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

- 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 90 days)
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