting (October)
- Field Research Centers at 21 locations, mostly Land Grant Universities and USDA farms
- Located in 4 Regions
  - Northeast (MD)
  - North Central (MI)
  - Western (CA)
  - Southern (FL)
- (3) Regional and (2) USDA Labs
- Nearly 20,000 new uses register

Canadian and U.S. Major and Minor Crop Field Trial Regions



Partnerships

	Responsibilities	Roles	Benefits
NA Growers	Identify needs	Choose priorities	Target limited resources efficiency and obtain new tools
PMRA, EPA, SENASICA-SAGARPA, COFEPRIS-SSA	Federal Regulator – submission review, enforcement and monitoring.	Review regulatory proposals and make decisions taking in account harmonization.	Fulfills federal mandate - Greater efficiencies.
Researchers, Universities and Crop specialists	Conduct research on grower-selected MU solutions to specific pest problems.	Conducting of field trials, compilation of data supporting new MU submissions.	Contributes to science and innovation strategy.
Provinces and States	Also conducts field trials. Provinces prepare as well submissions on behalf of growers.	Advocate Provincial/States grower needs.	Obtain new Crop Protection tools for their growers.
Registrants	R&D on new crop protection tools and technologies.	Agree to label expansion and new use submissions.	Market new uses of products.
IR-4 Project and PMC and MU WG in Mexico	Facilitates registration of sustainable pest management technology for specialty crops and minor uses.	Develop necessary data to facilitate registration of crop protection tools for specialty crop growers and work jointly to facilitate North American registrations.	US and Canadian growers get national registration and access to Canadian and US markets as MRL is set and equal.

Questions?

附件 6-2 **Minor Use Program -European Union**

Minor Use Program - European Union

Global Minor Uses Summit
1-4 October 2017, Montreal, Canada
Jeroen Meeussen - Coordinator

MinorUses
EU Minor Uses Coordination Facility

Co-funded by the European Union

Second Global Minor Use Summit Rome - February 2012

Coordination Facility

- February 2014: EU Report on the establishment of an independent Coordination Facility on minor uses which is co-funded by the Commission
- Hosted by the European and Mediterranean Plant Protection Organization (EPPO, located in Paris) and jointly funded by the EU and by the governments of France, Germany and the Netherlands. Initially for a period of 3 years
- Coordinator started 1 September 2015; Fully staffed since 1 November 2016
- Coordination Facility will work for all 28 Member States

Minor Uses - Importance

Only 3% of the cultivated area, but representing 22% of the value of the entire EU plant production value

Across the EU these speciality crops represent a value of more than 70 billion Euros per year

Coordination Facility - Mission

The mission of the Facility is 'to enable farmers in the EU to produce high quality crops by filling minor uses gaps through efficient collaboration to improve availability of chemical and non-chemical tools within an integrated pest management (IPM) framework'

Commodity Expert Groups

Currently there are 7 Commodity Expert Groups(CEG):

- CEG fruit and vegetables
- CEG ornamentals
- CEG tobacco
- CEG rice
- CEG hops
- CEG seeds
- CEG mushrooms

EUMUDA Homepage

EUMUDA

What information can I find in EUMUDA?

- A compiled list of minor uses needs from Member States
- An overview of ongoing projects and their status
- A table of crop acreages
- Reference lists of what are considered 'minor uses' in different Member States

Not all information on individual projects is accessible for everybody. The MUCF is working on rules for access rights and confidentiality

Project Funding

EUMUCF: Long-term funding

- EUMUCF is jointly funded by the European Union and the the governments of France, Germany and the Netherlands
- Currently, the funding of the Coordination Facility has been guaranteed by France, Germany and the Netherlands for the first three years (until April 2018)

EUMUCF: Long-term funding

- Already several other Member States have indicated their willingness to contribute to the funding of the Coordination Facility
- It is clear that minor uses problems will not all be resolved in three years
- A mid-/long-term planning (5-10 years) and a strategy how other Member States can contribute, has been prepared
- Member States will be approached with a request for a voluntary assessed contribution

THANK YOU FOR YOUR ATTENTION

ANY QUESTIONS

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附件 6-3

Minor Uses in Brazil

BRAZILIAN HEALTH REGULATORY AGENCY (ANVISA)

Minor Uses in Brazil

Carlos Alexandre Oliveira Gomes
Health regulatory expert
MS/Anvisa/GGTOX

Normative Instruction Minor Crops

ANVISA, Ministry of Agriculture and and Brazilian Institute of Environment (IBAMA)

- **Motivation:**

  - Co-responsibility of companies in misuse of pesticides to Minor Uses.
  - Improve of the dietary risk evaluation that it was probably sub estimated (ANVISA).
  - Improve the process of register of pesticides to Minor Uses. Demanded by supply chains of fruits and vegetables.

Agência Nacional de Vigilância Sanitária
www.anvisa.gov.br

Normative Instruction

ANVISA, Ministry of Agriculture and IBAMA

- **Methodology:**
  - Based in IR4/PMC
  - Analyze of Actives Ingredients actually demanded:
    - Demand of needs of the supply chains of fruits and vegetables;
    - Results of Brazilian Pesticide Residue Monitoring Program (ANVISA);
    - Results of monitory of pesticides in Wholesale in (Ministry of Agriculture).

Agência Nacional de Vigilância Sanitária
www.anvisa.gov.br

Normative Instruction

ANVISA, Ministry of Agriculture and IBAMA

- **Methodology :**

  - Availability of Active Ingredient registered for representatives crops;
  - Botanic and taxonomic Similarity;
  - Way how that fruits and vegetables are consumed;
  - Regional Characteristics.

Agência Nacional de Vigilância Sanitária
www.anvisa.gov.br

Normative Instruction

ANVISA, Ministry of Agriculture and IBAMA

- **Necessary:**

  - Create a permanent group to discuss about the issue and correlates;
  - Create a negative list of Actives Ingredients that won't be accepted because of lack of interest of Ministry of Agriculture (ex. Technical Barriers to exportation); ANVISA (ex. impact of ADI or human health); and IBAMA (impact to environmental);
  - Priority of Actives Ingredients with less toxicity.

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- ✓ Actions of the Brazilian's Group Work of Minor Crops to identify the main active ingredients detected in minor crops in Brazil (Brazilian Pesticide Residue Monitoring Program). And orient the change of actives ingredients with proprieties more toxic to other ones with proprieties less toxic.

Filter
- Occupational Adverse Effect Level (OAEL) - < 0,005
- Impact Acceptable Dose Intake (ADI) - > 75%
- A.I. in Revaluation
- A.I. with restriction to use in Brazil – Eg.: forbidden in backpack application

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A.I. with restriction to register using the INC 001/2014 (Minor Uses).

acephate	Gamma-Cyhalothrin	Etiona	iminoctadine	pymetrozine
aldicarb	clodinafop	epoxiconazole	linuron	prothioconazole
abamectin	diazinon	fenamiphos	mancozeb	Tiram
aviglicina	dicofol	phosmet	methamidophos	triazophos
carbaryl	dimethoate	fenpropimorph	methidathion	terbufos
carbofuran	diquate	Fenoxaprop-P	metiram	Tebupirinfós
chlorpyrifos	disulfoton	fipronil	Mevinphos	Tembotrione
carbendazim	diafenthiuron	fentin	paraquat	
cyhexatin	edifenphos	glyphosate	Parathion-methyl	
cadusafos	endosulfan	Glufosinate-ammonium salt	pyrazophos	
cyhalofop Butyl	ethoprophos	Haloxyfop-P	prochloraz	

Normative Instruction

ANVISA, Ministry of Agriculture and IBAMA

- **Necessary:**

  - supervised field trials in accord with new legislation, that recognized GLP, and these residues trials must be delivered after two years in a Minor use elected how representative of sub group.

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www.anvisa.gov.br

Normative Instruction

ANVISA, Ministry of Agriculture and IBAMA

- **Consequences:**

  - Improve the inclusion of AIs to Minor Uses;
  - Improve the inclusion of Minor Uses in labels;
  - Reduce the necessary numbers of supervised field trials to minor uses register;
  - Improve the officials programs of monitory the residues of pesticides in foods.

Normative Instruction

Art. 1º:

- Reason: Extrapolation of MRL
- Definitions:
  - Minor Uses
  - Groups and sub groups of crops
  - Representative Crops of Group and Sub-Group
  - ADI
  - MRL
  - Extrapolation of MRL
  - MRL provisory

INC – Minor Crops

Art. 2º:

- Groups of Minor Uses, conform Annex
- § Define procedures to include others crops, not contemplated in INC Minor Crops.
  - expert's report firmed by research
  - Data bibliographies
  - Meeting of group work minor Uses (ANVISA, MAPA e IBAMA)

INC – Minor Crops

Art. 3º:

- Inform who can solicit a Minor Uses and extrapolation of MRL:
  - Research Institutions or rural development;
  - Associations e cooperatives of rural farmers;
  - Companies registrants.
- Ministry of Agriculture, ANVISA and IBAMA approve

Art. 4º:

- Groups of Minor Uses can be altered, if scientifically justified, and conform Art. 2º.

INC – Minor Crops

Art. 5º:

- To extrapolation of MRL:
  - Solicitation on Ministry of Agriculture, mention of AI and the minor use, biologic target and GAP.
  - Publication of AI in Monograph of pesticides by ANVISA

Art. 6º:

- Exigency to a extrapolation of MRL:
  - MRL and Pre-harvest interval of representative crop must consist in monograph to be extrapolated (Provisory MRL).
  - Commitment Term (CT) , with dead line of 24 months, to carry out supervised field trials for representatives crops of Sub-Group (Definitive MRL of Sub-Group).

INC – Minor Crops

Art. 7º:

- Provisory MRL had a dead line of 24 months, until establishing of MRL by residue test in a representative crop of Sub-Group.
  - § 1º - In case of supervised field trials haven't been delivered – Withdraw the minor use from monograph.
  - § 2º - Temporally MRL ⟶ LMR definitive: after delivery of supervised field trials , since have not impact on ADI or ARfD.

INC – Minor Crops

Art. 9º:

- Minor Uses with MRL extrapolated will be included in Official Program of monitory of residues of pesticides to comparison of compatibility of the value extrapolated with the value observed.

INC – Minor Crops

Art. 11º:

- Should be demonstrated when included the Minor Uses in labels of pesticides:

  I – expert's report proving the efficiency agronomic for the biology target, and absence of phytotoxicity to the representative crop Sub-group; § 1° - The MRL, and Pre-harvest interval to the Minor Uses will be defined by ANVISA and Ministry of Agriculture, based on MRL; and Pre-harvest interval of representative crop of Group or Sub-group.

Art. 14:

- ANVISA, Ministry of Agriculture and IBAMA can propose exclusion of crop from monographer of the AI if necessary:

INC – Minor Uses

Table 1. Representatives Crops of Groups and respective Minor Uses

Groups	Representatives Crops	Minor Uses
1 – Fruits with no edible peel	Citrus, Melon, Coconut	Avocado, pineapples, Cacao, Cupuaçu, Guaraná, Passion fruits, watermelon, Pinha, papaya, Kiwi, Açaí, Anonaceas, Dendê, macadamia nut, Pupunha.
2 – Fruits with edible peel	Apple, grape	Acerola, mulberry, Plum, olive, cashew, Kaki, star fruit, Fig, raspberry, Guava, Quince, Whortleberry, Strawberry, Nectarine, Loquat, Peach, Pitanga, Pear.
3 – Roots, Tubers and bulbs	Potato, Carrot	Sweet potatoes, Beet, Cará, Ginger, yam, cassava, Arracacha, Celery cabbage, Radish, Wild radish.
4 – Leaf vegetable	lettuce, cabbage, Kale	Water-crass, Allium porrum, Wild chicory, Broccoli, Scallion, Endive, coriander, Cauliflower, Chinese cabbage, Brussels sprouts, spinach, Manjericão, rocket, Parsley
5 – Fruits vegetable	Tomato, cucumber	Pumpkin, Summer squash, Eggplant, Chayote, Scarlet, Sweet pepper, eggplant, cucumber, Pepper, Okra.
6 – Leguminosae and Oil seeds	Bens, Soybean	peas, Chick pea, Lentil, Canola, Sesame, Sunflower, Linseed.
7 – Cereal	Corn and wheat	Millet, sorghum, oats, rye, barley, triticale

Table 2. Representatives crops of Sub Groups to extrapolations of MRL to Minor Uses and to be reference in supervised field trials .

Sub-groups	Representative Crops	Minor Uses
Sub-group 1A	Melon	watermelon
Sub-group 1B	papaya, Avocado, Passion fruits	Avocado, Açaí, Cacao, Cupuaçu, Guaraná, Passion fruits., Anonaceas , pineapples
Sub-group 2A	Strawberry	Acerola, mulberry, olive, Fig, raspberry, Whortleberry, Pitanga.
Sub-group 2B	Kaki, Guava	cashew, Kaki, Guava, Kiwi, star fruit
Sub-group 2C	Plum, Peach	Plum, Quince, Nectarine, Loquat, Peach.
Sub-group 3A	Beet, Radish	Sweet potatoes, Beet, Cará, Ginger, yam, cassava, Arracacha, Celery cabbage, Radish, Wild radish.
Sub-group 4A	Lettuce	Water-crass, Allium porrum, Wild chicory, Scallion, Endive, coriander, spinach, Manjericão, Parsley, rocket.
Sub-group 4B	cabbage, Kale	Broccoli, Kale, Cauliflower, Chinese cabbage, Brussels sprouts, cabbage.
Sub-group 5A	Sweet pepper	Eggplant, Scarlet eggplant, Pepper.
Sub-group 5B	cucumber	Pumpkin, Summer squash, burr cucumber, Chayote, Okra.
Sub-group 6A	peas	Chick pea, Lentil.
Sub-group 6B	Sunflower	Canola, Sesame, Linseed.

Extrapolation of MRL

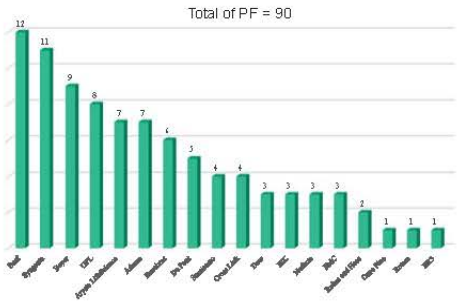
MRL OF AI

Inclusion in label and Bula

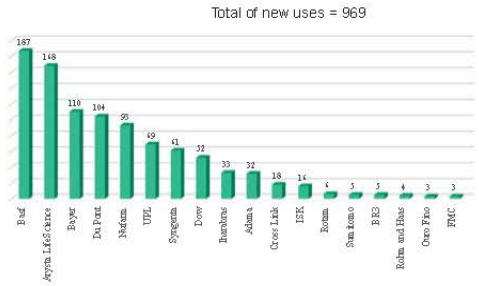
Group	Crop Group Representative	Crop Sub Group Representative	Minor Crops
5. Fruits Vegetables	Tomato (*Solanum licopersicum*) Cucumber (*Cucumis sativus*)	5A Sweet pepper 5B Cucumber	Eggplants, scarlet eggplant, pepper, Okra Pumpkin, summer squash, chayote e burr cucumber.

Field Trials (2 years)

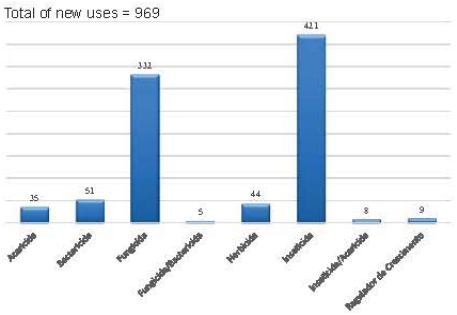
Nº. of Products Formulated (PF) by companies:



Nº. of new uses (crops) approved by companies:



Nº. of New uses per class products



PARTNERSHIP

THANK YOU

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Carlos Alexandre Oliveira Gomes – ANVISA
Carlos Ramos Venâncio – MAPA
Danilo Lima – IBAMA
Juliano dos Santos Malty – ANVISA
Tatiane Almeida do Nascimento – MAPA
Ubirajara Silva - IBAMA

附件 6-4 **Australian Minor Use**

AUSTRALIAN MINOR USE

Kevin Bodnaruk

Australian Minor Use

- Previously
  - Separate R&D Corporation programs
    - Grains ($2.3 mio pa) and Horticulture (~$1.6 mio pa)
      - Majority for Off-label permits
        - Data generation
        - One-on-one dialogue with registrants and regulators

Australian Minor Use

- Current approach
  - AgChem Access Priorities Forum
    - Key stakeholders represented

Australian Minor Use

- Current approach
  - AgChem Access Priorities Forum
    - Mix of government, registrant and industry funds
    - Federal funding
      - Forum establishment
      - Grants 2015/16 - $1.72M, 2016/17 - $2.58M, 2017/18 - $1.78M
      - Regulator initiatives (e.g., permit to label, Crop grouping)

Australian Minor Use

- Current approach
  - AgChem Access Priorities Forum
    - Provides a platform for cross sector/stakeholder dialogue.
    - Underpinned by:
      - Industry needs analysis (key crop protection gaps)
      - Consultation
        - Information sharing (industry ⟷ Registrants)
          - Development strategies
          - Identify opportunities for collaboration or co-investment
        - Regulators
          - Regulatory pathways & data requirements

Australian Minor Use

- Going forward
  - Funding
    - Forum funded by key stakeholders ($95K pa)
      - 8 RDC's & CropLife
    - Projects
      - Mix of industry and registrant funds
  - Primary purpose is to seek opportunities for:
    - early registrant & regulator engagement
      - New and review chemicals
    - data requirements, access/sharing

附件 7-1

CCPR eWG Minor Crops

anses

CCPR eWG Minor crops

Guidance to facilitate the establishment of MRLs for pesticides for minor crops

Xavier Sarda
Head of Pesticide Residues and Food Safety Unit.
DEPR - Regulated Products Directorate

CCPR eworking group on minor uses

– 2008-2011 WG: Definition: no agreement reached.
- Minor uses/crops/speciality: zones
- Consumption *Vs* Production (surface vs Tons) / Economic Importance

– 2011-2015: WG focus on criteria /nb of trials
- Based on consumption data (FAO STAT)
- Total world food consumption per capita is 1787.98 g/capita/day.
- cut-off 0.5% = 9 g/capita/day

New Cluster diets

Food and Chemical Toxicology 52 (2013) 180–187
Contents lists available at SciVerse ScienceDirect
Food and Chemical Toxicology
journal homepage: www.elsevier.com/locate/foodchemtox

New approach for the assessment of cluster diets

Mouhamadou Moustapha Sy[a], Max Feinberg[a], Philippe Verger[b], Tangui Barré[b], Stéphan Clémençon[c], Amélie Crépet[d,*]

Review world consumption

Crops	% of total consumption	N° of Cluster > 0.5%	N° of Trials	EWG Comments
	Tier 1	tier 2		
Wheat_t	9,394%	17		
Rice_t	9,208%	16		
Potatoes_t	5,448%	16		
Vegetable nes_t	5,097%	17		
sugar_t	4,544%	17		
Barley_t	4,232%	17		
Tomatoes_t	2,794%	14		
Maize_t	2,614%	16		
Bananas_t	2,373%	15		
Watermelons	1,932%	8		
Cassava_t	1,874%	8		
Sweet potatoes	1,747%	5		
Apples_t	1,612%	14		
Onions_t	1,570%	14		
Cabbages and other brassicas	1,502%	10		

CCPR criteria for number of trials

3 categories based on consumption levels (% of total daily consumption/capita) have been derived:

- Category 1 - No data in FAO Stat and No GEMS Food Cluster data: to be considered on a case by case basis
- Category 2 - < 0.5% worldwide and < 0.5% in all of the clusters: minimum of 4 trials
- Category 3 - < 0.5% worldwide and > 0.5% in one or more clusters: minimum of 5 trials

Table 1.List of crops for which consumption values are above the threshold of 0.5% worldwide total consumption.

CODEX Code	Commodity	CODEX Code	Commodity
001	CITRUS FRUITS	011	FRUITING VEGETABLES, CUCURBITS
FC 0003	Mandarin + mandarin-like hybrid	VC 0046	Melons, except watermelon
FC 0004	Orange, sweet, sour + orange-like hybrid	VC 0424	Cucumber
002	POME FRUITS	VC 0432	Watermelon
FP 0226	Apple	012	FRUITING VEGETABLES OTHER THAN CUCURBITS
FP 0230	Pear*	VO 0445	Peppers, sweet (incl. pim(i)ento) (bell pepper, paprika)*
003	STONE FRUITS	VO 0440	Egg plant (aubergine)
FS 0013	Cherries*	VO 0448	Tomato

Table 2: List of crops for which consumption values are below the threshold of 0.5% worldwide total consumption.

CODEX CODE	Commodity	Consumption weighted with population (g/habiday)	% of total consumption	N° of Cluster > 0.5%	Consumption category	Comments
		tier 1		tier 2		
001	CITRUS FRUITS					
FC 0005	Shaddock or pomelo + shaddock-like hybrid	1.351	0.1%	1	3	
FC 0204	Lemon	4.153	0.3%	3	3	
FC 0205	Lime	N/A	N/A	N/A	1	
002	POME FRUITS					
FP 0227	Crab-apple	N/A	N/A	N/A	1	
FP 0228	Loquat (Japanese medlar)	available under GEMS/FAO code 619: fruit fresh nes	N/A	N/A	2	
FP 0229	Medlar	available under GEMS/FAO code 619: fruit fresh nes	N/A	N/A	2	
FP 0231	Quince	0.174	0.01%	0	2	

recommandations to set MRL on minor crops

- **Label**
When there is no formal label, the data on minor crop should be accompanied by an official letter from a government agency that states the chemical is being used on the crop and outlines GAP being used by growers in that country.

- **Global data set**
Residue trials from different regions of the world might be taken into account for setting MRLs on minor crops.

- **Use of proportionality**
Should be use as for major crops but may be authorised for limited dataset on a case by case basis.

- **Extrapolation**
Manufacturers and members are encouraged to include minor crops when a compound is scheduled in the priority list

- Applicable
  Interim period until JMPR 2018
- Future work:
  - Update consumption data
  - Identify early in the priority list the possible extrapolations.

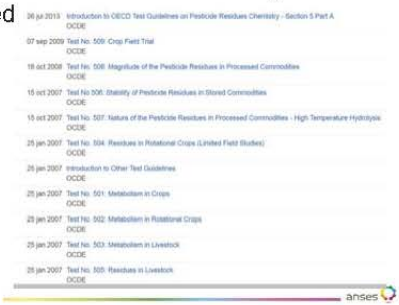
Residue Chemistry Expert Group (RCEG) update

OECD OCDE

Xavier Sarda
Head of Pesticide Residues and Food Safety Unit.
DEPR - Regulated Products Directorate

Past Activities

- 7 guidance documents and 9 test guidelines published



Current Activities

- Guidance Document on Residues in Rotational Crops
- Revision of TG 509 Crop Field Trials

Guidance Document on Crop Field Trials

- Review of document published in 2011
- Co-chaired by Karsten Hohgart (BVL, Germany) & Michael Kaethner (Bayer)
- Factors considered included review of sections on crop grouping, extrapolations, proportionality and geographical distribution of residues trials
- Published Sept 2016

Guidance Document on Residues in Rotational Crops

- Guidance document development first proposed at 2011 RSG
- Co-chairs Jason Lutze (APVMA, AUS) and Kathryn Jernberg (DuPont)
- Factors being considered include determination of application rates esp with accumulation, proportionality, MRL establishment for rotational crops
- Will support test guidelines 502 & 504
- Second round of comments with RCEG, closed 4 Dec 2015
- Significant advances on harmonization made post consultation
- WGP WNT commenting round

Exemple of extrapolations in the new guidance document on residues on rotational crops.

Table 3 Selection of crops for Tier 3 (extended field) studies

"Super" crop group (each consisting of one or more crop groups) [1]	Crops proposed for Tier 3 field studies for one or more subgroups (labelled 1, 2, 3), respectively [2]	Number of Trials [3]	Possible Extrapolation
Root and tuber	1. Carrots or radishes or sugar beets (*) or other beets	4	Subterranean parts: Extrapolation to root and tuber vegetables, potatoes, roots of sugar plants, of herbal infusions and of spices Aerial parts: root crop based forage crops (**)
	2. Potatoes (optional) [4]	4	Extrapolation to potatoes only
Bulb and stem vegetables	1. Leek or celery	4	Extrapolation to bulb vegetables and stem vegetables

The Future

- New work proposed:
  - Revision of Crop Field Trial test guideline (alignment to GD)
  - Residues in honey
  - Revision of residue definition guidance
  - Residues in aquaculture
  - IESTI – support review activities

附件 7-2 CCPR eWorking Group on Priorities

3rd Global Minor Use Summit
Montreal, Canada

CCPR eWorking Group on Priorities

- Procedures
- Openness and transparency
- Inclusivity
- JMPR workload
- National Registrations Database

Ian Reichstein
Director – Australian National Residue Survey
Chair – CCPR Electronic Working Group on Priorities

October 2017

Role of eWG Priorities

- Codex Procedural Manual
- Prepare draft Proposed Schedule of JMPR evaluations and maintain Priority Lists

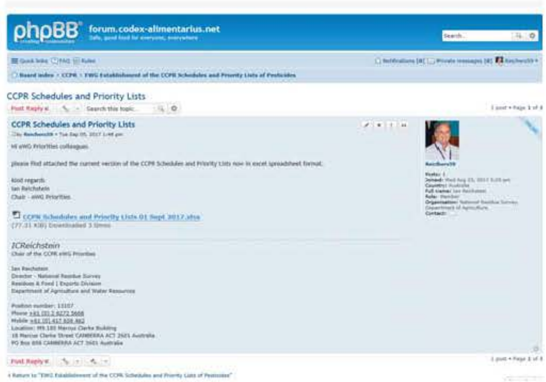
THE TABLES

- Proposed Schedule of JMPR evaluations
- Table 1: new pesticides plus new uses and other evaluations for existing codex pesticides
- Table 2A: Schedule of Periodic Review
- Table 2B: List of Periodic Reviews
- Table 3: Record of Periodic Review
- Table 4: Pesticide / Food combinations for which specific GAP is no longer supported

(CAC procedural Manual 25th edition)

Timeline for eWG Priorities

'Kick-off' letter issued by Codex Secretariat	August 2017
Registration of eWG participants on Codex IT portal	September 2017
Step 1	
Nomination with completed form due:	**30 November 2017**
CCPR Schedule and Priority List draft agenda paper:	**1 January 2018**
CCPR approves Proposed 2018 Schedule:	**April 2018 (CCPR50)**
Commission adopts 2018 Schedule of Evaluations	**July 2018**
JMPR data call in for 2018 Schedule of evaluations:	**October 2018**
JMPR conducts evaluations / meets (STEP 2)	Sept 2019
JMPR report published:	December 2019
CL for comments on JMPR proposals (STEP 3):	March 2020
If no concerns, CCPR proposes draft MRLs to CAC (STEP 5/8):	April 2020 (CCPR 51)
CAC adopts MRLs (to become CXLs):	July 2020



Openness, transparency, inclusivity

- All interested members and observers invited to participate
- Operates throughout the year with prescribed deadlines
- Increasing level of information:
    - commodity lists, number of field trials, manufacturer identity, registration status, MRL/LOQ status
- Compound given a date-stamp when all nomination and scheduling criteria are met

2019 Proposed Schedule of new compound evaluations

PRIORITY	DATE STAMP	TOXICOLOGY	RESIDUE	PRIORITISATION CRITERIA		COMMODITIES	RESIDUE TRIALS	MEMBER / MANUFACTURER	COMMENTS
				REGISTERED	MRL > LOQ				
3	4/13/15	Metconazole	Metconazole	Y	Y	USA- Stone fruit group; Blueberry; Banana; Garlic; Onion, Bulb; Legume vegetables; Pulses; Soya bean; Root and tuber vegetables (except Sugar beet root); Sugar beet roots); Barley; Maize; Oats; Rye; Triticale; Wheat; Sugar cane; Tree nuts; Oilseed (except Cotton seed, Peanuts, Soya bean and Sunflower)"; Cotton seed; Peanuts; Sunflower seed; Meat (from mammals other than marine mammals); Mammalian fats (except milk fats); Edible offal (Mammalian); Milks; Poultry meat; Poultry fats; Poultry, Edible offal; Eggs; Peanut oil, crude	USA- Banana (13), barley grain (13), blueberry (14), cotton seed (13), corn maize (38), sweet corn (13), tree nuts (18), peanuts (14), soya bean (38), stone fruits (30), sugar beet roots (13), sugarcane cane (8), sunflower (13), oats (13), rape oilseed (16), dried shelled peas pulses (15), dry beans (16), triticale wheat (34), potato (33), fresh legumes, peas without pod (13), onion (4), garlic (3)	Japan: Valent USA Corporation, on behalf of Kureha Corporation	fungicide: Request to reschedule from 2018 to 2019
5	15/2/17	Pyridate	Pyridate	Y	Y	Alfalfa, cabbage, kale collard, clover, Leek spring onion chive, Onion shallot garlic, chickpea	Alfalfa, cabbage, kale collard, clover, Leek spring onion chive, Onion shallot garlic, chickpea : Number of field trials to be advised	Belchim Crop Protection	

JMPR evaluations workload – training of new reviewers (eg. USDA-FAS)

2019 Proposed Schedule of new uses and other evaluations

PRIORITY	DATE STAMP	TOXICOLOGY	RESIDUE	COMMODITIES	RESIDUE TRIALS	MEMBER / MANUFACTURER	COMMENT
1	13/7/16		Chlorantraniliprole (230)	PALM OIL (MALAYSIA) LABEL PROVIDED ON 13 JULY 2016 / Pulses	Palmoil (4), peas (6), beans (6)	DuPont	
2	30/8/16	Chlorothalonil (81)	Chlorothalonil (81)	orange; lemon; grape fruit; lettuce; strawberry; almond; radish (root veg); mustard greens; guava; lychee, / USA- CRANBERRY (under the 4 year rule).	Orange (12), Lemon (6), Grapefruit (6), Lettuce (13), Strawberry (8), Almond (6) radish (7); mustard greens (8); guava (6); lychee (4) cranberry (6)	Syngenta	fungicide / requested move from 2018
3	30/8/16		Mesotrione	CITRUS, POME FRUIT, STONE FRUIT, TREE NUTS	Citrus – orange, grapefruit, lemon (23), Pome fruit – apple, pear (13), Stone fruit – cherry, peach, plum (21), Tree nuts – almond, pecan (10)	Syngenta	requested move from 2018
4	30/8/16		Thiabendazole	LEGUMES AND PULSES	Legumes and pulses (43)	Syngenta	

Extraordinary Meeting of JMPR
Supported by Canada

SUCCESS!!!!

Year	CCPR	new CXLs
2017	49	485
2016	48	392
2015	47	349
2014	46	300
2013	45	328
2012	44	251
2011	43	286
2010	42	205

Revocation of CXLs

CXLs can be revoked following periodic review and 'new use and other' evaluations:

- Periodic review - after compound evaluation, CCPR recommends revocation of CXLs for unsupported commodities
- Periodic review / New use & other evaluations – following evaluation, new MRL replaces old CXL
- Periodic review / New use & other evaluations - Crop grouping MRLs replace individual commodity CXLs

Deletion of compounds

- No known national registrations
- All CXLs revoked during periodic review

Compounds for which all CXLs revoked since 2002

2015/2016	diclofluanid (82), tolyfluanid (162), tecnazene (115), bioresmethrin (93) - no national registrations
2010/2011	vinclozolin (159), procymidone (136)
2008/2009	mevinphos (53)
2006/2007	fentin (40),
2004/2005	hexaconazole (170), ethion (34), bendiocarb (137)
2002/2003	monocrotophos (54), parathion – ethyl (58), phosphamidon (61), omethoate (55), mecarbam (124), propoxur (75), paclobutrazol (161), anilazine (163)

National Registrations Database

National Registrations Database

1. Assist efforts to maintain CXLs for unsupported commodities
2. Determine which compounds have no national registrations
3. Locate data to support new & other uses including minor uses

Currently, country-specific worksheets listed registered uses (product labels) for compounds listed in Table 2A and 2B.

CCPR49 – Suggestion to broaden scope to include all compounds
Future Management??

Worksheet: Australia & Codex

No.	Compound	Registered	Australia	Codex
46	hydrogen phosphide	Y	Assorted tropical and subtropical fruits – inedible peel Cereal grains Dried foods [except dried fruits; dried vegetables] Dried fruits Dried vegetables Oilseed Peanut Pulses Spices	Cacao beans Cereal grains Dried fruits Dried vegetables Peanut Spices Tree nuts
110	imazalil	Y	Chicken, Edible offal of Chicken meat Citrus fruits Eggs Melons, except watermelon Mushrooms Pome fruits Potato	Banana Citrus fruits Cucumber Gherkin Melons, except watermelon Persimmon, Japanese Pome fruits Potato Raspberries, Red, Black Strawberry Wheat Wheat straw and fodder, Dry

Conclusions

Openness / transparency = increased demand for evaluations ✓

System supports establishment of CXLs for new / minor uses ✓

Codex IT Platform - eWG Priorties forum - functional ✓

Ongoing concern - evaluator resources and availability ✓

Thank you very much for your kind attention

附件 7-3

Crop Classification and Grouping, Successes and Challenges

Crop Classification and Grouping, Successes and Challenges

William Barney
IR-4 Minor Use Program

1

Crop Grouping

Basic Concept:

- Crop Grouping is used to facilitate the establishment of pesticide MRLs for a large number of crops based on residue data from selected representative crops

2

Crop Grouping, an increasing need

- Address minor uses
- Consumer demand for more diverse food, and new commodities
- Increased globalization of markets, trade
- Need to facilitate import MRLs
- Need for international harmonization (Codex) of crop groups, definitions and vocabularies

3

Crop Grouping Overview

Crop Group considerations:

- Botanical and nomenclature aspects
- Geographical distribution and production
- Cultural practices
- Commercial importance
- Comparison of edible parts
- Comparison of potential residue levels
- Pest problems

4

Crop Grouping – per SUMMIT 1* Minor Uses

- Supports Codex in revising Codex Classification of Food and Animal Feeds including the consideration of the concept of representative crops (extrapolations)
- Recognition of the value of an international crop grouping scheme, with representative crops, which is important in facilitating authorizations for minor crops
- Encourage the development of harmonized global crop grouping scheme for efficacy data

*Common recommendations from GMUS 1 breakout groups

Sub Groups/Extrapolations

Group 003 Stone Fruits	Cherry, Sweet or Cherry, Sour; Plum or Prune Plum; Peach or Apricot	Stone fruits (FS 0012): Apricot; Bullace; Cherry, black; Cherry, Nanking; Cherry plum; Cherry Sour; Cherry, Sweet; Choke cherry; Japanese apricot; Jujube, Chinese; Klamath plum; Nectarine; Peach; Plum; Plum, beach; Plum, Chickasaw; Plumcot; Sloe;
Subgroup 003A, Cherries	Cherry, Sweet or Cherry, Sour	Cherries (FS 0013): Cherry, black; Cherry, Nanking; Cherry Sour; Cherry, Sweet; Choke cherry
Subgroup 003B, Plums	Plum or Prune Plum	Plums (FS 0014): Bullace; Cherry plum; Jujube, Chinese; Klamath plum; Plum, Plum, beach; Plum, Chickasaw; Plumcot; Sloe
Subgroup 003C, Peaches	Peach or Apricot	Peaches (FS 2001): Apricot; Japanese apricot; Nectarine; Peach

International Crop Grouping Consultants Committee (ICGCC)

- The ICGCC was organized and established after the 2002 International Crop Grouping Symposium.
- Led by IR-4, the ICGCC was composed of over 200 crop, agrichemical and regulatory experts, representing more than 30 countries.
- Based on input from the ICGCC, crop monographs and crop group petitions were written and submitted to the EPA.
- The ICGCC has completed its work by creating and submitting proposals to the EPA for revisions to all US crop groups.

Process for Crop Grouping at Codex

- Crop Group petitions from are submitted to the Chairs of the Codex EWG by IR-4.
- The US and the Netherlands prepare crop group proposals for review by CCPR Members.
- Proposed additions by CCPR Members are reviewed by the Codex EWG.
- Finalized proposals are then submitted to Codex Secretariat.
- Proposals are discussed at CCPR meetings
- After agreement each group is held at step seven until the entire "commodity type" is complete.

Codex Criteria for Crop Grouping

- Commodity's similar potential for pesticide residues.
- Similar morphology.
- Similar production practices, growth habits, etc.
- Edible portion.
- Similar GAP for pesticide uses.
- Similar residue behavior.
- To provide flexibility for setting (sub) group tolerances).

Codex Fruit type

Crop Group	NAFTA	Codex	Type (Codex)
Berry & Small Fruit Group	Codified	Adopted	Fruit
Pome Fruit Group	Codified	Adopted	Fruit
Citrus Fruit Group	Codified	Adopted	Fruit
Stone Fruit Group	Codified	Adopted	Fruit
Tropical Fruit Groups – edible and inedible peel	Codified	Adopted	Fruit

Codex Vegetable type

Crop Group	NAFTA	Codex	Type (Codex)
Bulb Vegetable	Codified	Adopted	Vegetable
Fruiting Vegetable	Codified	Adopted	Vegetable
Stalk, Stem and Leafy Petiole	Codified	Adopted	Vegetable
Leafy vegetables (incl brassicas)	Codified	Adopted	Vegetable
Brassica Head/Stem Vegetable	Codified	Adopted	Vegetable
Root/Tuber Vegetable	Submitted	Adopted	Vegetable
Edible Fungi Group	Codified	Adopted	Vegetable
Legume Vegetables	Submitted (7/13)	Adopted	Vegetable
Cucurbit Vegetable	Submitted (4/14)	Adopted	Vegetable

Other Commodity Types

Crop Group	NAFTA	Codex	Type (Codex)
Tree Nut Group	Codified	Step 7	Nuts and Seeds
Oilseed Group	Codified	Step 7	Nuts and Seeds
Seed for Bev and sweets	NA	To be submitted	Nuts and Seeds
Herbs and Spices	Submitted	Step 7	Herbs and Spices
Cereal Grains	Submitted	Adopted	Grasses
Forage/Fodder/ Straw of Cereal Grains	Submitted	To be submitted	Grasses
Grasses for sugar or syrup	To be submitted	Adopted	Grasses

CCPR 2012- Principles and Guidance for Selection of Representative Commodities For the Extrapolation of MRLs to Commodity Groups

- This document incorporates proposed *representative commodities* for all of the fruit (Table 1), vegetable (Table 2) and Grasses (Table 3) type groups.
- Tables 4 (Nuts and Seeds) and Table 5 (Herbs and Spices) will be discussed at CCPR50. This will complete all of the Class A Primary Food Commodities of Plant Origin
- Adopted as a separate document in the *Codex Classification of Foods and Animal Feeds*

The objective of this document

- (1) propose criteria for the selection of representative commodities;
- (2) propose example representative commodities and
- (3) provide a detailed justification for the selection of the representative commodities.

Criteria for Selection of Rep Commodity

- A representative commodity is most likely to contain the highest residues.
- A representative commodity is likely to be major in terms of production and/or consumption.
- A representative commodity is most likely similar in morphology, growth habit, pest problems and edible portion to the related commodities within a group or subgroup.

Challenges of crop grouping update

- Many many situations to deal with, different crop group schemes, different rep crops for different regions.
- Foot notes such as: Table 1. …Alternative representative commodities may be selected based on documented regional/country differences in dietary consumption and/or areas of production.
- Representative Commodities provide Significant benefits to Minor uses

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Crop Grouping Impacts

- NAFTA collaboration
  - Identical regulatory Directives in Canada
  - Adoption by Mexico
- The Codex Committee on Pesticide Residues (CCPR) is approving crop grouping, and this will continue advancing over the next several years
  - Codex may serve as a key model for other countries
- International collaboration is expected to result in increased potential for resource sharing
- Help to address many of the minor use needs
- Need a scheme for Performance or value data requirements.

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THANK YOU FOR YOUR KIND ATTENTION
Questions / Comments?

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附件 7-4

Recent Work in the WTO SPS Committee on MRLs

Recent Work in the WTO SPS Committee on MRLs

Third Global Minor Use Summit
Montreal, Canada
October 1, 2017

Julia Doherty
Deputy Assistant USTR for Agricultural Affairs
Office of the U.S. Trade Representative

Goals of this presentation

- Role of the WTO SPS Committee
- Recent Discussions on MRLs
- Joint proposal by Kenya, Uganda and the US
- Possible Next steps

WTO SPS Committee

- Regular forum for consultation and to carry out functions related to implementation of the SPS Agreement
  - Non-discrimination
  - Based on science: international standards or risk assessment
  - No more trade restrictive than necessary
  - Transperency

Role on International Standards

- Encourage and **monitor** the use of international standards
- Sponsor technical consultation and study
  - *"with objective of increasing coordination and integration between international and national systems and approaches for [...] establishing tolerances for contaminants in food..."*
- Maintain close contact with Codex
  - *"with objective of securing the best available scientific and technical advice..."*

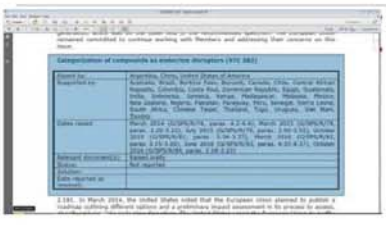
Role on Specific Trade Concerns (STCs)

- Forum for consultations with countries to resolve trade concerns with specific SPS measures
- Raise trade concerns, singly and in coalitions, on the "floor" of the Committee
- Provides regular access to SPS and trade officials for "bilateral" meetings on the margins

Recent Work on MRLs

- STC discussions on EU Proposal for the Categorization of Compounds as Endocrine Disruptors and EU Regulation 1107/2009
- Glyphosate: Monitoring Use of the International Standard
- India 2015 Paper: "Need for Measures on Detection of Pesticide Residues Not Registered in the Country of Import for Unimpeded Flow of Trade"
- October 2016 Pesticide MRL Workshop
- Joint Submission on MRL Next Steps – Kenya, Uganda and USA

EU Endocrine Disruptors



"Specific Trade Concerns – Note by the Secretariat"

7 March 2017

G/SPS/GEN/204/Rev.17

Codex Standard for Glyphosate

- July 2015: U.S. raises concern that Members are considering/taking action to withdraw tolerances based on hazard report; Ukraine supports.
- October 2015: U.S. again raises concern; Brazil, Canada, China and Paraguay support.
- July 2016: U.S. again raises concern, calls out EU for not reauthorizing based on EFSA opinion; Argentina, Brazil and Canada support.
- October 2016: U.S. raises concern, stresses JMPR conclusion; Argentina, Australia, Brazil, Canada and New Zealand support.
- March 2017: Argentina raises concern, calls out EU extension to end-2017; U.S., Canada, Brazil, New Zealand, Australia and Chile support.
- July 2017: Argentina raises concern, calls out EU extension to end-2017; Brazil, Canada, U.S., Dominican Republic, and Australia support

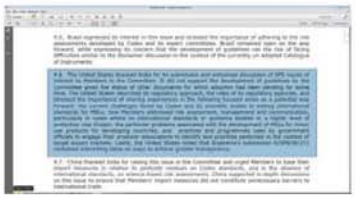
India – LOD Paper*

- Focused on LOD problems faced by developing country exporters in major import markets
- Recommended the Committee develop guidelines before importing countries resort to LOD for non-registered pesticides
- Many countries noted importance and complexity of issues; no consensus on developing guidelines
- Committee agreed to explore issues in more depth

*G/SPS/GEN/284

U.S. View: Focus Trade Community on…

- Current challenges in Codex and JMPR
- Central role of risk analysis in setting MRLs
- Minor use & specialty crop issues
- Vital role of producer groups/private sector
- Need to increase transparency



MRL Workshop: Objectives

- Review elements of the SPS Agreement and dispute settlement reports relevant to MRLs
- Review issues and approaches to MRL work in Codex and scientific bodies
- Share information on relevant international, regional and bilateral work on MRLs
- Share experiences in establishing and complying with MRLs, including information on Members domestic legal and regulatory frameworks

Workshop on Pesticide MRLs

October 2016

Joint Paper: Kenya, Uganda & US

- Set out core conclusions of workshop
  - Central role of risk analysis in protecting health, enabling safe use, and facilitating trade
  - Broad range of MRL-related issues are currently having a significant impact on trade in food and agricultural products
- Proposed next steps in 5 areas of MRL-related trade issues

Proposed Next Steps for Committee

- Enable JMPR to Better Respond to Increased Demand and Monitor Progress on New Codex MRLs
- Strengthen Notification Practices for Greater Transparency and Predictability on MRLs
- Expand Reporting to the Committee on International and Regional Activities on MRLs
- Collaborate on Solutions for MRLs for Minor Use and Specialty Crops
- Strengthen Role of the Committee in Increasing Coordination and Harmonization

Vehicle to Take Forward Consensus

Thank You

Julia Doherty
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附件 7-5

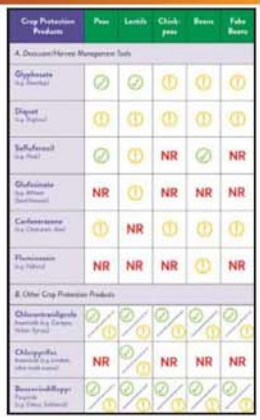
International MRL Harmonization Activities

Outline

- Objectives and approach
- The case for MRL harmonization – increasing impacts on growers
- Beginning time series data on publicly reported MRL noncompliances
- Status of International Agri-Food Network (IAFN) coalition, workplan and next steps; other global efforts by International Grain Trade Coalition

Managing Risk of Noncompliance

- Short term: ensure use of active ingredient will not create unacceptable level of trade risk:
  - Balance, not eliminate, trade risk
  - Canadian example: multi-commodity grower advisory www.keepingitclean.ca
- Medium term: work to attain the required MRL (if possible)
- Longer term: broader, multi-commodity, multi-country efforts to advocate for harmonization of MRLs through improved institutions (Codex), mutual recognition, regulatory cooperation, trade agreements, etc.



Is not using available technology an acceptable long-term solution?

- Farmers* spend more than:
  - $2.3 billion a year on crop protection products
  - $1.9 billion on seeds with novel traits
- Investments in crop protection and biotechnology result in:
  - Increased yield* - 42% more grain (wheat, corn, canola, barley, etc.)
  - Improved environmental sustainability – 35 million more acres would need to be in production in Canada if these products not used
  - Lowers the cost of production – benefiting growers and consumers - Savings on food that requires wheat flour or soy may be as high as 69%

*Canadian examples
Source: CropLife Canada

Structural shift in in trading environment

1. **More missing MRLs and potential application of defaults**

   (greater number of missing MRLs as more countries move away from the global standard (Codex) and adopt country-specific MRL lists)

2. **Residue testing more sensitive**

3. **Heightened monitoring/testing**

More missing MRLs – prevalence of national MRL lists

Number of countries – no weighting

- Other
- National, Codex
- National
- EU deferral
- Codex and Codex recommended

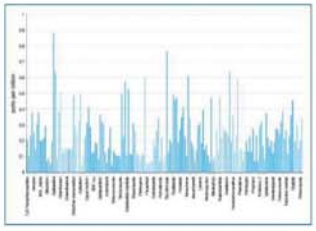
- Complex mix of systems in use globally
- Codex is global standard, but fewer countries utilizing
- Several key trading partners have national lists, but also defer to Codex if an MRL is missing
- National MRL lists by individual countries are now the majority of the value traded globally*

2015 Canadian Export Destinations – 91 Countries
India Codex

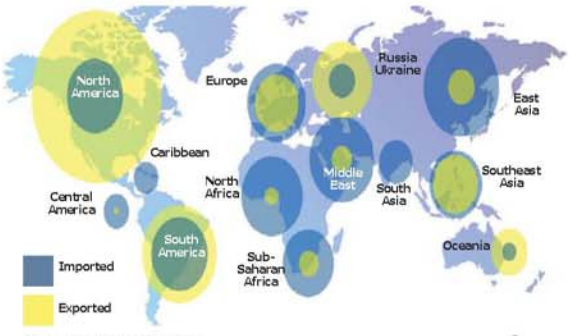
Residue testing more sensitive

Results from Quick, Easy, Cheap, Effective, Rugged, and Safe (QuEChERS) technique followed by analysis with a Triple Quadrupole Gas Chromatograph coupled with a Tandem Mass Spectrometer (GC-MS/MS).

Can identify over 260 pesticide residues per crop at well below 1 ppb with a good level of selectivity.



Who's testing?



Source: International Grains Council

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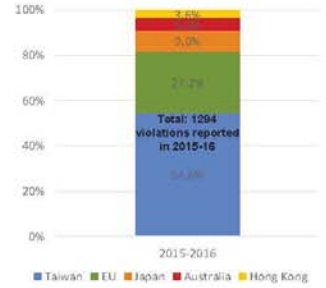
National list, defer to Codex – a solution?

Country	MRL Scheme
United States	National only, zero default (any detectable residue is a violation)
Canada	National only, 0.1 ppm default
Japan	National only, 0.01 ppm default
Australia	National only, zero default (any detectable residue is a violation)
Mexico	National , defers to US MRLs if missing national MRL, undefined default
Peru	Codex only, has announced plans to move to national MRL list, undefined default
Singapore	National, defers to **Codex** if missing national MRL, undefined default
Brunei	National, defers to **Codex** if missing national MRL, undefined default
Malaysia	National, defers to **Codex** if missing national MRL, 0.01 ppm default
New Zealand	Applies least restrictive of New Zealand national MRL or **Codex**, 0.1 ppm default
Chile	National, defers to **Codex** if missing national MRL, undefined default
Vietnam	National, presumed to defer to **Codex** if missing national MRL, undefined default

IAFN and IGTC

- IAFN (International Agri-Food Network) – 12 international associations or farm groups with unique access to UN events and processes; role of representing private sector in most food security and nutrition discussions. Elected focal point of the Private Sector Mechanism to the UN Committee on World Food Security.
  - Codex process improvement and reform
- IGTC (International Grain Trade Coalition) – 26 trade associations and councils around the world working to support trade of grains, oilseeds, pulses and other agri-bulks join forces under the guidance of their more than 8000 members in 85 countries.
  - Policy advocacy to achieve mutual recognition of risk assessments, MRLs and MRL deferral paths that reference Codex MRLs

Impact of zero- or near-zero default MRLs: Global MRL Violations



Five countries publicly report all MRL violations (US also does but without accompanying data)

These violations can be for two reasons:

1. residue exceeds established MRL
2. residue exceeds default MRL*

* zero- or near-zero MRL established in the absence of a risk assessment

MRL violations for Australia, EU, Hong Kong, Japan, & Taiwan, from July 1, 2015 until June 30, 2016.

Implied number of missing MRLs – MRL Counts by Country

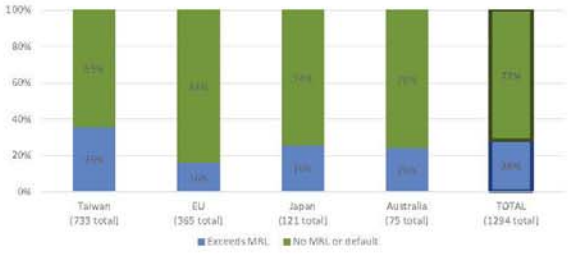
with Deferral MRLs without LOD/LOQ

Markets	Extrapolated MRL Counts with Deferral MRLs without LOD/LOQ
EU	52,768
Mexico	35,394
India	34,836
US	33,500
Taiwan	32,117
Canada	30,942
Thailand	22,878
Korea	19,983
Codex	19,822
Vietnam	15,505
China	12,861
Indonesia	6,416

- EU: over 50,000 MRLS
- By Comparison…
  - US = 33,500
  - Canada = 30,942
  - CODEX = 19,822
  - China = 12,861

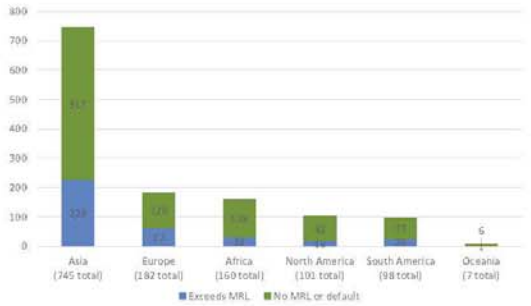
MRL violations due to no MRL or default

Taiwan, EU, Japan, and Australia



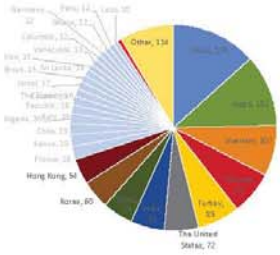
MRL violations from July 1, 2015 until June 30, 2016. Taiwan violations of 0.01 ppm or less marked as "No MRL or default"

MRL violations by continent of origin



MRL violations for Australia, EU, Japan, & Taiwan, from July 1, 2015 until June 30, 2016. Taiwan violations of 0.01 ppm or less marked as "No MRL or default"

MRL Violations by Country of Origin



	Country	Violations
1.	China	179
2.	Japan	152
3.	Vietnam	107
4.	Thailand	92
5.	Turkey	89
6.	The United States	72
7.	India	71

MRL violations for Australia, EU, Hong Kong, Japan, & Taiwan, from July 1, 2015 until June 30, 2016.

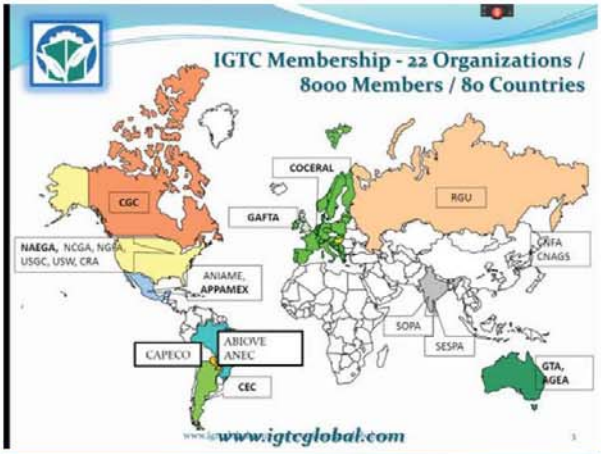
IAFN Coalition for an enhanced Codex

Current Members:

- Canadian Canola Growers Association
- The Coca-Cola Company
- CropLife International
- European Cocoa Association
- European Coffee Federation
- FoodDrinkEurope
- Global Pulse Confederation (GPC)
- Grain and Feed Trade Association (GAFTA)
- International Center for Tropical Agriculture (CIAT), member of the CGIAR
- International Citrus Growers
- International Organization of Spice Trade Associations (IOSTA)
- International Trade Center (affiliated with WTO and UNCTAD)
- Instituto Interamericano de Cooperación para la Agricultura (IICA)
- Minor Crop Farmers Alliance (MCFA)
- PepsiCo
- Rural Women in Agriculture (Kenya)
- Tea Association of Canada, on behalf of International Tea Commission
- World Spices Organisation

Current Observers:

- British Coffee Association (BCA)
- Dow AgroSciences
- European Rice Millers (no international rice organization)
- International Coffee Organisation (ICO)
- International Cotton Association
- International Grain Trade Coalition (IGTC)
- MAIZALL
- US Grains Council
- Syngenta



International Grain Trade Coalition

- Formed in 2001 to advise governments on implementation of the Biosafety Protocol; mandate broadened to focus on the goal of avoiding disruptions in the international trade of grain, oilseeds, pulses and derived products.
- *Position paper highlights*:
  - All countries to use available Codex MRLs as an automatic, interim measure until the country in question completes its evaluation process and formally establishes an MRL.
  - Address unnecessary time delays to adoption of a Codex MRL where prior assessments by member countries (e.g., global joint reviews) could form the basis of a Codex assessment.
  - Explore harmonized approached to MRL setting among the parties, such as agreement on workable elements of a policy on mutual recognition of MRLs or MRL equivalence.

IAFN Coalition Position Paper - highlights

- Never a greater need for a single, global MRL reference.
- JMPR and CCPR: important role for both consumer safety AND trade, food security
- Codex MRLs are referenced by WTO as international standards
- Lack of or misaligned MRLs may disrupt trade, constrain the use of pesticides including non-use of newer, safer compounds for farmers in developed and developing countries alike.

Meetings and presentations by IAFN coalition

- 2014 FAO Committee on Commodity Problems, Rome
- 2015 CCPR Beijing
- 2016 WTO Public Forum, Geneva
- 2016 International Grain Trade Coalition London
- 2016 Committee on Commodity Problems
- Oct 2016 WTO Workshop
- Nov 2016 CCLAC
- Feb 2017 FAO Open-Ended Working Group on funding
- March 2017 Americas Pesticide Workshop
- April 2016 CCPR

Thank you

Pulse Canada

附件 8-1

EU Legal framework for pesticides

EU Legal framework for pesticides

Global Minor Uses Summit
1-4 October 2017, Montreal, Canada

Klaus Berend
Head of Unit Pesticides and Biocides
DG Health and Food Safety
European Commission

The regulatory lifecycle of a Plant Protection Product

Production phase	Use phase	Consumption phase
Regulation (EC) No 1107/2009 on placing of PPP on the market	Directive 2009/128/EC on Sustainable Use of Pesticides	Regulation (EC) No 396/2005 on MRLs of pesticides

Horizontal legislation, esp. Regulation (EC) No 178/2002 General Food Law

Separation risk assessment / risk management

1. Application

Industry → Data dossier

2. Risk Assessment

1 Member State → Draft Assessment Report

European Food Safety Authority (EFSA) + all Member States → Expert meetings, Peer review of the DAR

EFSA → "Conclusion on the peer review"

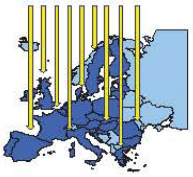
3. Risk management

Commission + all Member States → (Restricted) approval / Non-approval

"Approval" vs. "Authorisation"

Active substance

Formulated Product



Active Substances = Approval at EU level

- Application for approval
  - **Data requirements**
- Evaluation shared between 28 Member States: for each substance => one Rapporteur MS
  - **Uniform principles of evaluation**
- Peer review by the European Food Safety Authority
- Approval =>List of approved substances
  - http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=homepage&language=EN
- Total length of the procedure = 2,5 to 3 years
- First approval for 10 years – renewal for up to 15 years

Criteria for approval of substances

- *Plant protection products containing the substance must:*
  a) be sufficiently effective;
  b) have no immediate or delayed harmful effect on human health, including that of vulnerable groups, or animal health,
  c) have no unacceptable effects on plants or plant Products
  d) shall not cause unnecessary suffering to vertebrates to be controlled
  e) shall have no unacceptable effects on the environment (biotic and abiotic)

Exclusion from approval for substances of high concern (health or environment): **CMR Cat 1A or 1B, POP, PBT, vPvB, endocrine disruptor**

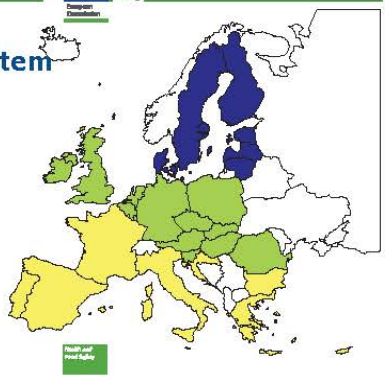
- Limited derogation possibilities from these criteria are provided:
  - ✓ Serious danger to plant health
  - ✓ negligible human exposure

Plant Protection products = Authorisation at national level

- In assessing applications, Member States evaluate the active substance- and the product-dossier
- In granting authorisations, MS set out the requirements for placing on the market, e.g.:
  - classification
  - conditions of use
  - labelling
- Member States enforce compliance with the authorisation
- Commission monitors and controls Member States activities

EU zonal system

- North
- Center
- South



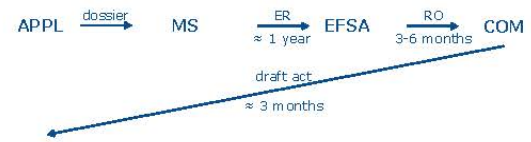
"Zonal" Evaluation and recognition of authorisations

- One evaluation per zone
  - even if applications in several Member States of the zone
  - carried out by on "zonal rapporteur" Member States
  - including a zonal peer review
- Obligatory recognition of authorisations within the zone, based on the zonal evaluation
- For greenhouse, seed treatment and post-harvest: One evaluation for whole EU
- Total length of the procedure = 16 to 22 months
- Duration of the authorisation = Duration of approval of substance + one year

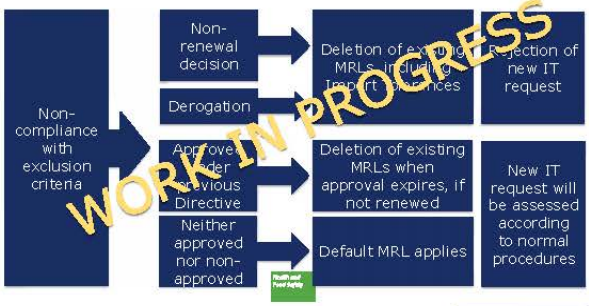
Regulation (EC) No 396/2005 – setting EU MRLs

From application to MRL setting

(MRL applications based on EU uses and import tolerance requests)



Impact of exclusion criteria on MRLs



Minor Uses Developments in the European Union

Global Minor Uses Summit

1-4 October 2017, Montreal, Canada

Jeroen Meeussen - EU Minor Uses Coordination Facility

MinorUses
EU Minor Uses Coordination Facility

Co-funded by the European Union

Content

- EU Regulatory Framework
- Regulatory hurdles

MinorUses
EU Minor Uses Coordination Facility

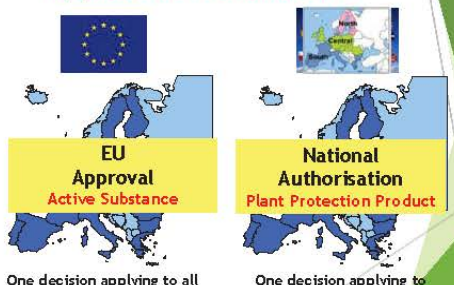
EU Pesticide Legislation

Impact on minor uses

PLACING ON THE MARKET → **Regulation 1107/2009**

RESIDUES IN FOOD/FEED → **Regulation 396/2005**

Regulation (EC) No 1107/2009
Approval vs Authorisation



One decision applying to all 28 Member States

One decision applying to one Member State

Minor Uses - definition

Regulation (EC) No 1107/2009 - Article 3(26):

Use of a plant protection product in a particular Member State on plants or plant products which are:

(a) not widely grown in that Member State,

or

(b) widely grown to meet an exceptional plant protection need

National dimension

Minor crop

Minor use on a major crop

Extension of Authorisation

- Existing authorisations can be extended to minor uses (derogation for efficacy and phytotoxicity)
- Member States may encourage /facilitate extension of uses
- Mutual recognition of extensions

Regulation 1107/2009

EU Pesticide Legislation

MRLs in food and feed

- EU: two residue zones
- Guidance Document: Rules for residue extrapolation

RESIDUES IN FOOD/FEED

Regulation 396/2005

REFIT

Regulatory Fitness & Performance Program

Formal evaluation process of Reg (EC) 1107/2009 and Reg (EC) 396/2005

Commission's commitment to ensure that EU legislation is effective and efficient in achieving its public policy objectives at minimum cost.

Review Clause:
Article 82: Reg (EC) 1107/2009
Article 47: Reg (EC) 396/2005

Content

- EU Regulatory Framework
- Regulatory hurdles

MinorUses

Minor Uses - Definition

Minor Uses - Definition

Regulation (EC) No 1107/2009 - Article 3(26):
Use of a plant protection product in a particular Member State on plants or plant products which are:
(a) not widely grown in that Member State,
or
(b) widely grown to meet an exceptional plant protection need.

Is this a workable definition?

- Leaves it up to individual Member States to define what is considered a 'minor use/crop';
- Hinders the zonal procedure and mutual recognition;
- A definition based on acreage (at least per zone) is favoured by EU growers associations.

2, 3, 4 zones

Reg 1107/2009 Zones

EPPO Zones

EPPO Zones
vs
Reg 1107/2009 Zones

Reg 396/2005 Zones

GLOBAL RESIDUE STUDY-Blueberry

"European Commission and Member States considered these findings as interesting and worthwhile to be further explored in the long term and at international level."

26 total field sites in 9 countries

Residue data generated outside the EU

- In general, Member States support the use of residue data generated outside the EU, when scientifically valid, in granting minor uses extensions.
- Active substance data requirements (Regulation (EC) No 283/2013) which state under Part A Section 6.3: *Part of the trials may be replaced by trials performed outside the Union, provided that they correspond to the critical GAP and that the production conditions (such as cultural practices, climatic conditions) are comparable.*
- What if all trials are generated outside the EU?

(Un) Harmonized Crop Grouping and Extrapolation

Some points for discussion...

- An EU wide definition of 'minor crop' and 'minor pest' is needed to facilitate minor use authorisations.
- Existing residue data from non-EU countries should be acceptable if the GAP is identical or comparable to the EU application.
- Applications for MRL's should always be maximally extrapolated to the entire crop group.
- When a Member State grants an authorization it should put all minor crops within a crop group on the label, even though the application may only have been done for the major crop.
- It is critical to increase the availability of sustainable PPPs even more now the EUs ongoing (regular) review of active substances raises doubts about the safety of several substances which are currently approved, which might lead to a further loss of products that were in use -also for speciality crops- up to now.

THANK YOU FOR YOUR ATTENTION

ANY QUESTIONS

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MinorUses

NEWSLETTER

附件 8-2

Minor Uses A North American Perspective

Health Canada / Santé Canada

Canada

Minor Uses

A North American Perspective

October 2, 2017
Dr. Peter Chan
Director General, PMRA Health Canada
Rick Keigwin
Director for Programs (acting), Office of Pesticide Programs EPA

YOUR HEALTH AND SAFETY... OUR PRIORITY.

Outline

- Regulatory Policy considerations and activities that support minor uses
- MRLs
- International Activities
- Regulatory Challenges

Regulatory Policy Considerations and Activities

Field Trial Requirements for joint US/Canada registration

- Reduced number of field trials required for crops for which a joint registration is sought. Based on total production across North America and dietary share of the crop.
- Results in savings of up to 50% of number of trials if trial requirements for United States and Canada were considered separately.

Exchangeability

- Analysis of field trial residue data from the United States and Canada indicated that, in general, there was very little difference in residue levels between Canadian and United States growing regions.
- Supports the exchange or use of data from one country to support a registration in another country.
- This work is now being considered at the global level (Global Zoning)
- Will reduce the data required to support minor uses

Regulatory Policy Considerations and Activities

Value Requirements

- Value data is not required for tolerance setting purposes for the EPA
- In Canada the updated Value guidelines provide 3 approaches to satisfy the data requirement for the addition of minor uses
  - No value data are required for the "A" Priorities chosen at the Canadian Minor Use Workshop. A label review will be conducted to ensure that the proposed use pattern is consistent with the registered use pattern.

Data Protection

- In Canada, an extension of the exclusive protection period is granted when minor uses are added to a label. This was developed with existing frameworks from other Regulatory Authorities in mind.
- The exclusive protection provided to the original data set is extended by one year for each three eligible minor use crops added to a label, up to a maximum of five additional years of exclusive data protection.
- The US framework was consulted while developing the regulations within Canada. Data protection is included in US statute.

Regulatory Policy Considerations and Activities

Residue Chemistry Crop Groups and International Crop Grouping Consulting Committee (ICGCC)

- Revisions to existing North American Residue Chemistry Crop Groups
- Purpose is to update the crop groups to include "orphan crops" that are not members of any existing groups
- To date have revised 10 existing crop groups and established 4 new crop groups
- Recently approved, in principle, 2 new crop groups for the Herbs and Spices to replace existing crop group 19 Herbs and Spices.
- Concurrent work at Codex to revise the Classification of Food and Feed
- Codex revisions are considered when revising the crop groups through the ICGCC work.
- Many of the additional commodities added to the revised and newly established crop groups are minor crops or specialty crops.

Regulatory Policy Considerations and Activities

Minor Use Specific Activities

- Minor Use Programs are established in both the United States (IR-4) and Canada (Pest Management Centre).
- Each country holds a Priority setting workshop each year and growers are able to identify and choose a number of top priorities for minor uses.
- PMC and IR-4 work together to identify any projects that can be conducted jointly between the two countries to support joint minor use review submissions.
- Provides growers in Canada and the US simultaneous access to crop protection tools.

Maximum Residue Limits (MRLs)

- United States and Canada use the OECD MRL calculator to determine MRLs
- MRLs are calculated by entering residue data from the crop field trials into the calculator, which generates a statistically robust and scientifically-defensible MRL value in the region of the 95th percentile of the underlying residue distribution (conservative).
- Provided the same data is inputted into the calculator, the same MRLs will be established.
- First step in determining an MRL is to use the OECD calculator.
- If a Codex MRL is established for the same pesticide/crop combination, this is taken into consideration when determining what MRL value will be established in order to support trade and minimize trade irritants
- Current work between the United States and Canada on how to address Crop Group MRLs when inputting data into the OECD calculator. Will lead to aligned crop group MRLs between the United States and Canada

International Activities that help support Minor Uses

Codex Committee on Pesticide Residues (CCPR) and Joint Meeting on Pesticide Residues (JMPR)

- Both the United States and Canada participate at CCPR and JMPR
- Enhances North America's influence on Codex deliberations and outcomes
- Promote the development of science-based standards resulting in fair practices in food trade (e.g. establishment of MRLs
- Ensure CCPR Priority Lists include common Canadian and American (pesticide/crop) priorities, including minor uses, based on stakeholder interests.
- At CCPR49, held in April, 2017, PMRA presented a proposal to fund an extraordinary session of the JMPR in May 2019 to help eliminate some of the backlog of work for JMPR.

International Activities that help support minor uses

OECD

- Working Group on Pesticides; Expert Groups including the Residue Chemistry Expert Group; Test Guideline Program; Registration and Risk Reduction Steering Groups; Minor Use

North American Free Trade Agreement (NAFTA)

- Technical Working Group on Pesticides
- Regulatory Cooperation Council

Joint Reviews

Supporting NAFTA Minor Use Joint Reviews and Workshares as well as OECD Global Joint Reviews

Asia-Pacific Economic Cooperation

- US EPA is working towards developing a guidance document for establishing import MRLs for imported foods where no domestic equivalent MRL exists. PMRA is engaged in these discussions.

Regulatory Challenges

Different MRLs

- May not be aligned for a variety of reasons, including:
- Different data packages submitted to different regulatory bodies
- Data packages submitted at different times
- Differences in residue definitions
- Different soil types, climate, pest pressures leading to different application rates, different cGAPs, hence different MRLs

Different Crop Grouping Schemes

- Different residue chemistry crop grouping schemes (ICGCC, Codex, EU) can affect what minor crops can be considered for registration based on data extrapolation from representative crops.

Successes

- Participating in the development of science policies, approaches and MRL-related activities at the Canadian, NAFTA, OECD and international level (e.g., Codex)
  - Adopted and implemented the use of the OECD MRL calculator
  - Continued collaboration on the alignment of the interpretation of the OECD Guidance Document on Residue Definition
  - Continued participation on the International Crop Grouping Consulting Committee (ICGCC) for alignment of Crop Groups
  - Capacity Building for Regulatory Authorities developing a Minor Use Program (Australia, Brazil, China)

Questions?

附件 8-3

ASEAN harmonized MRLs and Minor Use

ASEAN harmonized MRLs and Minor Use

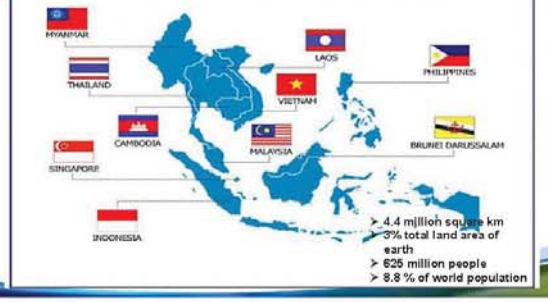
Panpilad Saikaew
National Bureau of Agricultural Commodity and Food Standards, Thailand

GMUS3, Quebec, Canada

Outline

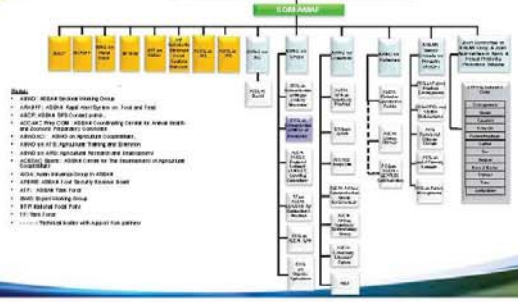
- Introduction of EWG-MRLs
- ASEAN Harmonised MRLs and current situation
- Way Forward

ASEAN Member Countries



- 4.4 million square km
- 3% total land area of earth
- 625 million people
- 8.8 % of world population

Structure of ASEAN Cooperation in Food, Agriculture and Forestry



Establishment of ASEAN MRLs

1. Adoption from Codex MRLs → *early stage of EWG MRLs.*
2. Extrapolation from similar crops → *very few cases due to lack of information on crop grouping and representative crops in the region.*
3. Pesticides residue trials → *following JMPR procedures*

Risk assessment

- Approach: JMPR
- Residue definition and toxicity data: JMPR
- Statistical Method for Estimation of MRLs: OECD Calculator
- Consumption data:
  For chronic: Cluster 05 and 09, GEMs/Food database
  For Acute: data from proposed ASEAN Member Country

MINOR CROPS

- A minor crop may be defined as:
  "a crop that is grown on a small area and therefore uses amounts of pesticides that are too small to justify standard pesticide registration"
- MRLs may be obtained for pesticide residues on commodities from minor crops by:
  I. Inclusion in a commodity group MRL
  II. Extrapolation from pesticide uses on a relevant major crop
  III. Evaluation of an adequate data package for the use on a minor crop
- Points to note
  I. GAP for the minor crop must be the same as or similar to that of the major crop
  II. GAP for the minor crop must be valid, e.g. on a registered label

Recent ASEAN Work on Minor Crops

- Conducting the Supervised Residue Trial (SRT)
  - carried out by government agencies (Thailand, Malaysia, Indonesia)
  - carried out under ASEAN – WTO STDF Project on Pesticide Residue Data Generation for Establishment of Codex MRLs
- Setting up ASEAN MRL from those SRT data
- Further Submission to JMPR for the establishment of MRLs as Codex MRLs
- Extrapolation from Codex MRLs : few cases

MRL Harmonisation for Minor Crop

- Promoting the registration for minor crop/crop group
- Recognizing of Codex MRLs and Crop Classification
- Sharing the SRT and relevant data
- Example : Import MRL Guideline for Pesticides (APEC)
  - ✓ emphasis on the use of JMPR evaluation and Codex MRLs
  - ✓ science-based using internationally accepted risk assessment methodologies

Way Forward

- Continually cooperation on conducing the SRT for submission in regional and international level
- Consider the possibility for the nomination of manufacture via the authority of ASEAN Member Country
- Recognize Codex Classification into regional level
- Establish official criteria for the establishment of subgroup and group MRLs and extrapolation
- Generate the relevant data (e.i. consumption data) and submit into the regional level and international level

附件 8-4

Emerging Challenges and opportunities for work in Minor crops in Africa

Emerging Challenges and opportunities for work in Minor crops in Africa

Presentation made during the
Third Global Minor Use Summit,
1st – 4th October, 2017
Fairmont Queen Elizabeth Hotel, Montreal, Canada

Lucy Namu
Kenya Plant Health Inspectorate Service (KEPHIS)
Head – Quality Assurance and Laboratory Accreditation

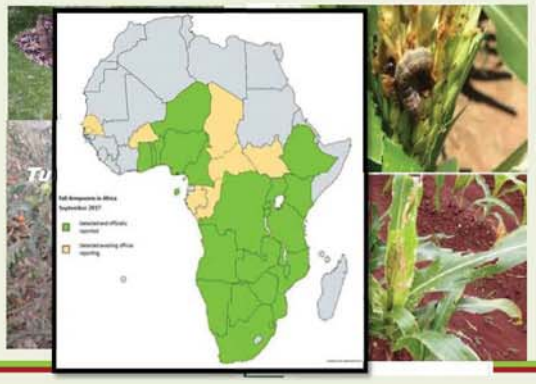
Presentation outline:

1. Emerging challenges in pest management – enhanced toolbox?
2. Regional Harmonization initiatives on pesticides
3. Areas of future work

1. Emerging challenges in pest management – enhanced toolbox?

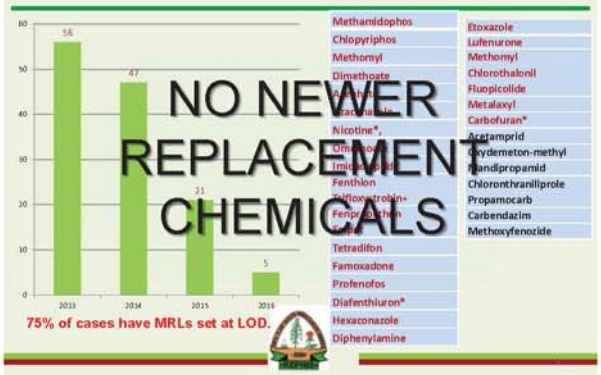
Plant protection needs / outbreaks

Migratory pests outbreaks



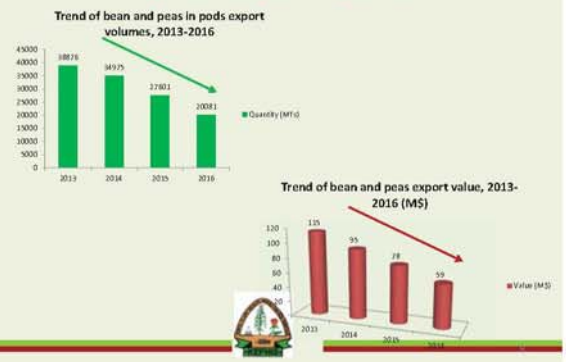
Emerging pests

Mitigation to increase compliance of legume vegetables



Default MRLs: effect on trade in minor crops

Group 014: Legume vegetables



2. Regional harmonization initiatives and achievements

Harmonization within the EA Region

Benefits:

Reduce unnecessary divergences across national pesticide regulatory approaches and legislation

Goal:

- Expedite reviews and registration timeframe
- Harmonize data needs to support minor uses
- Facilitates mutual recognition and enhance work sharing
- Establish system for EAC MRLs
- Increased trade therefore need for MRLs for minor crops

Harmonization within the EA Region.../2

Achievements in EAC harmonization

- Progress towards "single" registration:
  - Completion of Draft EAC efficacy trial and Draft Residue Trial guidelines – towards
  - agreed on modalities for implementation of regionally harmonized supervised trials & priority crops for implementation;
  - Commenced work on pesticide registration data requirements
- Participation in African regional Codex data generation project (KE, UG, TZ + SN, GH)
  - Supported by STDF, USDA, IR-4
  - Part of Global Codex Data generation project

Commodity	Challenge / Pest
1. Tomato	*Tuta absoluta*
2. Mango	Fruit fly
3. Maize	Storage pests – *Prostephanus truncatus*
4. Capsicum	False codling moth - *Thaumatotibia leucotreta*
5. French beans	Thrips – *Frankliniella occidentalis*
6. Coffee	Antestia bugs (*Antestiopsis*)

Harmonization within the Southern Africa Region

- The Southern African Development Community (SADC) **Southern African Pesticide Regulators Forum (SAPReF)** was established in 2011
- 15 Member States, Subcommittee of Plant Protection Technical Committee of the SADC Sanitary and Phytosanitary (SPS)

Objectives:

- Promote regional information exchange, and collaboration on pesticide and pest management and regulation.

Highlights:

- Portal established for information exchange;
- Development of Strategic Action plan identifying areas for collaboration would benefit the region, individual countries, pesticide traders, users and the general public.
- Establishment of WG to further develop a regional strategy for HHP risk reduction

Areas of future work

1. Modalities for mutual recognition
2. Ease of new registrations:
   - Explore crop grouping models - ease data requirements
   - New safer replacement pesticides
   - *Capacity building initiatives
3. Support for Minor use programs within RECs
   - Harmonized registration processes for minor crops
   - Data sharing
   - Minor crop data collection initiative (CX/PR 15/47)
     - Identify crops with pest / data needs to facilitate MRL setting

Areas of future work .../2

4. Explore possibilities to Establish EAC Data portal
   - Modalities in formats / use / access
5. Greater participation at WTO-SPS Committee
   - Strengthening Regional (EAC) and National SPS Committees
   - Provide updates in Regional initiatives on harmonization and MRL setting processes
   - Foster collaboration on minor uses and crops for more MRLs / PPP registrations

Thank you for your kind attention!

附件 8-5

A Regional Look at the Regulatory Landscape: Enabling Current and Future Opportunities

Global Minor Use Summit-3:
A Regional Look at the Regulatory Landscape:
Enabling Current and Future Opportunities

Montreal, Quebec, Canadá. Oct-2017

LATAM SITUTATION

Ing. Agr. Daniel Mazzarella
Directorate of Agrochemical and Biological products
National Animal Health and Agri-food Quality Service

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Overview on Latin America

Four major trade blocs in the region

Many additional regional agreement under development

Regional Plant Protection Organizations (RPPOs) differs from trade blocs in the region

Only Brazil and Argentina Request local residue trials to set national MRLs

without request of local residue trials to set national MRLS (other countries):
Adopt Codex and/or other Agencies MRLs.

Establishment of MRL in Argentina

Resolution SAGPyA 350/1999:
- 6 residues trails (3 agroecological zones/2 agricultural seasons)

Resolution SENASA 274/2010
Field trials conducted under GLP criteria

Residues Studies :	→	Establishment:
by active ingredient by crop		MRL Pre-harvest interval

Establishment of MRL in Brazil

Normative **RDC 4/2012** - ANVISA:
- 4 residues trails
- 2 degradation curves
- Recommended dose on GLP tested

Residues Studies :	→	Establishment:
by active ingredient by crop		MRL Pre-harvest interval

Chile

Export Market:
Respect Primary and Secondary standards to export food.

Domestic Market:
- Regulation that adopts MRLs for Domestic market. It is periodically updated.
- Criteria for adoption was reviewed at the end of 2016.
- Ministry of Health position is to give priority to Codex MRLs. If Codex has a MRL for a certain group, group MRL will be considered.
- **Criteria established was:**
  1. Codex MRLs.
  2. If there is no Codex MRL, selection criteria:
     1. EU MRL
     2. US MRL
     3. EU Default value
- No relationship between MRL selected and GAP.

Mexico

Export Market:
Respect Primary and Secondary standards to export food.

Domestic Market:
- Project of **Regulation on MRLs** to be possibly published at the end of 2017.
  - Objective is to establish criteria for MRL setting and revision.
  - **Criteria for MRL setting:**
    Sources of MRLs could be:
    - MRLs adopted from **CODEX, EPA, PMRA, EU, OECD countries, Brazil, Argentina and Japan**.
      In this case, **cGAP has to be similar to cGAP in Mexico** (according to extrapolation criteria described in the regulation).
    - If no MRLs can be adopted, they can be supported from Residue Studies done in Mexico (amount of studies are defined in the regulation depending on crop area and consumption level).

DECISION 804
Modification of Decision 436 (Andean Standard for the Registration and Control of Chemical Pesticides for Agricultural Use)

COMUNIDAD ANDINA

RESIDUES AND MAXIMUM RESIDUE LIMITS

Article 52.- For the determination of residues for registration purposes, the establishment of MRLs and monitoring activities, the methods provided by the manufacturer or formulator shall be used (FAO or other guidelines).

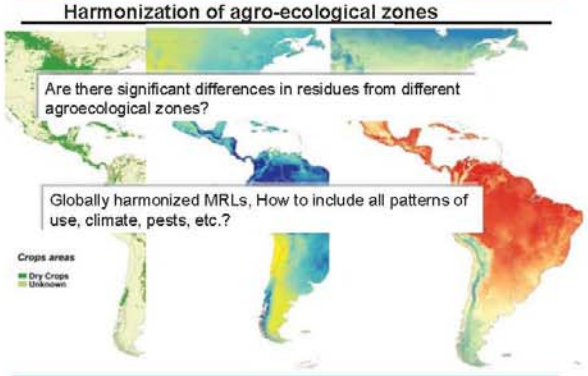
TRANSITORY DISPOSITIONS. Second.- As long as MRLs are not established and adopted in the Andean subregion, the Codex Alimentarius

Supervision of efficacy trials to determine good agricultural practice

CENTRAL AMERICA

- No local residues studies
- Based on Codex and EPA Mrls

Harmonization of agro-ecological zones



MINOR CROPS

- A minor crop may be defined as:
  "Minor uses are those uses of plant protection products (defined in relation to crops and pests) in which either the crop is considered to be of low economic importance at national level (minor crop), or the pest is of limited importance on a major crop (minor pest)" (EPPO 2017)
- MRLs may be obtained for residues residues trials in minor crops.
- MRLs may be obtained for residues residues trials in major crops.

EXTRAPOLATION → REGULATION

I. Harmonized Crop Grouping and Extrapolation
II. Data necessary (Efficacy trials? – similar major crops – Zonification?)
III. Financing programne → government-farmers-company

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Regional Situation: regulatory considerations related to minor uses

Argentina	• Res. SENASA 608/2012 (Minor Crops) established MRLs for 20 Crops.
Brasil	• IN (01/14) MRL extrapolation from a main crop to other crops with low availability of pesticides (Minor crops)
Bolivia-Peru-Colombia-Ecuador (CAN)	• Decision 804/2015 that approves the Andean Norm for the Registration and Control of Chemical Pesticides of Agricultural Use of the Andean Community of Nations. Art 19 – Minor crops
Costa Rica/Panama	• No active projects currently
Mexico	• SENASICA 2011-2013 support studies - submitted to registration in Federal Commission for Protection against Sanitary Risks (COFEPRIS).
Chile	• No active projects currently

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Current overview of the region regulation for minor crops.

Argentina	• Efficacy and field residue trials / Analytical residues • 20 crops (total 600 active / crops combinations) • Financing: international credit
Brasil	• Extrapolation MRL values of a representative crop for Minor crops. International guidelines for clustering and extrapolation of group MRLs for subgroups
Bolivia-Peru	• Extrapolation of efficacy test of a product already registered: a) same pest; b) same damage; c) Same plant and / or species; and, d) maximum approved use dose.
Costa Rica	• High costs for pesticide registration in smaller crops - low profitability for industry
Mexico	• SENASICA-COFEPRIS - Support studies - faster review process. I can register to date, 17 records (300 authorized uses in total) (avocado, nopal, pineapple, papaya, some citrus and aromatic herbs)
Panama	• In the last 5 years, IICA, USDA and Company led projects (Sumitomo - Pyryproxyfen in pineapple cultivation). The data generated were supplied to the CODEX Alimentarius. This is the first study conducted in the Panama and other trials are coordinated.

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Current overview of the region regulation for minor crops.

Peru	• Decree No. 001-2015-MINAGRI. 38.1. National Registries in minor crops without antecedents. Development Efficacy trials. 38.2. With a history of efficacy (= family-pest-dose approved) they can be validated for minor crop. For larger doses: efficacy-ERA

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Main issues to address in the future / needs to address these issues

Argentina	• Create permanent regulations. Set criteria for extrapolation of data between major and minor crops. Public-private interaction. New project: 18 crops - problem: financing
Brasil	• In Brazil there are no problems with specific technical skills. Modifying regulations and criteria to allow compatibility of data and mutual recognition of studies.
Bolivia	• Mutual recognition of studies: work to create a surpranational standard • Secondary or private residues regulations • Encourage crop grouping / Crops and Extrapolation
Costa Rica	• Achieve flexibility in the approach of minor crops compared to major crops. Challenges and advantages of using crop groups, extrapolations, field data exchange.
Mexico	• Establish the instrument of formal collaboration involving all actors. Work-diagnosis groups were created. In 2016, Appendix Classification of Crops by Botanical Groups to transfer technical information on Biological Effectiveness.
Panama	• Further use, updating and dissemination of existing data in the CODEX Alimentarius is necessary. Conduct field trials and sampling with study models to assess the impact of pesticide use.

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Main issues to address in the future / needs to address these issues

Peru	• There is access to data from other countries and data from efficacy trials. However, there are no national MRL data. One of the weaknesses is the insufficient articulation between the different organisms, which allows to work in a systematic way and with synergy, common themes that can affect plant health, animal health, human health, including food safety.

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MRL Harmonization

- **MERCOSUR**: SGT-3 (technical group): Resol GMC 15-2016

MRL Importer → MRL Codex (Risk Analysis) → MRL exporter (Risk Analysis).

- **COSAVE:** GTPF: Included in the agenda for 2017 - Not yet treated

- **CAN**: Decision 804 (Standard For the Registration and Control of Chemical Pesticides for Agricultural Use). Does not mention aspects on harmonization, only minor crops – Art 19

- **Central America:** CODEX - EPA

- **Mexico**: **CODEX, EPA, PMRA, EU, OECD countries, Brazil, Argentina and Japan. NAFTA?**

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Harmonization within the LATAM

QUESTION: Are there systematic differences in pesticide residue concentrations between zones?

- There is no harmonization with regard to the creation of MRLs at the LATAM level.
- Main difficulty: different pesticide registration standards.
- Local tests? Extrapolation with data from other GAP? ≈ cGAP
- National MRLs or Codex?

N Arg = S Bra
Caribean
Uruguay=Arg
Chile = W Arg
Bolivia / Bra / Py
Col – Peru

cGAP

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Areas of future work

1. Support for Minor use programs in LATAM
   - Work sharing and share experience
   - Joint data generation programs - **Regional Plant Protection Organizations**
   - Harmonized registration processes for minor crops: same cGAP and Agroecological Zone
   - Capacity building activities

2. Ease of new registrations:
   - Explore crop grouping, ease registration requirements through harmonized approaches

3. Harmonization

Explore future COSAVE/MERCOSUR/CAN harmonization

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Thank you

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附件 9-1

Introduction: From GMUS-2 to GMUS-3

CropLife INTERNATIONAL

Global Minor Use Summit III

Oct 1-4, 2017

Montreal, Quebec, Canada

Philip A. Brindle, PhD

1

Challenges for Minor Crop/Use registrations

- **Crop Protection Product registrations need data….. lots of it!**
  - Expensive to develop, and takes time
  - Different regulatory requirements must be met
  - Crops making up staple foods are first priority for Ag Industry
- **Minor Crops/Uses come second**
  - Many minor crops in production today
  - Increasing trade in minor crops → increasing data requirements!
  - Need more efficient ways to support these crops and uses

Quick Look Back

- **GMUS II, Feb 2012 → 5 yr plan developed**
  - **Coordination & Collaboration**
  - **Communication**
  - **Incentives**
  - **Capacity Development**
  - **Registration of Minor Uses and MRL Setting**

Key advances since GMUS II

- **1st Global MU Workshop/Priority-setting meeting (2015)**
- **EU Minor Uses Coordination Facility (2015)**
- **US-EPA/CA-PMRA Residue Exchangeability project**
- **USDA IR-4 and FAS capacity-building work for data generation**
- **National and International Crop Grouping updates**
- **Pulse Canada and CropLife capacity-building for Codex**
- **Codex adoption of Proportionality (2013)**
- **USDA-FAS MRL Workshops in Taiwan and Korea (2017)**
- **Expansion of US Grower MRL Priority Database**
- **APEC Guideline supporting Import MRL setting**
- **US-EPA Pilot project based upon APEC GL**

THANK YOU

Great progress being made, but still lots of work to be done!

附件 9-2

Overview of Industry Considerations for Minor Crop Registrations

CropLife

Overview of Industry Considerations for Minor Crop Registrations

Jessica Christiansen
Global Minor Use Summit 3 – Montreal
2 October 2017

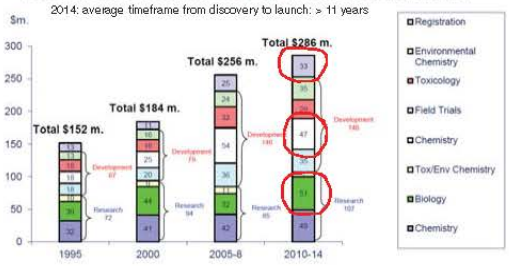
Helping Farmers Grow

Investment Costs

CropLife

Discovery and Development Costs of a New Crop Protection Product

2014: average timeframe from discovery to launch: > 11 years



Source: http://www.croplifeamerica.org/wp-content/uploads/pdf/2014%20Phillips%20Study%20Final%20Report_4-6-15.pdf

Managing Minor Crops

CropLife

➢ **Ag Industry is committed to help Minor Crop growers sustain their businesses**

But.....

- Considering high costs of data generation/registration, development of Minor Crop solutions have to be phased over time
- Registrations for Minor Crop uses are often as costly as Major Crop uses, yet market potential is very different → tough business justifications.....
  - crop safety and biological efficacy are key factors that must be addressed
  - direct vs. distribution model; what infrastructure and resources are required?
  - optimum formulations and supply chain costs must be considered

Managing Minor Crops

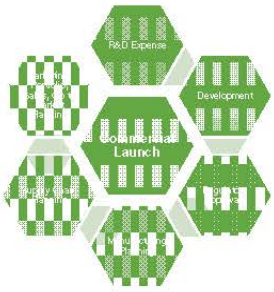
CropLife

➢ **However.....**

- 1st phase product registrations of new chemistries for the staple crops (e.g. soybeans, corn, rice, cereal grains, oilseeds) often do include several specialties (pome fruits, stone fruits, citrus, tree nuts, etc) today
- More specialty minor crop registrations/label expansions typically follow quite quickly either as label expansions or as uniquely-tailored new products

→ Delivering sustainable solutions to support Minor Crop growers in an even broader, faster manner sits with all of us attending this summit

CropLife



Maintenance of Business

- Approvals
- Sales Force and other Headcount
- Local Infrastructure
- Distribution Agreements & Programs
- Customer Claims
- General Freedom to Operate

附件 9-3

East African Community Efforts to Harmonization Pesticide Regulatory Systems: A Model Approach for Regional Solutions

East African Community Efforts to Harmonization Pesticide Regulatory Systems: A Model Approach for Regional Solutions

Global Minor Use Summit - 3
October 2, 2017

Jason Sandahl, PhD
Food Safety Technical Advisor
Office of Capacity Building and Development
USDA Foreign Agriculture Service

USDA UNITED STATES DEPARTMENT OF AGRICULTURE

Why harmonize national systems regionally?

GMUS-2: Theme 4, Capacity Building
- Task 4.1: Support Efforts in National and Regional Capacity

National/Regional Interests
- Provides incentives to pesticide companies to register new products, and establish new MRLs
- Helps growers gain access to newer products (often reduced risk products) and adds more tools control pests
- Helps reduce MRL violations in export markets
- Reduces the number of trials and time taken

Rest of the World Interests
- Again…reduces MRL violations at ports of entry
- But…also reduces MRL violations of exports to the region (registrations of new AIs, leads to new import MRLs of AI)

*TAKE AWAY: Supporting regional efforts benefits the region, but also facilitates trade into the region!

What is the vision of the EAC effort?

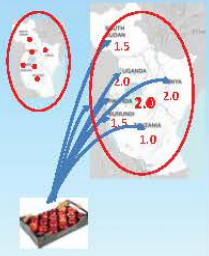
- Common Data Package: Information/Format

What is the vision of this effort?

- Common Data Package: Information/Format
- Mutual Recognition of Efficacy Data/Joint Trials
  - Reduce total number from 16 to 3 or 4

What is the vision of this effort?

- Common Data Package: Information/Format
- Mutual Recognition of Efficacy Data/Joint Trials
  - Reduce total number from X to Y
- Mutual Recognition of Residue Data/Joint Trials
- Common Adoption of MRLs (Codex, then decision process if no Codex)



What is the vision of this effort?

- Common Data Package: Information/Format
- Mutual Recognition of Efficacy Data/Joint Trials
  - Reduce total number from X to Y
- Mutual Recognition of Residue Data/Joint Trials
- Common Adoption of MRLs (Codex, then decision process if no Codex)
- Multi-year process, but ultimate goal of a single submission registration system

What is the mechanism?

- Effort is supported under the umbrella of the Treaty for the Establishment of the East African Community (1999)
  - Kenya, Uganda, Tanzania (1999)
  - Republic of Burundi, Rwanda (2007)
  - South Sudan (2016)
- Article 108 on Plant and animal Disease Control states: Partners states shall:
  - a) Harmonize policies, legislation and regulation for enforcement of pest and disease control
  - b) Harmonize and strengthen regulatory institutions
  - e) Adopt common mechanism to ensure safety, efficacy and potency of agricultural inputs including chemicals, drugs and vaccines etc

What is the process?

- Established 3 Expert Working Groups to discuss and work out technical details
  - Efficacy harmonization (# trials, # seasons, locations, etc)
  - Residue harmonization (residue data, MRL adoption considerations, etc)
  - Registrations (labeling, data requirements, etc)
- Have held 2 (of 3) EWG meetings (October 2016, February 2017)
  - Completed work on:
    - Harmonized Application Form for registration of conventional pesticides
    - Harmonized Labeling Requirements for pesticide products
- Next meeting (date TBD) will work toward agreement on guideline documents for efficacy, residue, and registrations

What was learned?

- Harmonization simplifies adoption/establishment of regional MRLs
- Harmonization encourages investment into, and from, the region
- Harmonization requires mutual trust, communication and cooperation
- Regular participation is essential by Expert Working Groups in the harmonization process

How can we all support this and similar efforts?

- Encourage other regions to work toward harmonization (find out what other regional efforts have been done, are in progress, or where there may be interest)
- Financial support to hold regional planning and implementation meetings (mostly travel/venue)
- Technical support to provide guidance at meetings
  - experts/consultants
  - guidance documents
- Need to harmonize the harmonization! Mechanism to coordinate between the regions

Acknowledgements

- Paul Ngaruiya (Kenya- Pest Control Products Board)
- Mike Odong, late (Uganda Pesticide Registrar, and one of lead delegates to EAC EWG)

THANK YOU!!!

Jason Sandahl, PhD
Food Safety Technical Advisor
Office of Capacity Building and Development
USDA Foreign Agriculture Service

USDA UNITED STATES DEPARTMENT OF AGRICULTURE

附件 9-4

Manufacturer's Experience with Capacity Building

Manufacturer's Experience with Capacity Building

By Carmen Tiu
Global Residue & MRL Strategy Leader

October 1-4, 2017
Fairmont Queen Elizabeth Hotel
Montreal, Quebec, Canada

Third Global Minor Use Summit (GMUS-3)

Dow AgroSciences

Solutions for the Growing World

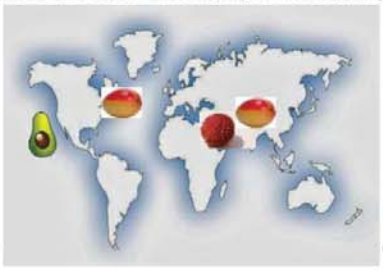
Presentation Index

1. Lessons Learned from USDA/IR-4 Projects
2. Other Capacity Building Projects
3. Industry Points of Interests
4. Recommendations for Selecting Projects

1. Lessons Learned from USDA/IR-4 Phase-1 Projects

1. Lessons Learned from USDA/IR-4 Phase-1 Projects

- 4 Studies funded by USDA-FAS were conducted by IR-4 Study Directors
- 2 DAS actives had data generated in: Thailand, Colombia, Africa
- On 3 tropical crops : avocado, mango, lychee
- 2 Registrations achieved and Codex –MRL ongoing for avocado, mango



What Worked Well?...

- For studies
  - Coordination amongst global stakeholders
  - GLP-test material preparation, orders, shipping
  - Analytical methods and standards shipping
  - Protocol and draft-report reviews
  - Significantly improved national capabilities towards GLP-studies
  - **Great coordination from experienced GLP Study Directors!**
- For regulatory submission
  - Generally timely submission and approval of national uses
  - Great coordination of Codex residue dossier completion (3 datasets)
  - **Excellent networks established in 3 continents and foot printing for future opportunities**

What needs further attention for future work?...

- Internal communication global – regional/national contacts
  - Everyone wants to be involved turns communication extremely difficult
  - Time-zones affect frequency of communications
  - Diverse communication technology makes quality of calls difficult
- Efficacy Data
  - The need of Biology data (GAP) is often overlooked
- Field phase – build GLP training to PFI's
  - Technical training for calibration, application, sample collection, shipping, etc.
- Analytical phase – validation of method *before* samples arrive to lab
  - Build knowledge working with stable isotopes, internal standards, confirmation ions, matrix interference, homogenization, integration modes, reporting rules.
- Develop local GLP Study Directors by hands-on training

2. Other Capacity Building Projects

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Solutions for the Growing World

Other Capacity Building Programs

- GLP implementation for residue studies in China and Argentina
  - Leverage on global Study Directors and private Quality Assurance
  - Technical training (e.g. OECD Residue guidelines) is also needed
- Workshops with agencies and MRL stakeholders
  - MRL harmonization to support Import Tolerances (MRL)
    - Asian and Latino-American countries: APEC procedure
  - Multiple MRLs standards compliance to support trade
    - Costa-Rica, Chile, Peru, Europe
- Tools developed to support MRL harmonization and Trade
  - Crop Grouping Extrapolation and Data Exchangeability
    - Korea, Taiwan, Costa-Rica, Codex

3. Industry's Points of Interests

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Solutions for the Growing World

4. Recommendations for Selecting Projects

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Solutions for the Growing World

3. Industry's Points of Interests

- Always open for collaboration projects to jointly develop new uses
  - Every new use to control pests, increase yield and is proved safe to people and the environment
- Advocate for updated regulation to enable:
  - **Mutual acceptance** of data and MRLs between countries
  - **Extrapolation** of uses and MRLs between crops, and countries
  - **Harmonization** of MRL through consistent GAP, MRL calculation and risk methodologies

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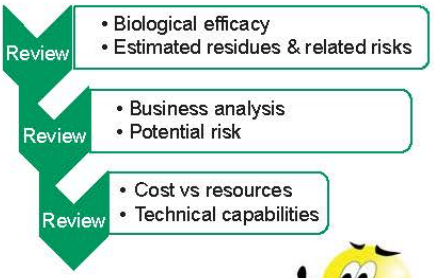
4. Recommendations on Selecting Projects



Most projects will be approved !

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Conclusion & Acknowledgement

- Pesticide Residue Collaboration projects as the BEST TOOL to enable more uses and MRLs, particularly on minor crops

Growers,Commodity groups + Agencies + Registrants + Contractors ☺

- Special recognition to IR-4's efforts for 50+ years to develop pesticides uses on specialty crops in USA, and since 2010 at the global level!
- Acknowledgement of USDA-FAS efforts to support capacity building across continents, and sponsor data generation!

Carmen Tiu
tcarmen@dow.com

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附件 9-5

BPG, Biocontrol Products and minor uses

BPG, Biocontrol Products and minor uses

BioProtection Global

David Cary IBMA
Nina Wilson BPIA

Biological Products - What Are They?

Low or minimal risk biocontrol and plant enhancement tools that may be naturally derived or synthetic equivalents

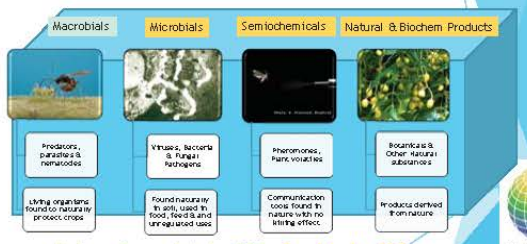
(definition is driven by the regulatory characterization)

Characterized as niche products with low mammalian and environmental impact; often, initially developed for minor or specialty crops but some expansion to broad acre crops

Usually not associated with a tolerance/MRL; not residue free but no residues of toxicological concern

May or may not comply with national organic regulations

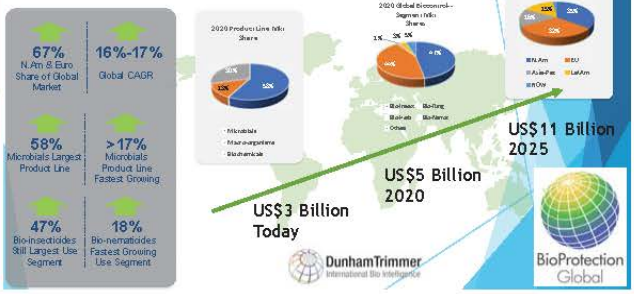
"Innovative Green Tools" of the Biocontrol industry



Not usually regulated as PPPs Regulated as PPPs

All groups can have niche solutions

BioProducts Market: Growing Globally



Biopesticide - What are the challenges?

- Residues and MRL harmonization is a recognized global discussion but
  - Tolerance/MRL exemptions are not
  - Exemptions are the product of risk assessments which are not easily harmonized (safety standards - no toxicity x exposure)
- Fee and time incentives (US EPA)
- Misperceptions on efficacy and role in IPM
- Efficacy requirements and guidelines are not geared to non-toxic MOAs and
  - Artificial borders create duplication and cost
  - Efficacy costs can be the biggest barrier to registrations
  - Smaller, innovative companies and small market sizes
- More government effort toward reciprocal organic agreements

Who is BPG?

IBMA bp'a SABO ABCBio

BioProtection Global

- BioProtection Global (BPG) is a **worldwide federation** of **biocontrol and biopesticides industry associations** comprised primarily of manufacturers of biocontrol and biopesticide products for professional use in agriculture, animal health and other non-crop uses. The mission of BPG is to **represent** the **bioprotection industry** for key topics on a global scale in order to **promote bioprotection** and **harmonise proportionate regulations**.

Member Associations

- ABC Bio
- ANBP
- BPIA
- IBMA
- SABO
- ASOBIOCOL
- Japan Biocontrol Association
- PMFAI

ASOBICOL 日本生物防除協議会 PMFAI

BioProtection Global Objectives

- Serve as a global platform for the biocontrol industry to express and share its views to further **shape common positioning** and **ensure consistency in policy** and other messages toward institutional actors and other stakeholders
- **Identify common needs and avoid duplication** in areas that extend beyond national or regional issues
- Work on proportionate regulations for biocontrol agents with relevant global or regional organisations and authorities and to **harmonise** such **regulations worldwide as much as possible**
- **Promote bioprotection and a broad adoption of the use of its products** in integrated pest management programmes with respect to human health and the environment to provide a more sustainable world

BPG: Biopesticides as Low Risk Solutions in IPM and Sustainable Agriculture

- Prevention of pest & disease explosion
- Use of all available tools
- Minimal risk to human health and the environment

Only through use of true IPM

Minor uses are of major importance to the Biocontrol industry!

What do biocontrol tools contribute to the IPM agricultural system?

- Resistance management
- Usage close to harvest (pre-harvest intervals)
- Short re-entry periods
- Targeted niche solutions - in seasonal programs with conventional pest control methods or by themselves in organic productions
- Minimal impact on human health and environment
- Can be quicker to the market
  - Low-risk
  - Product type eg Macrobials and Monitoring / Mass Trapping
  - No need for mrl setting

What has been achieved by BPG and Member Associations?

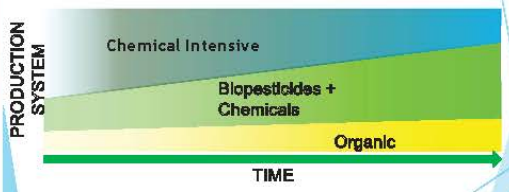
- Working with IGOs and Policymakers to bring BCAs to market
- Working with Regulators to develop guidance / better regulation
- Working with Researchers and Research bodies to target needs
- Working with other parts of industry to explore mutual benefits
- Working with Farmer Groups for targeting needs and optimising performance
- Working with the Food Value Chain for harmonised progress towards sustainability

Just some of the possible solutions

- Global or regional positive lists
  - EPPO list for IBCAs
  - FAO list of MBCAs
  - EU 2003/2003 proposed list of microbial biostimulants
- Single global data package and registration
- No renewal requirement using data call-in systems
- Notification only procedure for a.s. ie EU and SCLPs
- No requirement for product authorisations or a single regional product authorisation
- Ability to allow a minor use without needing a major use
- Concurrent a.s approval and a regional product authorisation in a single step
- Mutual Recognition between OECD Countries

- The food chain, consumers, governments and growers want more low risk, sustainable tools

The Shift Toward Bio-Based Systems



Thank you from BPG!

Nina Wilson, Vice Chair BPIA
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David Cary, Executive Director IBMA
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附件 9-6

Minor Uses: A regional perspective. A global View

Minor Uses:
A regional perspective. A global view.

GMUS-3

Dave Wright
Manager- Regulatory, R&D
Engage Agro Corporation
Guelph, Ontario, Canada.

ENGAGE AGRO
member of the Belchim Group

1995

Engage Agro Corporation
- based in Guelph, Ontario.

- a master copy label of propiconazole and a plan
- to support minor crop business

ENGAGE AGRO
member of the Belchim Group

1995 Niche market roots

- purchase a quantity of product
- market the product for minor crop and specialty uses
- handle unique packaging needs

1999

ENGAGE AGRO
member of the Belchim Group

1995 Around this time…

- re-organization and consolidation in Global Ag-Chem
- big changes afoot

1999

ENGAGE AGRO
member of the Belchim Group

Meanwhile in Canada…

- NAFTA joint review projects were coming to fruition
  - many with minor crop registrations

- rock-solid chemistry available in field crops with spectrums which would benefit horticulture

ENGAGE AGRO
member of the Belchim Group

1995

Engage Agro:
- support development, registration and label expansion in minor crops
- launch products and provide tech-service
- provide ongoing marketing support

- particularly for crop protection products which larger companies in Canada were not able to dedicate staff toward at that time.

1999

ENGAGE AGRO
member of the Belchim Group

1995

- The business began to expand…

- just 2 full time employees
- mushroom and ornamentals crop protection
- Dutch elm disease control
- potato seed piece treatment
- two fungicides for horticultural crops

1999

ENGAGE AGRO
member of the Belchim Group

1999 - 2000

- The propiconazole label had expanded via minor use activities
  - Stone fruit
  - Cranberries
  - Saskatoon berries
  - Blueberries

- credit to extension specialists and regional advocates for minor crops

- Engage Agro was to translate those efforts into commercially available tools for the minor crops

ENGAGE AGRO
member of the Belchim Group

1999 - 2000

- Relationships with suppliers grew, adding select products
- A phase of building capacity / expanding our horizons
- 5 employees joined Engage Agro through the year 2000.
  - to service regulatory, marketing and communication needs
  - adding tech support in fruit and vegetable regions

ENGAGE AGRO
member of the Belchim Group

2000 Remarkable growth in this decade

2010

ENGAGE AGRO
member of the Belchim Group

2000

- Our registration team grew by 4 personnel over five years
  - assisting with registration efforts of our suppliers
  - on-going compliance and label support
- Marketing team grew by 5 personnel
  - providing tech support
  - in-put into supplier assessments and forecasts
- *fueled in part by greater coordination across minor crop initiatives

2010

ENGAGE AGRO
member of the Belchim Group

2000

- The shift in Canada:
  - positive interactions between grower organizations, regulators and extension personnel
  - Establishment of the Minor Use Program and Pest Management Centre
  - minor use initiatives in Canada noticeably cooperative with IR-4
  - clear guidelines for minor uses, regulatory requirements and timelines
  - multinational suppliers adding minor crops directly to 1st tier labels
  - registrants directly submitting minor crop label expansions
  - broader ranging labels becoming the norm.

2010

ENGAGE AGRO
member of the Belchim Group

2000

Exciting times!

- a proliferation in cooperation within Canada
  - new solutions available where there had been fewer, historic options.
- rapid change in terms of crop protection options for minor crops
- acute awareness of discrepancies between tolerances (MRLs) at destination

2010

ENGAGE AGRO
member of the Belchim Group

2000

Minor crops with export markets:

- gaining registrations of new, highly effective active ingredients
- crop management protocols in place
  - ensure access to premium markets where MRLs were not yet established
- sensitive to the difference between set tolerances (MRLs) versus additional limits which may be prescribed by retail channels.

2010

ENGAGE AGRO
member of the Belchim Group

Production Risks:

An example (2004):

- in the USA, a Section 18 expired for control of *Monilinia* on blueberry
- time limited tolerances expired as well

- In the USA, there were new fungicides registered for mummy berry control.
- In Canada, the options for mummy berry control were limited.

- scramble to secure supply of the alternative fungicide
- the alternative product lost tolerances the following year

ENGAGE AGRO
member of the Belchim Group

Marketing Risks:

Scenario A.	B.	C.
✓ Effective Solution	✓ Effective Solution	✓ Effective Solution
✓ Registered Product	✓ Registered Product	✓ Registered Product
✓ Tolerance at Destination	X No Tolerance at Destination	? Unclear Tolerance at Destination
✓ Viable Option	X Not Viable	X May not be viable

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member of the Belchim Group

2000

- A decade of great strides in minor crop awareness
  - rapidly expanded crop protection options for producers in Canada
- Local collaboration drives a positive shift
  - Producers, Government Extension, Regulators
  - Clear requirements and timelines for label expansions
  - Order and clarity in the market
- Multinational companies with local presence further resource the minor crops with global solutions.

2010

ENGAGE AGRO
member of the Belchim Group

2010

A need to change and collaborate on a global basis
- grow business with suppliers who historically were without local representation

- assess market opportunities
- assess development costs for Canada
- where feasible, facilitate development and registration
- launch products for Canadian crops / specialty markets

- tolerances are high on the list of assessment criteria

2017

ENGAGE AGRO
member of the Belchim Group

2016

Within the last year:
- Engage Agro attracted international investment from Belchim Crop Protection
- minor crop connections
- advancing our overseas collaboration

2017

ENGAGE AGRO
member of the Belchim Group

Meanwhile around the Globe…

Work dedicated to minor crops:
- high value to engagement across a range of stakeholders
- working locally and creating global support for minor crops
- creating support for a global wealth of high quality food.

ENGAGE AGRO
member of the Belchim Group

附件 10-1

North America Perspective Facilitating Trade Through Cooperation

North American Perspective

Facilitating Trade Through Cooperation

James R. Cranney
California Citrus Quality Council

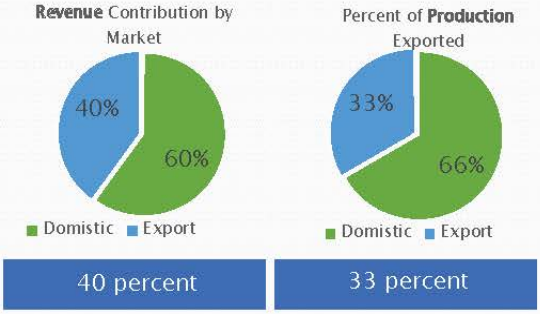
Major Points for Discussion

- Role of CCQC
- The importance of trade for minor crops
- Problems
- Suggestions for facilitating trade

California Citrus Quality Council

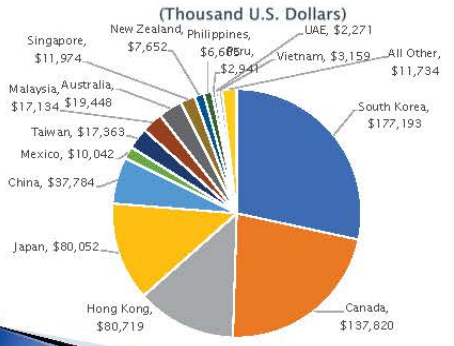
- Solve regulatory problems domestically and internationally
- Core mission is to facilitate trade
  - Maximum Residue Levels (MRLs)
  - Phytosanitary issues regarding insects and plant diseases
- Provide crop protection tools for growers

Exports are Economically Important

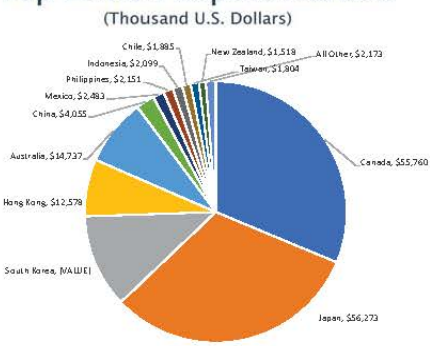


40 percent | 33 percent

Top Orange Export Markets



Top Lemon Export Markets



Exporting 101

- Export markets demand perfect maturity, blemish-free fruit, large sizes & uniform color
- This is the "cream" of the crop
- It may take select production from several groves to fill export orders
- Difficult to designate specific groves for specific export markets
- Production can go anywhere
- Pesticide residues should be "legal" anywhere, including post harvest fungicides used in packing houses

Production and Trade Interface Issues

- Need *many* pesticide options (resistance)
- Difficult to manage acreage for specific markets
- Delayed use until MRLs are established
- Emergence of secondary standards (restricted pesticides and lower residue levels)

- Are there MRLs?
- Are there MRLs?
- Can we avoid delays?
- Counterproductive

Harmonization Challenges

- Important trading partners are moving away from a single global standard, creating a proliferation of many different standards

- Japan
- Taiwan
- Korea
- Hong Kong
- China
- European Union (?)

How can we manage in this environment?

- Different MRLs
- Number of trials
- Crop groups
- Process
- Cost

Adopt APEC MRL Guidelines

- **Consistency in process and data requirements**
- **Saves resources**
- **Predictable**
- **More harmonized MRLs**

Communication and Flexibility

- Provide avenues and opportunity to discuss problems
- Maintain flexible process to address problems
- Korea Ministry of Food and Drug Safety
  - Flexibility in implementation
  - Added crop groups
  - Allow Codex data for generic pesticides
  - Open communication and dialogue

Can countries incorporate Codex in new MRL setting systems?

Use Codex standards as temporary standards to fill gaps

Summary

- Many countries are adopting proprietary MRL setting systems
- Increasing cost and complexity in establishing MRLs
- Many different MRL standards and delays for growers
- Use APEC guidelines
- Provide flexibility in adopting proprietary systems
- Incorporate Codex standards

California Citrus Quality Council

MCFA
Minor Crop Farmer Alliance

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MCFA Secretary
Chairman, MCFA International Subcommittee

附件 10-2

Minor use pesticides – a view from the Canadian horticulture sector

Canadian Horticultural Council | Conseil canadien de l'horticulture

The voice of Canadian fruit and vegetable growers

Minor use pesticides – a view from the Canadian horticulture sector

Rebecca Lee, PhD
Executive Director
Canadian Horticultural Council
October, 2017

Contents

- Overview of CHC
- Benefits and the use of dedicated minor use/assistance programs
- Managing emerging pest issues
- Export/trade and chemical review issues
- Degree of engagement with dedicated minor use programs and legislators to support outcomes for minor use
- Factors that could facilitate grower outcomes and support into the future

Overview of CHC

Who we are

- National non-profit advocacy group
- Based in Ottawa
- Governed by a Board of Directors
- 10 staff
- We are the voice of Canadian fruit and vegetable growers

Who we represent

- Over 22,000 growers
- Over 130 member organizations
- Over 120 different commodities
- Members are in Canada and beyond

What we do

- Advocate for members on key issues
- Facilitate government consultations
- Coordinate research projects and funding

How we are organised...

Core areas

- Labour
- Trade and marketing
- Industry standards and food safety
- Finance and business management
- Crop, plant protection and the environment

Commodity groups

- Apple & tree fruit
- Potato
- Greenhouse vegetables
- Berries
- Field vegetables

Benefits and the use of dedicated minor use/assistance programs

AAFC's Pest Management Centre (PMC) and Pesticide Reduced Risk Program (PRRP) impact on minor use (MU) crops in Canada has been very positive.

- From: few pesticides registered + many emergency registrations / year
- To: growers now have registered pesticides for most of our priority pests and diseases + the need for emergency registrations is greatly reduced.

Benefits and the use of dedicated minor use/assistance programs (cont.)

- Almost universal dependence on PMC to generate residue and efficacy data for MU food crops and Dislodgeable Foliar Residue (DFR) data for MU non-food crops.
- Benefits of the PMC:
  - Dedicated, reliable funding and staff for on-going MU registrations.
  - Transparency - Growers pick projects through provincial MU coordinators grower meetings and/or by attending the Ottawa meeting.
- Concerns:
  - PMC was never intended or budgeted to do DFR work.

Managing emerging pest issues

- AAFC's PMC, provincial ministries of agriculture and grower groups, e.g. CHC, are engaged in research and finding solutions for emerging pest issues such as Spotted Wing Drosophila (SWD) and Brown Marmorated Stink Bug (BMSB).
- PRRP is engaged in work to address priority pests and diseases e.g. Downy Mildew GH Cucumber working group
- Grower associations engaged in finding solutions to new and emerging economic pests, e.g. OGVG and pepper weevil on GH peppers

Managing emerging pest issues: Challenges

- Time between emergence of new pest and registration of control products
  - Government agencies can be slow to respond and growers pay the price
  - Can the regulatory system respond fast enough when a quarantine pest is found? What mechanisms are in place for CFIA and the PMRA to coordinate to address quarantine pest issues?
- Resistance management
  - Registration of products in different FRAC, HRAC and IRAC
- Discontinuing pesticide registrations with no viable or efficacious alternatives in place
  - e.g. imidacloprid can leave large gaps in growers IPM toolboxes
- Discontinuing broad spectrum pesticides resulting in secondary pest becoming serious problem
  - e.g. imidacloprid used to control aphids and whiteflies also controlled Lygus and stink bugs.

Export/trade and chemical review: Challenges

- Harmonization with our major trading partner
  - The many joint Canada-US (PMC-IR4) minor use projects are helping to address this issue.
  - Next step: Global MU projects. Same time registrations and same MRLs in OECD countries will help Canadian farmers who are seeking new export markets.
- Resources needed by CFIA to address phytosanitary barriers to trade
  - Bilateral agreements needed for Canadian farmers to gain access to new markets & to resolve barriers in existing markets
- Harmonization with the EPA
  - PMRA working on DFR database for greenhouse food and non-food crops, when DFR data could be used interchangeably. Burgeoning problem with re-evaluations, too.
  - Lack of harmonization = different registration decisions between CAN/US
- Risk based assessments vs. hazard based assessments
  - Will Canada move to hazard based assessments like Europe?
  - Could lose many important pesticides – what will replace them?
  - Will we go back to a situation where many EUR will be needed every year?

Degree of engagement with dedicated minor use programs and legislators to support outcomes for minor use

- Growers and grower associations are fully engaged with the PMUCs, PMC's MU workshops.
- CHC CPAC meets at least once yearly with top PMC and PMRA staff to discuss issues of concern to the growers around pesticide registrations.
- CHC and individual grower groups respond to PMRA proposed registration/re-evaluation decision consultations.
- CHC –educating politicians about issues of importance to agriculture - Fall Harvest

Factors that could facilitate grower outcomes and support into the future

- Biopesticides
  - Research and extension support for growers
- New invasive pests and diseases
  - Resources to minimize such events from happening
  - Improvement of government agency response times
  - Movement from a risk-based to a hazard-based model
  - Government supports if many pesticide registrations are discontinued/phased out?
  - Transition period to allow alternatives to be put in place or will we go back to a situation where many EURs are submitted every year?

Barriers to accessing crop protection products

- Canadian registrations without export MRLs
  - ➢Rovral, Dynomite and Vendex
- Investment too great for registrants
  - ➢Cyflufenamif, triflumizole
- PMRA is not the EPA
  - ➢Occupation exposure data (DFR)
  - ➢Value and efficacy data

To contact us:

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CHC AGM
March 13-15, 2018
Ottawa

FreshThinking MAGAZINE
HortShorts NEWSLETTER

附件 10-3 **The Journey of Dragonfruit and Difenoconazole**

Dragonberry
PRODUCE

The Journey of
Dragonfruit and Difenoconazole

Introduction –Dragonberry Produce

Dragonfruit with quality issues without Difenoconazole

Reaching Out to All Parties
January 2014

Governments

- United States Environmental Protection Agency (EPA)
- United States Department of Agriculture (USDA)
- Vietnam Embassy, WA-DC

Researcher & Private Sectors

- IR-4 Project, Rutgers University
- Syngenta –USA Office
- Importers from USA
- Exporters from Vietnam

Working Together = Result

Market Conditions

IMPROVEMNTS

- Dragonfruit qualities has less defects arrival issues
- Less reported cases of dragonfruit citations by law enforcement to order for destruction of fruits.
- Increased volume of dragonfruit importation into the USA

PROBLEMS

- Not all imported dragonfruits meet USA MRL tolerance
- Unfair trading prices of dragonfruits imported into USA and sold at price less than dragonfruits that do meet USA MRL tolerance

KEVIAR 325SC
by Brightonmax International
in the Approved Vietnam List of Chemical
Notice 34/2015/TT-BNNPTNT

THÀNH PHẦN

Azoxystrobin ..... 200 g/lit

Difenoconazole ..... 125 g/lit

AMISTAR TOP
by Syngenta -Vietnam
Not approved for use on dragonfruit
since Oct. 12, 2015

Azoxystrobin 200 GL

Difenoconazole 125 GL

Grower's Continued Difficulties

Vietnam Regulations

- MRL laws from different countries are not shared with growers
- No supports or educations programs to teach about MRL
- Unclear process of how trade name or chemical compound are registered for use.

Global Regulations

- Risk assessments used by countries do not share the same methods of evaluating the data
- Multiple different MRL requirements for dragonfruit, in different countries that doesn't grow the fruit

Finding Continued Success with help from Global Leader Countries

Global MRL

- All countries sharing their methods of evaluating risk and finding common ground standards
- Harmonization of MRL laws will help prevent lost for growers in all regions

Helping Developing Countries

- Stream lining the MRL registration process will help growers in developing countries with no resources the supports
- Providing education of MRL during trade agreements

Dragonberry
PRODUCE

Thank You !

Cảm ơn

附件 10-4

Regional look at growers challenges and engagement enabling current and future opportunities

copa*cogeca
european farmers european agri-cooperatives

Regional look at growers challenges and engagement enabling current and future opportunities

Luc Peeters | 04.10.2017
Chair of the Copa and Cogeca Working Party on Phytosanitary issues

Regional look at growers challenges and engagement enabling current and future opportunities

Index

- Introduction
- Current situation of minor uses and specialty crops in the EU
- European legislative framework
- Shortcomings and actions
- Proposals and recommendations
- Conclusion

Introduction

Introduction (I)

Two organisations....

Copa
Created in 1958, Copa represents 23 million European farmers and family members

Cogeca
Created in 1959, Cogeca represents 22, 000 European agricultural cooperatives

Copa and Cogeca
In 1962, a joint Secretariat was created, making it one of the biggest and most active lobby organisations in Brussels

« The united voice of farmers and their cooperatives in the European Union »

Introduction (II)

Mission
To ensure a viable, innovative and competitive EU agriculture and agri-food sector

Organisation
66 Member organisations and 34 Partner Organisations
25 agricultural sectors covered (many Minor Uses):

- Cotton
- Flax and Hemp
- Flower and plants
- Fruits and vegetables
- Hops
- Rice
- Seeds
- Tobacco
- ...
- And Major crops with Minor Uses

Current situation of minor uses and specialty crops in the EU

Current situation of minor uses and specialty crops in the EU (I)

Importance of Minor Uses

- Around 85-90% of total crops
- Around 5% of total European Utilised Agricultural Area (UAA)
- Mostly vegetables, fruits, nurseries and flowers: €70 billion EU production value
- 20% of total EU agri-production value
- Specialty crops provide diversity in diet: wide range of variety
- High speciality crops mostly on high specialised farms

Definition of MUSC: crops and pests for which industry does not provide solutions

Current situation of minor uses and specialty crops in the EU (II)

Main challenges

- Magnitude of impact of pest problems similar to major crops
- Economical impact on farm level is very high
- Crop protection solutions not available mainly due to high costs of development
- Resistance build up if no rotation in active substances
- Emergency authorizations are not long term solutions
- Develop new solutions for these quality crops
- Lack of involvement and participation from all EU Member States
- Distortion of competition at EU level

copa*cogeca

copa*cogeca

European legislative framework

Current situation of minor uses and specialty crops in the EU

copa*cogeca

European legislative framework (I)

Official regulatory framework

- Regulation 1107/2009 concerning the placing of plant protection products on the market
  - New active substances (February 2016)
    - **39 new substances submitted since June 2011**
    - **11 active substances have an Approval vote**
    - **9 have also an MRL vote**
    - **2 have MRL regulations**
    - **1 Product authorised**

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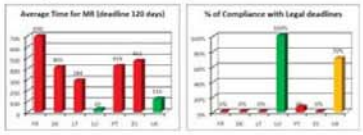
European legislative framework (II)

- Zonal system and Mutual recognition



Outcome of re-evaluation by second MS during MR application:

- Authorisation with identical conditions 56%
- Authorisation with different risk mitigation 27%
- Authorisation not possible 6%

Conclusion: Re-evaluation does NOT add value

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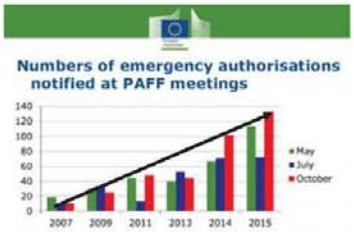
European legislative framework (III)

- Emergency authorisations



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European legislative framework (IV)

- Effects on minor uses and specialty crops depend on:
  - ***how the zonal system works in practice***
  - ***how mutual recognition is applied***

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European legislative framework (V)

- EU added value
  - Harmonisation (guidelines and interpretation, i.e. CfS, MUSC,…)
  - Risk assessment (EFSA)
  - Single zone for MRL → Single market and trade
  - Minor Uses Coordination Facility

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Shortcomings and actions

Shortcomings and actions (I)

Shortcomings

- Loss of active substances (EDs)
- Obstacles to mutual recognition within same zones
- Not unique list of minor uses and specialty crops / no definition
- National assessment for alternatives to Candidates for Substitution
- Lack of commitment and not enough funds for Minor Uses (CF)

Shortcomings and actions (II)

- Agri-Food Chain Roundtable (AFCRT)
- Update of Collaboration roadmap with International Biocontrol Manufacturers' Association
- Other collaborations
  - Low Yield report, workshops (neonicotinoids…)
- Participation in the EU Minor Uses Coordination Facility
- Participation in the Sustainable Plant Protection Initiative

Proposals and recommendations

Proposals and recommendations (I)

Regulatory aspects

- Propose a positive definition to Minor Uses and Specialty Crops
- Facilitate registration (including pan-European autorisation for MUSC)
- Provide more incentives for companies to invest:

Possible risk classes	Approval periods
Cut-off	No approval
CfS	7 → 10 years
Specific risk	10 → 15 years
Standard	10-15 → 20 years
Low risk	Unlimited approval period

- Application of Commission Implementing Regulation amending the criteria of low risk substances

Proposals and recommendations (II)

Other initiatives

- More integration/coordination of EU programmes with GMUS
- More European *vs* national initiatives (MRL, MR, CF, zonal and European authorisations…)
- Long-term funding of the Minor Uses Coordination Facility
- Allocate EU research funds for MUSC
- To develop chemical and non-chemical solutions for MUSC, according to IPM principles
- **Bottom-up approach: ensuring Farmers and Agri-Cooperatives' involvement**
- Stakeholders participation in the Sustainable Plant Protection Initiative

Proposals and recommendations (III)

Many of the recommendations are shared through the AGF Chain:

MUSC is a MUST => Need to build a solution

There is a momentum:

- Persistent call of AFCRT and its members on the need for a robust and long lasting solution
- MUSC was recognised through the setting up of the Minor Uses Coordination Facility Secretariat
- Pan-European cooperation based on trust is key to address the issue of MUSC
- Minor Uses Coordination Facility Secretariat = appropriate forum of debate and action
  - Commodity Experts Groups
  - Horizontal Experts Groups
- Role of European Commission , Member States Competent Authorities
- REFIT process of Regulation (EC) N° 1107/2009 = opportunity to review options for either taking benefit of existing provisions or identify new requirements to better address MUSC

Conclusion

Conclusions (I)

- EU competent authorities are very reluctant in dealing with MUSC
- PPPs industry is very active in "greening programmes", less in MUSC
- Both are hoping that farmers are doing the work and paying the bill (twice)
- Nice work is done in the technical groups where some MS and stakeholders are taking the lead, having big positive results
- More of this cooperation/collaboration is needed
- Implementation of Mutual recognisation in MS should be imposed by EC
- Big pressure on all kind of AI will influence MUSC in the first place
- Growers and PO are doing there part , please join/help us

because

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european farmers european agri-cooperatives

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european farmers european agri-cooperatives

Conclusion (II)

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european farmers european agri-cooperatives

Thank you for your attention

www.copa-cogeca.eu

附件 10-5

A Regional Look at Grower Challenges and Engagement: Enabling Current and Future Opportunities

A Regional Look at Grower Challenges and Engagement: Enabling Current and Future Opportunities

Tanzania Horticultural Growers Perspective

Kelvin Remen Swai
Policy and Advocacy Manager

Tanzania Horticultural Association (TAHA)

About TAHA

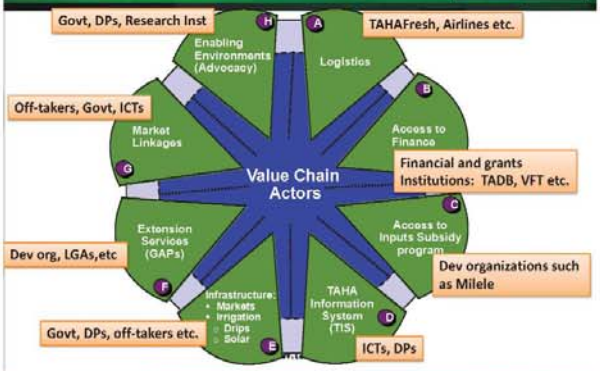
- Established in 2004 and became operational in 2005
- Established to promote and develop horticulture and address the general and specific needs of its members.

VISION: *"An economically vibrant and sustainably prosperous horticulture industry"*
MISSION: *"Driving inclusive, transformative, competitive and sustainable horticultural growth in Tanzania"*
Coverage: 15 regions including Unguja and Pemba
TAHA's four main Strategic Objectives:

1. Lobbying and Advocacy - Govt and donors,
2. Technical Support – projects, trainings, seminars, shows, etc
3. Information dissemination – media, researchers, govt, consultants, etc
4. Promotion – in and outside Tanzania

www.taha.or.tz

TAHA Approach and Coordination

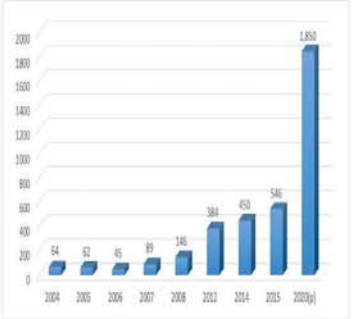


Logistics

Enhanced productivity

CONTRIBUTION OF HORTICULTURE IN TANZANIA

- Main contributor to foreign income earned from agriculture (38%)
- Rapid growth: US$ 545.5million in 2015 from UD$ 64million in 2005
- Employs about 2.5million people: 44 Million ha of arable land, only 6% utilized
- Food and Nutrition security
- Youth and women employment



Horti Production Trend in Tanzania

Aggregate production data (MT) 2013/14 – 16/17

No.	Crop	2013/14	2014/15	2015/16	2016/17
1.	Fruits	4,416,690	4,574,240	4,711,000	4,946,550
2.	Vegetables	1,005,305	1,041,375	1,189,000	1,236,560
3.	Flowers	10,790	11,140	11,500	11,615
4	Spices	8,377	8,609	20,400	21,420

-Three quarters of horticultural products is fruits (in terms of volume)

- Increasing number of customers of the products
- Increasing population and
- Awareness: horti as a key component to food and nutrition security

www.taha.or.tz

Our Advocacy work

Ensure access to quality agricultural inputs (availability, accessibility, affordability and proper utilization)

- In 2008, TAHA managed to secure a blanket registration for 300 pesticides for veggies and fruits in Tanzania
- Fertilizer (Amended) Regulations 2017
  - -Reduction of field trial period from three cropping seasons to one.
  - -Reduction of field trial costs from USD 30,000 to USD 10,000
- Registration of Biological Control Agents for veggies and fruits (Currently working on the regulations for registration of microbials).

Our Advocacy work.....

- Close working relationship with Government Registration Authorities/Agencies (TPRI, TFRA, TOSCI, NBCP)
- Strong relationship with Agro dealers (Allied members) i.e. Syngenta, Yara, Real IPM, Triachem, By trade
  - - Technology Testing, dissemination and promotion to farmers

Our Involvement in IR4 Project

- We are part of the research
- Local coordinators on the ground
  - -Funding Management
  - -Trial Farms identification
  - -Agronomic support to the project
- Participating in residue and efficacy trials
  - Supervised Residue Field Trials of Sulfoxaflur (Closure 240SC) on mangoes

Achievements from IR4 Project

- **Anticipated Increase in export/trade potentials** as veggies and fruits produced are in line with market requirements (MRLs levels)
- **Capacity building**
- ✓ of local research institutions and government regulators in conducting high quality residue field studies, conducting innovate research related to reducing pesticide residues on food crops
- ✓ Residue analysis
- **Food and Environmental Safety** as a result of proper application of less hazardous pest control products

Harmonization of Pesticide Registration in East Africa

- Three technical groups were constituted to work on three envisaged guidelines
  - harmonization of efficacy trials
  - harmonization of residue trials for pesticide registration
  - harmonization of pesticide registration data requirements
- **Harmonization of registration procedures** will facilitate movement of high quality products and increase farmers' access to quality pesticides
- **Abolition of red tape bureaucracies** in registration will increase farmers' access to newer and less hazardous pest control products

Our Contacts

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See Us At:

Website: www.taha.or.tz

FB: https://www.facebook.com/TanzaniaHorticulturalAssociationTaha?fref=ts

TAHA PHOTOS: https://www.flickr.com/photos/tahacommunications

www.taha.or.tz

附件 10-6

A Regional Look at Grower Challenges and Engagement: Enabling Current and Future Opportunities Chilean fresh fruit industry perspective

ACHIPIA
Agencia Chilena para la Inocuidad y Calidad Alimentaria

A Regional Look at Grower Challenges and Engagement: Enabling Current and Future Opportunities

Chilean fresh fruit industry perspective

Eduardo Aylwin
Agronomist, Chilean Food Safety and Quality Agency
Third Global Minor Use Summit (GMUS-3) Montreal, Quebec, Canada October 1-4, 2017

Alimentos seguros y saludables, tarea de todos y todas

Chile in the global economy

Chile has 26 free trade agreements with 64 markets, representing 64.1% of the world population and 86.3% of global GDP.

CODEX ALIMENTARIUS
International Food Standards
World Health Organization

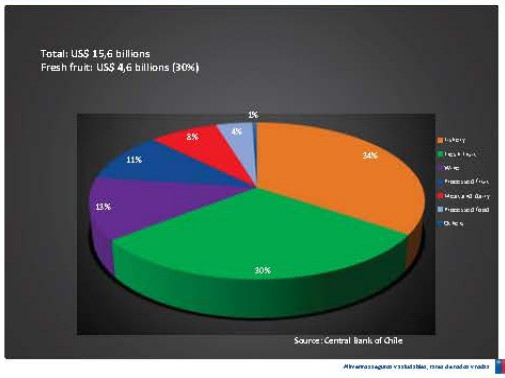
WTO OMC
SPS Agreement

OECD
BETTER POLICIES FOR BETTER LIVES

APEC
Asia-Pacific Economic Cooperation

Alimentos seguros y saludables, tarea de todos y todas

Chilean fresh fruits exports 2015 (2015: 2,4 millions tons)



Alimentos seguros y saludables, tarea de todos y todas

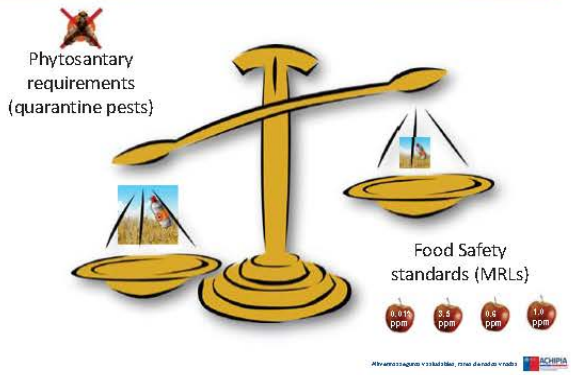
Facts

Fruits from Chile	Every day 82 million consumers in the world eat fruit from Chile.* Shipments to more than 180 countries on 5 continents
1 SHAFFE	Chile is currently the main exporter of fresh fruit in the southern hemisphere **and 4th fresh fruit exporting country in the world (2014)***.
1 Grapes from Chile / Blueberries from Chile	Chile is the leading exporter of grapes and blueberries in the world. **
2 Cherries from Chile	Chile is the second largest exporter of cherries in the world. **
FOODS FROM Chile	Chile is perceived as a reliable and "world-class" supplier in terms that meet the demands and regulations of the international market. ****

Source: *ASOEX y ProChile (2014), ** FAO (2011), ***Global Trade Information Services GTIS (2015), **** Promar (2011)

Alimentos seguros y saludables, tarea de todos y todas

The Chilean fruit industry has been successful in meeting phytosanitary requirements and food safety standards around the world.



Alimentos seguros y saludables, tarea de todos y todas

Pesticide Authorization & MRLs settings

The authorization (register) of pesticides in Chile is faculty of SAG, National Agricultural and Livestock Service (Regulation 3670/1999). The process follow guidelines of:

- FAO/WHO International Code of Conduct on Pesticide Management and international conventions and protocols (Rotterdam Stockholm Basel and Montreal)

The Ministry of Health through the dictation of the appropriate technical standard shall determine the **tolerances for residues of pesticides** in food allowed (Regulation No. 33/2010 and No. 762/2011)

In Chile it is not carried out a risk analysis process for the establishment of MRLs and are adopted from CODEX, EU or USA

Alimentos seguros y saludables, tarea de todos y todas

MRLs settings

Supreme Decree No. 977/96 art 162: "The Ministry of Health through the dictation of the appropriate technical standard shall determine the tolerances for residues of pesticides in food allowed"

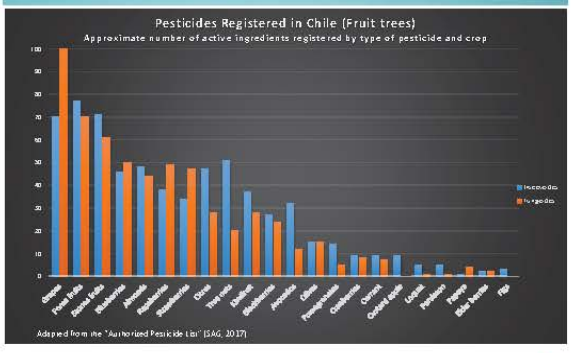
Regulation No. 33/2010 and No. 762/2011 (Current regulation)

In Chile it is not carried out a risk analysis process for the establishment of MRLs

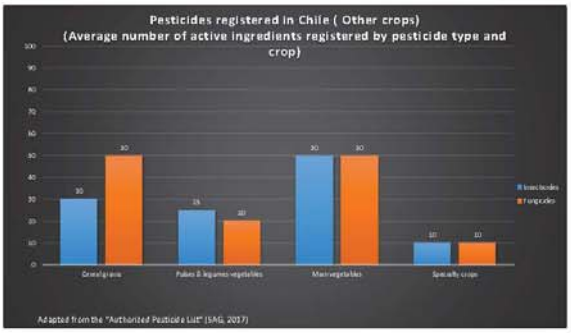
Criteria:

1. CODEX
2. EU or USA MRLs (depending on specific criteria)

Alimentos seguros y saludables, tarea de todos y todas



Alimentos seguros y saludables, tarea de todos y todas



Adressing Minor crops issues in Chile

Stakeholders

Regulator	Pesticides industry	Growers and exporters
Agriculture and livestock Service (SAG)	AFIPA (Croplife) IMPPA (Generic)	ASOEX / FEDEFRUTA
Authorization	Request autorizations	Use authorized pesticides

Market need

Pomegranate case

(A fast-growing crop in recent years with few pesticides authorized to control pests)

Growers and exporters	Pesticides industry	Regulator
ASOEX / FEDEFRUTA	AFIPA (Croplife) IMPPA (Generic)	Agriculture and livestock Service (SAG)
ask for new uses	Support new uses	Authorize new uses

Quarantine pest control need

Phytosanitary authority order obligatory controls in host crops. Some crops were not authorized for the recommended pesticides.)

Growers and exporters	Pesticides industry	Regulator
ASOEX / FEDEFRUTA	AFIPA (Croplife) IMPPA (Generic)	Agriculture and livestock Service (SAG)
		Authorized new uses

No market need, no quarantine need?

Is the case of some minor crops in Chile (herbs, spices, specialty vegetables)

Growers and exporters	Pesticides industry	Regulator
ASOEX / FEDEFRUTA	AFIPA (Croplife) IMPPA (Generic)	Agriculture and livestock Service (SAG)
Need pesticides for minor crops	Low interest in support new uses for minor crops	No Authorization

Summary

- Fruit growers and exporters in Chile have shown great adaptability in pest management considering both availability of pesticides, phytosanitary requirements and different official and private MRL standards around the world.
- Minor crops issues in Chile has been solved mostly under quarantine requirement situations and when the market demand is enough. In this cases, there has been engagement of stakeholders to support positive outcomes for minor uses.
- Stakeholders in Chile have not participated in assistance programs to seek solutions.
- There were some initiatives that proposed to jointly finance the effectiveness trials but did not prosper.
- There is a huge challenge for the country and its stakeholders to offer collaborative solutions to the problem of minor uses and to participate actively in regional or international assistance programs.

Acknowledgments

ASOEX 80 Años 1935-2015
Fruits from Chile
Foods from Chile

ACHIPIA

eduardo.aylwin@achipia.gob.cl
www.achipia.gob.cl

Alimentos seguros y saludables, tarea de todos y todas

附件 10-7

A Regional Look at Grower Challenges and Engagement

Through innovation, Hort Innovation strives to increase the productivity, farm gate profitability and global competitiveness of Australia's horticulture industries.

- Not-for-profit, grower-owned RDC for Australia's $9.5b horticulture industry
- Invest > $100m in research, development and marketing programs annually

Hort Innovation Minor-Use Program

- Facilitates Strategic Agrichemical Review Process (SARP)
- Data generation projects to support minor-use
- APVMA Permit applications
- Contact for permits/label extensions with the APVMA & Registrants
- Maintains database of industry permits/applications/data
- Provides updates to industry.

Some of the Challenges Industry Face

- Market Failure - Limited access to new or existing pesticides
- Timelines to gain access - permits / label registrations / new chemistry
- High cost of new pesticides
- Increased environmental and OH&S regulations
- Restrictions and / or loss of pesticides
- Maximum Residue Limit (MRL) / residue issues / violations
- Market requirements - Export
- New and emerging pests & diseases
- Pesticide resistance
- Consumer expectations

Pesticide Registration Challenges – Market Failure

- The Australian market represents only 1-2% of the global pesticide market
- Market often fails to provide access to suitable registered pesticides for many use patterns (small market & low return on investment)
- Problematic cost/benefit to register minor use when full data packages are required
- Prolonged timeframes can be involved to secure a minor use registration

APVMA National Permit System

- The APVMA's National Permit System adds some flexibility to the approval process and provides a legal framework that can allow access to products for minor-use purposes
- To issue an off-label permit, the APVMA must be satisfied the proposed use will be effective and will not have any adverse effects on humans, the crops, the environment and where relevant trade

Permit Applications

To satisfy the APVMA an application has to have addressed the statutory criteria (safety, efficacy & trade), by using one, or a combination, of the following methods:

- Providing relevant data (efficacy & safety, residues & trade, OH&S & environment)
- Providing a valid scientific argument (extrapolation)
- Using overseas data assessments and decisions

Minor-Use Permits

APVMA Registration Statistics

- Approx. 2/3 of the total volume of pesticides used in Australia is in grain crops
- APVMA receives about 250 permit applications per year,
  - 40% are for renewals
- 900-1000 permits are currently in force
  - 80-90% are for generic products
- 60% of applications are for horticulture; 10-15% are for broad acre crops
- 85% of applications have no trial data submitted and are assessed without provision of new data
- 85% of minor use applications require residue trial data to be provided for renewal
- 2/3 of new plant commodity MRLs come from minor use permits

APVMA Decision

- Issue of a permit – Notification plus any requirements for permit renewal
- How long is a permit issued for?
  - Minor-Use (3 years) with data requirements for renewal
  - Minor-Use (4 -10 years) no outstanding data requirements
  - Emergency Use-Permit (period necessary)
  - Research Permits (1 to 2 years)

Export / Trade and Chemical Review Challenges

Disparate approaches to MRL setting domestically and for import tolerances between countries;

- Varied processes for gaining import tolerances
- Data assessments
- Fees and data requirements
- Who can apply
- Timelines for assessments
- Differing default MRL's
- Differing commodity classifications

Export Compliance

Negative

- Lack of or different use patterns leading to different MRL's
- Can preclude use in export crops

Positive

- Where Codex MRLs recognised/adopted

Import Tolerances

Negative

- Gaining an import tolerance can be complex, expensive and difficult to achieve (data requirements, fees etc)

Positive

- Where Codex MRLs recognised/adopted

Regulatory Methodologies

Negative

- Differing risk philosophies can impact chemical review & new chemistry assessment outcomes causing a disconnect
- Differing toxicological end points (ADI & ARfD)
- Differing residue definitions – residue trial data and MRLs don't match between countries

Positive

- Where JMPR recommendations accepted/adopted
- Accepting Codex MRLs

By working together we hope to ensure a sustainable and productive industry for future generations.

Thank you

附件 10-8

How Growers Face the MRL Challenge

BRYANT CHRISTIE INC. | Exponent

How Growers Face the MRL Challenge

GLOBAL MINOR USE SUMMIT 3
OCTOBER 3, 2017, MONTREAL, QUEBEC, CANADA

MATT LANTZ
VICE PRESIDENT, GLOBAL ACCESS
BRYANT CHRISTIE INC.

DR. CAROLINE HARRIS
Corporate Vice President, Center Director & Principal Scientist
Exponent International Ltd.

BRYANT CHRISTIE INC. | Exponent

What We Hope You'll Come Away With

- How Commodity Groups Approach MRLs
- Areas of Challenge for MRLs
- Positive Developments and Areas of Cooperation on MRLs

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What We All Want to Avoid…

BRYANT CHRISTIE INC. | Exponent

I. How U.S. Commodity Groups Approach MRLs

- Major Transitions
- Day-to-Day Issues

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A. MAJOR MRL TRANSITIONS

Other markets with new MRL regulations pending: **Mexico; Morocco; Peru, Dominican Republic**

BRYANT CHRISTIE INC. | Exponent

A. Major Transitions: U.S. Industry Actions

- Assess MRLs Used and Missing in Foreign Market
- Relevant List of Needs: Even if MRL Missing - Possibly Not Issue
- Seek MRLs: Various Systems Employed
- Cooperate with U.S. Government During Transitions
- Engage Early

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B. Day-to-Day MRL Issues

- Pro-active Daily Work
- MRL Monitoring: WTO Notices; Providing Comments
- Work with Registrants on new Compounds
- Work with IR-4 on new MRLs
- Assist with Residue Violations

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II. Areas of Challenges Growers Face with MRLs

- Timing of MRL Approvals
- Differing Data Requirements
- Generic Products
- Challenging and Out–of–Proportion Sanctions Policies for Violations
- Insufficient Time to Comment or Ignoring Comments
- Codex Resources (improving)

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III. Positive MRL Developments and Areas of Cooperation From Our Perspective

- Elevation of MRL Issue
- Unintentional Trade Barrier
- Success in Major Transitions
- Improvement in WTO Notifications
- Availability of Data
- International Commodity Group Cooperation
- Codex Resources

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MRL Resource

- GlobalMRL.com
- All International MRLs
- Updated Daily
  - 100+ Markets
  - 900+ Active Ingredients
  - 700+ Commodities

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For More Information on MRLs and International Trade:

- *Declining International Cooperation on Pesticide Regulation; Frittering Away Food Security*
- https://www.palgrave.com/la/book/9783319605517

BRYANT CHRISTIE INC. Exponent

Thank You!

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陸、會議及參訪相關照片

圖 1 本次會議地點位於加拿大蒙特婁市伊莉莎白皇后飯店 (Hotel The Queen Elizabeth)。

圖 2 會議參與人員來自各國主管農藥的政府機構及相關植物保護業者共約 230 名。

圖 3 筆者於現場留影。

圖 4 與 Alan Norden (澳洲 AVPMA) 及 Lois Rossi (前美國農藥登記處處長) 合影。

圖 5 分組討論情形。

圖 6 田間參訪：田間釋放玉米螟卵寄生蜂 (人工懸掛及無人載具投放)。

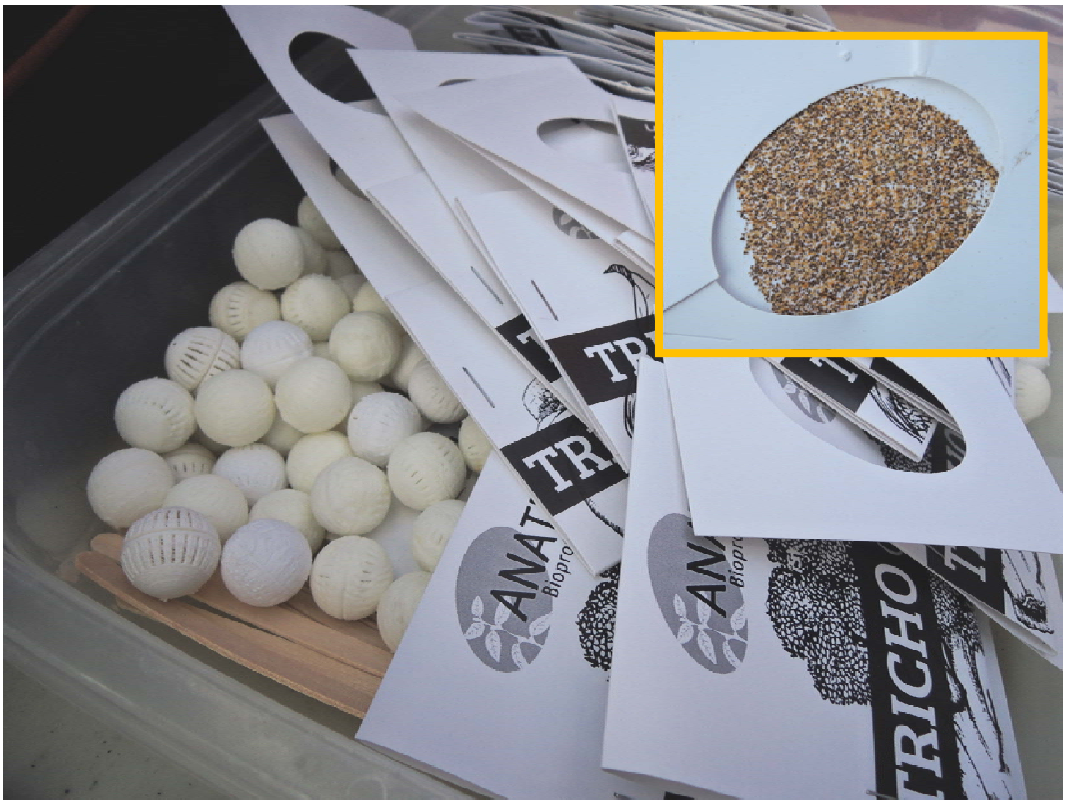

圖 7 玉米螟卵寄生蜂可裝載於白色球狀物內由無人載具投放或是人工懸掛卵片。

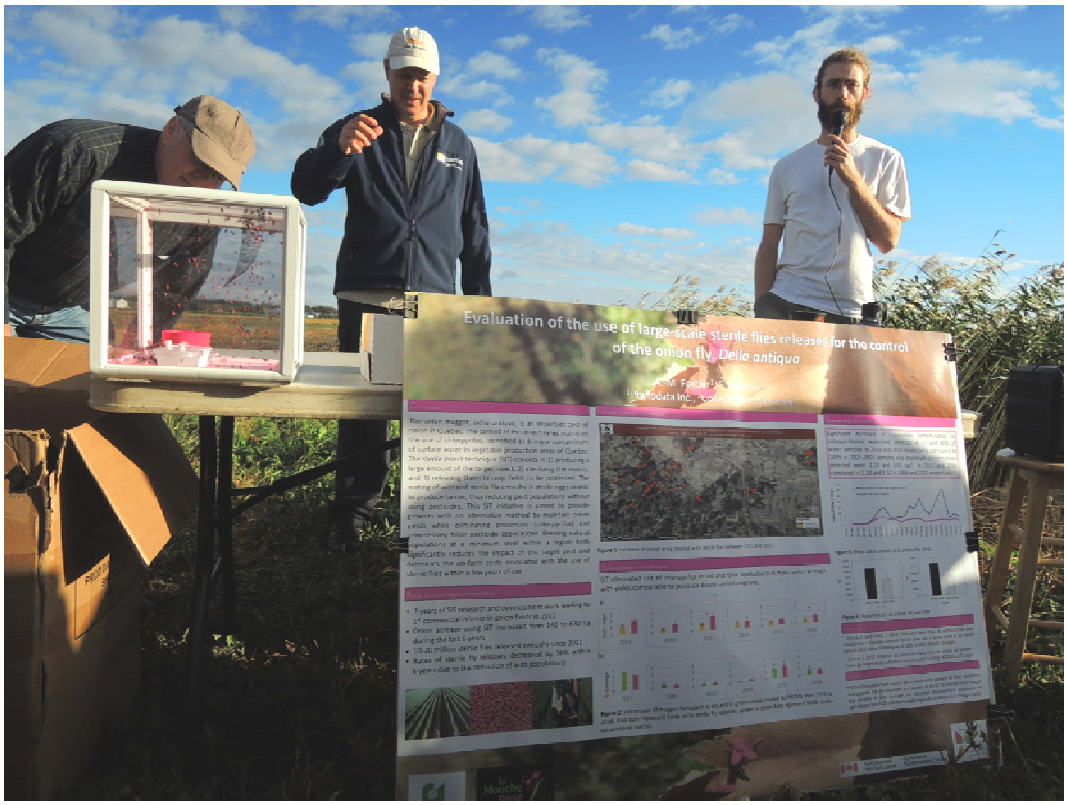

圖 8 以不孕性技術取代以往主要以陶斯松的方式防治蔥地種蠅。

圖 9 以紅色染劑區分已輻射處理之不孕性個體。

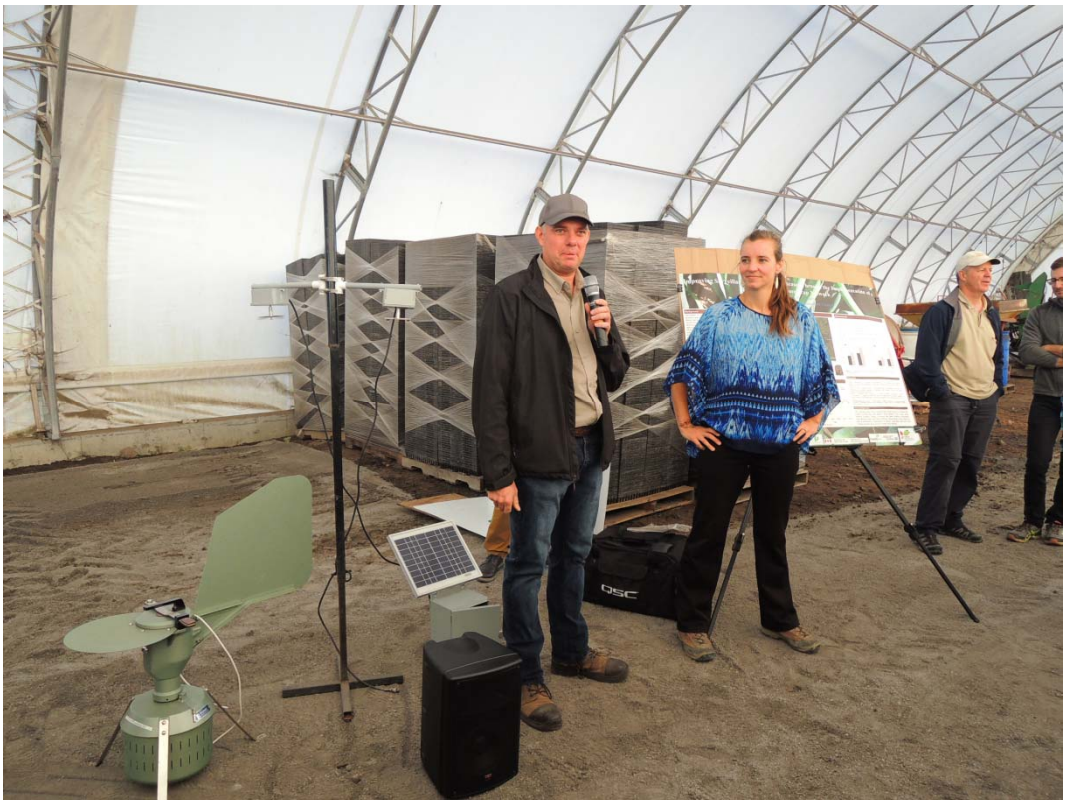

圖 10 介紹利用收集空中孢子來偵察區域性空氣傳播植物病害。

圖 11 搭乘耕耘機參訪結球萵苣現場採收工作。

圖 12 結球萵苣係以人工採收後，經藥劑初步處理後再自動化包裝。

圖 13 參訪加拿大農業及農業食品部之田間試驗中心，並介紹 IR-4 GLP 田間試驗流程及相關設備。

圖 14 參訪 IRDA 研究中心。

圖 15 介紹以網罩方式減少蘋果病蟲害之研究

圖 16 介紹改善噴藥器具以改善防治效果並減少農藥使用與飄散。

行政院農業委員會動植物防疫檢疫局