



Nuances to Regulation for PIP Products

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Nuances of Regulation – EPA / OPP

- EPA OPP is authorized under the Pesticide Registration Improvement Act (PRIA) to charge fees for regulatory actions, including but not limited to, pesticide determinations, experimental use permits, registrations, and study protocol review
- Timelines are also set by PRIA such that dates are clearly defined for various regulatory actions
- Fees are based in part on the size of the company developing the pesticide; USG scientists are exempt from fees and land-grant university scientists may qualify for a partial reduction in fees.
- PRIA is a statute passed by Congress and is periodically updated (we are using version 4 currently)



Nuances of Regulation – EPA / OPP

- Food tolerance exemptions for PIPs require toxicological data generation and PRIA fees can be expensive for new active ingredients
- IR-4 (at NCSU) can assist at no cost (under certain conditions) to aid in the regulatory submission to the EPA
- Assistance is typically provided for specialty crops and minor uses, especially for academic scientists and small companies
- IR-4 assists in exports of U.S. grown specialty crops by aiding in the harmonization of domestic tolerances with global Maximum Residue Levels (MRLs) and with standards of global trading partners



Nuances to Regulation – EPA/OPP

- Pesticides are reviewed at least once every 15 years to ensure the risk assessment remains up to date
- PIPs may be reviewed more often to ensure that resistance management goals are being met
- Inert ingredients require a food tolerance exemption
- See 40 CFR 174 for list of previously approved tolerances
 - https://www.ecfr.gov/cgi-bin/text-idx?node=pt40.26.174&rgn=div5#se40.26.174_1535
- Some tolerance exemptions are limited to certain crops
- Significant variation in amino acid sequence may require a separate tolerance for an inert ingredient with similar function but different sequence and biochemical properties
 - e.g., §174.523 CP4 Enolpyruvylshikimate-3-phosphate (CP4 EPSPS) synthase vs. §174.543 G10evo-EPSPS protein



Contact Information

- Chris Wozniak – Wozniak.Chris@epa.gov
 - General biopesticide and biotech inquiries
- Alan Reynolds – Reynolds.Alan@epa.gov
 - PRIA and regulatory questions, to set up a pre-submission meeting for biotech products