Harmonized Approaches to Crop Protection for Minor Uses: Past, Present, and Future

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THANK YOU!!!

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- Most of all – the nominators.
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  - And the many others that have had anything to do with it!
  - Family!!!

IR-4 Project

A publically funded program that

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

Bob Simerly - National Onion Assoc.

"Everyone who eats has an interest in the IR-4 Project whether they know it or not. The IR-4 Project is a vital part of the country's food safety security system and should be considered a national strategic imperative"

Minor Uses

- They are: “What’s for dinner”

- Everyone should be interested in protecting minor uses or specialty crops

Defining Minor Uses

The OECD Guidance Document on Defining Minor Uses of Pesticides published by the OECD in 2009 states:

- *"There is no one internationally or OECD accepted definition for minor use. … The criteria and guidelines for determining what constitutes a minor use varies amongst member countries…"*
- *"Minor use definitions serve as an important mechanism to ensuring that minor uses that are required by agricultural producers are appropriately regulated…."*
- *"Minor use classifications are utilised to provide things such as guidance on the number of trials required, incentives to encourage their registration…."*

Defining Minor Uses

The OECD document outlines two prominent, and often opposing approaches for OECD member countries to use in defining minor uses

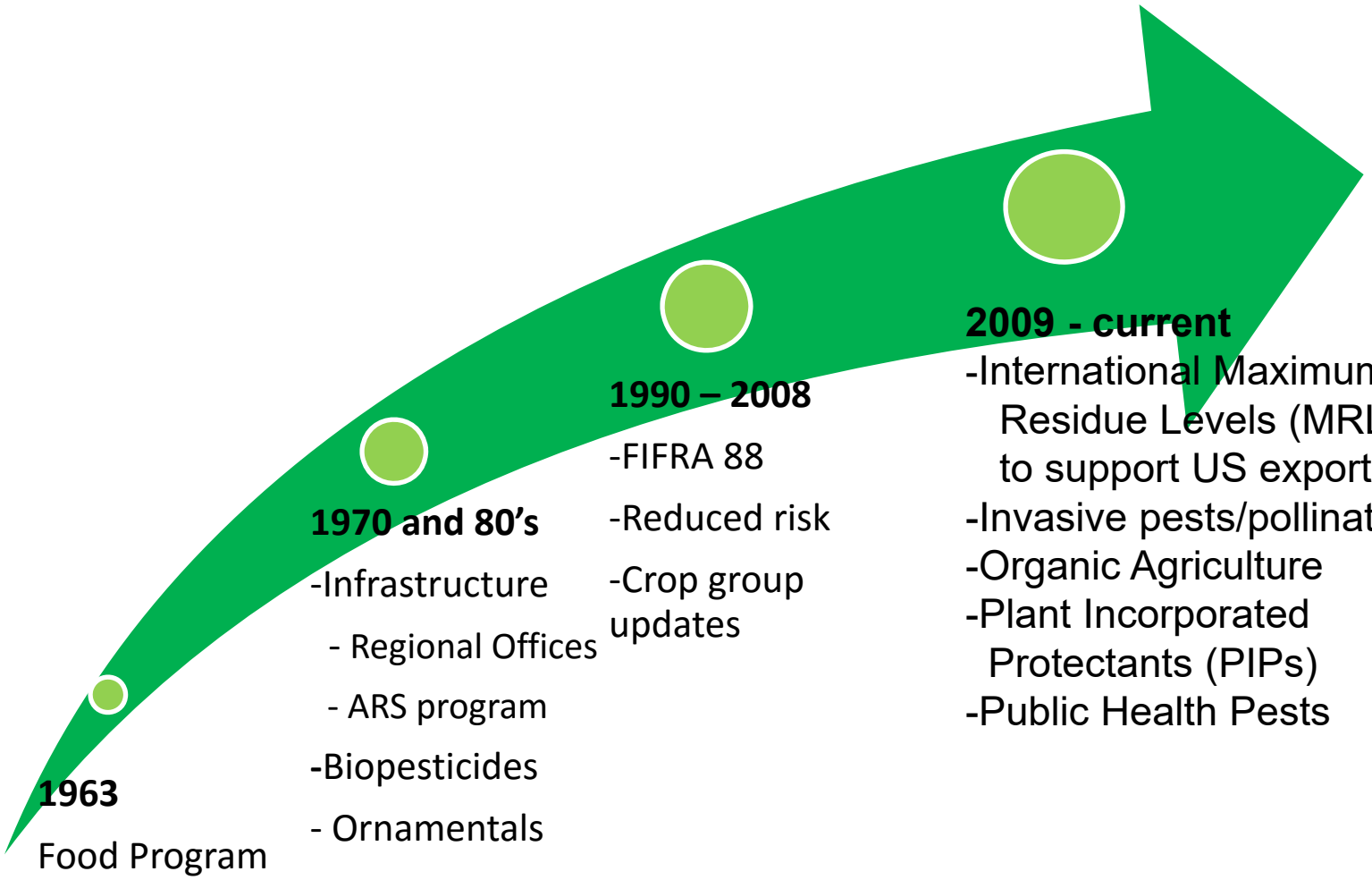
1. the 'risk assessment' approach, and
2. the 'economic return' approach

Regardless, is a situation where a grower has pest control issues that are not being addressed. …. how long do they need to go without a tool before it is considered a minor use

Past

- Julie Borlaug – 2016, *“we have to remind people that had we not had innovation in agriculture, we would not have grown out of the agrarian economy and wouldn’t have the lifestyles that we have now”*
- 2,4-D registered in 1947
- 1 US farmer feeds 150 people today

Evolution of IR-4



IR-4 Deliverables

Since its inception, IR-4 has facilitated the registration of 18,000 crop uses, 1175 in 2015 and over 650 new uses to date in 2016.

Also…Numerous biopesticides (sprayable BT, spinosad for organics), Biotech… Plum Pox resistant stone fruit.

Compton and Markle started in 1963

Current Executive Director, J. Baron

Trade- Past to Present

- **1980 – present…increase in the interdependence among countries, liberalization of trade**
- **Exports – is the major market expansion for growers/Agriculture.**
- **US markets are pretty mature**
  - **New crops, exotics..etc**

US Ag Trade – Exports

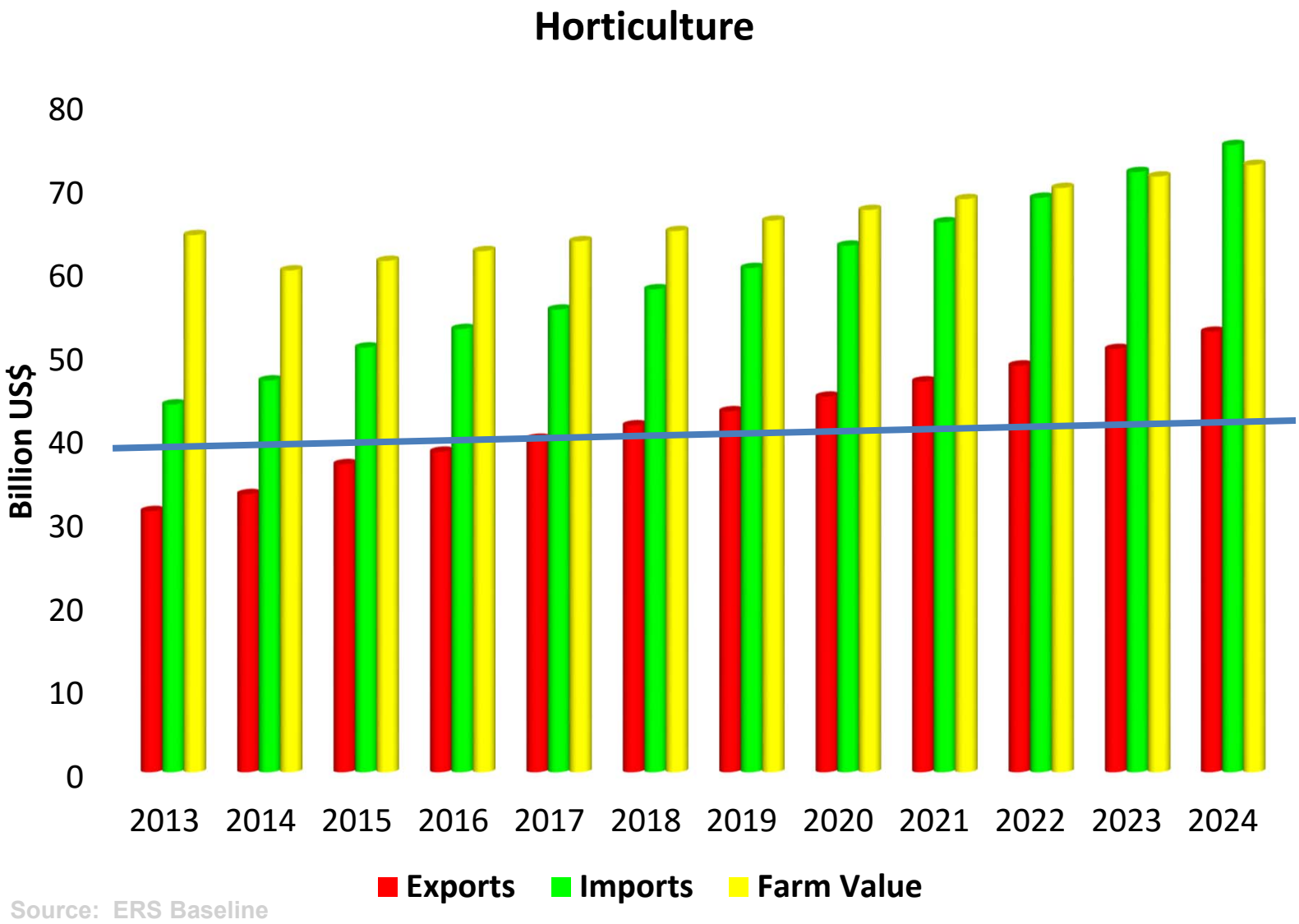
2000	2005	2010	2012	2013	2014
51*	63	116	141	162	169

*in Billions of dollars

USDA-FAS (http://www.fas.usda.gov/gats/default.aspx)

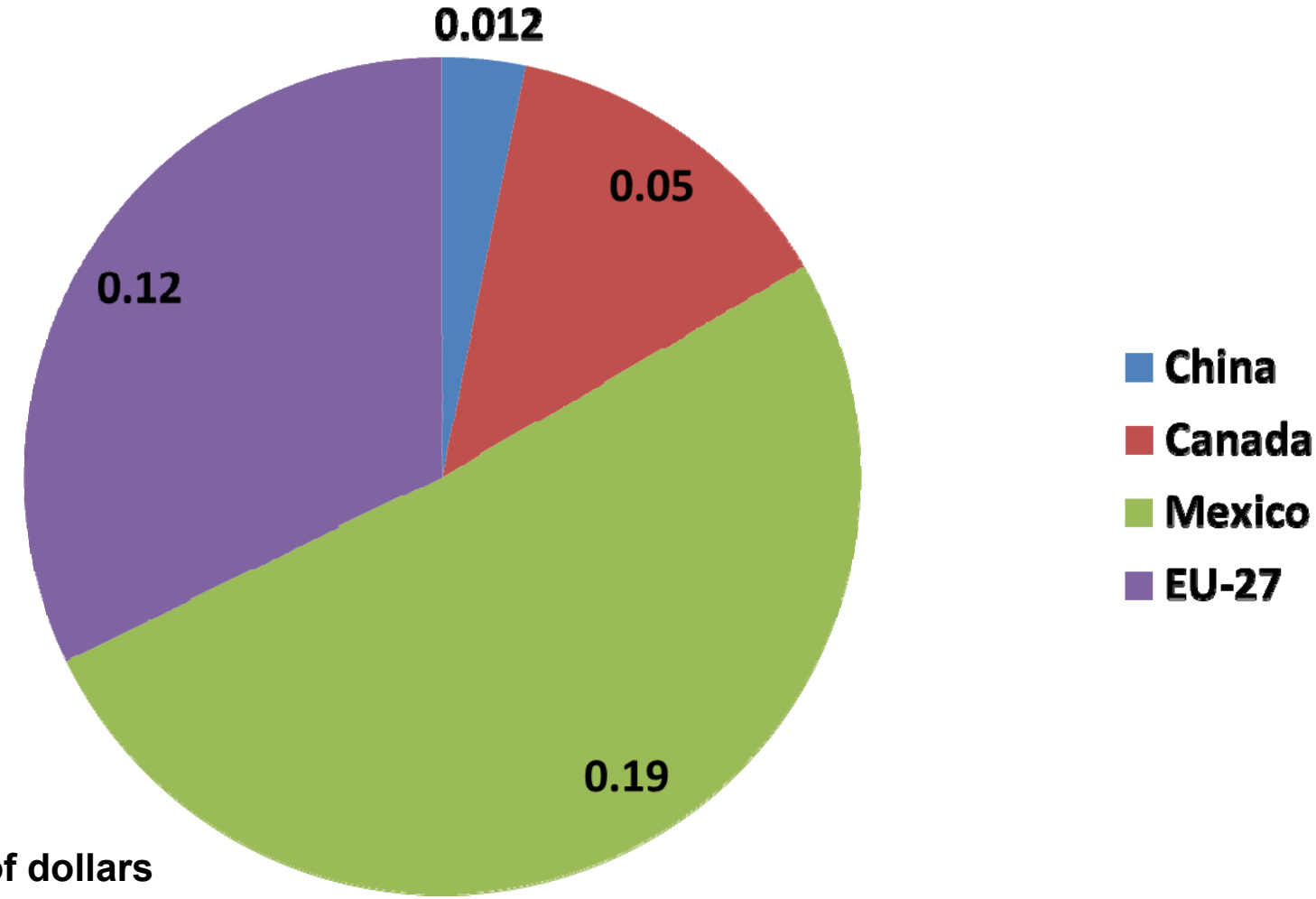
Long-Term Trends for U.S. Specialty Crops:

Production Stable, Both Imports & Exports Increase



Source: ERS Baseline

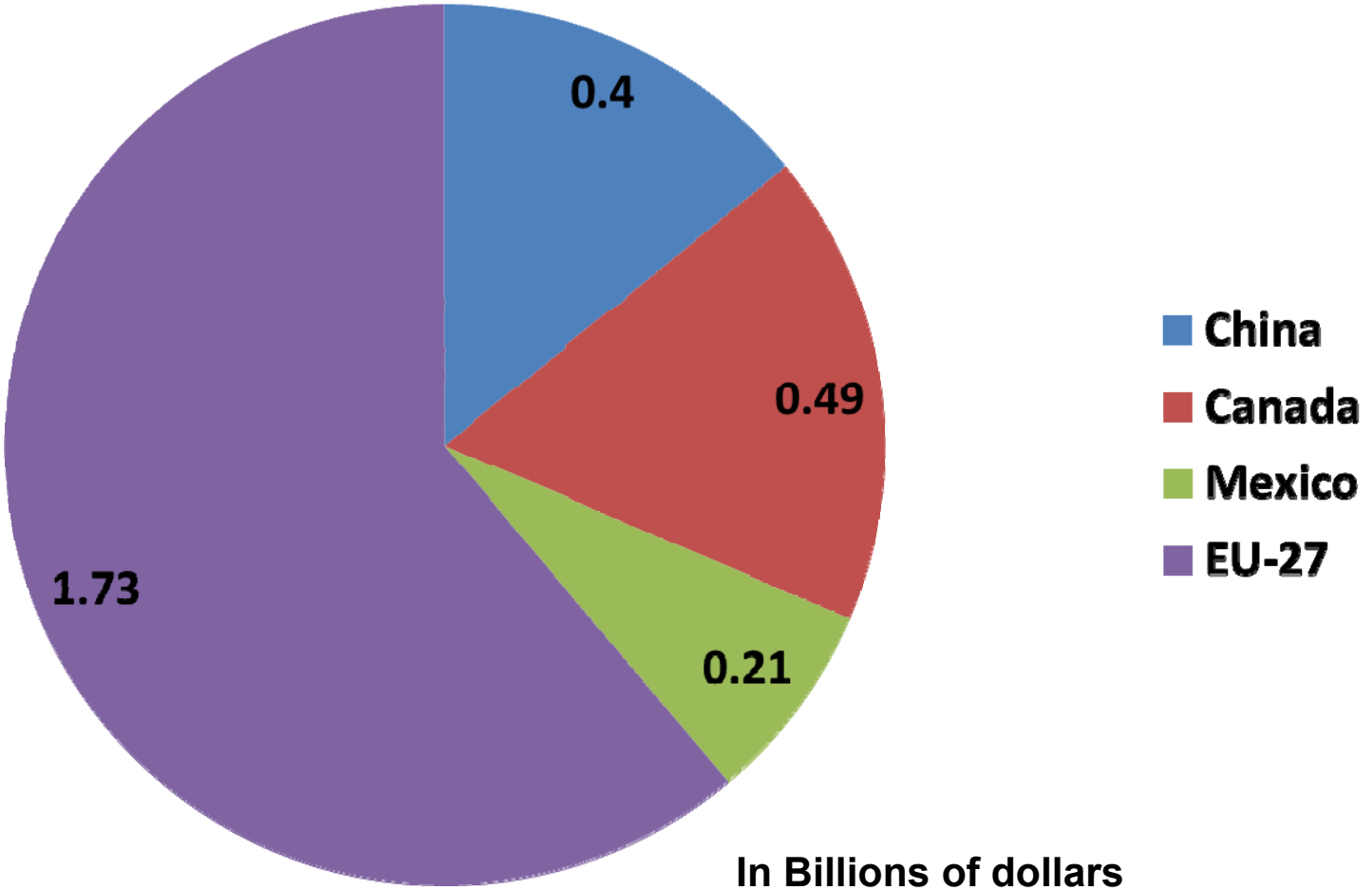
Exports of Pulses 2012



In Billions of dollars

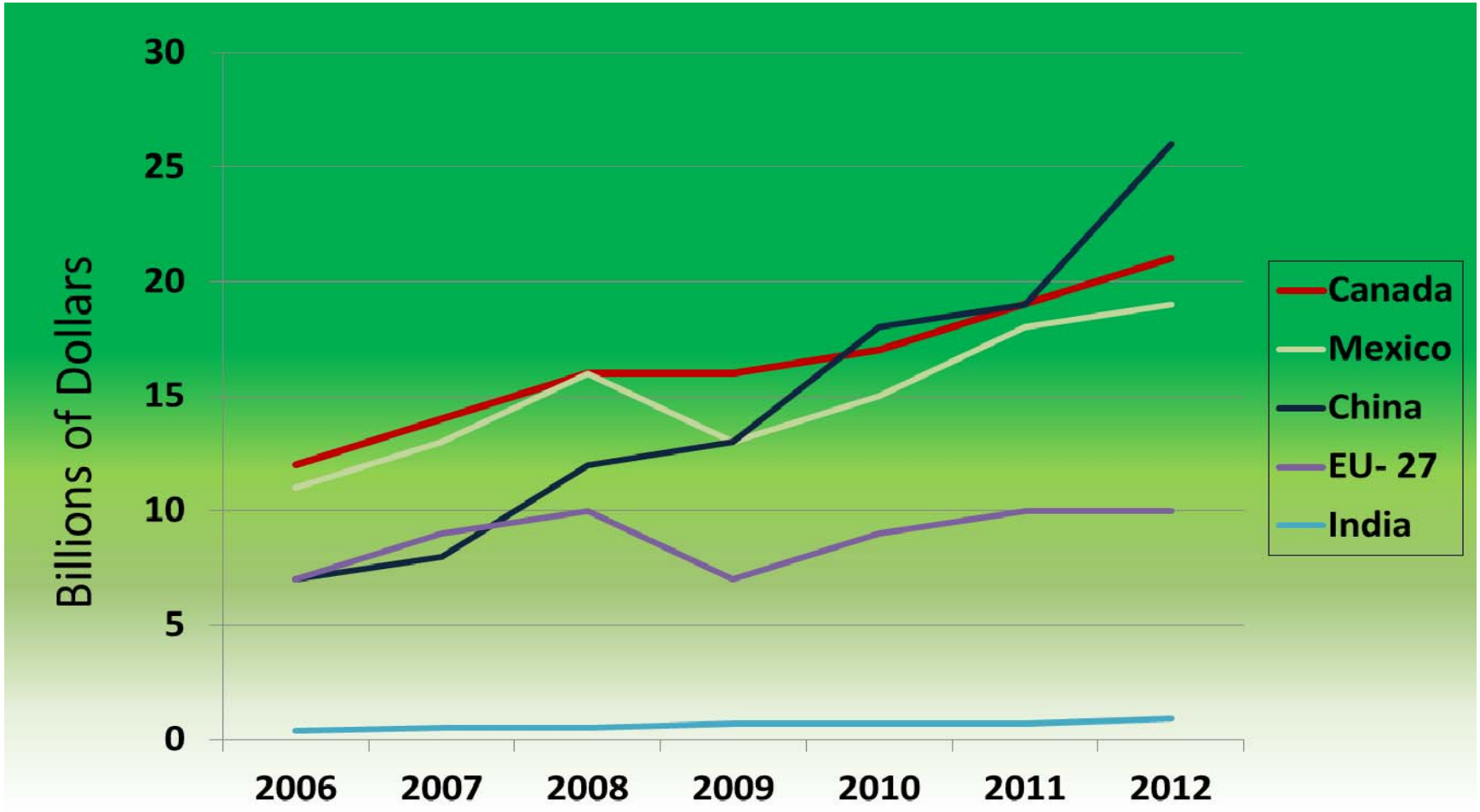
2016 is the year of the Pulse!

Exports of Tree Nuts 2012



In Billions of dollars

Ag Trade – last 7 years



*USDA-FAS (http://www.fas.usda.gov/gats/default.aspx)

It Starts with the Pests!

Pesticides are a reality

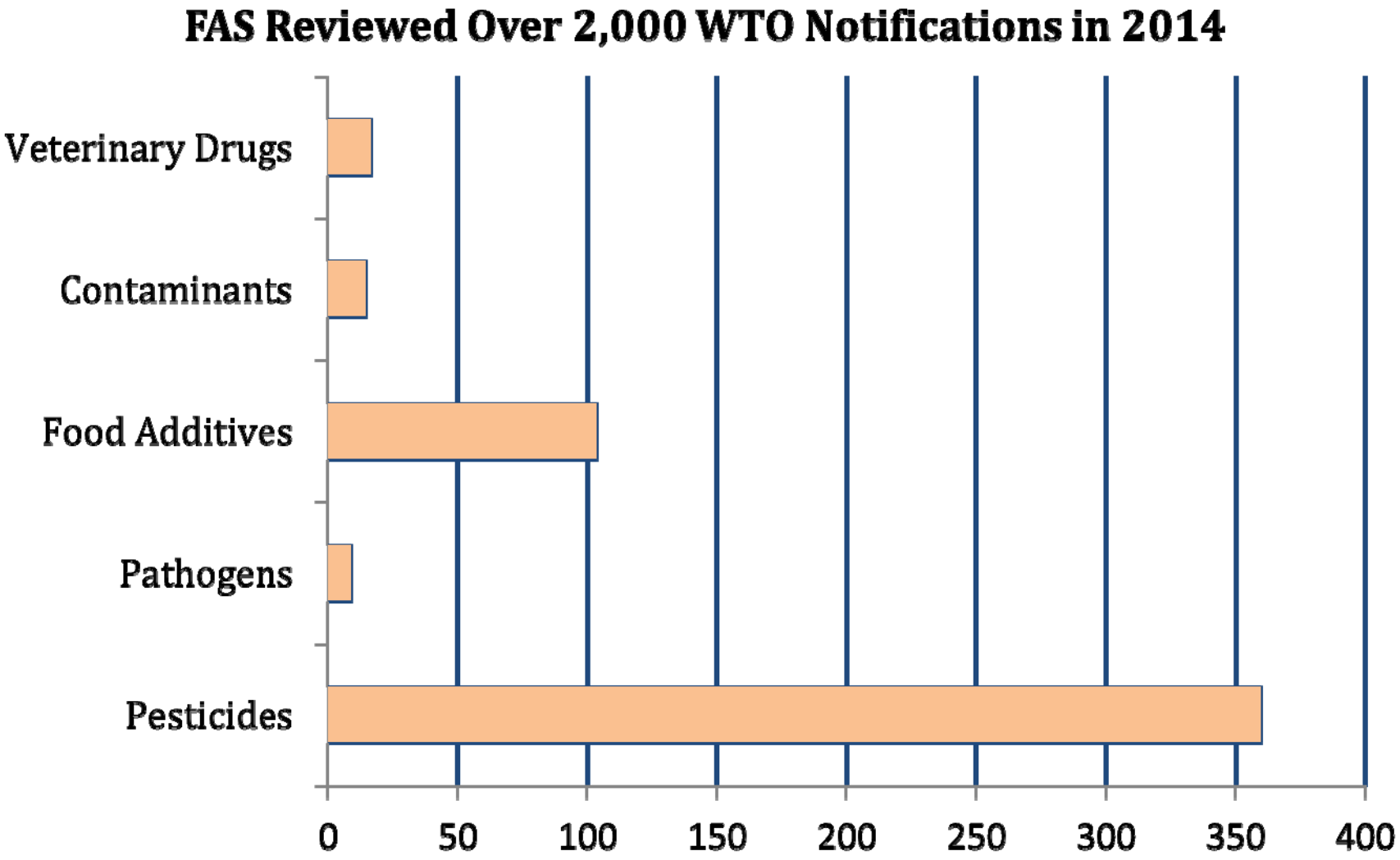
- Technologies to control plant diseases and insects are limited
- Phytosanitary demands require pesticides
- Growers large and small depend on pesticides to control plant diseases, insects (and weeds)
- Pesticides will continue to play a key role in IPM programs

Comment by California Citrus Quality Council, 2012

Pesticide residue limits (MRLs)

- **Pesticide residue limits (MRLs) are important for compliance of proper use of products and has become an important trade standard for agricultural commodities.**
- **Many countries are creating or modifying system of establishing /enforcing MRLs for imported crops and domestic use.**
- **The science improves, now 1 ppb is a reality.**
- **Regulations increase, greater complexity of moving commodities through global markets**
- **More data needed, thus the Minor use problem grows/ amplifies..**

MRL WTO Notifications



Other trade considerations

- Cranberries from the US are often shipped to Canada for juicing
- Grapes from Canada are often shipped to the US for juicing or for wine production.
- MRLs can preclude these shipments and more efficient use of resources.

Setting MRLs - Past

Regulations – Past, Present

- 1960s OECD, Codex (FAO/WHO)
  - Look and see, piecemeal data generation…submissions
- 1980s – EPA is up and running
  - Crop groups…kind of start..
  - Rejection rate analysis
- 1990 – clear(er) guidelines (OPPTS 860)
  - PMRA and other regulatory agencies established.
  - OECD - Pesticide Program initiated
    - Series on Pesticides No. 1, DATA REQUIREMENTS FOR PESTICIDE REGISTRATION IN OECD MEMBER COUNTRIES: SURVEY RESULTS
  - Registration review (ReReg, FIFIRA 88)

Regulations – Past, Present

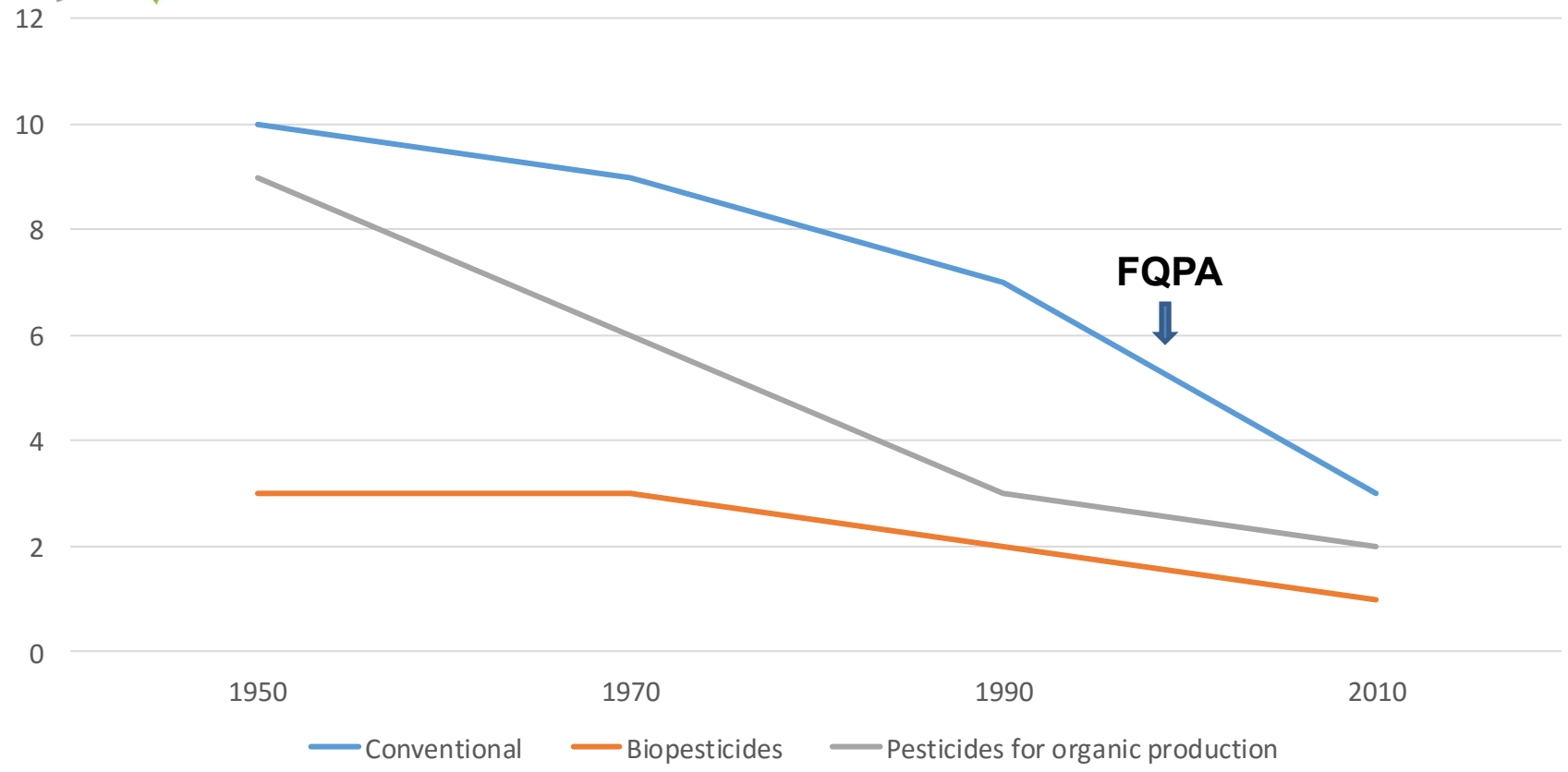
- **2000s – Joint reviews: NAFTA, OECD member countries..**
- **OECD - UPDATE OF THE "VISION FOR THE FUTURE: A GLOBAL APPROACH TO THE REGULATION OF AGRICULTURAL PESTICIDES" (REVISION 11; MAY 2009)**

Global JR – Early examples of Work Splits

Chemical	Toxicology	Residue Chemistry	Eco-toxicology	Environ-mental Fate	Product Chemistry
Pyrasulfatole	**Australia**	**Canada**	**United States**	**United States**	**Australia**
Pyroxsulam	**United States**	**Australia**	**Australia**	**Canada**	**United States**
Chlorantra-niliprole	**United States**	**Australia**	**United Kingdom**	**Ireland**	**Canada**
Spirotetramat	**United States**	**Canada**	**Austria**	**Austria**	**Canada**
Thiencarbazone /Cyprosulfamide	**United Kingdom**	**United Kingdom**	**Canada**	**United States**	**United Kingdom**
Saflufenacil *Australia peer reviewer	**Canada**	**Canada**	**United States**	**United States**	**United States**
Fluopyram *Japan peer reviewer	**Germany**	**United States**	**United States**	**Canada**	**Germany**

A good start! And a lot of progress since.

Relative Pesticide Toxicity

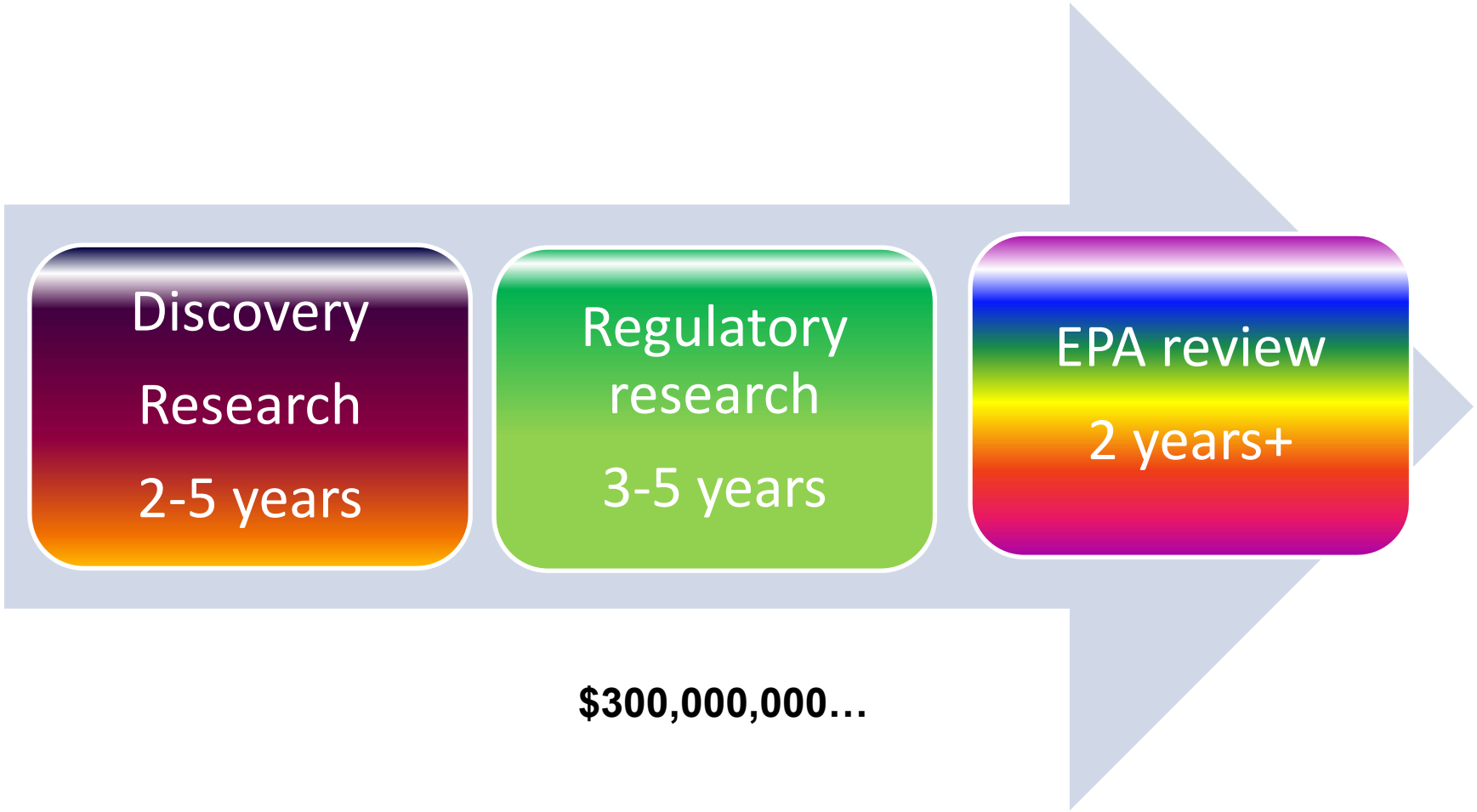


Maximum Residue Limits

- Used for enforcement – proper application etc (at the local level).
- 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
- Generally set beneath any level of potential toxicity for human health – often by an order of magnitude
- Proper use of product would seldom result in residues at the MRL level set locally.

The technology has changed

Timeline to registration



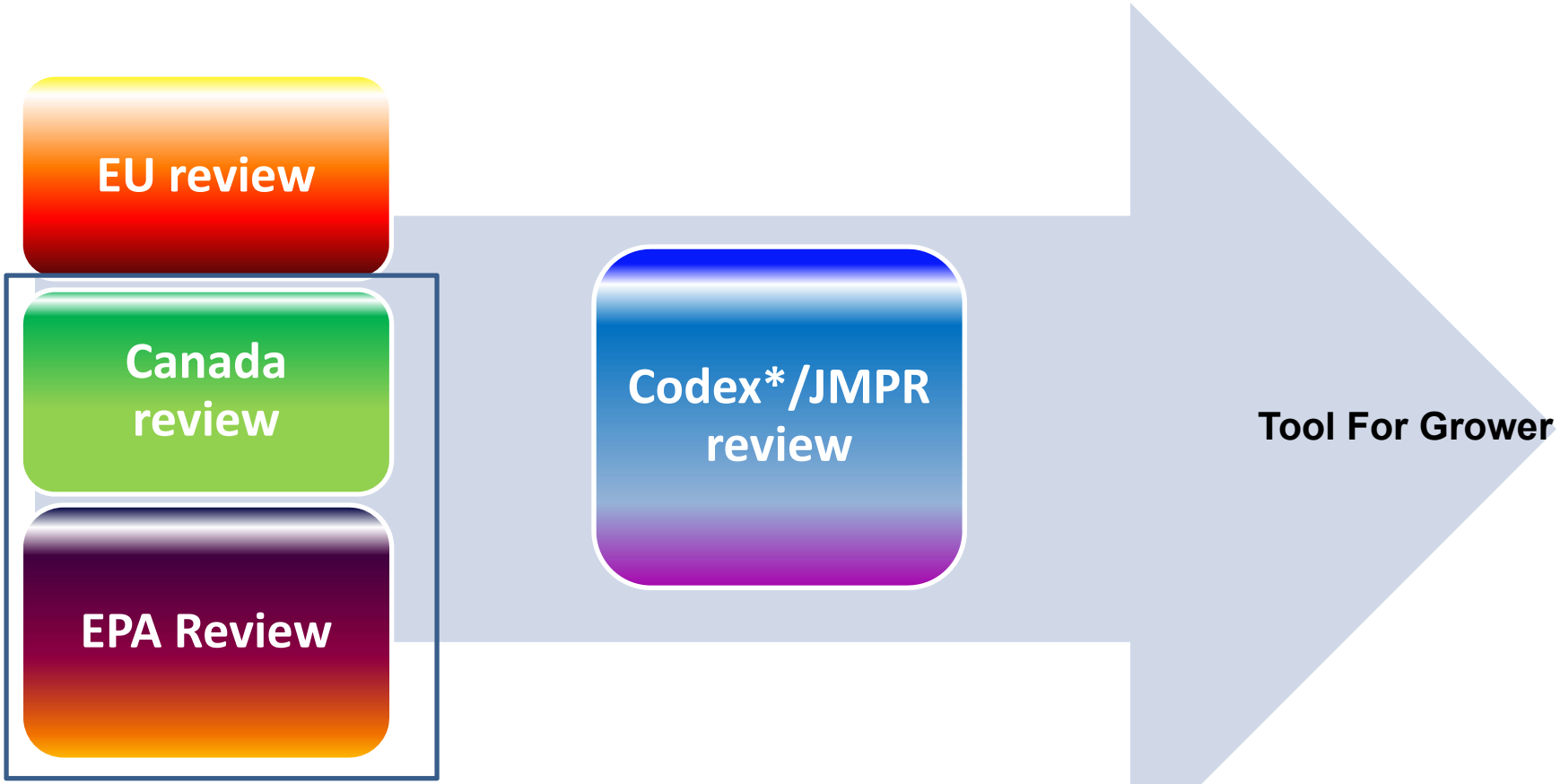
$300,000,000…

Global Regulation

When each country does a separate review

- **Adds time to when the grower can use the product**
- **Redundant reviews**
- **Different MRLs**

Global Regulation - Present

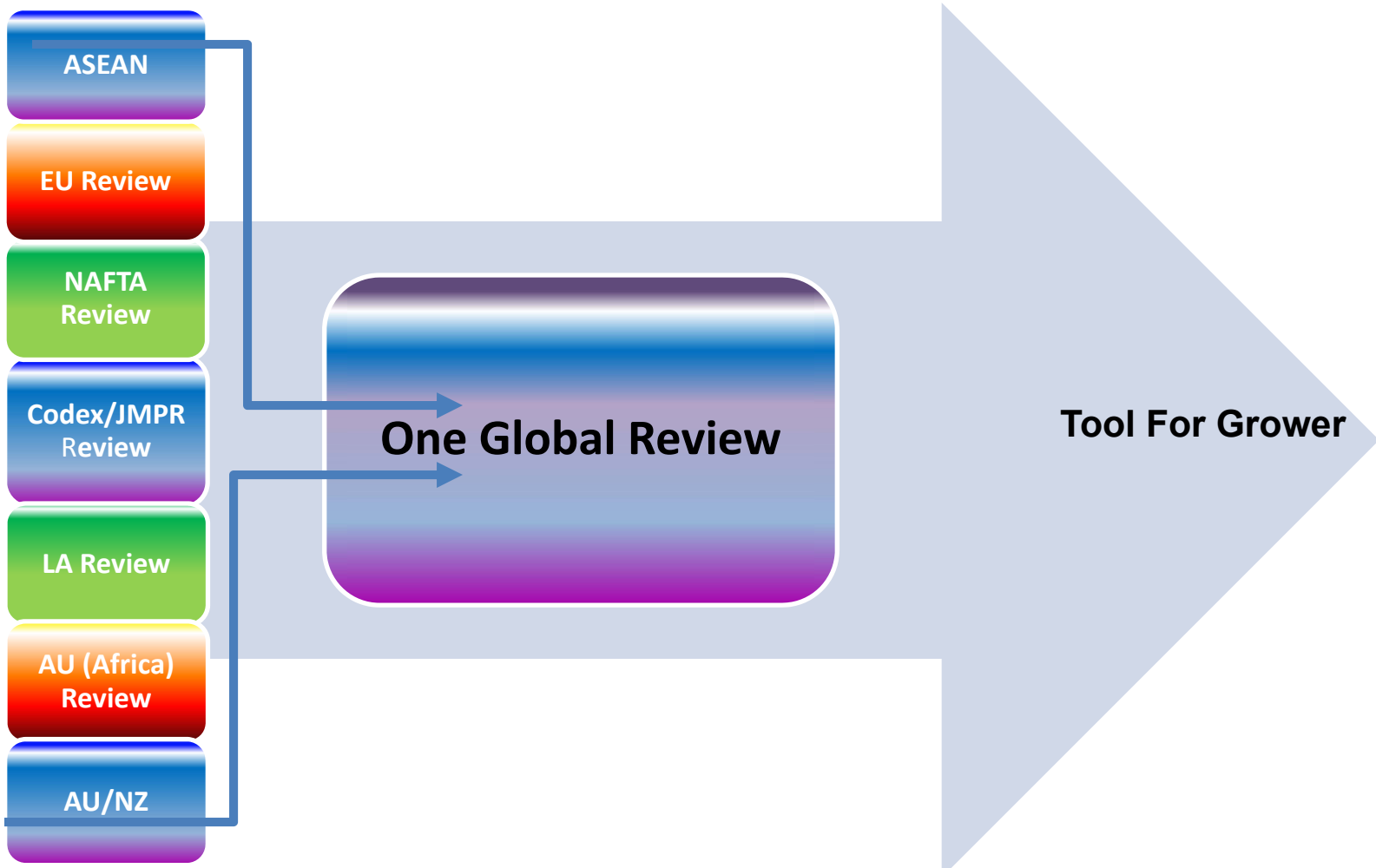


*There are more than 30 countries that still "default" to Codex standards,
An import standard for exports

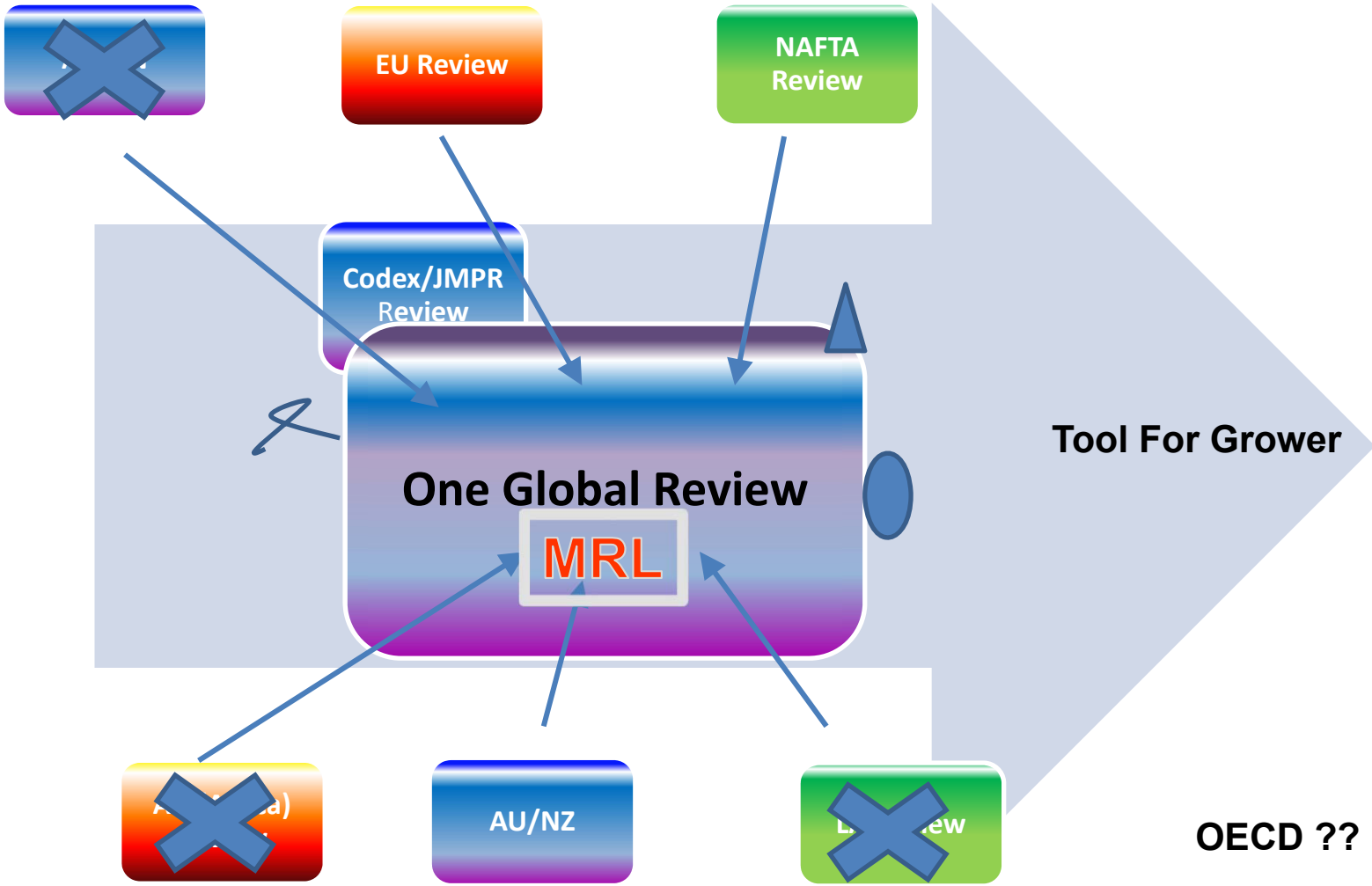
Pesticide Global Joint Reviews

- Several national authorities evaluate a pesticide active ingredient ***at the same time–***
  - Receive the same submission at the same time
  - Develop a joint schedule
  - Divide the work
- At the conclusion - each makes its own independent regulatory decision with the goal of harmonization of endpoint selection and MRL establishment.

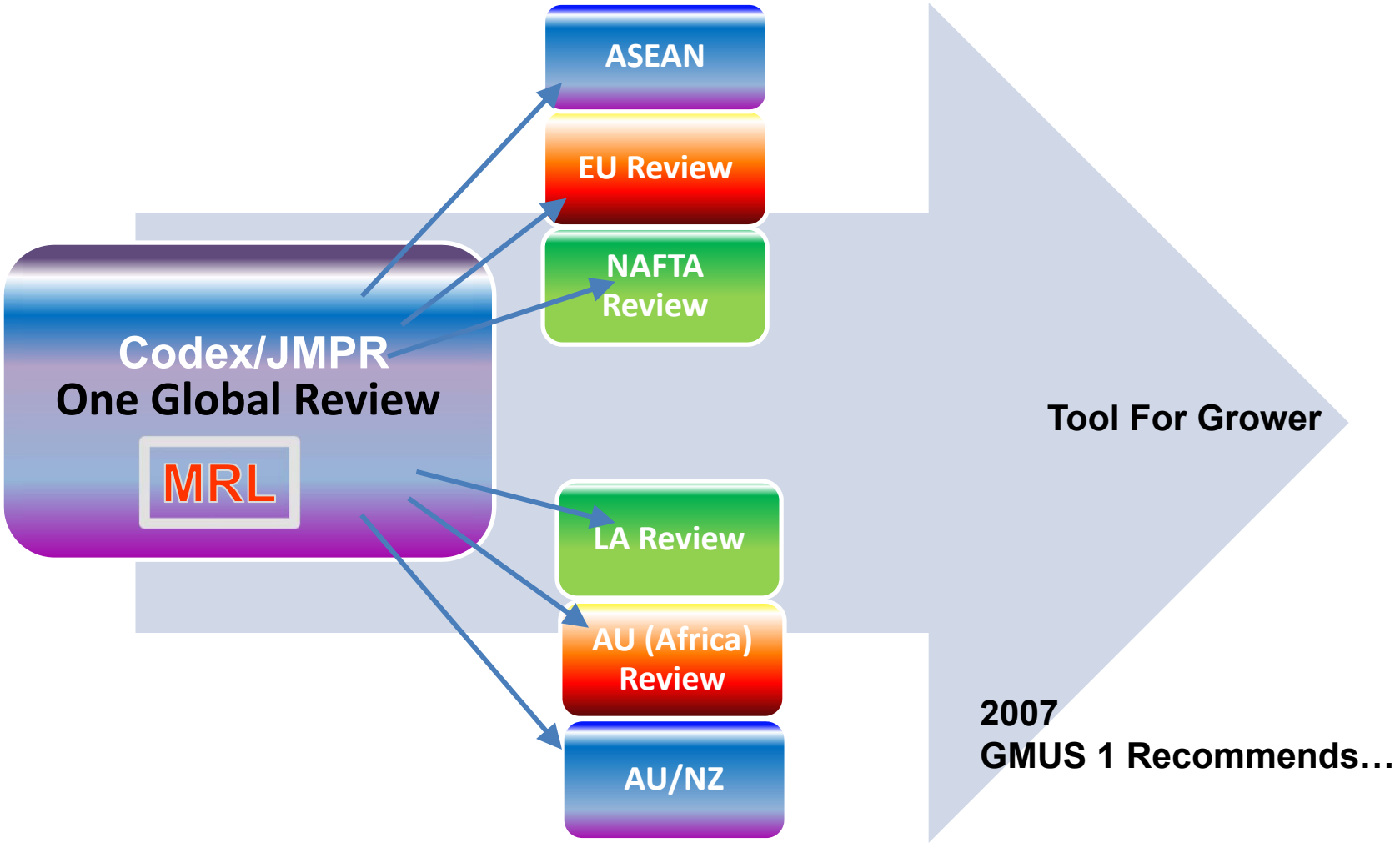
Global Regulation - Future



Global Regulation



Global Regulation



What if….

- Each country had multiple staff do the JMPR reviews – WHO and FAO, toxicology and residue chemistry (this work would not need to be repeated “at home”) – saving resources.
- Residue definition and MRLs agreed..
- Those reviews are then taken to country reviews with further Eco-Toxicology and Environmental fate

Toxicology	Residue Chemistry	Eco-toxicology	Environ-mental Fate	Product Chemistry

What if….

- Let Codex Regulate trade and let Domestic agencies regulate at the local level
  - Protect the environment, workers, and enforce proper use of pesticides..and monitor imports.
- Can society continue to afford the current redundancies, to feed a growing population?
- It will not come at the expense of safety.
  - Codex regulates diet
  - Government regulates workers, environment, other – aggregate exposure
  - Still a strong check and balance

The IR-4 Project

EU Review

LA Review

ASEAN

AU (Africa) Review

reviews

AU/NZ

NAFTA Review

Tools for Solutions – What do we need to make this work

- **Crop Grouping**
- **Global Zoning (exchangeability of field trials)**
- **Incentives for Industry**
- **JMPR/Codex Process Initiatives –** become reality
- **Capacity Building – more participation more** robust data sets
- **Global Minor Use Foundation –** public support for data
- **MRL Calculator,** Crop group calculator
- **Global Joint reviews** → A Global Review
- Global Guidelines, Env. Fate, field trials, etc. etc
  - Multiple countries working together
- Recognize One trade Standard

Furthering the work…

1. **COOPERATION ACTIVITIES**
   - **Joint Research, Global Datasets**
2. **TECHNICAL ACTIVITIES**
   - **Joint reviews, CCPR, OECD**
3. **POLICY ACTIVITIES**

   a) **Continue with guideline documents (OECD, Codex)**

   Eg implement exchangeability of field trials and other studies such as EFED..

   a) **Legislative changes**

   Recognize Trade standards (MRLs) vs local MRLs

   Mutual recognition…data, MRLs, end points etc…

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

WE CAN DO IT!
Flupyradifurone - Global Residue Project Status (IR-4 & PMC)

- ❑ GLP Study conducted under one protocol (one GAP), IR-4 was the Sponsor/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)

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

ALL pest control Products

- Conventional
- Biopesticide
- Etc..

Closing Thoughts..several

- Global trade of Ag products has increased tremendously over the past 20 years – in spite of economic factors
- There is considerable regulation of pesticides at the local, national and international level to ensure consumer safety
- Pesticides have evolved to be more specific to pest and safer to humans and the environment, however these new products complicate trade.

Closing Thoughts

- **This impact on trade requires considerable efforts to manage to ensure that trade continues to expand**
  - **Growers are impacted as it affects their pest control decisions**
  - **In many cases implementation delay of new products puts growers at greater risk and delays IPM and resistance management.**
- **What will the next paradigm shift in pesticide discovery mean?** **And it is coming…**

Next paradigm shift in pesticide

- Biopesticides
- Inert ingredients? Essential oils
- RNAi
- Other chemicals of very low public health concern
  - potassium phosphide
  - Next generation of pest control products
- We have to let the public know – they are safe

Who will carry the flag..

- Continuity…..to keep moving in a positive direction.

- Or join the FUN!
- Greater public investment in Harmonization.

THANK YOU FOR YOUR KIND ATTENTION
Questions/Comments?

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