IR-4 Global Activities

Supporting US Export Markets

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Harmonization CODEX MRLs etc.

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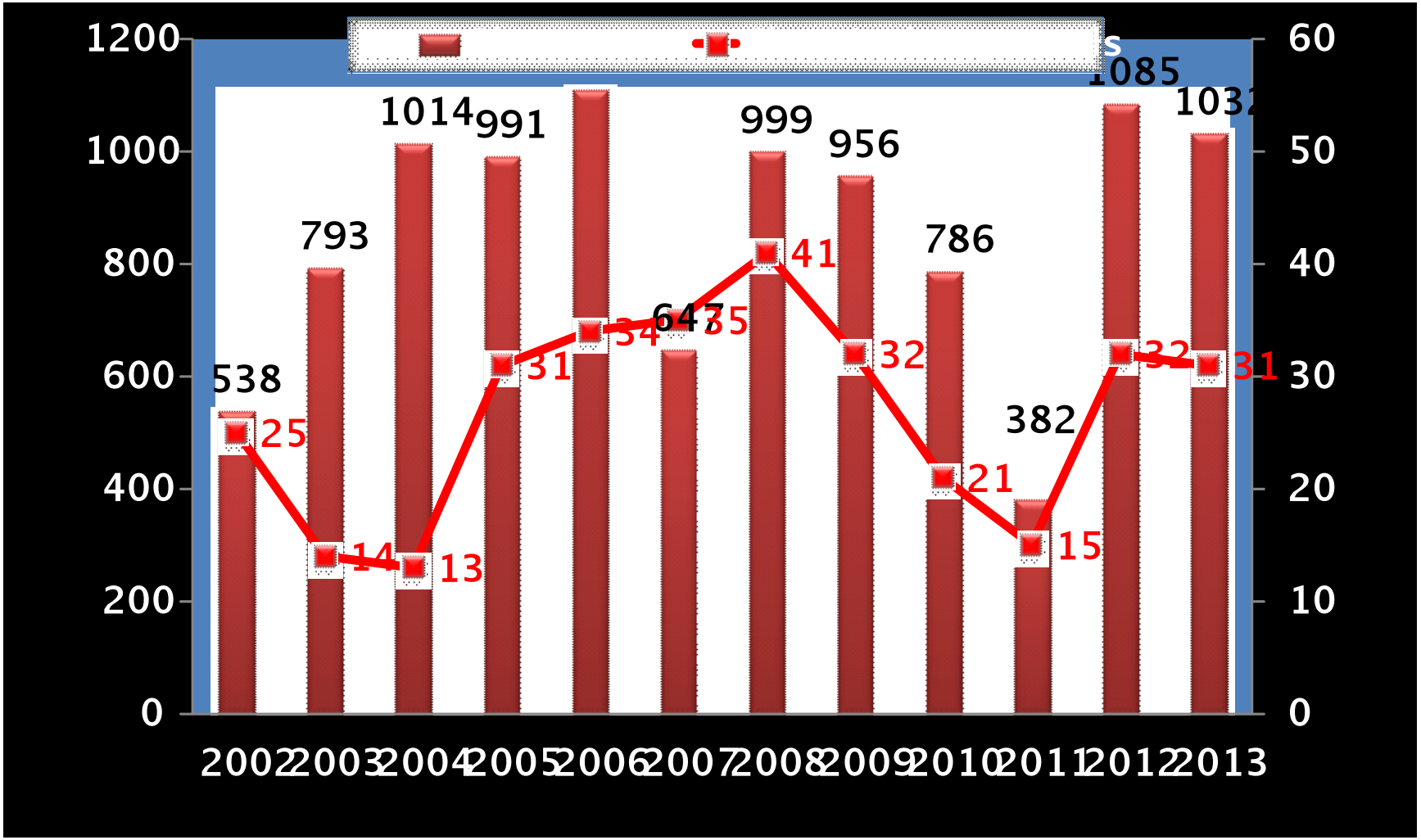
IR-4 Project Mission

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

USDA United States Department of Agriculture National Institute of Food and Agriculture

Deliverables w/Food Crops



What New Products Mean to trade

- Lower (reduced) risk Products – for growers etc.
- May not be recognized in other countries.
- Growers don't always know where crop is going.
- Globalization could preclude the use of a new pest control product in the US.
- Use of pesticides (insecticides, fungicides) often result in some measureable residues after use.

Northwest Horticultural Council

Summer Codling Moth Control

1983	1998	2013
azinphos methyl	azinphos methyl	chlorantraniliprole
phosmet	phosmet	thiacloprid
phosalone	methyl parathion	spinetoram
methyl parathion		spinosad
		phosmet
		methoxyfenozide
		novaluron

Source:
EB0419
WSU Crop Protection Guide for Tree Fruits in Washington

Maximum Residue Limits

- Used for enforcement – proper application etc
- Standards for commodities in trade (domestically and internationally)
- Only set if the dietary exposure risk assessment confirms that there are no human health concerns to any segment of the population
- Every country has or is developing their own regulatory system.
  - Independent
  - Default – Codex (a global standard but not recognized by all countries)

IR-4 Data

- Conduct 80 MOR studies per year on 30 or chemistries (about 550 field trials)
- Submit approximately 80 study reports to EPA each year
- EPA reviews and established Tolerances (MRLs) on 30 chemicals per year.
- Through crop group extrapolations etc the data supports nearly 1,000 new uses each year.

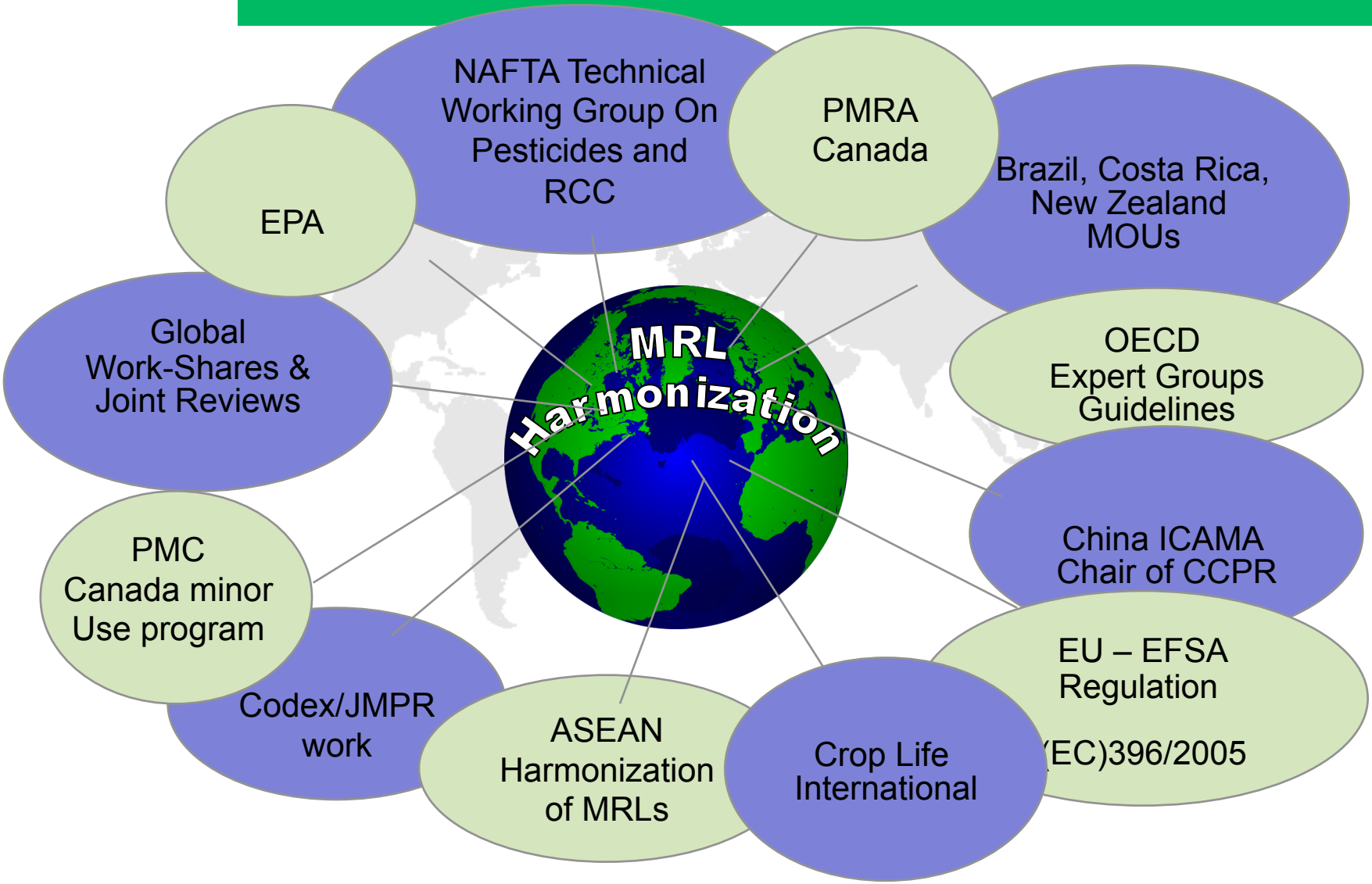
International Use of IR-4 Data

- Provide data to any commodity group that needs data to support export markets
  - Hop exports to the EU
  - Citrus and Berry growers to Asia markets
  - Cranberries to the EU

International Use of IR-4 Data

- Codex/JMPR
  - Work with commodity groups and EPA to add uses (chemicals) to JMPR work plan
  - Review JMPR work plan and dovetail IR-4 data with chemicals scheduled for review
  - Work with EPA and Registrants to submit data to JMPR
  - Consider working with other countries to nominate chemicals or add commodities to JMPR workplan

IR-4 efforts in International Cooperation



IR-4's International Activities

- NAFTA
- Leadership
  - Global Minor Use Summits
  - Codex (e.g. Crop Groups)
  - OECD
- Capacity building
- Research
  - Tomato
  - Blueberry

MOUs/Partnerships

- Canada – Joint work started in 1996
- New Zealand – 2009
- Brazil – 2012
- Costa Rica – 2013
- Global Minor Use Workshop - future

Case study: 2013 IR-4 Residue Program

- Canadian Partnership
  - 82 Residue Studies for IR-4
    - 16 joint studies with PMC – Common interest studies
    - 564 Field trials
    - 55 being conducted by Canada
    - $302,500 direct savings to the IR-4 program
    - PMC is SD for two studies – They cover administration of the study as well a analytical cost (min of $200,000).

Our Vision

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

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

Global Minor Use Foundation

Global Studies

- Generating data to support registrations
- Providing data to change domestic regulatory requirements.
  - Fewer domestically
  - More robust data set
- Have Global MRLs established at the same time.

IR-4 Global Residue Studies

- Zoning work with tomato
- GLP MOR on blueberry – new active
- Capacity Development - Tropical fruits in Asia, Africa, Latin America

Global Tomato Study*

- The purpose of the Global Residue study is to compare residues of 4 chemicals on tomato across a wide variety of geographical and environmental zones.
- In order to minimize differences:
  - Identical spray equipment
  - Test substances were pre-measured
  - A training video on how to conduct the study was posted on YouTube.
- Samples included a time zero sample to measure variability other than the environment and samples were taken at 24 and 72 hours after application.

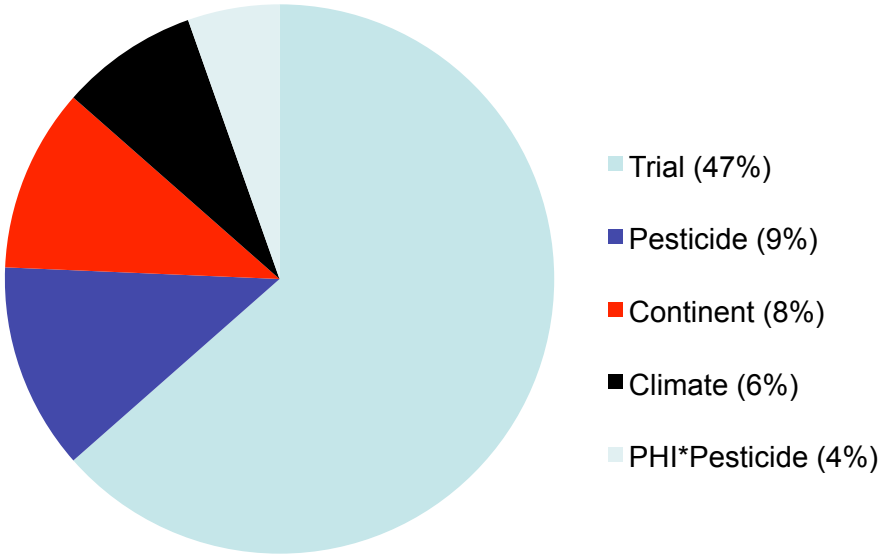
*funded by USDA TASC grant.

GLOBAL RESIDUE STUDY-Tomato

CONCLUSIONS

- Calculated MRLs were similar (difference 0.1 ppm or less) across all climatic zones and continents compared to the overall MRL (Complete data set).
- Has been analyzed statistically across sample times, climate, etc.
- Trial variance is greater than variance by zone/climate.
- Publication being prepared - draft

Variance Components
IR-4 study monitoring more variables



Other parameters (rainfall, fruit size) did not show correlated effects

BYI 02960 (Flupyradifurone)
Blueberry Global Residue Project Status (IR-4 & PMC)

- ❑ **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

GLOBAL RESIDUE STUDY-Blueberry

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

Capacity Building
Cooperation with USDA-FAS

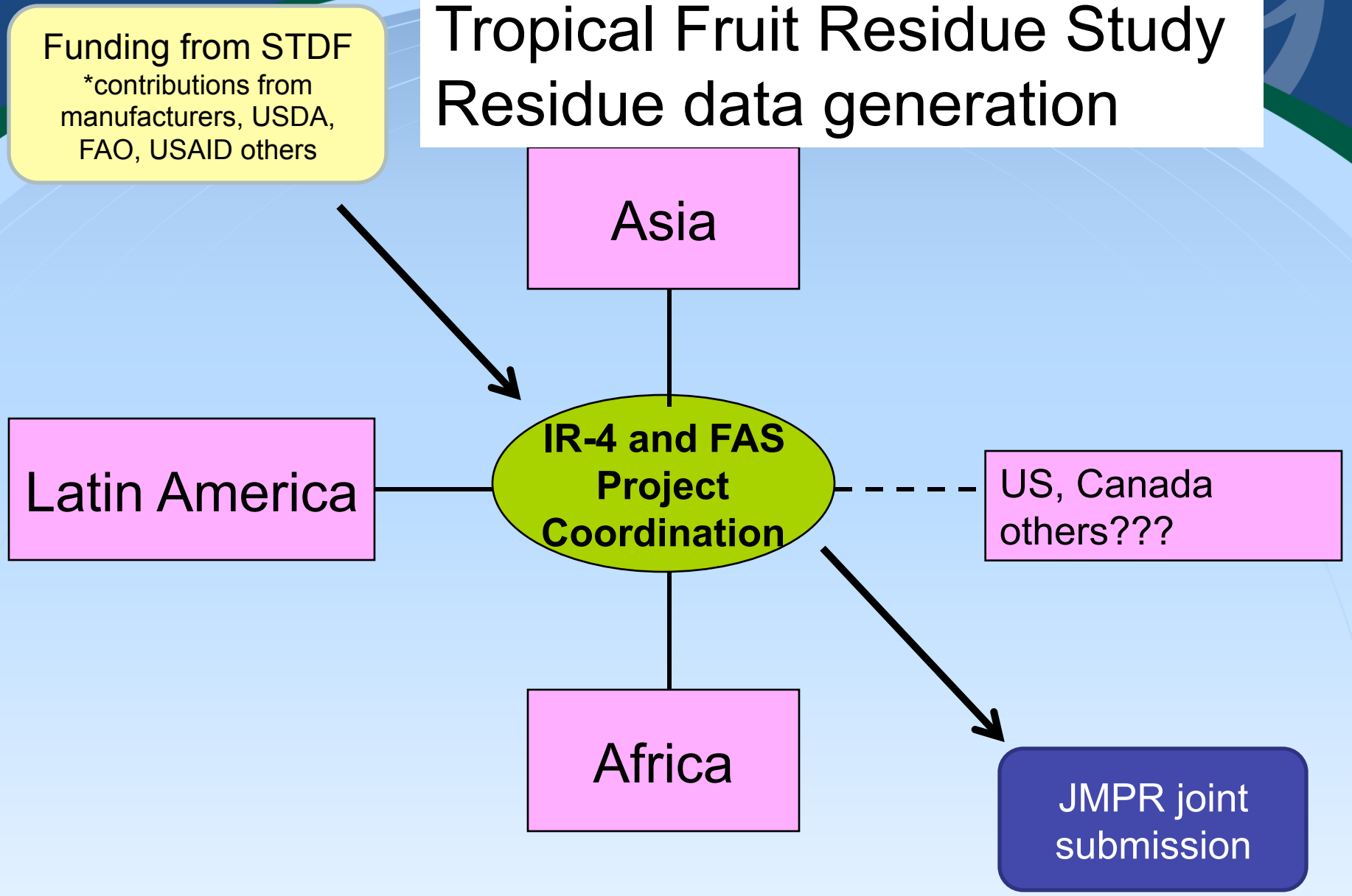
Capacity Development

Why is IR-4 involved

Vision of global network of capable minor use programs that can address grower needs and generate data.

- Help establish and mentor these minor use programs (e.g. China, Brazil, Costa Rica)
- Partner with other data development groups
- Promote lower risk products

Tropical Fruit Residue Study
Residue data generation



See: http://issuu.com/snovack/docs/vol45no1qxp

Going forward

- Conduct Global studies
- Make one global submission to regulatory bodies
- Have MRLs established globally at the same time.
- Consider separate MRLs for trade standards and those for enforcement at the local level.

Thank You!

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IR-4 Deliverables

Since its inception, IR-4 has facilitated the registration of nearly 27,000 crop uses.

- 16,000 food uses and 11,000 ornamental uses
- Numerous biopesticides (sprayable BT, spinosad for organics)
- Biotech-Plum Pox resistant stone fruit