



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2015-0794; FRL-9957-98]

Registration Review; Draft Human Health and/or Ecological Risk Assessment(s), and Final Tetrachlorvinphos Occupational and Residential Exposure Risk Assessment, and the Agency's decision to rely on data from human health research; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the availability of EPA's draft human health and ecological risk assessments for the registration review of bromacil, cyprodinil, and propamocarb; the draft human health risk assessment for the registration review of cyphenothrin; and the draft ecological risk assessment for the registration review of 2, 4-D, and opens a public comment period on these documents. This notice also announces the availability of EPA's final occupational and residential exposure assessment for the registration review of tetrachlorvinphos (TCVP) and EPA's explanation for relying on TCVP data from human research on TCVP exposure from pet collars. The TCVP draft risk assessments were published for a 60-day public comment period in the **Federal Register** of January 20, 2016 (81 FR 3128) (FRL-9940-81). Registration review is EPA's periodic review of pesticide registrations to ensure that each pesticide continues to satisfy the statutory standard for registration; that is, the pesticide can perform its intended function without unreasonable adverse effects on human health or the environment. As part of the registration review process, the Agency has completed comprehensive draft human health and draft ecological risk assessments for the registration review of bromacil, cyprodinil, and propamocarb; the draft human health risk assessment for the

registration review of cyphenothrin; the final occupational and residential exposure assessment for TCVP; and the draft ecological risk assessment for the registration review of 2, 4-D. After reviewing comments received during the public comment period for all pesticide cases named above (excluding TCVP), EPA may issue a revised risk assessment, explain any changes to the draft risk assessment, and respond to comments and may request public input on risk mitigation before completing a proposed registration review decision for the pesticides identified above. Regarding TCVP, the EPA has published a revised human health and final occupational and residential exposure assessment in addition to response to comments and other support documents, which explain changes to the preliminary risk assessments and responds to substantive comments. Through the registration review program, the EPA is ensuring that each pesticide's registrations are based on current scientific and other knowledge, including its effects on human health and the environment.

DATES: Comments must be received on or before [*insert date 60 days after date of publication in the Federal Register*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2015-0794, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at

<http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For pesticide specific information contact:* The Chemical Review Manager for the pesticide of interest identified in Tables I and II of Unit III.

For general questions on the registration review program, contact: Richard Dumas, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8015; email address: dumas.richard@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to a wide range of stakeholders including environmental, human health, farm worker, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action

to a particular entity, consult the Chemical Review Manager identified in Tables 1 and II of Unit III.

B. What Should I Consider as I Prepare My Comments for EPA?

1. *Submitting CBI.* Do not submit this information to EPA through [regulations.gov](http://www.regulations.gov) or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM as CBI and then identify electronically within the disk or CD-ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. Authority

EPA is conducting its registration review of the chemicals listed in Tables 1 and II of Unit III pursuant to section 3(g) of the FIFRA and the Procedural Regulations for Registration Review at 40 CFR part 155, subpart C. Section 3(g) of FIFRA provides, among other things, that the registrations of pesticides are to be reviewed every 15 years. Under FIFRA, a pesticide product may be registered or remain registered only if it meets the statutory standard for registration given in FIFRA section 3(c)(5) (7 U.S.C. 136a(c)(5)). When used in accordance with widespread and commonly recognized practice, the pesticide product must perform its intended function without unreasonable adverse effects on the environment; that is, without any unreasonable risk to man or the environment, or a human dietary risk from residues that result from the use of a pesticide in or on food.

III. Registration Reviews

As directed by FIFRA section 3(g), EPA is reviewing the pesticide registration for the pesticides listed in Tables 1 and 2 to ensure that they continue to satisfy the FIFRA standard for registration—that is, that these chemicals can still be used without unreasonable adverse effects on human health or the environment.

Table 1–Draft Risk Assessments Being Made Available for Public Comment

Registration Review Case Name and Number	Docket ID Number	Contact and Contact Information
2,4-D 0073	EPA-HQ-OPP-2012- 0330	Brittany Pruitt <i>pruitt.brittany@epa.gov</i> (703) 347-0289
Bromacil 0041	EPA-HQ-OPP-2012- 0445	Steven Snyderman <i>snyderman.steven@epa.gov</i> (703) 347-0249
Cyphenothrin 7412	EPA-HQ-OPP-2009- 0842	Margaret Hathaway <i>hathaway.margaret@epa.gov</i>

		(703) 305-5076
Cyprodinil 7025	EPA-HQ-OPP-2011- 1008	Leigh Rimmer <i>rimmer.leigh@epa.gov</i> (703) 347-0553
Propamocarb 3124	EPA-HQ-OPP-2011- 0662	Christina Scheltema <i>scheltema.christina@epa.gov</i> (703) 308-2201

Table 2– Final Occupational and Residential Exposure Assessment Being Made Available (No Public Comment Period)

Registration Review Case Name and Number	Docket ID Number	Contact and Contact Information
Tetrachlorvinphos (TCVP) 0321	EPA-HQ-OPP-2008- 0316	James Parker <i>parker.james@epa.gov</i> (703) 306-0469

Pursuant to 40 CFR 155.53(c), EPA is providing an opportunity, through this notice of availability, for interested parties to provide comments and input concerning the Agency's draft human health and ecological risk assessments for the registration review of bromacil, cyprodinil, and propamocarb; the draft human health risk assessment for cyphenothrin; and the draft ecological risk assessment for the registration review of 2, 4-D. Such comments and input could address, among other things, the Agency's risk assessment methodologies and assumptions, as applied to a draft risk assessment. The Agency will consider all comments received during the public comment period and make changes, as appropriate, to a draft human health and/or ecological risk assessment. EPA may then issue a revised risk assessment, explain any changes to the draft risk assessment, and respond to comments. In the **Federal Register** notice announcing the availability of the revised risk assessment, if the revised risk assessment indicates risks of concern, the Agency may provide a comment period for the public to submit suggestions

for mitigating the risk identified in the revised risk assessment before developing a proposed registration review decision on the pesticides identified above.

As directed by FIFRA section 3(g), EPA is also reviewing the pesticide registration for TCVP to ensure that it continues to satisfy the FIFRA standard for registration—that is, that TCVP can still be used without unreasonable adverse effects on human health or the environment. TCVP is an organophosphate (OP) insecticide used to control fleas, ticks, flies, lice, and insect larvae on livestock and domestic animals and their premises. TCVP is also applied as a perimeter treatment. TCVP is formulated into dusts, pet collars, emulsifiable concentrates, feed additives (solid and liquid), feed blocks, wettable powders, pellets and granular products. This **Federal Register** notice is announcing that the EPA has published the final registration review TCVP occupational and residential exposure risk assessment for all TCVP uses.

The final TCVP registration review occupational and residential exposure risk assessment incorporates several changes, including a reduction of the oral toxicological point of departure (POD) from 8.0 milligram/kilogram/day (mg/kg/day) to 2.8 mg/kg/day; the use of human research data (Davis, M. et al.,) “*Assessing Intermittent Pesticide Exposure from Flea Control Collars Containing the Organophosphorus Insecticide Tetrachlorvinphos*” to assess residential post-application exposure; and an approach to account for the potential release of TCVP from pet collar products as a liquid and solid form concurrently.

In addition to the final occupational and residential exposure assessment, the registration review docket for TCVP also includes other relevant documents related to the registration review of this case. The preliminary registration review assessments were

previously posted to the published in the **Federal Register** of January 20, 2016 for a 60-day comment period, during which time the public was invited to submit comments or new information.

During the 60-day comment period, comments were received from Bayer HealthCare (Bayer), The Hartz Mountain Corporation (Hartz), the Center for Biological Diversity (CBD), United States Department of Agriculture (USDA), Natural Resources Defense Council (NRDC) and the general public. The EPA's response to comments on the registration review preliminary risk assessments can be assessed in the TCVP docket (EPA-HQ-OPP-2008-0316) at www.regulations.gov.

In compliance with EPA's rule for protection of human subjects, specifically 40 CFR 26.1706(d), EPA is hereby publishing its full explanation of the Agency's decision to rely on data from human research "*Assessing Intermittent Pesticide Exposure From Flea Control Collars Containing the Organophosphorus Insecticide Tetrachlorvinphos (TCVP)*" by M. Keith Davis, J. Scott Boone, John E. Moran, John W. Tyler and Janice E. Chambers) on TCVP exposure from pet collars. Relying on this data is crucial to EPA's decision that more stringent regulatory restrictions are necessary to protect public health than could be justified without the data. EPA's full explanation can be found at [regulations.gov](http://www.regulations.gov) in docket number EPA-HQ-OPP-2008-0316, and on OPP's web page at <https://www.epa.gov/ingredients-used-pesticide-products/use-tetrachlorvinfos-exposure-data-human-research>.

1. *Other related information.* Additional information on the registration review status of the chemicals listed in Tables 1 and 2 of Unit III, as well as information on the Agency's registration review program and on its implementing regulation is available at

<http://www.epa.gov/pesticide-reevaluation>.

2. *Information submission requirements.* Anyone may submit data or information in response to this document. To be considered during a pesticide's registration review, the submitted data or information must meet the following requirements:

- To ensure that EPA will consider data or information submitted, interested persons must submit the data or information during the comment period. The Agency may, at its discretion, consider data or information submitted at a later date.

- The data or information submitted must be presented in a legible and useable form. For example, an English translation must accompany any material that is not in English and a written transcript must accompany any information submitted as an audiographic or videographic record. Written material may be submitted in paper or electronic form.

- Submitters must clearly identify the source of any submitted data or information.

- Submitters may request the Agency to reconsider data or information that the Agency rejected in a previous review. However, submitters must explain why they believe the Agency should reconsider the data or information in the pesticide's registration review.

As provided in 40 CFR 155.58, the registration review docket for each pesticide case will remain publicly accessible through the duration of the registration review process; that is, until all actions required in the final decision on the registration review case have been completed.

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

Dated: January 13, 2017,

Yu-Ting Guilaran

Director,

Pesticide Re-Evaluation Division,

Office of Pesticide Programs.

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