



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2012-0441; FRL-9396-7]

Difenzoquat; Denial of Objections

AGENCY: Environmental Protection Agency (EPA).

ACTION: Order.

SUMMARY: In this Denial of Objections Order, EPA is denying the objections submitted by Amvac Chemical Corporation (AMVAC) to a Revocation Order EPA issued in May 2013 under the Federal Food, Drug, and Cosmetic Act (FFDCA) revoking all tolerances for the pesticide difenzoquat. EPA revoked the tolerances, consistent with the terms of a previously issued Data Call-In Order, because no notices of intent to submit the required data were submitted, as directed by that Data Call-In Order. In its objections, AMVAC requested that EPA delay the effective date for revoking the difenzoquat tolerances for 4½ years to allow for importation of food commodities that will be treated with the pesticide in Canada over the next 2 years. EPA denies AMVAC's objections because AMVAC has not filed a proper objection to the Revocation Order.

DATES: This order is effective [**Insert date of publication in the Federal Register**].

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2012-0441, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading

Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Joseph Nevola, Pesticide Re-Evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-8037; email address: nevola.joseph@epa.gov.

SUPPLEMENTARY INFORMATION:

I. 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).

II. Introduction

A. What Action is the Agency Taking?

In this Denial of Objections Order, EPA is denying the objections submitted by AMVAC to a Revocation Order issued by EPA in the **Federal Register** of May 29, 2013 (Ref. 1), in which EPA ordered the revocation of all tolerances for the pesticide difenzoquat under FFDCA section 408, 21 U.S.C. 346a. EPA revoked the tolerances, consistent with the terms of a previously issued Data Call-In Order (Ref. 2), because no notices of intent to submit the required data were received by EPA as directed by that Data Call-In Order. In its objections (Ref. 3), AMVAC requested that EPA delay the effective date for the revocation of the difenzoquat tolerances for 4½ years to allow for importation of food commodities that will be treated with the pesticide in Canada over the next 2 years. EPA denies AMVAC's objections because AMVAC has not filed a proper objection to the Revocation Order. The AMVAC objections are discussed in Unit IV., and EPA's denial is discussed in Unit V.

B. What is the Agency's Authority for Taking This Action?

The procedure for filing objections to tolerance actions and EPA's authority for acting on such objections is contained in FFDCA section 408(g), 21 U.S.C. 346a(g), and 40 CFR part 178. For orders issued under FFDCA section 408(f)(2), the only material issue for consideration is whether a submission required under a FFDCA section 408(f)(1)(C) order was made by the time specified in that FFDCA section 408(f)(1)(C) order. 21 U.S.C. 346a(f)(2).

III. Background

A. Statutory Background

1. *In general.* EPA regulates the use of pesticides under the authority of two Federal statutes: The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7

U.S.C. 136-136y, and FFDCA, 21 U.S.C. 346a. FIFRA provides the basis for the regulation, sale, distribution, and use of pesticides in the United States, and authorizes EPA to review and register pesticides for specified uses. EPA also has the authority to suspend or cancel the registration of a pesticide if subsequent information shows that continued use would pose unreasonable risks. EPA establishes maximum residue limits, or “tolerances,” for pesticide residues in food under FFDCA section 408. Without such a tolerance or an exemption from the requirement of a tolerance, a food containing a pesticide residue is “adulterated” under FFDCA section 402 and may not be legally moved in interstate commerce. 21 U.S.C. 331 and 342. Monitoring and enforcement of pesticide tolerances are carried out by the U.S. Food and Drug Administration (FDA) and the U.S. Department of Agriculture.

2. *Safety standard for pesticide tolerances.* A pesticide tolerance may only be promulgated by EPA if the tolerance is “safe.” 21 U.S.C. 346a(b)(2)(A)(i). “Safe” is defined by the statute to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” 21 U.S.C. 346a(b)(2)(A)(ii). Section 408 of FFDCA directs EPA, in making a safety determination, to “consider, among other relevant factors . . . available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources.” 21 U.S.C. 346a(b)(2)(D)(vi).

3. *Data required for supporting tolerances.* In determining whether to establish, modify, or revoke a tolerance, EPA considers data to evaluate whether that tolerance meets the FFDCA safety standard. Generally, these data are provided in support of an application for registration of a pesticide under FIFRA, and a petition to establish a pesticide tolerance under FFDCA. If additional data are needed for an existing tolerance, EPA's first recourse is to use the broad data call-in authority in FIFRA section 3(c)(2)(B), 7 U.S.C. 136a(c)(2)(B). In some situations where there is no domestic pesticide registration and data cannot be obtained under the data call-in authority of FIFRA section 3(c)(2)(B), or section 4 of the Toxic Substances Control Act (TSCA), 15 U.S.C. 2603, FFDCA section 408(f)(1)(C) authorizes EPA to require, by order, submission of data "reasonably required to support the continuation of a tolerance...." 21 U.S.C. 346a(f).

Under FFDCA section 408(f)(1)(C), EPA can issue a data call-in order following notice and a comment period of not less than 60 days. 21 U.S.C. 346a(f)(1)(C). After the comment period closes, the Agency will respond to comments, if appropriate, and may issue a final order requiring the data necessary to support the continuation of a tolerance. Section 408(f)(1)(C) of FFDCA requires that a data call-in order contain the following elements:

- i. 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 and the date by which such notice(s) must be submitted.

ii. A description of the data necessary to support the tolerance, reports connected to such data, a requirement to submit such data and reports, and the date(s) by which such data and reports must be submitted.

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

If EPA issues a FFDCA section 408(f)(1)(C) data call-in order and any submission required by that order is not made by the time specified in that order, EPA may revoke, by order published in the **Federal Register**, the tolerance that is the subject of that data call-in order . 21 U.S.C. 346a(f)(2). 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.

4. *Procedures for objections.* Upon issuing an order under FFDCA section 408(f)(2), any affected party has 60 days to file objections with EPA and seek an evidentiary hearing on those objections. 21 U.S.C. 346a(g)(2). For FFDCA section 408(f)(2) orders, the only material issue for review of such order is whether a submission required by the order was made by the time specified in the FFDCA section 408(f)(1)(C) order.

5. *Channels of trade provision for revoked tolerances.* The FFDCA specifically addresses the legality of pesticide residues entering or remaining in the channels of trade following revocation of the associated tolerance. 21 U.S.C. 346a(1)(5). Under FFDCA section 408(1)(5), any residues of the pesticide in or on such food does not render the food adulterated so long as it is shown to the satisfaction of FDA that:

i. The residue is present as the result of an application or use of the pesticide at a time and in a manner that was lawful under FIFRA.

ii. The residue does not exceed the level that was authorized at the time of the application or use to be present on the food under a tolerance or exemption from tolerance. Evidence to show that food was lawfully treated may include records that verify the dates that the pesticide was applied to such food.

B. Regulatory Background

1. *Difenzoquat tolerances.* Difenzoquat is a herbicide that was previously registered under FIFRA for sale and distribution in the United States. The last FIFRA registration was canceled in 2010, although tolerances remained for this pesticide on the following commodities: Barley, cattle, goat, hog, horse, poultry, sheep, and wheat (40 CFR 180.369). In August 2011, in response to AMVAC's interest in maintaining the difenzoquat tolerances for import purposes, the Agency completed a screening-level evaluation for difenzoquat (Screening-Level Memorandum) (Ref. 4). 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, in order to determine whether it was appropriate to continue the tolerances, additional data--a neurotoxicity battery; an immunotoxicity study; and residue data for barley hay, wheat forage, and wheat hay--were needed to conduct a new dietary risk assessment on exposure from imported food commodities. The neurotoxicity battery and immunotoxicity study were required in accordance with the data requirements rule, which was updated in 2007 to add these tests (Ref. 5). In addition, EPA required, consistent with its guidance on applying U.S. data

requirements to import tolerances (Ref. 6), that field trial data on crops mentioned in this unit be conducted at the maximum application rates and in the countries where the pesticide would be used so that EPA could evaluate what level of residues may be present on imported treated food commodities (Ref. 4, p. 6).

2. *EPA's FFDCA section 408(f) Data Call-In Order.* On July 6, 2012, EPA issued in the **Federal Register** a proposed Data Call-In Order under FFDCA section 408(f)(1), 21 U.S.C. 346a(f)(1), proposing to require the submission of data for the pesticide difenzoquat to support the continuation of tolerances associated with that pesticide (Ref. 7). The proposed Data Call-In Order identified the following studies for submission as reasonably required to support the difenzoquat tolerances: Neurotoxicity screening battery (OPPTS 870.6200) (Ref. 8); immunotoxicity study (OPPTS 870.7800) (Ref. 9); and crop field trials (OPPTS 860.1500) (Ref. 10) for barley hay, wheat forage, and wheat hay (Ref. 7, p. 39964). The proposed Data Call-In Order explained, in accordance with the statutory requirements, why the data could not be obtained under FIFRA section 3(c)(2)(B) or TSCA section 4. In addition, the proposed Data Call-In Order proposed dates for submission of the data and related reports. Finally, the proposed Data Call-In Order requested comment by September 4, 2012. EPA received no comments in response to the proposed Data Call-In Order and issued a final Data Call-In Order in the **Federal Register** on December 19, 2012 (Ref. 2). Consistent with the proposed Data Call-In Order and statutory obligations, the final Data Call-In Order included the following elements:

- EPA required that any person who wishes to support the difenzoquat tolerances must submit a notice identifying that person or persons who commit to submit the data

and reports in accordance with the terms of the final Data Call-In Order. EPA explained that the notice must be submitted on a Data Call-In Response form, how to obtain that form, and that the deadline for submitting that form was March 19, 2013.

- EPA described the data and reports that were required to support the continuation of the difenzoquat tolerances and required them to be submitted by certain dates.

- EPA explained that it would proceed to revoke the difenzoquat tolerances at 40 CFR 180.369 under FFDCA section 408(f) if it did not receive by March 19, 2013, a Data Call-In Response form identifying the person or persons who commit to submit the required data and reports.

3. *International notification of EPA's FFDCA section 408(f) Data Call-In Order.* Shortly after publishing the proposed Data Call-In Order, EPA notified the World Trade Organization of the proposed order pursuant to its obligations under the Agreement on the Application of Sanitary and Phytosanitary Measures, January 1, 1995 (Refs. 11 and 12). The U.S. notification, which referenced and included a link to the proposed Data Call-In Order (Ref. 7), alerted potential U.S. trading partners to EPA's need for data to support the continuation of the difenzoquat tolerances and that if no notices of intent to submit such data were received by the Agency by March 19, 2013, EPA would proceed to revoke the difenzoquat tolerances, which would prohibit the export to the United States of food commodities bearing difenzoquat residues that did not qualify under the channels of trade provision (Ref. 12).

4. *EPA's FFDCA section 408(f) Revocation Order.* Subsequent to the issuance of the final Data Call-In Order, EPA received no submissions of the Data Call-In Response

form within the required 90-day period. Therefore, in the **Federal Register** on May 29, 2013 (Ref. 1), EPA issued an order revoking all difenzoquat tolerances (Revocation Order) in accordance with the terms of its final Data Call-In Order and FFDCA section 408(f)(2), which allows EPA to revoke by order any tolerances that are the subject of a final Data Call-In Order for which a submission required by that final Data Call-In Order is not received by the date specified in that order. The Revocation Order was effective upon the date of publication in the **Federal Register**, which means that food commodities bearing difenzoquat residues after May 29, 2013, are considered adulterated unless the commodities qualified under the channels of trade provision. The Revocation Order explained that it was subject to the objection and hearing procedure in FFDCA section 408(g)(2) and that the only material issue for review of the Revocation Order was whether a submission required by the final Data Call-In Order was made in a timely fashion. The Revocation Order established July 29, 2013, as the date by which objections must be received by the Agency.

IV. AMVAC's Objections

On June 24, 2013, AMVAC submitted its formal objections to the Revocation Order. See AMVAC Objections (Ref. 3). Rather than actually challenging the revocation itself, AMVAC submitted its objections solely for the “purpose of ... seek[ing] an extension of the effective date of the revocation....” AMVAC makes two specific objections to the timing of the Revocation Order. First, citing to its recent shipment of difenzoquat to Canadian growers for use through 2015, AMVAC argues that “insufficient time has been afforded to foreign growers that continue to rely on these tolerances.” Second, AMVAC asserts that immediate revocation, or even revocation in 2015, is

unrealistic because the FFDCA channels of trade provision is “unworkable in practice.” In support of this latter claim, AMVAC claims that barley and wheat, two crops covered by difenzoquat tolerances, “may be stored for a protracted period and that treated grain might also be intermingled with untreated grain while in storage.” These factors, AMVAC asserts, make it “difficult, if not impossible, to provide the information concerning the time that these crops were treated, which EPA requires as a means of providing evidence that the food was lawfully treated.” Based on its expectation that difenzoquat will be used in Canada through 2015 and the alleged unworkability of the FFDCA channels of trade provision, AMVAC requests an extension of the revocation date until December 31, 2017.

AMVAC concedes that it did not raise these concerns by commenting on the proposed Data Call-In Order or responding to the final Data Call-In Order within the time periods provided. Further, AMVAC does not assert that it submitted any Data Call-In Response form indicating its intent to submit the required data by the date specified in the final Data Call-In Order.

V. EPA's Response to AMVAC's Objections

EPA denies AMVAC's objections because AMVAC has not filed a proper objection to the Revocation Order. Section 408(f)(2) of FFDCA restricts the substance of objections the Agency may consider in reviewing an order issued under FFDCA section 408(f)(1) to the following limited issue: “whether a submission required under [an order issued under 408(f)(1)(C)] was not made by the time specified.” 21 U.S.C. 346a(f)(2). In its objections, AMVAC does not contend that it made a timely submission of a notice of intent to submit data, made any submission of data, or intends to submit any required data

as specified in the final Data Call-In Order. Rather, AMVAC concedes that it overlooked the notices and did not submit any comments on the proposed Data Call-In Order nor any response to the final Data Call-In Order. In addition, AMVAC does not disagree with the revocation of the tolerances, just to the timing of the effectiveness of the Revocation Order. Because AMVAC has not argued that “a submission required [by the final Data Call-in Order] was [] made by the time specified,” see 21 U.S.C. 346a(f)(2), its objections do not provide a proper basis for review of the Revocation Order under FFDCA section 408(f)(2).

AMVAC’s arguments concerning the need for additional time for Canadian farmers to use their recently purchased difenzoquat stocks and to simplify enforcement of the channels of trade provision are, by law, simply not relevant at this stage of the revocation proceeding under FFDCA section 408(f)(2). AMVAC or other interested parties had two opportunities to raise such concerns when EPA issued the proposed Data Call-In Order and when it issued the final Data Call-In Order. At this point, it would be advisable for Canadian farmers who have used difenzoquat prior to the revocation date of the tolerance to document the timing of that usage to show compliance with the FFDCA’s channels of trade provision. EPA has alerted FDA, which monitors pesticide residues in imported food, of the possibility that food qualifying under the channels of trade provision may be entering the country and will work with FDA to ensure that this provision is applied properly. Going forward, if Canadian farmers choose to use difenzoquat, they--like any foreign grower who uses a pesticide for which there is no U.S. tolerance--will need to take steps to ensure that commodities they produce that are

treated with and contain residues of difenzoquat are segregated from commodities intended for export to the United States.

VI. Statutory and Executive Order Reviews

This action, which denies an objection to a Revocation Order, is an adjudication in the form of an order and not a rule. 21 U.S.C. 346a(g)(2)(C). Under the Administrative Procedure Act (APA), orders are expressly excluded from the definition of a rule. 5 U.S.C. 551(4). Accordingly, the regulatory assessment requirements imposed on a rulemaking do not apply to this action, as explained further in the following discussion.

- Because this order is not a “regulatory action” as that term is defined in Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993), this order is not subject to review by the Office of Management and Budget (OMB) under Executive Orders 12866 and 13563, entitled “Improving Regulation and Regulatory Review” (76 FR 3821, January 21, 2011).

- For the same reason, this order does not require Agency considerations under Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997); Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001); and Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

- This order does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

- Since this order is not a rule under the APA (5 U.S.C. 551(4)), and does not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

- This order does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this order 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 order. In addition, this order does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (2 U.S.C. 1531-1538).

- This order 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 (15 U.S.C. 272 note).

- The Congressional Review Act (5 U.S.C. 801 *et seq.*), does not apply to this order because it is not a rule for purposes of 5 U.S.C. 804(3).

VII. References

The following is a listing of the documents that are specifically referenced in this order. The docket for this order, which is identified under **ADDRESSES** at the

beginning of this document, includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket.

For assistance in locating these other documents, please consult the person listed under

FOR FURTHER INFORMATION CONTACT.

1. EPA. Difenzoquat; Order Revoking Tolerances; Revocation order. **Federal Register** (78 FR 32155, May 29, 2013) (FRL-9386-5).
2. EPA. Difenzoquat; Data Call-in Order for Pesticide Tolerances; Final order. **Federal Register** (77 FR 75037, December 19, 2012) (FRL-9372-9).
3. AMVAC. EPA-HQ-OPP-2012-0441: Objection to Order Revoking Difenzoquat Tolerances. June 24, 2013.
4. Memorandum from Susan Hummel (OPP) to Eric Miederhoff (OPP). Difenzoquat Methyl Sulfate: Human Health Screening Level Document for Maintaining Tolerances for Import Use. August 11, 2011.
5. EPA. Pesticides; Data Requirements for Conventional Chemicals; Final rule. **Federal Register** (72 FR 60934, October 26, 2007) (FRL-8106-5).
6. EPA. Pesticides; Guidance on Pesticide Import Tolerances and Residue Data for Imported Food; Request for Comment; Notice. **Federal Register** (65 FR 35069, June 1, 2000) (FRL-6559-3).
7. EPA. Difenzoquat; Proposed Data Call-in Order for Pesticide Tolerance; Proposed order. **Federal Register** (77 FR 39962, July 6, 2012) (FRL-9352-9).
8. EPA. Health Effects Test Guidelines: OPPTS 870.6200 Neurotoxicity Screening Battery. EPA 712-C-98-238. Available at <http://www.regulations.gov>.

9. EPA. Health Effects Test Guidelines: OPPTS 870.7800 Immunotoxicity. EPA 712-C-98-351. Available at <http://www.regulations.gov>.

10. EPA. Residue Chemistry Test Guidelines: OPPTS 860.1500 Crop Field Trials. EPA 712-C-96-183. Available at <http://www.regulations.gov>.

11. Agreement on the Application of Sanitary and Phytosanitary Measures, January 1, 1995. 1867 U.N.T.S. 493.

12. United States. Notification. G/SPS/N/USA/2421. July 16, 2012.

List of Subjects in 40 CFR Part 180

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

Dated: September 5, 2013.

Steven Bradbury,

Director, Office of Pesticide Programs.

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