Overview of the GMUS–2 work plan
UN FAO, Rome, Italy
February 21–23, 2012

Daniel Kunkel
Main Themes

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

- Establish membership*
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.
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…..
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…
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.
White paper topics...

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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
Working Together on Minor Use Issues

• Minor Use Programs
• Government Support for Minor Uses
• International Organization Support for Minor Uses
• Crop Protection Industry
• Crop Grouping Solutions
• IPR Issues
• Standards

Announcement

First Global Minor Use Priority Setting Workshop:
Seeking pest management solutions for growers around the world. September 20-22, 2013 in Chicago, IL, USA. See details.

About Us

Minor uses encompass crop protection needs that are essential for production. Since minor uses relate to low acreage crops or are minor uses on large acreage crops, the crop protection industry is reluctant to conduct the research that is required to register products for minor uses. The low acreage of minor crops results in an insufficient return on investment of the expenditures that are required to attain regulatory approval.

Additionally, there are resources required to maintain minor crop registration and liability issues from possible crop damage that the crop protection industry is often unwilling to assume. On a global basis, this presents problems for producers because of a lack of authorized options to control pests and diseases. This also affects producers seeking market access as well as exporters and traders of those commodities. Trade barriers often occur due to a lack of or differences in acceptable Maximum Residue Levels (MRLs) on produce.

The Global Minor Uses Summits have been provided in order to assist in addressing these issues.

Minor Use Summits

Participants from over 60 countries throughout the world have come together on two significant occasions (2007 and 2012) to discuss issues regarding minor uses and the issues surrounding them. For information regarding the two summits click here.

Global Summits

Key themes and activities from Global Minor Use Summit 2
1. Coordination & Collaboration
2. Communication
3. Incentives
4. Capacity Development
5. Registration of Minor Uses and MRL setting

GMU Steering Committee members
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
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!
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
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.
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
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.
Joint Residue Project includes 20 countries from around the world, with USDA coordination and IR-4 leadership.
Global Residue Project for Tropical Fruits

IR4/USDA coordination

Codex Submission

Bolivia
Colombia
Costa Rica
Guatemala
Panama

Egypt
Ghana
Kenya
Senegal
Tanzania
Uganda

Brunei
Philippines
Malaysia
Indonesia
Thailand
Singapore
Vietnam

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....

GMUF
Global Needs

India
Malaysia
Thailand
Vietnam

Bolivia
Colombia
Costa Rica
Ecuador
Panama
Peru

Ghana
Kenya
Senegal
Tanzania
Uganda
GLP Field Residue Studies
Global Capacity Building

Michael Braverman, Ph.D.
IR-4 Headquarters, Rutgers, The State University of New Jersey,
500 College Road East, Suite 201 W, Princeton, NJ 08540.
E-mail: braverman@aesop.rutgers.edu
The Process Starts with Requests
Submitted from:
• Growers,
• Grower Groups,
• University Research & Extension Personnel

Request Reviewed by Manufacturer

Potential Projects Identified
Top Priority Researched That Year
Second Priorities Researched as Money Allows

Efficacy

Lab capabilities
Field capabilities

Field and Lab Research
• Measure Residue levels in Crop/Crop Group

Manufacturer Adds Crop/Pest to the Product Label

CODEX MRL

JMPR

Government Regulatory Agency

Efficacy
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
• Bolivia - Field
• Colombia - Field and Lab
• Costa Rica - Field and Lab
• Guatemala - Field
• Panama - Field and Lab
GROUP TRAINING
GROUP TRAINING
GROUP TRAINING
GROUP TRAINING
CALIBRATION
CALIBRATION
CALIBRATION
CALIBRATION
CALIBRATION
CALIBRATION
APPLICATION
APPLICATION
APPLICATION
HARVEST
HARVEST
HARVEST
HARVEST
ANALYSIS
ANALYSIS
STDF-Capacity Building

Asia

Latin America

Africa

Global Priority Setting Workshop

IR-4 Data

Combined Data Set

International data

JMPR joint submission
COOPERATIVE AGREEMENTS
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.
Sponsor: WTO-STDF
(World Trade Organization-Strategic Trade Development Fund)

ASEAN Secretariat & ASEAN Expert Working Group on Harmonisation of MRL

- Malaysia/Singapore (pyriproxyfen-mango)
- Brunei/Malaysia/Philippines (pyriproxyfen-papaya)
- Thailand (spinetoram-mango & lychee)
- Indonesia/Vietnam (azoxystrobin & difenoconazole-pitaya)

USDA-FAS & IR-4 Technical Co-ordinator

OVERALL PROJECT STRUCTURE
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.
TRAINING CONDUCTED FOR ASEAN COUNTRIES

Field trial training (January 2013) and laboratory training (March 2013) in Bangkok, Thailand,

Quality assurance training, Bangkok, Thailand, January 2016

GLP Training, Bali, Indonesia, November 2014
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
Colombian experiences in IR4 participation
Spinetoram/avocado

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

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

Jacqueline Guevara, Yohana Velandia
Strenghts

• Team work commitment
• Personnel proficiency
• 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
Lessons learned

- Planning
- Personnel commitment
- Two people per role
- 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
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)
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
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
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.
Laboratory and quality assurance training in Kenya
Laboratory and quality assurance training in Kenya
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.

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<tr>
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ACKNOWLEDGEMENT

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

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- USDA-FAS- advisors

Thank you!
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

The Process Starts with Requests
Submitted from:
- Growers,
- Grower Groups,
- State/Federal Research & Extension Personnel

Stakeholder:
Define Pest Problem
Identify Pest Management Solution
Request Assistance from MU Programs

Requests Prioritized
Request Reviewed by Manufacturer
Top Priority Researched That Year
Second Priorities Researched as Money Allows

Field and Lab Research
- Measure Residue levels in Crop/Crop Group
- Efficacy / Crop tolerances trials

Manufacturer Adds Crop to the Product Label

Risk Assessment
MRL / Tolerance Established by Agencies

Packages submitted to Agencies

Minor Uses Value
Canada: $ 6 B
US: $ 38 B
Mexico: ???

The Regulatory Registration Process
Minor Uses Value
Canada: $ 6 B
US: $ 38 B
Mexico: ???
Common zones from West to East
Zone 12
Zone 11
Zone 7
Zone 5
Zone 1
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
## Partnerships

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

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

- Several mechanisms in place under the new legislation. Need to implement them!
- National dimension
- ...but need for EU co-ordination
- Report on EU minor uses fund under finalisation
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
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
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

Member States

Growers’ Organisations

Crop Protection Industry

MinorUses
EU Minor Uses Coordination Facility
EUMUCF: Long-term funding

- EUMUCF is jointly funded by the European Union and 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

Jeroen Meeussen
Coordinator
European Union Minor Uses Coordination Facility
21 boulevard Richard Lenoir
75011 Paris
FRANCE

T  +33(0)1 84 79 07 55
M  +33(0)7 60 82 22 36
E  jeroen.meeussen@minoruses.eu

website: www.minoruses.eu
Minor Uses in Brazil

Carlos Alexandre Oliveira Gomes
Health regulatory expert
MS/Anvisa/GGTOX
Normative Instruction Minor Crops

ANVISA, Ministry of Agriculture and the 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 underestimated (ANVISA).
- Improve the process of register of pesticides to Minor Uses. Demanded by supply chains of fruits and vegetables.
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).
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.
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.
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
A.I. with restriction to register using the INC 001/2014 (Minor Uses).

<table>
<thead>
<tr>
<th></th>
<th>Gamma-Cyhalothrin</th>
<th>Etiona</th>
<th>iminocyclidine</th>
<th>pymetrozine</th>
</tr>
</thead>
<tbody>
<tr>
<td>acephate</td>
<td>Clodinafop</td>
<td>epoxiconazole</td>
<td>linuron</td>
<td>prothioconazole</td>
</tr>
<tr>
<td>aldicarb</td>
<td>Diazinon</td>
<td>fenamiphos</td>
<td>mancozeb</td>
<td>Tiram</td>
</tr>
<tr>
<td>abamectin</td>
<td>Dicofol</td>
<td>Phosmet</td>
<td>Methamidophos</td>
<td>Triazophos</td>
</tr>
<tr>
<td>aviglicina</td>
<td>Dimethoate</td>
<td>Fenpropimorph</td>
<td>Methidathion</td>
<td>Terbufos</td>
</tr>
<tr>
<td>carbaryl</td>
<td>Diquate</td>
<td>Fenoxaprop-P</td>
<td>Metiram</td>
<td>Tebupirinofos</td>
</tr>
<tr>
<td>carbofuran</td>
<td>Disulfoton</td>
<td>Fipronil</td>
<td>Mevinphos</td>
<td>Tembotrione</td>
</tr>
<tr>
<td>carbendazim</td>
<td>Diazafenthiuron</td>
<td>Fentin</td>
<td>Paraquat</td>
<td></td>
</tr>
<tr>
<td>cyhexatin</td>
<td>Edifenphos</td>
<td>Glyphosate</td>
<td>Parathion-methyl</td>
<td></td>
</tr>
<tr>
<td>cadusafos</td>
<td>Endosulfan</td>
<td>Glufosinate-ammonium salt</td>
<td>Pyrazophos</td>
<td></td>
</tr>
<tr>
<td>cyhalofop Butyl</td>
<td>Ethophos</td>
<td>Haloxyfop-P</td>
<td>Prochloraz</td>
<td></td>
</tr>
</tbody>
</table>
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.
• 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.
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
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 and 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.
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.
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; § 1º - 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:
### Table 1. Representatives Crops of Groups and respective Minor Uses

<table>
<thead>
<tr>
<th>Groups</th>
<th>Representatives Crops</th>
<th>Minor Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 – Fruits with no edible peel</td>
<td>Citrus, Melon, Coconut</td>
<td>Avocado, pineapples, Cacao, Cupuaçu, Guaraná, Passion fruits, watermelon, Pinha, papaya. Kiwi, Açaí, Anonaceas, Dendê, macadamia nut, Pupunha.</td>
</tr>
<tr>
<td>2 – Fruits with edible peel</td>
<td>Apple, grape</td>
<td>Acerola, mulberry, Plum, olive, cashew, Kaki, star fruit, Fig, raspberry, Guava, Quince, Whortleberry, Strawberry, Nectarine, Loquat, Peach, Pitanga, Pear.</td>
</tr>
<tr>
<td>4 – Leaf vegetable</td>
<td>lettuce, cabbage, Kale</td>
<td>Water-cress, Allium porrum, Wild chicory, Broccoli, Scallion, Endive, coriander, Cauliflower, Chinese cabbage, Brussels sprouts, spinach, Manjericão, rocket, Parsley</td>
</tr>
<tr>
<td>5 – Fruits vegetable</td>
<td>Tomato, cucumber</td>
<td>Pumpkin, Summer squash, Eggplant, Chayote, Scarlet, Sweet pepper, eggplant, cucumber, Pepper, Okra.</td>
</tr>
<tr>
<td>6 – Leguminosae and Oil seeds</td>
<td>Bens, Soybean</td>
<td>peas, Chick pea, Lentil, Canola, Sesame, Sunflower, Linseed.</td>
</tr>
<tr>
<td>7 – Cereal</td>
<td>Corn and wheat</td>
<td>Millet, sorghum, oats, rye, barley, triticale.</td>
</tr>
</tbody>
</table>
Table 2. Representatives crops of Sub Groups to extrapolations of MRL to Minor Uses and to be reference in supervised field trials.

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

<table>
<thead>
<tr>
<th>Group</th>
<th>Crop Group Representative</th>
<th>Crop Sub Group Representative</th>
<th>Minor Crops</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. Fruits Vegetables</td>
<td>Tomato (<em>Solanum lycopersicum</em>)</td>
<td>5A Sweet pepper</td>
<td>Eggplants, scarlet eggplant, pepper, Okra</td>
</tr>
<tr>
<td></td>
<td>Cucumber (<em>Cucumis sativus</em>)</td>
<td>5B Cucumber</td>
<td>Pumpkin, summer squash, chayote e burr cucumber.</td>
</tr>
</tbody>
</table>

Field Trials (2 years)
Nº. of Products Formulated (PF) by companies:

Total of PF = 90
Nº. of new uses (crops) approved by companies:

Total of new uses = 969

- Basf: 187
- Arysta LifeScience: 168
- Du Pont: 110
- Nufarm: 104
- UPL: 93
- Syngenta: 69
- Dow: 61
- Iharabras: 52
- Adama: 33
- Cross Link: 32
- ISK: 18
- Rotam: 16
- Sumitomo: 6
- BR3: 5
- Rohm and Haas: 5
- Ouro Fino: 4
- FMC: 3
**No. of New uses per class products**

Total of new uses = 969
MEMORANDO DE ENTENDIMENTO ENTRE A AGÊNCIA NACIONAL DE VIGILÂNCIA SANITÁRIA (ANVISA) E O PROJETO IR-4 DO DEPARTAMENTO DE AGRICULTURA DOS ESTADOS UNIDOS (PROJETO IR-4)

relativo a agrotóxicos e agrotoxídicos de risco reduzido para pestes e pragas prioritárias comuns ao Brasil e aos Estados Unidos da América.

A Agência Nacional de Vigilância Sanitária (ANVISA) e o Projeto IR-4, patrocinado pelo Departamento de Agricultura dos Estados Unidos, designado como “Participantes”,

Reconhecendo a importância de melhorar o acesso do produtor agrícola aos agrotóxicos de risco reduzido e àqueles para culturas de suporte sanitário insuficiente, segundo um sistema regulatório robusto;

Considerando que a ANVISA estabeleceu a Gerência Geral de Toxicologia para avaliar os riscos à saúde humana decorrentes do uso dos agrotóxicos, preocupações sobre o acesso do produtor rural aos agrotóxicos para culturas de suporte fitossanitário insuficiente e para facilitar o registro de novos usos de agrotóxicos para culturas de suporte fitossanitário insuficiente e agrotóxicos biológicos em culturas alimentares;

Considerando que o Departamento de Agricultura dos Estados Unidos estabeleceu o Projeto IR-4 para responder a preocupações sobre o acesso do produtor rural aos agrotóxicos para culturas de suporte sanitário insuficiente, sobre os riscos ao meio ambiente e à saúde humana decorrentes do uso de agrotóxicos, para gerar dados e preparar documentos necessários ao pleito para o registro de novos usos de agrotóxicos para culturas de suporte fitossanitário insuficiente e agrotóxicos biológicos, e para desenvolver ferramentas, tecnologias e técnicas para o manejo de pestes e pragas de risco reduzido;

Desejando promover a colaboração para gerar dados e preparar documentos visando à submissão do registro, para aumentar a eficiência e manter a efetividade dos custos, coordenando a geração e o compartilhamento para a submissão de registros de novos usos de agrotóxicos para culturas de suporte fitossanitário insuficiente;

Almejando estabelecer os parâmetros da colaboração para melhorar o acesso do produtor de culturas de suporte fitossanitário insuficiente e novos usos de agrotóxicos;

Chegaram ao seguinte entendimento:
THANK YOU

www.anvisa.gov.br

toxicologiapic@anvisa.gov.br

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
AUSTRALIAN MINOR USE
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
      - 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
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

  • 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 approach for the assessment of cluster diets

Mouhamadou Moustapha Sy\textsuperscript{a}, Max Feinberg\textsuperscript{a}, Philippe Verger\textsuperscript{b}, Tanguy Barré\textsuperscript{b}, Stéphan Clémençon\textsuperscript{c}, Amélie Crépet\textsuperscript{d,*}

\textsuperscript{a} INRA, Unité Met@risk, 16 rue Claude Bernard, 75231 Paris Cedex 05, France
\textsuperscript{b} World Health Organization, Department of Food Safety and Zoonoses 20, Avenue Appia, CH-1211 Geneva 27, Switzerland
\textsuperscript{c} Télécom-Paristech/CNRS No. 5141, 46 rue Barrault, 75634 Paris Cedex 13, France
\textsuperscript{d} ANSES, Risk Assessment Department, 27-31 avenue du Général Leclerc, 94701 Maisons-Alfort Cedex, France
## Review world consumption

<table>
<thead>
<tr>
<th>Crops</th>
<th>% of total consumption</th>
<th>Nº of Cluster &gt; 0.5%</th>
<th>Nº of Trials</th>
<th>EWG Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tier 1</td>
<td>tier 2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wheat_t</td>
<td>9,394%</td>
<td>17</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rice_t</td>
<td>9,208%</td>
<td>16</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Potatoes_t</td>
<td>5,448%</td>
<td>16</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vegetable nes_t</td>
<td>5,097%</td>
<td>17</td>
<td></td>
<td></td>
</tr>
<tr>
<td>sugar_t</td>
<td>4,544%</td>
<td>17</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Barley_t</td>
<td>4,232%</td>
<td>17</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tomatoes_t</td>
<td>2,794%</td>
<td>14</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maize_t</td>
<td>2,614%</td>
<td>14</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bananas_t</td>
<td>2,373%</td>
<td>15</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Watermelons</td>
<td>1,932%</td>
<td>8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cassava_t</td>
<td>1,874%</td>
<td>8</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sweet potatoes</td>
<td>1,747%</td>
<td>5</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Apples_t</td>
<td>1,612%</td>
<td>14</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Onions_t</td>
<td>1,570%</td>
<td>14</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cabbages and other brassicas</td>
<td>1,502%</td>
<td>10</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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.

<table>
<thead>
<tr>
<th>CODEX Code</th>
<th>Commodity</th>
<th>CODEX Code</th>
<th>Commodity</th>
</tr>
</thead>
<tbody>
<tr>
<td>001</td>
<td>CITRUS FRUITS</td>
<td>011</td>
<td>FRUITING VEGETABLES, CUCURBITS</td>
</tr>
<tr>
<td>FC 0003</td>
<td>Mandarin + mandarin-like hybrid</td>
<td>VC 0046</td>
<td>Melons, except watermelon</td>
</tr>
<tr>
<td>FC 0004</td>
<td>Orange, sweet, sour + orange-like hybrid</td>
<td>VC 0424</td>
<td>Cucumber</td>
</tr>
<tr>
<td>002</td>
<td>POME FRUITS</td>
<td>VC 0432</td>
<td>Watermelon</td>
</tr>
<tr>
<td>FP 0226</td>
<td>Apple</td>
<td></td>
<td></td>
</tr>
<tr>
<td>FP 0230</td>
<td>Pear*</td>
<td>VO 0445</td>
<td>Peppers, sweet (incl. pim( 잼)ento)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>(bell pepper, paprika)*</td>
</tr>
<tr>
<td>003</td>
<td>STONE FRUITS</td>
<td>VO 0440</td>
<td>Egg plant (aubergine)</td>
</tr>
<tr>
<td>FS 0013</td>
<td>Cherries*</td>
<td>VO 0448</td>
<td>Tomato</td>
</tr>
</tbody>
</table>
Table 2: List of crops for which consumption values are below the threshold of 0.5% worldwide total consumption.

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

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

- **7 guidance documents and 9 test guidelines published**

<table>
<thead>
<tr>
<th>Date</th>
<th>Title</th>
<th>OCDE</th>
</tr>
</thead>
<tbody>
<tr>
<td>26 jui 2013</td>
<td>Introduction to OECD Test Guidelines on Pesticide Residues Chemistry - Section 5 Part A</td>
<td>OCDE</td>
</tr>
<tr>
<td>07 sep 2009</td>
<td>Test No. 509: Crop Field Trial</td>
<td>OCDE</td>
</tr>
<tr>
<td>16 oct 2008</td>
<td>Test No. 508: Magnitude of the Pesticide Residues in Processed Commodities</td>
<td>OCDE</td>
</tr>
<tr>
<td>15 oct 2007</td>
<td>Test No 506: Stability of Pesticide Residues in Stored Commodities</td>
<td>OCDE</td>
</tr>
<tr>
<td>15 oct 2007</td>
<td>Test No. 507: Nature of the Pesticide Residues in Processed Commodities - High Temperature Hydrolysis</td>
<td>OCDE</td>
</tr>
<tr>
<td>25 jan 2007</td>
<td>Test No. 504: Residues in Rotational Crops (Limited Field Studies)</td>
<td>OCDE</td>
</tr>
<tr>
<td>25 jan 2007</td>
<td>Introduction to Other Test Guidelines</td>
<td>OCDE</td>
</tr>
<tr>
<td>25 jan 2007</td>
<td>Test No. 501: Metabolism in Crops</td>
<td>OCDE</td>
</tr>
<tr>
<td>25 jan 2007</td>
<td>Test No. 502: Metabolism in Rotational Crops</td>
<td>OCDE</td>
</tr>
<tr>
<td>25 jan 2007</td>
<td>Test No. 503: Metabolism in Livestock</td>
<td>OCDE</td>
</tr>
<tr>
<td>25 jan 2007</td>
<td>Test No. 505: Residues in Livestock</td>
<td>OCDE</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>“Super” crop group (each consisting of one or more crop groups)</th>
<th>Crops proposed for Tier 3 field studies for one or more subgroups (labelled 1, 2, 3), respectively</th>
<th>Number of Trials</th>
<th>Possible Extrapolation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Root and tuber</td>
<td>1. Carrots or radishes or sugar beets (*) or other beets</td>
<td>4</td>
<td>Subterranean parts: Extrapolation to root and tuber vegetables, potatoes, roots of sugar plants, of herbal infusions and of spices</td>
</tr>
<tr>
<td></td>
<td>2. Potatoes (optional)</td>
<td>4</td>
<td>Aerial parts: root crop based forage crops (*)</td>
</tr>
<tr>
<td>Bulb and stem vegetables</td>
<td>1. Leek or celery</td>
<td>4</td>
<td>Extrapolation to bulb vegetables and stem vegetables</td>
</tr>
<tr>
<td></td>
<td>2. Chicory or dandelion</td>
<td>4</td>
<td></td>
</tr>
</tbody>
</table>

1. See footnote 1 of Table 1. 2. See footnote 2 of Table 1. 3. See footnote 3 of Table 1. 4. See footnote 4 of Table 1.
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
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  
Registration of eWG participants on Codex IT portal

<table>
<thead>
<tr>
<th>Step 1</th>
<th>Event</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Nomination with completed form due:</td>
<td>30 November 2017</td>
</tr>
<tr>
<td></td>
<td>CCPR Schedule and Priority List draft agenda paper:</td>
<td>1 January 2018</td>
</tr>
<tr>
<td></td>
<td>CCPR approves Proposed 2018 Schedule:</td>
<td>April 2018 (CCPR50)</td>
</tr>
<tr>
<td></td>
<td>Commission adopts 2018 Schedule of Evaluations</td>
<td>July 2018</td>
</tr>
<tr>
<td></td>
<td>JMPR data call in for 2018 Schedule of evaluations:</td>
<td>October 2018</td>
</tr>
<tr>
<td></td>
<td>JMPR conducts evaluations / meets (STEP 2)</td>
<td>Sept 2019</td>
</tr>
<tr>
<td></td>
<td>JMPR report published:</td>
<td>December 2019</td>
</tr>
<tr>
<td></td>
<td>CL for comments on JMPR proposals (STEP 3):</td>
<td>March 2020</td>
</tr>
<tr>
<td></td>
<td>If no concerns, CCPR proposes draft MRLs to CAC (STEP 5/8):</td>
<td>April 2020 (CCPR 51)</td>
</tr>
<tr>
<td></td>
<td>CAC adopts MRLs (to become CXLs):</td>
<td>July 2020</td>
</tr>
</tbody>
</table>
Hi eWG Priorities colleagues

please find attached the current version of the CCPR Schedules and Priority Lists now in excel spreadsheet format.

Irnd regards
Ian Reichstein
Chair - eWG Priorities

[CCPR Schedules and Priority Lists 01 Sept 2017.xlsx]
(77.31 KIB) Downloaded 3 times
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

<table>
<thead>
<tr>
<th>PRIORITY</th>
<th>DATE STAMP</th>
<th>TOXICOLOGY</th>
<th>RESIDUE</th>
<th>PRIORITY CRITERIA</th>
<th>COMMODITIES</th>
<th>RESIDUE TRIALS</th>
<th>MEMBER / MANUFACTURER</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>4/12/15</td>
<td>Metconazole</td>
<td>Metaconazole</td>
<td>Y</td>
<td>Y</td>
<td>USA- Stone fruit group; Blueberry; Banana; Garlic; Onion, Bulb; Legume vegetables; Pulses; Soya bean; Root and tuber vegetables1 (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; Egg; Peanut oil, crude</td>
<td>USA- Banana (12), barley grain (28), blueberry (11), cotton seed (12), corn/maize (20), sweet corn (12), tree nuts (10), peanuts (14), soya bean (30), stone fruits (22), sugar beet roots (12), sugarcane cane (8), sunflower (12), oats (12), rape oilseed (16), dried shelled peas pulses (15), dry beans (19), triticale wheat (31), potato (32), fresh legumes, peas without pod (13), onion (4), garlic (3)</td>
<td>Japan / Valent USA Corporation, on behalf of Kureha Corporation</td>
</tr>
<tr>
<td>6</td>
<td>16/3/17</td>
<td>Pyridate</td>
<td>Pyridate</td>
<td>Y</td>
<td>Y</td>
<td>Alfalfa, cabbage, kale/collard, clover, Leek /spring onion/chive, Onion/shallot/garlic, chickpea</td>
<td>Alfalfa, cabbage, kale/collard, clover, Leek /spring onion/chive, Onion/shallot/garlic, chickpea</td>
<td>Belchim Crop Protection</td>
</tr>
</tbody>
</table>

**JMPR evaluations workload – training of new reviewers (eg. USDA-FAS)**
### 2019 Proposed Schedule of new uses and other evaluations

<table>
<thead>
<tr>
<th>PRIORITY</th>
<th>DATE STAMP</th>
<th>TOXICOLOGY</th>
<th>RESIDUE</th>
<th>COMMODITIES</th>
<th>RESIDUE TRIALS</th>
<th>MEMBER / MANUFACTURER</th>
<th>COMMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>18/7/16</td>
<td>Chlorantraniliprole (230)</td>
<td>PALM OIL (MALAYSIA) LABEL PROVIDED ON 18 JULY 2016 / Pulses</td>
<td>Palm oil (4), peas (5), beans (5)</td>
<td>DuPont</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>30/9/16</td>
<td>Chlorothalonil (81)</td>
<td>Chlorothalonil (81)</td>
<td>Orange; lemon; grapefruit; lettuce; strawberry; almond; radish (root veg); mustard greens; guava; lychee / USA-CRANBERRY (under the 4 year rule).</td>
<td>Orange (12), Lemon (5), Grapefruit (6), Lettuce (13), Strawberry (8), Almond (5) radish (7); mustard greens (9); guava (5); lychee (4) cranberry (5)</td>
<td>Syngenta</td>
<td>fungicide / requested move from 2018</td>
</tr>
<tr>
<td>3</td>
<td>30/9/16</td>
<td>Mesotrione</td>
<td>CITRUS, POME FRUIT, STONE FRUIT, TREE NUTS</td>
<td>Citrus – orange, grapefruit, lemon (23), Pome fruit – apple, pear (18), Stone fruit – cherry, peach, plum (21), Tree nuts – almond, pecan (10)</td>
<td>Syngenta</td>
<td>requested move from 2018</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>30/9/16</td>
<td>Thiabendazole</td>
<td>LEGUMES AND PULSES</td>
<td>Legumes and pulses (48)</td>
<td>Syngenta</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Extraordinary Meeting of JMPR Supported by Canada**
SUCCESS!!!!

<table>
<thead>
<tr>
<th>Year</th>
<th>CCPR</th>
<th>new CXLs</th>
</tr>
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<tbody>
<tr>
<td>2017</td>
<td>49</td>
<td>485</td>
</tr>
<tr>
<td>2016</td>
<td>48</td>
<td>392</td>
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<td>2015</td>
<td>47</td>
<td>349</td>
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<td>2014</td>
<td>46</td>
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<td>2013</td>
<td>45</td>
<td>328</td>
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<td>2012</td>
<td>44</td>
<td>251</td>
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<tr>
<td>2011</td>
<td>43</td>
<td>286</td>
</tr>
<tr>
<td>2010</td>
<td>42</td>
<td>205</td>
</tr>
</tbody>
</table>
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

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

Openness / transparency = increased demand for evaluations

System supports establishment of CXLs for new / minor uses

Codex IT Platform - eWG Priorities forum - functional

Ongoing concern - evaluator resources and availability
Thank you very much for your kind attention.
Crop Classification and Grouping, Successes and Challenges

William Barney
IR-4 Minor Use Program
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.
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
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
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
<table>
<thead>
<tr>
<th>Sub Group</th>
<th>Fruit Types</th>
<th>Sub Group Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 003 Stone Fruits</td>
<td>Cherry, Sweet or Cherry, Sour; Plum or Prune Plum; Peach or Apricot</td>
<td><strong>Stone fruits (FS 0012):</strong> 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;</td>
</tr>
<tr>
<td>Subgroup 003A, Cherries</td>
<td>Cherry, Sweet or Cherry, Sour</td>
<td><strong>Cherries (FS 0013):</strong> Cherry, black; Cherry, Nanking; Cherry Sour; Cherry, Sweet; Choke cherry</td>
</tr>
<tr>
<td>Subgroup 003B, Plums</td>
<td>Plum or Prune Plum</td>
<td><strong>Plums (FS 0014):</strong> Bullace; Cherry plum; Jujube, Chinese; Klamath plum; Plum, Plum, beach; Plum, Chickasaw; Plumcot; Sloe</td>
</tr>
<tr>
<td>Subgroup 003C, Peaches</td>
<td>Peach or Apricot</td>
<td><strong>Peaches (FS 2001):</strong> Apricot; Japanese apricot; Nectarine; Peach</td>
</tr>
</tbody>
</table>
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.
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.
<table>
<thead>
<tr>
<th>Crop Group</th>
<th>NAFTA</th>
<th>Codex</th>
<th>Type (Codex)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Berry &amp; Small Fruit Group</td>
<td>Codified</td>
<td>Adopted</td>
<td>Fruit</td>
</tr>
<tr>
<td>Pome Fruit Group</td>
<td>Codified</td>
<td>Adopted</td>
<td>Fruit</td>
</tr>
<tr>
<td>Citrus Fruit Group</td>
<td>Codified</td>
<td>Adopted</td>
<td>Fruit</td>
</tr>
<tr>
<td>Stone Fruit Group</td>
<td>Codified</td>
<td>Adopted</td>
<td>Fruit</td>
</tr>
<tr>
<td>Tropical Fruit Groups – edible and inedible peel</td>
<td>Codified</td>
<td>Adopted</td>
<td>Fruit</td>
</tr>
<tr>
<td>Crop Group</td>
<td>NAFTA</td>
<td>Codex</td>
<td>Type (Codex)</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>---------</td>
<td>--------</td>
<td>--------------</td>
</tr>
<tr>
<td>Bulb Vegetable</td>
<td>Codified</td>
<td>Adopted</td>
<td>Vegetable</td>
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<tr>
<td>Fruiting Vegetable</td>
<td>Codified</td>
<td>Adopted</td>
<td>Vegetable</td>
</tr>
<tr>
<td>Stalk, Stem and Leafy Petiole</td>
<td>Codified</td>
<td>Adopted</td>
<td>Vegetable</td>
</tr>
<tr>
<td>Leafy vegetables (incl brassicas)</td>
<td>Codified</td>
<td>Adopted</td>
<td>Vegetable</td>
</tr>
<tr>
<td>Brassica Head/Stem Vegetable</td>
<td>Codified</td>
<td>Adopted</td>
<td>Vegetable</td>
</tr>
<tr>
<td>Root/Tuber Vegetable</td>
<td>Submitted</td>
<td>Adopted</td>
<td>Vegetable</td>
</tr>
<tr>
<td>Edible Fungi Group</td>
<td>Codified</td>
<td>Adopted</td>
<td>Vegetable</td>
</tr>
<tr>
<td>Legume Vegetables</td>
<td>Submitted (7/13)</td>
<td>Adopted</td>
<td>Vegetable</td>
</tr>
<tr>
<td>Cucurbit Vegetable</td>
<td>Submitted (4/14)</td>
<td>Adopted</td>
<td>Vegetable</td>
</tr>
</tbody>
</table>
## Other Commodity Types

<table>
<thead>
<tr>
<th>Crop Group</th>
<th>NAFTA</th>
<th>Codex</th>
<th>Type (Codex)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tree Nut Group</td>
<td>Codified</td>
<td>Step 7</td>
<td>Nuts and Seeds</td>
</tr>
<tr>
<td>Oilseed Group</td>
<td>Codified</td>
<td>Step 7</td>
<td>Nuts and Seeds</td>
</tr>
<tr>
<td>Seed for Bev and sweets</td>
<td>NA</td>
<td>To be submitted</td>
<td>Nuts and Seeds</td>
</tr>
<tr>
<td>Herbs and Spices</td>
<td>Submitted</td>
<td>Step 7</td>
<td>Herbs and Spices</td>
</tr>
<tr>
<td>Cereal Grains</td>
<td>Submitted</td>
<td>Adopted</td>
<td>Grasses</td>
</tr>
<tr>
<td>Forage/Fodder/Straw of Cereal Grains</td>
<td>Submitted</td>
<td>To be submitted</td>
<td>Grasses</td>
</tr>
<tr>
<td>Grasses for sugar or syrup</td>
<td>To be submitted</td>
<td>Adopted</td>
<td>Grasses</td>
</tr>
</tbody>
</table>
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.
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.
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
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.
THANK YOU FOR YOUR KIND ATTENTION
Questions / Comments?

Bill Barney
IR-4 Project
phone: 732.932.9575  ext: 4603,
barney@aesop.rutgers.edu,
web: ir4.rutgers.edu
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
  ➢ Transparency
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

2.181. In March 2014, the United States noted that the European Union planned to publish a roadmap outlining different options and a preliminary impact assessment in its process to assess, classify and regulate endocrine disruptors. The United States urged the European Union to publish...
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

Program and Presentations:
https://www.wto.org/english/tratop_e/sps_e/wkshop_oct16_e/wkshop_oct16_e.htm

Summary Report:
G/SPS/R/85
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
Jdoherty@ustr.eop.gov
202-395-9559
International MRL Harmonization Activities

Gord Kurbis
Director, Market Access and Trade Policy
Pulse Canada
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](http://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.

<table>
<thead>
<tr>
<th>Crop Protection Products</th>
<th>Peas</th>
<th>Lentils</th>
<th>Chick-peas</th>
<th>Beans</th>
<th>Faba Beans</th>
</tr>
</thead>
<tbody>
<tr>
<td>Glyphosate (e.g. Roundup)</td>
<td>✓</td>
<td>✓</td>
<td>!</td>
<td>!</td>
<td>!</td>
</tr>
<tr>
<td>Diquat (e.g. Reglone)</td>
<td>!</td>
<td>!</td>
<td>!</td>
<td>!</td>
<td>!</td>
</tr>
<tr>
<td>Saflufenacil (e.g. Heat)</td>
<td>✓</td>
<td>!</td>
<td>NR</td>
<td>✓</td>
<td>NR</td>
</tr>
<tr>
<td>Glufosinate (e.g. MPower Good Harvest)</td>
<td>NR</td>
<td>!</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
</tr>
<tr>
<td>Carfentrazone (e.g. Cleanstar, Aim)</td>
<td>!</td>
<td>NR</td>
<td>!</td>
<td>!</td>
<td>!</td>
</tr>
<tr>
<td>Flumioxazin (e.g. Valtra)</td>
<td>NR</td>
<td>NR</td>
<td>NR</td>
<td>!</td>
<td>NR</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other Crop Protection Products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chlorantraniliprole Insecticide (e.g. Coragen, Voliam Xpress)</td>
</tr>
<tr>
<td>Chlorpyrifos Insecticide (e.g. Lorsban, other trade names)</td>
</tr>
<tr>
<td>Benzoquin  Fungicide (e.g. Elatus, Solamen)</td>
</tr>
</tbody>
</table>
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

- 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?

North America

Caribbean

Central America

North Africa

Sub-Saharan Africa

Europe

Middle East

South Asia

Russia Ukraine

East Asia

Southeast Asia

Oceania

Imported

Exported

Source: International Grains Council
## National list, defer to Codex – a solution?

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

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

- 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 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 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
IGTC Membership - 22 Organizations / 8000 Members / 80 Countries
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

Side Event on Need for MRLs at CCPR in Beijing, China is well attended by delegate body
Thank you