

Pesticide Registration Service Fees

Overview of Pesticide Registration Improvement Renewal Act

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Pesticide Registration Improvement Act (PRIA2)

- Coalition of Stakeholders (Farm Bureau, Registrants, Growers, Public Interest Groups) to ensure stable funding for OPP
 - American Chemistry Council Biocides Panel
 - Biotechnology Industry Organization
 - Biopesticide Industry Alliance
 - Chemical Producers & Distributors Association
 - Consumer Specialty Products Association
 - CropLife America
 - International Sanitary Supply Association
 - Natural Resources Defense Council
 - Protected Harvest
 - Responsible Industry for a Sound Environment

PRIA2

- Highlights of changes in PRIA for PRIA2
- PRIA2
 - signed by the President October 9, 2007,
 - retroactive to October 1, 2007
- Two Types of Fees
 - Maintenance Fees
 - Registration Service Fees

Maintenance Fees

- Support Reassessment of registered pesticides
 - “Old Chemical program”
- Support Reregistration – complete reassessment of nonfood pesticide and product reregistration
- Under PRIA2 – Maintenance fees can be used for registration review

Maintenance Fees

- \$110 M to be collected over 5 years
 - \$22M per year
- Caps slightly increase
- FY08 → FY12 approximately \$3M earmarked for fast tracks & new inert reviews

Registration Service Fee “Enhanced Service”

- PRIA
 - March 23, 2004 → September 30, 2008

- PRIA2
 - Implementation October 1, 2007

- Fees tied to specific decision completion timeframes

Other Fees

- Cannot levy other registration fees
- Suspends authority to collect the tolerance petition fee through September 30, 2012

Timeframes and Fees

- 90 to 140 fee categories
- Applications now covered by PRIA2
 - Protocols
 - Waivers
 - Refined eco/endangered species
 - Uncleared inerts in products

Timeframes and Fees

- Timeframes further reduced for reduced risk

- Fees:
 - FY08 increased for conventional applications, same for others from FY07
 - FY09 - +5% increase
 - FY11 - +5% increase

Fee Payments

- Full fee payment at time of submission
 - Developed web information
- All requests for small businesses waivers must include partial payment of at least 25% fee
- Additional fees may be billed:
 - Incorrect fee and decision review period
 - Waiver request denied
 - Different fee and decision review period determined

Fee Payment

- Refund if too much is paid
- 25% of fee nonrefundable
- If application is rejected, Agency will retain 25% of fee

Fee Payment

- If no payment is received 30 days after fee is due, fee will be treated as claim of the US Government (subchapter II of chapter 37 of title 31)
- Applications received by EPA as of October 1, 2007 fall under PRIA2, earlier applications continue under PRIA
 - Interim invoicing application received during October to allow applicants time to become familiar with new payment process

Waivers: Small Businesses

- If applicant provides adequate documentation demonstrating that it qualifies as a small business (i.e. average annual global gross pesticide revenues of less than \$60M)
 - 50% is waived
- If applicant provides adequate documentation demonstrating that it qualifies as a small business (i.e. average annual global gross pesticide revenues less than \$10M)
 - 75% is waived

Waivers: Other

- IR-4
 - Still to be resolved

- Minor Uses
 - May be waived or reduced

- Exempt from registration fees
 - Agencies of Federal and State Government

Withdrawal – Refunds

- If application withdrawn within 60 days after start, then 75% of fee is refunded
- If application is withdrawn more than 60 days after start date, then refund based on % of work not completed
 - Refunds can not exceed 75%
- Determination of the amount of the refund must be made within 90 days after the date of the withdrawal
 - Formula
<http://www.epa.gov/pesticides/fees/questions/waivers.htm>

Authority to Assess Fees

- Authority to assess fees is suspended if Congressional appropriations fall below the amount allocated to OPP in FY02 by more than 3%
- This protection applies for FY08 → FY12

Start of the Decision Time Review Period

- Decision time review period begins 21 days after EPA receives the fee payment and application
 - Administrator will perform an initial screening of contents of the application
 - Application contains necessary forms, data, and draft labeling in accordance with the Administrator's Guidance
 - If application does not pass initial screening and cannot be corrected in 21 days, Administrator reject no later than 10 days after determination

Start of the Decision Time Review Period

- For applications with a waiver
 - Provided the 25% or 50% have been paid, clock starts when waiver is granted
 - If denied, it starts when full payment is received

Timeframes

- The timeframes established in PRIA are the MAXIMUM allowable timeframes. In many cases, OPP is able to complete the registration prior to the PRIA due date
- PRIA provides expedited timeframes for “reduced risk” actions
- Can be extended by mutual agreement between registrant and EPA (i.e. negotiated due date)

Judicial Review

- Judicial review for new AIs & new uses where completion timeframe is exceeded by more than 2 years
 - Covers only new AIs & new uses and only those for which a fee has been paid
 - Can only be requested 2 years after the decision review period has expired

Judicial Review

- Registrant must request a meeting with the Agency to try to work out the problem 4 months prior to petitioning for judicial review
- Judicial review remedy can NOT result in any fee refund

Worker Protection

- Increase from PRIA
- To enhance scientific and regulatory activities, for FY08 → FY12, the Administrator shall use about 1/17th of the Fund (not less than \$1,000,000)
 - PRIA - \$750K per year

Worker Protection

- Partnership grants – New
 - FY08 and FY09 - \$750K
 - FY10 → FY12 - \$500K

- Fund Pesticide Safety Education Program (PSEP) – New
 - FY08 → FY12 – \$500K

Improvements

- Statutory Provision
 - ...the Administrator shall identify and evaluate reforms to the pesticide registration process under this Act with the goal of reducing decision review periods in effect...

- Stakeholder Subcommittee of PPDC formed
 - PPDC PRIA Process Improvement Workgroup

Accounting

- Annual inspector general audit report detailing
 - amount of fees received,
 - expenditures from the fund,
 - decision making performance achieved in comparison with decision completion time periods, and
 - reasonableness of overhead costs

- IG report goes to Administrator and appropriate Congressional Committees

Annual Reports

- # of applications reviewed and their individual decision timeframes
- # of label amendments reviewed using electronic means
- Amount of money from Reregistration and Expedited Processing Fund money used to carry out inert and similar application reviews
- # of applications completed for identical or substantially similar applications (and # completed within 90days)

Annual Reports

- # of actions pending in each covered category including new inert petitions
- Progress made in meeting timeline requirements
- Description of staffing and resource allocations to support decision-making for covered actions

Annual Reports

- Include as appropriate recommendations for:
 - Expansion of self-certification
 - Accreditation of outside reviewers
 - Broadening the scope of the notifications process
 - Electronic submission and review of labels
 - Use of acute toxicity study summaries

Annual Reports

- Use of Performance based contracts
- Review of progress of registration review
 - # of pesticide or pesticide cases reviewed
 - Staffing and costs related to Reregistration and Registration Review
- Recommendation for:
 - Process improvements handling registration review
 - Accreditation of outside reviewers
 - Streamlining registration review process

Annual Reports

- Review of timelines for Antimicrobials 3(h)
- Review of inert ingredients, including the number of applications pending, new applications, applications reviewed, staffing resources devoted to improve the timeliness
- Reports due March 1 (of each year) on the web
 - <http://www.epa.gov/pesticides/fees/>

Phase Out

- Sunset – September 30, 2012
- In FY13, the first year of the phase out, fees are reduced by 40% from FY08 levels
- In FY14, the second year of the phase out, fees are reduced by 70% from FY08 levels

PRIA2 Implementation

- IT systems modified
- Website – information updated
- Workshop – November
- Outreach to trade association and other groups