

August 16, 2018

Tom Sinks, Ph.D. Director, Office of the Science Advisor U.S. Environmental Protection Agency EPA Docket Center (Mail Code 28221T) 1200 Pennsylvania Avenue NW Washington, D.C. 20460

Submitted electronically via www.regulations.gov

Re: Strengthening Transparency in Regulatory Science; Docket ID: EPA-HQ-OA-2018-0259; 83 Fed. Reg. 18768 (April 30, 2018)

Dear Dr. Sinks:

The Pesticide Policy Coalition (PPC or "the Coalition") is pleased to submit comments in response to the United States Environmental Protection Agency (EPA or "the Agency") regarding its proposal to strengthen the transparency of EPA regulatory science announced in the *Federal Register* on April 30, 2018. (83 Fed. Reg. 18768).

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; and other interested stakeholders. PPC serves as a forum for the review, discussion, development and advocacy around pest management regulation and policy.

The Coalition provides the following input on the proposal in general, and in response to a few specific areas where EPA has requested comment:

I. Increased Transparency

PPC members encourage EPA's commitment in the proposed rule to regulatory decision-making grounded in sound and verifiable science. PPC members agree that increased transparency concerning the assumptions and methods employed in acceptance of underlying scientific studies

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will enhance meaningful review and public comment on proposed regulatory actions and decisions. EPA's use of modeling in its scientific studies can be an important tool to inform policy and regulatory decisions. However, models need to have a foundation that is replicable and reflective of relevant exposure scenarios. Often times there can be a significant gap in modeling assumptions and what occurs in relevant environmental conditions. Disclosure of the underlying assumptions and methodology will allow affected stakeholders to provide input that could enhance the validity (reproducibility) of modeled outcomes.

II. Privacy Concerns

EPA has requested comment on whether its proposed disclosure requirements should be expanded to cover other types of data and information, and/or other types of Agency actions, including individual permit proceedings, enforcement activities and non-binding regulatory determinations. At the individual level, release of underlying data creates privacy concerns for the pesticide user community. Agricultural landowners have unique privacy interests as many also maintain places of residence on their farms, and data disclosed could include physical addresses and other identifying information. Any new data disclosure requirements should maintain consistency with established statutory privacy protections and judicial precedent.

In general, it would be challenging for EPA to identify a compelling public interest in favor of disclosing this type of data that outweighs individual privacy rights. Given this vulnerability, the PPC does not recommend that EPA expand its proposed data transparency requirements beyond "significant regulatory actions."

III. Additional Clarity Regarding Exclusions

The PPC agrees that the proposed rule should be limited to "significant regulatory actions," which includes pesticide regulations that meet this definition. The PPC recommends that the final rule provide added clarity on those regulatory activities and functions that do not meet the "significant regulatory action" threshold.

Regulatory actions that are not, and should not, be included in the proposed regulations include pesticide registration decisions under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and tolerance setting under the Federal Food, Drug, and Cosmetic Act (FFDCA). It is important to note that pesticide registrations are subject to rigorous and well-defined EPA data quality, validity, and scientific credibility requirements. These actions do not meet the definition of "significant regulatory action" as set forth in Exec. Order (E.O.) 12866.

Registration decisions do not result in the promulgation of a rule or regulation with broad applicability. Instead, these are essentially licensing actions that are analogous to individual permitting decisions, and are not subject to not subject to the rulemaking process under the Administrative Procedure Act. While tolerance-setting or tolerance exemptions are issued

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through a notice-and-comment process, long-standing Office of Management and Budget (OMB) policy has exempted tolerances and tolerance exemptions from E.O. 12866 requirements.¹

The PPC also encourages EPA to review the detailed comments submitted by PPC member CropLife America regarding the legal basis for excluding pesticide registrations and tolerance setting from the proposed transparency rule requirements.

The PPC appreciates the Agency's consideration of the aforementioned comments. The Coalition looks forward to continued dialogue with EPA as it renews its commitment to transparency and science-based regulatory principles. A complete list of the PPC's member organizations is available at www.pesticidepolicycoalition.org.

Sincerely,

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Chair, Pesticide Policy Coalition

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Vice Chair, Pesticide Policy Coalition

¹ See OMB, Guidance for Implementing E.O. 12866 (Oct. 12, 1993), at App. C.