



EU Legal framework for pesticides

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

Klaus Berend
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DG Health and Food Safety
European Commission

The regulatory lifecycle of a Plant Protection Product



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

Separation risk assessment / risk management

1. Application

Industry → Data dossier

2. Risk Assessment

1 Member State → Draft Assessment Report
European Food Safety Authority (EFSA) + all Member States → Expert meetings, Peer review of the DAR
EFSA → "Conclusion on the peer review"

3. Risk management

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



European
Commission

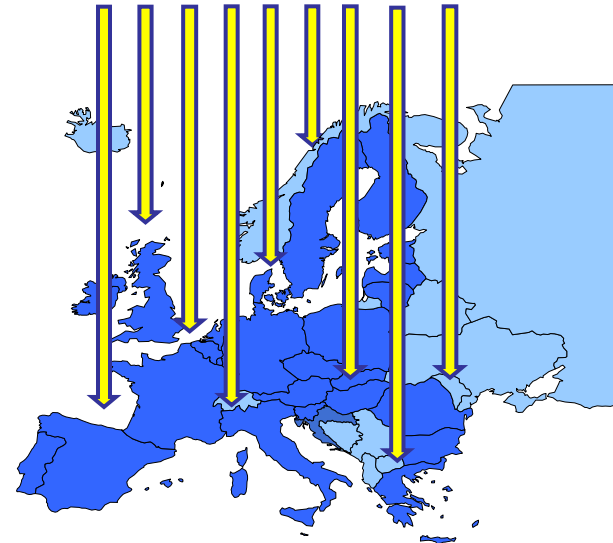
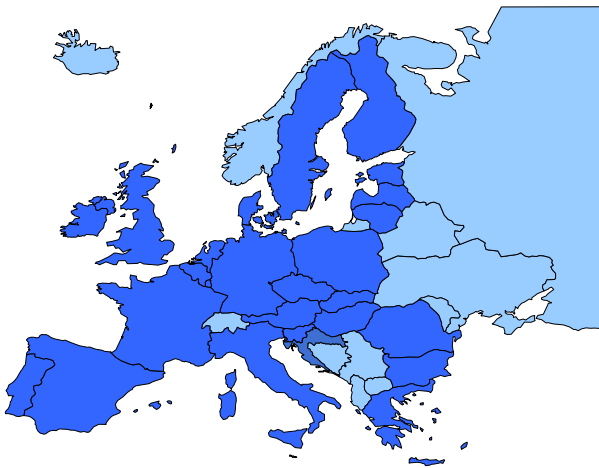
"Approval"

vs. "Authorisation"



Active substance

Formulated Product



Active Substances = Approval at EU level

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

Criteria for approval of substances

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

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

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

Plant Protection products = Authorisation at national level

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



European
Commission

EU zonal system



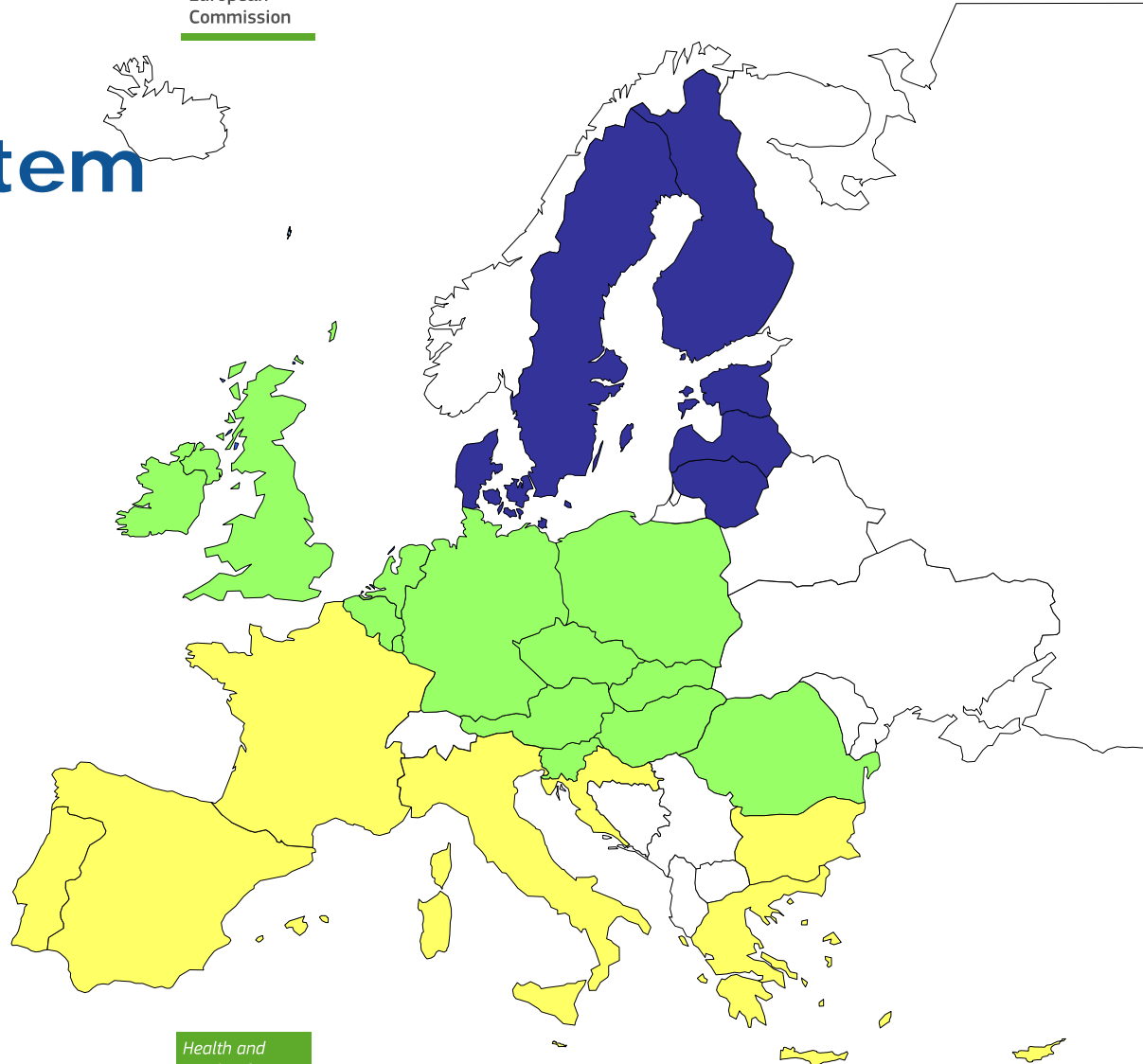
North



Center



South



Health and
Food Safety

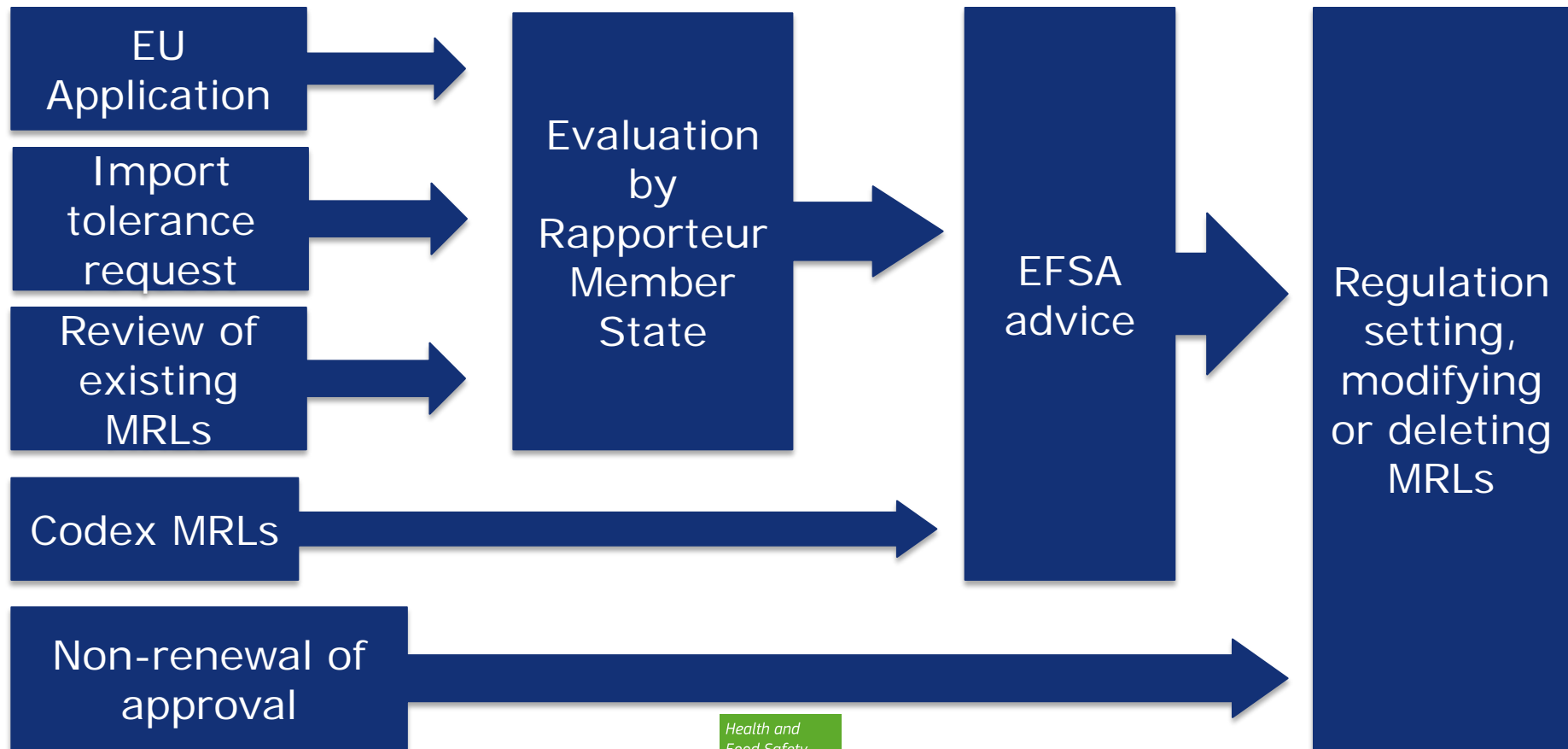
"Zonal" Evaluation and recognition of authorisations

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



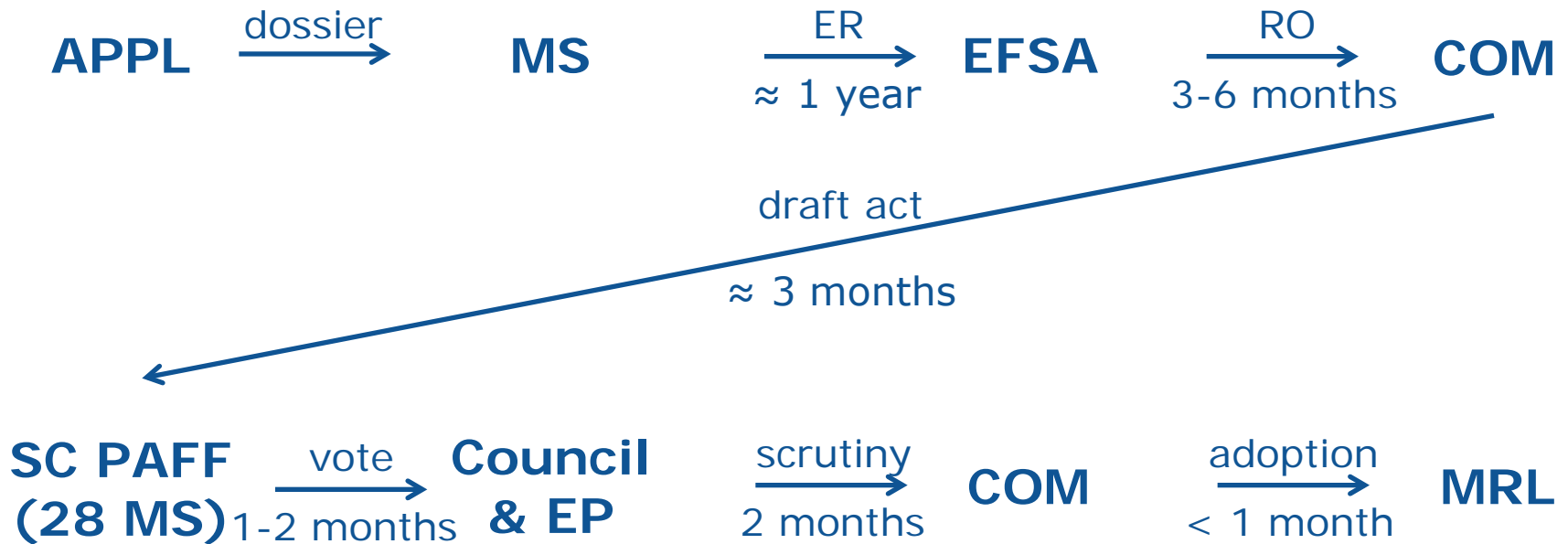
European
Commission

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



From application to MRL setting

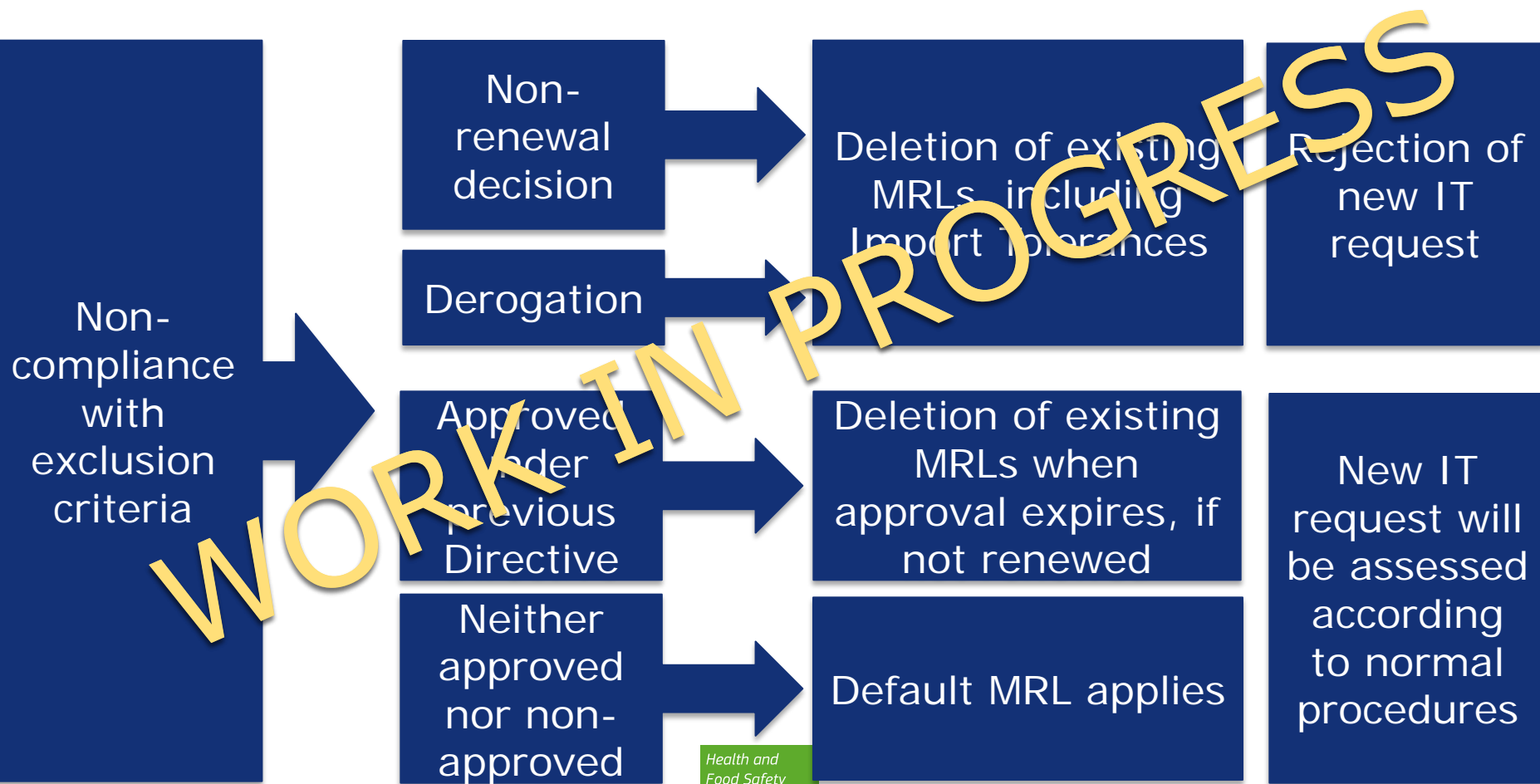
(MRL applications based on EU uses and import tolerance requests)





European
Commission

Impact of exclusion criteria on MRLs



Minor Uses Developments in the European Union

Global Minor Uses Summit

1-4 October 2017, Montreal, Canada

Jeroen Meeussen - EU Minor Uses Coordination Facility



Co-funded by the
European Union

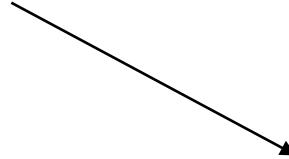
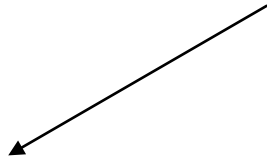
Content

- ▶ EU Regulatory Framework
- ▶ Regulatory hurdles



EU Pesticide Legislation

Impact on minor uses



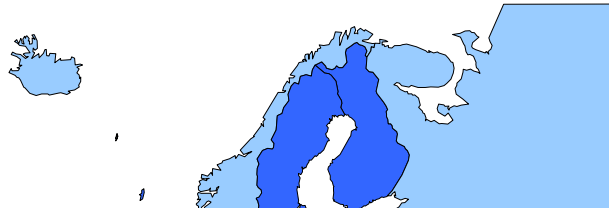
**PLACING ON THE
MARKET**

**RESIDUES IN
FOOD/FEED**



Regulation (EC) No 1107/2009

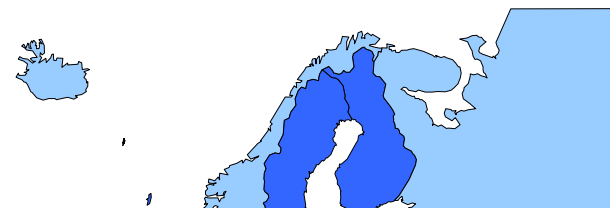
Approval vs Authorisation



EU
Approval
Active Substance



One decision applying to all
28 Member States



National
Authorisation
Plant Protection Product



One decision applying to
one Member State

Minor Uses - definition

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

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

(a) **not widely grown** in that Member State,
or

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

National dimension


Minor crop

Minor use on a major crop



Extension of Authorisation

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

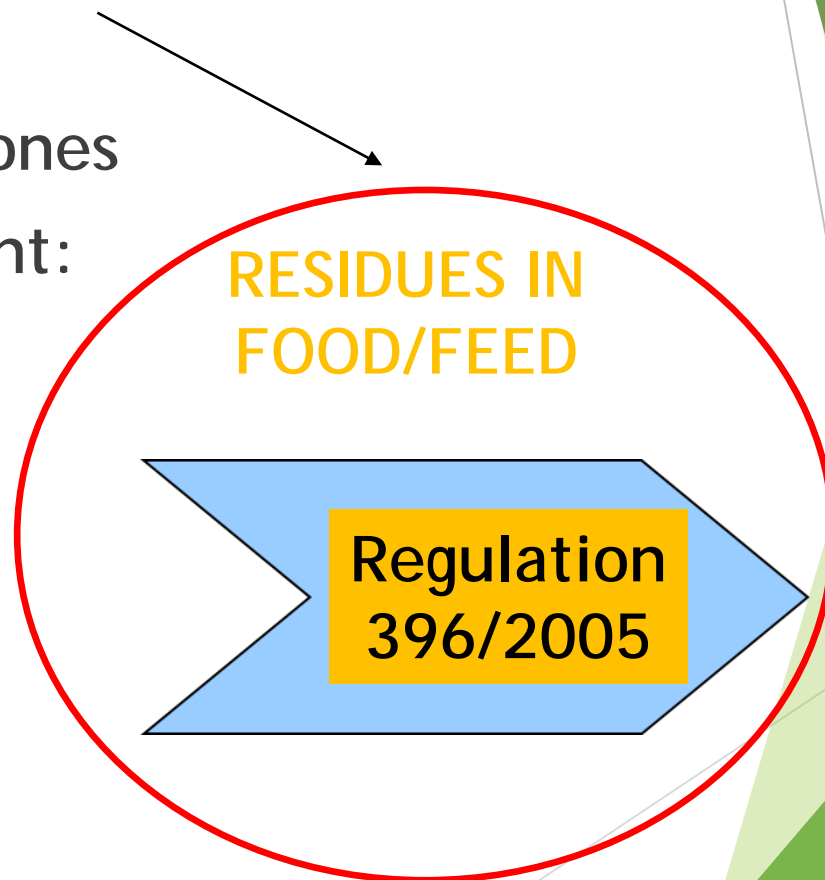


Regulation
1107/2009

EU Pesticide Legislation

MRLs in food and feed

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



REFIT

Regulatory Fitness & Performance Program

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

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



Review Clause:

Article 82: Reg (EC) 1107/2009

Article 47: Reg (EC) 396/2005

Content

- ▶ EU Regulatory Framework
- ▶ Regulatory hurdles



Minor Uses - Definition

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

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

- (a) **not widely grown** in that Member State,
or
- (b) **widely grown** to meet an **exceptional** plant protection need.

Is this a workable definition?

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



2, 3, 4 zones

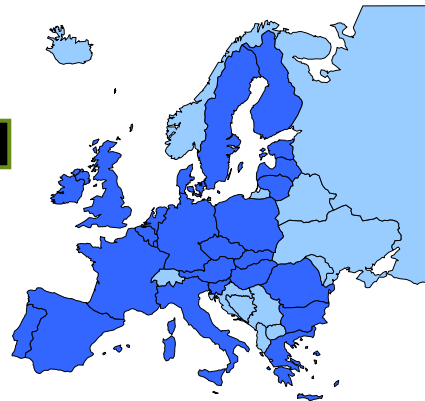
Reg 1107/2009 Zones



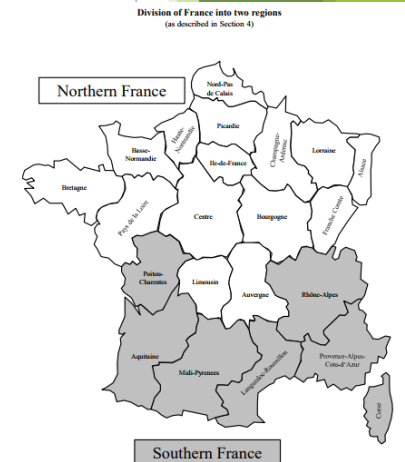
EPPO Zones



EPPO Zones vs Reg 1107/2009 Zones



Reg 396/2005 Zones



GLOBAL RESIDUE STUDY-Blueberry



Residue data generated outside the EU

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



(Un)Harmonized Crop Grouping and Extrapolation



SANCO 7525/V1/95
Rev. 10.3
13 June 2017

GUIDANCE DOCUMENT
Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs

● Extrapolation tables

The extrapolation tables should be used in conjunction with EPPO Standard PP 1/257 Efficacy and crop safety extrapolations for minor uses. The tables provide detailed lists of acceptable extrapolations organized by crop groups or pest groups for regulatory authorities and applicants in the context of the registration of plant protection products for minor uses. It is important to ensure that expert judgment and regulatory experience are employed when using these tables. EPPO excludes liability as to the reliability of the information provided through these tables.

All extrapolations should be viewed on a case-by-case manner and expert judgment should always be applied when employing these tables.

If you wish to comment on any of the tables below, please contact the EPPO Secretariat directly at hq@epppo.int.

- **EPPO Standard PP1/257 - Efficacy and crop safety extrapolations for minor uses**
- **Crop group definitions (revised version of 2014 - still under development):** this document aims to list all crops that should be encompassed by the groups of crops in the tables developed so far.



Home Food Crops Ornamental Horticulture Biopesticides & Organic Support Public Health **International Activities** Directory Outreach Materials Quality Assurance (QA)

Facilitating Registration of Sustainable Pest Management
Technology for Specialty Crops and Minor Uses

INDEX OF CROPS/CROP GROUPS/CROP SUBGROUPS, AND CROP DEFINITIONS
May 3, 2016
CROPS/CROP GROUPS/CROP SUBGROUPS (including crop grouping revisions per Federal Register [FR] Final Rules beginning Dec. 7, 2007):

C O D E X A L I M E N T A R I U S
International Food Standards

World Health Organization Food and Agriculture Organization of the United Nations

Google Custom Search

Pesticide Residues in Food and Feed
Codex Pesticides Residues in Food Online Database

This database contains Codex Maximum Residue Limits for Pesticides and Extraneous Maximum Residue Limits adopted by the Codex Alimentarius Commission up to and including its 39th Session (July 2016).

In the data base a user can obtain information on Codex Maximum Residue Limits (MRLs) and Codex Extraneous Maximum Residue Limits (EMRLs) for pesticide / commodity combinations. Names and definitions of commodities are found in the Codex Classification of Foods and Animal Feeds.



Some points for discussion...

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

THANK YOU FOR YOUR ATTENTION



ANY QUESTIONS



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Minor Uses

A North American Perspective

October 2, 2017

Dr. Peter Chan

Director General, PMRA Health Canada

Rick Keigwin

Director for Programs (acting), Office of Pesticide Programs EPA

YOUR HEALTH AND SAFETY... OUR PRIORITY.



Outline

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

Regulatory Policy Considerations and Activities

Field Trial Requirements for joint US/Canada registration

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

Exchangeability

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

Regulatory Policy Considerations and Activities

Value Requirements

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

Data Protection

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

Regulatory Policy Considerations and Activities

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

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

Regulatory Policy Considerations and Activities

Minor Use Specific Activities

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

Maximum Residue Limits (MRLs)

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

International Activities that help support Minor Uses

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

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

International Activities that help support minor uses

OECD

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

North American Free Trade Agreement (NAFTA)

- ❑ Technical Working Group on Pesticides
- ❑ Regulatory Cooperation Council

Joint Reviews

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

Asia-Pacific Economic Cooperation

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

Regulatory Challenges

Different MRLs

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

Different Crop Grouping Schemes

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

Successes

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

Questions?



ASEAN harmonized MRLs and Minor Use

Panpilad Saikaew

National Bureau of Agricultural Commodity and Food Standards,
Thailand

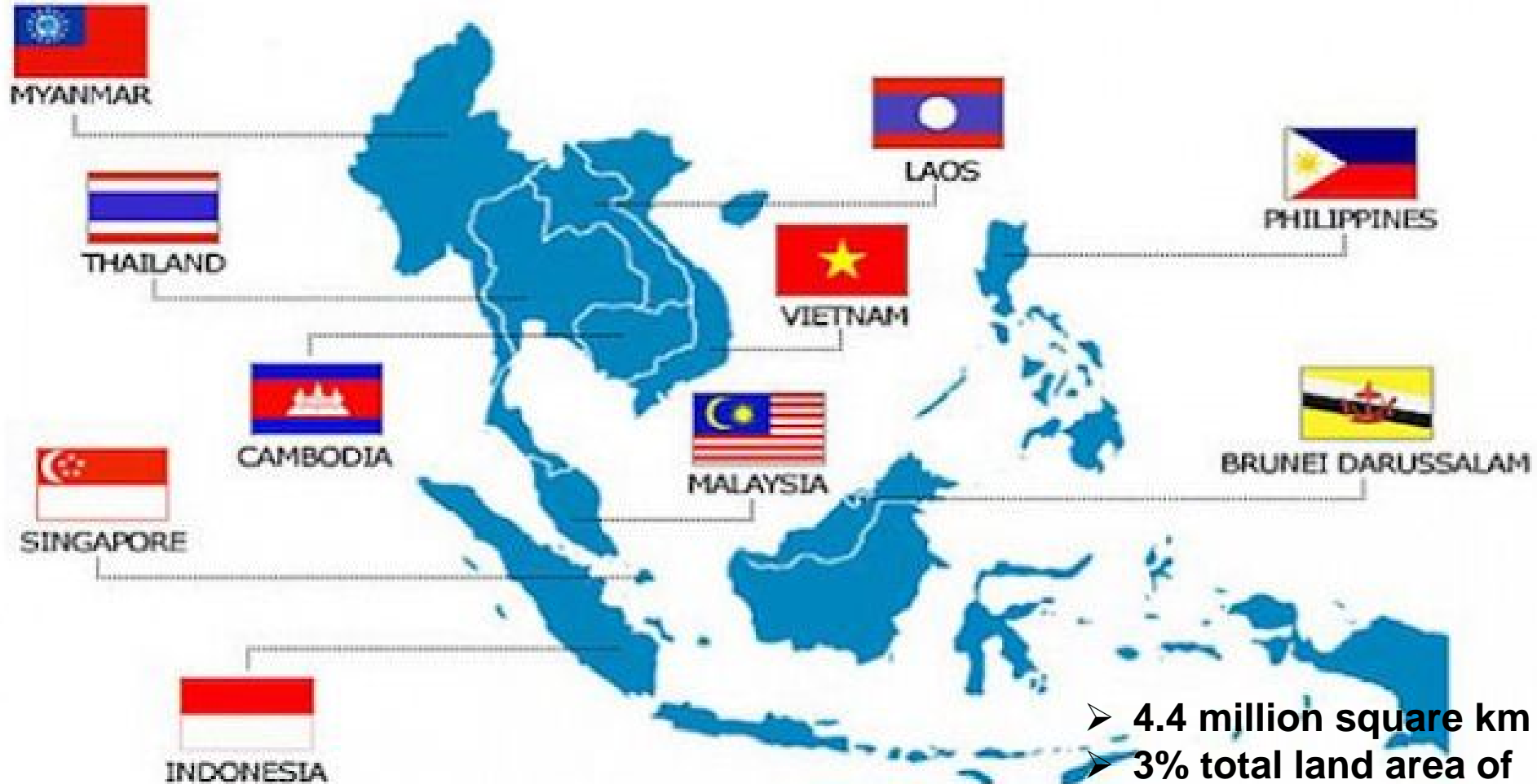
GMUS₃, Quebec, Canada



Outline

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

ASEAN Member Countries



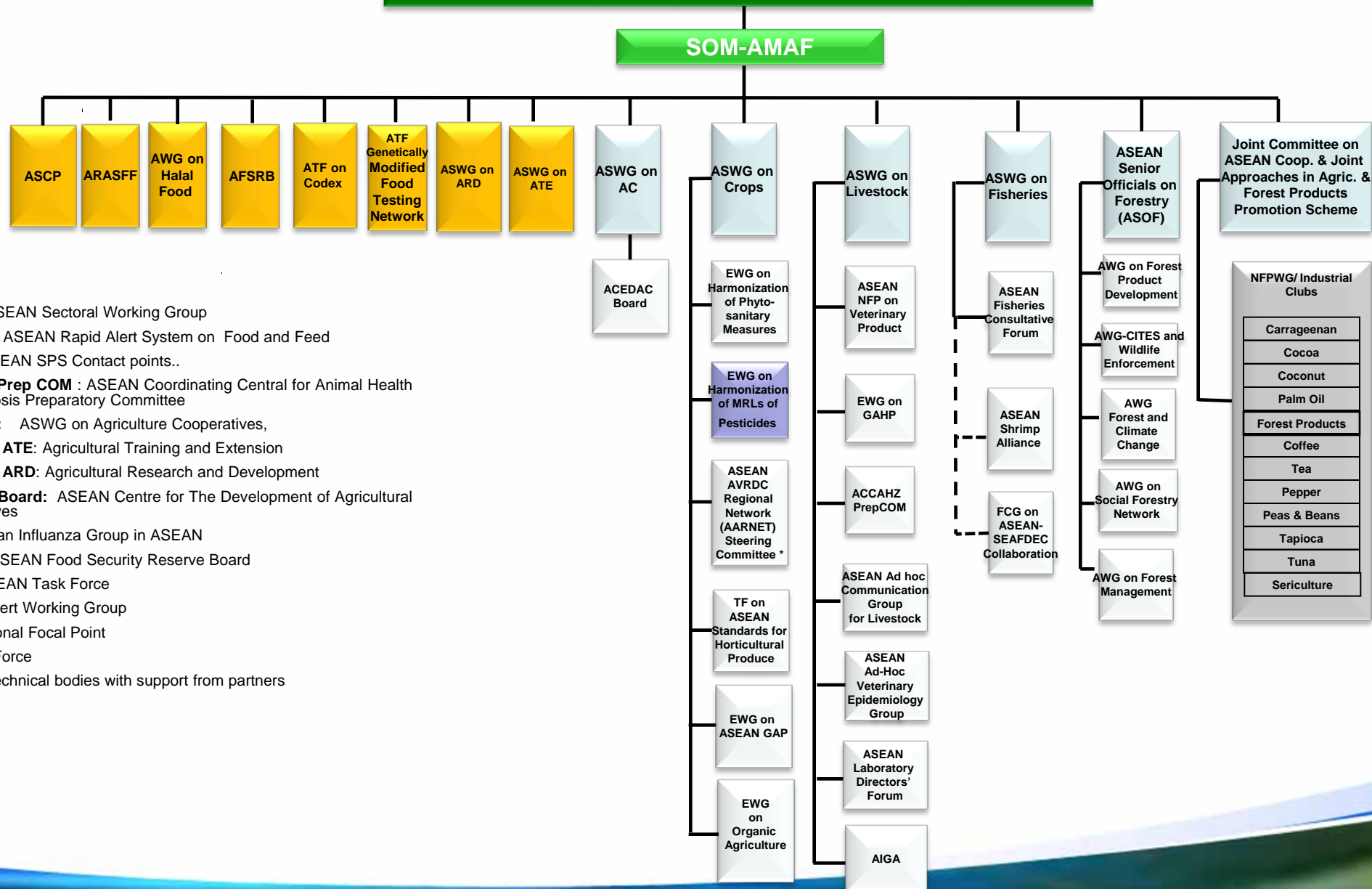
- 4.4 million square km
- 3% total land area of earth
- 625 million people
- 8.8 % of world population



Structure of ASEAN Cooperation in Food, Agriculture and Forestry



ASEAN Ministry of Agriculture and Forestry (AMAF)



Notes:

- **ASWG:** ASEAN Sectoral Working Group
- **ARASFF:** ASEAN Rapid Alert System on Food and Feed
- **ASCP:** ASEAN SPS Contact points..
- **ACCAHZ Prep COM :** ASEAN Coordinating Central for Animal Health and Zoonosis Preparatory Committee
- **ASWGAC:** ASWG on Agriculture Cooperatives,
- **ASWG on ATE:** Agricultural Training and Extension
- **ASWG on ARD:** Agricultural Research and Development
- **ACEDAC Board:** ASEAN Centre for The Development of Agricultural Cooperatives
- **AIGA:** Avian Influenza Group in ASEAN
- **AFSRB:** ASEAN Food Security Reserve Board
- **ATF:** ASEAN Task Force
- **EWG:** Expert Working Group
- **NFP:** National Focal Point
- **TF:** Task Force
- - - - - -: Technical bodies with support from partners



Establishment of ASEAN MRLs

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



Risk assessment

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



MINOR CROPS

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





Recent ASEAN Work on Minor Crops

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



MRL Harmonisation for Minor Crop

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



Way Forward

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



Thank you
Any Questions?



Emerging Challenges and opportunities for work in Minor crops in Africa

Presentation made during the
Third Global Minor Use Summit,
1st – 4th October, 2017

Fairmont Queen Elizabeth Hotel, Montreal, Canada

Lucy Namu

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



Presentation outline:

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



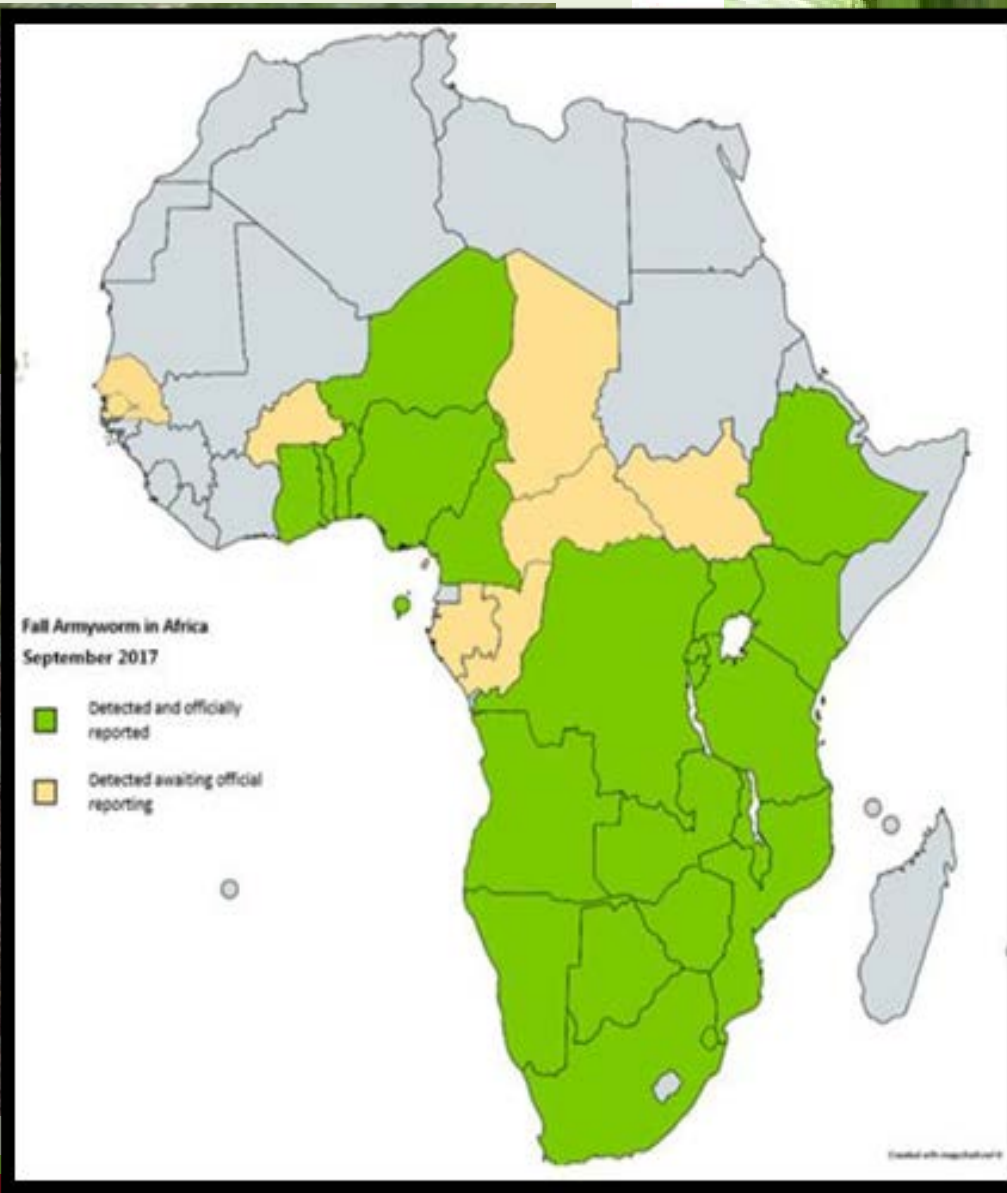
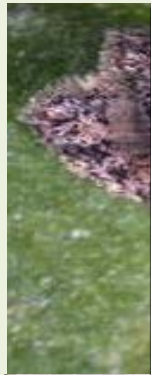
1. Emerging challenges in pest management – enhanced toolbox?



Plant protection needs / outbreaks



Migratory pests outbreaks



Emerging pests

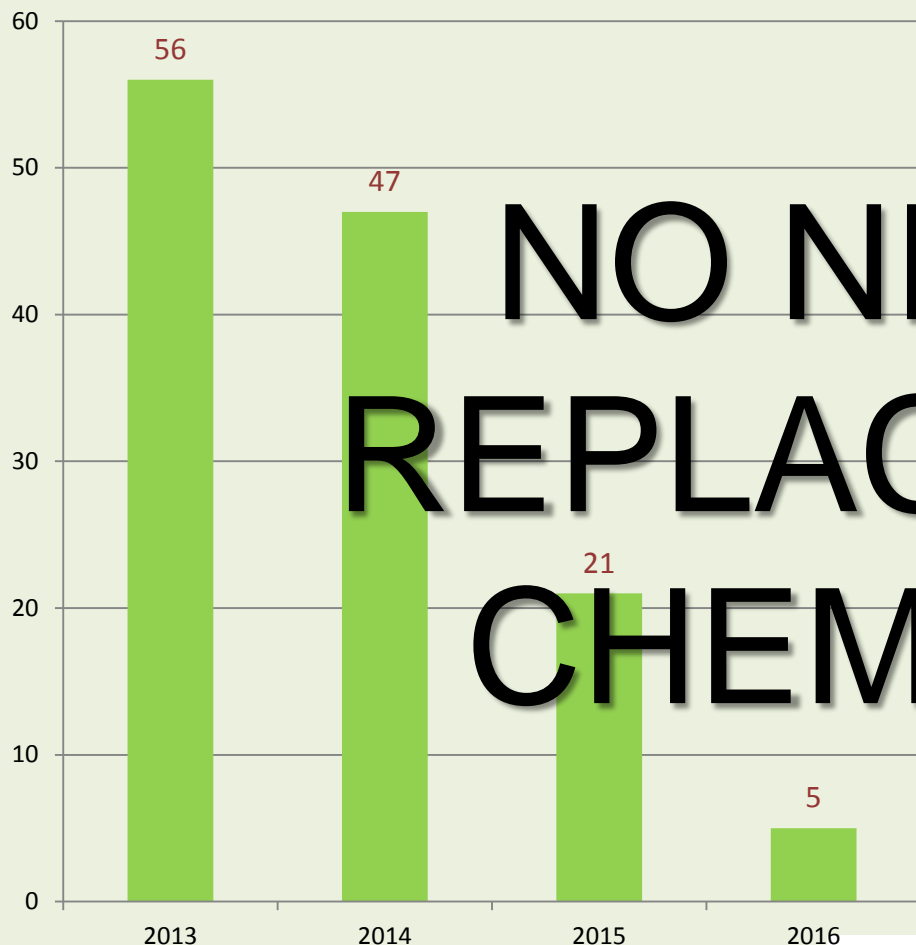
False codling moth,
Thaumatotibia leucotreta



Papaya mealybug,
affecting pawpaw



Mitigation to increase compliance of legume vegetables



75% of cases have MRLs set at LOD.

**NO NEWER
REPLACEMENT
CHEMICALS**

Methamidophos

Chlorpyrifos

Methomyl

Dimethoate

Azinphos

Izadnazole

Nicotine*,

Omethoate

Imidacloprid

Fenthion

Trifloxystrobin+

Fenpropathrin

Esipet

Tetradifon

Famoxadone

Profenofos

Diafenthiuron*

Hexaconazole

Diphenylamine

Etoxazole

Lufenurone

Methomyl

Chlorothalonil

Fluopicolide

Metalaxyl

Carbofuran*

Acetamprid

Oxydemeton-methyl

Mandipropamid

Chlorontraniliprole

Propamocarb

Carbendazim

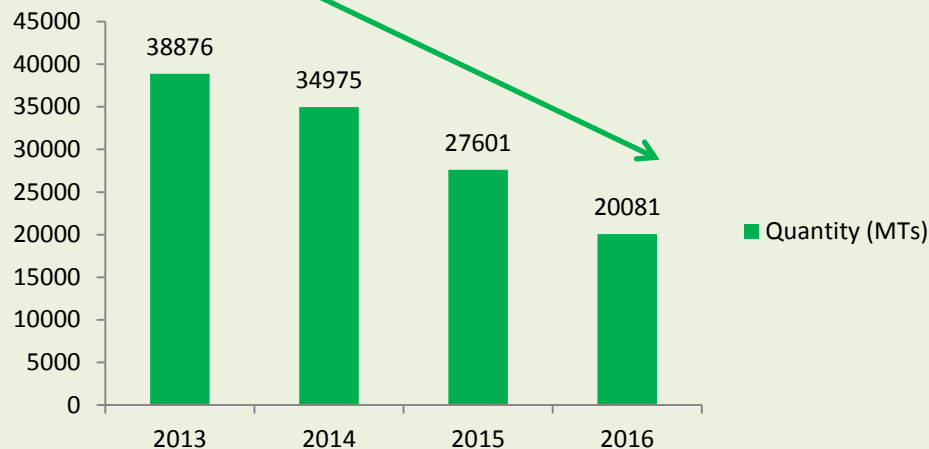
Methoxyfenozide



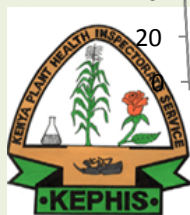
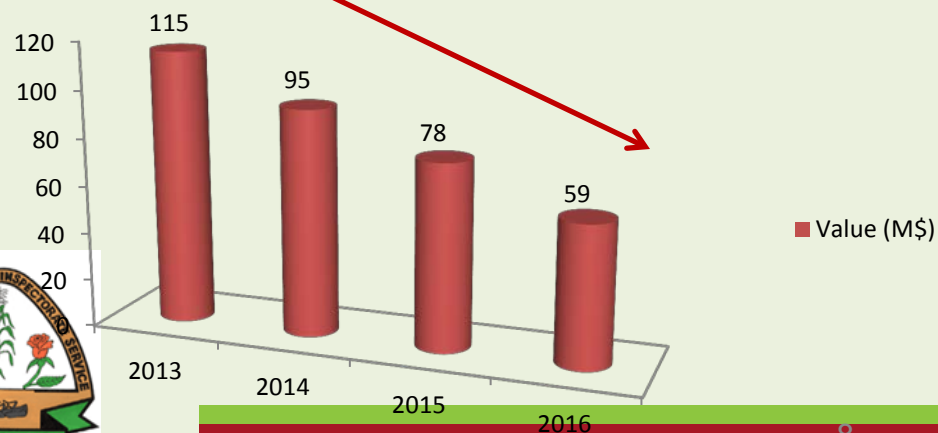
Default MRLs: effect on trade in minor crops

Group 014: Legume vegetables

Trend of bean and peas in pods export volumes, 2013-2016



Trend of bean and peas export value, 2013-2016 (M\$)



2. Regional harmonization initiatives and achievements



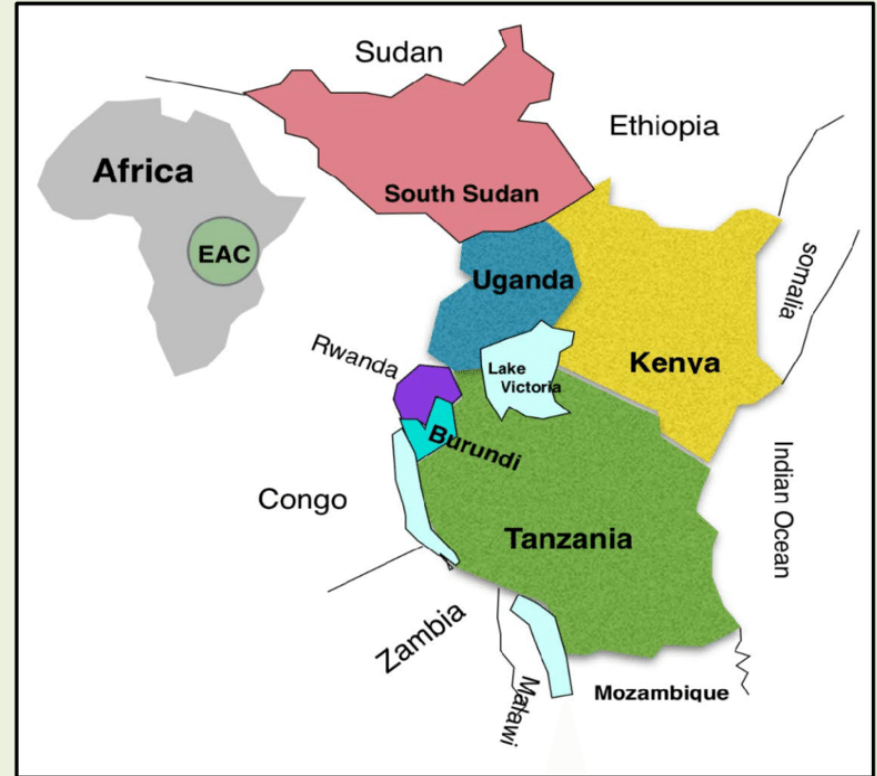
Harmonization within the EA Region

Benefits:

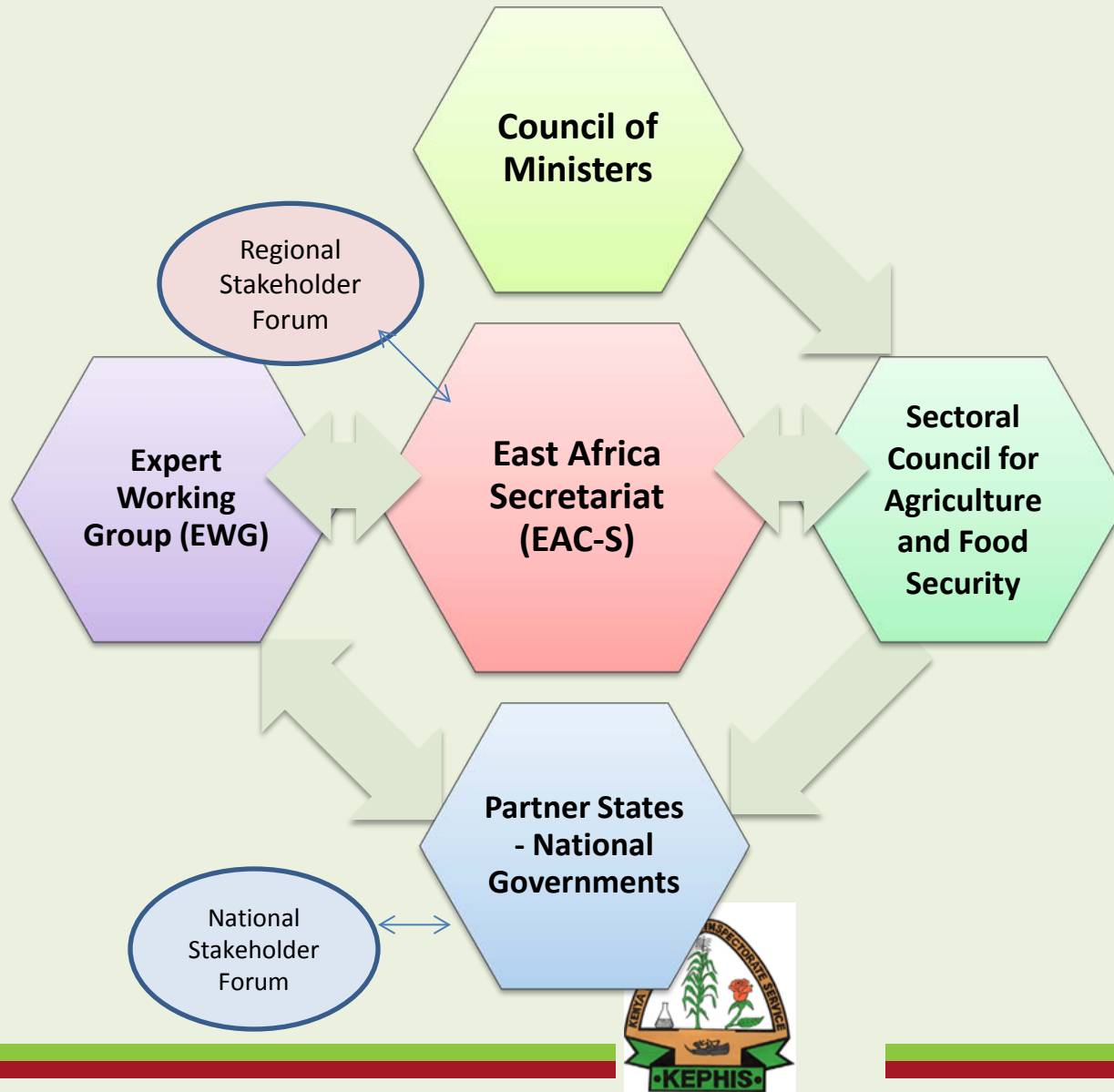
Reduce unnecessary divergences across national pesticide regulatory approaches and legislation

Goal:

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



Harmonization within the EA Region.../2



Achievements in EAC harmonization

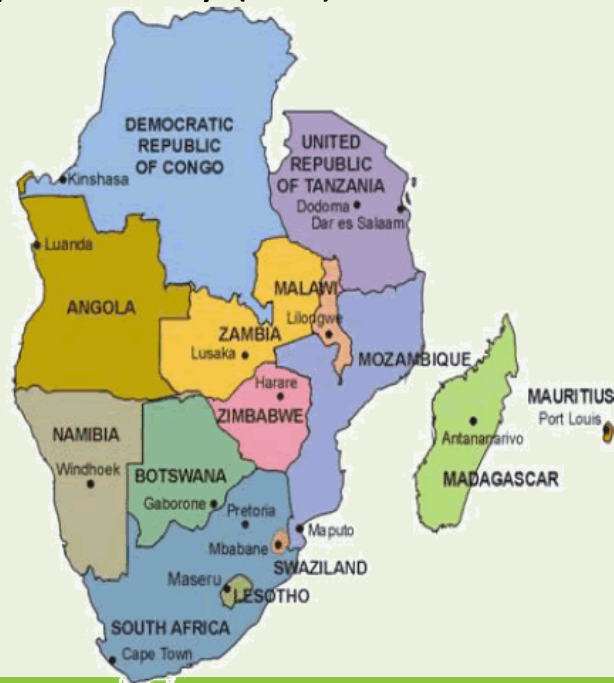
- Progress towards “single” registration:
 - Completion of Draft EAC efficacy trial and Draft Residue Trial guidelines – towards
 - agreed on modalities for implementation of regionally harmonized supervised trials & priority crops for implementation;
 - Commenced work on pesticide registration data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

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



Harmonization within the Southern Africa Region

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



Objectives:

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

Highlights:

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



Areas of future work

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



Areas of future work .../2

4. Explore possibilities to Establish EAC Data portal
 - Modalities in formats / use / access

5. Greater participation at WTO-SPS Committee
 - Strengthening Regional (EAC) and National SPS Committees
 - Provide updates in Regional initiatives on harmonization and MRL setting processes
 - Foster collaboration on minor uses and crops for more MRLs / PPP registrations



Thank you for your kind attention!



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

Montreal, Quebec, Canadá. Oct-2017

LATAM SITUTATION

Ing. Agr. Daniel Mazzarella

Directorate of Agrochemical and Biological
products

National Animal Health and Agri-food Quality
Service



Ministerio de Agroindustria
Presidencia de la Nación

Overview on Latin America

Four major trade blocs in the region

Many additional regional agreement under development

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

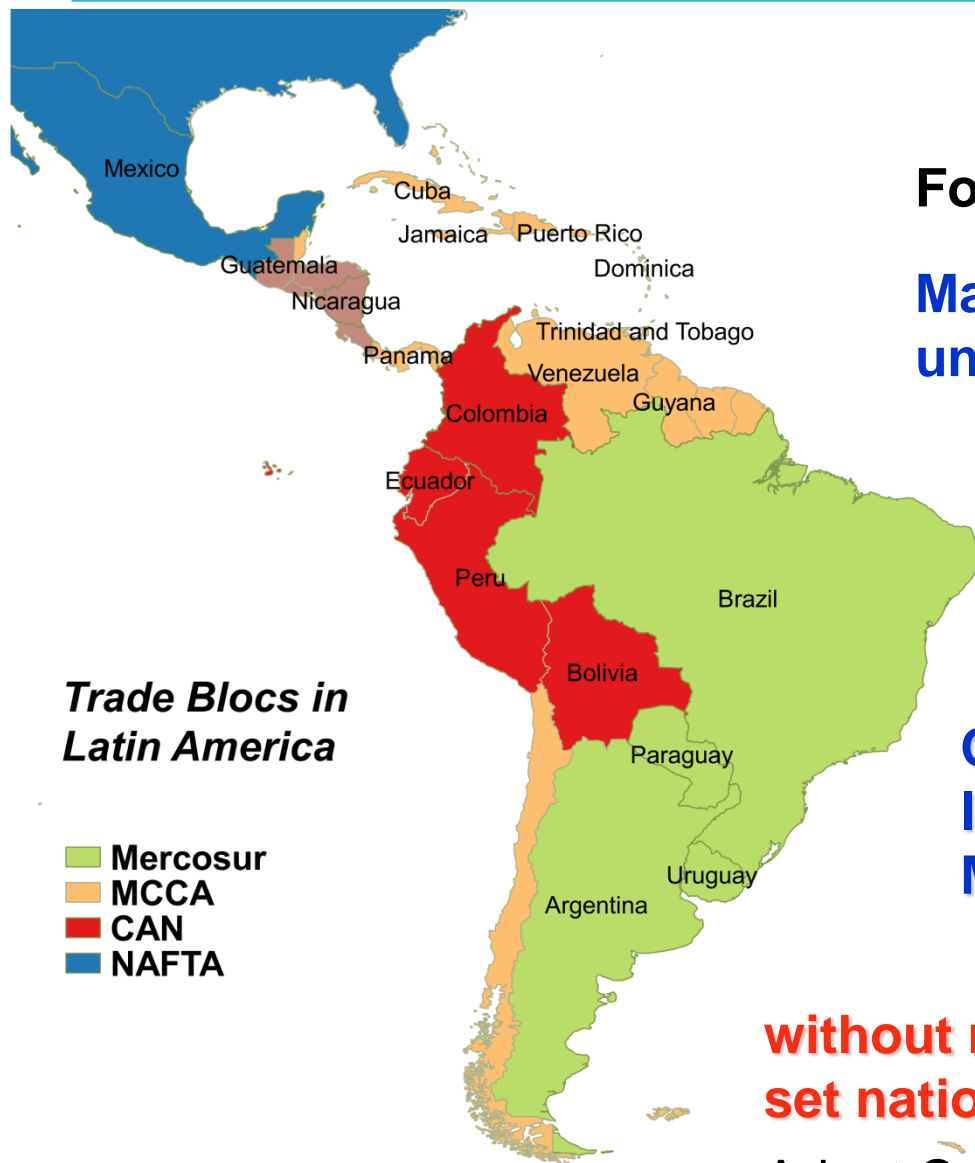
Only Brazil and Argentina Request local residue trials to set national MRLs

without request of local residue trials to set national MRLs (other countries):

Adopt Codex and/or other Agencies MRLs.

Trade Blocs in Latin America

- Mercosur
- MCCA
- CAN
- NAFTA





Establishment of MRL in Argentina

Resolution SAGPyA 350/1999:

- 6 residues trials (3 agroecological zones/2 agricultural seasons)

Resolution SENASA 274/2010

Field trials conducted under GLP criteria

Residues Studies :

by active ingredient

by crop



Establishment:

MRL

Pre-harvest interval

Establishment of MRL in Brazil

Normative **RDC 4/2012** - ANVISA:

- 4 residues trails
- 2 degradation curves
- Recommended dose on GLP tested



Residues Studies :

by active ingredient

by crop



Establishment:

MRL

Pre-harvest interval

Chile



Export Market:

Respect Primary and Secondary standards to export food.

Domestic Market:

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

Mexico



Export Market:

Respect Primary and Secondary standards to export food.

Domestic Market:

- Project of **Regulation on MRLs** to be possibly published at the end of 2017.

- Objective is to establish criteria for MRL setting and revision.

- **Criteria for MRL setting:**

Sources of MRLs could be:

- MRLs adopted from **CODEX, EPA, PMRA, EU, OECD countries, Brazil, Argentina and Japan.**

In this case, **cGAP has to be similar to cGAP in Mexico** (according to extrapolation criteria described in the regulation).

- If no MRLs can be adopted, they can be supported from Residue Studies done in Mexico (amount of studies are defined in the regulation depending on crop area and consumption level).

DECISION 804

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

**COMUNIDAD
ANDINA**



RESIDUES AND MAXIMUM RESIDUE LIMITS

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

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


Supervision of efficacy trials to determine good agricultural practice

CENTRAL AMERICA

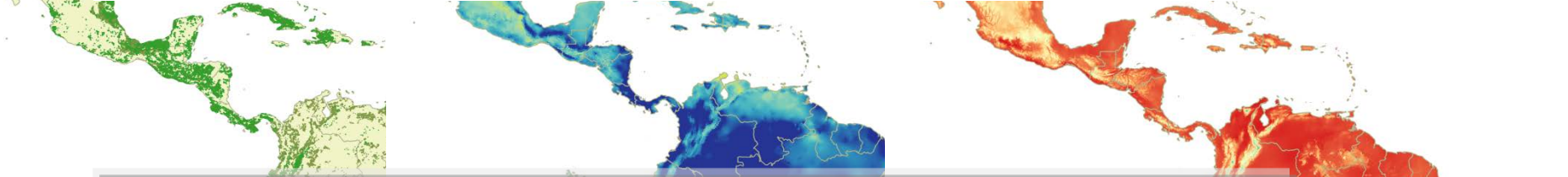
- No local residues studies
- Based on Codex and EPA Mrls



Harmonization of agro-ecological zones



Are there significant differences in residues from different agroecological zones?



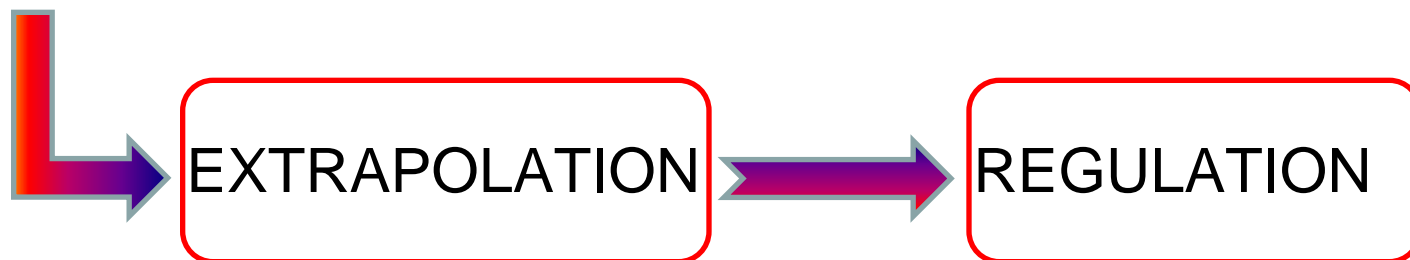
Globally harmonized MRLs, How to include all patterns of use, climate, pests, etc.?

Crops areas

- Dry Crops
- Unknown

MINOR CROPS

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



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

Regional Situation: regulatory considerations related to minor uses

Argentina

- **Res. SENASA 608/2012 (Minor Crops) established MRLs for 20 Crops.**

Brasil

- **IN (01/14) MRL extrapolation from a main crop to other crops with low availability of pesticides (Minor crops)**

Bolivia-Peru-Colombia-Ecuador (CAN)

- **Decision 804/2015 that approves the Andean Norm for the Registration and Control of Chemical Pesticides of Agricultural Use of the Andean Community of Nations. Art 19 – Minor crops**

Costa Rica/Panama

- **No active projects currently**

Mexico

- **SENASICA 2011-2013 support studies - submitted to registration in Federal Commission for Protection against Sanitary Risks (COFEPRIS).**

Chile

- **No active projects currently**

Current overview of the region regulation for minor crops.

Argentina

- Efficacy and field residue trials / Analytical residues
- 20 crops (total 600 active / crops combinations)
- Financing: international credit

Brasil

- Extrapolation MRL values of a representative crop for Minor crops. International guidelines for clustering and extrapolation of group MRLs for subgroups

Bolivia-Peru

- Extrapolation of efficacy test of a product already registered: a) same pest; b) same damage; c) Same plant and / or species; and, d) maximum approved use dose.

Costa Rica

- High costs for pesticide registration in smaller crops - low profitability for industry

Mexico

- SENASICA-COFEPRIS - Support studies - faster review process. I can register to date, 17 records (300 authorized uses in total) (avocado, nopal, pineapple, papaya, some citrus and aromatic herbs)

Panama

- In the last 5 years, IICA, USDA and Company led projects (Sumitomo - Pyreproxifen in pineapple cultivation). The data generated were supplied to the CODEX Alimentarius. This is the first study conducted in the Panama and other trials are coordinated.

Current overview of the region regulation for minor crops.

Peru

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

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

Argentina

- **Create permanent regulations. Set criteria for extrapolation of data between major and minor crops. Public-private interaction. New project: 18 crops - problem: financing**

Brasil

- **In Brazil there are no problems with specific technical skills. Modifying regulations and criteria to allow compatibility of data and mutual recognition of studies.**

Bolivia

- Mutual recognition of studies: work to create a surpranational standard
- Secondary or private residues regulations
- Encourage crop grouping / Crops and Extrapolation

Costa Rica

- **Achieve flexibility in the approach of minor crops compared to major crops. Challenges and advantages of using crop groups, extrapolations, field data exchange.**

Mexico

- **Establish the instrument of formal collaboration involving all actors. Work-diagnosis groups were created. In 2016, Appendix Classification of Crops by Botanical Groups to transfer technical information on Biological Effectiveness.**

Panama

- **Further use, updating and dissemination of existing data in the CODEX Alimentarius is necessary. Conduct field trials and sampling with study models to assess the impact of pesticide use.**

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

Peru

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

MRL Harmonization

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

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

- **COSAVE**: GTPF: Included in the agenda for 2017 - Not yet treated
- **CAN**: Decision 804 (Standard For the Registration and Control of Chemical Pesticides for Agricultural Use). Does not mention aspects on harmonization, only minor crops – Art 19
- **Central America**: CODEX - EPA
- **Mexico**: CODEX, EPA, PMRA, EU, OECD countries, Brazil, Argentina and Japan. NAFTA?

Harmonization within the LATAM

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

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



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

cGAP

Areas of future work

1. Support for Minor use programs in LATAM

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

2. Ease of new registrations:

- Explore crop grouping, ease registration requirements through harmonized approaches

3. Harmonization

Explore future COSAVE/MERCOSUR/CAN harmonization

Thank you



Ministerio de Agroindustria
Presidencia de la Nación

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Global Minor Use Summit III

Oct 1-4, 2017
Montreal, Quebec, Canada

Philip A. Brindle, PhD



Challenges for Minor Crop/Use registrations

- **Crop Protection Product registrations need data..... lots of it!**
 - Expensive to develop, and takes time
 - Different regulatory requirements must be met
 - Crops making up staple foods are first priority for Ag Industry

- **Minor Crops/Uses come second**
 - Many minor crops in production today
 - Increasing trade in minor crops → increasing data requirements!
 - Need more efficient ways to support these crops and uses



Quick Look Back

➤ GMUS II, Feb 2012 → 5 yr plan developed

- Coordination & Collaboration
- Communication
- Incentives
- Capacity Development
- Registration of Minor Uses and MRL Setting



Key advances since GMUS II

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



THANK YOU

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



Overview of Industry Considerations for Minor Crop Registrations

Jessica Christiansen

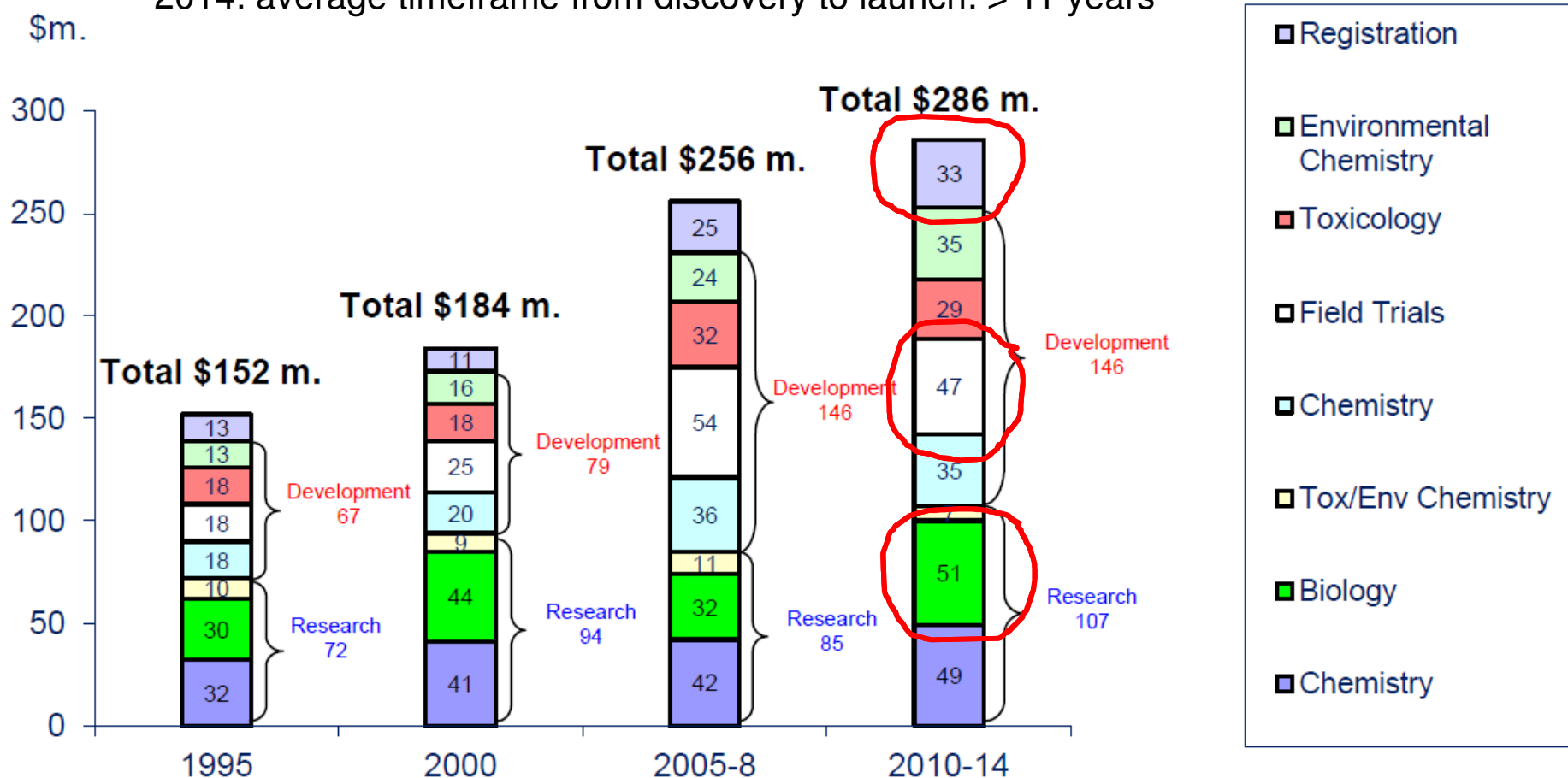
Global Minor Use Summit 3 – Montreal

2 October 2017

Investment Costs

Discovery and Development Costs of a New Crop Protection Product

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



Source: http://www.croplifeamerica.org/wp-content/uploads/2016/04/Phillips-McDougall-Final-Report_4.6.16.pdf

Managing Minor Crops

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

But.....

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



Managing Minor Crops

➤ However.....

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


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





Maintenance of Business

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



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

Global Minor Use Summit - 3
October 2, 2017

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



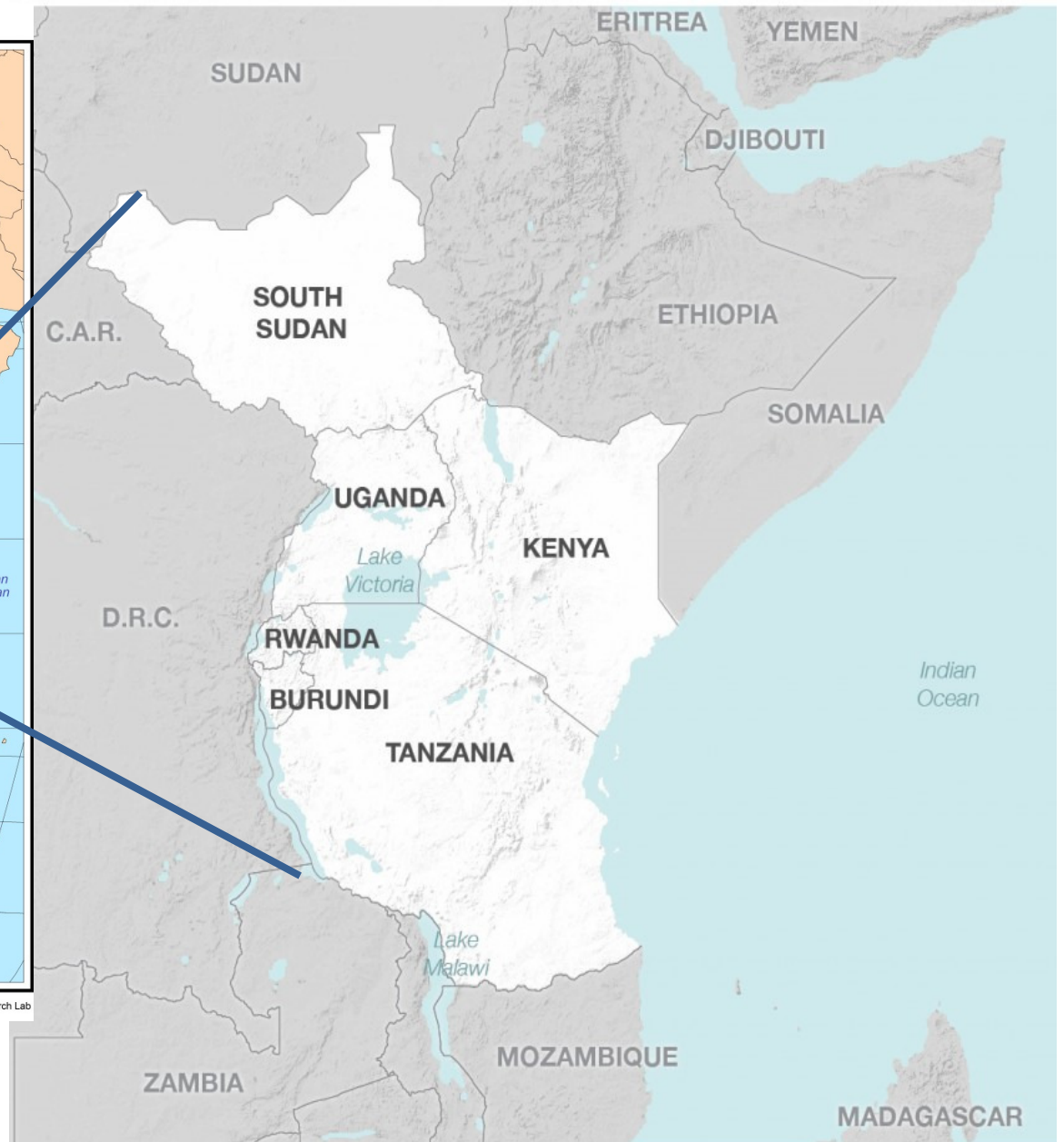
EAC Member Countries

The EAC now comprises six countries; South Sudan joined the EAC in early September 2016.

AFRICA



Produced by the Cartographic Research Lab
University of Alabama



Why harmonize national systems regionally?

GMUS-2: Theme 4, Capacity Building

- Task 4.1: Support Efforts in National and Regional Capacity

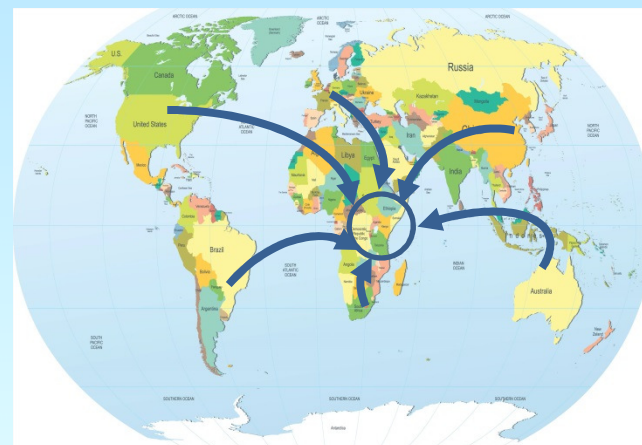
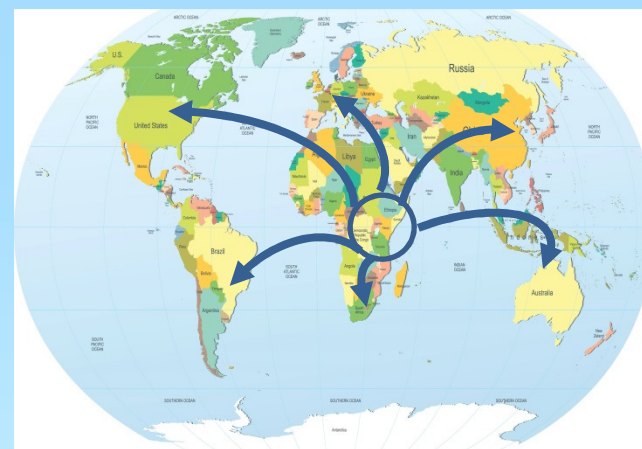
National/Regional Interests

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

Rest of the World Interests

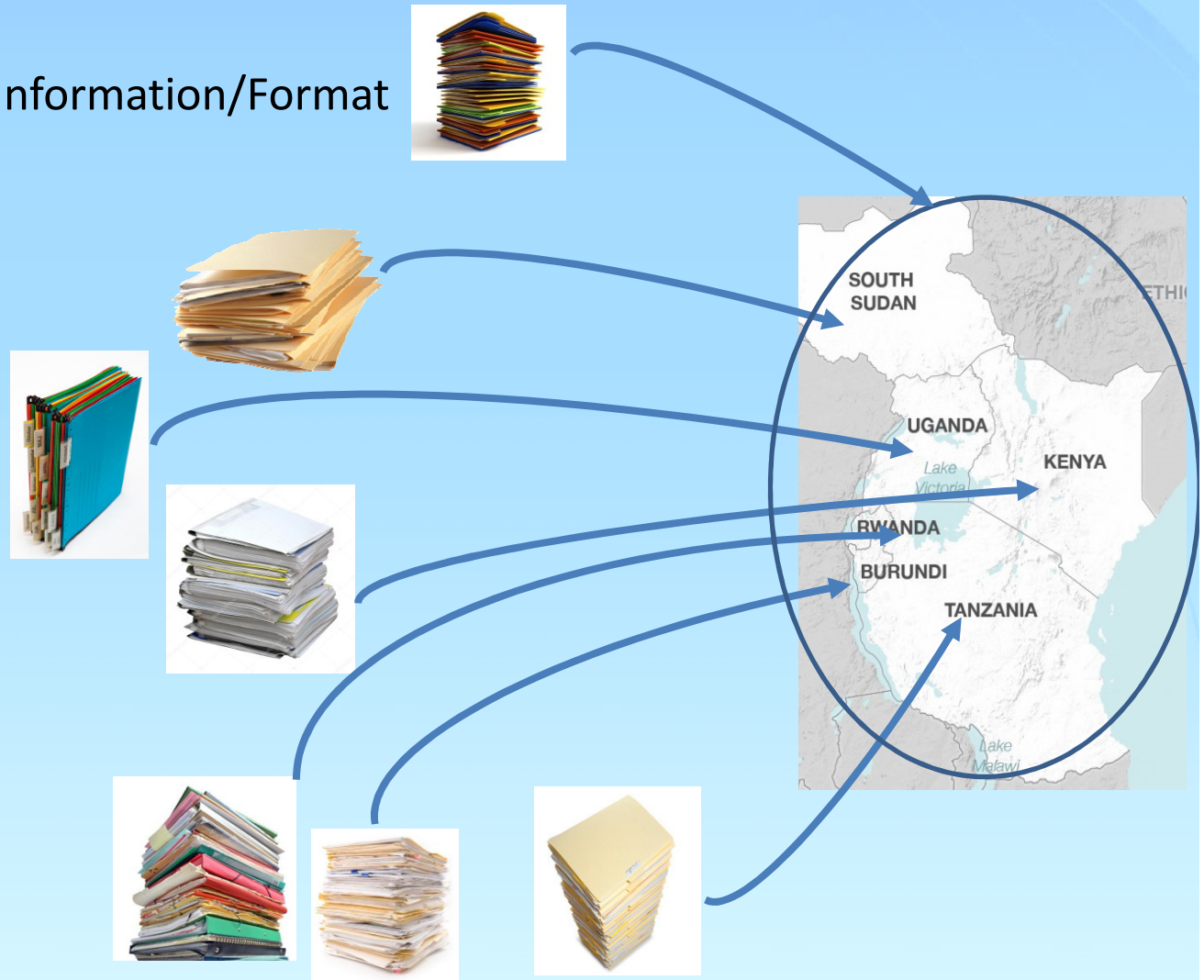
- Again...reduces MRL violations at ports of entry
- But....also reduces MRL violations of exports to the region (registrations of new AIs, leads to new import MRLs of AI)

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



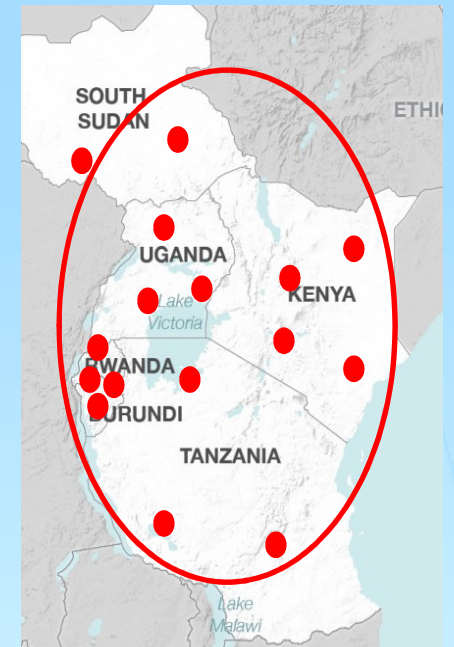
What is the vision of the EAC effort?

- Common Data Package: Information/Format



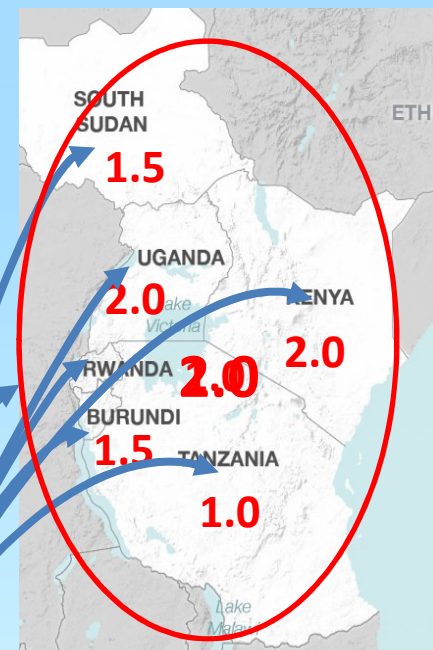
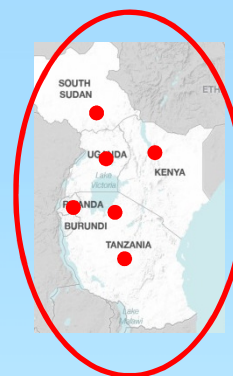
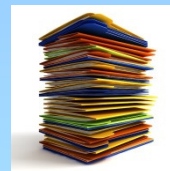
What is the vision of this effort?

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



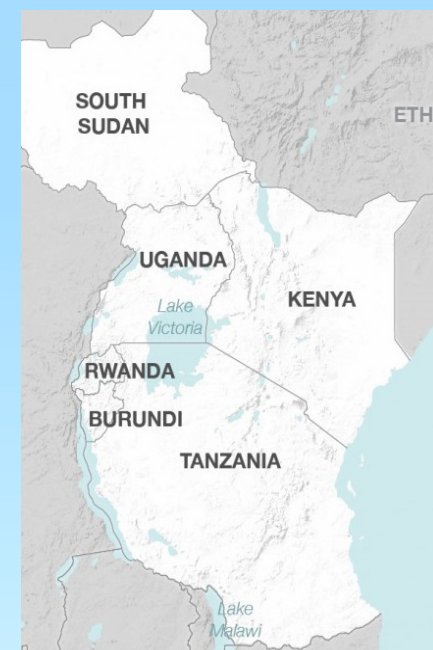
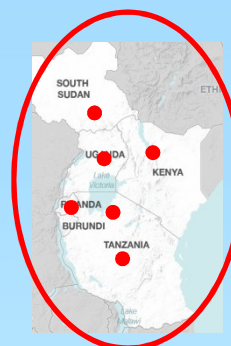
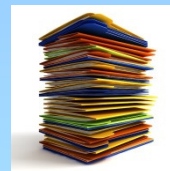
What is the vision of this effort?

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



What is the vision of this effort?

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



What is the mechanism?

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

What is the process?

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

What was learned?

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

How can we all support this and similar efforts?

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

Acknowledgements

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



THANK YOU!!!

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



Manufacturer's Experience with Capacity Building

By **Carmen Tiu**
Global Residue & MRL Strategy Leader



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

**Third Global Minor Use
Summit (GMUS-3)**



Dow AgroSciences

Solutions for the Growing World

Presentation Index

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



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

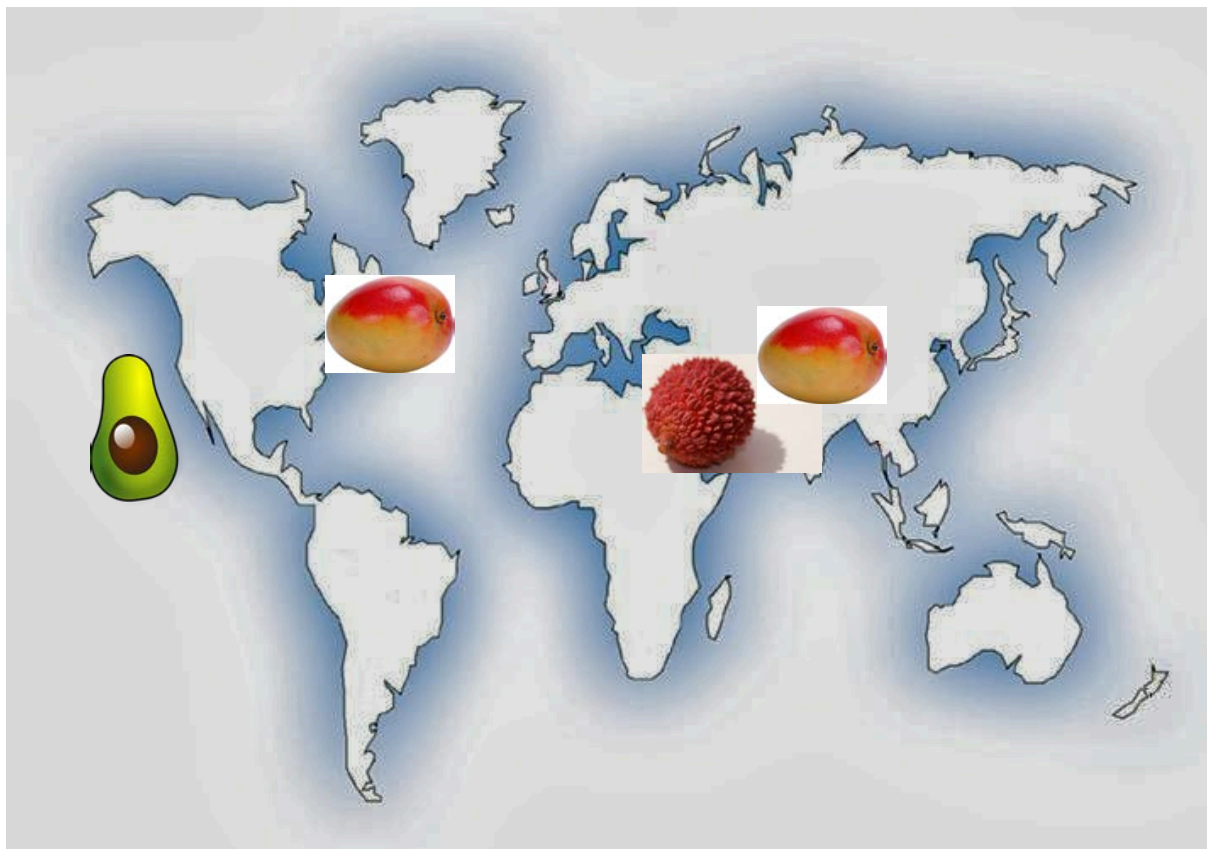


Dow AgroSciences

Solutions for the Growing World

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

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



What Worked Well?...

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



What needs further attention for future work...



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



2. Other Capacity Building Projects



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Solutions for the Growing World

Other Capacity Building Programs

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

3. Industry's Points of Interests



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Solutions for the Growing World

3. Industry's Points of Interests

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



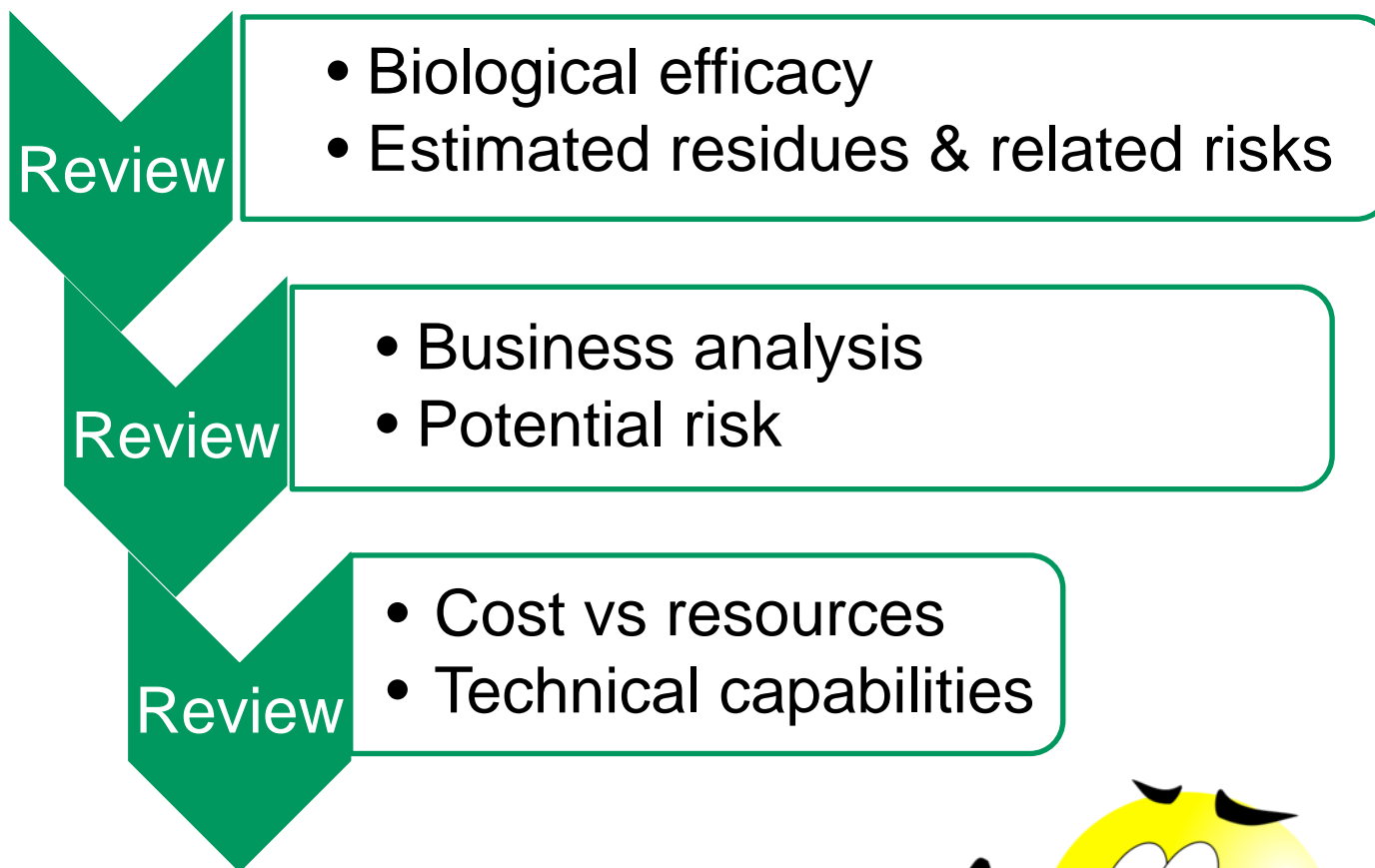
4. Recommendations for Selecting Projects



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Solutions for the Growing World

4. Recommendations on Selecting Projects



Most projects will be approved !



Conclusion & Acknowledgement

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

Growers, Commodity groups + Agencies + Registrants + Contractors 😊

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



Carmen Tiu
tcarmen@dow.com



Dow AgroSciences



BioProtection
Global

BPG, Biocontrol Products and minor uses

David Cary IBMA

Nina Wilson BPIA

Biological Products – What Are They?

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

(definition is driven by the regulatory characterization)

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

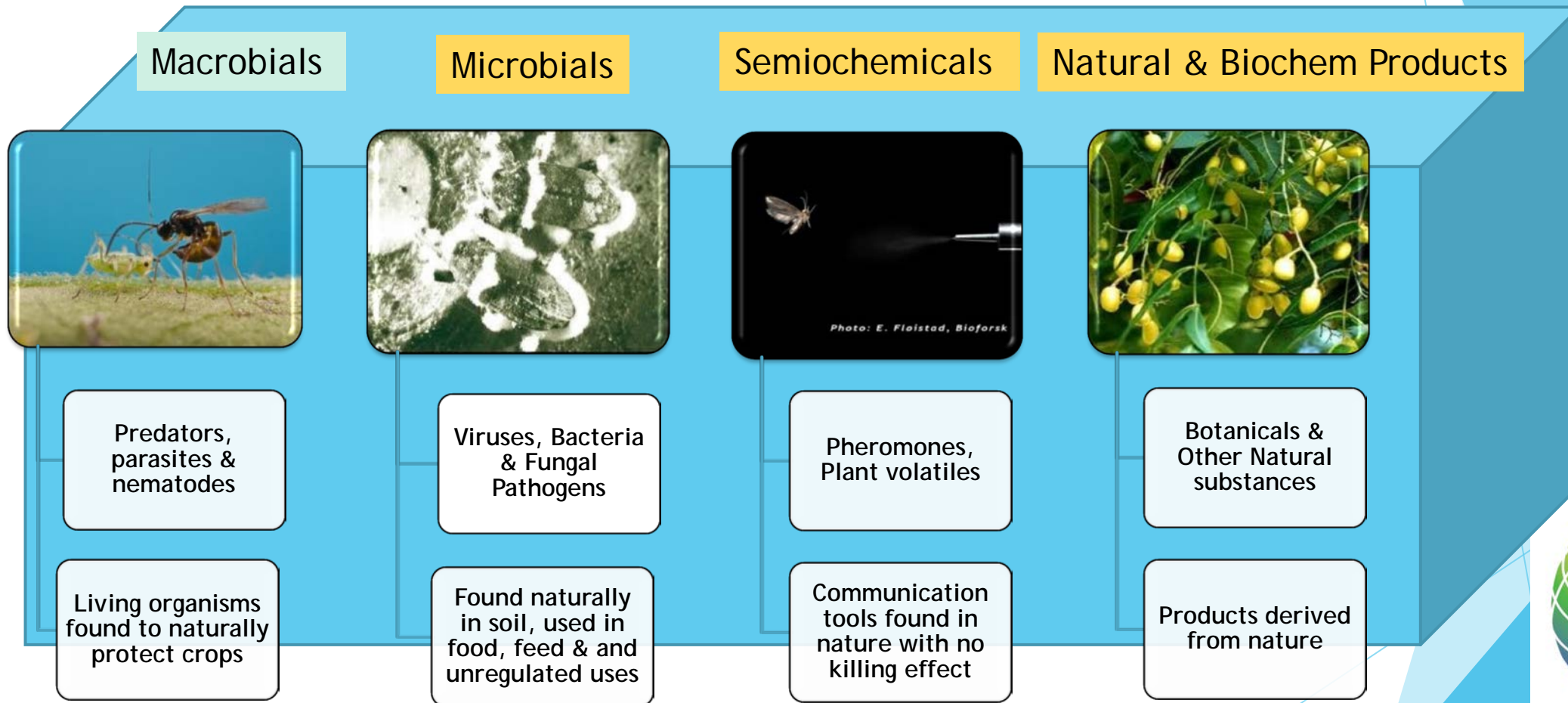
Usually not associated with a tolerance/MRL; not residue free but no residues of toxicological concern

May or may not comply with national organic regulations



BioProtection
Global

“Innovative Green Tools” of the Biocontrol industry



Not usually regulated as PPPs Regulated as PPPs
All groups can have niche solutions



BioProtection
Global

BioProducts Market: Growing Globally



67%
N.Am & Euro
Share of Global
Market



16%-17%
Global CAGR



58%
Microbials Largest
Product Line



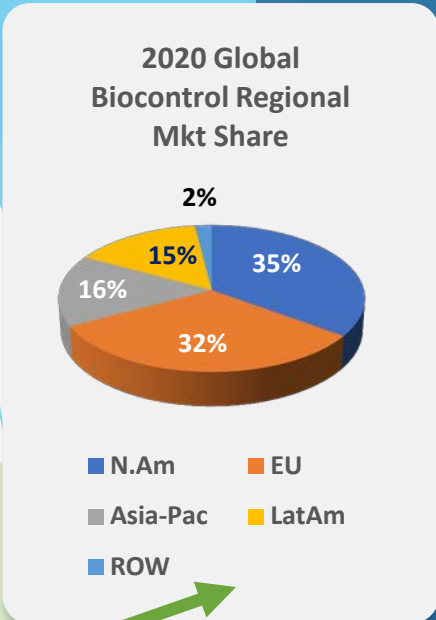
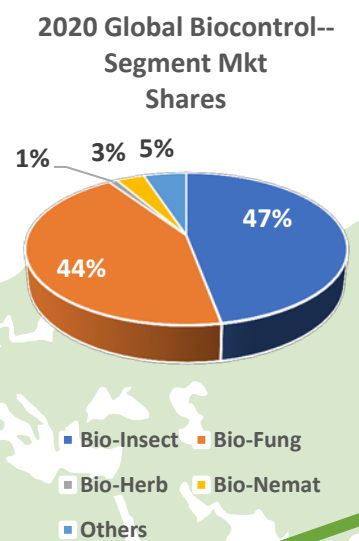
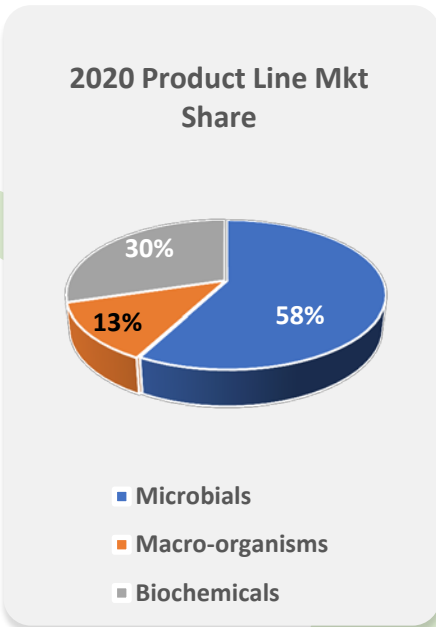
>17%
Microbials
Product Line
Fastest Growing



47%
Bio-insecticides
Still Largest Use
Segment



18%
Bio-nematicides
Fastest Growing
Use Segment



Biopesticide - What are the challenges?

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



Who is BPG?



BioProtection Global

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

Member Associations

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



BioProtection
Global

BioProtection Global Objectives

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



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



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

Only through use of true IPM

Minor uses are of major importance to the Biocontrol industry!



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What do biocontrol tools contribute to the IPM agricultural system?

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



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What has been achieved by BPG and Member Associations?

Working with IGOs and Policymakers to bring BCAs to market

Working with Regulators to develop guidance / better regulation

Working with Researchers and Research bodies to target needs

Working with other parts of Industry to explore mutual benefits

Working with Farmer Groups for targeting needs and optimising performance

Working with the Food Value Chain for harmonised progress towards sustainability

Just some of the possible solutions

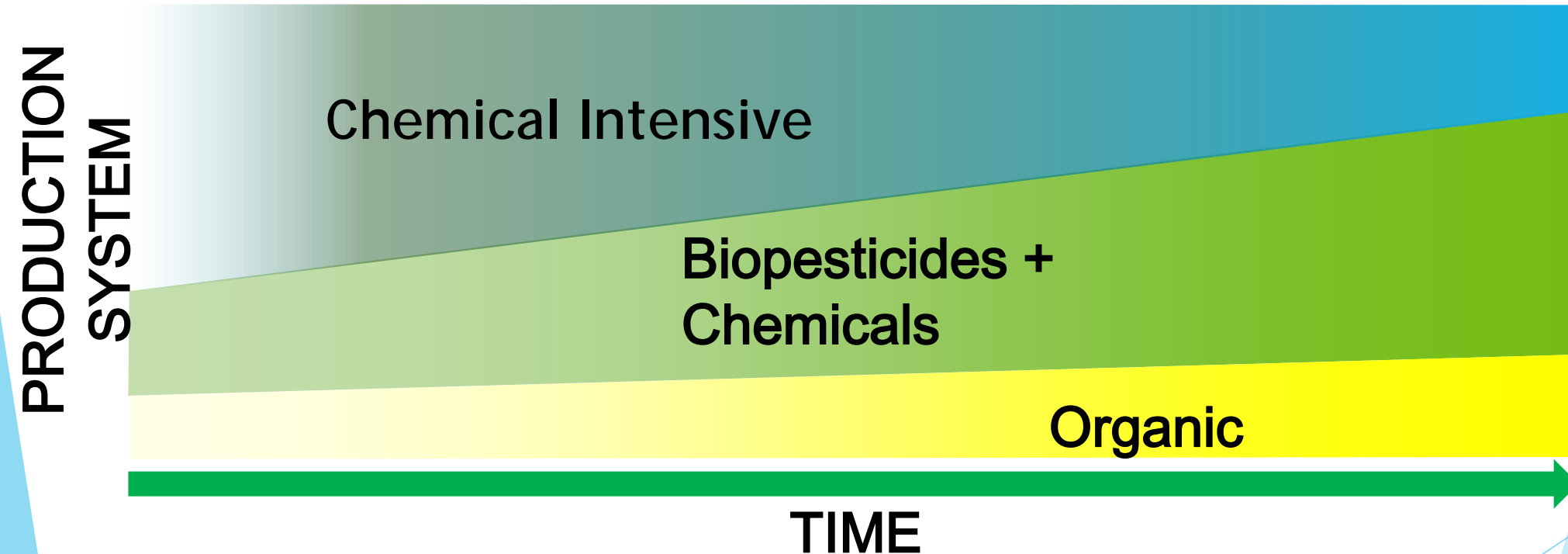
- ▶ Global or regional positive lists
 - ▶ EPPO list for IBCAs
 - ▶ FAO list of MBCAs
 - ▶ EU 2003/2003 proposed list of microbial biostimulants
- ▶ Single global data package and registration
- ▶ No renewal requirement using data call-in systems
- ▶ Notification only procedure for a.s. ie EU and SCLPs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

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



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The Shift Toward Bio-Based Systems



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Thank you from BPG!

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Minor Uses: A regional perspective. A global view.

GMUS-3

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

ENGAGEAGRO

member of the Belchim Group 

1995

Engage Agro Corporation

- based in Guelph, Ontario.
- a master copy label of propiconazole and a plan
- to support minor crop business

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1995

Niche market roots

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

1999

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1995

Around this time...

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

1999

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Meanwhile in Canada...

- NAFTA joint review projects were coming to fruition
 - many with minor crop registrations
- rock-solid chemistry available in field crops with spectrums which would benefit horticulture

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1995

Engage Agro:

- support development, registration and label expansion in minor crops
- launch products and provide tech-service
- provide ongoing marketing support
- particularly for crop protection products which larger companies in Canada were not able to dedicate staff toward at that time.

1999

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1995

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

1999

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1999 - 2000

- The propiconazole label had expanded via minor use activities
 - Stone fruit
 - Cranberries
 - Saskatoon berries
 - Blueberries
- credit to extension specialists and regional advocates for minor crops
- Engage Agro was to translate those efforts into commercially available tools for the minor crops

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1999 - 2000

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

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2000

Remarkable growth in this decade

2010



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2000

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

2010

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2000

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

2010

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2000

Exciting times!

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

2010

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2000

Minor crops with export markets:

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

2010

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Production Risks:

An example (2004):

- in the USA, a Section 18 expired for control of *Monilinia* on blueberry
 - time limited tolerances expired as well
-
- In the USA, there were new fungicides registered for mummy berry control.
 - In Canada, the options for mummy berry control were limited.
-
- scramble to secure supply of the alternative fungicide
 - the alternative product lost tolerances the following year

Marketing Risks:

Scenario A.

✓	Effective Solution
✓	Registered Product
✓	Tolerance at Destination
✓	Viable Option

B.

✓	Effective Solution
✓	Registered Product
✗	No Tolerance at Destination
✗	Not Viable

C.

✓	Effective Solution
✓	Registered Product
?	Unclear Tolerance at Destination
✗	May not be viable

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2000

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

2010

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2010

A need to change and collaborate on a global basis

– grow business with suppliers who historically were without local representation

- assess market opportunities
- assess development costs for Canada
- where feasible, facilitate development and registration
- launch products for Canadian crops / specialty markets
- tolerances are high on the list of assessment criteria

2017

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2016

Within the last year:

- Engage Agro attracted international investment from Belchim Crop Protection
- minor crop connections
- advancing our overseas collaboration

2017

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Meanwhile around the Globe...

Work dedicated to minor crops:

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

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