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PRIA 3 May Have Hidden Disadvantages For Industry

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Law360, New York (November 08, 2012, 4:47 PM ET) -- The Pesticide Registration Improvement Renewal Extension Act of 2012 (PRIA 3) (S. 3552), like PRIA and PRIA 2, has been lauded by industry because it sets time frames for the pesticide registration process. Not only does PRIA 3 provide greater certainty and agency accountability through mandated review time frames, but it also enhances the tracking of these time frames by funding improvements to the U.S. Environmental Protection Agency's information management system. Despite broad support, there is a possibility of some difficulties ahead for manufacturers of conditionally registered pesticides and those with contested labels.

PRIA 3 was a win-win for the PRIA coalition — a group composed of eight industry trade associations and two nongovernmetal organization partners, Natural Resources Defense Council and Farmworker Justice — that ushered it through Congress. The Senate and House both passed PRIA 3 in late September by unanimous consent, and President Obama signed PRIA 3 into law shortly thereafter.

PRIA 3 increases funding for applicator trainings and worker protection programs and registrations reviews important to environmentalists, farm worker groups and the EPA. For the industry, PRIA 3 increases predictability, which is important to spur research, development and innovation in the pesticide industry.

New Time Frames and Fee Schedule Provide Certainty

PRIA establishes a fee schedule and a time frame for pesticide registration. Fees are collected from registrants for pesticide registrations, amended registrations and related tolerance actions. In turn, the EPA abides by a set time frame for evaluation of these submissions, which provides a degree of certainty to industry.

Fees and time frames vary based on the type of chemical — conventional, antimicrobial or biopesticide — and the type of action (e.g., new active ingredient, new use, experimental use permit and certain tolerances), for a total of 189 categories. Small businesses may request a fee waiver, and if granted, the EPA will still abide by the stipulated review time frame. Due to PRIA 3, fees are reauthorized until Sept. 30, 2019, and time frames apply to applications received through Sept. 30, 2017.

Time frames begin 21 days after the EPA receives an application and fee. During the first 21 days, the EPA conducts an initial contents screen to determine whether the fee is paid, and the application is complete and formatted properly. The applicant must resolve any fee and application issues within the 21-day period, and the EPA will contact the applicant if there is missing content and instruct them how to bring its application into compliance.

If the applicant fails to correct its application, the EPA will reject the application within 10 days. Following the initial contents screen, the EPA performs a preliminary technical screen to determine whether the data and information submitted is accurate and complete, consistent with proposed labeling and tolerance exemptions and may lead to the granting of the application.

The EPA conducts this screen in either 45 or 90 days. Again, applicants are given an opportunity to correct deficiencies; if they fail to do so within 10 days, the EPA will reject the application.

Following these preliminary reviews, the EPA conducts its in-depth review in accordance with the PRIA 3 time frames. For example, under PRIA 3, decision review time for new active ingredients is from 14 months (new active ingredient, non-food use, indoor and reduced risk) to 24 months (new active ingredient and food use).[1]

If deficiencies are noted during the in-depth review period, the EPA will issue the applicant a 75-day deficiency letter, allowing the applicant 75 days to correct the deficiencies. If needed, the time frame may be extended by mutual agreement of the applicant and the EPA.

New Labeling Review Process

PRIA 3's new labeling review process is more iterative, allowing for increased industry-EPA collaboration. If part of an applicant's requested action involves the EPA's approval of a new or amended label, the EPA will review the proposed label submitted by the applicant during the decision review period.

According to EPA policy, if the agency has any changes to the label, it will submit these changes to the applicant four weeks before the PRIA due date if the PRIA due date is greater than 12 months or two weeks before the PRIA due date if the PRIA due date is 12 months or less. With this predecisional determination, the EPA will provide the applicant with the supporting data the EPA reviewed, which prompted its changes to the label.

According to a new footnote to the PRIA tables, on the date of the PRIA due date, the applicant has three options:

- Accept the EPA-amended label and request that the EPA use this version as the accepted final agency-stamped label
- Disagree with the changes and request up to 30 days to review the changes and reconcile the differences through discussion with the EPA
- Withdraw the application without prejudice (allowing a future resubmission) but forfeit the application fee

Once the applicant agrees to all changes in writing (including via email), as set forth in the first option, or through the process described in the second, the EPA will issue the final agency-stamped label within two business days.

Although a set time frame of 30 days is advantageous in that it moves the pesticide product to market, 30 days is very little time for an applicant to resolve labeling controversies. The applicant needs time to review the EPA's supporting data and may need to gather its own data to support its position.

If an applicant anticipates needing more than 30 days, it should negotiate an extension of the PRIA due date with the EPA product manager before the PRIA due date. If the PRIA due date elapses, and a consensus is not reached, the applicant will be left with a binary decision: accept the changes or withdraw its application.

Potential Impact on Conditional Registrations under FIFRA?

Section 3(c)(7) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) authorizes the conditional registration of a pesticide when the EPA determines that data, which would be required for unconditional registration of a similar product, is missing, but there is sufficient data upon which the EPA can allow a conditional registration, and the use of the pesticide during the conditional registration period would not significantly increase the risk of unreasonable adverse effects on the environment.

Upon receiving a conditional registration, the applicant can take its product to market. However, it is required to conduct studies and submit data according to a time frame set by the EPA and published in the Federal Register.

Conditional registrations have come under increased scrutiny by environmental groups, as deadlines for data submission have lapsed and pesticide products remain on the market. They have concerns that the EPA's Office of Pesticide Programs's enforcement is lax and that industry is slow in conducting studies or resolving outstanding questions with the agency.

In a review of conditional registrations, the EPA found that of 16,156 active FIFRA section 3 registrations, 11,205 are conditional registrations. The OPP currently uses a system called OPP Information Network (OPPIN) system to track some information about conditional registrations that require additional data submissions.[2]

This system is incapable of including all the details needed to monitor a conditional registration and is supplemented by hard copy files for each product. Critically, the OPPIN system "does not have the ability to automate the tracking of deadlines for conditional registrations,"[3] and tracking of over 11,000 such deadlines is a challenging task.

To solve this problem, PRIA 3 allocates $800,000 annually to improve OPP's information system capabilities, a portion of which will be allocated for the electronic tracking of registrations submissions and the status of conditional registrations.[4] The new, automated system makes it more likely that the EPA will crack down on data submission deadline violations for conditionally registered products.

Although the EPA has rarely taken a conditionally registered product off the market after receiving the requested data, this could change as companies may scale back robust studies as they face heightened pressure to meet data deadlines.

Further, tracking databases may be publicly accessible. This is advantageous to the industry as it allows them to track the progress of their application in real time. However, it increases the ease of monitoring deadlines for environmental groups, likely fostering their increased attention to missed deadlines. With this may come a rise in citizen suits and public awareness campaigns, all of which may damage a company's brand and decrease market share.

On the whole, PRIA 3 has many advantages, but some of its new, seemingly insignificant provisions — 30-day label collaboration and a new tracking system — may pose challenges for the industry, ones that pesticide manufacturers must be fully aware of and be prepared to tackle.

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[1] EPA, Pesticide Registration Improvement Extension Act (PRIA 3) Tables - FY 2013 Fee Schedule for Registration Applications, http://www.epa.gov/opp00001/fees/tool/category-table.html.

[2] EPA, Conditional Registration, May 10, 2010, http://www.epa.gov/pesticides/regulating/conditional-registration.html.

[3] Id.

[4] Id.

[5] 7 U.S.C. 136a–1(k)(4)(B)(i).