

Analysis & Perspective

PESTICIDES

REGISTRATION FEES

The Pesticide Registration Improvement Act, adopted last January, is intended to provide more stable funding for EPA and, as a result, greater predictability for industry with regard to the timing of reviews of their applications and products. Pesticide registrants will pay increased maintenance fees and new registration fees, and EPA will be subject to deadlines for the completion of reviews of certain pesticide products. Discussed below are the major provisions of the law, which was included in appropriations legislation, and an outline of the history of this initiative and some of its implementation issues.

Pesticide Registration Improvement Act

By JAMES V. AIDALA AND CARLA N. HUTTON

The user fees that industry has both long advocated and long dreaded became a reality for pesticide product registrants as part of the Consolidated Appropriations Bill (P.L. 108-199), enacted Jan. 22. The Conference Committee incorporated the text of the Pesticide Registration Improvement Act of 2003, which was introduced in the Senate on Sept. 25, 2003, by Sens. Thad Cochran (R-Miss.) and Tom Harkin (D-Iowa) with 21 co-sponsors. PRIA is the culmination of considerable negotiation among the Environmental Protection Agency, industry, and activist groups on the issue of whether new user fees should be imposed to fund pesticide registration and reregistration activities.

In essence, the Pesticide Registration Improvement Act (PRIA) is intended to provide more stable funding for EPA and, as a result, greater predictability for industry with regard to the timing of reviews of their applications and products. Pesticide registrants will pay increased maintenance fees and new registration fees, and EPA will be subject to deadlines for the completion of reviews of certain pesticide products.

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Discussed below are the major provisions of PRIA, and an outline of the history of this initiative and some of its implementation issues.

Major Provisions

■ Under the new law, the Federal Insecticide, Fungicide, and Rodenticide Act is amended to allow EPA to set and collect "registration fees" for new registrations. PRIA requires EPA to publish the schedule that appeared in the Sept. 17, 2003, *Congressional Record*, which was presented as a single table for all EPA's Office of Pesticide Programs (OPP) divisions and registration actions. In a March 17 *Federal Register* notice announcing the registration service fees and decisions times, EPA stated that it reformatted the information to be more user-friendly.¹ EPA divided the single table from the *Congressional Record* into 11 tables, organized by Office of Pesticide Programs division and by type of application or pesticide subject to the fee. These new fees are expected to raise \$18 million per year. The law terminates on Oct. 1, 2009, unless extended.

■ EPA is subject to a schedule for reviewing pesticide product registration applications. The decision review periods are included on the registration fee schedule.

■ There is oversight of EPA's registration efforts through an annual audit by the agency's Inspector General, who must report the findings and recommenda-

¹ 69 Fed. Reg. 12,772, 12,773 (Mar. 17, 2004), available at <http://www.epa.gov/fedrgstr/EPA-PEST/2004/March/Day-17/p6001.pdf> on the World Wide Web. On April 14, EPA published in the *Federal Register* a notice correcting typographical errors in the March 17 notice. 69 Fed. Reg. 19,843 (April 14, 2004). More information on PRIA is available at <http://www.epa.gov/pesticides/fees/> on the Web.

tions of the audit to the EPA administrator and to the appropriate committees of Congress.

- Judicial review is available to applicants if EPA fails to make a determination on an application for registration of a new active ingredient or new use for which a registration service fee is paid. Prior to filing a lawsuit, an applicant must request a meeting with EPA to set an acceptable alternative timeframe. An applicant must wait two years from the date on which the decision time review period for the application ends before obtaining judicial review of EPA's failure to make a determination within the decision time review period.

- Current maintenance fee limits (the "caps") have been increased during the first three years of the proposal and then decline in the last two years. The increases are expected to increase the current revenues from these fees to \$26 million in fiscal year 2004 from the current \$21.5 million in fiscal 2003, and to \$27 million in fiscal 2005 and fiscal 2006, followed by declines to \$21 million in fiscal 2007 and to \$15 million in fiscal 2008.

- The increased caps for registrants holding 50 or fewer registrations are a maximum of \$84,000 (up from the current maximum of \$55,000) in fiscal 2004; \$87,000 in fiscal years 2005 and 2006; \$68,000 in fiscal 2007; and \$55,000 in fiscal 2008.

- The increased caps for registrants holding more than 50 registrations are a maximum of \$145,000 (up from the current maximum of \$95,000) in fiscal 2004; \$151,000 in fiscal years 2005 and 2006; \$117,000 in fiscal 2007; and \$95,000 in fiscal 2008.

- Under the legislation, "small businesses" is defined as those with global gross pesticide revenue at or below \$60 million, and a lower fee schedule applies for small businesses holding 50 or fewer registrations—\$59,000 in fiscal 2004; \$61,000 in fiscal years 2005 and 2006; \$48,000 in fiscal 2007; and \$38,500 in fiscal 2008.

- For small business registrants holding more than 50 registrations, the following schedule applies—\$102,000 in fiscal 2004; \$106,000 in fiscal years 2005 and 2006; \$82,000 in fiscal 2007; and \$66,500 in fiscal 2008.

- Fees now charged by EPA to set tolerances are eliminated through September 30, 2008. This scheme not only replaces the long-standing tolerance fees charged by EPA, but also replaces the fees proposed by the tolerance fee rule issued under authority of the 1996 Food Quality Protection Act amendments.

- The funds collected pursuant to the bill's provisions go directly to EPA. EPA is to use them largely for registration, although a percentage will go to other programs, including between \$750,000 and \$1 million per year for worker protection research and regulatory programs and up to \$500,000 per year for EPA to review inert ingredients in pesticide mixtures.

- The legislation provides baseline budget protection for the Office of Pesticide Programs for fiscal years 2004, 2005, and 2006. During this period, EPA may not assess registration service fees unless the appropriation for the Office of Pesticide Programs is equal to or greater than the amount appropriated for that office in fiscal 2002. This is intended to ensure revenue collected from pesticides fees will not be offset by a decrease in

congressional appropriations for either EPA or the Office of Pesticide Programs.

History of the Issue

Historically, funding for the Office of Pesticide Programs has been a challenge. Congressional appropriations rarely provide adequate funding to meet everyone's expectations as the interests and objectives of the various stakeholders create conflicting pressures/priorities. Further, the pesticides program has not been a priority for most administrations and therefore has been more susceptible to periodic budget cuts. The only two sources of funding for the program currently are general appropriations and industry fees.

The current maintenance fees were established in the 1980s. These fees pay for about 190 people within the Office of Pesticide Programs who have reregistration responsibilities, as well as about 10 people who work on "fast track" registration actions. The tolerance fees currently collected by the Office of Pesticide Programs offset general appropriations dollars; therefore, they do not result in increased funding or support additional work.

Under the 1988 amendments to FIFRA, EPA imposed reregistration maintenance fees on registrants. EPA's authority to collect these maintenance fees expired in 2001, but Congress included a one-year extension in its fiscal 2002 appropriations bill (P.L. 107-73), allowing EPA to collect up to \$17 million. Congress included a similar extension in its fiscal 2003 omnibus appropriations bill (P.L. 108-7), allowing EPA to collect up to \$21.5 million.

EPA had first proposed registration fees in 1988 by rule (before and separate from the 1988 maintenance fee amendments), but EPA never has collected them because Congress has repeatedly denied EPA the authority to collect them.

The Food Quality Protection Act authorized EPA to collect significantly higher tolerance fees to reflect the additional work it required EPA to perform, including reassessing all existing tolerances and ensuring with "reasonable certainty that no harm will result from aggregate exposure" to each pesticide from dietary and other non-occupational sources. In 1999, EPA issued a proposed rule to collect those higher fees. Congress, however, has blocked that rule each year by attaching an amendment to the EPA appropriations bill. In September 2002, EPA submitted a final rule increasing tolerance fees to the Office of Management and Budget.

Many in industry, although believing that the Office of Pesticide Programs needs sufficient resources to deliver its core responsibilities, nevertheless had a great deal of concern as to whether EPA needed more resources to do its work, and whether the industry could or should support additional fees. The debate was complicated by the fundamental differences among and between basic registrants, formulators, distributors, and the user community as to who should bear the burden of these costs, and how.

Various efforts over the years have aimed at trying to capture the real cost of doing business in the Office of Pesticide Programs. As part of the Food Quality Protection Act discussion in 1996, and as recently as 2000, there were proposals for a "fee for service" legislative package that would have included higher fees in return for greater predictability and accountability. Modeled

after a similar scheme to facilitate accelerated drug application decisions at the Food and Drug Administration, these past efforts bogged down with no consensus on a specific proposal.

Past efforts suffered not only from general mistrust by industry of EPA's ability to deliver on predictable deadlines even with additional resources, and little interest by the environmental community, in seeing additional pesticide registrations. With only tepid support from the registrant community, as well as tensions among members of that community (e.g., conflicting goals between basic and generic manufacturers) and general indifference by the environmental community, consensus was not achievable in years past.

For much of this period, many in industry felt that they did not want to pay additional fees of any kind, although a solid core indicated that they might be willing to pay additional fees if the fee structure were equitable and there was greater assurance of decisions being made within fixed periods of time. Generally speaking, there is more support for maintenance fees than there is for registration fees.

Two things changed to promote this consensus behind the legislation: First, static or declining federal appropriations for nondefense, discretionary spending (that part of the federal budget where EPA competes for its resources) and the prospect for little relief in the foreseeable future made it clear that EPA timeframes for decisionmaking could only be greatly extended. Second, discussions of the proposal began to include representatives from environmental groups to propose fee-related activities that they would be interested in (i.e., worker protection programs, reduced-risk registrations, and completion of the tolerance reviews under the Food Quality Protection Act).

Implementation of New Law

On March 11, EPA held a workshop on its plans for implementing the Pesticide Registration Improvement Act. During the workshop, EPA provided the following information in presentations and during question-and-answer exchanges:²

Applicability.

- The new fees schedule applies to all submissions that fit into one of the 90 registration action categories and that were submitted on or after March 23.

- The new fees schedule also applies to all pending registration applications for new AIs submitted prior to March 23, but not on the fiscal 2003 work plan.

- Registrants with pending applications for other than new AIs are not required to pay the new fees. If the registrants want to benefit from the predictability of the decision deadlines in PRIA, they may voluntarily pay the fee associated with the type of pending action.

- If an application is submitted, the fee is paid, and EPA denies or otherwise returns the application, it may be resubmitted without a second fee.

² On April 7, EPA published "Questions and Answers," which is available at <http://www.epa.gov/pesticides/fees/newpestfee.htm> on the World Wide Web. There are links to pages on general questions, in-processing of applications, fee waivers, fund management, and inert ingredients, as well as a link to submit additional questions to EPA.

- So-called "fast track" amendments are not covered by PRIA. As a result, there are no fees associated with these amendments.

- Similarly, requests for EPA review and comment on study protocols are not covered by the fee categories and therefore are not subject to the new fees. EPA noted during the workshop that a draft protocol might be reviewed faster if a registrant could link a requested protocol review with an application for which a fee had been paid (i.e., the study is necessary to support the application).

Pending Applications.

Pending applications that are not required to pay fees may volunteer to pay the fees to obtain the benefit of the new decision deadlines. If a registrant with a pending application decides not to pay the fee, the Registration Division and the Biopesticides and Pollution Prevention Division have pledged to continue to work on the pending applications in a timely fashion to the best of their ability, but, for the reasons discussed below, not doing so could result in considerable delays. Decision deadlines established by the Food Quality Protection Act will continue to apply to pending applications in the Antimicrobials Division (AD) regardless of fee payments.

- For pending AIs that are required to pay the new fee, the clock on the decision period will begin 30 days after the PRIA effective date, or on April 22, 2004.

- EPA may grant partial fee refunds based on the amount of work completed on a pending application prior to the PRIA effective date. EPA will make this determination and so advise the affected registrant. If a fee is paid voluntarily for a pending action that has a new tolerance associated with it, EPA will reduce the fee by the amount of the previously paid tolerance.

- For pending applications not on the current Division work plans, EPA encouraged submitters to notify it about whether they continue to want the applications reviewed, and if so, whether they plan to pay the fees voluntarily and into what fee categories they think the applications fall. Submitters should send this information to EPA's Document Processing Center (VOLPAY); "VOLPAY" is a special distribution code that indicates the communication concerns a voluntary fee payment.

- In response to a question, EPA stated that a registrant with a pending application could decide not to pay initially but change its mind and elect to pay the voluntary fee at a later date.

New Administrative Process, Fee Payment.

- There are no new forms associated with the new fees program. Applicants should indicate on EPA Form 8570-1 (Application for Pesticide), in the explanation block of Section II, into which category the applicant believes its submission fits. New applications submitted after the effective date should be sent to EPA's Document Processing Center (REGFEE), where "REGFEE" is a distribution code that will alert EPA that the submission requires a registration fee category decision.

- EPA is creating a new master tracking database, "OPPINS," to maintain a record of each application, its associated decision timeframe, and its status in the review process.

- EPA plans to notify an applicant within three days of receipt of the application of its decision concerning the fee category into which the application falls. EPA

will send this notification and fee invoice by e-mail or telefacsimile if the appropriate contact information has been provided; it will also send a hard-copy notification and invoice by mail.

- Applicants are not to send payment for the fee until receiving an invoice from EPA. Payments will be sent to the EPA Headquarters Accounting Operations Branch in Pittsburgh, Pa. Payments will need to include a copy of the letter-invoice.

- The review period will begin 21 days after receipt of the application or when receipt of the fee payment has been confirmed, whichever is later. Applicants should make every effort, therefore, to pay the fee immediately upon receipt of EPA's invoice.

- Payments currently must be by check. EPA is making arrangements to accept other forms of payment, including credit card and wire transfer.

- EPA stated that payment must be made separately for concurrently submitted applications, for tracking and auditing purposes.

- When asked, EPA acknowledged that there will need to be a process whereby a submitter could discuss an application's fee if the application appears to have been assigned to an incorrect fee category, but this process has not yet been defined.

Fee Waivers.

- Fee waivers apply to the new one-time registration fees, not to the annual maintenance fees. There are, however, maximum total caps to the annual maintenance fees payable by small businesses.

- An application with a successful fee waiver is treated the same as a comparable application for which the fee is paid. That is, the maximum length of the review period will be the same for two applications (one that paid and one that waived the fee) that fit into the same fee schedule category and that are submitted in the same fiscal year.

- The request for a fee waiver and all required supporting documentation must accompany the application when it is submitted to EPA. What constitutes "all supporting documentation" is still being refined, and EPA invited industry feedback on what types of documentation would suffice. For the small business waiver, one commenter urged EPA to consider that available financial records for non-U.S. companies are likely to be different than those available for U.S. companies.

- EPA may take up to 60 days to review a waiver request. The "clock" for the decision period does not start until the waiver request is accepted or, if rejected, payment is received.

- A commenter asked if a fee waiver request could precede the application, to reduce the effect of the 60-day waiver review period. EPA said it might be able to accommodate this type of request eventually, but not initially. EPA also noted that the 60 days is a maximum review period for waiver requests, and eventually it hopes to complete waiver requests within 21 days.

- EPA stated that it is evaluating how to streamline the waiver request process. Workshop attendees urged EPA to develop a process that, for small businesses, would not require a *de novo* review of waiver eligibility for each subsequent submission.

There are two tiers of fee waivers for small businesses:

- For businesses with average annual global gross revenue from pesticides that does not exceed \$60 million, registration fees are reduced by 50 percent.

- For businesses with average annual global gross revenue from pesticides that does not exceed \$10 million, registration fees are completely waived.

The FIFRA definition of a small business has been changed.

- A small business is one with 500 or fewer employees and average annual global gross revenue from pesticides that does not exceed \$60 million.

- EPA currently defines "pesticides" for the purpose of calculating the average annual global gross revenue "from pesticides" to include pesticides and pesticidal devices. EPA acknowledged during the workshop, however, that this interpretation may be subject to further revision.

- EPA clarified the definition to include revenues from affiliated companies.

Miscellaneous.

- If an application is withdrawn within the first 60 days after submission, the applicant is eligible for a refund of 90 percent of the paid fee. If an application is withdrawn after 60 days, the amount of the refund will be prorated based on the amount of work completed on the application.

- EPA clarified that once the clock begins for an application's decision timeframe, EPA cannot unilaterally "stop" the clock. An applicant may elect to negotiate with EPA to extend the clock, however, particularly if the alternative is an adverse decision.

- EPA expressed its hope to improve communication with industry such that submitters would share their schedule for future submissions for EPA planning purposes.

- EPA emphasized that the statutory decision deadlines are maximum timeframes and expressed its hope that (eventually) decisions would be made in less than the maximum time allotted.

- The director of the Registration Division expressed her desire to make the division's work plan a "living" document that is readily available (e.g., via the Internet). A commenter encouraged the division to consider adding status updates to the work plan, so a submitter could determine from the work plan at what stage of review an application was currently.

- The Biopesticides and Pollution Prevention Division announced that it was releasing its first public work plan. The work plan is at <http://www.epa.gov/pesticides/biopesticides/workplan.htm> on the World Wide Web.

- Consultations for effects on endangered species are among the actions that must be completed within the specified timeframes. EPA acknowledged that the process for completing these evaluations within the specified timelines has yet to be developed.

Issues and Impacts

EPA will have to address several critical issues as it implements the legislation if it is to achieve its goals. The resolution of these issues will impact registrants, in some respect quite significantly. These issues include:

Applications Pending before the Effective Date of the New

Requirements: One of the most important and earliest issues EPA must decide is how to treat already submitted applications if the applicant does not voluntarily pay a registration fee. No fee is mandatory, but without the “voluntary” fee it is uncertain how EPA could simultaneously process the backlogged applications in any reasonable timeframe. If a fee is paid for a pending application, it guarantees that the timeline applies prospectively for that application. This guarantees a place in the queue and imposes a deadline on the expected time to a decision. Without a fee being submitted, it is unclear when and if EPA will ever be able to process the application. This will be one of the most difficult issues for EPA to address in the near term.

Definition of “Small Business” and Effect of Exemptions on EPA’s Ability to Meet the Timelines: The definition of “small business,” based on the Small Business Administration definition, could allow a much larger universe of registrants to be exempt from paying fees. If a waiver is granted, an application is treated as though a fee had been paid (*i.e.*, the deadlines apply). If EPA’s available pool of resources is limited or constrained in unpredictable ways as a result of these types of exemptions and like issues, EPA’s expected amount of revenues may be below its working assumptions, which will make more difficult EPA’s ability to manage the new process successfully.

Time Necessary for EPA to Establish New Requirements and Resultant Effect on Application Processing: Ramping up hiring, contractor support, and even office space is more time-consuming under federal programs than in the private sector. After the Food Quality Protection Act was enacted in 1996, for example, it took nearly a full year for EPA to put in place the newly required procedures and requirement. EPA will now need to devote significant management attention and staff time to put into place the newly required fees procedures and requirements, which will leave less time to tend to “ordinary” business of reviewing already submitted applications, resolving contentious issues, writing new regulations, etc.

When the Clock Starts and Stops: Definitions of how to “count time,” including starting the clock, stopping the clock, and allowing for additional data development without losing one’s place in the queue, will be critical to meeting the goal of predictability, accountability, and acceleration of decisionmaking. In the past, it was not uncommon for registrants to dispute elements of EPA’s assessments or to suggest that EPA delay decisions pending additional data development. Now, since the clock will count against EPA’s performance goals, EPA may be less likely to countenance delays. EPA is likely to be even tougher on the “front-end screens” that define a complete application, since once the application is accepted as complete, the clock will begin to tick. If applications are rejected on the front-end, no new fee will be required for resubmission, but the applicant will lose its place in the queue (or more precisely, it will not have a place in the queue) until the submission is accepted as complete.

Opportunities for Changes to Process: Reviewing current procedures to ensure that the new deadlines can be met will not only reveal what EPA may determine are flawed

current operating procedures, but also will present opportunities for registrants and others to suggest process improvements and reforms to help achieve the mandates of the new law. The legislation explicitly calls for EPA to consider process reforms and opportunities for regulatory innovation, and registrants (and others) should not ignore this opportunity as part of the implementation discussion. With or without a fees scheme, there are long-standing suggestions that could improve EPA time to decision and generally improve the process (*e.g.*, allow some form of third-party reviews, self-certification schemes, etc.).

The Potentially Double-Edged Sword of Judicial Review: Judicial review of missed deadlines was of critical importance to that part of the registrant community which is skeptical of EPA’s ability to meet the goals of the legislation. The judicial review provisions were difficult for EPA to accept as they will hold EPA’s processes up to additional scrutiny where functionally there was none before. At the same time, EPA can meet deadlines for decisions if an application is contentious and overdue simply by denying the application on the grounds that safety has yet to be proven to their satisfaction. In that case, the judicial review will not be of missed or met deadlines, but rather, of EPA’s discretion to decide on the safety standards underlying their registration responsibilities. Put more bluntly, in this regard the registrant community needs to be careful what it wishes for. The new legislation provisions for judicial review only apply to the potential review of EPA’s adherence to the requirements of this new fee for service scheme (*i.e.*, time to decisions), and did not change the judicial review provisions affecting other parts of the statute.

Baseline Protection of Appropriated Funds: Baseline protection of appropriated funds was an important criterion for the registrants to ensure that fees would guarantee greater available resources to EPA to meet the goals of the legislation. Appropriation baseline protection is only legislated for the first three years, however. After that, with declining or limited funds available for nondefense discretionary spending, EPA will be in a difficult budget situation, and it is unlikely that the Office of Pesticide Programs would be spared future budget cuts that apply to EPA more generally. The impact on the program at that time will depend on how well the new and revised procedures are working after the first three years.

Differing Impacts on Various Office of Pesticide Programs Divisions: Throughout all of the early implementation phases, some parts of the Office of Pesticide Programs likely will face more difficulty in re-engineering their registration review processes to comply with the new deadlines. Some divisions, such as the Registration Division, have had to live with relatively intense management control over their workload allocations and flow between component pieces of registration package evaluations. Others, such as the Biopesticides and Pollution Prevention Division, have not had such intense scrutiny up to this time. The result will be improvements and greater predictability in all corners of the program, but some processes and certain kinds of decisions will be more noticeably changed than others.

Possibly Reduced Number of Applications: One anticipated

result of imposing fees on all registration actions is an overall reduction in the number of applications submitted. Fewer “small label changes” are likely to be submitted now that each action will require a fee.

Sunset Will Provide New Challenges: At the end of the five-year period for which the legislation is authorized for (a five-year “sunset”), EPA will have to negotiate a renewal of the program which will need affirmative Congressional approval. In addition to any internal fears about whether some large numbers of staff may lose their positions, this will also mean that Congress will necessarily face some version of FIFRA legislative amendments. This will not only raise the possibility of further refinements to the fee for service scheme, but also might open the door to other FIFRA legislation.

Conclusion

The new legislation reflects the interests of both the industry and the broader stakeholder/NGO community as both want the program to have sufficient resources to do its job. By providing deadlines for EPA registration decisions, the new law provides industry more predict-

ability in determining how long it will take new products to be approved for market. The legislation also provides EPA a dependable stream of funding for the Office of Pesticide Programs to ensure it can meet those deadlines and better implement other activities such as the worker protection program. Whether this legislation will meet these goals will be revealed as EPA acts to implement it.

EPA will have to address several critical issues as it implements the legislation to achieve its goals. Even though great amounts of time and effort were put into this proposal as it went through the legislative process, the actual programmatic implementation of its requirements has just begun at EPA and the Office of Pesticide Programs. There are a number of internal task forces that will be engaged over the next number of months to deliberate and decide precisely how the new requirements will be implemented. There are innumerable items both large and small that will now have to be decided, from simple things like where to send the check (and what counts as having paid the fee) to how to count the clock in regards to meeting deadlines outlined in the legislation.