EPA Releases New PR Notice on Determination of Minor Use

Friday, March 30, 2018

On March 22, 2018, the U.S. Environmental Protection Agency (EPA) released the Pesticide Registration Notice (PR Notice) 2018-1 issued by the Office of Pesticide Programs (OPP) entitled “Determination of Minor Use under Federal Insecticide, Fungicide, and Rodenticide Act Section 2(ll)” (PR Notice 2018-1). Notice of Availability issued on March 21, 2018. 83 Fed. Reg. 12385. The PR Notice states that it “describes the revised approach to interpreting economic minor use based on the concept of the registration of a pesticide as an investment.” It “revises the method and criteria used by EPA for evaluating ‘sufficient economic incentive’ under FIFRA section 2(ll)(2),” and it “also clarifies that minor use under FIFRA section 2(ll)(1) is based on acreage reported in the [U.S. Department of Agriculture (USDA)] Census of Agriculture.”

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Section 2(ll)(1) defines a minor use of a pesticide as a use on a crop grown on 300,000 acres or less in the United States. Section 2(ll)(2) of FIFRA defines a minor use of a pesticide as one that lacks sufficient economic incentive to seek or maintain a registration but has private or social value.

PR Notice 2018-1:

- Clarifies that the USDA’s most recent Census of Agriculture, conducted every five years by the USDA’s National Agricultural Statistics Service (NASS), is the appropriate source for data on acreage or crops grown in the U.S. to establish a minor use under the acreage definition in FIFRA 2(ll)(1);

- Revises and provides guidance to registrants concerning the method used by EPA for evaluating “sufficient economic incentive” under FIFRA Section 2(ll)(2); and

- Explains how qualitative information may be used to inform the quantitative analysis and interpret the results.

Previously, EPA’s interpretation of economic minor use in Section 2(ll)(2) was based on PR Notice 97-2. EPA states PR Notice 2018-1 supersedes PR Notice 97-2. EPA states that through PR Notice 2018-1, EPA “seeks to identify and encourage the registration of pesticides for minor uses to protect communities from harmful pests.” EPA states in PR Notice 2018-1 that “the existing methods for identifying an economic minor use in PRN 97-2 do not consider all relevant factors which could affect the incentives of a registrant to apply to register a minor use,” and that “use of the approach in PRN 97-2 to identify economic minor uses could prevent applicants from registering pesticides that would be beneficial to users and growers, thus limiting the availability of pesticides for certain use sites.” For this reason, “EPA revised the method to determine an economic minor use.”

PR Notice 2018-1 is significant because it can be applied to conventional pesticides, biopesticides, and antimicrobial pesticides to determine whether they meet the definition of minor use. The criteria in PR Notice 97-2 only applied to conventional pesticides.
EPA states the rationale for revising the PR Notice to consist of the following:

- EPA has decided to revise the policy on determining minor use.
- First, PRN 97-2 is outdated regarding the crops that would not meet the acreage definition of a minor use under FIFRA section 2(II)(1). PRN 97-2 contained a fixed list of crops that were grown on more than 300,000 acres in 1997, but cropping patterns change over time and the list of crops provided in PRN 97-2 is no longer accurate.
- Second, the method in PRN 97-2 does not accurately reflect economic incentive to register pesticides. Gross revenue is not an appropriate measure for estimating returns on an investment; since it does not account for production and distribution costs, it overstates the returns to the investment. However, revenue from a single year understates the time period when a firm would receive a return on an investment. Finally, gross revenue at full market potential does not account for the difference in timing between costs of registration and future returns. Costs are likely to be incurred at the beginning of registration, whereas revenues will occur over multiple, future years.
- Third, PRN 97-2 applies only to registration actions on conventional pesticides. The notice specifically states that it does not apply to registrations of biopesticides and antimicrobials (e.g., disinfectants). The method described in this PRN may be used to evaluate the registration incentive for all types of products registered by each of OPP's registering divisions.

Additionally of note, EPA states in PR Notice 2018-1 that seeking minor use designation is not required as part of the pesticide registration process. It is an optional designation that an applicant can seek to obtain certain incentives associated with minor uses, such as:

- Extension of exclusive use of data under FIFRA Section 3(c)(1)(F)(ii); and
- Qualifying for an exemption from the fee or waiver of a portion of the registration service fee for an application for minor uses of a pesticide under FIFRA Section 33(b)(7)(D).

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