



Challenges and Considerations for Minor Uses in LATAM

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Topics for the Presentation

- Key Definitions
- Examples of Minor Uses Programs
- MRLs Establishment and the relevance of GAP
- Efficacy/Residue Data Needs for Minor Uses
- Data Sharing: Crop Grouping, Zoning, Extrapolation
- MRL needs for Minor Crops in Developing Countries
- Minor Use Program needs in LATAM



Key Definitions



- Minor Use
 - A Minor Use
 - Relative concept related to different proportionality of crops planted area in each Country.
 - In USA Minor use crops (specialty crops) are defined as any crop grown on $\leq 120,000$ ha (300,000 acres) (FIFRA).
 - “USDA includes most vegetables, fruit, nuts, herbs, spices, nursery, landscape plants, greenhouse and flowers. Almost all food crops are minor use crops except for the large acreage crops like corn, soybeans, wheat, oats, rice and cotton.” (IR-4)
 - In EU guidelines 7595/VI/95-rev.7 crops are divided in major and very minor. Criteria used:
 - Daily dietary intake contribution
 - Cultivation area $> 10\,000$ ha
 - Production $> 200\,000$ ton/year / < 600 ha: very minor



Key Definitions (Contd.)

FAO Manual 2002



- Maximum Residue Limits (MRL)
 - “the maximum concentration of a pesticide residue (mg/kg), recommended by the Codex Alimentarius Commission (CAC) to be legally permitted in or on food commodities and animal feeds. MRLs are based on GAP data and foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable. (Codex Alimentarius Vol. 2A)”
- Good Agricultural Practices (GAP)
 - “nationally authorized safe uses of pesticides under actual conditions necessary for effective pest control. It encompasses a range of levels of pesticide applications up to the highest authorized use, applied in a manner which leaves a residue which is the smallest amount practicable”
- Pre-harvest Interval (PHI)
 - The time between the last pesticide application and harvest of the treated crops (EPA)



Key Definitions (Contd.)



- Crop Grouping (Markle, Baron, and Schneider, 1998)
 - Refers to the grouping of crops according to a similar characteristics (14) that make possible to put the individual crop together, such as: Botany, geographical distribution and production, cultural practices, commercial importance, possible genetic improvements, codex classification, etc.
- Representative Crops
 - Crop(s) that represent the whole group
 - E.g. EPA Crop Grouping Scheme Group 1. Root and Tuber Vegetables (carrot, potato, radish and sugar beet would represent 39 other minor root and tuber crops)
- Trade Irritant Issue
 - Arises when there is an MRL discrepancy in an exporting and importing Country. There are 5 categories: A-E. This is a NAFTA definition and has affected trade among countries, mainly for Minor Uses.



Examples of Minor Uses Programs. Canada



<http://www4.agr.gc.ca/AAFC-AAC/display-afficher.do?id=1177525838285>

- The **Minor Use Pesticide Program** was launched in **June 2002**, committed **\$54.5 million over six years** to develop/implement joint initiative between AAFC and Health Canada Pest Management Regulatory Agency (PMRA)
- AAFC uses its \$33.7-million share of funding to improve access to minor use pesticides and to conduct field trials of minor use pesticides.
 - The PMRA will use its \$20.8-million share to increase its capacity to review submissions, and to provide shorter time lines for registration
 - Working closely with IR-4 officials to share information, consult on program content, and build strong relationships.
 - Headquarters located in Ottawa, field trials at 10 AAFC sites and at private contractors across the country, under GLP standards.
 - The **Pest Management Centre** reviews the data resulting from field trials and laboratory analyses, and prepares a submission to PMRA in support of registration on minor crops.



Example EU Minor Crop Programs



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- **Private initiatives** of research centers
 - Add uses for growers, registrant not involved
- **SANCO/D3/SI2.396179**, Oct. 2005
 - Proposed to extend extrapolation and reduce residue trials for minor crops
 - Registration data post 1995 was analyzed
 - Same major vs. minor classification
 - Tables Appendix D updated with extrapolations for early & late applications
 - Inter-groups extrapolations: apples – nuts, carrots – teas, lettuce – *Brassica*...
 - National databases for minor crops were proposed
- **Global Minor Use Summit**, Dec.2007 (FAO, IR-4, US – EPA, USDA)
 - Harmonization of crop grouping system, and extrapolation of zoning
 - Harmonized residues data generation and shared reviews
 - Countries access to advanced residues programs



Examples of Minor Uses Programs. Mexico



- A non-official program was initiated in Mexico 2005 attending the needs of Berry Growers (Minor Crops: avocado, nopal/cactus, species, etc) with adoption of MRLs
 - Minor Uses definition: not yet officially established
 - Key Stakeholders
 - Berry Growers/ Exporters/Packers
 - Field site and efficacy expenses
 - Crop Protection Industry
 - Government fees for Efficacy and Registration
 - Government (Minister of Agriculture SENASICA)
 - Efficacy verification and time for review
 - Academy/Nat. Research Institutes (Official researchers)
 - Reduction in cost of efficacy studies
 - Regulatory Agency, COFEPRIS (Minister of Health)
 - Priority Review and MRL acceptance (Oct 07)
- Pineapple program in coordination with IR-4 Program
 - MRL/Tolerance proposed (currently under review by EPA)



Example of Minor Uses Programs. Colombia (002668/ 8 Oct 2007)



- Resolution in 2007 defines Minor Uses
 - Crop for human consumption < 5,000 ha
- Needs base on
 - Import Country requirements (EUREPGAP)
 - Lack of crop protection products for these crops
- Resolution decided to take actions for increasing the time limited use of chemical pesticides, bio pesticides, and plant extracts in Minor Uses.
 - Art 1. ICA can authorize for 3 years a label expansion for products with registration in other crops by making **efficacy trials**.
 - Art 2. **Certificate** from the country where the product is registered; **GAP** (PHI, dose, # applications, REI; label project, and fee).
 - Art. 3. Authorization in **15 working days**.
 - Art 5. Once efficacy is completed, **full registration** will be granted.
- Res. 2906 of 2007 for MRLs food and feed
 - CODEX
 - Does not indicates link with current registration process



Examples of Minor Uses in Developing Countries. Other Experiences

- Ecuador (Cocoa exports)

- Issues with trade irritants with Japan (cacao, papaya, pineapple)
- Risk to cancel all importations from Ecuador



- Costa Rica

- Veg-crops to set/extrapolate MRLs, monitor residue, GAP improvement
 - Adoption according to import country (pineapple export)



Examples of Minor Uses in Developing Countries. Other Experiences. Brazil



- Public Consultation 055 (11 Sept 2006)
(good starting point, not published yet)
 - Criteria for LMR establishment for crops with very few “phytosanitary support” (no size of planted area cited)
 - It defines:
 - Crop grouping only for these crops (12) with representative crop (not harmonized)
 - MRL extrapolation temporal
 - Need residue study (24 months)
 - Efficacy studies required according to Normal procedures



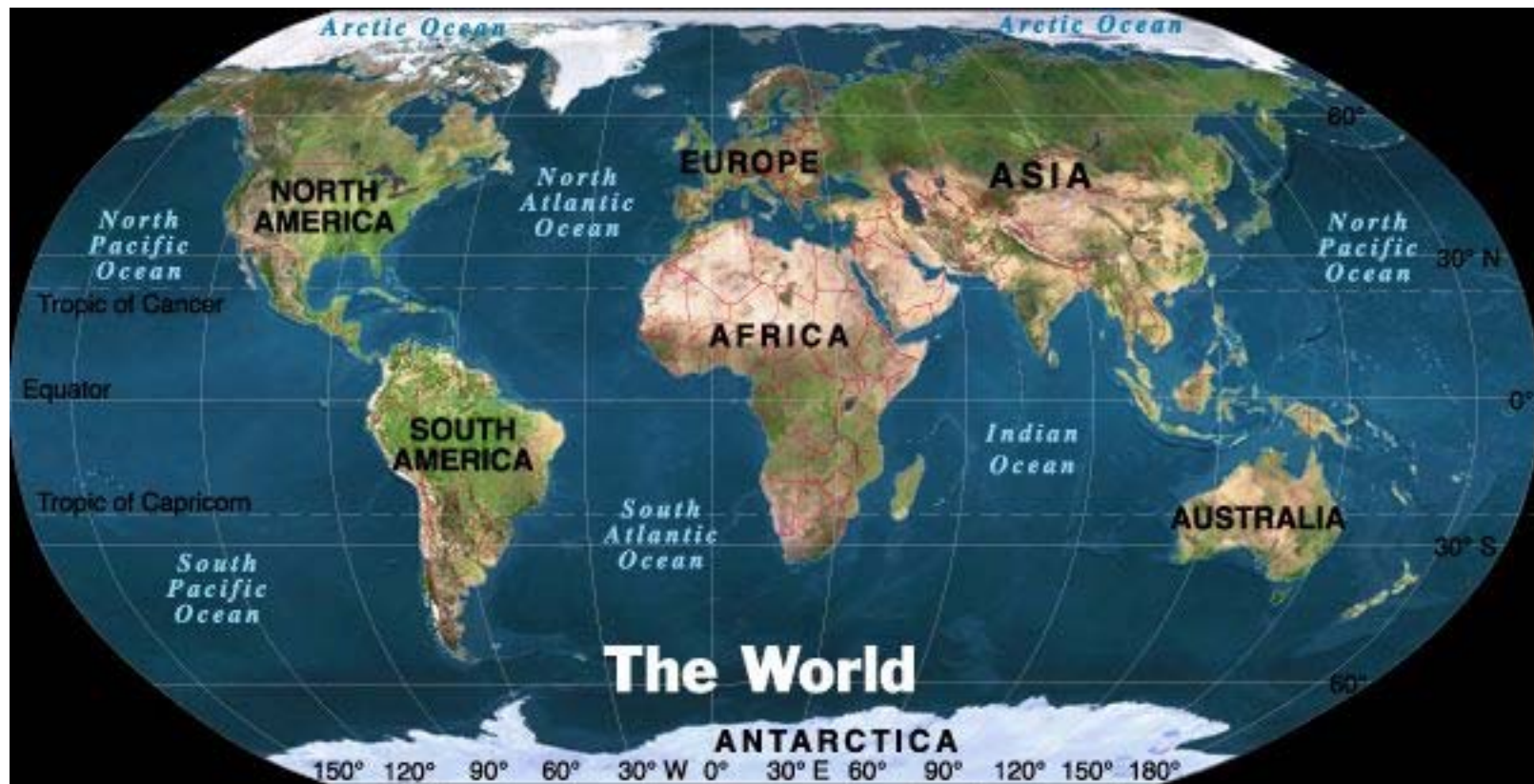
Examples of Minor Uses in Developing Countries. Other Experiences. Argentina



- Main Problems on Minor Crops
 - Low market for R&D companies
 - High cost for Efficacy, Residues, Metabolism, etc to grant registration
 - Extrapolation and Cost sharing
 - University or small group of farmers to run efficacy and residue trials
 - Lab Analysis in official institutions
 - Definition of Minor Uses/crops (area, consumption)
 - Crop Grouping (?)



Examples of Minor Uses in Developing Countries. Other Experiences



MRL Establishment and the relevance of GAP

- Metabolism in plants and animals
- Analytical methods and storage stability
- Residue crop field trials conducted according to critical GAP
 - Residues in food/feed commodities (RAC's) analyzed at harvest, decline curves, processed fractions
 - Several number of trials are required for major/minor crops (2-20)
- MRL calculated to account for range of data
 - (ND, ND, ND, 0.1, 0.1, 0.2, 0.5, 0.8 ppm)
 - Historically proposed MRL = 1 ppm
 - Currently statistics used EU-methods, NAFTA-MRL calculator, Australian binomial method.
- Dietary intake assessment to confirm safety of MRL's



Efficacy/Residue Data needs for Minor Uses



- **Efficacy Data Generation**
 - Information should be simplified for developing countries; i.e. administrative procedures, No. trials, review timing, extrapolation if applicable, etc.
 - Each Company should be responsible to generate their own information
- **Residues Data Sharing**
 - Residue data should be extrapolated from GLP existing data (“*Report of the OECD/FAO Zoning Project. 2002*”) for similar GAP (< 30% variation)
- Crop Grouping should be expanded to facilitate extrapolation



Data Sharing: Crop Grouping, Zoning and Extrapolation

- EPA
 - 2005 revised part 158 CFR 40 -19 groups (+ 9 A,B,C...)
 - 40 CFR Part 180 (180.41 miscellaneous – minor crops)
 - Representative Crop
 - A crop(s) that represent several members of that Family group and can be used as representative commodity to make efficacy/residue studies.
- IR-4/EPA/CCPR leading global crop harmonization (bulb and fruiting vegetables, berries, edible fungi, oil seeds group, so far...)
- EU: EU 91/414/EEC and FAO 2002 Manual, appendix VI - 33 groups



Crop Grouping & Representative Crops



- OECD: 2005 revised guidelines – 12 groups
- CODEX
 - Index for Classes, Types (01-19) and Groups of Commodities (FP. MM. AL, etc.)
 - Class A Primary food Commodity of Plant Origin (Pome fruits FP)
 - Class B Primary food Commodity of Animal Origin (Meat MM)
 - Class C Animal Feed Commodity (Legume animal feed AL)
 - Class D Processed Foods of Plants Origins (Dried fruits DF)
 - Class E Processed Foods of Animal Origins (Dried meat and Fish products MD)



Data Sharing: Crop Grouping, Zoning, Extrapolation

- Residue data is usually accepted to be extrapolated, on a case-by-case:
 - For same/similar crops when GAP's vary within 30% (rate, PHI)
 - For similar use patterns: soil from foliar applications (US)
 - Within same zone, or supporting similarity of zones
 - With limited side-by-side bridging for purified isomers of AI's, similar formulations
- Examples
 - EU 7525/VI/95: from major to minor/very minor crops
 - USA: from major/representative ones to all others in the crop group



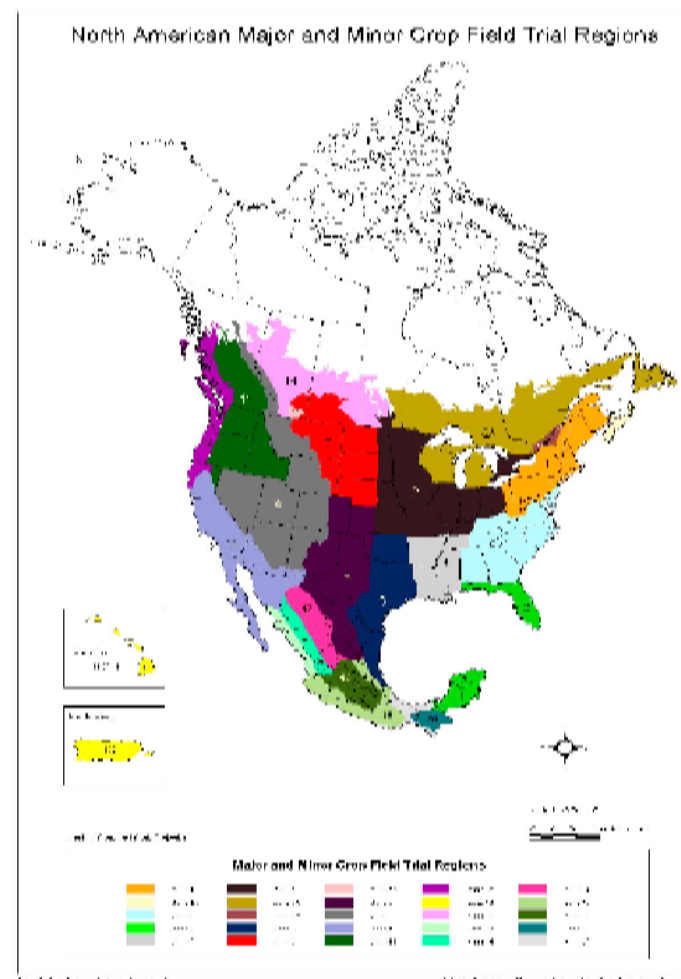
Number of trials for crop field residues

- Number of trials (1-20) for individual crops:
 - extension of crop planted area
 - intensity of consumption of food/feed commodities
 - intensity of trading commodities (OECD)
- US: 1-20 trials, >3 across regions, 2 decline curves for >15 trials.
- EU: 8 trials (4 N-EU + 4 S-EU)
- Brazil: 4 trials
- OECD: 3-12 trials
- Reduced number of trials (usually 25% less) is accepted for representative crops of crop groups.



Data Sharing for Residues and Zoning. Example

- Shared review for NAFTA registration
 - NAFTA Residue Zone Map from 13 to 21 regions
- EU with 2 regions
 - Northern and Central
 - Southern and Mediterranean
- OECD
 - 5 latitudinal regions



Projects/Initiatives for Global Zoning Maps

Objective: to define areas in the world where pesticide trials data could be considered comparable.

- Kopper-Geiger climate maps, since early '60s
- World biomes maps
- “Report of the OECD/FAO Zoning Project. 2002”, not conclusive but a good starting point for discussion on sharing data for residue and efficacy studies.
- US-EPA proportionality of zoning project
 - Review global/JMPR residue packages
 - Side-by-side confirmatory trials



MRL needs in Developing Countries

- Bottom up concept

- Key stakeholders committed:

- Growers
 - Exporters
 - Industry
 - Government Agencies
 - Food Chain



- Government Incentives

- Adopting MRLs (similar GAPs) from key importing Countries

- USA (EPA Tolerances)
 - Codex MRLs
 - EU MRLs
 - OECD Country MRL

- Data Protection



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ORGANISATION
FOR ECONOMIC
CO-OPERATION
AND DEVELOPMENT



Minor Use Program Needs in LTAM



- Future LATAM Minor Use Workshop (FAO sponsored)
 - Either Regional or Local on key Countries
- Alignment of Stakeholders
 - Authorities (Agriculture, Health and Environment according to Countries)
 - Facilitating registrations (MRL adoption, priority, costs, timing, number of trials)
 - Warranty Data protection and confidentiality
 - Growers + Food chain that export can share costs or other ways of cooperation
 - Industry: leading projects, generating data and sharing costs
 - Academy needs to develop Efficacy/Residue trials (priorities and costs)
 - International Organizations to support Minor Use programs in developing countries (FAO/CODEX, EU, USA, Japan)



Questions??

- Thank You!

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