



US EPA and Import Tolerances:

A Status Update on the EPA's Pilot Import Tolerance Process

Side Event on: GLOBAL EXPERIENCES OF IMPORT MRL REGULATION USING THE APEC IMPORT MRL GUIDELINES FOR PESTICIDES

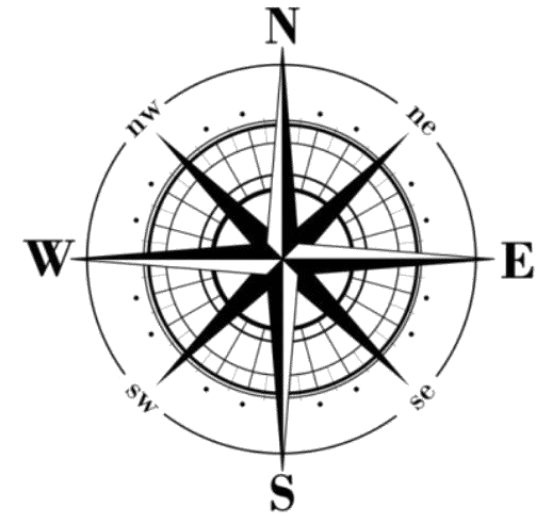


David J. Miller
Office of Pesticide Programs
United States Environmental Protection Agency

8 April 2019
51st Session of Codex Committee on Pesticide Residues
Studio City Macao, SAR, China

Plan for Talk

- Importance of MRL Harmonization Efforts
- Background on US EPA Tolerances (MRLs)
- US EPA Import Tolerance Pilot Program
 - Successes
 - Challenges
 - Lessons Learned
 - Next Steps



Harmonization of MRLs is Important in Achieving US EPA Office of Pesticide Programs Goals

International marketplace

Impact on U.S. health and environment

International acceptance of safer products

Opportunities to collaborate on international fora



Background on US EPA Tolerances

- EPA is responsible for regulating the amount of pesticide residues that can remain in or on food or feed commodities as the result of a pesticide application.
- Done through an EPA “tolerance” = maximum residue level of a pesticide
- Residues of a pesticide not registered for use in the U.S. may be present in raw agricultural commodities and processed foods produced abroad & imported into the U.S. if EPA has established an “import tolerance” for a pesticide residue and the residues are within the tolerance.
 - “Import tolerance” = a tolerance that exists in the U.S. for which there is no accompanying U.S. registration

Background on US EPA Tolerances

Two Important Points:

1. Import Tolerances Are Based on the Same Safety Standards As “Regular” U.S. Tolerances

There is no statutory or regulatory distinction between an import tolerance and any other tolerance established by EPA. Both must meet all current statutory requirements, including the safety standard (“reasonable certainty of no harm”) for pesticide residues in food.

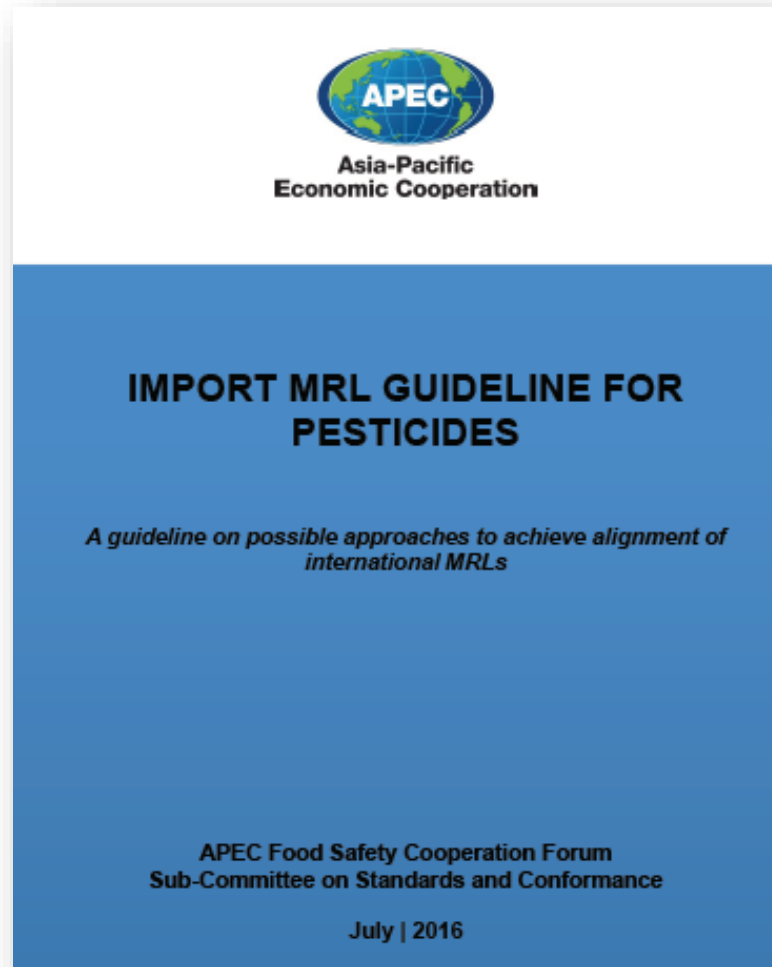
2. Import tolerances generally require the same types of data as are needed to establish tolerances associated with U.S. registrations

This includes: product chemistry, residue chemistry, and toxicology data, as well as data representative of actual growing conditions. EPA needs these data to assess the potential dietary risk and make the required safety finding.

Import Tolerance Standard Practice

- Investigate consumption and % imported
- Determine number of field trials needed
- Evaluate field trial data (and supporting data such as methods, storage stability)
- Calculate import tolerance level

APEC Import MRL Guideline for Pesticides



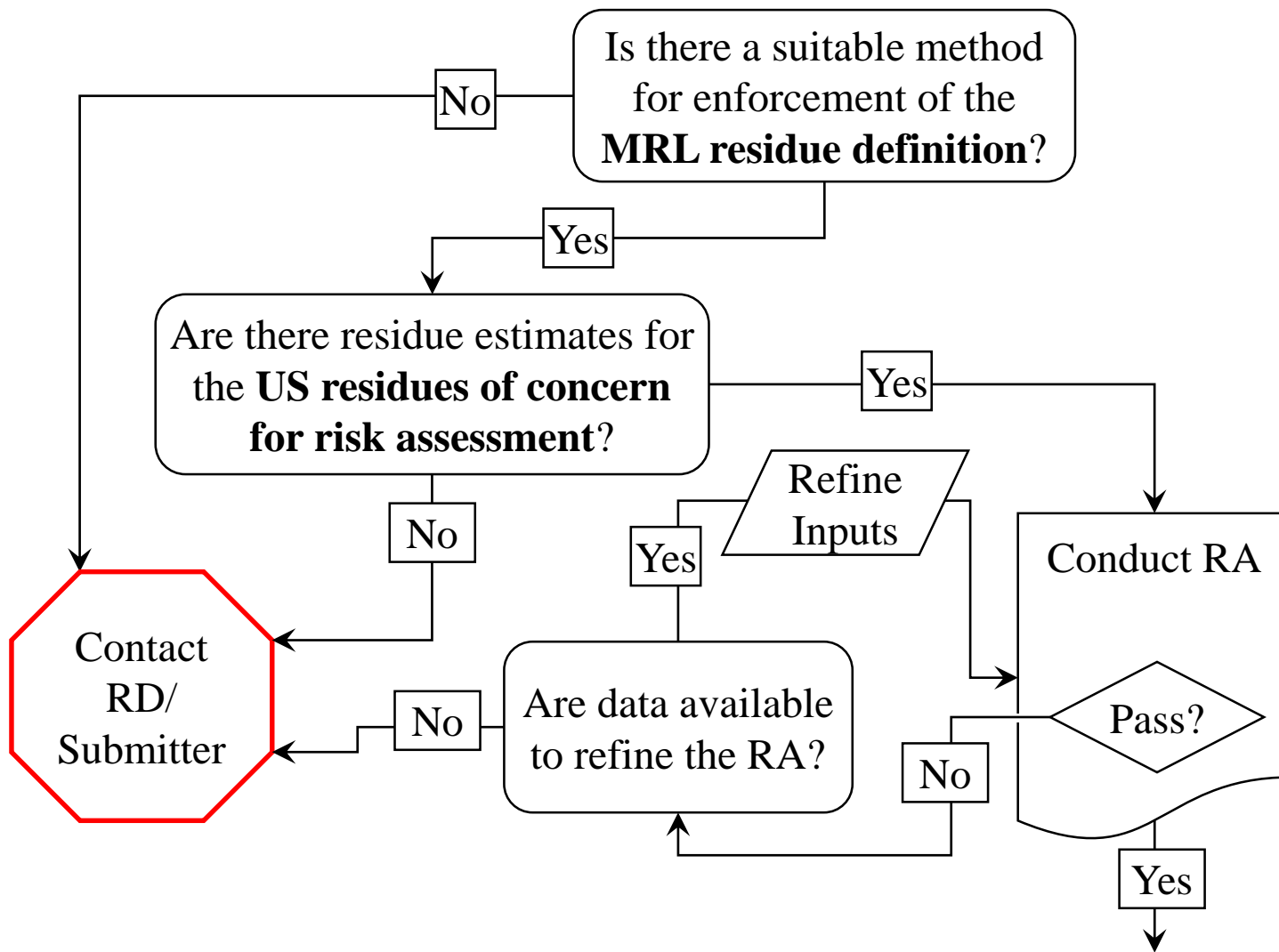
- Developed from a series of 2015 APEC workshops on Harmonization of Pesticide Maximum Residue Limits
- Held to assist in minimizing discrepancies in MRLs and facilitate trade while continuing to protect human health
- Guidance document (2016) developed on approaches to achieve alignment of MRLs for pesticides within APEC
- Seeks to provide a framework within which science-based standards can be developed and applied uniformly and transparently across APEC economies

US EPA's (APEC-inspired) Import Tolerance Pilot

- Test a streamlined data review strategy for establishing MRLs on imported commodities, APEC- and non-APEC
- Pilot to determine the feasibility of acceptance of other National Authority/JMPR reviews of residue chemistry data to support establishment of import tolerances
 - Rely on data reviews from JMPR or other National- or Supranational- authorities rather than a *de novo* U.S. review
 - Compound generally must have food-use registration in the U.S.
 - In-depth review of competent authority's data evaluation report
 - No OECD MRL Calculator
 - Tolerance = MRL from Codex, EU, or exporting country
 - if national/supranational authority reviews contain sufficient information, there may be significant resource savings to EPA and potentially reduced timelines to establish import tolerances.
- Will (still) require US EPA human health risk assessment/safety finding

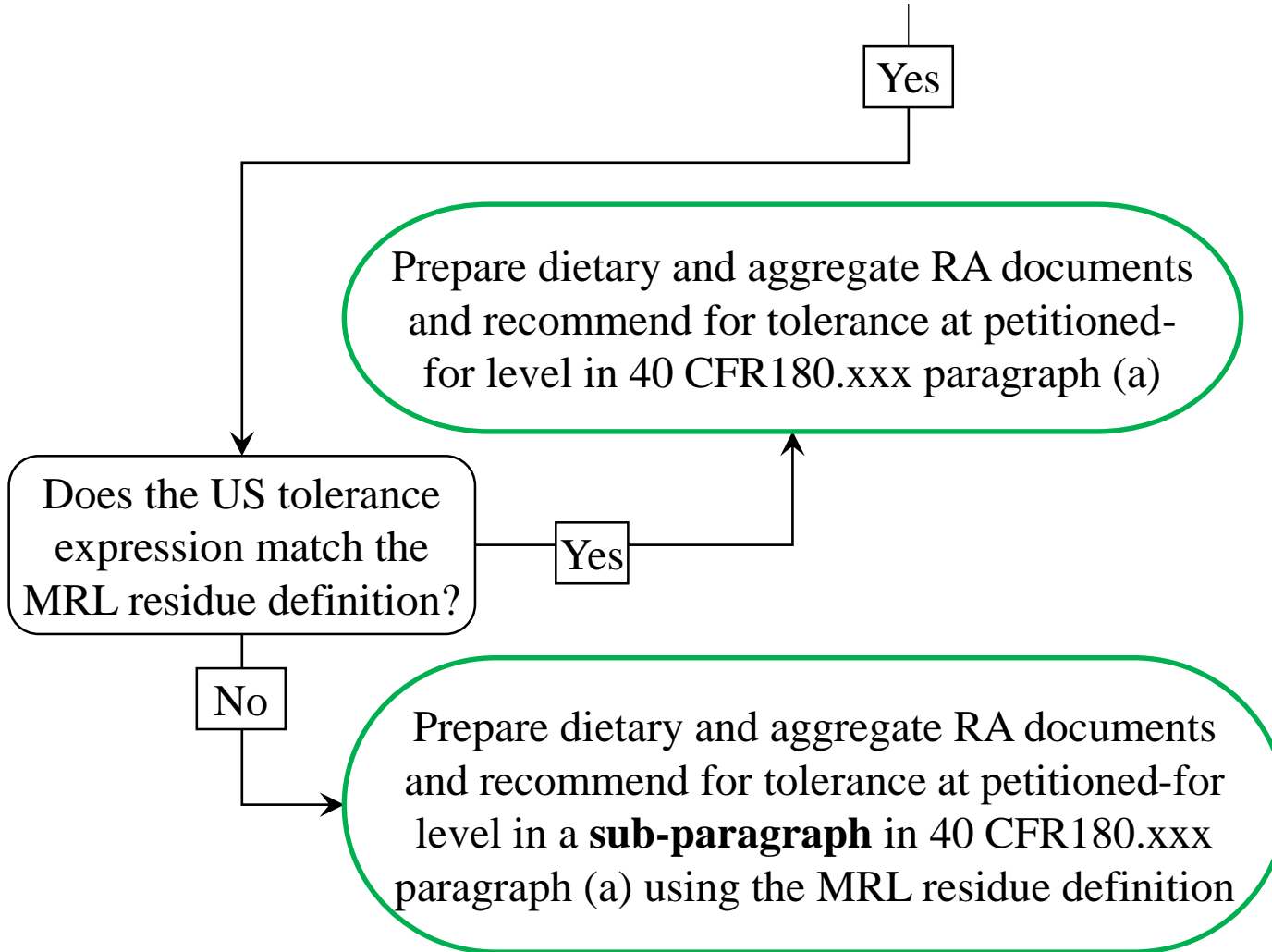
Import Tolerance Pilot Strategy

- Rely on data reviews from JMPR, EFSA, or National Authority rather than a de novo U.S. review
 - Compound generally must have food-use registration in the U.S.
 - In-depth review of report from competent authority
 - Tolerance = MRL from Codex, EU, or exporting country (No “extra” run through the OECD MRL Calculator)



Import Tolerance Pilot Strategy (1 of 2)

Review Process



Import Tolerance Pilot Strategy (1 of 2)

Review Process

Import Tolerance Pilot Status

- 14 chemical/crop combinations submitted
- 3 additional chemical/crop combinations were self-identified by the Agency
- 10 commodities: banana, barley, coffee, ginseng, hops, legumes, olive, oats, tea, and wheat
- Evaluations from Brazil, EFSA, Japan, JMPR
- Participation by major agrochemical companies

Import Tolerance Pilot Status

- Eleven MRLs have been established:
 - Boscalid on edible-podded legumes (subgroup 6A)
 - Ametoctradin on hops
 - Chlormequat chloride on cereals (3 separate MRLs)
 - Tebuconazole on ginseng
 - Abamectin on tea (+ banana, but not under pilot)
 - Spinetoram on tea
 - Pyriproxyfen on tea
 - Methoxyfenozide on tea
 - One petition (2 crops) had risk issues, so on hold
- Four additional chemical/crop combinations are in progress

US EPA Import Tolerance Pilot Challenges

- Initial reluctance
 - amongst registrants to submit pilot candidates
 - amongst science reviewers to accept reviews from other regulatory authorities
- Importance of enforcement methodology as part of submission
- Differing tolerance definitions

US EPA Import Tolerance Pilot Successes

- Most submissions to-date have been successfully reviewed
- All reviewers reported a positive experience
- Significant savings over “traditional” reviews
 - ~ 50 hours shorter science review time
- Some decisions have been faster
- Experience with EFSA, JMPR & national authority reviews

Import Tolerance Pilot Next Steps

- Continue pilot
- Need experience with reviews by other national authorities
- Use experience from current work to determine
 - Potential for a standard business practice
 - Boundaries for a revised import tolerance policy

Summary and Conclusions

1. MRL harmonization efforts are important to the U.S.
2. Alignment of Import Tolerances can be important activities associated with harmonization efforts
 - APEC activities in 2015 regarding import tolerances were important in moving these efforts forward in the U.S.
3. US initiated an import tolerance pilot
 - Has been a generally successful and learning experience
 - EPA will continue encouraging such submissions to gain experience with additional national authorities
 - EPA will determine if this can be transitioned to a standard operating practice in the future.

Thank you.

Questions?



Contact Info:

David J. Miller

Branch Chief, Chemistry & Exposure
U.S. Delegate To Codex CCPR

Office of Pesticide Programs
U.S. Environmental Protection Agency
Miller.Davidj@epa.gov



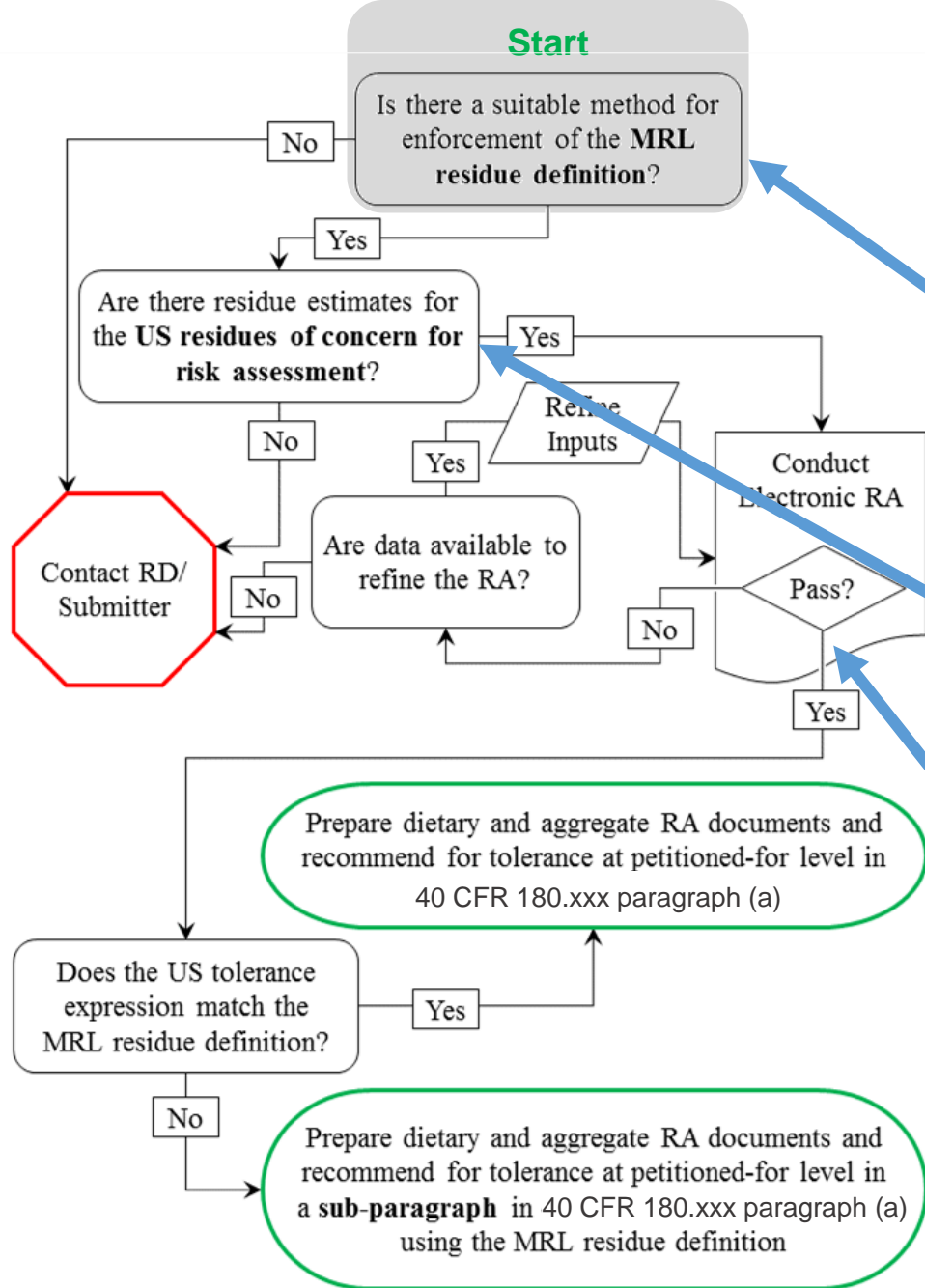
EXTRA SLIDES

Relevant PRIA Fees – PRIA 3 and PRIA 4

PRIA	Category	Action	Decision Time (Months)	Fee (\$)
3	R280	Establish import tolerance; new active ingredient or first food use	21	289,407
4	R280	Same as PRIA 3	Same	319,072
3	R290	Establish import tolerance; additional food use	15	57,882
4	R290	Same as PRIA 3	Same	63,816
3	R291	Establish import tolerances; additional food uses; 6 or more crops submitted in one petition	15	347,288
4	R291	Same as PRIA 3	Same	382,886
3	R292	Amend an established tolerance (e.g., decrease or increase); domestic or import; applicant-initiated	11	41,124
4	R292	Amend an established tolerance (e.g., decrease or increase) and/or harmonize established tolerances with Codex MRLs; domestic or import; applicant-initiated	Same	45,341

US EPA Import Tolerance Pilot Strategy requires:

- (i) suitable enforcement method for MRL residue definition
- (ii) residue estimates for US residues of concern for Human Health Risk Assessment (HHRA)
- (iii) EPA to conduct HHRA

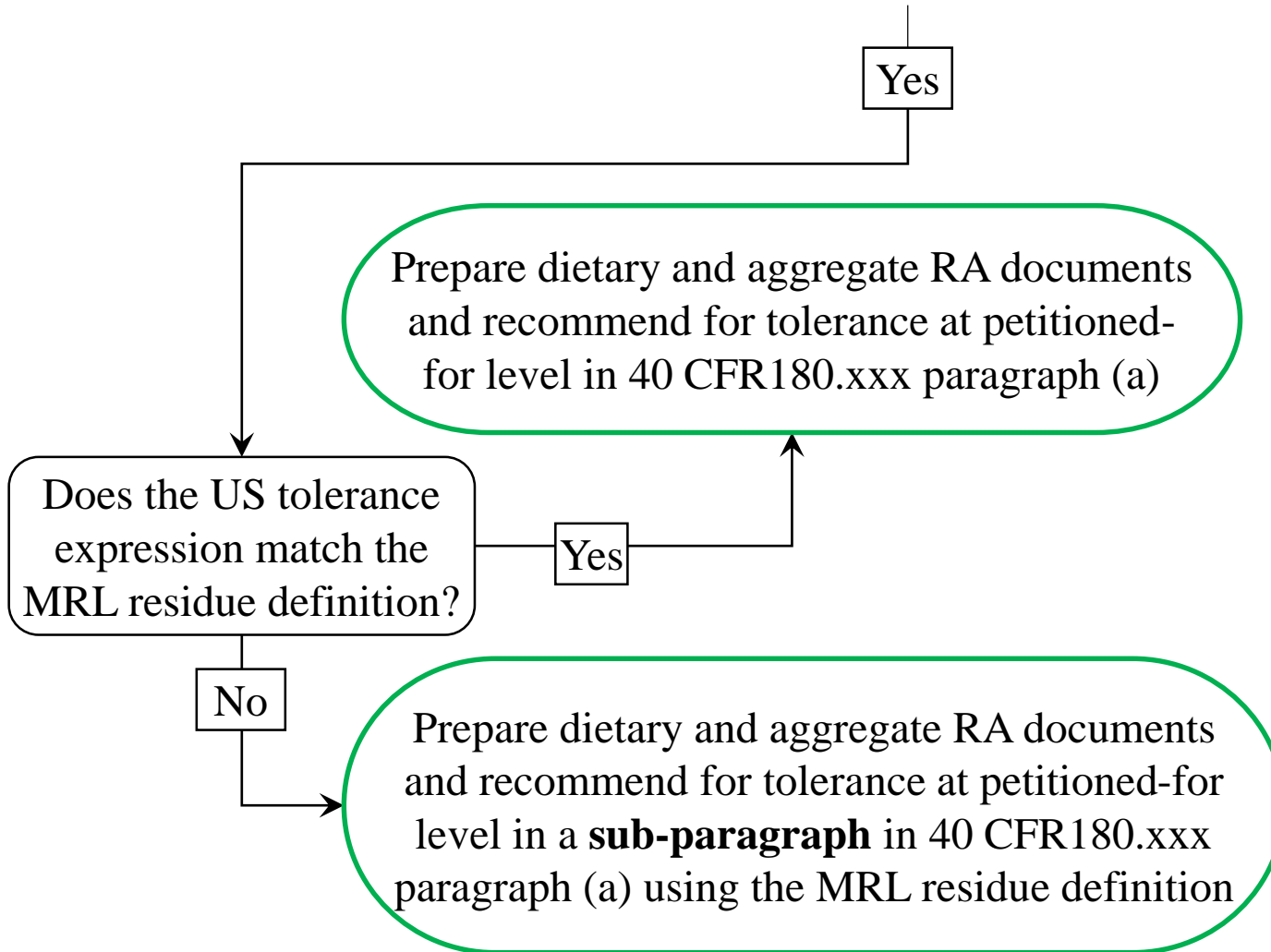


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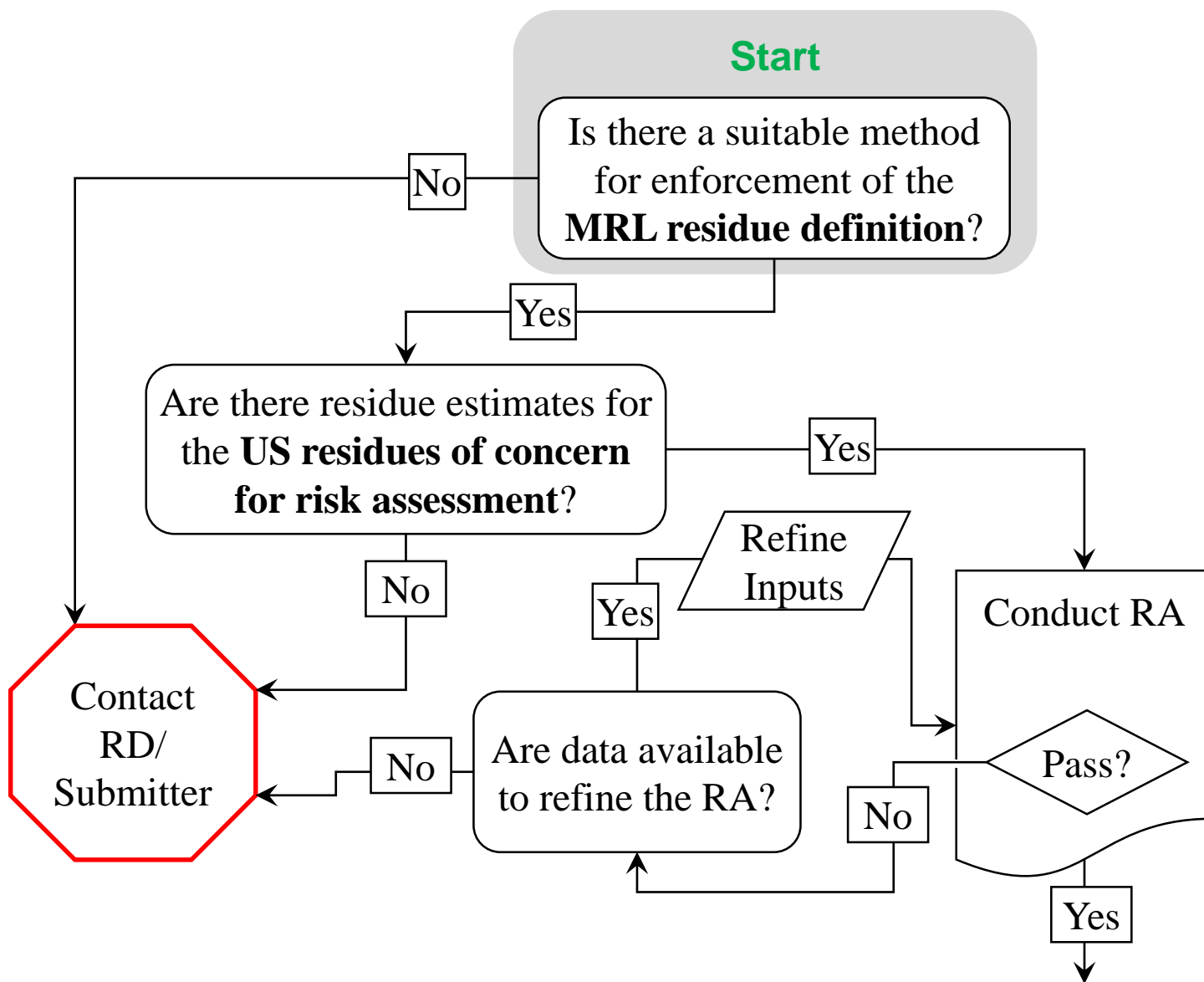
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US EPA Import Tolerance Pilot Strategy (1 of 2)

Review Process



US EPA Import Tolerance Pilot Strategy (1 of 2)

Review Process



US EPA Import Tolerance Pilot Program

- Evaluations from Brazil, EFSA, Japan, JMPR
- 10 chemical/crop combinations submitted since the inception of the pilot
 - Represents 7 chemicals x 10 uses (banana, barley, coffee, ginseng, hops, legumes, olive, oats, tea, and wheat)
- 3 additional chemical/crop combinations were self-identified by the Agency
 - 1 chemical x 3 uses
 - Foreign field trials only
- Participation by major agrochemical companies

Status:

- Two completed: [Boscalid on the \(edible podded\) legume subgroup 6A](#) and [Ametoctradin on hops](#)
 - Boscalid: <https://www.gpo.gov/fdsys/pkg/FR-2017-11-30/pdf/2017-25832.pdf>
 - Ametoctradin: <https://www.gpo.gov/fdsys/pkg/FR-2017-07-27/pdf/2017-15762.pdf>
- One chemical should publish shortly (three additional uses)