



ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2007-0099; FRL-9943-25]

Flubendiamide; Notice of Intent to Cancel Pesticide Registrations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Pursuant to section 6(e) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), EPA hereby announces its intent to cancel the registration of four (4) pesticide products containing the insecticide flubendiamide owing to the registrants' failure to comply with a required condition of their registrations. This document identifies the products at issue, summarizes EPA's basis for these actions, and explains how adversely affected persons may request a hearing and the consequences of requesting or failing to request such a hearing.

DATES: Under FIFRA section 6(e), affected registrants and other adversely affected persons must request a hearing within 30 days from the date that the affected registrant received EPA's Notice of Intent to Cancel. Please see Unit VII.A.2. for specific instructions.

ADDRESSES: All persons who request a hearing must comply with the Agency's Rules of Practice Governing Hearings, 40 CFR part 164. Requests for hearing must be filed with the Hearing Clerk in EPA's Office of Administrative Law Judges ("OALJ"), in conformance with the requirements of 40 CFR Part 164. The OALJ uses different addresses depending on the delivery method. Please see Unit VII. for specific instructions.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. What Action is the Agency Taking?

EPA is announcing its intent to cancel the registration of four (4) pesticide products containing the insecticide flubendiamide owing to the registrants' failure to comply with a required condition of their registrations. Specifically, EPA intends to cancel each of the following pesticide products, listed in sequence by EPA registration number.

- EPA Reg. No. 264-1025 - BELT SC Insecticide.
- EPA Reg. No. 71711-26 - FLUBENDIAMIDE Technical.
- EPA Reg. No. 71711-32 - VETICA Insecticide.
- EPA Reg. No. 71711-33 - TOURISMO Insecticide.

The following is a list of the names and addresses of record for all registrants of the products listed in this unit, in sequence by EPA company number (this number corresponds to the first part of the EPA registration numbers of the products).

- EPA Co. No. 264 - Bayer CropScience LP, P.O. Box 12014, 2 T.W. Alexander Drive, Research Triangle Park, NC 27709-2014.
- EPA Co. No. 71711 - Nichino America, Inc., 4550 New Linden Hill Road, Suite 501, Wilmington, DE 19808-2951.

In addition, this document summarizes EPA's legal authority for the proposed cancellation (see Unit II.), the registrants' failure to comply with a required condition of registration (see Unit III.), EPA's existing stocks determination (see Unit IV.), scope of the ensuing cancellation proceeding if a hearing is requested (see Unit V.), timing of cancellation of registration (see Unit VI.), and procedural matters that explain how eligible persons may request a hearing and the consequences of requesting or failing to request such a hearing (see Unit VII.).

B. What is the Agency's Authority for Taking these Actions?

The Agency's authority is contained in section 6(e) of FIFRA, 7 U.S.C. § 136d(e)

C. Who is Affected by this Action?

This announcement will directly affect the pesticide registrants listed in Unit I.A. and others who may distribute, sell or use the products listed in Unit I.A. This announcement may also be of particular 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. EPA believes the stakeholders described above encompass those likely to be affected; however, more remote effects are possible, and the Agency has not attempted to describe all the other specific entities that may be affected by this action.

II. Legal Authority

FIFRA generally governs pesticide sale, distribution, and use in the United States and establishes a federal registration scheme that generally precludes distributing or selling any pesticide that has not been "registered" by EPA. 7 U.S.C. 136a(a). A FIFRA registration is a license that establishes the terms and conditions under which a pesticide

may be lawfully sold, distributed, and used. See *id.* 7 U.S.C. 136a(c)(1)(A)-(F) and 136a(d)(1).

The flubendiamide products at issue in this proceeding were conditionally registered pursuant to FIFRA section 3(c)(7)(C) and EPA's regulations at 40 CFR 152.114 and 152.115. Those provisions allow that a conditional registration of an active ingredient not contained in any currently registered products be registered for a reasonably sufficient time for the registrant to generate and submit newly-required data on the condition that by the end of such time the Administrator determines the data do not meet or exceed risk criteria and subject to such other conditions as the Administrator may prescribe. The conditional registration provision was added to FIFRA to address the inequity created by the then-existing statutory scheme between existing registrants and new applicants, and to provide a "middle ground" in the registration process between totally denying registration and granting it. See *Woodstream Corp. v Jackson*, 845 F. Supp. 2d. 174,181 (D.D.C. 2012). However, the utility of conditional registrations depends on affected registrants' compliance with the terms and conditions of their registrations. If registrants accept registrations subject to conditions, but then fail to honor those conditions, EPA could well become more restrictive in its use of the conditional registration authority, and society would lose some of the benefits offered by a flexible registration process.

FIFRA section 6(e) establishes procedures for cancellation of conditional registrations issued pursuant to FIFRA section 3(c)(7). Pursuant to FIFRA section 6(e), the Administrator is required to issue a notice of intent to cancel a conditional registration under FIFRA section 3(c)(7) if (1) during the period provided for the satisfaction of the

condition, the Administrator determines that the registrant has failed to initiate and pursue appropriate action to satisfy any imposed condition, or (2) at the end of the period provided for satisfaction of any condition, the condition has not been satisfied. The Administrator is authorized to permit the sale and use of existing stocks of a pesticide whose conditional registration has been canceled to such extent and subject to such conditions as the Administrator may specify, if the Administrator determines that such sale or use is not inconsistent with the purposes of this Act and will not have unreasonable adverse effects on the environment.

If a hearing is requested by an adversely affected party, a hearing shall be conducted in accordance with FIFRA section 6(d) and 40 CFR Part 164 (the regulations establishing the procedures for hearings under FIFRA). The scope of a hearing under FIFRA section 6(e) is quite narrow; FIFRA provides that the only matters for resolution at that hearing shall be whether the registrant has initiated and pursued appropriate action to comply with the condition or conditions within the time provided or whether the condition or conditions have been satisfied within the time provided, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with FIFRA. A decision after completion of the hearing is final. Consistent with the narrowness of the scope of hearing, the statute also provides that a hearing under FIFRA section 6(e) shall be held and a determination made within seventy-five (75) days after receipt of a request for hearing.

III. Registrants' Failure to Comply with a Required Condition of Registration

Flubendiamide is an insecticide which targets lepidoptera pests approved for use on corn, cotton, tobacco, tree fruits, nuts, vegetables, and vine crops. EPA has determined

that the flubendiamide registrations listed in Unit I.A. should be cancelled because the registrants have failed to satisfy a required condition of their registrations.

EPA issued conditional registrations for each of the flubendiamide products identified in Unit I.A., beginning with the issuance of Flubendiamide Technical and Belt SC Insecticide on August 1, 2008. The Notices of Registration (“NOR”) issued on August 1, 2008, state that the product is conditionally registered in accordance with FIFRA section 3(c)(7), incorporating by reference conditions of registration set forth in EPA’s preliminary acceptance letter (“PAL”). Vetica and Turismo flubendiamide registrations were issued March 4, 2009, and the PAL applied to those registrations as well. The NOR states that “release for shipment of these products constitutes acceptance of the conditions of registration as outlined in the preliminary acceptance letter for flubendiamide, dated July 31, 2008. If these conditions are not complied with, the registration will be subject to cancellation in accordance with section 6(e) of FIFRA.” The Registrants subsequently released each of these products for shipment, thereby accepting the specified conditions of registration.

EPA’s PAL for flubendiamide (which, as noted previously, included conditions of registration which were specifically incorporated into the NORs) was issued on July 31, 2008, and specified the conditions under which EPA would approve registration of the flubendiamide products. The flubendiamide registrants, Bayer CropScience LP, as authorized agent for Nichino America, Inc., agreed to these terms by concurring with the Registration Division’s intended terms and conditions of registration. *Application for a New Section 3 Registration of Flubendiamide with Associated Tolerance, July 31, 2008.* At the time of registration, the product was conditionally registered subject to a time limit

of 5 years. EPA required flubendiamide to be conditionally registered because of concerns regarding flubendiamide's mobility, stability/persistence, accumulation in soils, water columns and sediments, and the extremely toxic nature of the primary degrade NNI-001-des-iodo to invertebrates of aquatic systems; in light of these concerns, the conditional registrations required use of vegetative filter strips and submission of additional data to address the concerns. In addition, instead of the registrations automatically expiring on a date certain, a condition was added that obligated the registrants to expeditiously request voluntary cancellation of the registrations if EPA notified them that EPA determined the registrations did not meet the FIFRA standard for registration.

The Registrants understood and agreed by signing the PAL that if, after EPA review of the referenced conditional data, EPA were to make a determination that continued registration of flubendiamide products will result in unreasonable adverse effects on the environment, EPA would notify the Registrants, and within one (1) week of notification of this finding, the Registrants would submit a request for voluntary cancellation of all the flubendiamide registrations. Without that condition, the registration would likely not have been approved by EPA. Moreover, pursuant to the terms of the NORs for the four flubendiamide registrations, each Registrant accepted all conditions of their flubendiamide registrations – expressly including the conditions specified in the PAL – upon sale or distribution of pesticide products pursuant to those registrations. The Registrants were notified on January 29, 2016 that EPA had made such a finding and, under the terms of the time-limited/conditional registration, the Registrants were obligated to submit an appropriate request for voluntary cancellation to EPA by or before

February 5, 2016. *Letter to Ms. Nancy Delaney, Regulatory Manager, Authorized Agent for Nichino America, Inc., c/o Bayer CropScience, from Jack E. Housenger, Director, Office of Pesticide Programs, January 29, 2016.* On February 5, 2016, Bayer submitted a letter to EPA on its behalf and as regulatory agent for Nichino, informing EPA that neither registrant would comply with the condition to submit voluntary cancellation requests for the flubendiamide registrations. *Response to Request to Submit Voluntary Cancellation Requests for Flubendiamide Technical Registration and Associated End Use Products, February 5, 2016.* Consistent with the position stated in the February 5, 2016 letter, neither Bayer nor Nichino has submitted a voluntary cancellation request in response to EPA's letter of January 29, 2016. Once EPA exercised the registration condition set forth in the NOR, the registrants' failure to comply with that condition of registration by submitting requests for voluntary cancellation makes the flubendiamide products identified in Unit I.A. subject to cancellation under FIFRA section 6(e).

IV. EPA's Existing Stocks Determination

Existing stocks of cancelled pesticides are those products that were "released for shipment" before the effective date of cancellation. FIFRA sections 6(a)(1) and 6(e) allow the Agency to permit the continued sale and use of existing stocks of pesticides that have been cancelled, to the extent that the Administrator determines that such sale or use would not be inconsistent with the purposes of this Act. 7 U.S.C. 136d(a)(1). FIFRA section 6(a)(1) authorizes the Administrator to "permit the continued sale and use of existing stocks of a pesticide whose registration is suspended or canceled ... under such conditions, and for such uses as the Administrator determines that such sale or use is not inconsistent with the purposes of this Act."

EPA's policy in regard to the disposition of existing stocks of cancelled pesticides appears in a policy statement issued in 1991 and amended in 1996. (56 FR 29362, June 26, 1991 (FRL-3846-4) and 61 FR 16632, April 16, 1996 (FRL-5363-8)). The existing stocks policy indicates that although registrants who fail to satisfy a general condition (i.e., one which requires a registrant to submit required data when all other registrants of the similar product are required to do so) would typically be allowed to distribute and sell existing stocks of the cancelled pesticide for one year,

“On the other hand, if a registrant of a conditional registration fails to comply with a specific condition identified at the time the registration was issued, the Agency does not believe it is generally appropriate to allow any sale and use of existing stocks if the registration is cancelled. Accordingly, the Agency does not anticipate allowing a registrant to sell or distribute existing stocks of cancelled products that were conditionally registered if the registrant fails to demonstrate compliance with any specific requirements set forth in the conditional registration.” 56 FR at 29366-67.

The registration condition in the instant case is specific and was identified at the time the registration was issued, so the Agency does not intend to allow any sale or distribution of existing stocks.

Neither FIFRA nor any other law gives the registrant or anyone else a right to continue to distribute or sell existing stocks of a cancelled pesticide. Per FIFRA section 6(a)(1), the disposition of existing stocks of cancelled pesticides is at the discretion of the Administrator. Inasmuch as the disposition of existing stocks of a cancelled pesticide is at EPA's discretion, EPA considers it inappropriate to reward registrants who disregard the terms and conditions of registration, like the condition at issue here, by allowing any distribution or sale of existing stocks. This is not a case where the registrants have made a diligent effort to comply with the condition of registration, only to fail through circumstances beyond their control. Rather, they simply refuse to comply with a

condition they earlier chose to accept in order to obtain the registration initially. Their refusal to comply with the condition will likely delay the cancellation for a number of months, during which time they may not only continue to sell and distribute the previously-produced product that should by the terms and conditions of registration now be cancelled, but also to continue to produce, sell and distribute additional quantities until cancellation through the FIFRA section 6(e) proceeding. For these reasons, and consistent with EPA's existing stocks policy, EPA has determined that it would not be appropriate to allow any further sale or distribution, by any person, of existing stocks of the products identified in Unit I.A. after those registrations are cancelled, except to the extent that distribution is for purposes of returning material back up the channels of trade, for purposes of disposal, or for purposes of lawful export.

EPA has determined that use of existing stocks of the technical flubendiamide registration (EPA Reg. No. 71711-26) should be prohibited upon the cancellation of that registration. Technical products are used solely for the purpose of manufacturing other pesticide products. For the same reason discussed above with respect to sale and distribution of cancelled products, EPA believes it would be inappropriate to allow use of existing stocks of EPA Reg. No. 71711-26 to produce additional flubendiamide pesticide products unless those products are clearly designated solely for lawful export.

EPA believes it would be appropriate to allow continued use of existing stocks of the cancelled end-use flubendiamide products EPA Reg. Nos. 264-1025, 71711-32, and 71711-33, currently held by end users, provided that such use is consistent with the previously approved-labeling accompanying the product. The quantity of existing stocks of these products currently in the hands of end users is expected to be sufficiently low

that the costs and risks associated with collecting them for disposal would be high compared to those associated with the use of the cancelled product in accordance with its labeling. When containers of flubendiamide have already been opened, transporting them can create a greater risk of spillage. Open containers also create additional burden when sent for disposal because proper disposal may require that the content be verified, adding additional expense. Because of the probable wide dispersal of product in user's hands, notification and subsequent supervision of users imposes significant costs on state and/or federal authorities. EPA may amend its position regarding use of existing stocks of end-use flubendiamide products at hearing if the quantity of those products in the hands of end users increases prior to cancellation. For these reasons, EPA intends to allow existing stocks of the end-use flubendiamide products EPA Reg. Nos. 264-1025, 71711-32, and 71711-33, in the hands of end users to be used until exhausted.

V. Scope of Proceeding

The scope of a hearing under FIFRA section 6(e) is quite narrow; FIFRA provides that the only matters for resolution at that hearing shall be whether the registrant has initiated and pursued appropriate action to comply with the condition or conditions within the time provided or whether the condition or conditions have been satisfied within the time provided, and whether the Administrator's determination with respect to the disposition of existing stocks is consistent with FIFRA. The Statute also provides that a hearing under FIFRA section 6(e) shall be held and a determination made within seventy-five days after receipt of a request for hearing.

A FIFRA section 6(e) proceeding is intended only to address whether conditions of registration have been met, not to assess the merits of conditions or whether the

registrants disagree with the conditions of their approved registration. Similarly, the FIFRA section 6(e) proceeding is limited to whether the Agency's existing stocks determination "is consistent" with FIFRA, not whether the existing stock provisions of the NOIC strike an optimal balance between the risks and benefits associated with the distribution, sale and use of existing stocks of a cancelled pesticide. FIFRA section 6(e)(2) provides that where a FIFRA section 6(e) cancellation hearing is requested, the scope of the hearing and the standard of review in regard to the Administrator's determination with respect to the disposition of existing stocks is limited to whether that determination is consistent with FIFRA.

Congress mandated a final decision within seventy-five (75) days, and a broader or more complex hearing could not reasonably be completed in such a limited timeframe. Accordingly, the only matters for resolution in any hearing requested regarding this matter shall be whether the registrants satisfied the condition of registration requiring them to submit timely requests for voluntary cancellation when notified by EPA of its determination that the registrations caused unreasonable adverse effects on the environment, and whether the proposed existing stocks provision is consistent with FIFRA.

VI. Timing of Cancellation of Registration

The cancellation of registration of each of the specific products identified in Unit I.A. will be final and effective thirty (30) days after the date of receipt by the registrant, unless a valid hearing request is received regarding that specific flubendiamide product.

In the event a hearing is held concerning a particular product, the cancellation of the registration for that product will not become effective except pursuant to a final order

issued by the Environmental Appeals Board or (if the matter is referred to the Administrator pursuant to 40 CFR 164.2(g)) the Administrator, or an initial decision of the presiding Administrative Law Judge that becomes a final order pursuant to 40 CFR 164.90(b). Pursuant to FIFRA section 6(e)(2), such order shall issue within seventy-five (75) days after receipt of a request for hearing.

VII. Procedural Matters

This unit explains how eligible persons may request a hearing and the consequences of requesting or failing to request such a hearing.

A. Requesting a Hearing

1. Who can request a hearing? A registrant or any other person who is adversely affected by a cancellation as described in this document may request a hearing.

2. When must a hearing be requested? A request for a hearing by a registrant or other adversely affected person must be submitted in writing within thirty (30) days after the date of the registrant's receipt of the Notice of Intent to Cancel. Under FIFRA section 6(e), the time period for requesting a hearing is calculated from the date the affected registrant receives the Notice of Intent to Cancel, without regard to the date of issuance or publication in the **Federal Register**. EPA issued this Notice of Intent to Cancel and promptly sent it to each registrant by certified mail on February 29, 2016. Registrants will be able to calculate the deadline for their request based on their receipt of the Notice of Intent to Cancel. In order to assure that any requests for hearing from persons other than the registrants are received in a timely manner, persons other than the registrants who wish to submit a request for hearing are urged to assume that the registrants received the Notice of Intent to Cancel on March 1, 2016, and make sure that a

request for hearing is received by EPA's Office of Administrative Law Judges on or before March 31, 2016.

3. How must a hearing be requested? All persons who request a hearing must comply with the Agency's Rules of Practice Governing Hearings under FIFRA, 40 CFR part 164. Among other requirements, these rules include the following requirements:

a. Each hearing request must specifically identify by registration or accession number each individual pesticide product concerning which a hearing is requested, 40 CFR 164.22(a);

b. Each hearing request must be accompanied by a document setting forth specific objections which respond to the Agency's reasons for proposing cancellation as set forth in this document and state the factual basis for each such objection, 40 CFR 164.22(a); and

c. Each hearing request must be received by the OALJ within the applicable 30-day period (40 CFR 164.5(a)).

Failure to comply with any one of these requirements will invalidate the request for a hearing and, in the absence of a valid hearing request, result in final cancellation of registration for the product in question by operation of law.

4. Where does a person submit a hearing request? Requests for hearing must be submitted to the OALJ. The OALJ uses different addresses depending on the delivery method. Please note that mail deliveries to federal agencies are screened off-site, and this security procedure can delay delivery. Documents that a party sends using the U.S. Postal Service must be addressed to the following OALJ mailing address:

U.S. Environmental Protection Agency
Office of Administrative Law Judges

Mail Code 1900R
1200 Pennsylvania Avenue N.W.
Washington, D.C. 20460

Documents that a party hand delivers or sends using a courier or commercial delivery service (such as Federal Express or UPS) must be addressed to the following OALJ hand delivery address:

U.S. Environmental Protection Agency
Office of Administrative Law Judges
Ronald Reagan Building, Rm. M1200
1300 Pennsylvania Ave., NW
Washington, D.C. 20460

B. The Hearing

If a hearing concerning any product affected by this document is requested in a timely and effective manner, the hearing will be governed by the Agency's Rules of Practice Governing Hearings under FIFRA, 40 CFR part 164, and the procedures set forth in Unit VII. Any interested person may participate in the hearing, in accordance with 40 CFR 164.31.

Documents and transcripts will be available in the Administrative Law Judges' Electronic Docket Database available at http://yosemite.epa.gov/oarm/alj/alj_web_docket.nsf. The physical public docket for the hearing is located at the U.S. Environmental Protection Agency, Office of Administrative Law Judges, Ronald Reagan Building, Rm. M1200, 1300 Pennsylvania Ave., NW, Washington, D.C. 20460 and documents can be viewed from 8:30 a.m. to 4:30 p.m., Monday through Friday, except federal holidays.

List of Subjects

Environmental protection, Pesticides and pests, Cancellation.

Dated: February 29, 2016

Louise P. Wise

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

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