MCFA

Minor Crop Farmer Alliance

December 21, 2016

Via Email and Docket Submission (yu-ting.guilaran@epa.gov)

Ms. Yu-Ting Guilaran, PE
Director, Pesticide Re-Evaluation Division
Office of Pesticide Programs
USEPA Headquarters
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1200 Pennsylvania Avenue, N.W.
Mail Code: 7508P
Washington, DC 20460

Re: Registration Review: Draft Malathion Human Health Risk Assessment; Notice of Availability, Docket Identification Number EPA-HQ-OPP-2009-0317—Comments

Dear Ms. Guilaran:

These comments on the subject draft Malathion human health risk assessment (HHRA), the availability of which was published in the Federal Register on September 22, 2016 (81 Fed. Reg. 65,354-56) are submitted on behalf of the members of the Minor Crop Farmer Alliance (MCFA).[1]

MCFA is an alliance of national and regional organizations and individuals representing growers, shippers, packers, handlers and processors of various agricultural commodities, including food, fiber, turf grass, nursery and landscape crops, and organizations involved with public health pesticides. Our members are extremely interested in the development and safe use of pest management tools including crop protection chemicals that are environmentally sound, safe for applicators and workers, and do not represent an unreasonable adverse risk to the environment, including humans.

While our commodities are often called "minor crops" or "specialty crops," they contribute to the diversity and highly nutritious diets available for the global population and to safe and

[1] On November 14, 2016 MCFA filed a request for a 60-day extension of the comment period. Other affected stakeholders filed similar extension requests. The Agency ultimately decided to extend the comment period only for half of the time MCFA requested. As a result, the comment period closes on December 21, 2016. There were simply many relevant background documents (such as the FQPA safety factor memorandum, the dietary risk assessment and the justification for the application of the FQPA uncertainty factor) that the Agency did not make readily available until November. Consequently, MCFA's members continue to believe that extending the comment period for the original 60 days requested is in the public interest. In view of the complexities and issues involved in the assessment, the full 60-day extension is warranted. Even at this juncture, MCFA renews its request for extension of the comment period.

aesthetic surroundings for our homes, schools, and places of business. U.S. farmers grow more than 500 types of fruit, vegetable, tree nut, flower, ornamental nursery and turf grass crops in addition to the major bulk (row) commodity crops. Specialty crop production accounts for more than $60 billion, or approximately 40% of total U.S. crop receipts.

Malathion is a broad spectrum non-systemic insecticide used on a number of commercial agriculture crops. These include:

Alfalfa; apricot; asparagus; avocado; barley; bean (succulent and dry); beets (table); birdsfoot trefoil; blackberry; blueberry; boysenberry; broccoli; broccoli rabe; Brussels sprout; cabbage (including Chinese); carrot; cauliflower; celery; chayote; cherry; chestnut; clover; collards; corn (field; sweet; and pop); cotton; cucumber; currant; dandelion; date; dewberry; eggplant; endive; escarole; potato; fig; garlic; gooseberry; grape; grapefruit; guava; hay grass; hops; horseradish; kale; kohlrabi; kumquat; leek; lemon; lespedeza; lettuce (head and leaf); lime; loganberry; lupine; macadamia nut; mango; melon; mint; mushroom; mustard greens; nectarines; oats; okra; onion; orange; papaya; parsley; parsnip; passion fruit; pea; peach; pear; pecan; pepper; pineapple; pumpkin; radish; raspberry; rice; rutabaga; rye; salsify; shallot; sorghum; spinach; spring wheat; squash; strawberry; sweet potato; Swiss chard; tangelo; tangerine; tomato (including tomatillo); turnip; vetch; walnut; watercress; watermelon; wheat (spring, and winter); wild rice; and yams.

Other uses include, for example, on commercial ornamental nursery stock and in helping to protect against various public health diseases, including Zika, West Nile, etc. It is a key component of various Integrated Pest Management (IPM) programs. It also has important quarantine uses either by itself or in combination with other products. These uses include, for example, treating for the cherry fruit fly as well as controlling the spotted winged drosophila in various commodities including blueberries, caneberries and strawberries. It is a very cost-effective product with relatively short restricted entry intervals and pre-harvest intervals. Clearly the product is important to agriculture and public health sectors.

In our view, the draft HHRA needs substantial revision before it is finalized. The draft HHRA is complex, employing new models and risk assessment approaches and involves important scientific policy issues. Of particular concern is the Agency's reliance on the epidemiological paper prepared by researchers associated with Columbia University on Chlorpyrifos, which apparently created an uncertainty within the Agency over the continued use of cholinesterase inhibition as the appropriate regulatory endpoint for protecting against neurodevelopmental effects. This has translated into the Agency maintaining the FQPA 10x uncertainty factor in its Malathion HHRA. We believe that EPA's approach lacks merit. The Agency's use of the Columbia paper was the subject of the recent Science Advisory Panel (SAP) review requested by the Agency. It was abundantly clear to all observers at the SAP meeting that the SAP members believed that the Columbia paper did not support the approach the Agency was trying to take. The SAP members noted strongly how the paper was not only inconsistent internally, but it also suffered from a major defect: the underlying data purportedly supporting its conclusions were not made available for review by the Agency and interested stakeholders. For some reason, that deficiency—which we believe is fatal—has not prevented the Agency from relying on the paper

for regulatory purposes.[2] As the record currently exists, it is not clear at all that any participant involved in the Columbia paper was exposed to Malathion, or if exposed, the level and duration of that exposure.

From a true science based perspective, the Agency should continue to rely on the numerous GLP laboratory animal studies that EPA has required to support the registration of Malathion and that justify the use of red-blood cell cholinesterase inhibition as the appropriate endpoint for the regulation of Malathion. The Agency has full access to the underlying data involved in those studies. The level at which that inhibition may occur is sufficiently protective of human health, including potential to cause neurodevelopmental effects.

The maintenance of the 10x FQPA uncertainty factor has significant impacts on the continued availability of many uses of the product.[3] We continue to believe it should be reduced or eliminated. Additionally, we understand that at least one of the registrants (FMC) is working with the Agency in building a physiologically based pharmacokinetic (PBPK) model that will potentially reduce the "standard" 100x uncertainty factor (10x interspecies uncertainty factor to reflect the sensitivities between test animals and man, and 10x intraspecies uncertainty factor to reflect sensitivities between humans). Prior to any final decision regarding the tolerances for this chemical, the Agency should fully consider the results of such a model and determine whether those uncertainty factors can be reduced or eliminated.

MCFA is also concerned about the Agency's drinking water assessment. We know that there are thousands of results from actual water monitoring sampling for Malathion. Those results demonstrate that Malathion is not a source of concern in drinking water. The Agency has seemingly ignored those actual results in favor of water modeling results that are built on a cascade of conservative assumptions. The Agency's model assumes the worst possible input parameters such as (a) taking soils with the highest potential for runoff, (b) with the worst topography, (c) with applications at maximum rates and (d) at the times during the year that have the most rainfall events. Those multiple conservatisms result in hyper-conservative overestimates of pesticide concentrations in water bodies that could be used as sources of drinking water. It is understood that the approach being used by the Agency is not even in accord with its own guidance for developing inputs for modeling drinking water exposure. If the Agency is going to resort to modeling potential drinking water exposure, it should only do so in a manner that is both consistent with its own guidance and also ultimately reflective of real world use. Rather than resorting to modeling, however, the Agency should instead use the actual reliable water monitoring data available in its drinking water assessment.

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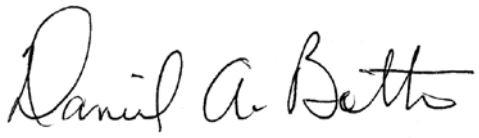
[2] MCFA believes that a core principle for the Agency should be if the Agency is going to consider the conclusions of a study for regulatory purposes, the data from that study should be available to the Agency to insure that the conclusions of the study are well founded. It is the height of arbitrariness to assert a regulatory decision is "science based" when the actual data underpinning that decision have not been reviewed to assure that the population being investigated was exposed to the chemical at doses that are known. The old axiom that the "dose makes the poison" continues to be relevant.

[3] It is interesting to note that in 2009, the Agency completed its extensive regulator review of Malathion as reflected in the revised Reregistration Eligibility Decision for Malathion, ultimately determining that with certain label changes, the safety requirements of FIFRA and FQPA were satisfied. Now a relatively short 7 years later, the Agency has preliminarily decided that these safety standards are not met. This change does not appear to reflect new, reliable scientific information.

MCFA is concerned with what appears to be the Agency's approach on Malathion as well as other organophosphates. The Agency should follow its publicly stated goal of insuring that the pesticide decisions they make are science based. If that was to occur in this instance, we believe the Malathion tolerances at issue would essentially be maintained.

We appreciate your consideration of these comments.

Sincerely,



Daniel A. Botts
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