

Pesticide Inert Ingredient Activities

CPDA Regulatory Policy Conference Program
March 13, 2018

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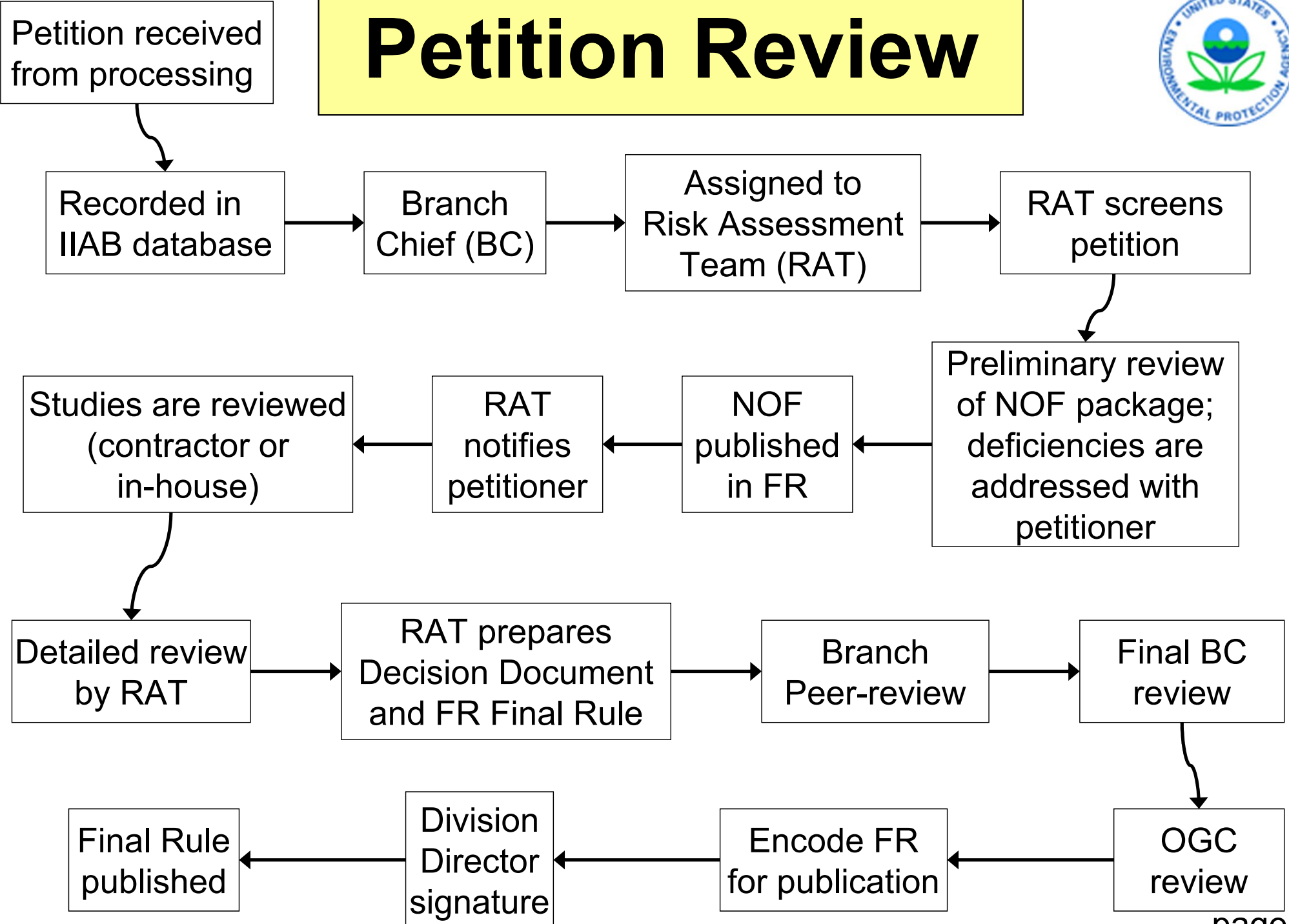
No. of Inerts Petitions Completed

- 2014- 33
- 2015- 56
- 2016- 49
- 2017- 42

We are working on about 55 petitions



Petition Review



the end!

Inert petitions

Toxicology:

- Good summary of literature studies with clearly defined NOAEL/LOAEL identification
- Appropriate surrogate analog and justification
- Endpoint selection for various exposure scenario and explanation
- Not addressing data gap- cancer and other long term effects
- Uncertainty factors and rationale
- Missing data- long time to get from the submitter

Inert Petitions (continued)

Exposure Assessment

- Lack of use information
- Amount in formulations
- Occupational and Residential exposure assessment not addressed adequately
- Often lack of quantitative exposure assessment
- No information provided on non-pesticidal uses
- Aggregate exposure assessment

Risk Mitigation Options

Options that might satisfy the “reasonable certainty of no harm” finding:

- Limiting use of inert with only certain active ingredients
- Limiting use of inert to only certain crops
- Limiting application timing (before crop emerges from the soil, before edible parts form)
- Limiting application methods (nonfoliar applications only)
- Limiting the percentage of the inert in end-use pesticide formulation
- Limiting application rates

Commodity Inert Ingredients

- CSF working group and AD, BPPD and RD
- CSF working group- CLA, CPDA, HCPA (formerly CSPA), ACC biocide and Rise committee
- Allow industry to buy chemicals from spot market
- Eliminate the need to submit change of supplier via notifications
- No need to review notifications and approval by EPA

Commodity Inert Ingredients (continued)

- EPA and Industry group developed the following criteria for inclusion of inert ingredients as commodity inert ingredients
 1. The substance must be on EPA's list of approved non-food inerts and/or have an established tolerance or exemption from tolerance published in 40 CFR §§180.910 through 180.960.
 2. The substance is used in the product formulation as an inert ingredient only.

Commodity Inert Ingredients (continued)

3. EPA's approval of the inert or the tolerance or the exemption from tolerance must not be supported by any data that are eligible for compensation under FIFRA §§3(c)(1)(F) or FIFRA §10 or FFDCA §408(i).
4. The substance must not be a mixture of other substances or a proprietary blend.
5. The substance must be identified by a single Chemical Abstract Service Number ("CASN"), if one has been assigned.
6. The substance may vary in the amount of water used as a diluent.

Commodity Inert Ingredients (continued)

7. The substance must be available from multiple commercial sources (at least 5 independent manufacturers and not distributors).
8. The substance must not meet the EPA criteria for a nanomaterial.

Commodity Inert Ingredients (continued)

Status Update

- EPA has evaluated list of chemicals provided by the CSF workgroup
- About 65 chemicals meeting these criteria
- Targeting Summer 2018

Commodity Inert Ingredients (continued)

- Post the list on the Inerts webpage
- <https://www.epa.gov/pesticide-registration/inert-ingredients-overview-and-guidance>
- Guidance for submitting new chemicals or removing chemicals will be posted on the web page

National Organic Program (NOP)

- EPA assists USDA
 - Compatible missions
 - Advancement of IPM and Biopesticides
- What EPA does
 - Reviews pesticides for NOP compliance
 - Certifies labeling claims
 - Shares technical knowledge
- EPA liaisons with FDA
 - Chris Pfeifer- BPPD (703-308-0031)
 - Kerry Leifer (703-308-8811)

NOP Program (continued)

- The August 2004 List 4 continues to apply (static list)
- Equivalency statements are not acceptable
- Non-List 4 inerts seeking to be NOP eligible must petition National Organic Standards Board (NOSB)

NOP Program (continued)

- **USDA is working with EPA's Design for Environment Safer Choice chemical program to add chemicals**

Other Activities

- **Product Chemistry**

- Currently Group B data self-certification
- Expand to all product chemistry reviews
- Need to work with stakeholders

Acute Toxicity

- Explore possibility of self-certification for acute toxicity reviews