



PRIA 4 Presentation to the PPDC

**Steve Schaible, PRIA Coordinator
U.S. Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
Office of Pesticide Programs**

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What's New in PRIA 4?

- The Pesticide Registration Improvement Extension Act of 2018 (PRIA 4) was signed into law on March 8, 2019;

PRIA 4:

- Reauthorizes PRIA for 5 years, through fiscal year 2023;
- Extends prohibition on collection of other fees under FIFRA (with the exception of pesticide registration service fees) and extends prohibition on levying tolerance fees under FFDCA authority;
- Updates FIFRA Section 5 (experimental use permits) to be consistent with PRIA 4 timeframes.



What's New in PRIA 4 - Pesticide Registration Service Fees

- Extends PRIA registration service fee collection authority for 5 years from FY'19 thru FY'23;
- Increases the number of covered fee categories from 189 to 212;
- Category changes include but are not limited to:
 - New and amended categories for pests requiring efficacy data and review for new products and amendments (AD, RD);
 - Additional categories for combination products where active ingredients not registered before in combination;
 - R292 expanded to include harmonization of existing tolerances with Codex MRLs;
 - New EUP categories for AD, BPPD and RD chemicals;



What's New in PRIA 4 – PRIA Fees (cont'd)

- Category changes (cont'd):
 - AD categories modified to be consistent with Part 158W;
 - New PIP categories;
 - New inert safener categories, certain inert category timeframes lengthened where warranted by their average completion times and the # of renegotiations under PRIA 3;
 - Non-FIFRA regulated determinations (e.g., minimum risk, treated article exemptions, device determinations);
 - Adds conditional ruling on pre-application substantial similarity submissions categories;



What's New in PRIA 4 – PRIA Fees (cont'd)

- Eliminates small business waivers for Gold Seal letters;
- Expands the “clean label/label resolution time period” process to include biopesticides;
- Allows for two 5% fee increases:
 - The first starting 10/1/19 and running through 9/30/21;
 - The second starting 10/1/21 and running through 9/30/23;
- Extends PRIA set-asides through 2023 for:
 - Worker protection activities (1/17th of fund, but not less than \$1M/yr);
 - Partnership grants (\$500K/yr);
 - Pesticide safety education program (\$500K/yr).



Changes in Maintenance Fees under PRIA 4

- Extends maintenance fee collection authority for 5 years from FY'19 thru FY'23;
- Fees increased from \$27.8M to \$31.0M per year;
- Can average across years to correct for over or under collection in previous years during PRIA 4;
- Eliminates appropriations constraint (“1-to-1” provision) on spending maintenance fees;
- Raises annual fee caps for registrants, including small businesses;



Changes in Maintenance Fees under PRIA 4 (cont'd)

- Fees can explicitly be used in registration review to offset costs for endangered species assessments;
- Extends the set-aside for review of inert ingredients and the expedited processing of substantially similar applications, amendments that do not require scientific review of data, and public health pesticide applications;
- Eliminates IT set-aside (\$800,000 per year) to improve (a) electronic tracking of registration submissions, (b) electronic tracking of conditional registrations, (c) electronic review of labels, (d) electronic CSFs and (e) ESA database enhancements;
 - reporting on the unspent balance of IT set-asides remains;



Changes in Maintenance Fees under PRIA 4 (cont'd)

- IT set-aside is replaced with new set-aside (up to \$500,000/yr) to support efficacy guideline development and rulemaking for invertebrate pests of significant public health or economic importance with a mandatory schedule of deliverables;
- Creates new set-aside to support GLP inspections (up to \$500,000/yr);
 - Preliminary summary of inspection observations be provided to laboratory not later than 60 days from completion of inspection;
- GLP and efficacy guideline development set asides authorized for 6 years, FY 2018 through FY 2023.



PRIA 4 Reporting Requirements- Registration Review

- Additional Registration Review (RR) Decision Capture Requirements:
 - Number of RR cases canceled;
 - Number of RR cases with risk mitigation;
 - Number of RR cases with mitigation rolled-back;
 - Number of RR cases that need no mitigation;
 - Number of RR cases fully implemented;
- Decision Capture database development has been completed;
- Training and implementation is ongoing, and report development is underway.



PRIA 4 Reporting Requirements- PRIA Set-asides

- Description of the amount and use of PRIA set-aside funds:
 - To carry out activities related to worker protection;
 - To award partnership grants; and
 - To carry out pesticide safety education program.
- Evaluation of the appropriateness and effectiveness of the activities, grants, and program;
- Description of how stakeholders are engaged in the decision to fund such activities, grants, and program; and
- With respect to worker protection activities, a summary of the analyses provided by stakeholders, including from worker community-based organizations, on the appropriateness and effectiveness of such activities.



PRIA 4 Reporting Requirements- Other New Requirements

- IT set-aside requirements;
- Identify reforms to streamline new AI and new use processes and provide prompt feedback to applicants during the process;
- Progress in meeting mandatory schedule in developing efficacy guidelines for invertebrate pests of significant public health and/or economic importance;
- # of GLP inspections/audits conducted;
- Progress in priority review and approval of new pesticides to control invertebrate public health pests that may transmit vector-borne disease for use in the U.S. (including territories) and U.S. military installations globally.



WPS and C&T Final Rules

Section 7 of PRIA 4 stipulates that EPA:

- Shall, during the period beginning on the date of enactment of this Act and ending not later than 10/1/2021, carry out:
 - The Agricultural Worker Protection Standard Revisions final rule published November 2, 2015; and
 - The Certification of Pesticide Applicators final rule published January 4, 2017;
- Shall not revise or develop revisions to these rules.
- Exception: EPA may propose, and after a notice and public comment period of not less than 90 days, promulgate revisions to the WPS rule relating to application exclusion zones.



WPS and C&T Final Rules (cont'd)

PRIA 4 directs GAO to:

- Conduct a study on the use of the designated representative, including the effect of that use on the availability of pesticide application and hazard information and worker health and safety; and
- Not later than 10/1/21, make publicly available a report describing the study, including any recommendations to prevent the misuse of pesticide application and hazard information, if that misuse is identified.



PRIA 4 Resources

- PRIA web pages have been updated;
- Specifically, PRIA Fee Tables, the Fee Determination Decision Tree, and the PRIA Interpretations pages have been updated to be reflective of PRIA 4 category descriptions and fees;
 - Fee Tables:
 - <https://www.epa.gov/pria-fees/fy-2019-fee-schedule-registration-applications>
 - Decision Tree
 - <https://www.epa.gov/pria-fees/pria-4-fee-determination-decision-tree>
 - Interpretations Document
 - <https://www.epa.gov/pria-fees/interpretations-pria-4-fee-categories>
- If you have any PRIA 4-related questions and can't find the answer on the PRIA web pages, please contact your division-level PRIA ombudsman mailbox or the OPP PRIA Coordinator.



PRIA Points of Contact

- Steve Schaible, Senior Advisor, PRIA Coordinator:
schaible.stephen@epa.gov
- *Vacant*, RD PRIA Ombudsman:
OPP_RD_PRIA_Ombudsman@epa.gov
balan.aswathy@epa.gov
- Diane Isbell, AD PRIA Ombudsman:
OPP_AD_Ombudsman@epa.gov
isbell.diane@epa.gov
- Andrew Bryceland, BPPD:
BPPDQuestions@epa.gov
bryceland.andrew@epa.gov



Questions to the PPDC on Reporting Requirements for PRIA Set-Asides

- How should EPA go about addressing new reporting requirements specified in PRIA 4 for PRIA set-asides for worker protection activities, partnership grants, and pesticide safety education program?
- What are the available information sources that would support evaluations of appropriateness and effectiveness?
- How should EPA gather the requested information?