

TABLE—REGISTRATION REVIEW DOCKETS OPENING

Registration Review Case Name and Number	Pesticide Docket ID Number	Regulatory Action Leader (RAL), Telephone Number, E-mail Address
<i>Nosema locustae</i> , Case 4104	EPA-HQ-OPP-2007-0997	(703) 347-8920, <a href="mailto:kausch.jeannine@epa.gov">kausch.jeannine@epa.gov</a>

EPA is also announcing that it will not be opening a docket for dried blood because this pesticide is undergoing a voluntary cancellation. Dried blood (CAS No. 68911-49-9, PC Code 000611 and Registration Review Case No. 4030) was first registered by EPA in 1971. The Registrant of the last product containing this active ingredient has requested voluntary cancellation of the product's registration. The Agency will inform the public of the Registrant's intent to voluntarily cancel the product registration through a **Federal Register** notice which is expected to be published early in 2008. If the Agency receives no comments from the public during the public comment period, the registration will be cancelled. There is no tolerance or an exemption from the requirement of a tolerance for this active ingredient.

The Agency will take separate actions to cancel any remaining FIFRA section 24(c) Special Local Needs registrations with this or any other active ingredient in these dockets and to propose revocation of any affected tolerances that are not supported for import purposes only.

#### B. Docket Content

1. *Review dockets.* The registration review dockets contain information that the Agency may consider in the course of the registration review. The Agency may include information from its files including, but not limited to, the following information:

- An overview of the registration review case status.
- A list of current product registrations and registrants.
- **Federal Register** notices regarding any pending registration actions.
- **Federal Register** notices regarding current or pending tolerances or pending exemptions from tolerances.
- Risk assessments.
- Bibliographies concerning current registrations.
- Summaries of incident data.
- Any other pertinent data or information.

Each docket contains a document summarizing what the Agency currently knows about the pesticide case and a preliminary work plan for anticipated data and assessment needs. Additional documents provide more detailed information. During this public

comment period, the Agency is asking that interested persons identify any additional information they believe the Agency should consider during the registration reviews of these pesticides. The Agency identifies in each docket the areas where public comment is specifically requested, though comment in any area is welcome.

2. *Other related information.* More information on these cases, including the active ingredients for each case, may be located in the registration review schedule on the Agency's website at [http://www.epa.gov/oppsrrd1/registration\\_review/schedule.htm](http://www.epa.gov/oppsrrd1/registration_review/schedule.htm). Information on the Agency's registration review program and its implementing regulation may be seen at [http://www.epa.gov/oppsrrd1/registration\\_review](http://www.epa.gov/oppsrrd1/registration_review).

3. *Information submission requirements.* Anyone may submit data or information in response to this document. To be considered during a pesticide's registration review, the submitted data or information must meet the following requirements:

- To ensure that EPA will consider data or information submitted, interested persons must submit the data or information during the comment period. The Agency may, at its discretion, consider data or information submitted at a later date.
- The data or information submitted must be presented in a legible and useable form. For example, an English translation must accompany any material that is not in English and a written transcript must accompany any information submitted as an audiographic or videographic record. Written material may be submitted in paper or electronic form.
- Submitters must clearly identify the source of any submitted data or information.
- Submitters may request the Agency to reconsider data or information that the Agency rejected in a previous review. However, submitters must explain why they believe the Agency should reconsider the data or information in the pesticide's registration review.

• As provided in 40 CFR 155.58, the registration review docket for each pesticide case will remain publicly accessible through the duration of the registration review process; that is, until

all actions required in the final decision on the registration review case have been completed.

#### List of Subjects

Environmental protection, Pesticides and pests.

Dated: December 4, 2007.

**Janet L. Andersen,**

*Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.*

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**BILLING CODE 6560-50-S**

#### ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2007-0181; FRL-8341-7]

#### Notice of Hearing Concerning a Request to Reduce Pre-Harvest Interval for EBDC Fungicides on Potatoes; Amendment to Statement of Issues

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

**ACTION:** Notice.

**SUMMARY:** EPA is amending its July 11, 2007 Notice of Hearing (July Notice) document concerning a request to reduce the pre-harvest interval for the use of EBDC fungicides on potatoes. The July Notice set forth EPA's determination, the rationale for that determination, a description of the issues of fact and law to be adjudicated in the hearing, and a schedule for the hearing. EPA's determination in the July Notice that a hearing was appropriate was in response to the EBDC/ETU Task Force's (Task Force) petition requesting that the 1992 cancellation order be amended to allow for a 3-day pre-harvest interval (PHI) nationwide for use of EBDC pesticides on potatoes.

**FOR FURTHER INFORMATION CONTACT:** Kevin Costello, Special Review and Reregistration Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5026; fax number: (703) 305-7070; e-mail address: [costello.kevin@epa.gov](mailto:costello.kevin@epa.gov) or Michele Knorr, Office of General Counsel, Pesticides and Toxic Substances Law Office (2333A),

Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-5631; fax number: (202) 564-5631; e-mail address: [knorr.michele@epa.gov](mailto:knorr.michele@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

In 1992, EPA issued a Notice of Intent to Cancel (NOIC) registrations containing EBDC's for use on certain crops. The crop at issue for this hearing is potatoes. The NOIC stated that use of EBDC's on potatoes would be canceled unless the registrants modified their pesticide product labels. For a product to remain registered for use on potatoes, the NOIC required that registrants amend their labels to incorporate certain directions for use, including maximum application rates, maximum number of applications per season, application interval, and PHI. For certain states, the NOIC required a minimum 14-day PHI and, for others, the NOIC allowed a minimum 3-day PHI due to disease pressures caused by late blight. (57 FR 7484, March 2, 1992).

In response to the NOIC, EBDC registrants and some non-registrants requested a hearing. However, there was never a formal hearing; the parties reached a settlement which included, among other things, an agreement to amend labels to extend the PHI to 14 days for EBDC use on potatoes in all states other than Connecticut, Delaware, Florida, Maine, Massachusetts, Michigan, New Hampshire, New York, Ohio, Pennsylvania, Rhode Island, Vermont, and Wisconsin. In these named states, EPA agreed to allow a 3-day PHI because of the presence of late blight. This settlement was approved by Judge Harwood in an order issued June 16, 1992. FIFRA Docket number 646 *et al.* (Accelerated Decision and Order, June 16, 1992).

On December 26, 1996, the Task Force submitted its first request to modify the existing cancellation order for the use of three products containing EBDC on potatoes: Mancozeb, maneb, and metiram. In that petition, the Task Force requested that the PHI be reduced from 14 days to 3 days nationwide to address the spread of late blight disease (*Phytophthora infestans*) in potatoes. Late blight is a fungal disease that caused the infamous "Irish Potato Famine" in the 1840's. If not adequately controlled, this disease is capable of destroying the crop in the field (foliar blight phase) and/or in storage (tuber rot phase). EPA delayed acting on this petition because intervening statutory amendments required the Agency to

reassess how it evaluated pesticide registration actions.<sup>1</sup>

Because EPA had not yet acted on the 1996 petition, on August 25, 2003, the Task Force resubmitted its request to the Agency as part of the EBDC reregistration process. Subsequently, the Agency informed the Task Force that EPA had to consider the impact of the Food Quality Protection Act of 1996 (FQPA) amendments to the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA) before any action could be taken on the request.

Under 40 CFR part 164, subpart D, the Agency treated the Task Force submission as a petition to modify the final cancellation order concerning EBDC pesticide products. Such a petition may not be granted without an opportunity for a formal adjudicatory hearing in front of an Administrative Law Judge (ALJ). EPA concluded that the submissions by the Task Force could provide an adequate basis for a hearing. Therefore, in the **Federal Register** of July 11, 2007 (72 FR 37771) (FRL-8118-4), EPA issued a notice of hearing that set forth the Agency determination on the registrants' request to modify the 1992 cancellation order.

That Notice: (1) Announced that EPA has decided to hold a hearing regarding the petition to modify the existing cancellation order as it applied to the use of products containing EBDC's (mancozeb, maneb, and metiram) on potatoes and the allowance of a 3-day, rather than a 14-day PHI, nationwide, (2) specified the issues of fact and law to be considered at that hearing, (3) identified what steps interested persons need to take if they wish to participate in the hearing, and (4) established a schedule for the hearing. The Agency did not determine as part of the Notice that the new information in fact warrants an amendment to the previous cancellation order. That determination is the subject of the hearing provided for in 40 CFR part 164, subpart D.

In response to the July Notice, the Natural Resources Defense Council (NRDC) filed a request for hearing on August 10, 2007. EPA and the EBDC/ETU Task Force (Task Force) are automatically parties to this hearing. The National Potato Council (NPC) requested and was granted leave to intervene in the hearing on September 18, 2007.

The Honorable Susan L. Biro, Chief ALJ, was designated to preside over this proceeding. Judge Biro issued a Pre-Hearing Order on September 19, 2007,

<sup>1</sup>The Food Quality Protection Act of 1996 amended FIFRA and the FFDCA.

directing the parties, among other things, to file pre-hearing exchanges. EPA, the Task Force and NPC (Movants) filed a motion requesting an extension of time to file the pre-hearing exchanges as well as a request for a pre-hearing conference (Motion). NRDC contested a portion of the Movants' motion and Movants replied to NRDC's response. The Movant's Motion explained that there appeared to be a concrete disagreement among the parties as to the scope of the hearing. Two issues were discussed in the Movants' Motion and Reply. First, the July Notice incorrectly identified an issue of law to be adjudicated by the Court. Second, the Notice did not provide a sufficiently clear explanation of the scope of the issues to be considered in the hearing.<sup>2</sup>

In light of the two issues stated above, EPA is amending the Statement of Issues by consolidating the issues of fact and law into the two relevant questions that must be determined by the ALJ consistent with 40 CFR 164.132 and the 1992 cancellation action. EPA believes the amended statement of issues provides necessary clarifications that will allow for a more efficient and effective hearing.

This amendment does not alter EPA's previous determination under 40 CFR 164.131. (72 FR 37771) Additionally, NRDC does not need to file a new request for hearing.

##### A. Does this Action Apply to Me?

You may be potentially affected by this action if you are a party to this hearing process, however, it may also be of interest to the public in general, and a wide range of stakeholders including environmental, human health, and agricultural advocates; the chemical industry; pesticide users; and members of the public interested in the sale, distribution, or use of pesticides. Since others also may be interested, the Agency has not attempted to describe all the specific entities that may be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

##### B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket*. EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2007-0181. Publicly available

<sup>2</sup>On October 29, 2007, Judge Biro issued an Order granting the extension of time to file pre-hearing exchanges, but deferred the request for a pre-hearing conference. Docket No. EPA-HQ-OPP-2007-0181.

docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the Office of Pesticide Programs (OPP) Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The hours of operation of this Docket Facility are from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgrstr>.

## II. Background

### A. What Action is the Agency Taking?

Pursuant to 40 CFR 164.23(b), EPA is amending its statement of issues for the hearing that the Agency announced in the July 11, 2007 Notice. (See 72 FR at 37778, Unit VII.) In the July Notice, EPA identified among the facts to be adjudicated certain questions associated with late blight on potatoes. Among the issues to be adjudicated in the proceeding, EPA identified the question of whether the substantial new evidence could with due diligence have been discovered prior to issuance of the 1992 cancellation order and whether a nationwide PHI of 3 days for EBDC use on potatoes would meet the standard of section 2(bb) of FIFRA. EPA believes amending the statement of issues is necessary. Therefore, EPA is amending the July Notice by replacing all the issues for hearing identified in that Notice with the following issues to be adjudicated in this proceeding:

1. Is there substantial new evidence not considered in the 1992 cancellation that relates to whether the dietary risks associated with nationwide use of EBDCs on potatoes with a 3-day PHI satisfy the relevant statutory standard for registration under FIFRA? For the purposes of this hearing, the relevant portion of the FIFRA standard for registration is whether the human dietary risk meets the safety standard in section 408(b)(2) of FFDCA.

2. Does the substantial new evidence with respect to dietary risk require the modification of the existing cancellation order, i.e., does it support a finding that the dietary risks associated with nationwide use of EBDCs on potatoes with a 3-day PHI satisfy the relevant statutory standard for registration under FIFRA? In other words, do the residues that result from EBDCs on potatoes meet the safety standard in section 408(b)(2) of FFDCA?

### B. Why is the Agency Taking this Action?

As required by 40 CFR 164.131(c), if the Administrator determines that a hearing is warranted, the Administrator must publish a notice in the **Federal Register**. The notice must set forth the issues of fact and law to be adjudicated at the hearing. Because the issues set forth by the Administrator in the notice of hearing establish the scope of the hearing, it is important that those issues be clear. After discussions with other parties to this proceeding and review of the ALJ's orders, EPA determined that its earlier notice contained an error concerning what factors are to be considered by the judge (i.e. "due diligence") and that other changes would clarify and better focus the relevant issues for this hearing.

First, EPA is amending the statement of issues to correct a misstatement by EPA in the July Notice. In that Notice, EPA identified as an issue of law to be adjudicated the following: "If it is substantial new evidence, could the applicant, through due diligence, have discovered this information prior to the issuance of the cancellation order?" (72 FR at 37778)

Whether or not the applicant met this "due diligence" test is an issue for the Administrator to determine before issuing the Notice of Hearing, not for the Court to determine at hearing. 40 CFR 164.131(a) sets forth the standard for determining whether, as a threshold matter, a petition to amend a cancellation order has merit. This regulation states that the Administrator will reconsider the merits of a prior cancellation order when the Administrator finds that:

(1) The applicant has presented substantial new evidence which may materially affect the prior cancellation or suspension order and which was not available to the Administrator at the time he made his final cancellation or suspension determination and, (2) such evidence could not, *through the exercise of due diligence*, have been discovered by the parties to the cancellation or suspension proceeding prior to the issuance of the final order. [emphasis added]

In contrast, 40 CFR 164.132(a) sets forth the issues for the ALJ to decide in the hearing. The purpose of the hearing is not to determine whether to reconsider the earlier order, but rather to determine whether or not the earlier order should in fact be modified. The relevant subsection of this regulation states:

The burden of proof in the hearing convened pursuant to § 164.131 shall be on the applicant and he shall proceed first. The issues in the hearing shall be whether: (1) substantial new evidence exists and (2) such

substantial new evidence requires reversal or modification of the existing cancellation or suspension order.

The regulation at 40 CFR 164.132(a) does not include the "due diligence" determination as one of the issues to be resolved at the hearing. Additionally, in the preamble to these regulations, EPA stated:

For the following reasons, EPA is adopting a new Subpart D to the Rules of Practice (40 CFR Part 164) setting forth the procedures to be followed in the case of an application under FIFRA sections 3 or 18 which requests use of a pesticide on a site and on a pest for which registration has been finally cancelled or suspended. These revised procedures require that in any such case the *Administrator will initially determine*, on the basis of the application and supporting data, whether there is substantial new evidence which may materially affect the prior order and *whether such evidence could not have been discovered by due diligence* on the part of the parties to the original proceeding. If it is determined that there is no such evidence, then the application will be denied. If it is determined that there is such evidence, then a formal hearing will be convened to determine whether such evidence materially affects the prior order and requires its modification. This determination will be made on the basis of the record in the hearing and the recommendations of the administrative law judge presiding over the hearing, taking into account the human and environmental risks found by the Administrator in his prior order and the cumulative impact of past, present, and anticipated uses in the future. [emphasis added] (53 FR 12261, 12264).

As the preamble and regulatory text make clear, the determination of whether the petitioner could have discovered and submitted the information during the original proceeding is one for the Administrator to make before any hearing is convened. This "due diligence" provision prevents registrants from wasting Agency resources and continually relitigating cancellation cases by allowing the Administrator to summarily reject applications that are based on factual information that should have been presented in the earlier proceeding. In contrast, the focus of the subpart D hearing itself is on whether the earlier cancellation decision is still correct in light of the new information. This is similar to the focus of the original cancellation hearing—whether the pesticide at issue meets the applicable standard for registration under FIFRA.

Because the "due diligence" test is one to be determined before commencement of a subpart D hearing, EPA is amending the statement of issues to delete this issue.

Second, EPA is amending the statement of issues to reflect the fact

that risk issues unrelated to the dietary risk of EBDC use on potatoes are not relevant for this hearing. Typically, the scope of the subpart D hearing would be determined by a detailed cancellation order from the earlier proceeding. However, as described above, there was no prior hearing because the parties to the earlier proceeding agreed to a settlement. Had there been a hearing and subsequent detailed cancellation order, the scope of this subpart D hearing would have been determined by that order. Since there was no detailed cancellation order, EPA's 1992 NOIC (as it relates to EBDC use on potatoes) must be used to determine the issues to be considered in the present hearing because it is the best evidence of what issues would have been presented at the cancellation hearing had it taken place. (57 FR 7484, March 2, 1992).

The NOIC was the result of a regulatory process known as "Special Review."<sup>3</sup> The NOIC stated that the basis for the initiation of the Special Review for the uses of EBDC fungicides. Specifically, for potatoes, the following issues were of concern: "carcinogenic, developmental, and thyroid effects caused by ethylenethiourea (ETU)." (57 FR at 7487). Had a cancellation hearing been held, these would have been the issues for the hearing. Only information related to these three risks, or to dietary exposures associated with these three risks, is material to the issue of whether the 1992 cancellation order should be modified to allow for a shorter PHI than called for in the NOIC.

The relevant statutory standard for determining whether dietary risks are acceptable under FIFRA is not the same today as it was in 1992. At the time of the 1992 cancellation proceedings, the presence of late blight in the New England states was relevant to a reduced PHI of 3 days being allowed in those states. At this time, however, whether late blight has spread nationwide and whether EBDCs are necessary are not appropriate for consideration by the ALJ when determining whether the 1992 cancellation order must be modified.

The 1996 Food Quality Protection Act amendments to FIFRA and FFDCA require that dietary risks associated with a pesticide chemical's residue on food now be evaluated under the risk-only safety standard as set forth in FFDCA section 408(b). The safety determination that now must be made is whether there is a "reasonable certainty that no harm

will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures." FFDCA section 408(b)(2)(A)(ii). Since this standard is a risk-only evaluation, EPA determined that it was necessary to amend the statement of issues to reflect the correct statutory standard and to eliminate the consideration of factual issues, such as the need for the pesticide, that are not relevant to the applicable standard.<sup>4</sup>

#### *C. What is the Agency's Authority for Taking this Action?*

EPA regulation at 40 CFR 164.132 states that the procedures for the hearing "shall follow the Rules of Practice set forth in subparts A and B." In subpart B, specifically 40 CFR 164.23(b), the Administrator has the authority to amend the statement of issues EPA set forth in a Notice of Hearing at any time prior to the commencement of the public hearing. Pursuant to these provisions, and the fact that a public hearing has not yet commenced, EPA is amending the statement of issues it issued in its July 2007 Notice of Hearing to ensure that the hearing is focused on the issues that are relevant to the risk-only determination. In light of this amendment, the ALJ may determine that additional time is necessary to permit the parties to prepare for matters raised in this amendment; and, upon such determination, the hearing shall be delayed for appropriate period. See 40 CFR 164.23(b).

#### **List of Subjects**

Environmental protection, EBDC fungicides, Pesticides and pests.

Dated: November 30, 2007.

**Steven Bradbury,**

*Director, Special Review and Reregistration Division, Office of Pesticide Programs.*

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**BILLING CODE 6560-50-S**

#### **ENVIRONMENTAL PROTECTION AGENCY**

**[EPA-HQ-OPP-2007-0937; FRL-8153-1]**

#### **Para-dichlorobenzene; Reregistration Eligibility Decision for Low-Risk Pesticide; Notice of Availability**

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

**ACTION:** Notice.

**SUMMARY:** This notice announces the availability of EPA's Reregistration Eligibility Decision (RED) for the pesticide para-dichlorobenzene, and opens a public comment period on this document, related risk assessments, and other support documents. EPA has reviewed the low-risk pesticide para-dichlorobenzene through a modified, streamlined version of the public participation process that the Agency uses to involve the public in developing pesticide reregistration and tolerance reassessment decisions. Through these programs, EPA is ensuring that all pesticides meet current health and safety standards.

**DATES:** Comments must be received on or before February 11, 2008.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2007-0937, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

- *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

*Instructions:* Direct your comments to docket ID number EPA-HQ-OPP-2007-0937. EPA's policy is that all comments received will be included in the docket without change and may be made available on-line at <http://www.regulations.gov>, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit information that you consider to be CBI or otherwise protected through [www.regulations.gov](http://www.regulations.gov) or e-mail. The [www.regulations.gov](http://www.regulations.gov) website is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through [www.regulations.gov](http://www.regulations.gov), your e-mail address will be automatically captured and

<sup>3</sup>The purpose of Special Review is to help the Agency determine whether to initiate procedures to cancel, deny, or reclassify registration of a pesticide product because uses of that product may cause unreasonable adverse effects on the environment. See 40 CFR part 154.

<sup>4</sup>The presence of late blight nationwide and the need for EBDC fungicides is not relevant to the risk-only finding that the court must make in order to determine whether the earlier cancellation order must be modified.