



MRL Harmonization: *Is it possible?*

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Overview of Presentation

- ▶ Background
- ▶ What are we trying to accomplish?
- ▶ Why is harmonization of MRLs important?
- ▶ What efforts have been made to advance harmonization of MRLs?
- ▶ What have we accomplished?
- ▶ Has MRL harmonization become more difficult? Easier?
- ▶ Is harmonization of MRLs possible?

What are we trying to accomplish?

▶ Goals of Harmonization

- ▶ To have MRLs established by Codex and national authorities set at same levels to provide safe, affordable food supply and allow commodities to move globally without trade irritants.
- ▶ To ensure freedom to export.

▶ Obstacles

- ▶ *Different* national safety standards and laws.
- ▶ *Different* data sets submitted and analyzed.
- ▶ *Different* assessment methods.
- ▶ *Different public expectations of what constitutes a safe food supply and how national authorities respond to public pressure.*
- ▶ *Different* use rates and pest pressures.
- ▶ *Different* levels of transparency.
- ▶ *Different* residue definitions.
- ▶ *Different* crop grouping schemes.
- ▶ *Different* consumption patterns.
- ▶ *Different* treatment of hazard versus risk.
- ▶ *Different* uncertainty factors.

Why is harmonization of MRLs important?

- ▶ Harmonization (as well as establishment of MRLs):
 - ▶ US agricultural export value continues to grow each year according to USDA reports.
 - ▶ Imports increasing as well.
 - ▶ Freedom to export agricultural crops grown with newest pest control tools available to growers; often present less human health and environmental risk.
 - ▶ Trade irritants resulting in violations are costly both tangibly and intangibly (public opinion).
 - ▶ Assures public of food safety when standard set is harmonized.
 - ▶ Not just a US concern: Some examples - Peru (quinoa); Vietnam (dragon Fruit); Korea (Unshi oranges); Olive oil (Italy, Spain); Tea (globally); Chile (fruits); Star fruit and lychees (Taiwan). Probably many more that we are not aware of.

What efforts have been made to advance harmonization of MRLs?

▶ International/National:

- ▶ **OECD:** Guideline harmonization and calculator (Residue Chemistry Expert Working Group), dossier and review formats, mission statement for joint reviews (Expert Group on Minor Uses (EGMU), Registration Steering Group Working Group on Pesticides).
- ▶ **NAFTA and Regulatory Cooperation Council (RCC):** Early harmonization efforts and joint work; continuation with focus on minor uses
- ▶ **IR-4:** Crop grouping support; global residue field trials, Global Minor Use Summit I and II; Global Minor Use Workshop; data generation to support MRLs.
- ▶ **CCPR:** Electronic working groups (Minor Uses resulting , Crop Grouping resulting in a); Pilot project to establish Codex MRL prior to national authorities.
- ▶ **US EPA:** Global joint reviews; CCPR concern form and 5/8 procedure; NAFTA/OECD calculator; Leadership in harmonization; pilot projects for evaluating a streamlined approach to establishing import tolerances (could have some beneficial outcomes that extend beyond import tolerances to advance harmonization.
- ▶ **US USDA:** Active work on bilaterals to establish MRLs; WTO notifications; treaty work (Asia- Pacific Economic Cooperation (APEC) - MRL harmonization with 21 countries), Transatlantic Trade and Investment Partnership (TTIP) - MRL coordination with EU, Trans-Pacific Partnership (TPP) - Japan Post-harvest fungicides); NAFTA and RCC; TASC grants - funding of global MRL data base and priority data bases.
- ▶ **Bilaterals Work:** Korea, Japan, Taiwan, China, Canada, Mexico,

What efforts have been made to advance harmonization of MRLs?

▶ Pesticide Manufacturers:

- ▶ Working together with national authorities.
- ▶ Leaders on OECD Calculator working with governments.
- ▶ Actively planning Codex submissions in early product development stage.
- ▶ Mapping out trade pathways to see early on where MRLs will be needed.
- ▶ Dedicated staff to deal with MRL issues: (*Job Titles like "Global MRLs and Import Tolerances" and "MRL Manager North America"*).
- ▶ CLA committees - Food and Beverage Committee; Residue Experts Work Group
- ▶ CLI delegation to CCPR.
- ▶ ACS/AGRO meeting each year.
- ▶ Sponsorship of IUPAC Award for Pesticide Harmonization.

What efforts have been made to advance harmonization of MRLs?

- ▶ Commodity Groups: Continuous efforts on MRLs and work with governments, CCPR, NAFTA.
 - ▶ Minor Crop Farmer Alliance (MCFA): regular meetings include international issues and MRLs with representation from many commodities groups.
 - ▶ California Specialty Crop Council: Annual MRL workshop.
 - ▶ US Dry Pea and Lentil Association, Global Pulse Confederation, Pulse Canada: coalition building and initiative on increasing JMPR capacity and other efficiency measures.
 - ▶ Many commodity groups have staff focused on MRL setting.

What have we accomplished?

- ▶ Laid foundation for harmonization to even be in realm of possibility. (*the requirements, the guidelines, the calculator, crop groupings, decreased time of establishing Codex MRLs, etc.*)
- ▶ Awareness raised across many sectors - public and private.
- ▶ Several initiatives going on to increase number of MRLs and increase harmonized MRLs.
- ▶ The Numbers: Bryant Christie Inc. presented some graphs in a presentation made at 2016 California Specialty Crop Council on the percentage of harmonization of International MRLs with US MRLs for 8 crops: nut(almond); plum(prune); orange (sweet); cherry (sweet); onion (bulb); lentil; raspberry, black and red; garlic (bulb); and, then for each crop separately.
 - ▶ Numbers show for these commodities the following:
 - ▶ 33% of Codex MRLs are harmonized or within 0.5 ppm of US MRLs.
 - ▶ 80% harmonized to or within 0.5 ppm of US MRLS - 2 countries (Canada, Japan)
 - ▶ 50% harmonized to or within 0.5 ppm of US MRLs - 8 countries
 - ▶ <50% harmonized to or within 0.5 ppm of US MRLs - 9 countries
 - ▶ Biggest issue is lack of MRLs.

What have we accomplished?

Some stats...



What have we accomplished?

Some Stats...



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Has MRL harmonization become more difficult? Easier?

- ▶ More difficult:
 - ▶ More countries announcing a national MRL setting programs. (*Except some countries do a full deferral to Codex, some have decision trees for deferral, some use Codex in their decision-making in some way*)
 - ▶ Gap between number of US MRLs established and those in other countries and Codex seems to be widening.
 - ▶ Information is hard to keep track of, requirements of various countries often hard to obtain or understand, communication is often an issue.
 - ▶ Concerns that harmonization will result in higher MRLs than needed in response to public food safety concerns.
 - ▶ Heighten public concern on pesticide residues in food - (*Who regulates pesticides?*)
- ▶ Easier:
 - ▶ More involvement by all sectors than ever before.
 - ▶ More focus on MRL setting internationally.
 - ▶ Fora for cooperation expanding among countries.

Is harmonization of MRLs possible?

- ▶ *And the answer is...closer to "yes" than "no"!*
- ▶ BUT....we have to continue the efforts with increased focus.
 - ▶ Use continuously growing information available to guide the course of action, carefully and precisely framing each and every the problem. Talking in generalities is not productive.
 - ▶ Collaboration within and between the sectors of stakeholders is essential but not always done.
 - ▶ Try to be predictive of how you think your data will be interpreted and MRL likely to result; can you modify a use pattern to ensure greater probability of harmonization?
 - ▶ MRL strategies are critical in the development phase of new pesticide active ingredient or in developing new uses for already registered active ingredients.
 - ▶ Continued support and for EPA and USDA on efforts to establish and harmonize MRLs with other governments.
 - ▶ Seek out opportunities to engage with partners in other countries (governments, grower groups, pesticide companies) that have similar needs and concerns; as trade increases globally the issue becomes more important to many more.

*Thank you for your attention and
your thoughts!*

