ASSISTANT ADMINISTRATOR FOR CHEMICAL SAFETY AND POLLUTION PREVENTION
WASHINGTON, D.C. 20460

December 18, 2023

PESTICIDE REGISTRATION (PR) NOTICE 2023-2

NOTICE TO MANUFACTURERS, PRODUCERS, FORMULATORS, AND REGISTRANTS OF PESTICIDE PRODUCTS

ATTENTION: Persons Responsible for Federal Registration of Pesticide Products

SUBJECT: **Establishment of the Vector Expedited Review Voucher (VERV) Program**

I. PURPOSE AND APPLICABILITY

A. Purpose

The Office of Pesticide Programs (OPP) of the Environmental Protection Agency (EPA) announces the establishment of the Agency's Vector Expedited Review Voucher (VERV) Program. The implementation of the VERV Program will incentivize the development of new insecticides to control and prevent the spread of vector-borne disease.

B. Applicability

OPP issues PR Notices to inform pesticide registrants and other interested persons about important policies, procedures and regulatory decisions.[1] This PR Notice provides guidance and clarification to pesticide applicants. While the requirements in the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and EPA regulations are binding on EPA and applicants, this PR Notice is not binding on EPA personnel, pesticide registrants and applicants, or the public. EPA may depart from the guidance where circumstances warrant and without prior notice. Likewise, pesticide applicants may assert that the guidance is not appropriate generally or not applicable to a specific pesticide or decision. Registrants and applicants may propose alternatives to the guidance provided in any application to the Agency.

II. BACKGROUND

The Pesticide Registration and Improvement Act (PRIA) was enacted in 2004 and established a new system for registering pesticides including fees and guaranteed decision times, along with funding for farmworker protection activities. PRIA was reauthorized in 2007, 2012, 2019, and most recently on December 29, 2022 (PRIA 5). PRIA 5 requires EPA to establish the VERV Program by December 29, 2023. Under the VERV Program, EPA will issue a voucher to the registrant of a new, qualifying pesticide product for mosquito control once it is successfully registered. An applicant may then redeem this voucher when submitting a future application for a different product under one of the specified PRIA

[1] *https://www.epa.gov/pesticide-registration/pesticide-registration-notices-year.*

categories. EPA will then expedite its review of the application, potentially allowing a shorter time to market for the product involved. Once issued, vouchers may be sold or transferred to other registrants.

III. ELIGIBILITY REQUIREMENTS

To qualify for a voucher under the VERV Program, application for a new active ingredient must show[2] that the ingredient:

1. Demonstrates a proven efficacy against pyrethroid or other insecticide-resistant mosquitoes (*see* 40 C.F.R. part 158, Subpart R[3]), (*see* FIFRA Section 4(k)(7)(B)(iv)(I)(aa));
2. Prevents, kills, mitigates, or repels pyrethroid- or other insecticide-resistant mosquitoes, with a novel or unique mechanism or mode of action (MOA), different from other insecticides already registered by the Administrator for mosquito control (*see* FIFRA Section 4(k)(7)(B)(iv)(I)(bb));
    - EPA will determine whether or not an application has a novel MOA on a case-by-case basis. Novel MOAs may include pesticides with new chemical classes (as determined by the Insecticide Resistance Action Committee). New pesticides using a unique mechanistic approach to control (*e.g.*, targeting different receptors, interrupting mosquito behavior, targeting different life stages, prohibiting reproduction) may also qualify.
    - This requirement may be waived if the Administrator determines there is a significant public health benefit, which would allow an existing agricultural product to be repurposed for control of mosquitoes (*see* FIFRA Section 4(k)(7)(B)(III)). Waiver requests must be submitted with the application and decisions will be made on a case-by-case basis.
3. Targets mosquitoes capable of spreading such diseases as malaria, dengue, Zika, chikungunya, St. Louis encephalitis, Eastern equine encephalitis, Western equine encephalitis, West Nile encephalitis, Cache Valley encephalitis, La Crosse encephalitis, and yellow fever (*see* FIFRA Section 4(k)(7)(B)(iv)(I)(cc));
4. Is made accessible for use in the United States, including territories or possessions of the United States, and countries where mosquito-borne diseases, such as malaria, are prevalent (*see* FIFRA Section 4(k)(7)(B)(iv)(I)(ff));
5. Broadens the adoption of integrated pest management strategies, such as insecticide resistance management, or makes those strategies more effective (*see* FIFRA Section 4(k)(7)(B)(iv)(I)(hh));
6. Is not contained in any pesticide product registered by the Administrator as of December 29, 2022 (*see* FIFRA Section 4(k)(7)(B)(iv)(I)(ii)), or does not contain an active ingredient approved in the 2-year period preceding the date of registration by any global stringent regulatory authority for the same uses, vectors, and applications (*see* FIFRA Section 4(k)(7)(B)(iv)(I)(jj)).

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[2] FIFRA Section 4(k)(7)(B)(iv)(I)(gg) requires that a voucher applicant must also demonstrate that the product "meets registration requirements for human health and environmental effects, labeling, and presents no unreasonable adverse effects to the environment." This applies to all applications for registration of pesticide products. *See* FIFRA Section 3.

[3] *See* 87 FR 22475, April 15, 2022 (FRL-5331-05-OCSPP) at *https://www.govinfo.gov/content/pkg/FR-2022-04-15/pdf/2022-07963.pdf*.

- This requirement may be waived if the Administrator determines there is a significant public health benefit, which would allow an existing agricultural product to be repurposed for control of mosquitoes (*see* FIFRA Section 4(k)(7)(B)(III)). Waiver requests must be submitted with the application and decisions will be made on a case-by-case basis.

In addition to meeting the above requirements, the applicant must provide with their application:

- A global access plan that will be made publicly available for the active ingredient and that addresses:
    a. Manufacturing locations, including any licensed third-party manufacturers;
    b. Distribution and procurement processes for malaria vector control programs in selected countries; and
    c. The prices for common quantities of the product.

  (See FIFRA Section 4(k)(7)(B)(iv)(I)(dd)).

IV. TRANSFER OF VOUCHERS AND CBI CLAIMS

When granting a voucher, EPA will notify the registrant at the same time the Agency approves the application for the new active ingredient registration. All vouchers issued by EPA will be posted on the EPA web page with a unique identifying number, along with the date of issuance, registrant of the mosquito-control registration, status, date of redemption and application each voucher was redeemed for (once redeemed). When redeeming a previously-issued voucher, any redeemer—other than the registrant to which the voucher was initially issued—must provide to the Agency documentation demonstrating transfer of the voucher from the initial recipient to the redeemer, including confirmation from each recipient. This documentation must be submitted with the 90-day notice submitted prior to redeeming the voucher, as described in section V below.

Although it is strongly recommended that an entity seeking to redeem a voucher minimize the amount of information claimed as confidential business information (CBI), the submitter may assert a claim of confidentiality for all or part of the information submitted to EPA documenting transfer of the voucher from the initial recipient to the redeemer. See 40 C.F.R. § 2.307. Any claim of confidentiality must accompany the information at the time the information is submitted to EPA. Failure to assert a claim at that time constitutes a waiver of confidentiality for the information submitted, and the information may be made available to the public, subject to FIFRA Section 10(g), with no further notice to the submitter. Any claim of confidentiality must be accompanied, at the time the claim is made, by comments substantiating the claim and explaining why the submitter believes that the information should not be disclosed. The submitter must address each of the points listed in 40 C.F.R. § 2.204(e)(4) in the substantiation.

V. REDEMPTION

Prior to redeeming a voucher, an applicant must notify EPA of their intent at least 90 days prior to submitting the application to be eligible for the expedited review process. No other requirements for registration will change and applicable registration service fees are still required under FIFRA Section

33(b). Pursuant to FIFRA Section 4(k)(7)(B)(vi), EPA will expedite decisions only for the following PRIA categories and timeframes:

PRIA Category	Expedited Decision Review Times (compared to standard times)
R010, New Active Ingredient, Food use	30 months (6 months shorter than 36 months)
R020, New Active Ingredient, Food use; reduced risk	21 months (6 months shorter than 27 months)
R060, New Active Ingredient, Non-food use; outdoor	24 months (6 months shorter than 30 months)
R110, New Active Ingredient, Non-food use; indoor	14 months (6 months shorter than 20 months)
R070, New Active Ingredient, Non-food use; outdoor; reduced risk	20 months (4 months than 24 months)
R120, New Active Ingredient, Non-food use; indoor; reduced risk	12 months (2 months shorter than 14 months)

As with any pesticide application, the quality of the application for which a voucher is redeemed can impact EPA's ability to complete its review within the specified deadline. Issues such as scientific or use complexity or incomplete or insufficient data sets may significantly impact deadlines.

Consistent with the Endangered Species Act (ESA) Section 7(a)(2) and EPA's 2022 *ESA Protection Policy for New Pesticides*[4], before EPA registers any new conventional active ingredient, the Agency will first evaluate the potential effects of the active ingredient on federally threatened or endangered (listed) species and their designated critical habitats, require registrants to implement ESA mitigation measures if needed, and initiate ESA consultation with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service where appropriate. This requires significant resources and time when evaluating new pesticides. EPA is currently evaluating approaches to streamline the associated steps, since the Agency has experienced challenges in meeting deadlines when considering impacts to listed species.

Once a voucher has been redeemed and the application has cleared the 21-day content screen (*see* FIFRA Section 33(f)(4)(B)(i)(I)), it cannot be submitted with or transferred to another application.

VI. GUIDANCE

As outlined in PRIA 5, the Agency must establish the VERV Program for use by potential registrants no later than December 29, 2023. To achieve this, the Agency requests that registrants should indicate they are applying for a voucher or that a previously granted voucher is being redeemed within the cover letter of their application. Registration applicants may also attach an explanation for their voucher request, that includes a description of the insecticide and public health impacts with other

[4] *https://www.epa.gov/endangered-species/epas-workplan-and-progress-toward-better-protections-endangered-species.*

required information, to the cover letter. The Agency will review the voucher application and award the voucher if the application meets the requirements of FIFRA Section 4(k)(7).

EPA Form No. 8570-1, entitled "Application for Pesticide Registration/Amendment", is used for the registration, registration review (reregistration), and special review of pesticides.

A. EPA Form No. 8570-1: Application for Pesticide Registration/Amendment
Registrants must use this form if they want to apply for a pesticide registration or amendment to their pesticide product. In addition, as specified in EPA regulations at 40 C.F.R. § 152.119(c), applicant-submitted information, including that provided on EPA Form No. 8570-1, entitled "Application for Pesticide Registration/Amendment," will, on request, be made available to the public for inspection after a pesticide product is registered. EPA has previously determined that none of the information that applicants provide on EPA Form No. 8570-1 is confidential business information (CBI) or otherwise protected under FIFRA. As such, the Agency is able to release the form in response to a request under the Freedom of Information Act (FOIA), 5 U.S.C. § 552, and EPA implementing regulations at 40 C.F.R. § 2.100.

B. Obtaining the blank forms to complete.
The Pesticide Registration Manual5, which serves as a resource for companies and individuals who want to have their pesticide products registered for sale in the United States, describes the EPA's review and decision-making process for registering a pesticide product and its use. Detailed information for pesticide registrants (the company or individual applying to register a pesticide) concerning their responsibilities before, during and after the review process is also included in the manual. Chapter 20 of the Pesticide Registration Manual, titled "Forms and How to Obtain Them," identifies the forms required to be submitted when applying for the registration of a pesticide product and describes how to obtain the forms and submit them to EPA. You can also view electronic copies of these forms at *https://www.epa.gov/pesticide-registration/pesticide-registration-manual-blank-forms*.

C. Submitting the completed form.
As described in Chapter 21 of the Pesticide Registration Manual, titled "Directions for Submitting Applications and Contacting EPA," OPP established the Pesticide Submission Portal (PSP)6 to allow registrants to create and submit packages electronically in leu of submitting multiple paper copies. PSP is accessed through the EPA's Central Data Exchange (CDX) Network7, which is a web-based system used for various electronic environmental data submissions to EPA.

VII. PAPERWORK REDUCTION ACT NOTICE
The information-collection activities associated with EPA Form No. 8570-1 and the activities described in this PRN are already approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq*. The approved activities and related instruments are contained in the Information Collection Requests (ICR), entitled "Consolidated Pesticide Registration Submission Portal", identified as EPA ICR No. 2624.02 and approved under OMB Control

[5] *https://www.epa.gov/pesticide-registration/pesticide-registration-manual*.
[6] *https://www.epa.gov/pesticide-registration/electronic-submissions-pesticide-applications.*
[7] *https://cdx.epa.gov/.*

No. 2070-0226. For additional information about this ICR, use the link *https://www.reginfo.gov/public/* and search for the ICR records using the provided OMB control number.

VIII. FOR ADDITIONAL INFORMATION

If you have questions about the forms, please contact one of the following:

For other pesticides: *OPP_RD_PRIA_Ombudsman@epa.gov* (OPP PRIA Ombudsman).

You may also mail a written inquiry to EPA using the following mailing address:

U.S. Environmental Protection Agency
Office of Pesticide Programs (Mailcode: 7505M)
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

VI. EFFECTIVE DATE

This PR Notice is effective upon signature. Since the revised form is already approved and in use, all older versions of the form will not be accepted after the effective date of this PR Notice.

VII. SIGNATURE

MICHAL FREEDHOFF

Digitally signed by MICHAL FREEDHOFF
Date: 2023.12.18 14:39:24 -05'00'

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.