



May 18, 2020

Cheryl Hawkins
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Policy and Engagement
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, D.C. 20460

Submitted through Regulations.gov: EPA-HQ-OA-2018-0259

Dear Ms. Hawkins:

CropLife America (CLA) and Responsible Industry for a Sound Environment (RISE) appreciate the opportunity to provide comments to the U.S. Environmental Protection Agency (EPA or the Agency) on its March 18, 2020 Supplemental Notice of Proposed Rulemaking (SNPR), "Strengthening Transparency in Regulatory Science" (85 Fed. Reg. 15396), which proposes revisions to certain aspects of EPA's April 30, 2018 proposal, "Strengthening Transparency in Regulatory Science" (83 Fed. Reg. 18768). We also appreciate EPA's extension of the public comment period to May 18, 2020 (85 Fed. Reg. 21340).

CLA was established in 1933 and represents the developers, manufacturers, formulators and distributors of plant science solutions for agriculture and pest management in the United States. CLA's member companies produce, sell and distribute virtually all the vital crop protection and biotechnology products used by farmers, ranchers and landowners. Crop protection products are necessary to ensure safe, predictable and adequate supplies of food, fiber and fuel. CLA members support science-based regulation of pesticides to ensure that these products are available for these important uses consistent with the laws that protect human health and the environment. CLA submitted public comments on EPA's original April 30, 2018 proposal on August 16, 2018.

RISE is a national trade association representing more than 220 producers and suppliers of specialty pesticide and fertilizer products to both the professional and consumer markets. RISE member companies manufacture more than 90 percent of domestically produced specialty pesticides used in the United States, including a wide range of products used on lawns, gardens, sport fields, golf courses, and to protect public health. RISE also submitted public comments on EPA's original April 30, 2018 proposal on August 16, 2018.

CLA and RISE members are pesticide applicants and registrants regulated under two related statutes -- the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). Decisions made under these two statutes with respect to food-use pesticides have been inextricably linked by Congress. *See, e.g., FIFRA*

§ 2(bb). Under these two statutes, our members submit risk and benefit data and models¹ to obtain product- and chemical-specific permits (called “registrations” under FIFRA and related food safety “tolerances” under the FFDCA) and to maintain those permits on an ongoing basis.²

The data that our members submit to EPA are subject to rigorous and well-defined statutory and regulatory requirements that confirm their quality, validity, and integrity, consistent with the principles in the SNPR. CLA and RISE generally believe that all research EPA relies on to make individual pesticide permit decisions should be required to meet the same standards, as detailed in our earlier comments. EPA also issues rules of general applicability and effect to govern the pesticide program. *See* FIFRA § 25(a)(1). In contrast to individual pesticide permit decisions, for reasons discussed below, these general program rules would be subject to the provisions of the SNPR and the manner in which they would be addressed under the SNPR is of direct interest to CLA and RISE members.

As requested, CLA’s And RISE’s comments today address EPA’s new SNPR. CLA and RISE continue to support EPA’s efforts to strengthen the integrity of its regulatory actions and recognizes the Agency’s need to independently validate the data that support many of its decisions. The SNPR provides two new Options for addressing circumstances in which relevant data do not meet all of these standards. CLA and RISE support Option 2, under which EPA would give greater or lesser consideration to data, by taking into account both the degree of access to and the attributes of the data.

CLA’s and RISE’s comments today are focused on three issues raised by the SNPR: (1) the scope of the actions encompassed by the rulemaking; (2) implementing the rulemaking consistent with statutory requirements protecting proprietary data and confidential business information; and (3) whether to adopt Option 1 or 2 for 40 CFR 30.5. CLA and RISE generally support EPA’s approach to issues (1) and (2) in the SNPR, subject to confirming our understanding of the SNPR as discussed below, and support Option 2 for 40 CFR 30.5.

First, CLA and RISE understand that EPA’s original April 30, 2018 proposal was applicable to data underlying final regulations determined to be “significant regulatory actions” by the Office of Management and Budget (OMB), consistent with definitions, formal exclusions, and practices dating to 1993. *See* Executive Order (EO) 12866; OMB Guidance for Implementing EO 12866 (Oct. 12, 1993), App. C. Consistent with this longstanding approach, EPA appropriately excluded data submitted in support of individual pesticide permit decisions from the scope of its original proposal. In so doing, EPA also ensured that it would comply with the statutory framework established by Congress to carefully balance the requirements of public

¹ We use the word “data” in these comments to encompass EPA’s references to both data and models.

² We use the phrase “individual pesticide permit decisions” in these comments to encompass these various permit actions.

notice and transparency (which are accomplished through several statutory provisions under FIFRA and FFDCA) with the need to incentivize pesticide product innovation through the protection of proprietary data rights (also accomplished through specific provisions of FIFRA and FFDCA).

EPA's SNPR proposes to expand the scope of the rulemaking to "influential scientific information" in addition to "significant regulatory actions." The SNPR proposes to define influential scientific information as "scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions." Proposed 40 CFR 30.2 at 85 Fed. Reg. 15405.

This definition is drawn directly from OMB's December 16, 2004 "Final Information Quality Bulletin for Peer Review" (OMB M-05-03). As with the EO 12866, OMB M-05-03 expressly exempts from its peer review requirements any "official disseminations that arise in adjudications and permit proceedings," explaining that "[t]his exclusion is intended to cover, among other things, licensing, approval and registration processes for specific product development activities as well as site-specific activities." OMB M-05-03 at 32.

In light of the above, CLA and RISE wish to confirm that the SNPR (and any final rule that EPA promulgates) does not include individual adjudications or permit proceedings, such as FIFRA or FFDCA decisions on individual pesticide registrations or tolerances. By contrast, and also consistent with longstanding practice, the scope would encompass more broadly applicable rulemakings under FIFRA or FFDCA that do meet the definition of "significant regulatory action." See CLA's August 16, 2018 public comments at pp. 4-5 (providing detailed citations and examples).

Second, CLA and RISE appreciate that EPA has continued in the SNPR to confirm that it will apply the rule consistent with statutory requirements to protect proprietary data and confidential business information. See 85 Fed. Reg. 15402. This would include the FIFRA and FFDCA provisions outlined by CLA in its August 16, 2018 comments, and discussed below in the context of revisions proposed in the SNPR.

Third, the SNPR provides two Options for 40 CFR 30.5 to address circumstances in which EPA does not have full access to the details of potentially relevant data. CLA and RISE support Option 2, under which EPA would give greater or lesser consideration to data, by taking into account both the degree of access to and the attributes of the data.

We have provided further detail on these three issues below.

1. Consistent With Longstanding Federal Government Policy And Practice, Data Associated With Individual Pesticide Permit Decisions Are Excluded From “Influential Scientific Information”

In its new SNPR EPA proposes to expand the scope of the regulation to EPA’s use of data and models when “finalizing influential scientific information.” This is in addition to “significant regulatory actions,” as provided in EPA’s original 2018 proposal. CLA and RISE support this expansion, subject to the Agency’s confirmation of the information below.

As discussed in more detail in CLA’s August 16, 2018 comments, and consistent with EO 12866 and longstanding federal policy and practice, individual pesticide permit decisions are not “significant regulatory actions.” EO 12866 defines a “significant regulatory action” to mean any regulatory action that is likely to result in a rule meeting certain specified criteria (*i.e.*, any substantive action by an agency that promulgates or is expected to lead to the promulgation of a final rule or regulation). 58 Fed. Reg. 51735 (Oct. 4, 1993).

EPA’s individual pesticide permit decisions do not involve the promulgation of any rule or regulation with broad application. Instead, EPA issues individual pesticide product registrations as specific permits under FIFRA and, for food-use pesticides, issues related tolerances under the FFDCA, based on the Agency’s evaluation of the data required for the specific permits.

Similarly, EPA should confirm that it does not intend to draw proceedings associated with individual pesticide permit decisions, including pesticide registration decisions and associated tolerances (and the data that underlie them) within the SNPR’s expanded scope. The term “influential scientific information” is defined at newly proposed 40 C.F.R. § 30.2 to mean:

“Scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions.”

This definition is drawn directly from OMB’s December 16, 2004 “Final Information Quality Bulletin for Peer Review” (OMB M–05–03), which established that important scientific information must be peer reviewed by qualified specialists before it is disseminated by the federal government. In that 2004 memorandum, OMB expressly exempted from its peer review requirements any “official disseminations that arise in adjudications and permit proceedings,” explaining that “[t]his exclusion is intended to cover, among other things, licensing, approval and registration processes for specific product development activities as well as site-specific activities.” OMB M-05-03 at 32.

OMB’s exclusion for permit decisions has long been recognized by EPA. *See, e.g.*, EPA Science and Technology Policy Council, “Peer Review Handbook” (4th Ed. Oct. 2015), at 44 (identifying registration determinations among those “influential work products” that do not need to be peer reviewed, even if they might otherwise be considered “influential scientific information” or “highly influential scientific assessments”). This exclusion is preserved by

EPA's SNPR at proposed 40 C.F.R. § 30.3, which provides that the rule's provisions "do not apply to any other type of agency action, including individual party adjudications, enforcement activities, or permit proceedings."

2. FIFRA And The FFDCA Already Ensure Public Access To Pesticide Studies "In A Manner Sufficient For Independent Validation," While Protecting The Proprietary Nature Of Pesticide Data

The two federal statutes governing pesticide data have long-provided a successful balance of providing transparency while protecting proprietary data. EPA's SNPR is consistent with the statutory protections.

Even if data submissions in support of individual pesticide permit decisions were considered "influential scientific information" in certain circumstances, EPA's SNPR recognizes that it must be able to use data even when they are not made fully available to the public because of statutory restrictions necessary to protect proprietary information. Specifically, the SNPR provides that scientific studies or analyses that underlie influential scientific information ("pivotal science") include studies:

- "that include confidential business information (CBI), proprietary data, or Personally Identifiable Information (PII) that cannot be sufficiently de-identified to protect the data subjects) if there is tiered access to these data models in a manner sufficient for independent validation." Proposed 40 C.F.R. § 30.5 (Option 1); or
- "based on data and models that include confidential business information, proprietary information or personally identifiable information if these data and models were available through restricted access, such as through a secure data enclave, in a manner sufficient for independent validation." Proposed 40 C.F.R. § 30.5 (Option 2).

Both approaches are expressly based on EPA's recognition that "there are statutory restrictions to public availability for some data and models that could make independent validation difficult." 85 Fed. Reg. at 15402. Accordingly, both proposed Options provide that, where EPA is making data or models publicly available, "it shall do so in a manner that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security." Proposed 40 C.F.R. § 30.5 (Options 1 and 2). Furthermore, EPA will consider data "available in a manner sufficient for independent validation" even when that availability is "subject to access and user restrictions" where necessary. *Id.*

EPA's proposed framework is consistent with existing statutory transparency mandates for pesticide registration and tolerance data. FIFRA requires EPA to make available to the public information concerning the objectives, methodology, results, or significance of any test or experiment performed on or with a registered pesticide, and any information concerning the

effects of such pesticide on any organism or the behavior of such pesticide in the environment -- subject to important restrictions necessary to protect the proprietary nature of pesticide studies. FIFRA §§ 10(d)(1), 10(g)(1).

Recognizing the possibility that industry competitors might obtain and seek to improperly use copies of another submitter's unpublished data to satisfy their own pesticide regulatory requirements in other jurisdictions, FIFRA expressly prohibits EPA from disclosing studies submitted by a pesticide applicant or registrant to any employee or agent of a foreign or multinational pesticide company. FIFRA § 10(g)(1).

Underscoring the importance of this prohibition, FIFRA requires EPA to obtain an affirmation (submitted subject to criminal penalties under 18 U.S.C. § 1001) from any person seeking access to pesticide registration data to ensure that such individuals will not deliver or offer the data to any such business or entity. FIFRA §§ 10(g)(1), (3). Before EPA will provide a member of the public with access to a pesticide submission, the requestor must affirm that it:

- is not a business or other entity engaged in the production, sale, or distribution of pesticides in countries other than the United States or in addition to the United States (nor an employee or agent of any such business or entity);
- does not seek access to the information for purposes of delivering it or offering it for sale to any such business or entity or to any of its employees or agents; and
- will not purposefully deliver the information (or negligently cause it to be delivered) to any such entity or to any of its employees or agents.

EPA has confirmed that it would be unlawful for a person to execute the required affirmation while having the intent to publish or otherwise deliver a pesticide data submitter's previously unpublished data submission to a foreign or multinational pesticide producer, explaining that "the information delivered likely could be used to satisfy a data requirement imposed by a foreign country as a condition of producing, distributing, selling, shipping, or using the product in that country." *See* EPA, "Limitations on Disclosure of Information Under Pesticide Law" (available at: <https://www.epa.gov/foia/limitations-disclosure-information-under-pesticide-law>).³ Under this FIFRA and FFDCA framework, secure access to pesticide studies is made available to any member of the public affirming non-multinational status.

The framework provided under FIFRA and the FFDCA is a successful example of balancing the importance of transparency with the need to ensure protection of data submitters' proprietary rights. FIFRA and the FFDCA ensure the general public is provided secure access to pesticide studies in a manner sufficient for independent validation, while at the same time

³ FFDCA § 408(i) extends the same protections as FIFRA's to data submitted in support of EPA tolerance decisions.

protecting the proprietary nature of those studies by prohibiting, through the required affirmation, publication or any other type of delivery of the studies to foreign or multinational pesticide producers.

3. 40 CFR 30.5 Option 2 Would Ensure EPA's Ability To Consider Data To Varying Degrees Depending On The Degree Of Access To and Attributes Of The Data

The SNPR provides two Options for 40 CFR 30.5 to address circumstances in which EPA does not have full access to the details of potentially relevant data. CLA and RISE support Option 2, under which EPA would give greater or lesser consideration to data, by taking into account both the degree of access to and the attributes of the data.

CLA and RISE appreciate that there are circumstances in which there may be data that contain potentially relevant information that EPA should be able to consider, but that may not meet all the standards of transparency and quality that the majority of the data meet under FIFRA and the FFDCA, for instance. Two routine examples in the FIFRA and FFDCA context include (a) benefits data (often developed by agricultural experts) that must be submitted to, and evaluated by, EPA under FIFRA § 3 and §§ 6(b-e) and (b) information that must be submitted to and evaluated by EPA under FIFRA § 6(a)(2) adverse effects reporting requirements. In some circumstances, despite EPA's best efforts, it may not have the optimum degree of access. In such circumstances, EPA should have the option to assess both the degree of access to and the attributes of the data and, based on those two factors, to determine how much consideration to give to the particular data. In doing so, it should take into account the full set of data available to the Agency and ensure that the proper relative weight is given to specific items within that data set.

This approach is consistent, for instance, with the way in which EPA has addressed FIFRA's explicit provision authorizing EPA to consider data that appear in the "public literature." FIFRA § 3(c)(1)(F). In implementing this statutory provision, EPA has long taken into account the validity of the data and other considerations about the extent to which the Agency should rely on such data, consistent with Option 2. *See, e.g.*, 40 CFR 152.94. In this statutory example, EPA may give more or less consideration to publications, depending on the degree of access and attributes of the data.

Although EPA's individual pesticide permit decisions under FIFRA and the FFDCA are not within the scope of the SNPR, CLA and RISE hope that the examples provided in our comments of how the SNPR's data transparency objectives have been met under FIFRA and the FFDCA provide helpful perspective on the sound nature of EPA's proposal with respect to general program rules and other actions that are within the scope of the SNPR.

4. Conclusions

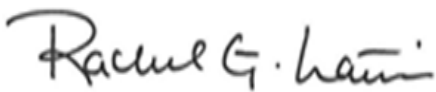
CLA and RISE support EPA's approach of applying its proposal to "significant regulatory actions" and "influential scientific information," including pesticide regulations that

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meet that threshold. CLA and RISE also support the exclusion of individual pesticide permit decisions and related data under FIFRA or the FFDCA, which is consistent with that threshold. CLA and RISE appreciate that EPA has continued in the SNPR to confirm that it will apply the rule consistent with statutory requirements to protect proprietary data and confidential business information. Finally, CLA and RISE support Option 2 for 40 CFR 30.5.

Should you have any questions about, or wish to have further information on these comments, please contact us. Thank you for your consideration of these comments.

Respectfully,



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