Efficiencies in the Regulation of Product Chemistry

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Efficiencies in the Regulation of Product Chemistry

- Commodity Inert Ingredients

- Product Chemistry Self-Certification
Commodity Inert Ingredients
Commodity Inert Ingredients Proposal

- Initial proposal submitted to Agency by Crop Life America (CLA)/Council of Producers & Distributors of Agrotechnology (CPDA) to allow specific inert ingredients designated as commodity inert ingredients to be listed on the Confidential Statement of Formula for a pesticide product, without the need to include their specific commercial sources and included definitional criteria.

- Following discussions with EPA, CLA/CPDA submitted a revised proposal with modifications to the definitional criteria and included a proposed list of commodity inert ingredients.
EPA Consideration of Proposal

- EPA is evaluating proposal to determine its ability to reduce burden to both OPP and the regulated community.

- Based upon a preliminary examination of the proposed list of commodity inert ingredients by OPP, the vast majority of the substances listed appear to meet criteria for designation as commodity inert ingredients.

- Working on resolution of some inconsistencies in chemical names/CAS Reg. Nos. on proposed list.
Next Steps

- Finalize the proposed list of commodity inert ingredients and criteria
- Development of implementation plan including identifying vehicle for implementation (i.e., web posting, update to Registration Manual, etc.)
- To be completed by end of FY ‘19
Product Chemistry Self-Certification
Product Chemistry Group B
Self-Certification

- Self Certification of Group B data
  - PR Notice 98-1 allows Self Certification of group B data in a tabular form
  - Voluntary Program
  - Limited to end-use products
  - Self-certification rate is about 30 to 40 percent

- Expansion
  - Significant resource savings
  - Product Chemistry (PC) Team will be exploring options to expand self-certification to technical products
  - PC Team will be working with industry on ways to incentivize submission of self-certified group B data
Product Chemistry Group A
Self-Certification Pilot

Group A Product Chemistry Data Includes

• Product identify, composition & analysis, production process/formulation process, and certified limits

• Full requirements outlined in 40 CFR 158.320 to 40 CFR 158.355

• OCSPP Test Guidelines Series 830 – Product Properties
Product Chemistry Group A Self-Certification Pilot

- Group A Self-Certification Pilot
  - Eligible products could include both technical and end use products
  - Pilot Process is under development and includes:
    - Registrant submission of completed template along with the studies having assigned MRID numbers
    - Certification that reported information represent a true and accurate record of the test results generated on the product
  - EPA will evaluate the quality of the submissions and accuracy of self-certification
  - Encourage participation
  - Contact Bruce Kitchens (kitchens.bruce@epa.gov) for more information.
Thank You!