UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

MEMORANDUM

SUBJECT: Response to Comments Received to the Aldicarb New Uses on Oranges and Grapefruit in Florida Notice of Receipt (NOR)

DATE: 01/12/2021

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DOCKET: Aldicarb; uses of aldicarb on oranges and grapefruit in Florida and Texas (EPA-HQ-OPP-2020-0600)

Summary

On 12/06/2020, the EPA published a Notice of Receipt (NOR) in the Federal Register (Docket ID Number EPA-HQ-OPP-2020-0600) of applications for registration of the new uses of oranges and grapefruit in Florida for the active ingredient, aldicarb and announced a public comment period of 30 days. The comment period closed on 01/06/2021.

During the comment period, the Agency received 8,017 comments from stakeholders, non-governmental organizations, the US Department of Agriculture (USDA), Florida Fruit and Vegetable Association (FFVA) and members of the general public. A mass signature campaign represented 7975 signatures to one letter. Additionally, there were 43 unique comments received from various stakeholders and the public.

The Agency is posting this *Response to Comments* (RTC) document to address substantive comments received on the proposed decision to register the new aldicarb uses. The Agency is only addressing comments received to the docket that relate to the proposed uses of aldicarb on oranges and grapefruit in Florida and Texas. This RTC document combines comments by topic, when possible and also responds to some individual stakeholders. Please note that several of the comments received on the proposed use are substantively similar to comments received to the Pesticide Reevaluation Division (PRD) registration review docket for aldicarb. The PRD

response to comments will be viewable at www.regulations.gov under docket ID # EPA-HQ-OPP-2012-0161.

The Agency considered all of these comments and submissions and responded to the substantive comments in this document. The comments and submissions received to the public docket did not result in changes to the Agency's risk assessments or the mitigation applied to the approved label as listed in decision document. The Agency thanks all commenters for their comments and submissions.

Public Comments and Agency Responses

I. List of Public Commenters

a. Anonymous; private citizens and individual citrus growers, citrus grove mangers and former aldicarb certified applicators with personal stories
b. Citrus Groups, Groves and Associations: Winter Haven Citrus Growers Association, Wm. G. Roe & Sons - Noble Worldwide, Tamiami Citrus, LLC, McGillicutty Groves, McKenna Brothers, Inc., Dixie Bell, Ben Hill Griffin, Inc., Consolidated Citrus, Gulf Citrus Growers, Keith Davis Groves, Highlands County Citrus Growers Association, Inc., Florida Citrus Mutual, Texas Citrus Mutual, Florida Farm Bureau Federation, Graves Brothers Company
c. Chemical Company: AgLogic Chemical, LLC
d. Specialty Crop Organization: Florida Fruit and Vegetable Association (FFVA)
e. Non-Governmental Organizations (NGOs): Center for Biological Diversity (CBD), Earthjustice, Environmental Working Group
f. Federal Government: US Department of Agriculture (USDA)

II. List of Mass Comment Campaigns

a. U.S. Public Interest Research Group - 7975 signatures

III. Responses to Comments

A. General support of the proposed registration of aldicarb use on oranges and grapefruit in Florida.

Description of Comments: The Agency received supportive comments from USDA, FFVA, Citrus Groups, Citrus Groves and Associations, individual citrus growers, citrus grove mangers and former aldicarb certified applicators. The comments focused on the general benefits of the proposed use of aldicarb on oranges and grapefruit. Commenters noted:

- the destruction to citrus crops by citrus greening disease/huanglongbing disease (HLB) vectored by the Asian citrus psyllid (ACP) and the economic risk posed to the citrus industry

- past effectiveness of aldicarb use before voluntary cancelation use of aldicarb use on citrus
- effective nematode control and increased plant health
- critical asset to improve tree health and fight HLB

Highlights from the supportive comments:

FFVA stated:
"Prior to its voluntary removal from the market, a significant segment of Florida's citrus production industry relied on aldicarb to provide acceptable pest management, high yields and high quality fruit for the marketplace, while simultaneously helping to assure competitiveness in this highly sophisticated industry. Aldicarb was a cornerstone and foundation of immediate and long-term sustainable production for citrus crops."

"Historical research has shown that net returns for mature citrus trees that receive an aldicarb application can be as much as $500 greater per acre (± 25%) than net returns for identical acreage that uses alternative pest control options."

"Significant increases in yields are also noted following application of aldicarb in older and under-performing groves as well, because of the confirmed plant growth regulator effects aldicarb exhibits on citrus trees."

"Because of the proposed type of application methodology, where the active ingredient is only located well below the surface of the soil, potential exposure by birds and other terrestrial organisms is not possible."

"Ground and surface water monitoring programs, which were in place for many years in Florida when aldicarb was originally registered for this citrus use, failed to observe any threatening detections of aldicarb"

USDA stated:
"Like other carbamates, aldicarb inhibits acetylcholinesterase, thus causing neuro-toxic paralysis in target insects and also has very good efficacy against nematodes. Prior to cancellation, aldicarb had historically been used on citrus for soil-applied nematode management and broad-spectrum insect control within established integrated pest management (IPM) programs."

"The primary benefit of aldicarb use on citrus is expected to be for control of citrus nematodes (Diepenbrock and Stelinski, 2020), with some side benefits also possible via incidental control of sap-feeding pests such as aphids, leafminers, mealybugs, and Asian citrus psyllid (ACP) (Qureshi and Stansley, 2008). Prior to cancellation, aldicarb was the most widely used nematicide in Florida citrus (AMRD, 1998-2014). Historically, it has been observed by many citrus IPM experts that aldicarb use also provides an observable improvement of overall tree health, though the reasons for this particular impact are difficult to quantify (Aerts, 2020; Diepenbrock and Stelinski, 2020)."

"We urge EPA to consider how the proposed legal and voluntary restrictions around this restored use might provide an added measure of precaution for potential exposure of groundwater and for protection of applicators and other agricultural workers."

EPA Response:
The Agency agrees that HLB has had a devastating impact on the citrus industry and agrees that tools are necessary to mitigate its negative effects. While aldicarb does not control HLB, aldicarb helps manage the Asian Citrus Psyllid (ACP) that vectors the disease. The Agency concludes that citrus growers would immediately benefit from the availability of aldicarb to help decrease the impact ACP has on transmitting HLB to orange and grapefruit trees in Florida. With regards to the application method, while incorporation will reduce potential aquatic and terrestrial exposure, it will not completely eliminate potential exposures, and this was considered in the human health and ecological risk assessments.

B. Opposition to the proposed registration of aldicarb use on oranges and grapefruit in Florida will be seperated into several overarching areas.

1. The CBD Comments (presented in summary form):
CBD submitted the following comments to the docket in response to the NOR.

CBD Comment #1:
Comply with duties under Section 7 of the Endangered Species Act (ESA), including completion of consultation on all synergistic and cumulative uses.

EPA Response:
OPP's ecological risk assessment process is based on EPA's Guidelines for Ecological Risk Assessment (https://www.epa.gov/risk/guidelines-ecological-risk-assessment) and consists of a comprehensive, robust, and peer-reviewed process that considers extensive environmental fate and ecological effects data used to evaluate the potential ecological exposure and impacts of a pesticide in the environment. This risk assessment is conducted to support the overall decision making for the final pesticidal use.

In November 2013, the EPA, along with the U.S. Fish & Wildlife Service (USFWS), the National Marine Fisheries Service (NMFS) (collectively, the Services), and the U.S. Department of Agriculture (USDA) released a summary of their joint Interim Approaches for assessing risks to Federally listed threatened and endangered species (collectively, listed species) from pesticides. The Interim Approaches were developed jointly by the agencies in response to the National Academy of Sciences' (NAS) recommendations and reflect a common approach to risk assessment shared by the agencies as a way of addressing scientific differences between the EPA and the Services. The NAS report outlines recommendations on specific scientific and technical issues related to the development of pesticide risk assessments that EPA and the Services must conduct in connection with their obligations under the Endangered Species Act (ESA) and FIFRA.

The details of the joint Interim Approaches are contained in the white paper "*Interim Approaches*

for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report," dated November 1, 2013.

Since that time, EPA has conducted biological evaluations (BEs) on three pilot chemicals representing the first nationwide pesticide consultations (final pilot BEs for chlorpyrifos, malathion, and diazinon were completed in January 2017). These initial pilot consultations were envisioned to be the start of an iterative process. The agencies are continuing to work to improve the consultation process. For example, after receiving input from the Services and USDA on proposed revisions to the pilot interim method and after consideration of public comments received, EPA released an updated *Revised Method for National Level Listed Species Biological Evaluations of Conventional Pesticides* (i.e., Revised Method) in March 2020 (https://www.epa.gov/endangered-species/revised-method-national-level-listed-peciesbiological-evaluations-conventional).

EPA also released draft BEs for several active ingredients, including carbaryl and methomyl, which were the first to be conducted using the Revised Method. Also, a provision in the December 2018 Farm Bill included the establishment of a FIFRA Interagency Working Group to provide recommendations for improving the consultation process required under section 7 of the Endangered Species Act for pesticide registration and Registration Review and to increase opportunities for stakeholder input. This group includes representation from EPA, NMFS, FWS, USDA, and the Council on Environmental Quality (CEQ). Given this new law and that the first nationwide pesticide consultations were envisioned as pilots, the agencies are continuing to work collaboratively as consistent with the congressional intent of this new statutory provision. EPA has been tasked with a lead role in this group, and EPA hosted the first Principals Working Group meeting on June 6, 2019.

Given that the agencies are continuing to develop and work toward implementation of the Interim Approaches to assess the potential risks of pesticides to listed species and their designated critical habitat, the risk assessment for aldicarb does not include a complete ESA analysis and effects determinations for specific listed species or their designated critical habitat. With respect to the evaluation of aldicarb and as explained in the final decision, current evaluation of existing data indicate that the ecological risks exhibited by the new uses on oranges and grapefruit are largely similar to those determined in previous risk assessments. The labels require that granules be incorporated to at least 3 inches, reducing risk to wildlife and the potential for runoff. 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). The new uses on oranges and grapefruit will have a limited footprint and are contingent upon submission of confirmatory pollinator data. As the EPA reviews the new studies, the EPA will reevaluate the terms of registration and determine whether additional use restrictions are necessary.

CBD Comment #2:
Require that the registrant provide all necessary data and studies.

EPA Response:
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 on orange and grapefruit is satisfactory for moving forward with conditional registration. All required 40 CFR Part 158 guideline data are available for aldicarb. 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. The submission of the non-guideline studies will expand our understanding of how aldicarb use may impact pollinators.

CBD Comment #3:
Incorporate necessary factors (effects on ESA listed species, effects on pollinators and other beneficial insects, endocrine disruption, and cumulative or synergistic effects) into evaluation and any proposed decision.

EPA Response:
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. Cumulative exposure to aldicarb from these new uses is based on the previously active registration on citrus was included in the 2007 N-Methyl Carbamate Cumulative Risk Assessment (NMC CRA). 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 new 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. 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, based on the 3-inch soil incorporation depth and 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. With regards to synergistic effects as mentioned above see response to CBD comment #1 and #7.

CBD Comment #4:
Place appropriate restrictions on uses to avoid and minimize adverse effects.

EPA Response:
Based on all available data and our own assessments, the Agency has determined that use of aldicarb on oranges and grapefruit in Florida according to the approved label directions and

terms of registration limiting the use to no more than 100,000 acres per use season will not significntly increase the risk of unreasonable adverse effects on the environment.

Resistance management language has been incorporated into the label language to not only help maximize the effectiveness of tools available for growers but to reduce pesticide loading in the environment and human exposure to pesticides and to minimize adverse effects. Restrictions and mitigation necessary to protect human health and the environment from unreasonable adverse effects are included on the final labels.

CBD Comment #5:
The EPA must support any assertion that products with new active ingredients are "safer" or that they will actually replace older pesticide use.

EPA Response:
Aldicarb is not a new active ingredient. There are no claims or assertions that aldicarb is "safer" than or will replace other chemistries. The longer broad-spectrum activity and longer residual control may lessen the need for the application of additional chemistries for the same pests.

CBD Comment #6:
The EPA must take into account real-world scenarios.

EPA Response:
The Agency does take into account real-world scenarios from both ecological and human health perspectives. Ecological estimates of exposure are generally conservative and following a tiered approach, the exposure estimates may be refined as higher levels of realism are needed (more details on the process and models used in risk assessment are available in *USEPA. 2004a. Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs;* https://www.epa.gov/sites/production/files/2014-11/documents/ecorisk-overview.pdf). Aquatic exposure estimates utilize high-end modeling inputs with respect to mobility and degradation and are based on a reasonably conservative conceptual model of a standard ecological water body. Monitoring data rarely detect or report values that are above modeling values used in risk assessment. Terrestrial exposure estimates are based on field data and, therefore, represent real-world exposure values. They also represent high-end values from the distribution such that higher exposure values are expected to be rare. However, misuse or accidental exposures are speculative and are not specifically modelled but may be considered when appropriate for the action. Both state and federal agencies enforce pesticide label requirements. A state has primary enforcement responsibilities for pesticide use violations if EPA determines that such state has adopted and is implementing adequate pesticide use laws and regulations, enforcement procedures, and recordkeeping and reporting requirements. Potential areas of environmental justice concerns, to the extent possible, were considered in this human health risk assessment, in accordance with U.S. Executive Order 12898, "Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations," (https://www.archives.gov/files/federal-register/executive-orders/pdf/12898.pdf).

As a part of every human health risk assessment, the Agency considers a large variety of consumer subgroups according to well-established procedures. In line with the Agency policy,

risks to population subgroups from pesticide exposures are estimated based on patterns of that subgroup's food and water consumption, and activities in and around the home that involve pesticide use in a residential setting. Extensive data on food consumption patterns are compiled by the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA) and are used in pesticide risk assessments for all registered food uses of a pesticide. These data are analyzed and categorized by subgroups based on age and ethnic group. Moreover, the Agency is able to assess dietary exposure to smaller, specialized subgroups and exposure assessments are performed when conditions or circumstances warrant. Whenever appropriate, non-dietary exposures based on home use of pesticide products and associated risks for adult applicators and for toddlers, youths, and adults entering or playing on treated areas post-application are evaluated.

CBD Comment #7:
The EPA must assess the enhanced toxicity of pesticide mixtures.

EPA Response:
EPA believes synergism to be a rare event, and intends to follow the National Research Council's recommendation for government agencies to proceed with estimating effects of pesticide mixtures with the assumption that the components have additive effects in the absence of any data to support the hypotheses of a synergistic interaction between pesticide active ingredients. This is not a liquid formula or a wettable powder and the label does not contain directions for use in tank mixes or the incorporation of or other non-pesticidal components before application. The end use products that will be amended or registered with this action only contain a single active ingredient and both are granular formulations that will be soil incorporated. The application also requires specialized equipment. EPA has carefully assessed the potential risk concerns to all populations and added mitigation to the label to be protective. Additionally, most pesticide products contain substances in addition to the active ingredient (known as inert ingredients) which aid in the performance and effectiveness of the pesticide product. All active and inert ingredients must also be approved by the agency when a product is first registered. The agency has evaluated the hazard potential (i.e., toxicity) of aldicarb and any inert ingredients with a battery of toxicity data from a multitude of studies throughout the risk assessment process.

CBD Comment #8:
While EPA did not make the Section 3 application available for this comment period (which really hampers the ability for the public to provide input), we can only assume the same issues remain.

EPA Response:
The Agency published a Notice of Receipt as required by FIFRA 3(c)(4), which makes the application available for public comment. Based on all available data and our own assessments, the Agency has determined that use of aldicarb on oranges and grapefruit in Florida, according to the approved label directions and terms of registration limiting the use to no more than 100,000 acres per use season, will not significntly increase the risk of unreasonable adverse effects on the environment. Due to the critical nature of HLB, which is vectored by ACP, the Agency

determined that is was important to make a regulatory decision to assist the orange and grapefruit growers so they were fully aware of what pest management options would be available to them this growing season.

CBD Comment #9:
The EPA must analyze the true costs of registering new uses of aldicarb as outlined in the recent 9th Circuit Court of Appeals 2020 ruling on dicamba.

EPA Response:
The Agency appropriately considered the costs and impacts of approving this use. While potential ecological risks to bees were identified, pollinator data will be required as a condition of registration. Therefore, the Agency was able to determine that benefits outweigh any identified risks for the proposed orange and grapefruit uses in Florida as described in the Decision Document.

CBD Comment #10:
Furthermore, if EPA believes it has identified label mitigations that reduces risk to a reasonable level, the agency must take into account how feasible those mitigations are and whether it is reasonable to assume they will be followed. The 9th Circuit Court of Appeals recently vacated EPA's registration of multiple dicamba products, in part, because the label was too complex and non-compliance was all but certain. Therefore, EPA cannot simply pile restrictions onto a label without first analyzing whether those restrictions are reasonably expected to be followed.

EPA Response:
The Agency has worked with other federal partners and state agencies to make sure the mitigation required for the new use was enforceable and could be easily understood by growers and stakeholders. Additionally, the product must be applied with specialized equipment (calibrated to provide the proper amount of product at a soil depth of 3 inches or greater), and can only be administered by certified applicators (and those under their direct supervision).

CBD Comment #11:
In a previous FIFRA "Special Local Needs" application in 2018 by AgLogic LLC to the state of Florida, AgLogic asked for support from EPA in its quest for 24(c) approval. The EPA subsequently chose not to support AgLogic's application due to the agency being unable to ensure its use would be safe. Now that AgLogic has applied for a FIFRA section 3 new use approval for aldicarb, the same issues remain.

EPA Response:
With this action the EPA is only evaluating the FIFRA Section 3 application, and prior submissions to the Agency are beyond the scope of this action. Therefore, the Agency has made the appropriate findings to approve the orange and grapefruit uses per FIFRA 3(c)(7)(B).

CBD Comment #12:
Aldicarb is banned in more than 100 countries, one of only 36 pesticides that is classified as "extremely hazardous" by the World Health Organization, and one of only 35 pesticides subject to regulation under the Rotterdam Convention, an international treaty designed to reduce trade of the most hazardous chemicals in the world.

EPA Response:
The agency is aware of the status of aldicarb internationally. With regard to human health and ecological risks, EPA determines whether a pesticide can be registered based not solely on the hazard or toxicity associated with the chemical, but on the risk associated with its use. In assessing human health and ecological risk, the agency considers both hazard and exposure. For aldicarb, dietary and drinking water exposures resulting from use of the pesticide are sufficiently low that there are no aggregate risk concerns. Also, significant personal protective equipment (PPE) or engineering controls are required to limit risks to agricultural workers. The potential risks 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 experienced. However, 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.

3. Commenter #44: Earth Justice
In summary Earth Justice cited aldicarb risk of concerns from drinking water exposure, aldicarb's risks to workers, and urged the Agency to reject the application and not register any additional uses. Earth Justice refers to their comments previously submitted in 2016 on EPA's human health risk assessment for aldicarb about neurotoxicity associated with exposure to carbamates, including aldicarb and asked that the contents of that entire docket be used to inform the Agency's decision in consideration of the registration of these new uses.

EPA Response:
With the exception of "EPA should revoke all tolerances because of unacceptable food and drinking water risks" and "EPA must conduct a cumulative organophosphate risk assessment and assess cumulative risk associated with organophosphate-carbamate mixtures", many of the comment received on the proposed use are substantially similar to comments received to the Pesticide Reevaluation Division (PRD) registration review docket for aldicarb. The PRD response to comments will be viewable at www.regulations.gov under docket ID # EPA-HQ-OPP-0161-0092.

The agency has conducted a comprehensive human health risk assessment which includes assessing food, drinking water, and aggregate risks to aldicarb, and concluded that there are no aggregate risks of concern associated with the proposed or existing uses of the chemical. Regarding cumulative risk assessment, 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 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. The agency has determined that N-methyl carbamates and organophosphates do not share a common mode of toxicity because, among other reasons, of the rapid reversibility of cholinesterase binding for N-methyl carbamates relative to organophosphates. Therefore, a cumulative risk assessment was not performed combining exposures from these different common mechanism groups.

Exposure to aldicarb based on the previously active registration on citrus was included in the 2007 *N*-Methyl Carbamate Cumulative Risk Assessment (NMC CRA). Since the proposed uses on oranges and grapefruit is a subset of the previously evaluated citrus uses, the cumulative exposure to the class of NMC pesticides through food would not be significantly impacted by the proposed citrus use for aldicarb. For the 2007 NMC CRA, food exposure to aldicarb was estimated based on measured pesticide residues in orange, orange juice, and grapefruit[1]. 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, similarities in well set-backs and use rates along with a 3-inch incorporation depth, exposure through drinking water residues resulting from the proposed use would not contribute significantly to the cumulative risk.

Additionally, the Health Effects Division has been working on toxicity-adjusted dietary index for the NMC pesticides, which tracks changes in exposure estimates over time based on measured pesticide residue data collected annually by USDA PDP. The dietary exposure index was adjusted for the differences in toxicity between the NMC pesticides using the same relative potency factors documented in the NMC cumulative risk assessment report. This draft toxicity-adjusted dietary indicator indexes NMC food exposures to 100 for the baseline year 2006. The dietary index indicates exposure to NMCs through food decreased ~50% from 2006 to 2015 based on reduction in residues observed in USDA PDP data. In more recent years, PDP residues on orange (2009-2010 & 2015), orange juice (2011-2012) and grapefruit (2015) have minimal impact on the 99.9th percentile of exposure for children 1-2 years old. To determine the potential impact of the proposed aldicarb citrus use on cumulative food exposure, HED included the years of PDP residues data with the highest residues in the dietary index: orange (2005), orange juice (2005), and grapefruit (2006). Including aldicarb citrus residue from PDP with the highest observed residues did not significantly impact exposure (~0.1%) at the 99.9th percentile of exposure for children 1-2 years old.

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[1] 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).

4. Commenter #51: The Environmental Working Group

The Environmental Working Group, or EWG, a nonprofit research and policy organization with offices in Washington, D.C., Minneapolis, Minn., San Francisco and Sacramento, Calif., urges the Environmental Protection Agency to reject the proposed new uses of aldicarb on oranges and grapefruit in Florida and Texas. Aldicarb is a neurotoxic insecticide that can cause acetylcholinesterase inhibition, a toxicity target shared by other neurotoxic pesticides, including organophosphates. In 2010, as part of the human health risk assessment, aldicarb use on citrus and potatoes was identified as a concern for children's health. Subsequently, the EPA signed a Memorandum of Agreement with the aldicarb manufacturer at the time, Bayer CropScience LLC, to phase out its use, with the uses that can cause the greatest public health risk, application on potatoes and citrus, ended immediately after this EPA-Bayer voluntary agreement.
In a striking reversal of the public health protections, new registrations by another pesticide manufacturer, Ag Logic, for use of this pesticide on peanuts, cotton, sugar beets, sweet potatoes and dry beans were approved in 2011, and aldicarb use continued, as did the resulting aldicarb contamination of drinking water. This development was made possible by the fact that the EPA did not ban aldicarb outright, an action that was and is warranted, given the pesticide's neurotoxicity, its ability to contaminate ground water sources and its risks to children's health.

In the 2016 human health risk assessment, the EPA estimated that aldicarb levels in food and drinking water exceeded by nearly 3,000 percent the safe levels of exposure to aldicarb for infants less than one year old. According to the U.S. Geological Survey, approximately 0.1 to 0.2 million pounds of aldicarb were used in 2017, mostly on cotton, primarily in southeastern states and Texas. Additionally, drinking water testing by community water systems documented that more than 900,000 people who rely on public water supplies had detectable levels of aldicarb sulfoxide in their drinking water between 2015 and 2017. Some of these detections were above 0.87 parts per billion, the value the EPA identified as potentially causing risk when combined with dietary exposures. Importantly, this value is likely too high, since the EPA reduced the Food Quality Protection Act tenfold safety factor, despite acknowledgement of increased susceptibility to the neurotoxic effects of aldicarb during early development, noted in the 2016 human health risk assessment.

Given the risks to children's health from aldicarb, it is unacceptable to consider new proposed uses of this insecticide that have already been phased out, namely those on citrus. To protect human health and the environment, the EPA should deny the proposed new uses and cancel all uses of aldicarb. Thank you for the opportunity to comment. Submitted on behalf of the Environmental Working Group,

EPA Response:

Human health risks, as noted in your comment, associated with a pesticide's use are a function of both the toxicity and the exposure to a pesticide. The currently proposed use, as well as currently registered uses, have sufficient safeguards included on the pesticide labels such that dietary and aggregate risks are below the agency's level of concern. For the proposed use on citrus, these safeguards include a limit on the number of acres that can be treated, a requirement for a 3-inch incorporation depth to minimize run-off into surface water, and a well set-back to minimize contamination of groundwater used for human consumption. With these label requirements in

place, there are no dietary or aggregate risk concerns for aldicarb related to the proposed or existing uses.

2. Commenter U.S. Public Interest Research Group: Letter Campaign – 7975 signatures

"I strongly oppose expanding the use of the pesticide aldicarb to 400,000 acres of citrus trees in Florida and Texas. Decades of evidence demonstrate aldicarb's dangers to public health. The insecticide is known to contaminate drinking water and leave residues on food. High levels of exposure to aldicarb can cause brain damage in children. Aldicarb is banned in 100 countries, and it's considered "extremely hazardous" by the World Health Organization. The U.S. must maintain aldicarb restrictions to keep the public safe. I urge the Environmental Protection Agency to deny this application and maintain current restrictions on aldicarb."

EPA Response:

The agency is aware of the status of aldicarb internationally. EPA determines whether a pesticide can be registered based not solely on the hazard or toxicity associated with the chemical, but on the risk associated with its use. In assessing risk, the agency considers both hazard and exposure – if there is no exposure, there is no risk. For aldicarb, dietary and aggregate exposures resulting from use of the pesticide are sufficiently low that there are no risk concerns, and therefore the chemical may be safely registered for these uses. For the proposed use on citrus, safeguards are in place to limit exposure to the pesticide including a limit on the number of acres that can be treated, a requirement for a 3-inch incorporation depth to minimize run-off into surface water, and a minimum 500-ft well set-back to minimize contamination of groundwater used for human consumption. With these label requirements in place, there are no aggregate risk concerns for aldicarb related to the proposed or existing uses.

It important to note that Aldicarb is not being registered for use in Texas and the amount of product allowed for use per application season is constrained to approximately 100K acres in Florida, thereby limiting overall exposure and risk if registered for greater acreage. The aldicarb human health risk assessment is based on the most sensitive endpoints in the toxicity database. 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. Aldicarb is only being registered for use in Florida on orange and grapefruit crops. Additionally, to minimize potential runoff to surface water drinking water sources, the product must be soil incorporated (3 inches or greater), and to minimize leaching into the groundwater, minimum well setback restrictions of 500 – 1000 ft. are imposed to minimize exposure to groundwater drinking water sources.

5. Individual Commenters: Anonymous (2X); G. Bottoms; Christopher Lish; B. Kel

Individual commenters provided additional criticism to the application to register aldicarb on oranges and grapefruit in FL and TX citing: broad concerns for children's developing nervous systems and sensitivities to neurotoxins; effects of aldicarb toxicity and impact on gastrointestinal pathogenesis; aldicarb's diminishing global use; and, aldicarb's contribution to the poisoning of humans and overall negative impact on the environment.

EPA Response:
The agency has extensive toxicity data for aldicarb, including data on the specific toxicity to developing young. A data-derived Food Quality Protection Act (FQPA) safety factor of 4.8X was applied to account for the increased susceptibility of the young to the neurotoxic effects of aldicarb. Furthermore, an additional 10X safety factor to account for variability in susceptibility across the population was also applied. The toxic effect upon which the human health risk assessment is based is neurotoxicity (RBC cholinesterase inhibition) seen in human volunteers in a human toxicity study, thus minimizing the uncertainty introduced by using results from laboratory animals to assess health concern to humans. The exposure estimates used to assess risk will not underestimate people's exposures. Incorporating all of this information into a comprehensive risk assessment shows no risks of concern related to the proposed or registered uses of aldicarb for any population, including infants and children. With regard to the environmental fate and effects, the EPA does not believe that the approval of these narrow uses (up to 100,000 acres), will significantly increase the risk of any unreasonable adverse effects on the environment.

EPA is aware of the international status of aldicarb, but again notes that the agency regulates based not solely on hazard, but on the risk associated with a pesticide's use, i.e., the consideration of both the toxicity and exposure to the pesticide. Dietary and aggregate risks for aldicarb based on the proposed use, including label-required restrictions to minimize exposure, are not of concern that would alter overall risk conclusions. Also, significant personal protective equipment (PPE) or engineering controls are required to limit risks to agricultural workers. The agency is also aware of poisonings related to aldicarb exposure but notes that these have typically resulted from misuse of the chemical.

It important to note that Aldicarb is not being registered for use in Texas and the amount of product allowed for use per application season is severely constrained to approximately 100K acres in Florida, thereby limiting overall exposure and risk than if registered for greater acreage. With regard to aldicarb's suggested impact on gut flora and gastrointestinal fortitude, gut microbiomes (colonies of microbes in the gut) are unlikely to be altered from aldicarb exposure since the aromatic amino acids produced via the Shikimate pathway are also available in the human gut via the diet since humans are unable to synthesize them. Therefore, despite inhibition of this metabolic pathway, the microorganisms are still capable of growing and surviving. Gut microbiomes are not evaluated directly in guideline toxicity studies; however, the stomach and gastrointestinal tract are routinely examined in several studies by gross evaluation and histopathological investigations. There are no indications in these studies that exposure to aldicarb induces adverse effects in those organs.

The Agency also recognizes that some individuals believe that pesticides should be banned on agricultural crops. As part of the FIFRA finding, EPA has determined that the existing tolerances for oranges and grapefruit tolerances meet this safety finding therefore the Agency has made the appropriate findings to approve the orange and grapefruit uses per FIFRA 3(c)(7)(B). The commenter has provided no information that would support a determination that these tolerances are unsafe.