Registration Decision for the Uses on Oranges and Grapefruit in Florida, Aldicarb

Approved by: _____

Ed Messina, Esq., Acting Director
Office of Pesticide Programs
US Environmental Protection Agency

Date: _____

RD Decision Template (Public Process) v.20171107

Table of Contents

[TOC \o "1-3" \h \z \u]

I. SUMMARY

The U.S. Environmental Protection Agency (referred to hereafter as "the EPA" or "the Agency") is conditionally registering, under section 3(c)(7)(B) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), uses for two existing pesticide registrations containing the active ingredient aldicarb. The uses registered with this decision include the following crop/use sites, restricted to the state of Florida: oranges and grapefruit. These uses amend both the manufacturing use product, MEYMIK TECHNICAL (EPA Reg. No. 87895-2; 96% aldicarb), and the granular end-use product, AGLOGIC 15GG (EPA Reg. No. 87895-4; 15% aldicarb). During the evaluation of the these products, the Agency requested the submission of a separate new product (EPA Reg. No. 87895-7; 15% aldicarb) which is labeled for use only on oranges and grapefruit in Florida, which will allow EPA to better monitor the compliance with the terms of these registrations. The Agency is amending the existing products to add these uses under FIFRA 3(c)(7)(B) as time-limited registrations with a sales and distribution cap, and an expiration date as noted in the terms of registration. The additional Florida-only product for use on oranges and grapefruit will then be registered under FIFRA 3(c)(7)(A). In order to meet agency safety standards, the EPA is requiring a sales and distribution cap of 2.5 million pounds of product on these registrations limiting the number of acres that can be treated (i.e., 100,000 acres). Furthermore, the product must be soil incorporated (3 inches or greater) to reduce runoff potential and potential for wildlife exposure, and well set-backs of 500 ft. to 1000 ft. (based on soil types as identified by the United States Department of Agriculture (USDA) Natural Resources Conservation Service) to ensure that the product does not contaminate drinking water sources. Additional conditions of these registrations are the submission of confirmatory pollinator data identified in the recent interim registration review decision, a robust registrant stewardship plan including applicator training and monitoring, and enhanced reporting of where and how much product is applied.

Aldicarb is a systemic carbamate used to control certain insects, mites, and nematodes and is currently registered for use on cotton, dry beans, peanuts, soybeans, sugar beets, and sweet potatoes. Aldicarb is formulated as a granular pesticide and is usually applied early in the growing season (pre-plant, at-plant, or early post-emergent) using ground application equipment. Aldicarb may only be applied as a soil treatment by any of the following methods: sidedress, band/T-band, and in-furrow treatment. Aldicarb is a Restricted Use Pesticide (RUP) and may only be purchased and applied by certified applicators or persons under their direct supervision. Aldicarb use on citrus crops and potatoes was voluntarily phased out in 2010 by Bayer, the initial registrant. However, the tolerances on citrus commodities remain to allow for the legal importation of crops treated with aldicarb. Since the proposed use on oranges and grapefruit is similar to the previously registered use, the cumulative exposure to the class of NMC pesticides through food would not be significantly impacted by the proposed orange and grapefruit uses for aldicarb.

The Insecticide Resistance Action Committee (IRAC) includes aldicarb in Group 1A. These new uses (oranges and grapefruit) have been added to the currently registered technical product (EPA Reg. No. 87895-2) as time-limited uses subject to the continued uses supported on an end-use product; as a time-limited supplemental label to the currently registered end-use product (EPA Reg. No. 87895-4), for use this application season (which ends on April 30, 2021); and a time-

limited registration for the new product registration (EPA Reg. No. 87895-7) for use on oranges and grapefruit in Florida, described above, for the following two application seasons. These end-use products are RUPs based on acute oral, dermal and inhalation toxicity and due to ground water contamination and may only be applied by certified commercial applicators or persons under the direct supervision of a certified applicator. The supplemental label for the currently registered end-use product may only be used on oranges and grapefruit in Florida and will expire at the end of the current application season, April 30, 2021. The new product registration (EPA Reg. No. 87895-7), which will not be sold or distributed until after the supplemental label expires, will have similar restrictions and limitations; however, in order to facilitate the implementation and tracking of the sales and distribution cap, the new product will only be registered for the use on oranges and grapefruit in Florida and will expire April 30, 2023. The maximum application rate for these end-use products on oranges and grapefruit is 33 lbs. product (4.95 lbs a.i.)/acre. The label also restricts the lowest application rate to 25 lbs. product/acre to prevent FIFRA 2(ee) use of the product on a greater number of acres. Only one application is allowed within the application season of November 15-April 30.

II. REQUESTED ACTION

In April 2019 the EPA received application from AgLogic, Inc. seeking to register the new uses of aldicarb to the end-use product containing aldicarb (CAS Number 116-06-3) on oranges and grapefruit in Florida and Texas. The Agency published the notice of receipt of the application for public comment (30 days) on December 7, 2020. During the application review, the registrant amended the request and the use was limited by amount of product that can be sold and distributed (i.e., 2,500,000 lbs product) for use during an application season (November 15 – April 30), limited to oranges and grapefruit in Florida, only, and will expire after the third application season (April 30, 2023).

III. USE PROFILE

The proposed use patterns evaluated by the EPA in the assessment of human health risks, the assessment of environmental and ecological risks and biological and economic benefits assessment are included in the approved labeling and limited by the terms of registration. These products are RUPs and applications may only be made by certified applicators or persons under the direct supervision of a certified applicator. The maximum labeled application rate for these end-use products on oranges and grapefruit is 33 lbs. product (4.95 lbs a.i.)/acre. Only one application is allowed within the application season of November 15-April 30. In addition, there are several restrictions and prohibitions for these uses on the label that must be adhered to including a specified type of application equipment, specific soil incorporation depths (minimum of 3 inches) and well set-back distances (minimum 500 feet). To minimize leaching into the water systems, the application timing begins November 15 and ends April 30 prior to the Florida rainy season. Further details on label restrictions, use patterns and terms of registration can be found on the approved labels (EPA Reg. No. 87895-2, EPA Reg. No. 87895-4 and EPA Reg. No. 87895-7) posted in the docket (Docket ID: EPA-HQ-OPP-2020-0600) and also in Pesticide Product and Label System (PPLS).

IV. EVALUATION

In evaluating a pesticide registration application, the EPA assesses a wide variety of exposure information (i.e., where and how the pesticide is used) and environmental fate (i.e., how the chemical will move in the environment) and toxicity studies (i.e., effects on humans and other non-target organisms) to determine the likelihood of adverse effects (i.e., risk) from exposures associated with the proposed use of the product. Risk assessments are developed to evaluate the environmental fate of the compound as well as how it might affect a wide range of non-target organisms including humans, terrestrial and aquatic wildlife (plants and animals). In addition, a biological and economic benefits assessment (benefits vs. risk) may be conducted. Based on these assessments, the EPA evaluates and approves language for each pesticide label to ensure the directions for use and safety measures are appropriate to mitigate any potential risk. In this way, the pesticide label communicates essential limitations and mitigations that are necessary for public safety. It is a FIFRA violation to use a pesticide in a manner inconsistent with its labeling.

The EPA requires a wide range of studies in order to assess a pesticide use scenario. For the new uses of aldicarb on oranges and grapefruit in Florida, the database of studies required to support the assessment of risk to human health is complete. A summary of the findings of the human health risk assessment are discussed below, and further details can be found in the memorandum, D453397. ***Aldicarb:*** *Human Health Risk Assessment in Support of New Uses on Oranges and Grapefruits in Florida.* Nadrchal, et.al. 01/07/2021 (Docket ID: EPA-HQ-OPP-2020-0600).

A. Assessment of Risks to Human Health[1]

1. Toxicology Profile

Aldicarb is highly acutely toxic[SEQ CHAPTER \h \r 1] *via* the oral, dermal, and inhalation routes of exposure in the acute lethality studies (Toxicity Category I). Aldicarb is not considered to be a dermal sensitizer and immunotoxicity was not observed in the available toxicity data. The acute toxicity profiles of the technical formulation (96% a.i.) and both end-use product formulations (15% a.i.) are Toxicity Category I via the oral, dermal and inhalation routes of exposure. Based on these toxicity profiles, the signal words are "DANGER/POISON" for these products.

Aldicarb is classified as Category E, Evidence of Non-Carcinogenicity for Humans, based on the lack of evidence of carcinogenicity in rats and mice studies and the absence of a mutagenicity concern. A quantitative cancer risk assessment is not required.

The aldicarb human health risk assessment is based on the most sensitive endpoints in the toxicity database. The endpoint for all exposure scenarios is red blood cells (RBC) acetylcholinesterase (AChEI), and points of departure (PODs) were selected from a human oral study. The POD for the acute dietary (all populations) exposure scenario was 0.013 mg/kg/day; no POD was selected for chronic dietary exposure because the magnitude of AChEI does not

[1]D453397; ***Aldicarb:*** *Human Health Risk Assessment in Support of New Uses on Oranges and Grapefruits in Florida.* D. Nadrchal, et.al.; 01/07/2021.

increase with continued exposure due to the reversibility of AChEI (< 24 hours). There are no chronic toxic effects more sensitive than AChEI. The POD selected for the dermal and inhalation worker scenarios was also 0.013 mg/kg/day based on the same study.

Since a human study was used to derive the RBC AChEI endpoint, the interspecies uncertainty factor is reduced from 10X to 1X; the intraspecies uncertainty factor is retained at 10X. A non-guideline Comparative Cholinesterase Assay (CCA) is available showing pups to be 4.8X more sensitive than adult animals for AChEI; thus, a data-derived FQPA safety factor is retained for infants and children. No increased susceptibility was observed in fetuses. Because of the rapid onset and recovery of the enzyme following carbamate exposure, in contrast to the irreversible binding and permanent inhibition of the bound enzyme that occurs following OP exposure, an additional safety factor is not warranted for the aldicarb. Therefore, the combined safety factor for dietary and aggregate assessment is 48X to assure protection of infants and children, and for adult occupational assessment is 10X.

N-methyl carbamates like aldicarb share the ability to inhibit AChE through carbamylation of the serine residue on the enzyme leading to accumulation of acetylcholine and ultimately cholinergic neurotoxicity.

Endpoints used in these analyses can be found in the supporting memorandum.

2. Percent Crop Treated Analysis[2]

The percent crop treated (PCT), based on the proposed sales and distribution limitation proposed by the registrant, allows for a maximum of ~100,000 total orange and grapefruit acres across Florida to be treated with aldicarb annually while taking into account total US orange and grapefruit production and the potential for orange and grapefruit imports to be treated with aldicarb. This PCT also accounts for a projected decline in Florida orange acreage to estimate national PCT values for the proposed uses on orange and grapefruit in Florida through 2023, when the proposed registrations would expire. Therefore, the PCT used in support of the orange and grapefruit uses will be protective of the actual current acreage treated.

The maximum percent crop treated estimates of orange, 13%; orange juice, 63%; grapefruit, 13%; and grapefruit juice, 16% were used in the acute dietary risk assessment. Other residue refinements are described in supporting memos.

3. Dietary (Food + Water) Risks[3]

The acute dietary exposure assessment for aldicarb is highly refined and conducted for food and drinking water. This assessment incorporated an estimated half-life for RBC AChE1 of two

---

[2] D454270; *Aldicarb (PC #098301) Use on Oranges and Grapefruit: Benefits, Estimated Percent Crop Treated (PCT), Response to Registrant Comments, and Soil Incorporation Depth.* J. Hansel, et.al.; 01/07/2021

[3] D453397; ***Aldicarb:*** *Human Health Risk Assessment in Support of New Uses on Oranges and Grapefruits in Florida.* D. Nadrchal, et.al.; 01/07/2021.

hours which is based on data from rats and human subjects. The EPA refined the acute dietary risk from food and drinking water by using an eating occasion approach which considers each individual eating occasion as a source of exposure as opposed to conducting the assessment based on the total amount of food consumed throughout the day. This is then used to estimate exposures and risks by factoring in the AChE1 half-life related to multiple aldicarb dietary exposures throughout a day. Pesticide Data Program (PDP) monitoring data for imported potatoes only were used; residues from domestic potato samples were not included in the analysis since use on potatoes is no longer registered in the U.S. Moreover, the PDP monitoring data for the affected commodities from the new uses on orange and grapefruit have been further refined by the percent crop treated (PCT) based on the limitation of use on 100,000 acres in Florida. Based on these refinements, the probabilistic dietary exposure assessments for aldicarb show that food and water exposures do not exceed the EPA's level of concern for any population subgroup at the 99.9th percentile of exposure, when aldicarb is applied at a minimum soil incorporation of 3 inches, minimum well set-backs of 500 ft., and following sales and distribution limits for orange and grapefruit. These dietary assessments show that the general U.S. population occupies 43% of the acute population adjusted dose (aPAD), while the most highly exposed population subgroup, children 1-2 years old, occupies 95% aPAD.

4. Occupational Handlers Risks

The aldicarb product label allows for either open pour/open cab applications (with personal protective equipment (PPE)) or closed loading/closed cab applications (i.e., engineering controls). The granular aldicarb products are considered low dust materials, due to their substrate, and result in reduced exposure levels relative to the high dust formulations for which exposure data are available for closed loading/closed cab applications. Chemical- and formulation-specific handler exposure data (MRID 43852501) are available in support of open pour/open cab application scenarios for "low dust" aldicarb formulations. The EPA relied on the chemical-specific data for unit exposures for open pour/open cab applications. For the closed loading/closed cab scenarios, the EPA relied on available Occupational Pesticide Handler Exposure Data as surrogate data [specifically, the Pesticide Handlers Exposure Database (PHED)].

For the open pour/open cab application scenarios, using chemical-specific unit exposure data, representative of a single layer of clothing, gloves, and, for mixer/loaders only, a standard filtering facepiece respirator, there are no combined dermal and inhalation risk estimates of concern (i.e., margins of exposure (MOEs) are $\geq$ 10).

For the closed loading/closed cab application scenarios, using available surrogate PHED unit exposure data for engineering controls, all combined dermal and inhalation risk resulted in estimates of ~~are of~~ concern (i.e., MOEs < 10). However, e~~E~~xposure and risk estimates for handlers using closed systems are considered overestimates as the PHED surrogate unit exposures are not representative of the low dust aldicarb formulations. The closed loading scenario data are representative of liquid formulations and the closed cab applicator scenario data are representative of typical granular formulations. Where exposure exceedances exist, the combined risk estimates are driven by dermal exposure. It should be noted that an assumption of 100% dermal absorption was used in the dermal exposure/risk calculations since an acceptable

dermal absorption study was not submitted. Given that the registered product is a granular formulation, it is unlikely that 100% dermal absorption would occur.

A quantitative occupational post-application dermal assessment was not conducted for aldicarb since aldicarb is incorporated into the soil and there is limited potential for exposure to workers from soil incorporated pesticides. Based on the Agency's current practices, a quantitative non-cancer occupational post-application inhalation exposure assessment was not performed for aldicarb at this time. However, if new policies or procedures are implemented, the Agency may revisit the need for a quantitative occupational post-application inhalation exposure assessment for aldicarb.

5. Residential Risks

There are currently no registered residential uses of aldicarb; therefore, a quantitative residential handler and post-application assessment was not conducted.

6. Aggregate Risk

In accordance with the Food Quality Protection Act (FQPA), the EPA must consider and aggregate pesticide exposures and risks from three major sources: food, drinking water, and residential exposures. In an aggregate assessment, exposures from relevant sources are added together and compared to quantitative estimates of hazard, or the risks themselves can be aggregated. When aggregating exposures and risks from various sources, the EPA considers both the route and duration of exposure.

There are no residential uses of aldicarb. Therefore, aggregate risks include only acute dietary contributions. The acute dietary risk estimates for food plus drinking water are not of concern when aldicarb is applied to oranges and grapefruit following the use pattern described in Section III, which includes minimum soil incorporation of 3 inches, minimum well set-backs of 500 ft. and no more than 100,000 acres treated (95% of the aPAD for children 1-2 years old, the most highly exposed population subgroup).

7. Cumulative Risk

The FQPA requires the Agency to consider the cumulative risks of chemicals sharing a common mechanism of toxicity. Aldicarb is a member of the NMC common mechanism group. NMCs like aldicarb share the ability to inhibit AChE through carbamylation of the serine residue on the enzyme leading to accumulation of acetylcholine and ultimately cholinergic neurotoxicity. This shared MOA/AOP is the basis for the NMC common mechanism grouping per OPP's *Guidance For Identifying Pesticide Chemicals and Other Substances that have a Common Mechanism of Toxicity* (USEPA, 1999). The 2007 Cumulative Risk Assessment (CRA) and the subsequent revision used brain AChEI in female rats as the source of dose response data for the relative potency factors and PODs for each NMC, including aldicarb.

Exposure to aldicarb based on the previously active registration on citrus was included in the 2007 *N*-Methyl Carbamate Cumulative Risk Assessment (NMC CRA)[4]. Since the proposed use on oranges and grapefruit is similar to the previously registered use, the cumulative exposure to the class of NMC pesticides through food would not be significantly impacted by the proposed orange and grapefruit uses for aldicarb. For the 2007 NMC CRA, food exposure to aldicarb was estimated based on measured pesticide residues in orange, orange juice, and grapefruit[5]. For the most sensitive subpopulation, children 1-2 years old, the food exposure to aldicarb for these citrus foods was minimal for those at high-end of the exposure distribution. Furthermore, assuming a 3 inch soil incorporation depth and a minimum 500 ft drinking water well set-backs, exposure through drinking water residues resulting from the proposed use would not contribute significantly to the cumulative risk. Therefore, no new cumulative assessment is required at this time.

B. Assessment of Environmental and Ecological Risks[6]

Ecological risk characterization integrates the results of the exposure and ecotoxicity data to evaluate the likelihood of adverse ecological effects. The means of integrating the results of exposure and ecotoxicity data is called the quotient method. For this method, risk quotients (RQs) are calculated by dividing exposure estimates by ecotoxicity values, both acute and chronic (RQ = Exposures/Toxicity). RQs are then compared to the EPA's levels of concern (LOCs). The LOCs are criteria used by the EPA to indicate potential risk to non-target organisms. The criteria indicate whether a pesticide, when used as directed, has the potential to cause adverse effects to non-target organisms.

The battery of tests required to assess the environmental fate and ecological effects of aldicarb is sufficient for conducting the risk assessments and developing regulatory determinations pertaining to the current and proposed uses, but additionally required data will help confirm risk conclusions and better able the agency to further understand ecological risks from aldicarb's use.. Additional information on the environmental fate profile of aldicarb can be found in the previous risk assessment for agricultural uses (Reregistration Eligibility Decision, USEPA 2006 and Registration Review Risk Assessment, USEPA 2015[7]). Previous risk assessments identified the lack of Tier I honey bee data as an uncertainty. In EPA's risk assessment evaluation for the proposed use on oranges and grapefruit, EPA conservatively assessed potential risk to bees using

---

[4] http://itrcweb.org/FileCabinet/GetFile?fileID=6883

[5] USDA's PDP collects thousands of food samples annually and analyzes these samples for residues of hundreds of pesticides. Residue data from PDP was used to estimate food exposure for the NMC CRA. PDP found a number of detectable residues of aldicarb or its metabolites in grapefruit, orange, and orange juice. More specifically, the number of detectable residues (and years sampled) were 4 out of 1462 grapefruit samples with concentrations <= 0.063 ppm (2005-2006); 13 out of 4864 orange sample with concentration <= 0.025 ppm (1994-1996, 2000-2001, & 2004-2005); and 46 out of 2879 orange juice samples with concentrations <= 0.035 ppm (1997-1998 & 2004-2006).

[6] D453398; *Aldicarb– Proposed Section 3 New Use Registration for Oranges and Grapefruit Crops in Florida.* W. Wagman, et.al.; 01/07/2021

7 USEPA. 2006. EFED Aldicarb Ecological Risk Assessment (RED). Environmental Fate and Effects Division, Office of Pesticide Programs, Office of Prevention, Pesticides, and Toxic Substances. Washington, D.C. September, 2006.
USEPA. 2015. Preliminary Ecological Risk Assessment for Registration Review of Aldicarb. Environmental Fate and Effects Division, Office of Pesticide Programs, Offices of Chemical Safety and Pollution Prevention. Washington, D.C. October 6, 2015. D424563.

the most sensitive available toxicity data for structurally similar surrogate chemicals and conservative estimates of exposure based on aldicarb's fate properties and Tier I screening level residue modeling. EPA is calling in aldicarb-specific bee toxicity and exposure information in order to confirm risk conclusions based on the use of surrogate toxicity data and to refine the risk assessment for bees exposed to aldicarb from use on citrus.

1. Environmental Effects

The anticipated effects of the new uses of aldicarb on oranges and grapefruit in Florida do not substantially differ from those described in the EPA's previous risk assessments for agricultural uses (USEPA 2006; USEPA 2015) based on existing information. The proposed use rates for oranges and grapefruit are not higher than previously assessed for other registered use sites. Additionally, since aldicarb was previously registered for use on citrus, it is anticipated that the ecological risks would be the same as during the previous registration. The exception to this may be for potential risk to honey bees, as while there are other registered uses of aldicarb that are considered bee-attractive, due to the lack of honey bee data, potential risk to honey bees beyond acute contact exposures were not previously assessed. Therefore, a conservative Tier I risk assessment for honey bees was conducted for this proposed action.

The EPA expects acute and chronic risks for birds (and reptiles and terrestrial-phase amphibians, for which birds are considered surrogates) and mammals consuming granules and fish and aquatic invertebrates exposed to aldicarb residues in runoff from dissolved granules. Ingestion of a single granule is sufficient to result in mortality to birds and mammals. Given the high application rate, the level of risk is anticipated to be more similar to risks previously identified for sugar beets than for use sites with lower application rates. Incorporation of granules at application helps reduce the consumption opportunities of birds and mammals.

For potential risks to aquatic organisms, although incorporation of the granules will reduce runoff of aldicarb into nearby aquatic systems, it will not eliminate runoff exposure. Based on the previous risk conclusions in the Registration Review draft risk assessment[8], even with only 0.1% of the compound available (99.9% incorporated, based on banded/sidedress and in-furrow application), all fish and aquatic invertebrate acute and chronic RQs calculated exceed LOCs for current uses.

As identified in the previous risk assessment for agricultural uses and consistent with the mechanism of action and target taxa (insects), aldicarb is highly toxic to bees on an acute contact basis. Contact exposure and risk are not expected for honey bees for the proposed uses on oranges and grapefruit since the pesticide granules will be incorporated into the soil. Other soil dwelling bees and other beneficial invertebrates living in the soil could experience contact exposures to aldicarb.

Although aldicarb has only granule applications which limits contact with bees, it is a systemic pesticide that may be available to honey bees in citrus pollen and nectar. Orange and grapefruit

[8] Available at: [HYPERLINK "https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0161-0021"]. Docket ID: EPA-HQ-OPP-2012-0161-0021

trees produce highly attractive pollen and nectar for honey bees (USDA 2017). Based on the conservative risk assessment using the most sensitive data available for surrogate carbamate chemicals and conservative modeling of residues, EPA concludes there is potential acute and chronic dietary risk to adult bees and chronic dietary risk to larval bees. It is noted that these risk conclusions would be consistent for other registered uses of aldicarb that are bee attractive and have the same application rate. Submission of the following Tier I honey bee toxicity data using aldicarb would provide confirmatory data for potential aldicarb risks to honey bees (and other bee species): 1) Non-guideline, OECD TG 213 (Tier I): Honey bee adult acute oral toxicity; 2) Non-guideline, OECD TG 237 (Tier I): Honey bee larvae acute toxicity; 3) Non-guideline, OECD TG 245 (Tier I): Honey bee adult chronic oral toxicity; and 4) Non-guideline, OECD Guidance Document 239 (Tier I): Honey bee larvae chronic toxicity. Moreover, based on the consideration of the most sensitive data available for surrogate carbamate chemicals for the screening level risk assessment, submission of Tier II data on empirical residues in orange and/or grapefruit and Tier II semi-field testing for pollinators studies are required for further refinement of the risk assessment. Submission of Tier III data (850.3040) will be required if needed based on the Tier II results.

C. Alternatives and Benefits Assessment[9]

Orange and grapefruit growers in Florida and Texas are facing significant pressure to mitigate the effects of the Asian citrus psyllid (ACP)-vectored bacterial disease Huanglongbing (HLB) because infection leads to yield losses and eventual tree death. ACP is considered the most important pest of citrus worldwide. Researchers from the University of Florida, Institute of Food and Agricultural Sciences estimated that there are $1.75 billion in cumulative losses in the value of production in Florida citrus that are due to HLB over a 10 year period, growing seasons from 2006/7 to 2015/16, which is an average annual loss of $175 million. Additionally, it should be noted that the annual magnitude of these losses in individual years has been increasing, with over $670 million in losses estimated in 2015/16. This is equivalent to about 80% of the expected value of production if HLB did not exist. Efforts to slow the transmission of HLB to trees is dependent on managing populations of ACP. There are approximately 30 active ingredients registered for use on grapefruit and oranges in Florida and Texas that manage ACP. However, the continued decline of grapefruit and orange acreage in these states indicates that ACP and HLB are still problematic and these currently available controls do not sufficiently manage ACP. One benefit of aldicarb is that when it was previously registered for use on oranges and grapefruit, aldicarb was recommended by the Florida Citrus Pest Management Guide for control of ACP and was known to provide "good" control (the highest rating assigned). Field data highlight aldicarb's efficacy of killing ACP in treated trees versus untreated trees. However, BEAD does not anticipate that aldicarb will completely control ACP. When it was previously registered, aldicarb did not completely control ACP. Orange and grapefruit acreage continued to decline after the 2005 introduction of HLB in Florida due to the continued spread of the pathogen and pest during the previous registration. Moreover, it will only be possible to treat less

[9] D454270; *Aldicarb (PC #098301) Use on Oranges and Grapefruit (DP #454270): Benefits, Estimated Percent Crop Treated (PCT) for use In Risk Assessments and Anticipated Impacts of Mitigation.* J. Hansel, et.al.; 01/07/2021.

than half of citrus acres in Florida with this registration due to production and sales caps, which will limit annual usage, thus, the potential of aldicarb to control ACP, state-wide.

There is one other carbamate, carbaryl, registered in Florida for ACP, and while it once had a "good" rating against ACP, it is currently acknowledged to provide "short term" control of this pest. Relative to untreated trees, carbaryl provides on average two to 16 days of control of ACP nymphs and adults, respectively. The 2020-2021 Florida Citrus Production Guide does not list carbaryl as a recommended chemical control of ACP. The registration of aldicarb would make it the only carbamate that provides "good" control of ACP. Based on the extension literature, carbaryl is not considered an effective management tool for ACP, and rotation with aldicarb, another recommended mode of action, will assist with insecticide resistance management. Finally, aldicarb's activity against ACP on mature trees can last on average 10 and 15 weeks for nymphs and adults, respectively. This is a benefit relative to any of the foliar-applied chemicals that at most have an average of four to eight weeks of activity in controlling ACP.

Aldicarb also provides control of other pests. It provides "good" control of two economically important groups of plant-feeding mite pests; rust and spider mites. The only other chemicals that provide "good" control of both mite groups are other selective (i.e., kills only mites) chemicals. This benefit signifies that a single chemical controls two pests, which reduces the need to apply chemicals multiple times or tank mixing multiple chemicals. Spider mites, in particular, are prone to develop miticide resistance. Therefore, for mite management, aldicarb is another chemical group that could reduce miticide resistance pressure.

The proposed aldicarb label for orange and grapefruit also includes suppression of citrus nematode, which may be beneficial; however, as commercial citrus growers use grafted citrus plants with nematode-resistant rootstocks, EPA does not expect citrus nematode to be an important target pest for aldicarb applications.

Finally, aldicarb has a "low" impact on some natural enemy (i.e., predatory) insects (i.e., ladybeetles) and spiders found on the foliage of trees compared to many of the other insecticides and miticides in use in Florida. Minimizing the negative effects on natural enemies is important because of the biological control services that these predators confer against other plant-feeding pests.

V. PUBLIC COMMENTS

On December 7, 2020, the EPA published a Notice of Receipt in the Federal Register of an application for registration of proposed uses of aldicarb on oranges and grapefruit in Florida and announced a public comment period of 30 days. 43 comments were posted to the docket. The Agency's response to these comments can be found in Docket ID: EPA-HQ-OPP-2020-0600.

VI. REGULATORY DECISION

In accordance with FIFRA, the EPA may register a pesticide conditionally to permit additional uses, even if the data concerning the pesticide may be insufficient to support an unconditional registration, if the Agency determines that the applicant has submitted satisfactory data

pertaining to the proposed additional use(s); and amending the registration in the manner proposed by the applicant would not significantly increase the risk of any unreasonable effect on the environment. This conditional determination also considers the economic, social, and environmental costs and benefits of the use of the pesticide. Under FIFRA, the EPA is charged with balancing risks posed by using a pesticide against its benefits. For the EPA to register a pesticide use, the EPA must determine that the benefits of its use outweigh the risks.

A. Rationale and Risk Mitigation

The EPA is conditionally approving the uses on oranges and grapefruit to the products MEYMIK TECHNICAL (EPA Reg. No. 87895-2), AGLOGIC 15GG (EPA Reg. No. 87895-4) and AGLOGIC 15GG OG (EPA Reg. No. 87895-7). These conditional, time-limited registrations will allow for a narrow use of aldicarb on oranges and grapefruit in Florida to help in the control of certain insects, mites, and nematodes, including ACP.

In conditionally approving these new uses for the existing products under FIFRA section 3(c)(7)(B), the EPA has determined that there is insufficient data to register these uses unconditionally. The EPA identified in the Interim Registration Review Decision (ID)[10], a need for additional data to assess aldicarb's effects on bees. In the ID, the Agency identified several non-guideline Tier I and Tier II/III studies (including Acute oral toxicity to adult honey bees; Chronic oral toxicity to adult honey bees; Acute oral toxicity to larval honey bees; Chronic oral toxicity to larval honey bees; and Semi-field and full field colony-level studies) that represent data gaps in the aldicarb database. As aldicarb-specific data are still not available, for this decision, EPA has used the most sensitive data available for surrogate carbamate chemicals and conservative modeling of residues to calculate risk estimates for this use. Using this approach, EPA concludes that it has satisfactory data to assess the orange and grapefruit uses. EPA is conditioning this approval on submission of the data listed above to confirm the characterization of the toxicity of aldicarb to pollinators.

While confirmatory data has been made a condition of registration for these uses on orange and grapefruit, the EPA does not believe that the approval of these narrow uses (up to 100,000 acres), with label mitigation requiring soil incorporation at greater than 3 inches and minimum 500 ft. drinking water well set-backs, will significantly increase the risk of any unreasonable adverse effects on the environment. The toxicity database for aldicarb is complete for assessing risk to human health. The database used to assess the risk to the environment and pertaining to the proposed new uses is satisfactory for moving forward with conditional registration. Based on the conservative risk assessment EPA performed for this use, the levels of risk to pollinators identified here are unlikely to be substantially different than for other use patterns already registered for aldicarb (that did not previously have risk quantified). Additionally, based on the restricted use pattern allowed for these new uses, the EPA has not identified any risks of concern regarding human health.

The current ecological risk assessment for these new uses also indicated potential risks to bees; however, although oranges and grapefruit are bee-attractive crops, they do not require managed

[10] EPA-HQ-OPP-2012-0161-0101

bees for pollination and there will be limited spatial exposure to pollinators expected from the narrow use that will be allowed (i.e., ~100,000 acres in Florida). EPA concludes that the risks to bees are not unreasonable in light of the benefits to the citrus industry in combatting ACP.

FIFRA is the risk-benefits law under which EPA regulates the use of pesticides. The EPA must balance the potential exposures to humans (e.g., worker exposure) and the environment against the benefits (economic, social and environmental) that use of the pesticide will provide to the agricultural community. As such, these uses of aldicarb, while limited, will provide the Florida citrus industry with a critical tool for control of ACP. Aldicarb will also play a key role in IPM. The potential exposures to non-target taxa which may occur is offset by the benefits of increased control of ACP in struggling orange and grapefruit groves which many growers in the Florida citrus industry are experiencing.

The EPA is requiring the submission of non-guideline Tier I pollinator data and Tier II residue and semi-field studies in conjunction with these new uses on oranges and grapefruit, to better characterize the potential risk to pollinators. While there remain some potential risks to non-target taxa due to possible exposure to aldicarb and its degradates from these new registrations, the EPA concludes that the new uses of aldicarb meet the criteria for conditional registration under FIFRA section 3(c)(7)(B) for EPA Reg. No. 87895-2 and EPA Reg. No. 87895-4, provided all of terms of registration are complied with and completed. Additionally, EPA Reg. No. 87895-7 is substantially similar to EPA 87895-4, thus will be subsequently registered conditionally under FIFRA section 3(c)(7)(A).

B. Terms and Conditions of Registration

As part of its decision to register aldicarb on orange and grapefruit in Florida, the registrant has agreed to certain terms as elements of the registration. These terms will include a time-limited registration for the new uses, a sales and distribution cap, stewardship plan, and submission of non-guideline pollinator studies.

Registration Expiration

EPA's determination that the benefits of the use of aldicarb on orange and grapefruit in Florida outweigh the potential risks is based in part on the requirement that orange and grapefruit uses are only registered for a limited time. The supplemental label for EPA Registration Numbers 87895-4, which contains the orange and grapefruit use, automatically expires on April 30, 2021. For the second and third application seasons, EPA Registration Number 87895-7 will be the only registered end-use product for orange and grapefruit use and the registration automatically expires on April 30, 2023. The registrant has agreed to remove the uses from EPA Reg. No. 87895-2 if the uses for oranges and grapefruit are not extended.

As noted in Section IV.C of this decision, approving the registration of aldicarb use on orange and grapefruit in Florida until April 30, 2023, will enable citrus growers to have continued access for at least a limited time for a tool that is important to control ACP, while simultaneously allowing EPA and the state of Florida to monitor the effectiveness of the mitigation, stewardship, and evaluation of the current percent crop treated in Florida for the orange and grapefruit uses.

Data Requirements

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
Non-Guideline*	(OECD 213) Honey bee adult acute oral toxicity
Non-Guideline*	(OECD 237) Honey bee larvae acute oral toxicity
Non-Guideline*	Honey bee adult chronic oral toxicity
Non-Guideline*	Honey bee larvae chronic oral toxicity
Non-Guideline**	Residues in pollen and nectar/field residue analysis
Non-Guideline**	(OECD 75) Semi-field testing for pollinators (tunnel or colony feeding studies)
850.3040***	Field testing for pollinators
*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.	

Annual Reporting

The Agency is requiring annual reporting of both the implementing of the stewardship plan and the sale and distribution of the end use products. No reporting is required of the technical product since the registrant holds all current U.S. registrations for aldicarb. The aggregated yearly summary report of the stewardship plan must be submitted to the Agency by May 31st of each year for confirmatory purposes.

They must also submit annual reports to the EPA Product Manager for the 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.

Reporting dates seperated by end use product registrations:

EPA Reg. No. 87895-4 by May 31, 2021
EPA Reg. No. 87895-7 first season by May 31, 2022
EPA Reg. No. 87895-7 second season by May 31, 2023

Sales and Distribution Requirements as agreed upon by the registrant.

a. 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.
b. 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 sold and distributed.
c. 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 may, at its sole discretion, allow the registration to expire within 10 days of such notification.
d. 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.

Aldicarb Stewardship Plan

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 (minimum of 500 ft..) from all wells.

C. Label Requirements

Use Parameters and Restrictions on Technical label (EPA Reg. No. 87895-2)

- Registration of the new uses (orange and grapefruit) is conditional upon the continued registration of the uses on the end-use products.

Use Parameters and Restrictions on End-Use label (Supplemental label EPA Reg. No. 87895-4) and (EPA Reg. No. 87895-7)

Environmental Hazards:

- This product is potentially toxic to honey bees through translocated residues in pollen and nectar.

Product Restrictions:

- Restricted use pesticide
  - For retail sale to and use only by Certified Applicators or persons under the direct supervision of a Certified Applicator, and only for those uses covered by the Certified Applicator's Certification.
- Labels have use, sale and distribution expiration dates corresponding to application seasons.
- REI: 48 hours

Elements to Reduce Environmental Exposure:

GROUND WATER RESTRICTIONS

- Observe Environmental Hazard statements regarding Decomposition and Movement in Soil, and carefully follow Directions for Use.
- In fields having soils with less than 15% field moisture holding capacity, special care must be taken not to over-irrigate, since over-irrigation promotes the leaching of chemicals.
- **Do not apply within 500 feet of any drinking water well used for human consumption. See the *Environmental Precautions and Soil Type Restriction Tables.***
- Do not wash, load or empty application equipment near any well, as this practice is a potential source of ground water contamination.

RESTRICTIONS FOR ORANGES AND GRAPEFRUIT

- **Only for use in Florida.**
- **DO NOT USE ON ANY CROP OTHER THAN ORANGES AND GRAPEFRUIT IN FLORIDA**.
- Do not apply more than once during the use season between November 15 through April 30 not to exceed 33 pounds of product (4.95 lbs a.i.) per acre per year.
- Do not apply at a rate of less than 25 pounds of product per acre.
- Do not make more than one application to any tree per use season.
- Do not allow livestock to graze in treated areas.
- Granules must be applied and immediately covered with 3 inches or greater of soil.
- Application must only be made using motorized ground application equipment which use Positive Displacement Metering Units. All other application methods, including aircraft, backpack spreaders, or push-type spreaders are prohibited.
- Required application equipment must be calibrated and adjusted to ensure proper rate and accurate placement. Application equipment must be cleaned thoroughly after use. For any leftover material, see instructions for STORAGE AND DISPOSAL in this booklet.
- Only make applications of the product to oranges and grapefruit with applicators which use Positive Displacement Metering Units.
- Apply only during the time period (November 15 through April 30) and at sites for which written or electronic authorization has been issued by the Florida Department of Agriculture and Consumer Services (FDACS).
- Do not apply within 500 feet of any drinking water well used for human consumption.
- Do not apply within 1,000 feet of any drinking water well used for human consumption on any soil series identified by the USDA Natural Resources Conservation Service as a highly permeable well-drained soil such as (but not limited to): Adamsville, Archbold, Astatula, Candler, Cassia, Lake, Neilhurst, Orsino, Palm Beach, Paola, Satellite, St. Lucie, and Tavares. The 1,000-foot setback requirement shall not apply to drinking water wells used for human consumption for which the permit applicant has furnished the Florida Department of Agriculture and Consumer Services with well construction documentation confirming that the well is continuously cased to a depth of at least 100 feet below the ground surface or at least to a minimum depth of 30 feet below the top of the shallowest water-producing zone recognized at the time of well construction.

<u>Elements to Reduce Exposure to Handlers:</u>

Personal Protective Equipment (PPE) for Handlers NOT Using Closed Loading Systems
Personal Protective Equipment (PPE):
All handlers (including mixers, loaders and applicators) must wear a minimum of coveralls over a long-sleeved shirt and long pants, chemical-resistant gloves made of any waterproof material, and chemical-resistant footwear plus socks. In addition, during mixing and loading, equipment cleaning or repair, spill cleanup, or other handling activities, handlers must wear protective eyewear (goggles or face shield), a chemical-resistant apron, and use a NIOSH approved particulate respirator with any N, R, or P filter; with NIOSH approval number prefix TC-84A; or a NIOSH approved powered air purifying respirator with HE filter with NIOSH approval number TC-21C.

Engineering Controls for Enclosed Cab Vehicles:
Applicators using an enclosed cab that meets the definition in the Worker Protection Standard for Agricultural Pesticides [40 CFR 170.240(d)(5)] may wear reduced personal protective equipment provided they wear a long-sleeved shirt, long pants, and shoes plus socks and, are provided, have immediately available, and use in an emergency, such as a broken package, spill, or equipment breakdown: chemical-resistant gloves made of any waterproof material, a chemical-resistant apron, chemical-resistant footwear, protective eyewear (goggles or face shield), and a NIOSH approved particulate respirator with any N, R, or P filter with NIOSH approval number prefix TC-84A, or a NIOSH-approved powered air purifying respirator with HE filter with NIOSH approval number TC-21C. Applicators must take off any PPE that was worn in the treated area before reentering the cab, and store all such PPE in a chemical-resistant container, such as a plastic bag, to prevent contamination of the inside of the cab.

VII. SUPPORTING DOCUMENTS

All supporting documents can be found in docket ID number EPA-HQ-OPP-2020-0600 at regulations.gov.