



BILLING CODE 6560-50-P

**ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-OPP-2016-0093; FRL-10015-11]**

**Pesticides; Draft Guidance for Waiving Acute Dermal Toxicity Tests for Pesticide Technical Chemicals and Supporting Retrospective Analysis; Notice of Availability and Request for Comment**

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

**ACTION:** Notice.

**SUMMARY:** The Environmental Protection Agency (EPA) is announcing the availability of and seeking public comment on a draft guidance document entitled “Guidance for Waiving Acute Dermal Toxicity Tests for Pesticide Technical Chemicals & Supporting Retrospective Analysis.” Guidance documents 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 This draft guidance document provides information to pesticide registrants concerning the Agency’s consideration to expand the potential for data waivers for acute dermal studies to single technical active ingredients (technical AIs) used to formulate end use products. The reasoning and analysis in this dermal waiver guidance for technical active ingredients is similar to what was presented in the 2016 guidance for end-use products. While more acute toxicity studies are submitted to OPP annually for formulated pesticide products than for technical AIS, there is still the potential for animal and resource savings from waivers for acute toxicity studies.

**DATES:** Comments must be received on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2016-0093, through the Federal eRulemaking Portal at <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.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Tara Flint, Antimicrobial Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 347-0398; email address: [flint.tara@epa.gov](mailto:flint.tara@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

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

This action is directed to the public in general. Although this action may be of particular interest to those persons who are or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA), or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also 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 person listed under **FOR FURTHER INFORMATION CONTACT**.

*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* 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 <https://www.epa.gov/dockets/commenting-epa-dockets>.

*C. How can I get copies of this document and other related information?*

A copy of the draft guidance document is available in the docket under docket ID number EPA-HQ-OPP-2016-0093.

**II. What action is the Agency taking?**

*A. Authority*

This guidance is provided under the authority of FIFRA (7 U.S.C. 136 *et seq.*) and addresses the utility of the acute dermal toxicity study for single technical chemicals in pesticide labelling, such as the signal word and precautionary statements as described in 40 CFR 156.64 and 40 CFR 156.70.

*B. Background*

EPA's OPP regularly receives acute lethality studies for oral, dermal and inhalation routes along with eye irritation, skin irritation, and skin sensitization – these data are required for

both the registration of new and reregistration of existing pesticidal products.

In 2016, OPP published the “Guidance for Waiving Acute Dermal Toxicity Tests for Pesticide Formulations & Supporting Retrospective Analysis” to support the Agency’s goal to reduce unnecessary animal testing. The retrospective analysis supports the conclusion that the dermal acute toxicity study for formulations provides little to no added value in regulatory decision making.

In 2017 Canada’s Pest Management Regulatory Agency (PMRA) released their Acute Dermal Toxicity Waiver. This policy includes both end use products and technical active ingredients. Stakeholders have requested that EPA expand its waiver guidance for technical active ingredients to support North American harmonization.

In 2019 EPA Administrator Wheeler directed Agency leadership to prioritize animal testing reduction efforts.

This draft guidance document will expand the potential for data waivers for acute dermal studies to single active ingredient technical chemicals (technical chemicals) used to formulate end use products. The reasoning and analysis in this dermal waiver guidance for technical chemicals is similar to what was presented in the 2016 guidance for end-use products. While more acute toxicity studies are submitted to OPP annually for formulated pesticide products than for technical chemicals, there is still the potential for animal and resource savings from waivers for technical chemical acute toxicity studies. Further, this guidance would allow EPA to harmonize with the PMRA.

### **III. Do Guidance Documents Contain Binding Requirements?**

As guidance, this document is not binding on the Agency or any outside parties, and the Agency may depart from it where circumstances warrant and without prior notice. While EPA

has made every effort to ensure the accuracy of the discussion in the guidance, the obligations of EPA and the regulated community are determined by statutes, regulations, or other legally binding documents. In the event of a conflict between the discussion in the guidance document and any statute, regulation, or other legally binding document, the guidance document would not be controlling.

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

Dated: October 2, 2020.

**Alexandra Dapolito Dunn,**

*Assistant Administrator, Office of Chemical Safety and Pollution Prevention.*

[FR Doc. 2020-22325 Filed: 10/7/2020 8:45 am; Publication Date: 10/8/2020]