Draft Conditions of Registration for Aldicarb

01/06/2020

The terms and conditions of registration include the following:

1. Pollinator data requirements:
    a. Submission of all Tier II protocols by March 31, 2021 for Agency review.
    b. Submission of all Tier I pollinator data by June 30, 2022.
    c. Submission of all Tier II studies (including the final reports) by December 31, 2022.
    d. If the submission of Tier II studies is delayed due to circumstances that EPA agrees could not have been foreseen by, or are outside the control of AgLogic and the studies cannot be submitted by December 31, 2022 the registrant will let the Agency know by June 31, 2022 and will work with the Agency on a new timeline.
    e. The registrant and the Agency will work on the submission timing of any Tier III studies that are triggered.

Aldicarb Pollinator data requirements	
Guideline Number	Study (Time Frame for Submission)
Non-Guideline*	(OECD 213) Honey bee adult acute oral toxicity (12 months)
Non-Guideline*	(OECD 237) Honey bee larvae acute oral toxicity (12 months)
Non-Guideline*	Honey bee adult chronic oral toxicity (12 months)
Non-Guideline*	Honey bee larvae chronic oral toxicity (12 months)
Non-Guideline**	Residues in pollen and nectar/field residue analysis (24 months)
Non-Guideline**	(OECD 75) Semi-field testing for pollinators (tunnel or colony feeding studies) (24 months)
850.3040***	Field testing for pollinators (24 months)

*Tier 1

**Tier 2

***Tier III The need for Tier III test for pollinators will be determined based upon Tier II tests and/or other lines of data and the need for a refined pollinator risk assessment.

2. Time limited registrations Sections 3 registrations for use on oranges and grapefruit in Florida expire on the following dates:
    a. EPA Reg. No. 87895-2 orange and grapefruit use expires on April 30, 2023
    b. EPA Reg. No. 87895-4 supplemental label expired on April 30, 2021
    c. EPA Reg. No. 87895-7 registration expires on April 30, 2023.

3. An aggregated yearly summary report describing the stewardship implementation details must be submitted to the Agency by May 31st of each year for confirmatory purposes.

4. Submit annual reports to the EPA Product Manager for aldicarb orange and grapefruit registrations as stated below. In addition to required reporting in compliance with FIFRA Section 7, a copy of the most recent annual production report must be included in these annual reports to the Office of Pesticide Programs.

a. Registrations:
    i. EPA Reg. No. 87895-4 by May 31, 2021
    ii. EPA Reg. No. 87895-7 first season by May 31, 2022
    iii. EPA Reg. No. 87895-7 second season by May 31, 2023
b. Sale and distribution of aldicarb for orange and grapefruit use in Florida, is limited to 2,500,000 lbs of product per year (representing no more than 100,000 acres treated) as directed on the label.
c. If sales cap is reached prior to the end of the application season, this information will be sent to the agency no later than 30 days after the last of the product was applied.
d. Should EPA become aware that more than 2,500,000 lbs has been sold and distributed in any given year, EPA will notify AgLogic LLC and if AgLogic LLC is determined to be at fault, EPA may, at its sole discretion, allow the registration to expire within 10 days of such notification.
e. Should another company apply to register an aldicarb product for use on orange and grapefruit in Florida, the Agency will notify AgLogic so a discussion about the sales and distribution limitations can occur.

5. Registrant will maintain a robust Stewardship Plan that will include at a minimum: monitoring of product distribution orange and grapefruit application; ensuring online education and training requirements have been completed for growers, applicators, dealers and distributors; and flagging appropriate setbacks (500 or 1,000 ft.) from all wells.

6. If the registrant chooses to seek an extension for the orange and grapefruit use, you will be required to submit the request via a letter and an updated label for EPA Reg. No. 87895-7 with the proposed extension date to the agency by June 30, 2022.

   The following will be evaluated prior to approval of the request:
   a. On time submission of pollinator studies by dates listed above.
   b. Evaluation of current percent crop treated in Florida.
   c. Agency review of 6 (a)(2) submissions
   d. Any additional information received after consultation with state and federal partners to reevaluate the current risk picture for Aldicarb

If the Agency determines it will not be able to grant an extension of the registration you will be notified two months prior to the use expiring. Upon notification, you must submit revised labeling with the orange and grapefruit use removed for EPA Reg. No. 87895-2 by 1 month prior to expiration. If no revised labeling is received within that timeframe, the registration will expire on April 30, 2023.