American Association of Pesticide Safety Educators

August 14, 2018

Acting Administrator Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460

Submitted electronically at www.regulations.gov

RE: Docket No. EPA–HQ–OA–2018–0259: Strengthening Transparency in Regulatory Science (April 30, 2018)

The American Association of Pesticide Safety Educators (AAPSE) represents Cooperative Extension pesticide safety educators; state, federal, and tribal pesticide regulators; private educators; and members from the regulated community. In furtherance of the Federal Insecticide, Fungicide and Rodenticide Act (administered by EPA), our members are responsible for developing and providing training to pesticide applicators in agriculture, green industries (landscapers, greenhouse operators, nurseries, etc.), structural and food-processing pest management, public health, and many other categories. Nationwide, we reach over 900,000 certified pesticide applicators.

Safe and effective use of pesticides requires an understanding not only of their many benefits but also of potential adverse effects on the applicator, his or her fellow workers, the public, and the environment. Such an understanding requires the use of the best science available to underpin the registration and regulation of pesticide products. This is the reason AAPSE finds it necessary to comment on EPA's proposed rule "Strengthening Transparency in Regulatory Science," which if put into effect would impact future rulemaking under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).

We have several concerns about the proposal, as outlined below.

1) Because the preamble and proposal are contradictory as to what data is subject to the proposed rule, we feel this is a critical point that must be addressed first. In the preamble, EPA makes the following statement that is unsupported by the text of the proposal: "Implementation of this rule will be consistent with the definition of 'research data' in Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards." In the cited regulation, the Office of Management and Budget (OMB) defines "research data" within the context of identifying what information a federal agency must release to satisfy a Freedom of Information Act (FOIA) request for data generated by research funded through that agency. Because it would be illegal for an agency to release confidential data even to satisfy a FOIA request, OMB specifically excludes certain confidential information from the definition of "research data" (shown here and viewable in §200.315(e)(3), (3)(i), and (3)(ii) at https://www.gpo.gov/fdsys/pkg/FR-2013-12-26/pdf/2013-30465.pdf; underlining added for emphasis):

"Research data means the recorded factual material commonly accepted in the scientific community as necessary to validate research findings, but not any of the following: preliminary analyses, drafts of scientific papers, plans for future research, peer reviews, or communications with colleagues. This "recorded" material excludes physical objects (e.g., laboratory samples).

Research data also do not include:

(i) Trade secrets, commercial information, materials necessary to be held confidential by a researcher until they are published, or similar information which is protected under law; and

(ii) Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study."

This definition of "research data" actually excludes types of data (items (i) and (ii)) that are nonetheless discussed throughout the proposal to strengthen transparency. Thus, contrary to its statement in the preamble mentioned earlier, EPA disregards this definition throughout the actual proposal, as evidenced by the following:

- Though EPA references this definition in §30.2 ("What definitions apply to this subpart?") of the proposed rule, the term "research data" is absent from the rest of the proposed regulation (except in §30.10, described below). EPA instead refers only to "data" without ever requiring that "data" be limited by the definition (and exclusions) of "research data."
- In describing the data to which the proposal applies, EPA states in §30.3 "The provisions of this section do not apply to physical objects (like laboratory samples), drafts, and preliminary analyses." As these are already excluded from the definition of "research data," it would be redundant for EPA to exclude them if they were using said definition. Also, by mentioning these exclusions while remaining silent on trade secrets and privacy information that are excluded from the definition of "research data," EPA clearly signals that those data are not excluded from the "data" to which EPA refers in the proposal.
- Given that the cited definition of "research data" excludes privacy data, the following concern about privacy in §30.5 of the proposal would be a non-issue if EPA were to actually adhere to that definition: "The agency shall make all reasonable efforts to explore methodologies, technologies, and institutional arrangements for making such data available before it concludes that doing so in a manner consistent with law and protection of privacy, confidentiality, national and homeland security is not possible."
- In §30.10, EPA states "EPA shall implement the provisions of this section consistent with the definition of 'research data'" cited previously. However, such definition applies only to §30.10; if EPA meant for it to apply to the entire proposed regulation (as stated in the preamble), they would have stated that they "shall implement the provisions of this part consistent with" the cited definition. If this were merely a transcriptional error and EPA indeed meant to say "of this part," then once again the concern cited in §30.5 above would be a non-issue and would not appear in the proposed regulation.

It is clear, then, that the proposal applies to a much broader range of data than that included in the cited definition of "research data." This presents serious consequences for EPA, the people whose mission it is to protect, and the regulated community because the proposal would allow EPA to ignore research findings if it were not possible to make public all the underlying data, including data that is excluded from the definition of "research data."

2) Yet the references EPA cites in support of this proposal actually endorse and provide the means for sharing, publishing, and using data and findings from studies in which some data cannot be made publicly available (e.g., personal health data, trade secrets). We list here a few of the approximately two dozen examples that undermine EPA's proposal:

- To support its stated purpose of "enhancing the public's ability to understand the regulatory process," EPA cites the Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity (available at http://seedmagazine.com/content/article/scientific_integrity_memorandum/) as stating "If scientific and technological information is developed and used by the Federal Government, it should ordinarily be made available to the public. To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking." While even this mentions "to the extent permitted by law," the source further supports the use of science even if some data cannot be made public when it states "Except for information that is properly restricted from disclosure under procedures established in accordance with statute, regulation, Executive Order, or Presidential Memorandum, each agency should make available to the public the scientific or technological findings or conclusions considered or relied on in policy decisions."
- EPA states "This proposed rule is also consistent with...the focus on transparency in OMB's Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies" (available at https://www.gpo.gov/fdsys/pkg/FR-2002-02-22/pdf/R2-59.pdf). Yet the OMB Guidelines state (underlining added for emphasis) "If an agency is responsible for disseminating influential scientific, financial, or statistical information, agency guidelines shall include a high degree of transparency about data and methods to facilitate the reproducibility of such information by qualified third parties. With regard to original and supporting data related thereto, agency guidelines shall not require that all disseminated data be subjected to a reproducibility requirement. Agencies may identify, in consultation with the relevant scientific and technical communities, those particular types of data that can practicably be subjected to a reproducibility requirement, given ethical, feasibility, or confidentiality constraints." OMB clearly states that data can be used even if confidentiality constraints make reproducibility impractical.
- EPA states the proposal "builds upon prior EPA actions in response to government-wide data access and sharing policies." Yet prior EPA actions support the sharing of scientific findings from underlying confidential data, as shown here:
  - "Whether research data are fully available to the public or available to researchers through other means does not affect the validity of the scientific conclusions from peer-reviewed research publications." (Plan to Increase Access to Results of EPA-Funded Scientific Research https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf);

- "The program promotes transparency by exposing the reason data is restricted, and makes data more available to the public." (EPA Open Government Plan 4.0 https://www.epa.gov/sites/production/files/2016-09/documents/2016epaopengovplan4_0draft091516update1.pdf); and
- "The Agency understands that the information it manages is of significant interest and value to the public and reaffirms its commitment to share uncontrolled information.... EPA must designate one of three "access levels" for each data asset (public, restricted public and non-public). Exceptions to publicizing data may result from law, regulation or policy, which address privacy, confidentiality, security or other valid restrictions." (EPA Open Data Implementation Plan https://www.epa.gov/sites/production/files/2015-05/documents/opendatapolicyimplementationplan_030415_finalb.pdf)

- EPA also states that its proposal is informed by the policies recently adopted by some major scientific journals, specifically the *Proceedings of the National Academy of Sciences*, *PLOS ONE*, *Science*, and *Nature*. Yet in a joint statement (http://science.sciencemag.org/content/sci/early/2018/04/30/science.aau0116.full.pdf), the editors-in-chief of these journals object to the EPA's proposal and state "It does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them; rather, it is paramount that the full suite of relevant science vetted through peer review, which includes ever more rigorous features, inform the landscape of decision making. Excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes."
- EPA states "The proposed rule takes into consideration the policies or recommendations of third party organizations who advocated for open science." However, all sources cited by EPA support using and sharing data and findings while simultaneously protecting confidential data. For example, at https://bipartisanpolicy.org/wp-content/uploads/sites/default/files/BPC%20Science%20Report%20fnl.pdf, the Bipartisan Policy Center's Science for Policy Project states "Studies used in the formulation of regulation should be subject to data access requirements equivalent to those under the Data Access Act (Shelby Amendment) and its implementing circular regardless of who funded the study." The implementing circular is OMB Circular A-110 (https://www.gpo.gov/fdsys/pkg/FR-1999-10-08/pdf/99-26264.pdf), which directs federal agencies to use and share research data but specifically notes that "research data" do not include trade secrets and "Personnel and medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy."

These references, as well as others cited by EPA, show that current regulatory, scientific, and third party policies and efforts to expand data transparency and access are sufficient to meet EPA's stated goal of ensuring that data that underpin regulations are available in a manner sufficient for independent validation. The additional requirements proposed by EPA to meet the "transparency" standard are unnecessary and counterproductive.

3) For studies concerning environmental risks to human health, it is often impossible to make all of the underlying data publicly available because doing so would compromise confidential information such as individual identities and/or health information. While many commenters have pointed out the potential harm from chemical exposures that could result by excluding such studies from consideration in rulemaking, we must consider that the proposal could also unfairly skew rulemaking

against use of chemicals that would not result in an expectation of unreasonable harm. For example, a recent paper based on findings of the National Institutes of Health's (NIH) Agricultural Health Study (https://aghealth.nih.gov/) showed no association between exposure to glyphosate and any cancer. In deciding how and whether to regulate glyphosate (e.g., setting tolerances), EPA would have to ignore this real-world study, thus giving disproportionate weight to other studies (some lab-based as opposed to conducted under real-world conditions) that suggest glyphosate could cause cancer under some circumstances. This could result in an unfair burden on the regulated community in terms of stricter regulation or the discontinued use of products.

4) Without citing a supporting reference, EPA states "Information is considered 'publicly available in a manner sufficient for independent validation' when it includes the information necessary for the public to understand, assess, and replicate findings." However, to "replicate" findings means to repeat an entire experiment, generate new data, and get the same results. To "reproduce" findings, which requires publicly available data, means to analyze the data provided and come to the same conclusions. It is clear that, by itself, making data publicly available is insufficient to allow someone to replicate findings. Also, long-term studies that involve a specific mix of individuals with their own medical histories and chemical exposures (e.g., NIH's Agricultural Health Study) cannot possibly be "replicated," nor can studies which rely on data obtained after a natural or man-made disaster (e.g., oil spill). Therefore, EPA's insistence that data must be made public in a manner that allows the findings to be replicated is fundamentally unworkable. Sources discussing the difference between replicable and reproducible include http://www.replicability.tau.ac.il/index.php/replicability-in-science/replicability-vs-reproducibility.html, https://jblevins.org/log/rep, and https://osf.io/tvyxz/wiki/6.%20Future%20Directions/.

5) In the preamble to the proposed rule, EPA states "This proposed regulation is intended to apply prospectively," meaning it will apply only to future regulations (though that limitation in scope is left out of the proposed rule itself). However, EPA is silent as to whether it will apply only to future scientific findings. As worded, it seems the rule would apply its restrictions to any scientific study conducted before or after the rule is promulgated. Given that most science conducted prior to the Internet age would likely fall short of the rule's transparency standard, this poses a problem for EPA. If we discover a previously unknown or overlooked source of exposure to an "old" toxicant (e.g., lead, mercury, inorganic arsenicals), and the decades-old data confirming the risks of such exposure fail to meet the rule's transparency requirements, EPA will be faced with two untenable options:

    1) Ignore the threat despite universal agreement of its existence and severity. Or
    2) Sanction new studies to reaffirm that people exposed to the chemical will be harmed. This could require the unethical practice of doing controlled studies in which some patients are exposed to the toxicant and others are not---an option the EPA would of course refuse to endorse.

    The proposed rule would essentially throw out a century (and more) of scientific and medical knowledge and progress. This certainly contradicts the stated purpose of the proposal in the preamble, which is that the proposal will "help ensure that EPA is pursuing its mission of protecting human health and the environment."

6) Related to and drawing from the previous 3 points, scientific consensus and subsequent regulatory action are based on assessing all accumulated evidence rather than relying on any one study or subset of studies. Applying an arbitrary filter to any peer-reviewed findings would subject the regulatory process to a flawed and detrimental approach.

7) The proposal would diminish the effectiveness of pesticide safety educators, who often assuage public fears by pointing out that pesticide use and regulation are based on the best available science. The Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and its implementing regulation are risk based. Risk is assessed by quantifying both the hazard (toxicity) of a pesticide and a person's likely exposure to it. Dose-response data are therefore critical to assessing risk. By allowing EPA to ignore real-world, risk-based studies such as those coming out of the Agricultural Health Study, the proposed rule would seriously, and perhaps fatally, undercut EPA's ability to assess risk as required under FIFRA. Without an adequate risk assessment to justify the use of pesticide products, pesticide safety educators will in turn lack any basis for passing on safety information to pesticide users and the public.

   The result will be increased harm to people and the environment and the public's complete distrust of pest management professionals and agricultural producers. This would extend to distrust of the food supply and food industry (pest management is key to reducing the risk of foodborne illness), public health officials (pesticides are a key weapon in controlling mosquitoes, ticks, and other disease vectors), many other sectors of industry, and EPA itself. Thus, the proposal would actually undermine its stated purpose (in the preamble) to "help ensure that EPA is pursuing its mission of protecting public health and the environment in a manner that the public can trust."

For the reasons cited above, we strongly urge EPA to rescind the proposed rule in its entirety.

Sincerely,

Kim Pope Brown
American Association of Pesticide Safety Educators President-Elect
Chair of Issues and Evaluations Committee

cc: Tony Cofer, AAPCO President
Liza Fleeson Trossbach, SFIREG Chairperson