



PPC

PESTICIDE POLICY COALITION
A Coalition Working for Sound Pest Management Policies

March 21, 2019

OPP Docket, Environmental
Protection Agency Docket,
Mail Code: 28221T
1200 Pennsylvania Ave. NW
Washington, DC 20460-0001

Submitted electronically via www.regulations.gov

**Re: Petition Seeking Revised Testing Requirements for Pesticides Prior to Registration,
Docket No. EPA-HQ-OPP-2018-0262, 83 Fed. Reg. 65672 (December 21, 2018)**

The Pesticide Policy Coalition (PPC or “the Coalition”) appreciates the opportunity to provide comments on the petition filed by Center for Food Safety (CFS) seeking revisions to testing requirements for pesticides prior to registration (hereinafter “the Petition”). The Petition raises issues that affect the timely availability of safe, effective, and affordable pesticide technologies relied on by PPC members to produce food and fiber, as well as provide vital public health services, which benefit all Americans

The PPC is an organization of food, agriculture, forestry, pest management and related industries, including small businesses/entities, which support transparent, fair and science-based regulation of pest management products. PPC members include: nationwide and regional farm, commodity, specialty crop, and silviculture organizations; cooperatives; food processors and marketers; pesticide manufacturers, formulators and distributors; pest and vector-control operators; research organizations; equipment manufacturers and other interested stakeholders. PPC serves as a forum for the review, discussion, development and advocacy around pest management regulation and policy.

PPC members rely on the predictable and timely availability of a diverse array of pesticide technologies. Access to a variety of pesticide products, in combination with best management practices, ensures pesticides are applied in a manner that is safe, effective, and manages pesticide resistance. The practice of tank mixing is a vital tool in the pest management toolbox that provides practical, economic, and agronomic benefits. Mixing pesticides that work via differing modes of actions is a critical component of pesticide resistance management.

In its Petition, CFS requests a number of revisions to the United States Environmental Protection Agency’s (EPA) testing requirements for pesticides prior to registration, including requiring testing for whole pesticide formulations to account for the toxicological effects of inert and adjuvant ingredients and the testing of tank mixes to assess the interaction between pesticide ingredients. CFS asserts these requirement changes are necessary to meet applicable Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) safety standards and statutory requirements under the Food Quality Protection Act (FQPA) and the Endangered Species Act (ESA).

For the reasons addressed in PPC's comments below, CFS' grounds for testing revisions are flawed, inaccurate, and not based on sound science. EPA's well-established testing regime meets FIFRA's safety standards, and in turn satisfy statutory requirements under FQPA and ESA. Furthermore, the expansive and unnecessary additional testing requirements sought by CFS would contradict Congressional intent in its enactment of FIFRA. In addition to the following comments highlighting key discrepancies in the Petition, PPC encourages EPA to consider individual comments submitted by PPC members, including detailed comments submitted by CropLife America.

COMMENTS

I. CFS' grounds for seeking revised testing are flawed, misleading, and inaccurate

a.) Synergistic effects

In its Petition, CFS asserts that formulated pesticides are generally more toxic than active ingredients (AIs) alone, due to synergistic or additive effects. CFS further asserts that EPA is not able to predict the potential effects of combining inert or another ingredient with an AI without testing each and every formulated product made with the subject AI. These claims are inaccurate and not supported by science.

The scientific community that has engaged in studying potential synergistic effects between pesticide ingredients, have long held that synergy (*i.e.*, a combination producing an effect significantly greater than the sum of the individual ingredients effects) is 1) a rare incurrence; and 2) not likely to occur under real-world scenarios involving lawful use of registered pesticide products. Accordingly, in 2013, the National Research Council issued recommendations that agencies assume that synergistic effects are not occurring in the absence of relevant and reliable data to suggest otherwise, and at concentrations relevant to pesticide risk assessment.¹ Previously, up until the early 1980s, EPA required data submissions on tank mixtures before it would permit tank mixes. However, a comparison of data gathered over years on tank mixes and ground truthing in the field demonstrated that synergistic effects are rare. For this reason, EPA revised their policy and no longer required data on every individual mixture, while still reserving the right to request data if it determines that the safety assessment could be impacted.² More recently, both EPA and the National Research Council concluded that, absent any data to support a hypothesis of a synergistic interaction between an AI and other mixture components, the assessment of a mixture's potential hazards should be based on the assumption that components do not interact.

b.) Testing of all end-use formulations

CFS is also incorrect in its claim that a complete battery of testing of all end-use formulations is required to accurately assess risks associated with formulated products. CFS argues that EPA's current testing regime cannot predict the effect of inert and other ingredients in formulated products. As addressed above, synergistic effects are rare, and EPA currently requires sufficient data on formulations and formulation components to evaluate each end use product and support risk assessments for end-use

¹ See NATIONAL RESEARCH COUNCIL, *Assessing Risks to Endangered and Threatened Species from Pesticides* (2013) at p. 134, available at <https://doi.org/10.17226/18344>.

² See Pesticide Registration Notice 82-1, available at <https://www.epa.gov/pesticide-registration/prn-82-1-revised-policy-label-claims-tank-mixing>.

products. Further, EPA employs reliable and peer-reviewed models for understanding the additive effects of multiple ingredients.³

II. EPA's well-established review process adequately accounts for risks from formulations

Prior to registration, EPA considers the hazard characteristics of product's inert and AI components and likely effects of the end-use formulation. This rigorous review process includes, gathering data on inert ingredients. EPA must review and approve each inert ingredient before it can be used in a formulated pesticide product. Inerts used in food use products must also meet data requirements for EPA's tolerance setting process under the Federal Food Drug and Cosmetic Act (FFDCA) – including all of the additional protections added by the Food Quality Protection Act (FQPA), including, among other things, consideration of risk to children, additional safety factors. Inert ingredients are also subject to EPA review under the Toxic Substances Control Act (TSCA). Under TSCA, EPA must review data on the hazard characteristics of an inert prior to approving manufacture. As with FIFRA, absent sufficient data to assess the risk to human health and the environment from reasonably foreseen uses of the inert, EPA will not approve the manufacture of an inert ingredient and will require additional data development before proceeding with its review and final determination.

EPA also considers additive effects of inert ingredients in the formulated products and any potential synergistic effects with active ingredients. Although EPA maintains a list of approved inerts which it has deemed safe for use in formulated products, with each new registration application EPA considers the safety of inert ingredients in the proposed pesticide product. EPA requires acute toxicity data for the complete formulation, thereby allowing it to assess any potential synergistic effects of mixtures of active and inert ingredients in a pesticide product.

Additionally, EPA's robust analysis of AI, inert ingredients, and formulated end products, is more than adequate to meet ESA consultation requirements. The current testing requirements, and EPA's authority to request additional data where sufficient data is lacking, enable it to adequately determine whether an end-use formulated product may affect endangered species or critical habitat. Similarly, EPA satisfies FQPA requirements under the current testing regime, requiring sufficient data to move forward with setting tolerances or tolerance exemptions before inerts are used in a formulated food use pesticide.

III. The expansive testing sought by CFS runs contrary to Congressional intent

In enacting FIFRA, Congress intended that EPA focus its assessments on components of the formulation and then apply this evaluation to end-use products. Congress adopted this approach to reduce duplicative testing that would place an unnecessary burden on pesticide registrants and EPA, and in turn unnecessary added costs to consumers. In furtherance of the goal of avoiding unnecessary and duplicative testing, Congress expressly permitted pesticide registration applicants to rely on data generated by registrants of a similar pesticide, provided that the applicant compensated the original registrant for data generated. The expansive testing sought by CFS would render the data compensation program imbedded in FIFRA moot, as it would subject every single end use product to every test with each new registration application regardless of previous review and approval of similar pesticides. Unnecessary and duplicative

³ The "response addition" model or "concentration addition" model may be use to accurately predict toxicity of pesticide mixtures. See U.S. EPA, Guidelines for the Health Risk Assessment of Chemical Mixtures (Sept. 24, 1986), Fed. Reg. 51(185):34014-34025; Committee of Toxicity; Risk assessment of mixtures of pesticides and similar substances (2002), *available at* <https://cot.food.gov.uk/sites/default/files/cot/reportindexed.pdf>; NATIONAL RESEARCH COUNCIL, Assessing Risks to Endangered and Threatened Species from Pesticides (2013), *available at* <https://doi.org/10.17226/18344>.

testing would also unnecessarily require the sacrifice of an enormous number of additional test animals contrary to the goal of reducing such testing where scientifically appropriate.

CONCLUSION

For the reasons cited above, CFS' proposal to require every test on all pesticide end-use products lack merits and would result in unnecessary and overly burdensome requirements to an already scientifically rigorous and resource-intensive registration review process. In practice CFS' proposed expansive testing regime would unnecessarily delay and potentially prevent access to safe and affordable pesticide technologies and divert resources from the development of new and innovative pesticide products. Finally, CFS' proposed changes run contrary to Congressional intent.

PPC encourages EPA to deny the Petition and appreciates review of the Coalition's input on this important matter.

Sincerely,



Renée Munasifi
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