BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2012-0441; FRL–9352–9]

Difenzoquat; Proposed Data Call-in Order for Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed order.

SUMMARY: This document proposes to require the submission of various data to support the continuation of the tolerances for the pesticide difenzoquat. Pesticide tolerances are established under the Federal Food, Drug, and Cosmetic Act (FFDCA).

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

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2012-0441; FRL-9352-9, 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), Mail Code: 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.htm.

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: Eric Miederhoff, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave, NW., Washington, DC 20460–0001; telephone number: (703) 347-8028; e-mail address: *miederhoff.eric@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

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. Potentially affected entities may include, but are not limited to, those involved with:

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

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. 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 e-mail. 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 submitting comments, remember to:

i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date and page number).

ii. Follow directions. The Agency may ask you to respond to specific questions or organize comments by referencing a Code of Federal Regulations (CFR) part or section number.

iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.

iv. Describe any assumptions and provide any technical information and/or data that you used.

v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.

vi. Provide specific examples to illustrate your concerns and suggest alternatives.

vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.

viii. Make sure to submit your comments by the comment period deadline identified.

II. FFDCA Data Call-In Authority

In this document, EPA proposes to issue an order requiring the submission of various data to support the continuation of the difenzoquat tolerances at 40 CFR 180.369. Under section 408(f) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(f), EPA is authorized to require, by order, submission of data "reasonably required to support the continuation of a tolerance" when such data cannot be obtained under the Data Call-In authority of section 3(c)(2)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136a(c)(2)(B), or section 4 of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2603. A section 408(f) Data Call-In order may only be issued following notice and a comment period of not less than 60 days.

After the 60-day comment period closes, the Agency will respond to comments, if appropriate, and may issue a final order requiring the submission of various data for difenzoquat in the **Federal Register**. A section 408(f) Data Call-In order must contain the following elements:

1. A requirement that one or more persons submit to EPA a notice identifying the person(s) who commit to submit the data required in the order;

2. A description of the required data and the required reports connected to such data;

3. An explanation of why the required data could not be obtained under section 3(c)(2)(B) of FIFRA or section 4 of TSCA; and

4. The required submission date for the notice identifying one or more interested persons who commit to submit the required data and the required submission dates for all the data and reports required in the order. (21 U.S.C. 346a(f)(1)(C)).

If EPA issues such an order, persons who are interested in the continuation of the difenzoquat tolerances must notify the Agency by completing and submitting the required "§ 408(f) Order Response" form (available in the docket) within 90 days after publication in the **Federal Register**.

The "§ 408(f) Order Response Form" requires the identification of persons who will submit the required data and lists the following options available to support the required data:

a. Develop new data,

b. Submit an existing study—submit existing data not submitted previously to the Agency by anyone,

c. Upgrade a study – submit or cite data to upgrade a study classified by EPA as partially acceptable and upgradable,

d. Cite an existing study – cite an existing study that EPA classified as acceptable or an existing study that has been submitted but not reviewed by the Agency.

If EPA does issue a final order requiring the submission of data on difenzoquat and if the Agency does not receive a § 408(f) Order Response Form identifying a person who agrees to submit the required data within 90 days after publication of the final order, EPA will proceed to revoke the difenzoquat tolerances at 40 CFR 180.369. Such

revocation order is subject to the objection and hearing procedure in FFDCA section 408(g)(2), but the only material issue in such a procedure is whether a submission required by the order was made in a timely fashion.

Additional events that may be the basis for modification or revocation of difenzoquat tolerances if a final order requiring data is issued include, but are not limited to, the following:

1. No person submits on the required schedule an acceptable proposal or final protocol when such is required to be submitted to the Agency for review.

2. No person submits on the required schedule an adequate progress report on a study as required by the order.

3. No person submits on the required schedule acceptable data as required by the final order.

4. No person submits supportable certifications as to the conditions of submitted data, where required by order and where no other cited or submitted study meets the data requirements the study was intended to fulfill.

III. Regulatory Background for Difenzoquat

Difenzoquat is an herbicide. It is not currently registered under FIFRA. Difenzoquat's last FIFRA registration was canceled in 2010. However, 25 FFDCA tolerances remain for residues of difenzoquat on the following commodities: barley, cattle, goat, hog, horse, poultry, sheep, and wheat (40 CFR 180.369). Since there are currently no domestic registrations for difenzoquat, these tolerances are referred to as "import tolerances."

The Agency completed a Reregistration Eligibility Decision (RED) for

difenzoquat in September 1994. The RED evaluated the potential human health and ecological risks associated with all registered uses of difenzoquat, and concluded that difenzoquat products, when labeled and used as specified in the RED, did not pose unreasonable risk or adverse effects to humans or the environment. Additionally, in connection with its obligation under the Food Quality Protection Act of 1996 (FQPA), the Agency evaluated whether all difenzoquat tolerances in existence at the time of the passage of FQPA met the revised safety standard that the FQPA adopted for FFDCA section 408. A Report of the Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision (TRED) for Difenzoquat was completed in April 2002. The TRED concluded that the risks of difenzoquat met the revised safety standard in FFDCA section 408.

In August 2011, in response to a registrant's interest in supporting tolerances for import purposes, the Agency completed a screening-level evaluation for difenzoquat. As there are no domestic registrations for difenzoquat products, the evaluation was limited to the potential dietary risk from exposure to difenzoquat residues in imported food commodities. The evaluation concluded that additional data are needed to support a new dietary risk assessment on exposure from imported food commodities. The necessary data include: a neurotoxicity battery; residue data for wheat hay, wheat forage, and barley hay; and an immunotoxicity study. These data requirements are discussed in detail in Unit IV.

IV. Proposed Data Requirements

A. Proposed Data and Reports

Pursuant to FFDCA section 408(f), EPA has determined that additional data are

reasonably required to support the continuation of the import tolerances for difenzoquat, which are codified at 40 CFR 180.369. These data cannot be obtained under FIFRA section 3(c)(2)(B) because difenzoquat is not registered under FIFRA and the data call-in authority under that section only extends to registered pesticides. These data cannot be obtained under TSCA because pesticides are excluded from coverage under that statute. 15 U.S.C. 2602(2)(B)(ii).

Accordingly, EPA proposes to issue a final order requiring the submission of the following data:

1. *Neurotoxicity Screening Battery (870.6200). Rationale*. EPA does not have a neurotoxicity screening battery (870.6200) for difenzoquat. This is a data requirement under 40 CFR Part 158 as a part of the data requirements for registration of a pesticide (food and non-food uses) and establishment of FFDCA tolerances. 40 CFR 158.500. The Neurotoxicity Screening Battery (870.6200) is designed to evaluate the potential adverse effects on the nervous system from exposure to pesticide chemicals. The acute neurotoxicity study is required to detect possible effects resulting from a single exposure. The subchronic neurotoxicity study is intended to detect possible effects resulting from repeated or long-term exposure.

2. *Immunotoxicity Study (870.7800).* A final report and protocol are required. *Rationale*. EPA does not have a functional immunotoxicity study (870.7800) for difenzoquat. This is a data requirement under 40 CFR Part 158 as a part of the data requirements for registration of a pesticide (food and non-food uses) and for establishment of a tolerance. 40 CFR 158.500. A functional immunotoxicity study under the Immunotoxicity Test Guideline (870.7800) is designed to evaluate the potential of a

repeated chemical exposure to produce adverse effects (i.e., suppression) on the immune system. Immunosuppression is a deficit in the ability of the immune system to respond to a challenge of bacterial or viral infections such as tuberculosis (TB), Severe Acquired Respiratory Syndrome (SARS), or neoplasia.

3. *Crop Field Trials (860.1500)* – (wheat hay, wheat forage, and barley hay) *Rationale.* EPA does not have crop field trials (860.1500) for difenzoquat for the commodities wheat hay, wheat forage, or barley hay. Field trials are required for each commodity/commodity group under 40 CFR part 158. These data are used to establish the legal maximum residue that may remain on food and to assess the risk posed by the pesticide residue.

EPA guidelines recommend that crop field trials be designed to take into account where the crop is grown and how much of the crop is grown. Field trials are generally needed for each type of formulation because the formulation can have a significant effect on the magnitude of the pesticide residue left on the crop. Residue trials also need to represent the maximum application rate on the label and have a geographic distribution representative of the commodity/commodity group so that EPA can evaluate what level of residues may be present from use of the pesticide. On June 1, 2000 (65 FR 35069) (FRL-6559-3), EPA published in the **Federal Register** a Notice which provided detailed guidance on applying current U.S. data requirements for the establishment or continuance of tolerances for pesticide residues in or on imported foods. A copy of that Notice is available in the docket of this proposed order. That Notice contains instructions for determining number and location of field trials.

EPA is requesting comment on these proposed data requirements.

B. Proposed Dates for Submission of Data/Reports

The table below lists the time proposed for both the completion and submission of each study. The proposed submission date is calculated from the date of publication in the **Federal Register** of the final order.

Guideline Requirement Number	Study Title	Timeframe for protocol submission	Timeframe for data submission
870.6200	Neurotoxicity Screening Battery	Not Required	24 months
870.7800	Immunotoxicity Study	6 months	12 months
860.1500	Crop Field Trials (wheat hay, wheat forage, and barley hay)	Not Required	24 months

V. Statutory and Executive Order Reviews

As required by statute, this document proposing to require submission of data in support of tolerances is in the form of a proposed order and not a rule. (21 U.S.C. 346a(f)(1)(C)). Under the Administrative Procedures Act, orders are expressly excluded from the definition of a rule. (5 U.S.C. 551(4)). Accordingly, the regulatory assessment requirements imposed on rulemaking do not, therefore, apply to this action.

This document proposes to require data from any party interested in supporting certain tolerances. Because this proposed order is not a significant regulatory action it is exempt from review by the Office of Management and Budget (OMB) under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993), and also not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This proposed order also does not require any special considerations under Executive Order 12898, entitled

Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994). This proposed order does contain information collections that have been approved by OMB under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*

This document proposes to require data from any party interested in supporting certain tolerances and does not impose obligations on any person or entity including States or tribes; nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this proposed final rule. In addition, this proposed order does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, difenzoquat, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 22, 2012.

Michael Goodis,

Director, Pesticide Re-evaluation Division, Office of Pesticide Programs.

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