



## **ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-OPP-2023-0398; FRL-8944-02-OCSP]**

### **Pesticide Registration Notice 2025-1; Revised Procedures for Citing Data to Support Pesticide Registrations (EPA Forms No. 8570-34 and 8570-35); Notice of Availability**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA or Agency) is announcing the availability of Pesticide Registration Notice (PR Notice) 2025-1, entitled “Revised Procedures for Citing Data to Support Pesticide Registrations (EPA Forms No. 8570-34 and 8570-35).” PR Notices are issued by the Office of Pesticide Programs (OPP) to inform pesticide registrants and other interested persons about important policies, procedures, and registration related decisions, and serve to provide guidance to pesticide registrants and OPP personnel. This PR Notice supersedes PR Notice 98-5, entitled “New forms for the Certification with Respect to Citation of Data” dated June 12, 1998. The revised procedures eliminate the requirement to submit two paper versions of the completed data matrix form and establishes electronic online submissions. EPA anticipates that these changes will reduce burden for the registrants and the Agency.

**DATES:** PR Notice 2025-1 is effective upon signature.

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2023-0398, is available online at <https://www.regulations.gov>. Additional instructions for visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Earl Ingram, Office of Chemical Safety and Pollution Prevention (7603M), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 566-1381; email address: [ingram.earl@epa.gov](mailto:ingram.earl@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. Executive Summary**

#### *A. Does this action apply to me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this proposed action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

#### *B. What is the Agency's authority for taking this action?*

Pesticide registration activities are governed by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*

#### *C. What action is the Agency taking?*

EPA is announcing the availability of PR Notice 2025-1, entitled “Revised Procedures for Citing Data to Support Pesticide Registrations (EPA Forms No. 8570-34 and 8570-35).” PR Notices are issued by the Office of Pesticide Programs (OPP) to inform pesticide registrants and other interested persons about important policies, procedures, and registration related decisions, and serve to provide guidance to pesticide registrants and OPP personnel.

This PR Notice provides updated guidance to registrants and applicants (both of which are referred to in this notice as “registrants”) concerning their submission of the forms used for

citing data to support pesticide registrations. This PR Notice will supersede PR Notice 98-5, entitled “New forms for the Certification with Respect to Citation of Data” dated June 12, 1998, that announced the availability of these forms to use for citation of data to support pesticide registrations, which were newly established in 1998 to streamline the forms previously used. With this PR Notice, OPP is revising the procedures established in 1998. Specifically, OPP is eliminating the instruction in PR Notice 98-5 that registrants submit two versions of EPA Form 8570-35 (“Data Matrix”), i.e., one the “Internal Agency Use Copy” and the other the “Public File Copy”. Consistent with federal mandates that direct agencies to adopt electronic submissions, OPP is also eliminating the instruction to use paper submissions as described in PR Notice 98-5 because these forms can be completed and submitted electronically.

Pursuant to existing regulations none of the information provided on EPA Form No. 8570-35 is confidential. EPA regulations at 40 CFR 152.119(c) require that, when requested, the Agency provides the form to the public for inspection after a product is registered. The information in the data matrix form is specified by EPA regulations at 40 CFR 152.119(b):

“Materials that will be publicly available include an applicant's list of data requirements, the method used by the applicant to demonstrate compliance for each data requirement, and the applicant's citations of specific studies in the Agency's possession if applicable.”

CBI claims for information submitted under EPA’s data requirements in 40 CFR part 158 is strictly limited in 40 CFR 158.33 to manufacturing or quality control processes, the details of any methods for testing, detecting, or measuring the quantity of any deliberately added inert ingredient of a pesticide, and the identity or percentage quantity of any deliberately added inert ingredient of a pesticide, pursuant to FIFRA section 10(d)(1) (A) through (C). None of this information is reported in the data matrix form.

In addition, OPP is eliminating the instruction to use paper submissions as described in PR Notice 98-5 because these forms can be completed and submitted electronically. This PR Notice provides updated instructions for completing and submitting these forms electronically through the Pesticide Submission Portal (PSP) that OPP established to allow registrants to create

and submit packages electronically in lieu of submitting multiple paper copies. The PSP is accessed through the EPA's Central Data Exchange (CDX) Network (<https://cdx.epa.gov/>), which is a web-based system used for various electronic environmental data submissions to EPA.

The changes in procedure presented in this PR Notice are necessary updates to reflect current operations established to help reduce the burden associated with completing, submitting and processing these forms for both applicants and the Agency, as well as to provide improved efficiencies for providing public access to the information without the extra burden associated with the use of formal requests for the additional information contained in the "Internal Agency Use Copy" of EPA Form 8570-35 ("Data Matrix"). In 2024, OPP received a total of 3,309 Data Matrices. The current process for submitting Data Matrices requires respondents to fill out and submit a secondary copy of EPA Form 8570-34. According to the Form's PRA Burden statement it takes anywhere between 0.25 to 1.25 hours to fill out the form. In 2024, the total burden sum of all respondents was a total range of 1,654.5 to 8,273 hours to fill out and submit the forms. With this PRN, respondents will only need to submit just one form instead of two, halving the total sum burden by 50% between 827.25 and 4,136.5 hours.

## **II. Background**

In the *Federal Register* of June 10, 2024 (89 FR 48893; FRL-8944-01-OCSP), EPA solicited public comments on the draft PR Notice. EPA received two public comments: Bayer CropScience (Bayer) provided comments that are addressed in this unit. The other comment was not relevant to this PR Notice, so EPA is not providing a specific response to that comment.

*Comment:* Bayer requested clarity as to how the Agency plans to administer the update of data matrices in existing registration jackets and asked if there will there be a need for registrants to provide updated data matrices.

*Response:* There is no need for registrants to provide updated data matrices. This PR applies only to data matrices going forward. The existing data matrices will not be considered obsolete but will be used by OPP staff as needed.

*Comment:* Bayer asked why EPA previously required a redacted form when we claim there is no CBI on the form.

*Response:* There is no historical evidence for why this was done; however, it led to confusion as registrants thought the material on the form might be CBI. Since the Agency does not now believe that there is a need for separate internal use and public file copies of the data matrix, EPA is now clarifying this to prevent continued confusion.

*Comment:* Bayer requested that we be more careful with use of the terms “registrant” and “applicant” and revise the PR Notice to replace “registrant” with “applicant.”

*Response:* The FR notice and the PR notice expressly use the term “registrant” to cover both registrants and applicants.

*Comment:* Bayer requested clearer language on page 3 of the proposed PR Notice to indicate whether both the Data Matrix and Certification with Respect to Citation of Data forms need to be submitted electronically.

*Response:* In response to this comment, EPA edited the language on page 3 to clarify that both forms will now be submitted electronically.

*Comment:* Bayer commented that they believe the Agency has misinterpreted what qualifies for CBI claims, with EPA referencing only the regulations implemented under 40 CFR section 158.33 related to manufacturing or quality controls processes and inert ingredients. Bayer stated the following sections should also qualify for protection as confidential: (1) Information submitted in connection with an application for tolerance or exemption to the same extent (40 CFR section 158.33(b)(2)); (2) Information related to plant incorporated protectants substantiated at the time of application (40 CFR section 158.33(b)(1)); and (3) Properly designated safety and efficacy information (40 CFR section 158.33(d)(1)).

*Response:* Bayer misreads 40 CFR section 158.33(b)(2)), which merely provides that information submitted with an application for a tolerance or exemption is subject to the same confidentiality provisions as information submitted under FIFRA. Likewise, Bayer misreads 40

CFR section 158.33(d)(1), which (in part) subjects allowable CBI claims pertaining to plant-incorporated protectants to an upfront substantiation requirement. Lastly, EPA agrees that under 40 CFR 158section158.33(d)(1), information properly designated by the submitter as FIFRA section 10(d)(1)(A), (B), or (C) may be considered for confidential protection; however, as discussed in the draft PR notice, none of the information provided on EPA Form No. 8570-35 is within the scope of FIFRA section 10(d)(1) (A), (B), or (C).

### **III. Do PR Notices contain binding requirements?**

The PR Notice discussed in this document is intended to provide guidance to EPA personnel and decision makers and to pesticide registrants. While the requirements in the statutes and Agency regulations are binding on EPA and the applicants, this PR Notice is not binding on either EPA or pesticide registrants, and EPA may depart from the guidance where circumstances warrant and without prior notice. Likewise, pesticide registrants may assert that the guidance is not appropriate generally or not applicable to a specific pesticide or situation.

### **IV. Are these forms approved under the Paperwork Reduction Act (PRA)?**

According to the PRA, 44 U.S.C. 3501 *et seq.*, an agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires approval under the PRA, unless it has been approved by the Office of Management and Budget (OMB) and displays a currently valid OMB control number. The information collection activities associated with EPA Forms 8570-34 and 8570-35 and the activities described in this PR Notice are already approved by OMB under the PRA and are contained in the Information Collection Requests (ICRs) entitled “Consolidated Pesticide Registration Submission Portal” identified as EPA ICR No. 2624.01 and approved under OMB Control No. 2070-0226; and the “Pesticide Data Call-in Program” identified as EPA ICR No. 2288 and approved under OMB Control No. 2070-0174. For additional information about these ICRs, go to <https://www.reginfo.gov/public/> and search on the applicable OMB control number.

**Authority:** 7 U.S.C. 136 *et seq.*

**Dated:** March 28, 2025.

**Edward Messina,**

*Director, Office of Pesticide Programs.*

[FR Doc. 2025-05866 Filed: 4/3/2025 8:45 am; Publication Date: 4/4/2025]