Minor Crop Farmer Alliance

By mail and electronically
January 5, 2016

Mr. Jack E. Housenger
Director, Office of Pesticide Programs
C/o OPP Docket
Environmental Protection Agency Docket Center (EPA/DC), (28221T)
Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, DC 20460–0001

Dear Mr. Housenger:

Re: Chlorpyrifos; Tolerance Revocations; Proposed Rule; Docket ID No. EPA-HQ-OPP-2015-0653

Dear Mr. Housenger:

These comments are submitted by the Minor Crop Farmer Alliance ("MCFA") on the subject notice published in the Federal Register on November 6, 2015, 80 Fed. Reg. 69080-110.[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,

[1] Many stakeholders including members of MCFA timely filed requests for a modest extension of time to file comments on the Agency's proposed Chlorpyrifos tolerance revocation. Despite the significant impacts on stakeholders in the agricultural community if the proposed action was finalized and also the significant policy issues involved in this matter, the Agency chose to deny those requests. EPA primarily relied on the rationale that it was under a court imposed deadline to make a final decision on the Chlorpyrifos tolerances by December 30, 2016 and that the comment period for the Revised Human Health Risk Assessment (RHHRA), originally published in January 2015 (Docket No. EPA-HQ-OPP-2008-0850) and which is an essential part of the Agency's proposed tolerance revocation decision, had previously been briefly extended. Apparently the Agency believed that any modest extension of time on the tolerance revocation proposal would adversely affect its schedule and EPA was not inclined to advise the 9th Circuit that a brief extension of the comment period was needed. Although as EPA acknowledges in the subject notice it has not been able to complete its review of the comments that were received on the RHHRA, the Agency still feels compelled to proceed with the revocation proposal.

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 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.

On behalf of our members, MCFA objects to the revocation of the Chlorpyrifos tolerances (40 CFR § 180.342). Those tolerances should remain in effect. Chlorpyrifos is the only viable option in certain pest management situations and plays a very important role in the production of various crops produced by some of our members. For example, it has been the primary response to several newly emerging insect pests such as vine mealybug when it first attacked grape vines in California, as well as the brown marmorated stinkbug in other regions of the country. The revocation of the tolerances would essentially eliminate the use of the product, adversely affecting our members' interests. The affected crops include alfalfa, asparagus, beets (sugar), Cole crops, carrots, citrus, nectarine, clover, corn, cotton, cranberry, cucumber, fig, ginseng, grapes, legume vegetables (beans, peas), mint, peppermint, spearmint, onions, peanut, peppers, pineapple, apple, cherries, peach, pear, plum, prune, pumpkin, radish, rutabaga, sorghum (grain), soybeans, strawberries, sunflower, sweet potatoes, tobacco, turnip, tree nuts (almonds, hazelnut, pecans, walnuts), wheat, and triticale. [2]

The factual underpinnings, policy and scientific issues involved in this matter are significant and warrant a more complete and comprehensive investigation and review by the Agency. MCFA is extremely disappointed with the process being followed in this matter. Apparently for administrative convenience, the Agency decided to bypass the registration cancellation

[2] Growers need the current list of tolerances for these crops and for any processed fraction or food tolerance, animal feed tolerance, and animal commodity tolerance (such as, but not limited to milk, meat, or eggs) that would be associated with the use on these crops, to be maintained.

procedures contained in Section 6 of the Federal Insecticide, Fungicide and Rodenticide Act, as amended ("FIFRA") in favor of the tolerance revocation pathway offered by the Federal Food, Drug and Cosmetic Act ("FFDCA") as amended by the Food Quality Protection Act ("FQPA"), thereby avoiding the procedural safeguards established under Section 6 of FIFRA. The Agency appears to have adopted a predetermined conclusion namely that Chlorpyrifos should not be available for the agricultural community. That conclusion is after-the-fact being supported with information cobbled together from various sources, but most notably certain epidemiological papers. For example, despite EPA acknowledging that it has not completed its review of the comments on the RHHRA[3] which, in turn, involves those papers, the Agency continues to press forward with the tolerance revocation.[4] This calls into question EPA's objectiveness and transparency when reviewing the comments submitted on the RHHRA, as well as the comments being submitted challenging the Agency's proposed tolerance revocation decision.[5]

Many of MCFA's members are submitting information directly to the Agency in response to the proposed tolerance revocation. That information will include the parameters concerning their use of Chlorpyrifos and the importance to them of maintaining the current necessary tolerances.

[3] 80 Fed. Reg. at 69083.

[4] It is understood that while EPA is relying on the epidemiological papers, the Agency has not secured or reviewed all the raw data upon which the papers are based. This is a fundamental problem. At the very least, the Agency should secure that information so it can critically evaluate the analysis and conclusions in the cited epidemiology papers, if the Agency intends to continue to rely on these papers to justify the retention of the 10X FQPA safety factor. In our view, it is unlawful for the Agency to default to the views of authors of these papers in making a regulatory decision. The Agency does not know in fact that the reported conclusions are actually consistent with the data collected for the papers. Additionally, the Agency is required to determine itself: (1) whether the participants were actually exposed to Chlorpyrifos, and if so, (2) at what dose, (3) over what time period, (4) whether the reported effects actually occurred, (5) that the measurements were accurate, and, (6) if the measurements were accurate, whether there were factors other than exposure to Chlorpyrifos which caused the purported effect. Apparently the Agency believes that the researchers' evaluation of the underlying data (assuming its veracity) must have been objective, and the Agency can default to the researchers' conclusions. Under this novel approach, adherence to Good Laboratory Practices ("GLP") and scientific merit are irrelevant for purposes of justifying a regulatory decision that will significantly adversely affect many agricultural producers.

[5] While it may prove to be a futile exercise because the Agency appears to have already made up its mind regarding the proposed tolerance revocation, MCFA incorporates by reference herein the comments submitted in Docket No. EPA-HQ-OPP-2008-0850 identifying issues with the RHHRA, including those submitted by the American Farm Bureau, Dow AgroSciences, LLC, Michigan Farm Bureau, Western Growers, CropLife America, California Citrus Quality Council, US Department of Agriculture, Northwest Horticultural Council, National Agriculture Aviation Association, California Specialty Crop Council, Western Agricultural Processors Association, California Fresh Fruit Agreement, National Cotton Council, American Mosquito Control Association, United Fresh Produce Association, California Walnut Commission, the Almond Hullers & Processors Association, Florida Department of Agriculture and Consumer Services, California Grape and Tree Fruit League, Cheminova and the Cranberry Institute.

Recognizing that providing a scientific critique of all the underlying information involved in this matter is beyond the expertise of MCFA, nevertheless there are certain issues involved that we are commenting on. These include the substantial weight that the Agency accords the epidemiological evidence to justify its proposed revocation decision. In addition, comments are provided herein on EPA's substantial reliance on screening-level drinking water models to estimate drinking water risks from potential exposures to Chlorpyrifos and EPA's expressed intention to provide the public an opportunity to comment only "to the extent practicable" on the Agency's new or modified analysis of the relevant action before it issues a final rule. *See* 80 Fed. Reg. 69083. MCFA is also concerned that the assessment approaches reflected in the Chlorpyrifos tolerance revocation proposal may serve as a precedent for the future evaluation of other pesticides. Consequently, this magnifies the importance of the issues involved, including for MCFA members that do not use Chlorpyrifos.

EPA should reconsider its reliance on the epidemiology papers in this instance

EPA should reconsider its approaches used in its revised Chlorpyrifos human health risk assessment, particularly the emphasis given to the Columbia University epidemiology paper. The information in that paper, in conjunction with two other epidemiological papers, underpins EPA's decision to increase the FQPA safety factor by an additional 10X. This additional 10X is crucial in determining whether Chlorpyrifos exceeds the total aggregate/dietary risk under FQPA. Essentially, the Agency is choosing to set aside the results of carefully conducted Chlorpyrifos laboratory animal exposure studies and instead rely on these limited epidemiological papers. Prior to this time, it was understood that the Chlorpyrifos toxicological database was very extensive and the endpoints were well understood. In this instance, however, the Agency has decided to give undue weight to the epidemiological papers, using the conclusions of those papers to redefine toxicity endpoints.[6]

[6] It is understood that there are other epidemiological publications and studies the results of which are not consistent with the conclusions of the three studies in question. Those other studies appear to indicate that at the measured levels of exposure, the evidence is insufficient to show causality between Chlorpyrifos and adverse neurological effects in infants and children. Further, a review of approximately 600 studies contracted by the EU European Food Safety Agency concluded that there is no evidence to suggest an association between pesticide exposure, including Chlorpyrifos, and neurodevelopment effects. These publications and references were identified in previous comments submitted on the RHHRA by CropLife America as referenced *supra*. MCFA respectfully requests the

MCFA agrees with those commentators who have previously advised the Agency that it is critically important that exposures referenced in epidemiological studies, including the above-mentioned three papers, be evaluated against exposures and internal doses in toxicological studies when assessing environmental exposures to a pesticide and the potential to cause harm. This is particularly important for human health conditions that can be influenced by a myriad of factors including lifestyle. When the Agency intends to override the results of carefully constructed GLP laboratory animal toxicology studies in favor of epidemiological studies, it should be assured that the exposures to the pesticide are clearly documented. Otherwise, the Agency is replacing scientific results with guesswork. By giving epidemiology studies such primacy in its decision making without having the raw data available and public consultation or discussion, EPA is reordering the hierarchy of information it uses to make regulatory decisions. This raises a host of questions that need to be considered including: What is the relationship between animal studies and human epidemiology in determining risk? Will the Agency issue guidelines for conducting epidemiology studies that will be used for regulatory decision-making? What criteria will EPA use to choose between animal studies or epidemiology studies when the results are conflicting? Based on the current record, can the Agency objectively conclude that the three epidemiological papers are rigorous enough to override the vast array of existing GLP animal toxicology studies? We think not.

As mentioned above, MCFA is concerned that EPA is making a major shift in its decision-making process in a way that will lead away from science-based decisions and to the loss of many more crop protection tools. Certainly MCFA supports efforts to protect human health and the environment. If, in its analysis, EPA determines that the science establishes that a specific use is unsafe, we will support the regulatory decision. However, the process must be scientifically reliable, robust, transparent, and objective. In this instance, basing regulatory decisions on the three epidemiology studies introduces considerable uncertainty into the regulatory process and appears to be inconsistent with sound science. Rather than advancing a

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Agency to review those 600 studies to determine whether under a weight of evidence approach continued reliance on the three epidemiological papers is appropriate.

science-based decision, the proposed tolerance revocation decision moves away from the reliable scientific data reflected in GLP animal toxicology studies.

EPA should refine its drinking water models in this instance

EPA's screening-level drinking water model is an important driver in EPA's human health risk assessment. Modeling can be a useful tool in risk assessment, but a model must be based on realistic scenarios if a credible exposure estimate is desired. Certainly, the modeling should be compared with available monitoring data to see whether or not the model is robust and reliable. At the very least, monitoring data can help refine drinking water assessments. In this case, EPA acknowledges the existence of monitoring data and suggests since the results of its modeling are within one order of magnitude of the monitoring results, the models results are not "overly conservative" and are suitable for risk assessment purposes. With all due respect, it is understood that a difference of one order of magnitude (10X) is not considered acceptable in the scientific community. What is more typical is a 3-4X difference. A difference of 10X indicates that the models' results are not reflective of the monitoring results.

The drinking water modeling used to estimate the dietary risk from Chlorpyrifos appears unrealistic because of the inaccurate assumptions used. For example, the Agency assumes that the entire watershed area is treated with Chlorpyrifos at the maximum rate on a single day, using the maximum possible amount of runoff from the treated area and that all of the runoff is drinking water. The Agency does not identify even one watershed in which all of these assumptions are true at the same time. It is understood that for Chlorpyrifos, there are almost 47,000 water data monitoring points available to the Agency that should be considered. Further, we understand that data on actual application rates and use patterns have not been used to refine modeling inputs. Rather, the models appear to rely on unrealistically exaggerated worst-case scenarios.

MCFA urges EPA to refine its drinking water modeling by using more realistic assumptions and using available monitoring data as an input in the models. The modeling is recognized as overly

conservative and does not reflect the extensive real-world monitoring data for Chlorpyrifos. EPA highlights the high level of refinement of their dietary food (residue) assessment and should require the same level of refinement for their drinking water assessments before relying on them for any regulatory decision. We believe a more refined modeling will show that there is an acceptable level of dietary risk from continued Chlorpyrifos use.

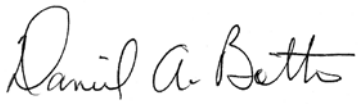
Conclusion

Chlorpyrifos is an important tool that many MCFA members rely on to control serious insect pests. Finalizing the proposed tolerance revocation will result in growers not being able to use Chlorpyrifos. In such circumstance, EPA will have unreasonably made the growers' ability to manage various pests much more difficult.[7] Reliance on unsubstantiated epidemiology papers and results from unrefined drinking water models that reflect unrealistic assumptions, is not a basis for a robust science-based decision. Before EPA finalizes its tolerance decision, the Agency should reevaluate its approach and revise it in accordance with the comments presented above. Further, the Agency should unconditionally commit to allow the public to comment on its new or modified analysis of the relevant action before it issues a final rule. The Agency's inclination to provide an opportunity for public comment only "to the extent practicable" is simply inappropriate and inconsistent with the principles reflected in the Administrative Procedure Act. The policy issues involved in this action are too significant to not allow full public comment on the analysis, including when that analysis is modified by the Agency. If the

[7] It should be noted that while EPA would be hurting our Nation's growers by eliminating the Chlorpyrifos tolerances, growers in foreign countries that use Chlorpyrifos on the commodities they export to the US should be able to continue to use the chemical, since the Agency acknowledges in the subject notice that the risk from residues in foods is acceptable. This unfair competitive advantage would not exist but for the unreasonable action that EPA is proposing.

rulemaking process requires additional time, then the Agency can so advise the 9th Circuit that the obligation to permit the interested public meaningful opportunity to comment fully on the Agency's analysis before a final decision is made necessitates an extension.

Sincerely



Daniel A. Botts

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