UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

Friday, January 29, 2016

Ms. Nancy Delaney, Regulatory Manager
Authorized Agent for Nichino America, Inc.
c/o Bayer CropScience LP
P.O. Box 12014, 2 T.W. Alexander Drive
Research Triangle Park, NC 27709-2014

SUBJECT: **Flubendiamide**
BELT™ SC Insecticide, EPA Reg. No. 264-1025
SYNAPSE™ WG Insecticide, EPA Reg. No. 264-1026
FLUBENDIAMIDE Technical, EPA Reg. No. 71711-26
VETICA® Insecticide, EPA Reg. No. 71711-32
TOURISMO® Insecticide, EPA Reg. No. 71711-33

Dear Ms. Delaney:

Bayer CropScience LP, on its behalf and as an agent for Nichino America, Inc., hereafter jointly identified as BCS/NAI, was granted a time-limited/conditional registration under section 3(c)(7) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) for flubendiamide on August 1, 2008, with an original registration expiration date of July 31, 2013. The expiration date was included in the registration in large part because of EPA's initial concerns regarding flubendiamide's mobility, stability/persistence, accumulation in soils, water columns and sediments, and the extremely toxic nature of the primary degradate NNI-001-des-iodo (des-iodo) to invertebrates of aquatic systems. As a condition of registration as established in the preliminary acceptance letter (PAL) for flubendiamide, dated July 31, 2008 (copy attached), if the Agency were to make a determination that further registration of the flubendiamide technical and end-use products would result in unreasonable adverse effects to the environment, within (1) week of notification of this finding, BCS/NAI will submit a request for the voluntary cancellation of the flubendiamide technical and all end-use products.

BCS/NAI's original release for shipment of the flubendiamide products constituted acceptance of the conditions of registration as outlined in the PAL. As stated in the notices of registration for each flubendiamide product, if the conditions of registration are not complied with, the registration for all flubendiamide products would be subject to cancellation in accordance with section 6(e) of FIFRA. In addition, as part of these conditions of registration, BCS/NAI agreed to generate and submit a vegetative buffer strip and water monitoring studies. These two studies were submitted to the Agency and have been reviewed.

A series of meetings between EPA scientists and BCS/NAI scientists have occurred since March 2015, where the Agency and BCS/NAI have continued to engage in dialogue about the referenced conditional data, various label mitigation proposals, and all the Agency's conclusions regarding the same. EPA has not altered its original conclusion that flubendiamide and its des-iodo degradate are mobile, stable/persistent, accumulate in soils, water columns and sediments and are toxic to aquatic invertebrates. In fact, EPA's most recent analysis suggests that the continued use of flubendiamide is expected to have significant negative impact on invertebrates of aquatic systems, which could lead to negative impacts on other taxa as well. For a complete Agency regulatory conclusion, please refer to

the following attached document: "*EPA Recommendation to Cancel All Currently Registered Flubendiamide Products.*"

The benefits of flubendiamide are that it plays a role in integrated pest management and insecticide resistance management based upon the following characteristics: (1) specificity to Lepidopteran larvae; (2) non-systemic but translaminar properties; and (3) no to low impacts on beneficial arthropods. Overall, EPA concludes that there are efficacious alternatives for flubendiamide. For a complete Agency benefits conclusion, please refer to the following attached document: "*Review of Bayer CropScience Benefits Document Supporting the Continued Registration of Flubendiamide (Belt SC) and BCS White Paper.*"

The Agency has made a determination that the continued use of the currently registered flubendiamide products will result in unreasonable adverse effects on the environment. These conclusions are contained within the attached documents: "*Flubendiamide: Ecological Risk Assessment Addendum Summarizing All Submissions and Discussions to Date*" and "*EPA Recommendation to Cancel All Currently Registered Flubendiamide Products.*"

BCS/NAI understood and agreed by signing the PAL that if, after review of the referenced conditional data, EPA makes a determination of unreasonable adverse effects on the environment, that BCS/NAI would within one (1) week of notification of this finding submit a request for voluntary cancellation of all the flubendiamide registrations. We are hereby notifying you that we have made such a finding and under the terms of the time-limited/conditional registration, you are obligated to submit an appropriate request for voluntary cancellation to EPA by or before Friday, February 5, 2016. This request for voluntary cancellation must include a statement that BCS/NAI recognizes and agrees that the cancellation request is irrevocable. Failure to submit a timely voluntary cancellation request will result in the Agency initiating cancellation of all currently registered flubendiamide products under section 6(e) of FIFRA.

If you have any questions about anything contained in this letter, please contact either Mr. Carmen J. Rodia, Jr. by phone at (703) 306-0327 or via e-mail at Rodia.Carmen@epa.gov or Mr. Richard J. Gebken by phone at (703) 305-6701 or via e-mail at Gebken.Richard@epa.gov. If there are any legal concerns, you may contact the Office of General Counsel's Ariadne Goerke by phone at (202) 564-5471 or via e-mail at Goerke.Ariadne@epa.gov.

Sincerely yours,

Jack E. Housenger, Director
Office of Pesticide Programs

Attachments: *Copy of Preliminary Acceptance Letter for Flubendiamide, dated July 31, 2008*
Copy of Decision Memorandum "EPA Recommendation to Cancel All Currently Registered Flubendiamide Products," dated January 29, 2016
Copy of BEAD "Review of Bayer CropScience Benefits Document Supporting the Continued Registration of Flubendiamide (Belt SC) and BCS White Paper," dated July 24, 2015
Copy of EFED Memorandum "Flubendiamide: Ecological Risk Assessment Addendum Summarizing All Submissions and Discussions to Date," dated January 28, 2016
Copy of EFED "Addendum to Clarify Invertebrate Terminology in January 28,2016 Ecological Risk Assessment Addendum Summarizing all Submissions and Discussions to Date" dated January 29, 2016

cc: *Ms. Lydia Cox, Nichino America, Inc.*

RE 7

Jack E. Housenger, Director
Office of Pesticide Programs (7504C)
US Environmental Protection Agency
One Potomac Yard
2777 South Crystal Drive
Arlington, VA 22202

Date: 2016 February 5
Bayer CropScience LP
2 T.W. Alexander Drive
P. O. Box 12014
RTP, NC 27709

Subject: Response to Request to Submit Voluntary Cancellation Requests for Flubendiamide Technical Registration and Associated End Use Products:
Flubendiamide Technical, EPA Reg. No. 71711-26
Belt SC Insecticide, EPA Reg. No. 264-1025
Synapse WG Insecticide, EPA Reg. No. 264-1026
Vetica Insecticide, EPA Reg. No. 71711-32
Tourismo Insecticide, EPA Reg. No. 71711-33

Dear Mr. Housenger:

Bayer CropScience LP (Bayer), on its behalf and as regulatory agent for Nichino America, Inc. (Nichino), provides the following response to the January 29, 2016 letter from Director Housenger requesting Bayer and Nichino to submit requests to voluntarily cancel all registrations issued under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for products containing flubendiamide, as identified above.

As noted in Bayer's December 21, 2015 letter to EPA, Bayer stopped using the Synapse WG Insecticide (EPA Reg. No. 264-1026) registration in 2012 and submitted a voluntary cancellation request for that registration by letter dated December 12, 2014. Bayer stands by its cancellation request for Synapse WG Insecticide, which has been pending for more than a year, and does not plan to resubmit a cancellation request for that registration. For the reasons stated below, Bayer and Nichino decline to issue voluntary cancellation requests for the remaining flubendiamide registrations.

First, EPA's demand that Bayer and Nichino issue immediate, forced "voluntary" cancellation requests for the flubendiamide registrations in response to EPA's just-issued, January 29, 2016 Recommendation to Cancel All Currently Registered Flubendiamide Products is unlawful. In making this demand, EPA relies on an unlawful condition of registration that EPA devised in an effort to bypass required statutory cancellation proceedings, deny Bayer and Nichino due process rights in their registrations granted by Congress, and shield EPA's future scientific and regulatory determinations from required interagency and scientific peer review. In granting the first flubendiamide registrations on August 1, 2008, EPA determined, as required under FIFRA Section 3(c)(7)(C), that conditional registration of flubendiamide would not cause "any unreasonable adverse effect on the environment" and served the public interest given flubendiamide's many benefits and its excellent human health and environmental safety profile. In the eight years since, EPA has expanded flubendiamide registrations to approximately 200 crops, each time applying the FIFRA registration standard. Yet EPA refused in 2008 to issue the flubendiamide

registrations without an unlawful condition purporting to require Bayer and Nichino to "voluntarily" cancel their registrations if at some future point EPA changed its mind and concluded that the registrations posed unreasonable adverse effects. EPA cannot grant itself the right to bypass required cancellation proceedings and deny registrants the due process rights they possess by statute.

Second, if EPA has now determined that further registration of flubendiamide will cause unreasonable adverse effects and wishes to cancel the registrations, EPA must initiate the normal cancellation process under FIFRA Section 6(b). The full Section 6(b) cancellation process requires EPA, among other things, to submit its findings for interagency and scientific peer review before initiating cancellation proceedings, and to provide registrants and other interested stakeholders the right to contest the substance of EPA's findings in an administrative hearing. Congress imposed these requirements to ensure that the benefits of the product to the agricultural community and the potential agricultural and commercial harms cancellation could cause are fully considered, and that the scientific grounds for the proposed cancellation are subject to and can withstand independent scientific peer review before a cancellation order issues. EPA, apparently concerned that its determinations would not withstand this required scrutiny, seeks to bypass the Section 6(b) cancellation process by demanding that Bayer and Nichino "voluntarily" cancel the registrations, and by threatening to seek cancellation under the streamlined Section 6(e) process if Bayer and Nichino do not comply with the unlawful cancellation demand. Bayer and Nichino decline to request that their registrations be cancelled and will challenge any effort by EPA to cancel the registrations without the required Section 6(b) process.

Third, and most significantly, Bayer and Nichino do not agree that continued registration of flubendiamide poses unreasonable adverse effects on the environment. EPA's concerns are focused solely on the possibility that flubendiamide and a metabolite might accumulate in ponds and water systems to levels that may be toxic to aquatic invertebrates that dwell in sediment. In July 2013, EPA confirmed that Bayer had submitted all data required in support of the original conditions of registration as of July 2012, and granted the first of several extensions of the registrations to allow for EPA's further review and discussion of the submitted data. In addition, during 2015, Bayer and EPA engaged in scientific exchanges, which included Bayer submitting pertinent new data and information, including an aqueous photolysis study showing the first identified degradation pathway for the des-iodo metabolite of flubendiamide, flubendiamide benefits information requested by EPA, and detailed responses and scientific critiques of EPA's assumptions on the accumulation of flubendiamide and the des-iodo metabolite. In meetings and discussions from July through November 2015, EPA identified a list of additional data that could be useful to address any remaining uncertainty regarding potential accumulation and indicated that it planned to extend the registration for three years while Bayer generated the additional data.

However, in early December, EPA abruptly shifted course and expressed its intent to discount the real world monitoring data, conducted as EPA directed and required, and to rely on overly conservative and unrealistic theoretical modeling to argue that flubendiamide is accumulating in the environment at or beyond levels of concern. This approach culminated in EPA's issuance of the January 29, 2016 Recommendation that all flubendiamide registrations should be cancelled.

To support its finding, EPA suddenly shifted back to a toxicity endpoint that is 70 times lower than the endpoint that had been the basis of EPA's and Bayer's 2015 scientific and regulatory analyses and discussions. According to EPA's guidance, the appropriate study to evaluate potential toxicity to sediment dwelling organisms is a spiked sediment study. Bayer conducted and submitted the appropriate spiked sediment study. Yet EPA is now ignoring that study in favor of a less appropriate study with a different endpoint. Notably, after seven years of flubendiamide use and monitoring, not one of the water monitoring samples that EPA required and that was collected has met or exceeded even this lower endpoint.

EPA also relies on theoretical modeling that is based on highly unrealistic assumptions – including a farm pond model that assumes 30 years of substantial agricultural runoff carrying flubendiamide residues into the pond without any outflows. In fact, the real world monitoring data that Bayer collected as required and as directed by EPA, as well as substantial real world data gathered by the United States Geological Survey (USGS), also at the request of EPA, show that when flubendiamide and its metabolite are found, it is in minute quantities well below levels of concern.

Moreover, although the unreasonable adverse effects registration standard requires consideration of benefits as well as risks, EPA downplays or ignores the significant benefits flubendiamide provides compared to alternatives, including its excellent safety profile and its targeted control. EPA has repeatedly concluded that use of flubendiamide raises no human health or safety concerns, and EPA has identified no environmental concerns with respect to fish, birds, mammals, crustaceans, mollusks, beneficial insects, and plants. Flubendiamide provides highly effective and selective control of lepidopteran insects (caterpillar pests and worms), is compatible with Integrated Pest Management (IPM) techniques that focus on natural predation and minimization of impact to beneficial insects, and provides an alternative mode of action that is important to resistance management efforts. The scientific and regulatory record strongly supports the continued registration of flubendiamide. Removal of this important tool will have negative impacts on growers, the nation's food supply, and the environment.

For all these reasons, Bayer and Nichino decline EPA's request to voluntarily cancel all flubendiamide registrations. We remain available to address the science in a transparent and methodical way, consistent with the FIFRA registration standard and process. If this is done as Congress envisioned, the products should remain registered.

Sincerely,

Dana Sargent
Vice President of North American Regulatory Affairs
Bayer CropScience LP

cc: Susan Lewis, Division Director, Registration Division (RD)
Lydia Cox, Director, Regulatory Affairs, Nichino America

Department of Energy's National Nuclear Security Administration's FSEIS #20160047, filed with EPA on 02/24/2016. TVA is a cooperating agency for the project. Therefore, recirculation of the document is not necessary under Section 1306.3(c) of the CEQ Regulations.

Amended Notices

EIS No. 20150343, Draft, NPS, AZ, Backcountry Management Plan Grand Canyon National Park, Comment Period Ends: 04/04/2016, Contact: Rachel Bennett 928–638–7326. *Revision to FR Notice Published 12/11/2015;* Extending Comment Period from 03/04/2016 to 04/04/2016.

EIS No. 20160028, Final, FHWA, WI, I–94 East-West Corridor (70th St–16th St), Review Period Ends: 04/15/2016, Contact: Michael Davies 608–829–7500. *Revision to FR Notice Published 02/12/2016;* Extending Comment Period from 03/14/2016 to 04/15/2016.

Dated: March 1, 2016.

Dawn Roberts,

Management Analyst, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 2016–04833 Filed 3–3–16; 8:45 am]

BILLING CODE 6560–50–P

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 Tourismo 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 degradate 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 NW., Washington, DC 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, DC 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, DC 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.

[FR Doc. 2016–04905 Filed 3–3–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9943–37-Region 1]

Proposed Cercla Administrative Cost Recovery Settlement: Former Athol Rod and Gun Club Superfund Site, Athol, Massachusetts

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed settlement; request for public comments.

SUMMARY: Notice is hereby given of a proposed administrative cost settlement for recovery of response costs concerning the Former Athol Rod and Gun Club Superfund Site, located in Athol, Worcester County, Massachusetts with the Settling Party the Town of

ENVIRONMENTAL PROTECTION AGENCY

[OPP-38509; FRL-3846-4]

Existing Stocks of Pesticide Products; Statement of Policy

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; statement of policy.

SUMMARY: This Statement summarizes the policies that will generally guide EPA in making individual decisions concerning whether, and under what conditions, the Agency will permit the continued sale, distribution, and use of existing stocks of pesticide products whose registrations under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) are amended, cancelled, or suspended. Although most of the policies reflected in this Statement have already been applied by the Agency on a case-by-case basis, EPA now intends to formalize these policies and is soliciting comments from interested persons. If, after reviewing any comments, EPA determines that changes to this Statement are warranted, the Agency will issue a revised Statement of Policy in the **Federal Register**.

DATES: The policies announced in this Statement are currently in effect. The Agency will review any comments on these policies received by the Agency on or before August 26, 1991. After reviewing such comments, the Agency may issue a revised Statement of Policy.

ADDRESSES: By mail, submit comments to: Public Docket and Freedom of Information Section, Field Operations Division (H7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington DC 20460. In person, deliver comments to: Rm. 246, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

FOR FURTHER INFORMATION CONTACT: By mail: Martha Lamont, Special Review and Reregistration Division (H7508W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington DC 20460. Office location and telephone number: Special Review Branch, rm. 31L3, Crystal Station 1, 2800 Crystal Drive, Arlington, VA 22202, (703)-308-8033.

SUPPLEMENTARY INFORMATION: The general statement of policy on existing stocks of pesticide products whose registrations under FIFRA are amended, cancelled, or suspended follows.

GENERAL STATEMENT OF POLICY

Table of Contents

I. Application

This Statement of Policy applies to determinations the Agency will make concerning existing stocks of pesticide products whose registrations have been amended, cancelled, or suspended pursuant to sections 3, 4, or 6 of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA). This Statement also applies to existing stocks of products sold or distributed under a supplemental distributor agreement. It is the responsibility of the registrant to notify such distributors of any applicable existing stock provisions.

For purposes of this Statement, existing stocks are defined as those stocks of a registered pesticide product which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the action.

This Statement establishes general principles which the Agency generally will apply in determining whether and under what conditions to allow the sale and use of existing stocks. In general, if there are significant risk concerns associated with a cancelled pesticide, the Agency will make a case-by-case determination as to whether to allow the continued sale or use of existing stocks of the pesticide. The Agency will not allow continued sale, distribution, or use of such a pesticide unless the benefits associated with such sale, distribution, or use exceed the risks.

Where there are no significant risk concerns associated with the cancellation of a pesticide, the Agency will generally allow unlimited use of existing stocks, and unlimited sale by persons other than the registrant. A registrant will generally be allowed to continue to sell existing stocks for 1 year after the date cancellation is requested, or 1 year after the date the registrant has ceased to comply with the responsibilities that are placed upon registrants, whichever date is sooner.

This policy will be implemented on the date of publication of this notice. Because registrants were unaware of the policies contained in this notice, the Agency has decided to provide a 6-month "grace period" before certain aspects of this Policy become fully effective. Specifically, in cases where the Agency has not identified any significant risk concerns, the Agency will allow registrants of products cancelled on or before December 26, 1991 to continue to sell or distribute existing stocks at least until December 26, 1991, notwithstanding the fact that application of the policies set forth in this statement might result in a shorter existing stocks period or an outright prohibition against the sale or distribution by the registrant of any existing stocks.

II. Applicable Statutory Provisions

Under FIFRA section 3, a pesticide product must be registered with EPA before it may be sold or distributed in commerce. EPA may not register a pesticide unless, among other things, it first determines that the product and its use will not cause unreasonable adverse effects on the environment. Once a pesticide product is registered, FIFRA provides a number of different mechanisms for changing the status of a registration. These mechanisms can be grouped into three categories: Changes requested by a registrant; changes imposed by EPA for failure to comply with various obligations imposed upon registrants; and changes imposed by EPA because of a determination by the Agency that use of the pesticide product results in unreasonable adverse effects to man or the environment.

A registrant may request at any time, for any reason, to voluntarily cancel a registration (FIFRA section 6(f)) or to amend the terms and conditions of the registration, most frequently by amending the pesticide product label (FIFRA sections 3(f) and 6(f)). Voluntary amendments to registration can include, among other things, adding or deleting uses, increasing or decreasing application rates, changing the formulation of a pesticide, or changing the label language (such as changing directions for use, warning statements, etc.).

Other changes in registration status are the result of Agency action because of the failure of a registrant to fulfill

certain responsibilities adequately. Each registrant has a continuing obligation to ensure that its registered products comply with the standards for registration. Note that the the term "registration" includes reregistration (see FIFRA section 2(z)). As part of this obligation, a registrant may be required to submit to EPA additional information which the Agency considers necessary to support continued registration. See FIFRA section 3(c)(2)(B). Failure to submit information required by the Agency pursuant to section 3(c)(2)(B) may result in the suspension of a registration until the information is provided.

In addition, registrants of pesticide products containing active ingredients first registered before November 1, 1984, must demonstrate, under FIFRA section 4, that their products meet the current standards for registration and should be reregistered. Failure to comply with certain provisions of section 4 can result in the cancellation or suspension of pesticide registrations. For example, registrations may be cancelled if a registrant fails to pay fees mandated by section 4(i) or fails to provide EPA with certain information during the early stages of the reregistration process (see FIFRA sections 4(d)(5), 4(e)(3) and 4(i)(7)(C)). Failure by registrants to supply other information required during reregistration may result in the suspension of registrations until the required information is provided to EPA (see, e.g., FIFRA sections 4(d)(6) and 4(f)(3)).

If a registration is a conditional registration, the Agency may also take action to cancel the registration pursuant to FIFRA section 6(e) if the registrant fails to meet any of the conditions imposed upon the product at the time of registration.

Finally, changes in the status of a registration may be mandated by EPA to assure that the product or its use does not result in unreasonable adverse effects on the environment. The Agency may reevaluate a pesticide at any time. If EPA determines that a pesticide product (without change in its terms of registration) no longer meets the standard for registration, the Agency may propose cancellation of the product under FIFRA section 6(b) or propose to classify the product for restricted use. Such Agency proposals may at times allow changes in the terms of registration (such as the deletion of particular uses or addition of specified protective measures) as alternatives to cancellation or change in classification. If the Agency determines that use may result not only in unreasonable adverse effects but in an "imminent hazard," EPA may initiate action to suspend the pesticide registration during the pendency of cancellation proceedings (FIFRA section 6(c)).

It is a violation of FIFRA section 12(a)(1)(A) to sell or distribute any pesticide that has been cancelled or suspended, except to the extent that sale or distribution is authorized by EPA. It is also a violation of FIFRA section 12(a)(2)(J) and (K) to violate the terms of a suspension or cancellation order. Thus, unless expressly permitted by the Agency, distribution or sale of existing stocks of cancelled or suspended pesticides is unlawful. Use of such existing stocks, on the other hand, is not unlawful unless specifically prohibited by the Agency in a cancellation or suspension order.

If a pesticide is cancelled under section 6(b) or section 6(e), FIFRA provides in section 6(a)(1) and (e) that the Administrator may permit the continued sale and use of existing stocks of the cancelled pesticide "to such extent, under such conditions, and for such uses as he may specify if he determines that such sale or use is not inconsistent with the purposes of (FIFRA) and will not have unreasonable adverse effects on the environment." FIFRA section 2(bb) defines "unreasonable adverse effects" as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." Thus, in determining whether to permit distribution, sale, or use of existing stocks of pesticides cancelled under sections 6(b) or 6(e), EPA must apply the same risk/benefit considerations that are applicable to other Agency actions under FIFRA (except that such considerations would be limited to the context of allowing distribution, sale, or use of existing stocks).

FIFRA does not specify a standard for the Agency to apply in determining whether to allow the distribution, sale, and use of existing stocks of pesticide products cancelled voluntarily pursuant to FIFRA section 6(f) or for failure of the registrant to comply with the requirements of section 4. The Agency has decided to make existing stocks determinations with respect to products cancelled under sections 4 and 6(f) based upon whether distribution, sale, or use of existing stocks would be consistent with the purposes of FIFRA. In determining whether such distribution, sale, or use would be consistent with the purposes of FIFRA, the Agency will first determine whether there are any significant risk concerns associated with the cancelled product. If there are such risk concerns, the Agency will generally require a risk/benefit analysis before allowing the sale, distribution, or use of existing stocks. If there are no significant risk concerns, the Agency will generally not require a risk/benefit analysis before making an existing stocks determination.

In the case of suspension of pesticide registrations for failure to submit data, FIFRA has explicitly provided the Agency with broad discretion in the area of existing stocks. Section 3(c)(2)(B) provides that the Administrator may make such provisions for the sale and use of existing stocks of a pesticide whose registration is suspended for failure to submit data as EPA "deems appropriate."

As to existing stocks of pesticides that have had their registrations amended, the Agency generally considers sale or distribution of a pesticide bearing a label or containing a formula other than the label or formula currently approved by the Agency to be a violation of FIFRA section 12(a)(1)(B), (C), or (E). The Agency has, however, established regulations (at 40 CFR 152.130) which provide for the continued sale of a product bearing previously approved labeling for certain periods of time depending upon the nature of the amendment. These regulations do not apply to changes in composition. The Agency will treat sale and distribution of products containing a previously accepted formula that is different from the currently accepted formula in the manner described in unit III.C (Amendments of Registration) of this Policy Statement.

III. General Policies Applicable to All Existing Stocks

This Policy Statement contains the general policies that the Agency intends to apply in making determinations concerning the sale or use of existing stocks of pesticides, as defined in unit I (Application) of this statement. In any individual case, the Agency will consider additional factors if appropriate. To the extent that a particular action or cancellation can fit into more than one category discussed below, EPA will generally select the most restrictive existing stocks provision that may apply. Whenever an existing stocks provision is issued, the Agency reserves the right to amend that provision on its own initiative or at the request of any interested person (either by allowing additional time to sell or use stocks or by placing additional restrictions on the sale or use of existing

stocks) if later circumstances warrant. Finally, unless an existing stocks provision stipulates otherwise, any sale or use of existing stocks must be in accordance with the previously approved label and labeling on, or accompanying, the product.

A. Cancelled Pesticides

In determining what existing stocks provision is appropriate with respect to a pesticide whose registration has been cancelled, the Agency generally will base its determination on the total circumstances affecting the cancelled registration. The actual mechanism triggering cancellation will not always be the controlling factor. Instead, the Agency generally will focus on three factors: (1) Whether there are significant potential risks which raise a question as to whether the use of the cancelled pesticide results in unreasonable adverse effects on man or the environment (this category consists primarily of cancellations where the registration is the subject of a notice of intent to cancel issued pursuant to section 6(b) or a special review initiated pursuant to 40 CFR part 154); (2) whether the registrant of the cancelled pesticide has failed to meet an obligation of registration (such as payment of fees under section 4, or submission of data required under section 3(c)(2)(B), 3(c)(7), or (4); and (3) whether the Agency has taken some regulatory position with respect to the cancelled registration (such as issuance of a Registration Standard, Label Improvement Program, or a document describing the reregistration status of a pesticide or active ingredient). Consideration of these factors in a particular case may suggest differing provisions for the sale, distribution, or use of existing stocks. In such situations, the Agency generally will apply the most restrictive existing stocks provision to the cancelled product.

1. *Cancellations where the Agency has identified particular risk concerns.* Whenever a pesticide registration is cancelled, the Agency will determine whether there are significant potential risk concerns associated with the use of the pesticide. If there are such concerns, the Agency generally will make a case-by-case determination as to whether to allow continued distribution, sale, or use of existing stocks of the cancelled pesticide. This likely will be the case whether a product is cancelled by Agency mandate after issuance of a risk-based notice of intent to cancel, whether the product is cancelled because of the registrant's failure to comply with the reregistration requirements of section 4, or whether the cancellation was requested voluntarily by the registrant.

In most cases, the Agency will not permit continued distribution, sale, or use of existing stocks of a cancelled pesticide raising risk concerns unless it can be demonstrated that the social, economic, and environmental benefits associated with such distribution, sale, or use exceed the social, economic, and environmental risks. A risk/benefit analysis for existing stocks purposes is somewhat different from the analysis that is performed by the Agency in determining whether or not to cancel a registration. In making existing stocks determinations, the Agency may consider any or all of the following criteria, to the extent that information is provided or available:

a. The quantity of existing stocks at each level of the market (i.e., in possession of registrants, distributors, retailers, end-users, etc.)

b. The risks resulting from the use of such stocks. The examination of risk may take into account the limited nature of use of existing stocks where relevant (such as where limited use might result in a level of exposure that may not result in much risk). In many cases, however, it may turn out that the risks posed by use of existing stocks will be similar or identical to the risks posed by continued registration (such as, for example, where the risk is primarily an acute risk from single exposure). In assessing the risks posed by use of existing stocks, the Agency will, to the extent possible, also consider the risks posed by likely alternatives (if any).

c. The benefits resulting from the use of such stocks. In considering the benefits of existing stocks, the Agency may consider the short-term problems (if any) in switching to alternatives, including the length of time before which such alternatives could be available to retailers and users and any hardships that might be presented to users before alternatives are available. The consideration of benefits may also include (insofar as it affects existing stocks) the type of analysis of benefits that the Agency performs in its other risk/benefit analyses (i.e., whether alternatives are available, how any such alternatives compare in terms of cost and efficacy, and what the economic effects to the user will be if the cancelled product is unavailable).

d. The dollar amount users and others have already spent on existing stocks (which would be lost if distribution, sale, or use were not permitted).

e. The risks and costs of disposal or alternative disposition of the pesticide if distribution, sale, or use are not permitted. The Agency may assess whether existing stocks could be used for other purposes. If disposal appears likely, the Agency may consider relevant aspects of disposal, including the nature, feasibility, and cost of proper disposal of the cancelled product.

f. The practicality of implementing restrictions on distribution, sale, or use of existing stocks. For instance, it may be that in some circumstances the Agency would allow continued use of a product because the product could not, as a practical matter, be retrieved.

In addition to the factors listed above, the Agency may consider any other information relevant to either the risks posed by, or the benefits resulting from, the sale and use of existing stocks.

In performing a risk/benefit analysis the Agency will consider all information and/or comments from registrants and interested persons regarding existing stocks that are received in response to public documents that the Agency issues in the course of its regulatory process. For example, where an active ingredient is in special review, the Agency will often issue a Preliminary Determination (position document (PD) 2/3) and request public comment on all proposed regulatory actions. Where a registrant's request for voluntary cancellation is received prior to initiation of special review, but while one is under consideration, the Agency will publish a notice in the **Federal Register** acknowledging receipt of the request and may solicit public comments regarding existing stocks provisions.

If registrants or others indicate that there is an interest in the continued sale or use of existing stocks of cancelled pesticides raising risk concerns, and if information is provided to the Agency to support such distribution, sale, or use, the Agency will generally conduct an analysis of the risks and benefits of the distribution, sale, and use of existing stocks. If information is not provided to the Agency or no interest in continued sale, distribution, or use is expressed to the Agency, the Agency will generally not conduct a risk/benefit analysis and will not permit any sale, distribution, or use of existing stocks.

While a risk/benefit analysis will be an important factor in the Agency's determination of whether or not to allow distribution, sale, and use of existing stocks of cancelled pesticides raising risk concerns, the Agency must also determine that further distribution, sale, or use would be consistent with the purposes of FIFRA. There may be unusual circumstances where the Agency will place restrictions on the distribution, sale, and use of existing

stocks beyond those limits otherwise identified in a risk/benefit analysis (e.g., to prevent stockpiling by distributors and users).

In addition, in determining whether distribution, sale, or use of existing stocks would be consistent with the purposes of the Act, the Agency will generally look at the circumstances surrounding the cancellation. If a cancellation is the result of a final Agency action after a special review and a hearing pursuant to section 6(b), the Agency is unlikely to allow continued sale or distribution (and quite possibly, use) of the cancelled pesticide. In such circumstances, registrants, other distributors, and users of the pesticide have had ample notice of the Agency's intentions and sufficient time to take appropriate steps accordingly (such as to procure alternatives, not stockpile large quantities of the pesticide involved, use up stocks already on hand, etc.). On the other hand, where a voluntary cancellation occurs well before the Agency could take final action (i.e., prior to the completion of a special review or in lieu of a hearing under section 6(b)), the Agency may take into consideration the shorter period of notice sellers and users may have had before cancellation, the degree to which the registrant's actions accelerated the removal of the pesticide from the market, and whether the cancellation would have occurred at all without an existing stocks provision.

In a special review situation, the Agency will publish its final determination on whether to allow any sale, distribution, or use of existing stocks of cancelled pesticides, and if so, what conditions to place on such sale, distribution, or use, as part of the Final Determination (PD 4) and any other documents the Agency may issue either with or subsequent to the issuance of the PD 4 (such as notices of intent to cancel, cancellation orders, etc.). If a chemical raising a risk concern is cancelled without issuance of a Notice of Final Determination at the conclusion of a special review, the Agency will include a final existing stocks determination in a cancellation order. Existing stocks determinations contained in cancellation orders will be enforced under section 12(a)(2)(K) or 12(a)(1)(A) of FIFRA.

The Agency may allow the continued sale, distribution, and use of existing stocks of a voluntarily cancelled product raising risk concerns without performing a risk/benefit analysis if similar products with substantial share of the market remain on the market. For example, if a registration raising risk concerns is cancelled voluntarily, the Agency may examine whether the cancelled registration comprises a significant share of the market for the particular active ingredient and use pattern, and the circumstances surrounding the cancellation. If the cancelled registration does not comprise a significant share of the market, a prohibition on existing stocks would not be likely to significantly reduce environmental risks, because similar products would continue to be sold and used. Further, the Agency believes that it makes sense to encourage the early, voluntary cancellation of registrations when risk concerns arise.

If such an early cancellation is truly voluntary (i.e., the registration is not facing imminent cancellation or suspension), the Agency may allow the registrant to sell and distribute existing stocks for 1 year without performing a detailed risk/benefit analysis, and may allow other persons to distribute, sell, and use existing stocks until the stocks are exhausted. The Agency does not believe it should penalize registrants, distributors, or users in cases where a registrant voluntarily cancels a registration before other registrants are compelled to do so. Moreover, it is unlikely that a detailed risk/benefit analysis would yield a different result; so long as similar registrations comprising a predominant share of the market remain, it is unlikely that distribution, sale, or use of existing stocks of a relatively small volume of cancelled product would significantly (if at all) increase the risk of any unreasonable adverse effect on the environment.

On the other hand, if registrations constituting a dominant share of the market are cancelled, and the Agency does not believe that the remaining registrants can fill the previous demand for the product, the Agency will generally not allow continued sale, distribution, or use of existing stocks unless a risk/benefit analysis supporting such sale, distribution, or use is performed.

In cases where the Agency allows continued sale and use of existing stocks of cancelled products raising risk concerns because of the continuing nature of other registrations, it should be understood that the existing stocks allowance may be amended if the conditions concerning the registrations of the remaining products change. (The Agency in all cases reserves the right to amend existing stocks provisions where appropriate.) If other registrations are cancelled or amended during an existing stocks period for a voluntarily cancelled product, and the Agency establishes restrictions on existing stocks of these other registrations or requires relabeling of product made prior to the amendment, the Agency will likely impose similar restrictions on the existing stocks of the earlier voluntarily cancelled registration.

2. *Cancellations where a registrant has failed to comply with an obligation of registration.* This category consists of cancellations where the Agency does not have significant risk concerns with respect to the cancelled pesticide, but where the registrant has failed to respond appropriately to an obligation of registration. In these situations, the Agency has no particular reason to believe that continued distribution, sale, or use of the cancelled product would result in unreasonable adverse effects on the environment.

If a cancellation is not triggered by section 6(b) or 6(e) of FIFRA, the Agency is not required to perform a risk/benefit analysis before determining whether to allow continued sale, distribution, or use of existing stocks. Unless there are significant risk concerns associated with the cancelled pesticide, the Agency generally does not intend to perform such an analysis. Even where a cancellation is triggered by section 6(b) or 6(e), the Agency generally intends to make existing stocks decisions for cancelled products without performing a detailed risk/benefit analysis if there are no significant risk concerns associated with the cancelled pesticide. EPA believes it would be a poor use of resources to perform such an analysis when the Agency is not aware of any risk/benefit considerations that would serve as a basis for cancelling a registration. The Agency believes it highly unlikely that any analysis of risks and benefits of products not raising significant risk concerns would result in prohibition of distribution, sale, or use of existing stocks.

EPA does, however, believe that where registrants of cancelled products have failed to comply with requirements of registration, the nature of noncompliance with the particular obligation involved should be taken into account in determining whether distribution, sale, or use of existing stocks would be consistent with the purposes of FIFRA. Since such noncompliance does not itself raise concerns of unreasonable adverse effects on the environment, EPA will generally allow persons other than the registrant to continue to distribute, sell, or use stocks of cancelled products in this category until such stocks are exhausted (although the Agency may

place some restrictions on sale or use if inventories are not exhausted in a reasonable period of time). In the case of the noncompliant registrant, however, EPA will generally apply the policies set forth below in determining whether to allow continued sale and distribution. Those policies would generally prohibit a registrant from selling or distributing existing stocks more than 1 year from the date the registrant first failed to comply with an obligation of registration.

In any given case, multiple existing stocks dates might apply if a registrant has failed to comply with more than one obligation of registration. In such circumstances, the most restrictive date will generally apply, regardless of the triggering mechanism for cancellation. For example, if a registrant of a cancelled product failed to pay a maintenance fee due on March 1, 1990, and a reregistration fee due on June 1, 1990, the registrant would likely not be allowed to sell or distribute any existing stocks of the product after March 1, 1991 (regardless of whether the product was actually cancelled for failure to pay maintenance fees or reregistration fees).

a. *Failure to pay maintenance fees.* FIFRA section 4(i)(5) requires all registrants to pay annually by March 1st certain maintenance fees for registrations. Failure to pay such fees may result in the cancellation of a registration by order without a hearing (although the cancellation itself does not become effective until the Agency issues the cancellation order). If a maintenance fee is not paid for any given year, the Agency will generally not allow a registrant to continue to sell or distribute existing stock of a cancelled product for more than 1 year after the date when payment to support the cancelled registration was due, regardless of when the actual cancellation occurs. For example, if a registrant fails to pay a maintenance fee due March 1, 1991, to support a particular registration, and the registration is later cancelled, the Agency will generally not allow that registrant to sell or distribute existing stocks of the pesticide after March 1, 1992.

b. *Failure to pay reregistration fees.* FIFRA section 4(i) also requires some registrants to pay a reregistration fee (either in one or two deposits). This fee is to be apportioned among the applicable registrants on the basis of market share information that registrants are required to submit to the Agency. Failure to submit market share information or to pay an appropriate fee can lead to cancellation of a registration by order without a hearing (FIFRA section 4(i)(7)(C)). If a registrant fails to pay the appropriate reregistration fee or submit the required market share information, and an applicable product is later cancelled, a registrant will generally not be allowed to sell or distribute existing stocks of the cancelled product more than 1 year after the date the market share data or fee were due.

c. *Failure to file information during reregistration.* FIFRA section 4 establishes a five-phased process for reregistration activities. If a registrant elects to pursue reregistration, a registrant may have to commit to supply, and then supply, information to the Agency during Phases 2, 3, 4, and 5 (sections 4(d), (e), (f), and (g)). Failure to provide appropriate commitments or information can result in suspension or cancellation of a registration. If a registrant fails to comply fully with any particular phase of reregistration, and an affected product is later cancelled, the Agency will generally not allow a registrant to sell or distribute existing stocks of the cancelled product more than 1 year after the date that a registrant commitment for that particular product was due. For example, if an initial Phase 3 response is due from a registrant on July 24, 1991, the registrant fails to submit an adequate response, and the product is later cancelled, the Agency will generally not allow the registrant to sell existing stocks of the product after July 24, 1992.

Registrants will not be penalized for voluntarily cancelling a product at the beginning of any particular phase of reregistration (i.e., a registrant who cancels as of the commitment date will have a full year from the commitment date to sell or distribute existing stocks). Noncompliance in any phase, however, will generally be treated as if the registrant had requested voluntary cancellation at the beginning of the phase.

Agency policy with respect to existing stocks of suspended products that failed to comply with the requirements of reregistration are discussed later in this document.

d. *Failure to comply with the terms of a conditional registration.* FIFRA section 3(c)(7) allows the Agency to issue registrations before all applicable supporting data are provided. Such registrations, however, are conditional upon submission of the missing data in a timely manner (and upon compliance with any other conditions contained in the registration at the time of issuance). Failure to comply with the terms of a conditional registration can lead to issuance of a notice of intent to cancel under section 6(e).

Where a conditional registration is cancelled (and the Agency has not identified significant risk concerns), the Agency will base its existing stocks decision on the nature of any conditions that have not been met by the registrant. For purposes of this analysis, conditions of registration can be categorized as "general" conditions or "specific" conditions. A general condition, frequently applied to conditional registrations issued pursuant to FIFRA section 3(c)(7)(A) (i.e., registrations issued to products that are identical or substantially similar in chemical composition and use to one or more existing registered products), requires a registrant to submit required data when all other registrants of the similar product are required to do so. Such a general condition neither establishes specific data requirements nor specific dates; the condition is generally triggered by issuance of a data call-in notice. On the other hand, some conditional registrations, particularly those issued pursuant to FIFRA section 3(c)(7)(B) and (C) (i.e., conditional registrations of products containing new chemicals or bearing significant new uses), contain conditions requiring the submission of specified studies or information by specified dates. Where data requirements and submission dates are specifically identified in the conditional registration, such requirements are considered "specific" conditions.

The Agency will treat the failure to comply with a general condition of a conditional registration in the same manner as a failure by a registrant to comply with the terms of any other data call-in. If a registrant of a conditional registration with a general condition to submit data upon request does not thereafter submit data after issuance of a data call-in, and the registration is cancelled for any reason, the registrant would generally be allowed to continue to sell or distribute existing stocks for 1 year after either the day the 90-day response to the data call-in was due or the date at which the registrant ceased to remain in compliance with the terms of the data call-in, whichever date is later. (See unit III.A.3 below).

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.

3. *Cancellation of products while subject to data call-in notices under section 3(c)(2)(B).* Section 3(c)(2)(B) allows the Agency to require data from registrants. Registrants are required to make an initial response to data call-in notices in 90 days, and thereafter to submit the required data in accordance with the schedule established by the Agency. Failure to respond appropriately can result in the suspension of any registration subject to the data call-in.

Similar to reregistration, data call-in notices require a commitment from a registrant to supply data, and the timely submission of data, to maintain an active registration. Accordingly, the Agency will generally not allow registrants to sell existing stocks of cancelled products more than 1 year after the date a 90-day response to a data call-in notice is due unless the registrant remains in compliance with the terms of the notice. For example, if a registrant commits to submit a 3-year study and the product registration is thereafter cancelled upon request by the registrant pursuant to section 6(f) 9 months after the 90-day response date, sale and distribution of existing stocks by the registrant will be permitted for no more than 3 months (1 year from the 90-day response date). However, if a product subject to a data call-in is cancelled and the registrant can demonstrate full compliance with the requirements of the data call-in up to a certain date, the Agency will likely allow the registrant to continue to sell and distribute existing stocks for 1 year from the date that compliance ended. For example, if the registrant had contracted with a lab to perform a 3-year study, the lab had commenced work, and the registrant instructed the lab to cease work 6 months later, the registrant would generally be allowed to sell and distribute existing stocks of cancelled products for 1 year from the date the lab was asked to cease work on the required study. The Agency will generally allow persons other than the registrant to continue to distribute, sell, or use stocks of cancelled products in this category until such stocks are exhausted (although the Agency may place restrictions if such stocks are not exhausted in a reasonable time).

The preceding discussion assumes that data generated under the data call-in have not disclosed significant potential risks associated with the product. Registrants should be advised that voluntary cancellation of a product during a data call-in response period does not excuse the registrant from compliance with the requirements of FIFRA section 6(a)(2) to report to the Administrator any information regarding unreasonable adverse effects on the environment.

4. *Cancellation of registrations subject to reregistration requirements and label improvement programs.* In the case of a registration subject to a Label Improvement Program (LIP) or determination resulting from decisions made during reregistration, the Agency has determined that the registration of the product may continue, provided that certain changes are made to the terms of registration (generally involving the product label). If a product subject to an LIP or reregistration requirement is cancelled, whether voluntarily or upon action by the Agency (e.g., for failure to pay fees), the Agency will generally not allow a registrant or any other person to sell or distribute existing stocks unless such sale or distribution is consistent with the terms of the LIP or reregistration determination.

For example, if an LIP states that registrants may not sell or distribute a product after January 1, 1992, without a certain label change and states that other persons may not sell or distribute product without the new label after January 1, 1994, and a product subject to the LIP is voluntarily cancelled on July 1, 1991, the registrant of the cancelled product will not be allowed to sell or distribute existing stocks of the cancelled product after January 1, 1992, unless the existing stocks are relabeled to be in compliance with the LIP. Similarly, no other persons would likely be allowed to sell or distribute existing stocks of the cancelled product after January 1, 1994, unless the stocks were in compliance with the terms of the LIP.

5. *Other voluntary cancellations.* If a registrant requests to voluntarily cancel a registration where the Agency has identified no particular risk concerns, the registrant has complied with all applicable conditions of reregistration, conditional registration, and data call-ins, and the registration is not subject to a Registration Standard, Label Improvement Program, or reregistration decision, the Agency will generally permit a registrant to sell or distribute existing stocks for 1 year after the cancellation request was received. Persons other than registrants will generally be allowed to sell, distribute, or use existing stocks until such stocks are exhausted.

B. Suspended Pesticides

FIFRA provides for two different types of suspension. Under section 6(c), EPA may suspend a pesticide registration if use of the pesticide results in an imminent hazard. Under section 3(c)(2)(B), EPA may suspend a registration if a registrant fails to submit required data to the Agency in a timely fashion. Section 4(d)(6) and 4(f)(3) provide for suspensions pursuant to section 3(c)(2)(B) if registrants fail to make timely progress of data development to meet commitments for data submission, tests are not initiated within 1 year after issuance of a Phase 4 data call-in notice, or data are not submitted by the due date.

Where a pesticide is suspended because of an imminent hazard, EPA will apply the policies applicable to cancellations where the Agency has identified significant risk concerns. The Agency is highly unlikely to allow significant sale, distribution, or use of pesticides suspended because of imminent hazard concerns.

Where a pesticide is suspended because of failure to comply with the provisions of a data call-in or reregistration requirement, the Agency will generally not allow the registrant to sell or distribute any existing stocks during the pendency of the suspension. Registrants who sell or distribute a pesticide which has been suspended under FIFRA section 3(c)(2)(B) will be in violation of FIFRA section 12(a)(2)(J). Unlike imminent hazard suspensions, the Agency does not anticipate generally placing restrictions on the sale, distribution, or use of existing stocks by persons other than the registrant where a pesticide is suspended because of failure to comply with the provisions of a data call-in or reregistration requirement unless risk concerns were identified.

C. Amendments of Registrations

The Agency has promulgated regulations (at 40 CFR 152.130) dealing with the sale or distribution of products bearing labeling other than the labeling currently approved by the Agency. Section 152.130(c) of the CFR states that the Agency will "normally" allow registrants to sell products bearing old labeling for 18 months after Agency approval of a revised label and allow others to sell products bearing the old label until all such products are sold, if the product labeling is amended "on the initiative of the registrant." Section 152.130(d) goes on to say that if a

200091

revision is the result of a Registration Standard, Label Improvement Program, or notice concluding a Special Review, the Agency may establish alternate dates after which product sold by a registrant, or sold by others, must bear currently approved labeling.

The regulations do not address the issue of time periods for sale of products bearing a different composition or packaging from that currently approved by the Agency. The Agency believes that if the composition or packaging is required to be changed by the Agency, the policies expressed below concerning label changes should apply. However, if the composition or packaging of a product is changed by a registrant voluntarily, the Agency will generally allow registrants to sell or distribute product for 18 months after the Agency approves the change; other persons will generally be allowed to sell product using the old composition or packaging until all such product is sold.

Changes in labeling made at the behest of the Agency are covered by paragraph (d) rather than paragraph (c) of 40 CFR 152.130. Thus, if label changes are imposed in a document issued during Phase 5 of reregistration (under FIFRA section 4(g)(2)(A)) or if label revisions (or other changes) are in part attributable to concerns that the product may pose unreasonable adverse effects without the change, the Agency may impose appropriate restrictions on the sale or distribution of products not only by the registrant but by others in the distribution chain as well ("channels of trade" dates).

The Agency believes that, although such channels of trade dates may be relatively lengthy, they are necessary to effective enforcement, serving as a form of "closure" on old labeling. In the Agency's enforcement experience, products bearing old labels can be found in channels of trade far longer than foreseen. Besides enforcement difficulties, lack of an absolute cutoff point for needed label changes prolongs inconsistency among similar products, leading to confusion among users as to what label instructions are correct. More importantly, the lack of a channels of trade date creates uncertainty that product labels actually represent current and protective standards. Under FIFRA, the assurance of risk reduction depends heavily on expectations that labeling instructions will be followed. Uncertainty that such compliance is occurring and inconsistency among labels can frustrate efforts by both the Agency and registrants to effect real and consistent risk reduction. Accordingly, in each label change either imposed by the Agency, or attributed in part to risk concerns under review by the Agency, EPA intends to impose both a date for introduction of new labeling into channels of trade (a registrant sale and distribution date), and a date for removing old labeling from channels of trade. Except in the case of labeling changes imposed through Special Review, EPA is unlikely to impose restrictions upon use of product bearing old labeling.

The exact restrictions that the Agency may impose will, of course, depend upon the particular circumstances involved. Nonetheless, the Agency can identify certain principles it generally will apply to label changes directed by the Agency. Label changes directed by the Agency are currently imposed under three specific activities:

1. *The Special Review Process.* Special reviews often culminate in an Agency determination that use of the pesticide without labeling changes would cause unreasonable adverse effects. Also, registrants of pesticides in special review may propose label changes prior to the conclusion of a special review to reduce the risks that are the focus of the review. When label changes are approved in such situations, existing stocks provisions will be determined on a case-by-case basis. In determining what provisions are appropriate, the Agency may consider any or all of the following factors:

a. The nature of the risk posed by the pesticide.

b. The nature of the labeling change required.

c. Whether an amendment to effect the labeling change was submitted in a timely manner.

d. The potential adverse effects associated with continued sale of product not bearing the revised labeling.

e. The volume and location of affected products in the distribution chain.

f. The feasibility, expense, and effectiveness of either requiring relabeling of existing stocks, or of restricting sale and distribution of product not bearing the revised labeling.

2. *Reregistration of current products.* Under FIFRA section 4(g), Phase 5 of the reregistration scheme requires that products containing active ingredients first registered before November 1, 1984, be reregistered. The Agency anticipates that labeling changes (amendments) will likely be required upon issuance of a document stating the Agency's determination of the reregistrability of an active ingredient under FIFRA section 4(g)(2)(A). This Reregistration Eligibility Document (RED) will ask for label changes to be submitted within one of two timeframes—normal or expedited.

In the first instance, the reregistration process envisioned in Phase 5 will normally encompass changes in labeling, composition, or packaging. These changes will be of a more routine nature, or will depend upon the development of product-specific data, such as acute toxicity or efficacy data. Dates for submission of labeling, timeframes for Agency review of labeling changes, and existing stocks provisions will be specified in the RED. Generally, submission of labeling changes will be required 8 months from the date of submission of the RED, and Agency review will be completed 6 months following submission. Registrants will generally be permitted to sell or distribute products bearing old labeling (or composition or packaging) for 1 year after the timeframe established in the RED for Agency approval, and persons other than registrants will generally be permitted to sell or distribute those products for an additional 24 months. Thus, existing stocks dates for sale and distribution of products bearing old labeling will generally be 26 months from the date of issuance of the RED for registrants and 50 months from the date of issuance of the RED for persons other than registrants.

In the second instance, the Agency may require expedited labeling changes if it has significant concerns about the risks of the active ingredient that do not warrant placing it into the Special Review process, but that labeling changes could mitigate. Although EPA believes this situation will be rare, nonetheless the significance of Agency concerns will dictate early submission and review of labeling, and relatively short existing stocks provisions. Existing stocks timeframes will be established case-by-case, depending on the number of products involved, the number of label changes needed, and other factors.

3. *The Label Improvement Program (LIP).* An LIP provides a framework for upgrading labeling that is unconnected with reregistration, and can be initiated at any time that circumstances warrant. The LIP was established to provide a mechanism for the Agency to target a particular labeling problem or a group of products having a common label element and to implement a labeling solution uniformly for all affected products. In that respect it should be viewed as neither active ingredient-specific nor product-specific, but rather "problem-specific." Fundamental to this approach is that the program does not depend upon the development or

interpretation of data, such as is required for reregistration. With such a cross-cutting but focussed approach, the LIP generally endeavors to impose labeling requirements that can be specified exactly or with a minimum of variability. Although labeling may be required to be submitted and reviewed in a LIP, EPA's preferred approach is to obtain agreement via certification that registrants will make the changes. Thus, registrants can rapidly begin implementing the changes in products they distribute and sell. EPA anticipates that any submission of labeling or certification would be required in a comparatively short time after issuance of the LIP. Unless the LIP is a singularly complex one or involves large numbers of products or registrants, submissions of labeling or certifications will normally be required within 3 months. Registrants will generally be allowed to sell or distribute products bearing old labeling for 1 year after issuance of the LIP and persons other than registrants for 3 years after issuance of the LIP.

The Agency acknowledges the impact multiple and frequent required label changes have in escalating registrant costs, potentially disrupting the distribution chain, and creating user confusion. EPA will make every effort to consolidate labeling efforts resulting from reregistration with those that may be under way from LIPs or from parallel regulatory activities.

Interested persons are invited to sumbit written comments on this notice of statement of policy on or before December 26, 1991. Comments must bear a notation indicating the document control number, (OPP–38509). Written comments should be addressed to the Public Docket and Freedom of Information Section, Field Operations Division, at the address given above.

Dated: June 17, 1991.

Douglas D. Campt,

Director, Office of Pesticide Programs.

[FR Doc. 91–14958 Filed 6–25–91; 8:45 am]

BILLING CODE 6560–50–F

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of:	)	
	)	
Bayer Crop Science LP and	)	FIFRA-HQ-2016-0001
Nichino America, Inc.	)	
	)	
Petitioners.	)	

Written Testimony of Susan T. Lewis, Director of the Registration Division, Office of Pesticide Programs, Office of Chemical Safety and Pollution Prevention, U.S. Environmental Protection Agency

I am currently the Director of the Registration Division (RD) in the Office of Pesticide Programs (OPP), Office of Chemical Safety and Pollution Prevention (OCSPP) with the U.S. Environmental Protection Agency (EPA). I have been the Director of RD since October 2014 and previously was the Division Director and Acting Director of the Antimicrobials Division (over 1.5 years), Acting Division Director and Associate Director of the Biological and Economic Analysis Division (3.5 years), and Branch Chief in the Special Review and Reregistration Division (10 years) (renamed the Pesticide Re-evaluation Division). I have spent 35 plus years of my EPA career with OPP; I have worked for approximately 20 of those years in either staff or managerial positions within RD.

My division is the regulatory component of OPP responsible for the product registration for conventional chemical pesticides, including flubendiamide. The other OPP divisions that had a role in analyzing flubendiamide were the Health Effects Division (HED), responsible for assessing pesticide exposure and risks to humans; the Environmental Fate and Effects Division (EFED), responsible for assessing ecological risks of pesticides; and the Biological and

Economic Analysis Division (BEAD), responsible for pesticide use-related information and economic analysis in support of pesticide regulatory activities.

In my capacity as Director of RD, my staff and I are responsible for risk management and regulatory decisions related to new and existing registrations. One of RD's principal responsibilities is responding to applications for new registrations and amendments to existing registrations involving conventional pesticides. In that capacity, RD reviews labels and applications submitted by registrants or applicants for registration; considers risk and benefits assessments and other input from HED, EFED and BEAD; considers whether risk mitigation is necessary or appropriate for a particular product; considers whether additional data are needed; discusses with applicants modifications to the license or labeling that are needed to mitigate any identified risks; and ultimately either rejects or grants a registration based on the relevant statutory factors, including whether use of the registered product as labeled and under the terms of the registration will cause unreasonable adverse effects on the environment.

I have extensive experience in the evaluation and registration of pesticides and a thorough understanding of the registration of flubendiamide. I have developed this knowledge through discussions with my staff, staff in EFED and BEAD, and reviewing all of the exhibits I reference in my written testimony.

Background on Conventional Pesticide Registration Decision-Making

Much of the decision-making on registration applications centers on whether use of the product under the terms of the proposed registration will result in unreasonable adverse effects to man or the environment. The unreasonable adverse effects determination is (with the exception of dietary risk issues) primarily a comparison of the expected risks and benefits. Our determinations on whether use of a product will result in unreasonable adverse effects on the

environment are complicated ones, requiring the consideration of numerous studies on the pesticide at issue, as well as consideration of likely alternative pesticides.

When making a registration decision, RD considers, among other things, the potential toxicity of a pesticide to humans, other mammals, birds, insects, a variety of forms of aquatic life, and non-target plants; the environmental fate characteristics of the pesticide, including its persistence and mobility; the possible routes of exposure of humans and other animal and plant species, and the likelihood and potential extent of exposure; the extent of pesticide residues that could be available on food; and the potential economic and/or health benefits that use of the pesticide could provide, including a comparison of the pesticide with likely alternative pesticides.

In our analysis, RD considers both what we know about the pesticide and what we don't know; how we deal with uncertainties in the analysis can play an important role in the overall unreasonable adverse effects determinations. Through label requirements and other terms and conditions of registration, we require risk mitigation measures as necessary in order to prevent unreasonable adverse effects on the environment, or, if no such measures are feasible, we do not proceed with registration (typically registrants then withdraw their application rather than ask for a denial hearing that is available to them under FIFRA).

When OPP makes a no unreasonable effects determination, we use all available data, including the most current scientific information, policies and methodologies. We also consider the most current information about alternatives, including, but not limited to, the development of resistance to older pesticides and the availability of newer alternatives.

Uncertainties in OPP's assessments can affect our unreasonable adverse effects determinations in a number of ways. For instance, we need a certain level of confidence in the

appropriateness of our determinations in order to issue a registration under FIFRA; in some cases, the existence of significant uncertainties can deprive us of that confidence and oblige us to issue a denial instead. In other circumstances, uncertainties can be resolved without having to deny an application by including more protective license conditions instead. These conditions are agreed upon before EPA can issue the license. Uncertainties can also lead to more mitigation measures to reduce risks of concern, as well as requirements to generate additional studies, conduct monitoring, or submit additional information about incidents related to use of the pesticide. Sometimes, the nature of EPA's analysis and any attendant uncertainties allows OPP to make a no unreasonable adverse effect finding for a limited period of time, but not for an indefinite period of time.

In considering possible risk mitigation measures when reviewing applications, EPA typically considers a wide array of options. Depending upon the particular risk at issue for a pesticide, mitigation measures could include, just to name a few of the possibilities: label requirements to utilize engineering controls or additional protective equipment; limiting the timing of applications; limiting the amount of pesticide that can be applied at a particular site; requiring the use of buffer zones between the application and sources of water or neighboring locations; restricting particular methods of application; restricting who can apply the pesticide; requiring specific training for applicators; prohibiting use on specific sites or crops; requiring changes in the formulation of a pesticide product; or limiting the overall amount of product that can be used, through limits on the quantity allowed to be produced. Another possible risk mitigation measure is limiting the duration of the registration.

Whenever EPA's review suggests that license conditions or risk mitigation measures may be necessary in order for OPP to grant an application, we typically have discussions with the

applicants on the need for the conditions or measures; what conditions or measures may be practicable or appropriate; and, where applicable, an applicant's preference where, as is often the case, a number of alternative options could address EPA's concerns. Our ultimate goal is to come up with conditions and mitigation measures that resolve our concerns and enable us to make the regulatory findings necessary to allow the product to become registered for use, while allowing applicants wide latitude in identifying the particular suite of conditions and mitigation measures that if incorporated into their licenses would enable us to make those necessary findings.

Initial Registration for Flubendiamide

I was not Director of RD in 2008 when the initial registrations of flubendiamide were issued. But I have discussed the matter with my staff who were involved in the review of the initial application, and I have reviewed many of the key decision documents from 2008 as well as email traffic between EPA staff and employees of the flubendiamide registrants pertinent to the 2008 flubendiamide registration decision.

On April 6, 2006, Bayer CropScience LP and Nichino America, Inc. (hereafter identified as BCS/NAI) jointly submitted an application for registration of the flubendiamide technical product and BCS submitted an application for registration of two flubendiamide end-use products. Flubendiamide is an insecticide which targets lepidoptera pests and acts against the larvae of the target pests (Lepidoptera spp.) via oral ingestion of toxic residues on plants.

Flubendiamide was a new active ingredient, not previously registered by EPA. When OPP receives an application for a new active ingredient pesticide registration, we evaluate a variety of potential human health and environmental effects associated with use of the product. The company that wants to sell and distribute the pesticide must provide data from studies that

comply with our testing guidelines, found in EPA Regulations at 40 CFR Part 158. In order to approve a registration, EPA must make a determination that there are no unreasonable adverse effects to human health and the environment.

Flubendiamide has an attractive toxicity profile in many respects, particularly with regard to its relatively low toxicity to humans and many non-target animals. But the EPA reviewers of flubendiamide identified some troubling aspects with the application as well. Flubendiamide is a very persistent compound, especially in aquatic systems. Flubendiamide itself is toxic to freshwater benthic invertebrates, and it breaks down in water into a degradate (des-iodo) that is even more toxic than flubendiamide to freshwater benthic organisms. While the applicants argued that flubendiamide levels in water were not likely to exceed levels where toxicity could be expected, EPA was uncertain about whether this would in fact be the case.

From what I know about flubendiamide, EPA could have resolved the concerns with the application in a number of ways. Because EPA could not definitively conclude that flubendiamide would not get into water or aquatic sediment in concentrations that could have harmful effects on freshwater benthic organisms, and because the persistent characteristics of flubendiamide could mean that any such harm to the aquatic environment could be long-lasting, EPA could have denied the application. That could well have precluded flubendiamide from ever coming to market. But EPA was also mindful of flubendiamide's relatively low toxicity to humans and most other taxa. In the end, EPA determined that it was appropriate under FIFRA to give a time-limited registration for flubendiamide with a requirement that vegetative buffers be used, during which time the registrants would be required to generate data to try and resolve the uncertainty over whether flubendiamide caused unreasonable adverse effects.

Including a time-limitation on the flubendiamide registration was an important part of the decision to issue the initial registrations. Considering the persistence of flubendiamide and its potential toxicity in water, the EPA decision-makers on flubendiamide at the time seemed to be very concerned that the long-term use of flubendiamide may result in unreasonable adverse effects of the environment. At the same time, those decision-makers appear to have concluded that it would be appropriate to grant a short-term registration and acquire more information, in order to not unnecessarily prevent a potentially attractive replacement insecticide from reaching the market. Accordingly, EPA proposed to the applicants to grant a time-limited registration to allow registrants to conduct additional studies based on the actual use of flubendiamide, and that registration would have expired five years after its issuance unless EPA determined that further use of flubendiamide would not cause unreasonable adverse effects on the environment.

The applicants were well aware of EPA's concerns. The issue of whether the registration should include terms that would allow the product to be quickly removed from the market-place if EPA's concerns were unresolved five years later was the topic of much discussion between EPA and the applicants. That the ability to quickly cancel the registration was an important factor in EPA's decision to grant the registration is reflected in the Registration Division's 2008 memorandum recommending that the Director of the Office of Pesticide Programs approve the FIFRA section 3(c)(7) registrations: "If there are risk concerns [after review of data, consideration of uncertainties, and mitigation measures] that result in the Agency being unable to determine that there are no unreasonable adverse effects to the environment, the registrants have agreed that the pesticide will be voluntarily cancelled." (Respondent Exhibit 1). This clearly shows that EPA relied upon the mutually agreed-upon conditions in the registration in order to grant the registration.

After much deliberation over the two years between application and approval, EPA and BCS/NAI discussed the final conditions to be included on the requested registration, and on August 1, 2008, EPA granted a conditional registration under section 3(c)(7)(C) of FIFRA for flubendiamide. EPA issued the registration conditionally, due to the initial concerns regarding flubendiamide's mobility, stability/persistence, accumulation in soils, water columns and sediments, and the extremely toxic nature of the primary degradate NNI-001-des-iodo (des-iodo) to freshwater benthic invertebrates. Because of the uncertainties of how flubendiamide and its degradate des-iodo would accumulate in the aquatic environment and potentially pose risk to freshwater benthic invertebrates, EPA determined that certain conditions were necessary in order for EPA to be able to make a no unreasonable adverse effects determination.

One condition of the flubendiamide registrations required that if the Agency makes a determination that further registration of the flubendiamide technical and end-use products would result in unreasonable adverse effects on the environment, within one week of this finding, the Registrants must submit a voluntary cancellation of the flubendiamide technical and all end-use products. These conditions were agreed to by the Registrants and RD and memorialized in the Preliminary Acceptance Letter (PAL). (Respondent Exhibit 2) The PAL memorialized the conditions that had been negotiated between EPA and the Registrants. The Registrants signed the PAL, concurring on the proposed conditions on July 31, 2008, and the PAL was subsequently incorporated by reference into each of the flubendiamide registrations. Per the Agency's Notice of Registration the Registrants' original release for shipment of the flubendiamide products constituted acceptance of the conditions of registration expressly including those specified in the PAL. (Respondent Exhibit 3)

The terms of flubendiamide's registration were negotiated by staff in the Registration Division and the previous Director of the Registration Division. EPA and the Registrants worked out the conditions to be included in the final registration and I have reviewed emails between EPA staff and the Registrants that support my belief that Registrants understood and agreed with the voluntary cancellation provision. EPA's initial proposal stated that the registration would automatically expire in July 2013 unless EPA, at its sole discretion, extended the registration. (Respondent Exhibit 4) This condition would have been equivalent to an expiration date condition that we have used on other registrations. The Registrants' counterproposal objected to the language concerning automatic cancellation, but appears to have still presumed that registration would end on September 1, 2013 unless EPA approved an unconditional registration or the parties agree to another path forward.

Subsequent discussions shifted away from the initial plan for the registrations to expire on a date certain to the situation where if after review of the new studies and discussions with the Registrants, EPA concluded that the products still did not meet the registration criteria for an unconditional registration, the Registrants would be required to submit a request for voluntary cancellation within one week of EPA informing them of a finding of unreasonable adverse effects. The Registrants' comments on a draft of the PAL illustrate both the Registrants' engagement in the negotiations regarding the process for cancellation and their acquiescence to the process ultimately specified in the PAL.

In an email exchange between EPA and Bayer concerning the negotiations on the conditions for the registration, the Bayer representative, Clive Halder, described the status of the negotiations two days before EPA issued the first flubendiamide registration:

> Basically, there is only one remaining 'sore point', … it appears to allow EPA to demand cancellation without any due process from us. My take is that the Agency

would like to avoid having to go through Section 6 cancellation proceedings. We understand this, so have little problem with fitting in the 'fast death' approach, i.e., voluntary cancellation within a week of the decision. From our side, we expect that a fair cancellation demand can only occur after the conditions of part 5(b) and 7(b) have been met, specifically, that all the submitted data have been reviewed [by EPA] alongside all voluntary data submitted by Bayer, plus following a measured dialogue between the scientists.

Mr. Halder's email goes on to propose alternative language that is almost identical to the final language incorporated in the final PAL as paragraphs 6(d) and 8(d). His rewrite of the paragraphs, which he stated "hopefully addressed our collective needs…", offered the following language for EPA's consideration:

5(c) If after review of the data, as set forth in 5(b) above, the Agency makes a determination that further registration of the flubendiamide technical product will result in unreasonable adverse effects on the environment, within one (1) week of this finding, Nichino will submit a request for voluntary cancellation of the registration of the flubendiamide technical product. That request shall include a statement that Nichino recognizes and agrees that the cancellation request is irrevocable.

7(c) If after review of the data, as set forth in 7(b) above, the Agency makes a determination that further registration of the flubendiamide end-use products will result in unreasonable adverse effects on the environment, within one (1) week of this finding, Bayer will submit a request for voluntary cancellation of the registration of the flubendiamide end-use products. That request shall include a statement that Bayer recognizes and agrees that the cancellation request is irrevocable.

Taken together, the discussions between Registrants and EPA demonstrate that the Registrants were well aware of the cancellation provisions, were materially engaged in shaping those provisions, and ultimately acceded to the cancellation provisions included in the PAL. This exchange not only shows the Registrants involvement in the discussions, it also demonstrates their willing acceptance of the conditions, and negates their notion that they were coerced or threatened into acceptance. I am not aware of any objection Registrants may have

had to the cancellation conditions until late in 2015, when it appeared likely that EPA would invoke the voluntary cancellation condition.

Failure to Comply with the Voluntary Cancellation Provision

The Registration included a condition 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 week of notification of this finding, the Registrants would submit a request for voluntary cancellation of all the flubendiamide registrations. The specific language:

> 6.(d) If, after EPA's review of the data as set forth in 6(b) above, the Agency makes a determination that further registration of the flubendiamide technical product will result in unreasonable adverse effects on the environment, within one (1) week of this finding, to be effective no earlier than September 1, 2013, Nichino will submit a request for voluntary cancellation of the flubendiamide technical product registration. That request shall include a statement that Nichino recognizes and agrees that the cancellation request is irrevocable.

> 8.(d) If, after EPA's review of the data as set forth in 8(b) above, the Agency makes a determination that further registration of the flubendiamide end-use products will result in unreasonable adverse effects on the environment, within one (1) week of this finding, to be effective no earlier than September 1, 2013, Bayer will submit a request for voluntary cancellation of the flubendiamide technical product registration. That request shall include a statement that Bayer recognizes and agrees that the cancellation request is irrevocable.

The PAL was designed so that the conditional registrations for flubendiamide would end July 31, 2013, either through amendment or voluntary cancellation. Registrants requested, and EPA agreed to, several extensions to the conditional registration expiration date, to facilitate submission and review of the 3-year farm pond water monitoring study (submitted December 22, 2014). The final extension to January 29, 2016 allowed EPA to host a final technical discussion between its scientists and the Registrants' scientists on January 6, 2016, related to the conditional

data and the EPA's conclusions related to flubendiamide. This extension also allowed additional time for EPA to review two newly submitted studies and to consider the most recent label proposal submitted by the Registrants on January 8, 2016.

On January 29, 2016, I submitted a Decision Memorandum to Jack Housenger, the Director of OPP, which recommended the cancellation of all flubendiamide registrations because the risks of allowing the continued use of flubendiamide outweigh the benefits and continued use will result in unreasonable adverse effects to the environment. (Respondent Exhibit 5) The Registrants were notified on January 29 of our finding, and that the condition of their registration was triggered that required their submission of a voluntary cancellation. (Respondent Exhibit 6) On February 5, 2016, Bayer on its own behalf and as a regulatory agency for Nichino, submitted to EPA a letter informing EPA that neither Registrant would comply with the condition to submit voluntary requests for cancellation of the flubendiamide registrations. (Respondent Exhibit 7) We did not receive a voluntary cancellation request by February 5 or thereafter, and subsequently informed Registrants that because the Registrants have not submitted requests for voluntary cancellation and failed to comply with the condition of registration, the flubendiamide products identified in the Notice of Intent to Cancel (NOIC) are subject to cancellation under FIFRA section 6(e). (Respondent Exhibit 8)

Existing Stocks

Existing stocks are those stocks of a registered pesticide product which are currently in the United States and which have been packaged, labeled, and released for shipment before the effective date of cancellation. FIFRA allows 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 FIFRA's purposes. EPA

published in the Federal Register a Statement of Policy for Existing Stocks of Pesticide Products which is a guide that assists with decisions concerning whether and under what conditions the Agency will allow continued sale, distribution and use of existing stocks of pesticide products. (Respondent Exhibit 9)

I made the determination for how to handle the existing stocks of flubendiamide with the OCSSP management team. The Agency does not intend to allow any further sale or distribution, by Registrants or any other person, of existing stocks of their products, except to the extent that distribution is for the purposes of returning material back up the channels of trade, for purposes of disposal, or for purposes of lawful export. Among the reasons we determined not to allow any further sale or distribution of existing stocks were our belief that registrants should not benefit from failing to follow through with commitments they make to obtain registrations; that much of the existing stocks at the time of a delayed cancellation may well never have entered the channels of trade if the flubendiamide Registrants had complied with the cancellation condition; and the impact that failure of registrants to comply with conditions could have on the registration program in the future.

The Registrants' refusal to comply with the voluntary cancellation provision of their registrations will likely delay a cancellation by a minimum of 3 months. If Registrants had submitted their voluntary cancellation request on February 5, 2016 as required in their registrations, we would have moved quickly to have published the voluntary cancellation request in the Federal Register as required by FIFRA 6(f), with a 30 day comment period. Assuming all comments were received by mid to late March, EPA could have issued the cancellation notice by the end of March or early April 2016. Instead, Registrants may continue to manufacture and sell

flubendiamide until at least July 6, 2016[1], the scheduled end of this hearing process (the hearing was requested on March 31, 2016 and the hearing must be concluded under FIFRA in 75 days plus the additional 22 days requested by the parties due to scheduling). If Registrants do not prevail before the ALJ and EAB, they could seek Court of Appeals review and a stay of any cancellation order, which could take many more months, and possibly years. So, Registrants may continue to put material in the channels of trade for many months after the cancellation should have taken place, and the release of new existing stocks should have ceased.

EPA's existing stocks policy states that registrants who fail to satisfy a general condition (*i.e.*, a condition which requires a registrant to submit required data when all other registrants of a similar product are required to do so) would typically be allowed to distribute and sell existing stocks of the pesticide for one year. However, the existing stocks policy states that if a registrant 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 further sale and distribution by the registrant after the registration is canceled. In this case, because Registrants intentionally reneged on a commitment to cancel their registrations, and as a result of their actions much of the existing stocks in the channels of trade when these registrations are finally cancelled could be material that should never have entered the channels of trade in the first place, we believe it appropriate to not allow sale and distribution by others as well.

Existing stocks can be analogized to the material left in a pipeline or garden hose when the tap is turned off. EPA believes it inappropriate to delay closing the tap in order to deliberate extensively on what should be done with material still in the pipeline. EPA's position on

[1] My Written Testimony signed April 22, 2016 listed the scheduled end of the hearing process as August 1, 2016, but the correct date is July 6, 2016.

existing stocks was set forth in the Notice of Intent to Cancel, where we stated our determination not to allow any further sale or distribution of existing stocks because the registrants in this proceeding should not benefit from failing to comply with a specific term of their conditional registrations. Specifically, they should not benefit from delaying the cancellation of the flubendiamide registrations for a number of months, potentially longer, during which time they could produce and release additional stocks that they would not have been able to lawfully release into commerce had Registrants complied with the terms of their conditional registrations.

Our rationale for the determination on how to handle the existing stocks for flubendiamide was based on the fact that the Registrants willingly decided to disregard the agreed upon voluntary cancellation provisions of their registration and the OCSPP management team and I agreed that Registrants should not benefit from violating this specific condition, especially where the condition was not only important to the Agency, but where the Registrants were clearly aware of how important that condition was to us in approving their registrations.

OCSPP considers it inappropriate to permit registrants who disregard the terms and conditions of registration, like the condition at issue for flubendiamide, to benefit by allowing any distribution or sale of existing stocks. In this case, the Registrants did not make a diligent effort to comply with a condition of registration; but instead, refused to comply with a condition they knowingly accepted to obtain a registration in 2008.

If registrants are allowed to ignore a condition of registration without consequences, EPA would have to reconsider whether its current practice of approving conditional registrations is adequate to prevent unreasonable adverse effects. If EPA is unable to rely on registrants' compliance with the terms and conditions of registration, EPA will, at least in some circumstances, become less able to make the finding that the terms and conditions of a

pesticide's registration are sufficient to conclude that the pesticide will not cause unreasonable adverse effects. Such a scenario could impact many companies and applications not involved in this proceeding, and slow the introduction of promising new pesticide products into the market.

The existing stocks determination in the NOIC relies solely upon the conclusion that continued sale or distribution of existing stocks of the cancelled pesticides would be inconsistent with the purposes of FIFRA because the Registrants have reneged on commitments they made to comply with a specific condition of registration that was material to EPA's approval of the registration. Conditions of registration and the associated commitments by registrants to fulfill those conditions are vitally important to the registration process.

To continue to allow conditional registrations, we must be able to trust that registrants will comply with those conditions of registration. I am disappointed and troubled that the flubendiamide registrants accepted a registration with specific conditions and later elected not to comply with those conditions. While this is hopefully an isolated example, if it is not, OCSPP will need to seriously examine whether we can continue to issue conditional registrations for pesticide products with ostensibly promising new benefits. We do not want to encourage other registrants to ignore conditions of registration. We are concerned that if we do not take a strong position on existing stocks of flubendiamide that may have entered the channels of trade because the Registrants reneged on their commitments, other registrants may be encouraged to ignore their commitments in the future.

EPA has made a determination that the risks posed by the quantities of existing stocks expected to be in end users' hands are reasonable compared to the burdens and risks associated with recovering those existing stocks. Users can continue to use existing stocks of flubendiamide products until their supply of the product is exhausted. It is difficult to track

existing stocks of end-use products to user's hands, and notifying end users about and supervising disposal activities would impose significant and unnecessary costs to government authorities. Additionally, users may have open containers which can present additional challenges for disposal or return. As part of the process of packaging a pesticide, the registrant must apply the closure so it will be leakproof, secured against loosening, and applied according to the packaging manufacturer's instructions. It is unlikely that an end user would be able to apply a closure in the same way and would not have access to the packaging manufacturer's instructions. Therefore, we would not want containers that had already been opened by the end user to be shipped because of the potential for leaks during transportation.

Dated April 27, 2016

Susan T. Lewis

Susan T. Lewis