Minor Crop Farmer Alliance

Via Electronic Docket Submission http://www.regulations.gov August 31, 2020

Mary Reaves, Ph.D.
Acting Director, Pesticide Re-Evaluation Division
Office of Pesticide Programs
Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460-0001

Re: Comments Regarding NRDC Petition To Revoke Tolerances: Neonicotinoid EPA-HQ-OPP-2020-0306

Dear Dr. Reaves:

The following comments are submitted on behalf of the Minor Crop Farmer Alliance ("MCFA") and its members in response to the subject request for comments regarding a petition submitted by the Natural Resources Defense Council ("NRDC") published by the U.S. Environmental Protection Agency ("EPA" or "Agency") in the Federal Register on July 30, 2020 (85 Fed. Reg. 45883-84).[1] MCFA strongly believes the Agency should deny the petition.

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. MCFA's 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, workers and the public, 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 diverse and highly nutritious diets available for the global population, and to safe and aesthetic surroundings for our homes, schools, and places of business. These 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.

In its petition, NRDC is requesting the Agency to revoke all the existing tolerances for the residues of five neonicotinoid pesticides, Acetamiprid, Clothianidin, Dinotefuran, Imidacloprid, and Thiamethoxam. As summarized in the subject Federal Register notice, NRDC is essentially alleging that the tolerances which have existed for many years and which were evaluated in the EPA registration review process, do not meet the safety standard established under section 408 of the provisions of the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. 346a,

[1] Currently, comments are required to be submitted to the Agency by August 31, 2020.

namely a reasonable certainty of no harm.[2] NRDC asserts that the tolerances are flawed because allegedly,

> EPA failed to use the most sensitive endpoint and appropriate uncertainty factors, including the full 10x children's safety factor, in not considering the potential for developmental effects in children from neonicotinoid exposure and evidence of toxic effects at low exposure levels; failed to assess the potential for cumulative toxicity from exposure to multiple neonicotinoids; failed to assess the aggregate toxicity of neonicotinoids and other chemicals resulting from interactions between neonicotinoids and chemicals used in drinking water sanitation; and failed to consider risks to highly-exposed individuals in the acute dietary risk assessment.

85 Fed. Reg. 45884.

A review of the applicable dockets established for the registration review of these chemicals demonstrates that the Agency thoroughly assessed the potential human health effects from potential exposure to residues in food and drinking water for each of the five neonicotinoids. The Agency's analysis and conclusions that each of the five neonicotinoids met the required safety standard to reaffirm the tolerances (i.e., a reasonably certainty of no harm) is science-based, transparent, thoroughly and well documented, and clearly based on substantial evidence. The Agency conducted an exhaustive review of all reliable data. It employed very conservative assumptions in its human health risk assessment, assuming for example in most cases, 100% crop treated for each of the neonicotinoids, as well as often residues at the tolerance value. Each of these assumptions is extremely conservative, unlikely to actually occur and represents a significant over-estimate of potential human exposure. These assumptions are certainly protective of human health.

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[2] (2) Standard

(A) General rule

(i) Standard

The Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.

(ii) Determination of safety

As used in this section, the term "safe", with respect to a tolerance for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

21 U.S.C. 346a(b)(2).

Issues concerning the reduction in the FQPA safety factor are expressly addressed by the Agency for each of the products involved. For Clothianidin and Thiamethoxam, EPA stated:

> The toxicology databases for both clothianidin and thiamethoxam are complete. Studies for clothianidin were performed via the oral, inhalation, and dermal routes of exposure. For thiamethoxam, studies were only conducted for oral and dermal routes of exposure, where the agency's Hazard and Science Policy Council (HASPOC) found that the inhalation toxicity study could be waived based on a weight-of-evidence (WOE) approach (TXR# 0057630, M. Lewis, 09/22/17). The risk assessments for each of these two active ingredients use conservative assumptions, and the most sensitive endpoint from the respective toxicity databases, and are therefore protective of all potential reproductive, developmental and neurotoxic effects. Given the completeness of the toxicity database; clear reproductive and developmental NOAELs; and protective neurotoxic endpoints, the agency determined that reductions of the Food Quality Protection Act (FQPA) safety factors to 1X are appropriate for both clothianidin and thiamethoxam.

Proposed Interim Registration Review Decision for Clothianidin and Thiamethoxam-January 2020 at page 19

Similarly, for Imidacloprid, the Agency determined that

> Humans may be exposed to imidacloprid in food and drinking water from crop uses, residential applications, in occupational settings, and from exposures to spray drift. The primary target system for mammals via the oral route is the nervous system; observed effects include tremors/trembling, decreased motor activity, etc., in multiple neurotoxicity studies in the dog and rat. No signs of toxicity were observed through the dermal and inhalation routes in the available studies and there was no evidence of carcinogenic potential in the database. Imidacloprid is classified as a Group E chemical ("Evidence of non-carcinogenicity for humans"), oral Toxicity Category II (high oral lethality), and dermal Toxicity Category IV (low lethality by the dermal and inhalation routes). Because the toxicology database is sufficient to support risk assessment, the assessments are unlikely to underestimate exposure, and the observed neurotoxic and fetal and offspring effects are well characterized and protected for, and the FQPA Safety Factor was reduced to 1X. Therefore, the level of concern (LOC) for all assessments is 100 based on the interspecies (10X) and intraspecies (10X) extrapolation….

Imidacloprid Proposed Interim Registration Review Decision January 2020 at page 15.

For Dinotefuran, the Agency determined it could also reduce the FQPA Safety Factor explaining that:

> The Food Quality Protection Act (FQPA) Safety Factor (SF) for dinotefuran has been reduced to 1X because (1) there is an adequate toxicity database for dinotefuran; (2) the prenatal developmental studies in rabbits and rats and the 2-generation reproduction study in rats showed no indication of increased susceptibility to in utero and/or postnatal

> exposure to dinotefuran; (3) the neurotoxic potential of dinotefuran has been adequately considered; and (4) there are no residual uncertainties identified in the exposure databases.

Dinotefuran Proposed Interim Registration Review Decision January 2020 at page 15.

Finally, for Acetamiprid, EPA determined the FQPA Safety Factor should be reduced to 1X, explaining that:

> HED reduced the required FQPA SF for acetamiprid from 10X to 1X based on the completeness of the toxicology data base, the selection of endpoints based upon the most sensitive effects of concern (i.e., developmental effects), for which a clear no observed adverse effects level (NOAEL) and lowest observed adverse effects level (LOAEL) were identified, the lack of residual uncertainties for pre- and/or post-natal toxicity, and the complete exposure databases which account for all metabolites and/or degradates of concern and do not underestimate the potential exposure and risk for infants or children.

December 15, 2017 Acetamiprid. Draft Human Health Risk Assessment for Registration Review at page 6.

Further, in considering the potential for cumulative risks, after conducting its exhaustive review of the scientific data, EPA expressly declined to make a finding of common mechanism of toxicity to humans as to any neonicotinoid and any other substance, and these products do not produce a toxic metabolite also produced by other substances. Therefore, in evaluating cumulative risks as required by statute, EPA appropriately concluded that none of the five neonicotinoids shares a common mechanism of toxicity with any other substance.[3]

There is an additional important point to note regarding the extensive review conducted by EPA of each of the five neonicotinoids. In conducting its reviews, which were initiated in 2008, EPA provided many opportunities for the public to provide comments on numerous occasions. Applicable to the instant situation, this included allowing the public to comment on the draft Human Health Risk Assessments and the Proposed Interim Registration Review Decisions. NRDC is seeking to second-guess the analysis and conclusions that were made by the Agency. In short, NRDC is unhappy with the outcome of the process, and as such seeks to undermine the process by filing its petition. The Agency should deny the petition, and reaffirm that the evaluation it conducted on the five Neonicotinoids was science-based, comprehensive and reliable and that the associated tolerances meet the requirements of the FFDCA. The Agency

[3] For example, for Clothianidin and Thiamethoxam, EPA stated regarding cumulative risks that "EPA has not made a common mechanism of toxicity to humans finding as to clothianidin or thiamethoxam and any other substance, and they do not appear to produce a toxic metabolite produced by other substances. Therefore, EPA has not assumed that either clothianidin or thiamethoxam have a common mechanism of toxicity with other substances." Proposed Interim Registration Review Decision for Clothianidin and Thiamethoxam-January 2020 at page 19. Similar analysis and findings are contained in the documents supporting the human health risk assessments for the other neonicotinoids conducted by the Agency.

should rightfully express its confidence in the objective and thorough analysis it conducted regarding the tolerances established for the five products, and decline NRDC's petition to revoke the tolerances.

MCFA appreciates the opportunity to provide these comments on the NRDC petition.

Sincerely,

Michael Aerts, Co-Chair of the Technical Committee

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