UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

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Dear Mr. Rathvon and Ms. Rose:

I am writing to follow up on our meeting on July 26, 2018, as well as responding to your letter dated July 2, 2018. The meeting and the letter requested support for a FIFRA Section 24(c) Special Local Need registration (SLN) for AgLogic 15GG to control Asian citrus psyllid, citrus rust mites, spider mites, aphids, and nematodes on Florida citrus.

In the meeting and in your letter, AgLogic presented the impact of citrus greening disease on growers and the potential role of aldicarb as an available pesticide tool, the history and risk associated with aldicarb, and the State of Florida's advice regarding AgLogic's request for a SLN on Florida citrus. Specifically, your letter noted that the state of Florida does not wish to submit the 24(c) application to the Agency "unless it is assured that EPA will not disapprove it." As we discussed in the meeting, the Agency's primary concern is that the expansion of use, when combined with the exposures from all existing uses of aldicarb, may raise the risk over the Agency's level of concern. As a result, 24(c) registrations are not likely to be an appropriate means for this particular use expansion; please refer to EPA's guidance on FIFRA 24(c) Registrations found at https://www.epa.gov/pesticide-registration/guidance-fifra-24c-registrations#General%20Policies.

The Agency understands the importance of controlling citrus greening disease in Florida citrus and is hopeful that new chemistries, new growing techniques, planting with greening-tolerant rootstocks, continued hybridization of citrus trees, cybrids, nutritional supplements, and biological controls will continue to be developed to help manage citrus greening. EPA has worked to advance and expedite many new technologies under FIFRA to support the industry and producers in its response to this severe issue. For instance, EPA has worked with impacted states on several Special Local Needs and emergency exemptions projects. Also, EPA has worked with registrants and approved several section 3 labels that are indicated for the Asian citrus psyllid vector. Going forward, EPA views the review and safety evaluation of new technologies that can support the citrus greening response as a high priority.

In terms of the registration and regulatory history, on August 16, 2010, Bayer and the EPA signed a memorandum of agreement in which the use of aldicarb on citrus (and on potatoes) was to be cancelled immediately because these uses were the greatest contributors to risk These results are described in the August 4, 2010 revised aggregate dietary assessment (available at regulations.gov under EPA-HQ-OPP-2005-0163-0250.) As a result, the last date on which any existing products containing aldicarb could be used legally on citrus was on May 9, 2012 (77 FR 27226). The cancellation of the citrus and potato uses was necessary because the magnitude of the residues found in USDA Pesticide Database Program (PDP) data on oranges and potatoes was such that residues from food consumption alone could not meet the acceptable levels without removal of both citrus and potatoes, per the same 2010 dietary assessment.

The Agency is now evaluating aldicarb in the registration review process. The revised acute aggregate dietary (food and drinking water) exposure and risk assessments were completed on November 28, 2017 and posted to the aldicarb docket on February 27, 2018 (EPA-HQ-OPP-2012-0161-0102). The aldicarb food-only dietary exposure estimate is currently at 74% of the acute level of concern for children 1-2 years old (the most highly exposed subgroup). The residues of aldicarb on citrus was considered only in imported citrus because the use on domestic citrus has been cancelled. With the comments received, the Agency updated the maximum percent crop treated estimates for imported orange and orange juice and they are at 3% and 20%, respectively. In the meeting, AgLogic stated that it assumed in its assessment there is no aldicarb use on imported oranges and orange juice. This contradicts the information EPA received from the Deputy Director for Certification and Recognition of the Mexican General Directorate for Food, Fisheries and Aquaculture Safety, Ms. Alma Liliana Tovar Díaz, MSc. In her August 17, 2017 e-mail to EPA, the Deputy Director indicated that aldicarb "has a registration in Mexico with number INAC-0103-001-005-015, belonging to Bayer de México, S.A. de C.V.," with a number of uses that includes citrus and potato. If AgLogic has information that supports its assumption regarding the aldicarb use on imported citrus, please provide it to the Agency at your earliest convenience.

When combining food consumption with the estimated drinking water exposure, the total exposure was close to 30 times greater than allowable exposure in the acute risk threshold. The Agency could make a safety finding during registration review only because the existing aldicarb uses are concentrated in geographic areas with significantly less vulnerable groundwater resources than those simulated by the Agency's model. Unlike the existing uses, however, Florida citrus is grown in an area highly vulnerable to groundwater exposure. The Agency would not be able to apply the same risk characterization mentioned above to Florida citrus. In addition, concentrations detected in ground-water monitoring data for aldicarb were in line with the concentrations simulated in the exposure modeling, further indicating that registration of aldicarb on citrus would prevent the Agency from making a safety finding.

During our meeting, AgLogic's expert, Dr. Beth Mileson, described her acute aggregate dietary assessment that was submitted to the Agency. While Dr. Mileson used the same modeling methods as the Agency in her assessment of potential aldicarb use on citrus in Florida, there were some key modeling input differences. One such input was a maximum drinking-water concentration of 0.001 microgram per liter, which was derived from a ground-water exposure assessment performed by the consulting firm Waterborne. Given the similarity of modeling

inputs described in Waterborne's report, it appeared that the maximum drinking-water concentration may have resulted from a different simulated lateral ground-water flow velocity from a treated field to a drinking-water well. The Agency's Environmental Fate and Effects Division determined through a back-calculation that Waterborne may have used a lateral flow velocity of 0.3 ft/day, as opposed to the 1 ft/day in the Agency's assessment. If AgLogic has information that supports this lateral flow velocity as representative of the PRZM-GW scenario for central Florida, please provide it to the Agency at your earliest convenience.

Dr. Mileson's conclusion that the expanded use of aldicarb on citrus would not result in unacceptable acute aggregate dietary exposure also hinged on the assumption that aldicarb would not be used in imported citrus or be applied to more than 20% of the citrus crop nationwide. The 20% assumption was based on the historical percentage of the citrus crop which had been treated with aldicarb before this use was voluntarily cancelled, and the percentage of citrus nationwide which is currently grown in Florida. Given the grower affidavits AgLogic provided with its letter to the Agency, which detailed both the widespread threat of citrus greening, and the ability of aldicarb to increase citrus yield, it seems likely that the historical use of aldicarb might underestimate the percentage of citrus which would be treated if the registration of aldicarb on citrus were re-established.

In summary, the Agency's assessments conducted to date indicate it is unlikely that the program could make a safety finding for the dietary assessment if registration of use of aldicarb on oranges were to be pursued. However, it may be appropriate to revise this assessment if AgLogic can provide information to support (1) the key modeling inputs mentioned above used in Dr. Mileson's acute aggregate dietary assessment, (2) proof that aldicarb is no longer registered or used in Mexico, and (3) justification for why future use of aldicarb on citrus will not exceed 20% of the national citrus crop.

If you have any additional questions, please do not hesitate to contact Mike Goodis, Director of Registration Division at 703-308-8157 or Yu-Ting Guilaran, Director of Pesticide Re-evaluation Division at 703-308-0052. Thank you.

Sincerely,

Edward J. Messina for

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cc:

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