Minor Crops

Approaches to addressing minor uses internationally

OECD and Codex Activities
Summits and Workshops

Daniel Kunkel, Ph.D.,
IR-4 Project,
Associate Director, Food and International Programs

This material is based upon work that is supported by the National Institute of Food and Agriculture, U.S. Department of Agriculture, under award number 2015-34383-23710 with substantial cooperation and support from the State Agricultural Experiment Stations, USDA-ARS and USDA-FAS. In accordance with Federal Law and U.S. Department of Agriculture policy, this institution is prohibited from discriminating on the basis of race, color, national origin, sex, age or disability.

IR-4 Project

- **Started in 1963 as a publically funded (USDA) program to facilitate registration of Sustainable Pest Management Technology for Specialty Crops and Minor Uses.**
- **Main program areas**
  - Food Crop Program
    - Residue studies, some efficacy & crop safety
  - Biopesticide and Organic Support Program
  - Ornamental Horticulture Program
  - Public Health Pesticides

Daniel Kunkel, PhD, Associate Director,
IR-4 Project. Rutgers University

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Three core principles to support Minor uses

- Technical
  - Build a platform for sharing….. Needs, reviews, crop grouping
- Collaboration
  - Working with others….using global data, develop data jointly, joint reviews etc.
- Policy
  - Regulatory approach, data requirements, public support/public programs, incentives to register minor uses.

Technical areas

- Technical and Cooperative areas:
  - Minor Use working groups (from Summits) – Global needs, Capacity development and Communication. Steering committee.
  - International data sharing and research collaboration
  - A focus on limiting duplication of efforts, but still providing robust data sets, data review.
  - Greater involvement of all stakeholders, especially specialty crop grower's/commodity associations in identifying needs and facilitating solutions to the minor use problems.
  - Capacity building to provide quality regulatory data and residue monitoring
  - Review, discuss and implement guidance on crop groups and use of extrapolation.

The NEED FOR PEST CONTROL CONTINUES	Results of Global Workshop - 2015 Surveyed 40 countries, 2500 pest problems		
Cropping System	**Pest/Crop rank 1 - A (highest votes)**	**Pest/Crop rank 2 - B (votes)**	**Pest rank 3 – B (votes)**
Protected (green house)	**Aphids /lettuce** **Possible Solutions:** Flonicamid, Pymetrozine, Cyantraniliprole, Sulfoxaflor, NA 11630	**Thrips /fruiting vegs.** **Possible solutions:** Cyantraniliprole, Novaluran, Cyclaniliprole	**Whiteflies/fruiting veg.** **Possible solutions:** Flupyradifurone, Cyantraniliprole, Novaluran, NA 11630
Temperate	**Downy mildew/leafy vegetables** **Possible solutions:** Ametoctradin + Dimethomorph, Acibenzolar, Zoxamide, Fluopicolide + Propamocarb Cyazofamid, Oxathiapiprolin Famoxadone + Cymoxanil	**Aphids/legumes crops** **Possible solutions:** Flonicamid, Pymetrozine Cyantraniliprole, Sulfoxaflor, Dinotefuran Spirotetramat Flupyradifurone, NA 11630	**Weeds/leafy vegetables** **Possible solutions:** s-metolachlor
Tropical Fruit	**Fruit flies** **Possible solutions:** Spinosad, Cyantraniliprole Kaolin, NA 11630	**Anthracnose** **Possible solutions:** Trifloxystrobin + Fluopyram Pyraclostrobin + Metiram Mandistrobin, Isofenamid Azoxystrobin + Difenoconazol Cyprodinil + Fludioxonil Penthiopyrad	**Psyllids on Citrus crops** **Possible solutions:** Diflubenzuron, Flonicamid Sulfoxaflor, Buprofezin, NA 11630

Technical areas

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/classification:**
  - **Places crops into appropriate groups or subgroups**
  - **Representative crops have been identified as the appropriate commodity for residue research purposes**
  - **Data from the representative set of crops allows establishment of the maximum allowable residue levels (tolerances) for multiple related crops**

Technical areas

Crop Grouping – per SUMMIT 1*

- 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

Technical areas

Group 12A, Tomatoes

Group 12A, Tomatoes	**Tomato**	**<u>Tomatoes (VO 2045):</u> Bush tomato; Cherry tomato; Cocona; Currant tomato; Garden huckleberry; Goji berry; Ground cherries; Sunberry; Tomatillo; Tomato**

Technical areas

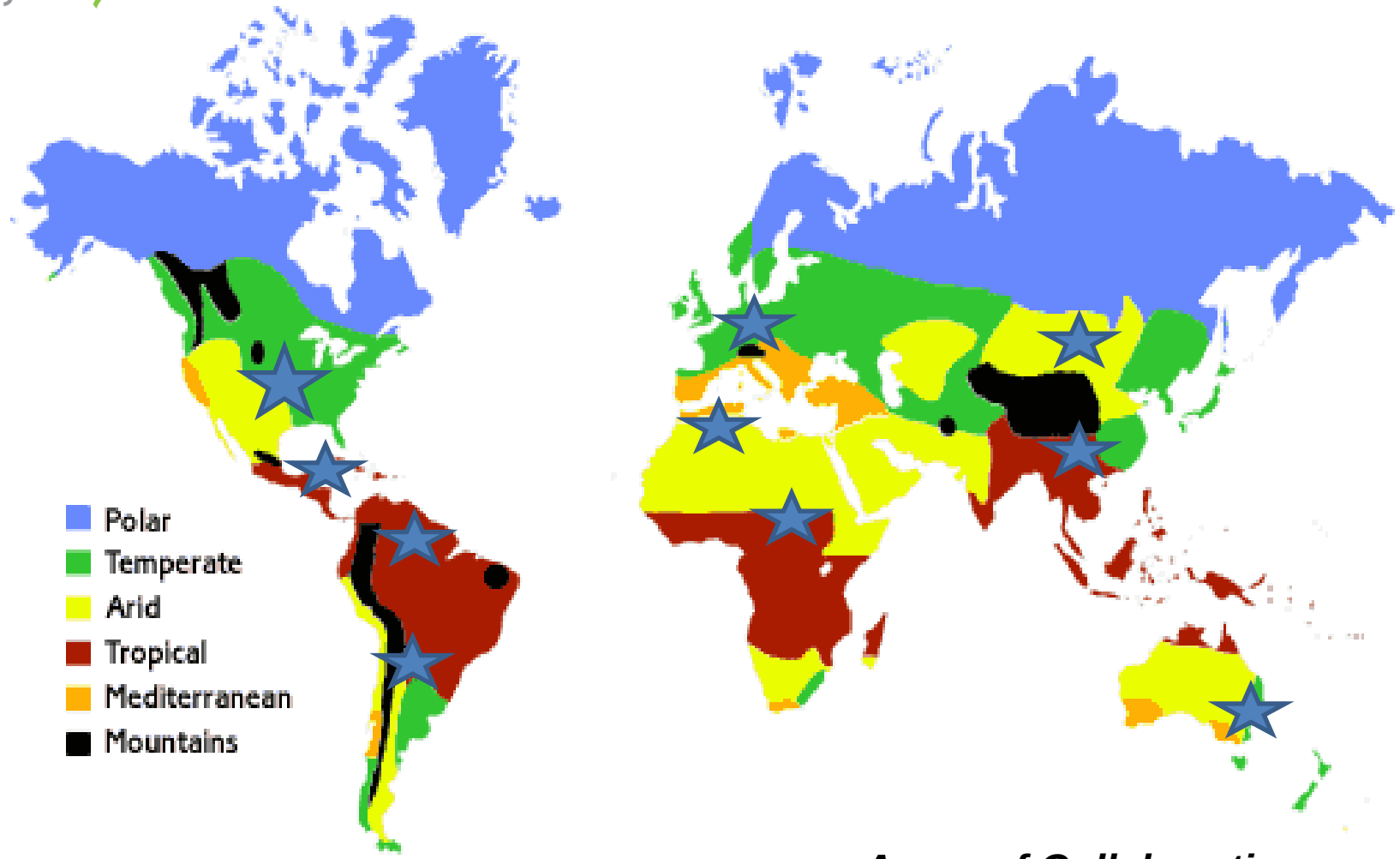
Collaboration

- Collaboration
  - Working with others….using global data, develop data jointly, joint reviews etc.

Global Studies

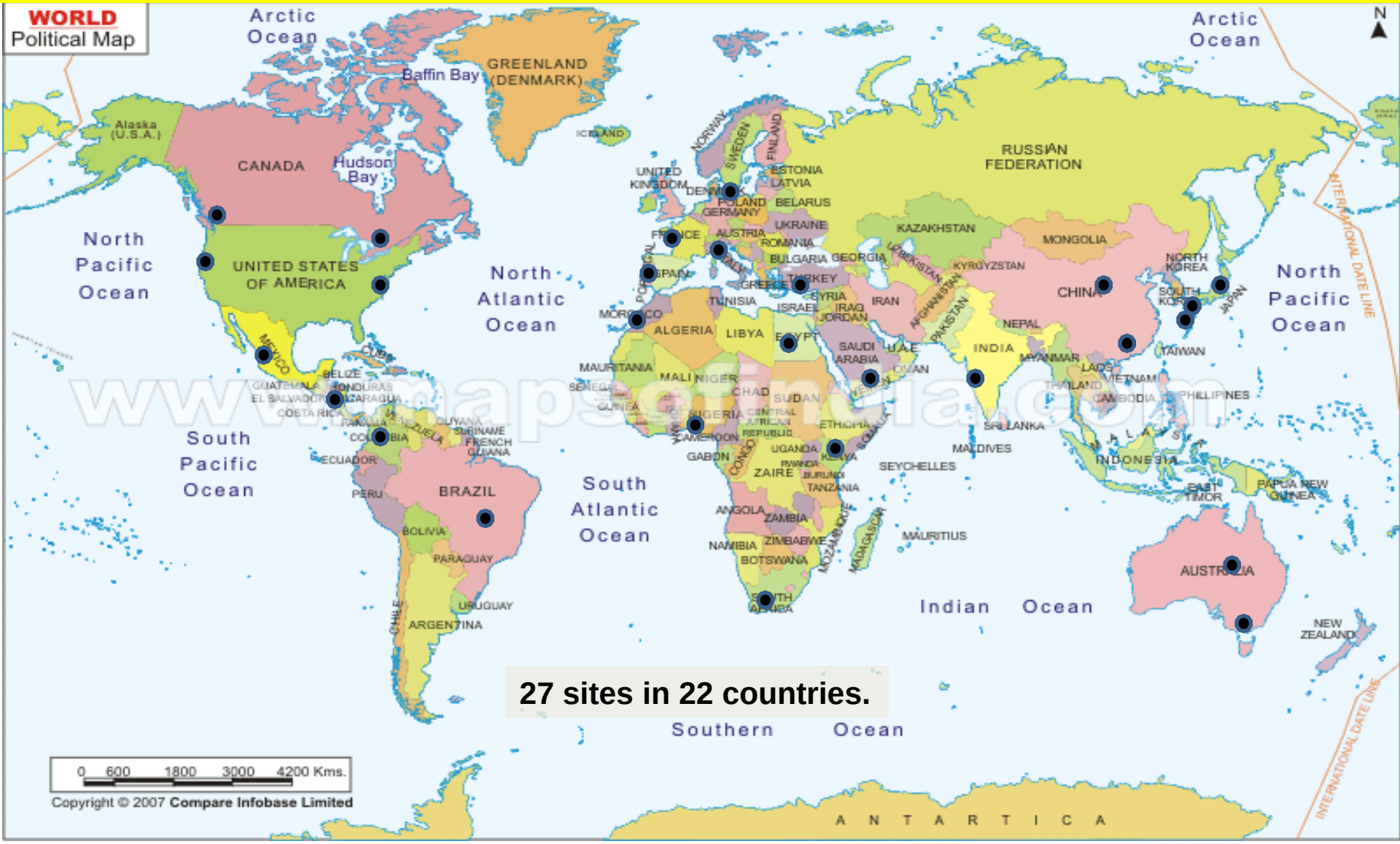
- Generating data to support registrations
- Providing data to enhance regulatory requirements to support Minor Uses.
  - Allow data from other countries, fewer domestically
  - More robust data set
- Have Global MRLs established at the same time.

Zoning (Kopper-Geiger climate map)



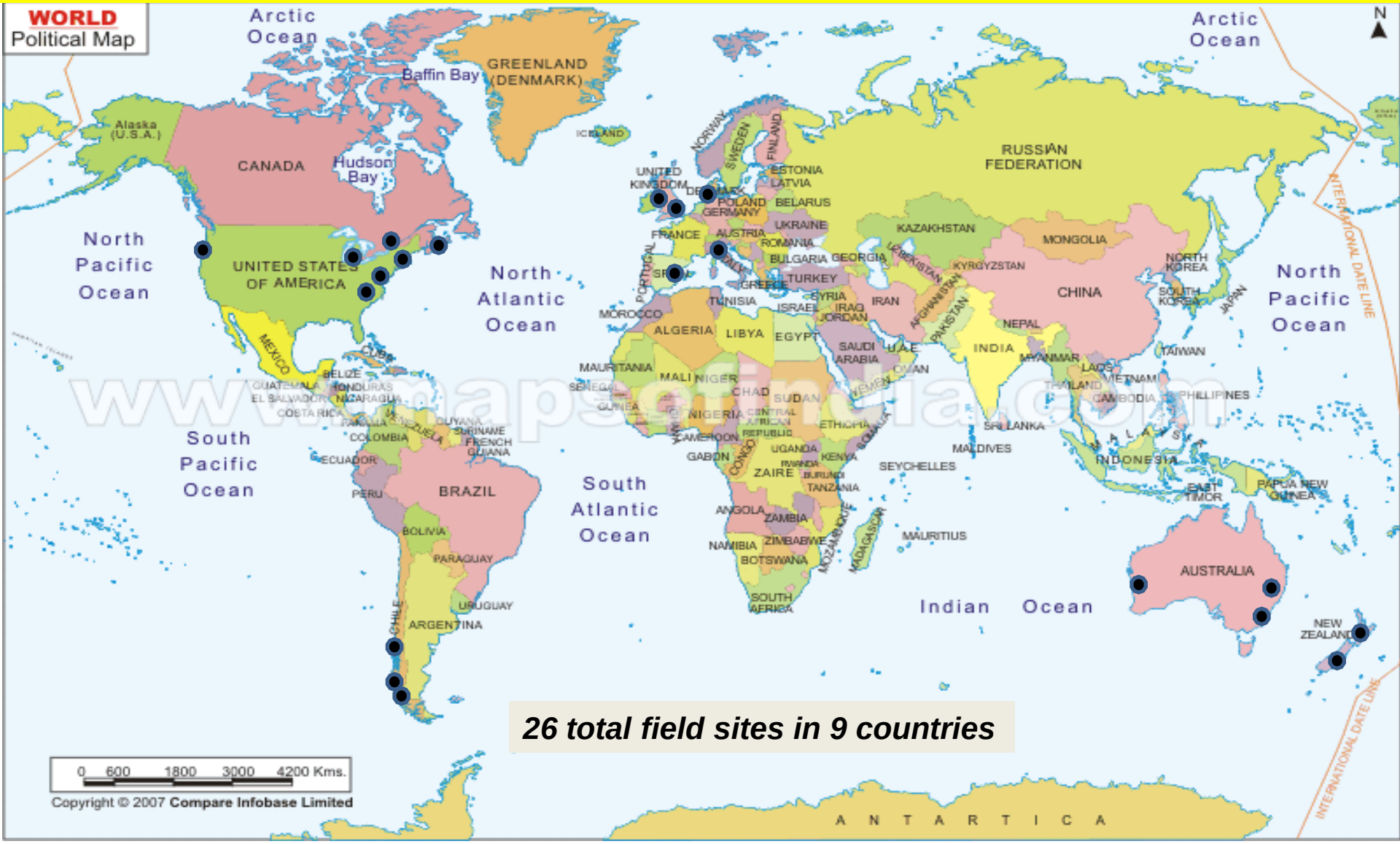
Areas of Collaboration

GLOBAL RESIDUE STUDY-Tomato



Areas of Collaboration

GLOBAL RESIDUE STUDY-Blueberry



26 total field sites in 9 countries

Areas of Collaboration

Flupyradifurone

Blueberry Global Residue Project Status (IR-4 & PMC)

- ❑ GLP Study conducted under one protocol (one GAP), IR-4 is the Sponsor and Study Director.
- ❑ All samples analyzed by Bayer Crop Science Laboratory
- ❑ Study submitted for Global Joint Review Fall 2012.

- **LOWBUSH Blueberry:**
  - 3 trials in Nova Scotia (one decline)
  - 1 trial in Maine

- **HIGHBUSH Blueberry:**
  - 2 trials in New Jersey
  - 3 trials in Michigan (one decline)
  - 2 trials in North Carolina
  - 1 trial in Oregon
  - 1 trial in Quebec

- **European trials**
  - 1 trial in Spain - decline
  - 1 trial in Denmark
  - 2 trials in the U.K. – decline
  - 1 trial in Italy - decline
  - Note:2 trials using “protected” crop.

- **Other Sites (HIGHBUSH)**
  - 3 trials in Australia
  - 2 trials in New Zealand
  - 3 trials in Chile (one decline)

26 total field sites in 9 countries (OECD countries)

Areas of Collaboration

Analysis Using the OECD MRL Calculator

NAFTA sites only

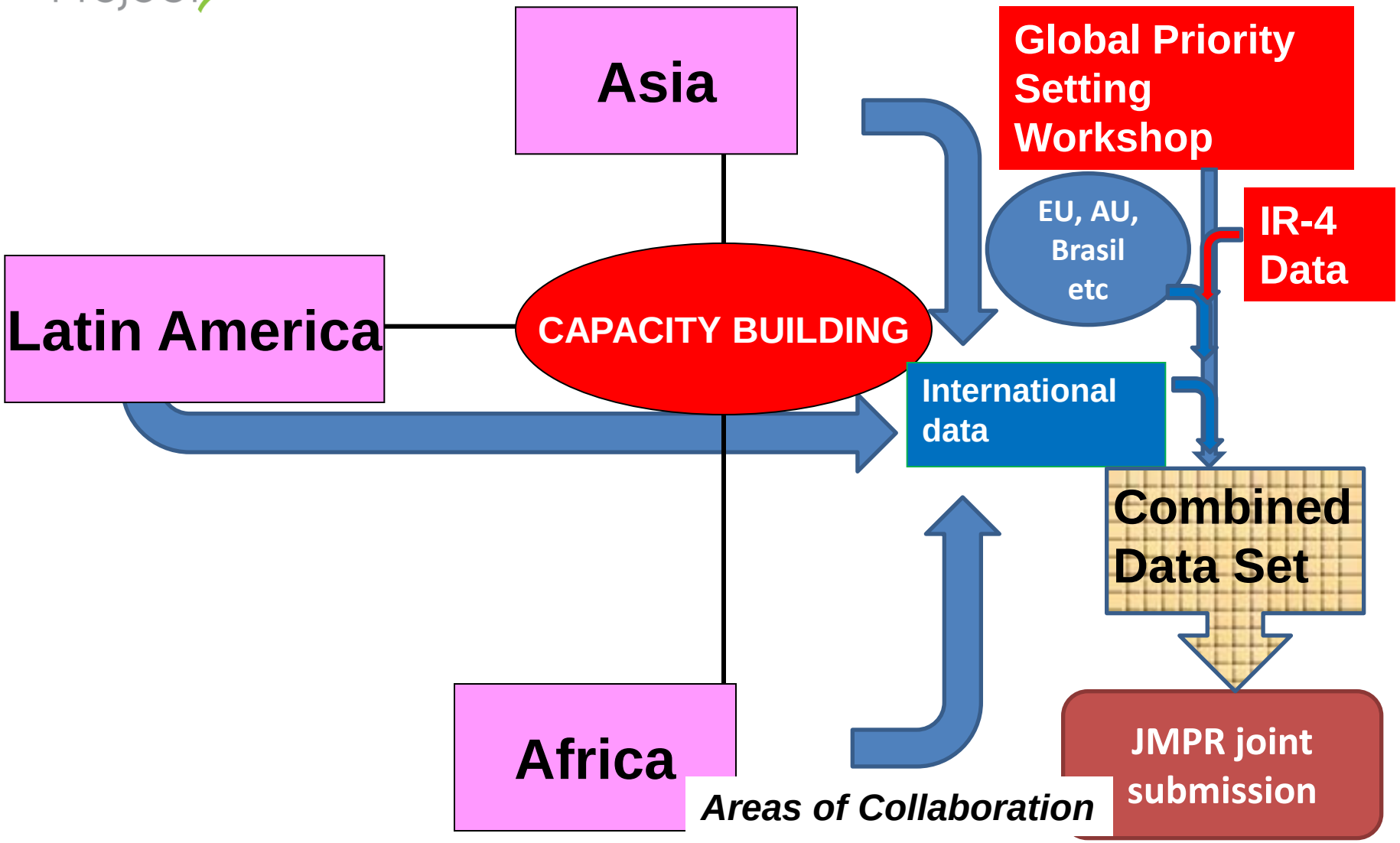
- 13 field trials
- Lowest residue 0.290 ppm
- Highest residue 2.59 ppm
- Median residue 0.834 ppm
- Mean residue 0.912 ppm
- SD 0.630
- Unrounded MRL 3.431 ppm
- Rounded MRL 4 ppm

Global data (all sites)

- 26 field trials
- Lowest residue 0.193 ppm
- Highest residue 2.59 ppm
- Median residue 0.867 ppm
- Mean residue 0.974 ppm
- SD 0.632
- Unrounded MRL 3.504 ppm
- Rounded MRL 4 ppm

Areas of Collaboration

Pooling data to address minor uses



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Red Font indicates active projects

Areas of Collaboration

Policy considerations and Tools for Harmonization

- Crop Grouping
- Global Zoning (exchangeability of field trials)
- Incentives for Industry
- Management of product liability to facilitate minor use registrations, such as sharing of efficacy and crop safety data across countries
- JMPR/Codex Process Initiatives – support MRLs on minor uses
- OECD MRL Calculator, Crop group calculator
- Global Joint reviews
- Global Guidelines, Env. Fate, field trials, etc. etc
  - Multiple countries working together
- Establish and support Minor Use Programs
- Share and implement criteria standards that define and recognize minor uses

CodexCPR 2012- Principles and Guidance for Selection of Representative Commodities (Crop Groups, extrapolations)

- **Revised document incorporates proposed *representative commodities* for all of the fruit type crop groups (Table 1).**
- **Adopted in the *Codex Classification of Foods and Animal Feeds***
- **Listed Standard under CAC/GL 84-2012 http://www.codexalimentarius.org/codex-home/en/**
- **Progress**
  - **All Fruit type adopted**
  - **All Vegetable type – to be adopted…2017**
  - **Cereal grains – to be adopted …2017**
  - **Others to follow.**

Policy considerations

Global Data sharing, Precedents to date

- **Global Zoning Concept**
- NAFTA Pilot Project to Validate Residue Zone Maps, 2001
- OECD/FAO Zoning Project (2003)
- Bourma Paper exchange of efficacy & crop safety (2005)
- EPPO guidelines for E/CS
- **Regulatory Framework**
- OECD CFT 509: 40% less trials for global programs (2009 and 2016)
  - Guidance document needed more support for zoning
- JMPR 2012 requested evidence proportionality and provided comparisons

Policy considerations

Global Zoning Analysis

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

- If not, residue data from various zones conducted under the same or similar application scenarios could be combined to develop globally harmonized MRLs (to include all possible variability)

- **US-EPA**
- **OECD-RCEG**
- **CropLife**
- **EFSA**
- **Canadian PMRA**
- **JMPR/CCPR**
- **IR-4**

- EPA's synthetic data, real data from DAS, IR-4, CropLife, PMRA

Real datasets: 73 crops, 76 pesticides, 2-4 regions, > 4,000 data points

Policy considerations

Incentives to encourage Minor Use Registrations (increasing the value)

- **Data Protection**
  - Add one year when 3 minor uses are registered, max of 3 additional years.
- **Minor Use Fee Waiver/Reduction**
  - Public organizations (IR-4) are exempt from paying fees
  - MFG need to demonstrate, economically, that it is a minor use – up to 75% waiver
- **Crop Groupings**
- **Data generation assisted programs**
  - IR-4, PMC, etc..
- **Support Public Interest finding**

Policy considerations

OECD – Residue Chemistry Expert Group

OECD MRL Calculator

- Statistical procedure for setting Maximum Residue Limits (MRLs).
- Calculator, user guide & white paper is available from OECD website.
- Also used by JMPR
- Apply to crop groups…

Guidance Document on Crop Field Trials – updated 2016

- Used for planning of residue trials and interpretation of results.
- Covers: crop grouping, extrapolation, proportionality, geographical distribution & numbers of trials, equivalency of formulations etc.

Our Vision

Global network of capable minor use programs working together to solve the MUP

- Help establish and mentor minor use programs
- Partner with other data development groups
- Address the many unresolved needs

Questions/Comments

THANK YOU FOR YOUR KIND ATTENTION
Questions/Comments?

Daniel Kunkel, Ph.D.,
Associate Director, IR-4 Project phone: 732.932.9575 ext: 4616,
kunkel@aesop.rutgers.edu, web: ir4.rutgers.edu

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