

public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

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

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

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

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

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

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

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

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

II. Background

A. *What Action is the Agency Taking?*

Under section 4 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), EPA is reevaluating existing pesticides to ensure that they meet current scientific and regulatory standards. EPA has completed a Reregistration Eligibility Decision (RED) for the pesticide, aliphatic alcohols under section 4(g)(2)(A) of FIFRA. The aliphatic alcohols subject to this RED include 1-hexanol, 1-octanol, 1-decanol and 1-dodecanol, and are used as a growth regulator for tobacco sucker control, and as a Lepidopteran pheromone in apple and pear orchards. EPA has determined that the data base to support reregistration is substantially complete and that products containing aliphatic alcohols are eligible for reregistration, provided the label amendments described in the RED are implemented. Upon submission of any required product specific data under section 4(g)(2)(B) and any necessary changes to the registration and labeling (either to address concerns identified in the RED or as a result of product specific data), EPA will make a final reregistration decision under section 4(g)(2)(C) for products containing aliphatic alcohols.

EPA is applying the principles of public participation to all pesticides undergoing reregistration and tolerance reassessment. The Agency's Pesticide Tolerance Reassessment and Reregistration; Public Participation Process, published in the **Federal Register** on May 14, 2004, (69 FR 26819) (FRL-7357-9) explains that in conducting these programs, EPA is tailoring its public participation process to be commensurate with the level of risk, extent of use, complexity of issues, and degree of public concern associated with each pesticide. Due to its uses, low human health and ecological risks, and other factors, the aliphatic alcohols were reviewed through a modified, 1-phase, low risk process.

The reregistration program is being conducted under Congressionally mandated time frames, and EPA recognizes the need both to make timely decisions and to involve the public. The Agency is issuing the aliphatic alcohols RED for public comment. This comment period is intended to provide an opportunity for public input and a mechanism for initiating any necessary amendments to the RED. All comments should be submitted using the methods in **ADDRESSES**, and must be received by EPA on or before the closing date. These comments will become part of the Agency Docket for aliphatic alcohols. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

The Agency will carefully consider all comments received by the closing date and will provide a Response to Comments Memorandum in the Docket and regulations.gov. If any comment significantly affects the document, EPA also will publish an amendment to the RED in the **Federal Register**. In the absence of substantive comments requiring changes, the aliphatic alcohols RED will be implemented as it is now presented.

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

Section 4(g)(2) of FIFRA as amended directs that, after submission of all data concerning a pesticide active ingredient, the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration, before calling in product specific data on individual end-use products and either reregistering products or taking other "appropriate regulatory action."

List of Subjects

Environmental protection, Pesticides and pests.

Dated: July 2, 2007.

Peter Caulkins,

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

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2007-0181; FRL-8118-4]

Notice of Hearing on Request to Reduce Pre-Harvest Interval (PHI) for EBDC Fungicides on Potatoes

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of Hearing.

SUMMARY: The EPA is issuing this Hearing Notice under the authority set forth in 40 CFR part 164 subpart D (subpart D hearing). A subpart D hearing is required when a registrant wants to modify an existing cancellation order that was issued after the opportunity for a hearing. In 1992, EPA issued a Notice of Intent to Cancel (NOIC) registrations containing EBDCs for use on certain crops. The crop at issue for this hearing notice is potatoes. The NOIC stated that use of EBDCs on potatoes would be canceled unless the registrants modified their pesticide product labels. At issue in this notice is the 1992 requirement to extend the preharvest interval (PHI) to reduce the dietary risk. EPA issued the 1992 NOIC with an opportunity for a hearing. EPA and the registrants reached a settlement, including the agreement to amend labels to extend the PHI to 14 days. The purpose of this notice is to announce that EPA has determined that the petition requesting a modification of the cancellation order has merit and to announce an opportunity for a hearing.

DATES: Requests to participate in the hearing announced by this notice must be received by the Office of the Hearing Clerk at the address given below by August 10, 2007. A pre-hearing conference will be held and the evidentiary hearing will commence as soon thereafter as practicable, according to the schedule outlined herein.

ADDRESSES: Submit your request to participate in the hearing, identified by docket identification (ID) number EPA-HQ-OPP-2007-0181, by the following method:

- Mail: Office of Hearing Clerk, USEPA, 1200 Pennsylvania Ave., N.W., Washington, DC 20460.
- Hand delivery: Office of the Hearing Clerk, 1099 14th St., NW., Suite 350, Washington, DC 20005.

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) 308-7070; e-mail address: costello.kevin@epa.gov or Michele Knorr, Office of General Counsel, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-5631; fax number: e-mail address: knorr.michele@epa.gov.

SUPPLEMENTARY INFORMATION:**I. General Information**

The EPA is issuing this Hearing Notice under the authority set forth in 40 CFR part 164 subpart D (subpart D hearing). A subpart D hearing is required when a registrant wants to modify an existing cancellation order that was issued after the opportunity for a hearing. In 1992, EPA issued a NOIC registrations containing EBDCs¹ for use on certain crops. The crop at issue for this hearing notice is potatoes. The NOIC stated that use of EBDCs on potatoes would be canceled unless the registrants modified their pesticide product labels. At issue in this notice is the 1992 requirement to extend the preharvest interval (PHI)² to reduce the dietary risk. EPA issued the 1992 NOIC with an opportunity for a hearing. EPA and the registrants reached a settlement, including the agreement to amend labels to extend the PHI to 14 days.

On December 26, 1996, the EBDC/ETU Task Force³ (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 order to reduce otherwise-unacceptable dietary risks, the cancellation order restricted the PHI for potatoes to 14 days in 37 States.

In this request, the Task Force requested that the PHI be reduced from 14 days to 3 days nationwide to address the spread of the late blight disease (*Phytophthora infestans*) in potatoes. Late blight is a fungal disease that caused the infamous "Irish Potato Famine" in the 1840s. If not adequately controlled, this disease is capable of totally destroying the crop in the field

(foliar blight phase) and/or in storage (tuber rot phase). For the foliar phase of the disease, the primary source of inoculum is infected tubers, which are present in cull piles, or remain in the soil after harvest, or are used as seed-pieces for new plantings. Spores produced on foliage and stems during the foliar phase of the disease serve as the primary inoculum for tuber infections, which generally occur prior to harvest. Infected potatoes placed in storage lots can then serve as a source of inoculum for the storage rot phase of the disease.

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. The Agency decided to consider the request after completion of the Reregistration Eligibility Decision (RED) process for the EBDCs⁴. To date, EPA has not taken any substantial actions on the Task Force request. This Notice represents EPA's determination that the 2003 request to modify the existing cancellation order merits a subpart D hearing.

Under subpart D of 40 CFR part 164, the Task Force submission constitutes 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. EPA has concluded that the submissions by the Task Force provide a basis for modification of the order canceling EBDC products. This Notice (1) announces that EPA has decided to hold a hearing regarding the petition to modify the existing cancellation order as it applies to the use of products containing EBDCs (mancozeb, maneb, and metiram) on potatoes and the allowance of a 3-day, rather than a 14-day PHI, (2) specifies the issues of fact and law to be considered at that hearing, (3) identifies what steps interested persons need to take if they wish to participate in the hearing, and (4) establishes a schedule for the hearing.

A. Does this Action Apply to Me?

This action is directed to the public in general, and may be of interest to 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 ID number EPA-HQ-OPP-2007-0181. Publicly Available 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 Building), 2777 S. Crystal Drive 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 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/fedrgstr/>.

II. Background**A. What Action is the Agency Taking?**

The purpose of this document is to announce that the Agency has determined that the petition requesting a modification of the cancellation order has merit and that an opportunity for a hearing is being announced.

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

When the Agency receives an application to permit use of a pesticide in a manner inconsistent with a cancellation order issued after a cancellation proceeding has commenced (i.e., after publication of a notice of intent to cancel and receipt of a request for a hearing on that notice), that application will be treated by the Agency as a petition to modify the cancellation order. Because of the opportunity for a formal adjudicatory hearing, which precedes entry of such a final cancellation order, EPA has

¹ EBDC refers to products containing ethylene bisdithiocarbamate.

² PHI refers to the number of days between the last application of a pesticide and when the crop can be harvested.

³ The EBDC Task Force represents registrants who hold EBDC registrations. The current members of the Task Force are Dow AgroSciences, DuPont, Griffin, Cerexagri, and BASF.

⁴ Mancozeb was first registered in 1948. Maneb was first registered in 1962. Metiram was first registered in 1948.

determined that such an order should not be modified or rescinded without affording interested parties a similar notice and opportunity for hearing concerning such modification or rescission. The procedures governing all applications to modify or reverse a previous final cancellation order are set forth in 40 CFR part 164, subpart D, § 164.130 through 164.133.

The Administrator has determined that the applicant has met the criteria for a subpart D hearing. This notice sets forth the 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.

III. Regulatory History

EBDC fungicides currently registered under FIFRA for food uses include mancozeb, maneb, and metiram. The following is a summary of the regulatory history of the EBDCs.

In 1977, the Agency initiated a Rebuttable Presumption Against Registration⁵ (RPAR), which later became the Special Review Program, based on concerns that EBDCs and ethylene thiourea (ETU) posed potential significant risks to humans and the environment. In 1982, EPA concluded the RPAR and announced measures designed to mitigate potential unreasonable adverse effects pending the development of additional data. At that time, EPA deferred a decision on one risk of concern, carcinogenicity. The decision was deferred to allow for the development of residue data in order to better characterize the risk. (See 61 FR 42244, August 14, 1996).

In 1987, the Agency placed the EBDCs into Special Review because of concerns that the common metabolite, ETU, could cause carcinogenic and adverse developmental and thyroid effects in humans. The EBDCs metabolize to ETU in the body and all degrade to ETU in the environment. (See 52 FR 27172, July 17, 1987).

In response to the Agency placing the EBDCs in Special Review, the four technical registrants of mancozeb, maneb and metiram requested that

registrations be maintained for only 13 of the 55 food uses registered at that time and that all other uses be canceled. (See 54 FR 50020, December 4, 1989) Shortly thereafter, the Agency approved the requested amendments.

After the approval of the amendments, the Agency issued a Notice of Preliminary Determination⁶ (PD 2/3) that proposed canceling the uses on an additional three crops, including potatoes. The Agency received comments in response that recommended mitigation options to allow continued use of EBDCs on potatoes. Among these mitigation options was to “(e)xtend the preharvest interval to 14 days as most growers already observe a 14-day interval,” noting that “(t)he 0-day preharvest interval invites contamination of tubers with fungicide residues,” which could result in unacceptable dietary risks. (See 54 FR 52158, December 20, 1989). As a result of the PD 2/3, the EPA also issued a proposal to revoke and reduce tolerances for the 42 deleted uses plus the additional three uses proposed for cancellation. (See 55 FR 20416, May 16, 1990).

On March 2, 1992, the Agency issued the “Notice of Intent to Cancel and Conclusion of Special Review” (PD 4)⁷ concluding that the relatively high estimated dietary risk outweighed the relatively low benefits of the use of EBDCs on potatoes. (See 57 FR 7484, March 2, 1992). In order to allow the use on potatoes to remain, the Agency required certain mitigation language to be included on the label. This included the 14-day PHI for all but nine potato-producing states. Because of the presence of late blight in certain states (Connecticut, Florida, Maine, Massachusetts, New Hampshire, New York, Pennsylvania, Vermont, and Wisconsin), a 3-day PHI for use of EBDCs on potatoes was allowed in those states. The Agency allowed the 3-day PHI in these states because the data on late blight, efficacy of possible alternatives, and residue data allowed EPA to find that the benefits outweighed the risks. (See 57 FR 7484, 7526, March 2, 1992).

The adoption of the 14-day PHI was intended to be consistent with common practice in the other potato growing states at the time. (Ref. 1). The tolerance for the EBDC fungicides was based on EBDC and ETU residues detected in the

Market Basket Survey⁸ (MBS) of 1989–1990. As part of the Special Review, and in order to conduct a highly refined dietary exposure assessment, the EBDC registrants conducted a large-scale MBS to determine EBDC and ETU residues in a variety of foods as close to the point of consumption as possible (i.e., grocery stores and small markets). The survey was completed in 1990 and used in the Special Review PD 4, which was completed in 1992. The distribution of 14-day and 3-day PHIs was designed to best replicate the conditions under which the residues detected in the MBS occurred. (See 57 FR 7484, March 2, 1992).

Subsequently in 1996, the Agency allowed a 3-day PHI for use of EBDCs on potatoes in four additional states (Delaware, Michigan, Ohio, and Rhode Island). At the time the 1992 NOIC⁹ was issued, the Agency had no information suggesting that Delaware, Michigan and Ohio had a late blight problem and included those states among the states subject to a minimum 14-day PHI. Subsequent to the NOIC being issued, a group of registrants and growers submitted to the Agency information on late blight supporting a minimum 3-day PHI for Delaware, Michigan, and Ohio. This group requested a hearing to add these three states to the list of states for which a 3-day PHI was permitted. Additionally, at the time the Agency issued the NOIC, EPA believed that the “New England” states as well as some other states had a late blight problem and allowed a minimum 3-day PHI for those states. Rhode Island was erroneously omitted from the list of states. The Agency determined that in the states with substantial late blight occurrence, the benefits outweighed the risks associated with a 3-day PHI and amended the cancellation order. (See 61 FR 42244, August 14, 1996).

During the reregistration process, EPA evaluated the 14- and 3-day PHIs as part of the mancozeb, maneb, and metiram REDs, which were completed by September 2005 as part of the FIFRA reregistration process. (Refs. 2, 3, and 4)¹⁰. The REDs noted receipt of the

⁸ Samples were purchased at consumer retail outlets and shoppers were instructed to select blemish free commodities in amounts similar to those purchased by typical consumers. The study was conducted over a 1-year period to ensure that seasonal differences in residues would be addressed. The samples were analyzed using methods that are still in use at this time.

⁹ See, Settlement Agreement in *In re: American Food Security Coalition (AFSC) et al.*, FIFRA Docket Nos. 646, et al.

¹⁰ FIFRA section 4 requires EPA to make reregistration eligibility determinations for all older chemicals (those registered before November 1,

⁵ RPAR was a regulatory review process used prior to Special Review to consider potential risks that might warrant the cancellation of the registration. The regulations were changed in the mid-1980's to review pesticide products (leading to an ultimate determination of whether their use or uses pose unreasonable adverse effects to humans or the environment) and the procedures for the Special Review process. The regulatory changes were based primarily on changes made to FIFRA in 1978 and on the experience acquired by EPA in regulating pesticides pursuant to the RPAR process. See 40 CFR part 154 for the procedures associated with Special Review.

⁶ The PD 2/3 is the Notice of Preliminary Determination, which was based on information on risks and benefits received in public comments and on additional analyses performed since the Special Review process began. See 40 CFR 154.31.

⁷ A PD 4 is issued in accordance with 40 CFR 154.33.

petition to allow for a 3-day PHI in all states, but the Agency did not address whether the petition warranted a subpart D hearing or if the registration amendment requests would be granted. Through the reregistration process, EPA determined that the exposure that would result from a nationwide 3-day PHI for potatoes would be safe under the FFDCa reasonable certainty of no harm standard (Refs. 5, 6, and 7). In that analysis, the Agency assumed 67% crop treated for the use of EBDCs on potatoes. The 67% crop treated is a conservative overestimate for the actual crop treated. Even assuming a greater conservative and unlikely scenario of 100% crop treated, EPA believes the risk increase would be insignificant.

IV. Statutory and Regulatory Background

A. Standards for Granting or Maintaining a Registration

A pesticide product may be registered or remain registered only if it performs its intended pesticidal function without causing "unreasonable adverse effects on the environment." (FIFRA section 3(c)(5)). "Unreasonable adverse effects on the environment" is defined as "(1) any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of the pesticide, or (2) a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the standard under section 408 of the [FFDCa]." (FIFRA section 2(bb)).

Under FIFRA section 6, the Agency may issue a NOIC the registration of a pesticide product whenever it is determined that the product no longer satisfies the statutory criteria for registration. The Agency may specify particular modifications in the terms and conditions of registration, such as deletion of particular uses or revisions of labeling, as an alternative to cancellation. If an adversely affected person requests a hearing, the final order concerning cancellation of the product is not issued until after a formal administrative hearing.

B. Subpart D Proceedings

When the Agency receives an application to permit use of a pesticide in a manner inconsistent with a cancellation order issued after a cancellation proceeding has commenced (i.e., after publication of a NOIC and receipt of a request for a hearing on that notice), that application will be treated

by the Agency as a petition to modify the cancellation order. Because of the opportunity for a formal adjudicatory hearing, which precedes entry of such a final cancellation order, EPA has determined that such an order should not be modified or rescinded without affording interested parties a similar notice and opportunity for hearing concerning such modification or rescission. The procedures governing all applications to modify or reverse a previous final cancellation order are set forth in 40 CFR part 164, subpart D, § 164.130 through 164.133.

As stated previously, 40 CFR 164.131(a) provides that the Administrator will consider modifying a prior final cancellation order when he 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.

In deciding whether or not to initiate a hearing, the Administrator does not need to determine that the evidence submitted by the Task Force would in fact justify modification of the prior order. Rather, a decision to initiate a hearing means only that the Administrator has determined that the evidence submitted, if substantiated on the record in the hearing, may "materially affect" the evidentiary rationale upon which the prior order was based. On the other hand, if the evidence submitted, even if substantiated on the record, would be unlikely to provide a basis for modification of the prior order, then a hearing would serve no purpose.

If the Administrator determines that an applicant has met the criteria for a subpart D hearing, the Administrator then publishes a notice in the **Federal Register** setting forth the 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. The purpose of the hearing is to determine whether: (1) Substantial new evidence exists and (2) such substantial new evidence requires reversal or modification of the existing cancellation order. For purposes of any decision in the hearing, those portions of the substantive rationale for the existing order concerning which the applicant did not submit substantial new evidence are assumed to be correct.

Thus, the scope of any subpart D hearing is intrinsically narrower than the original cancellation proceeding.

If a hearing is requested, a notice of the hearing will be published in the **Federal Register** announcing the formal public hearing to be held in accordance with 5 U.S.C. 554. In such a hearing, the Administrative Law Judge transmits a recommended decision to the Administrator, who then issues a final decision retaining, modifying, or reversing the existing order. (See 40 CFR 164.131).

V. Submissions - Substantial New Evidence Provided by Task Force

As stated above, the Task Forces submission constitutes a petition to modify the EBDC cancellation order. In order for the Agency to find that a subpart D hearing is warranted, it must determine:

(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. (See 40 CFR 164.131(a)).

The Task Forces 2003 petition to reduce the PHI for use of EBDCs on potatoes from 14 days to 3 days nationwide included a number of points described as "substantial new evidence" that could not have been known at the time of the cancellation order. The asserted "substantial new evidence" includes information on the spread of late blight to additional potato-growing states, field trial data for mancozeb and maneb use on potatoes and the Agency's revision of the cancer endpoint for EBDC breakdown product, ETU.

A. Spread of Late Blight

The Agency has determined that the information submitted by the Task Force concerning the spread of late blight fungal disease nationally is substantial new evidence which supports the adoption of a nationwide 3-day PHI for EBDCs on potatoes beyond the 13 states in which the 3-day PHI is currently in effect. Late blight is a severe fungal disease, which attacks leaves of potato plants in the field, killing the leaves and decreasing the size and number of potato tubers. Late blight also attacks tubers in storage, causing them to rot. Late blight was once controlled by metalaxyl, until metalaxyl resistant strains developed.

1984). The Agency announced these determinations through REDs.

The disease spreads rapidly by spores, with a new disease cycle occurring every 4 to 6 days. As mentioned above, the Agency was aware of the presence of late blight in nine states when the NOIC was published, and was made aware of its presence in four additional states soon thereafter (Ref. 7), and consequently the Agency determined that it was appropriate to reduce the PHI in those four states as well. The Task Force has since submitted new information that late blight has now spread nationwide. The following is background information on the spread of late blight and why this information is material to allowing a modification to the cancellation order.

Until 1989, late blight was very rarely of concern in any potato producing state, due primarily to the fact that metalaxyl products provided virtually 100% control of the foliar phase of the disease. (Ref. 8). The Task Force indicated that by 2003, the Agency had granted FIFRA section 18 emergency exemptions for the use of products to control late blight in 23 states to which the disease had spread since the issuance of the NOIC (Ref. 9). Pesticides for which exemptions were granted included dimethomorph, cymoxanil, and propamocarb hydrochloride. State crop specialists documented the distribution of metalaxyl-resistant forms and grower crop damage incidents associated with the failure of metalaxyl to provide adequate disease control (Refs. 8 and 10). Metalaxyl was thus no longer regarded as an effective control for late blight in potatoes.

If late blight is not adequately controlled, this disease is capable of totally destroying a crop of potatoes in the field (foliar blight phase) and/or in storage (tuber rot phase). Generally speaking, the number of infected tubers present at harvest is primarily a function of the level of foliar disease control attained during the growing season, especially during the latter half of the season. At present, even when low levels of tuber infection are detected in a field at harvest, growers typically need to sell potatoes right away, rather than store them and risk losing a large number of stored potatoes (Refs. 8 and 10).

Once plants are initially infected, the foliar phase of the disease can rapidly progress by producing multiple generations of spores, which can be transported up to 150 miles in the air as well as locally in water or air. One spore cycle can occur in a 4- to 6-day period. In addition to destroying aboveground plant parts, the foliar blight phase of the

disease can cause a significant decrease in the size and number of marketable potatoes. Accordingly, even the planting of a single infected tuber can quickly result in extensive crop losses and a high percentage of tuber infections over a large area (Refs. 8 and 10).

The foliar phase of the disease is favored by cool and moist conditions, which commonly occur in most potato production states. Long periods of high relative humidity (over 90%) with night temperatures of 50 to 60° F and day temperatures of 60 to 80° F are favorable for disease development. The spread and control of this disease is complicated by the fact that most fungal forms are also capable of infecting and reproducing on tomatoes as well as certain other solanaceous plants (including certain weeds). It is suspected that the new, sexually reproducing forms of late blight were introduced to the United States through the importation of infected tomatoes from Mexico (Ref. 11). The potential for spreading the disease via infected tomato transplants or fruits is of particular concern, in light of the widespread homeowner gardening and composting practices associated with tomatoes.

Most of the harvested potatoes in the United States go directly into storage and are gradually released into the marketplace over a period of 1 to 10 months. Many of the existing storage facilities are conducive to the rapid spread of tuber rot, especially during wet or humid weather. Potato late blight specialists agree that, under these storage conditions, even if only a small percentage of any lot of stored potatoes is infected with tuber rot, it is likely that the majority of them will spoil prior to their release into the marketplace. When this occurs, the whole lot is generally considered unmarketable. The stored tuber spoilage problem can be due solely to late blight, or to a series of tuber rots initiated by late blight infected tubers and followed by bacterial soft rots, which develop in response to the anaerobic conditions created by the development of late blight tuber rot (Refs. 8 and 10).

B. Field Trial Data

As mentioned above, the potential exposure to humans that could result from the use of EBDCs on potatoes was considered during reregistration and was found to meet the standard for reregistration. EPA was able to make this determination because of the new information submitted by the Task Force as well as revised risk assessment methodologies. The residues detected in

the 1989–1990 MBS were considered to reflect common practices that included either 14-day or 3-day PHIs for potatoes treated with EBDC fungicides. Additional field trial data submitted by the Task Force in support of its 2003 petition are available for two of the three EBDCs, which further support the establishment of a nationwide 3-day PHI. The following describes the field trial data available for each EBDC chemical.

1. Mancozeb. The Mancozeb Task Force conducted residue trials on potatoes in 1995–1996. A summary of relevant residue data for mancozeb and ETU are presented in Table 1 below. The maximum mancozeb value found in residue studies using the maximum seasonal rate for mancozeb on potatoes with a 3-day PHI was 0.1 parts per million (ppm) and for a 14-day PHI was 0.02 ppm. The average mancozeb value with a 3-day PHI was 0.02 ppm and with a 14-day PHI was 0.01 ppm.

From this newly submitted data, the Agency has now determined that reduction of the PHI to 3 days for the entire United States would not result in mancozeb residues exceeding the reassessed tolerance of 0.2 ppm for potatoes. A separate dietary risk assessment was not required to support the PHI change request because existing dietary assessments used for the EBDC REDs showed no appreciable differences in the residue levels at different pre-harvest intervals. Additionally, as stated earlier, even if the percent crop treated rose from 67% to 100% the resulting increase in risk would be insignificant. Therefore, the Agency found that the use of EBDCs on potatoes with a 3-day PHI would meet the FFDCA safety determination (Ref. 12).

EPA used monitoring data from the MBS in the dietary risk assessment for the reregistration eligibility decision. Based on these new field trial data, EPA has now determined that the MBS is representative of the residues that may be expected in potato tubers at PHIs ranging from 3 to 14 days.

Low residues are expected because mancozeb is applied to the foliage, and metabolism studies have not shown translocation of mancozeb throughout the plant (Ref. 6). Therefore, it is not surprising that there are minimal residues on the day of application, as the residues would not transport from the potato leaves to the tubers below the ground. The minimal residues that are present on the tubers may be from some soil that adhered to the tuber when harvested.

TABLE 1.— SUMMARY OF MANCOZEB RESIDUE DATA FOR POTATOES (MRIDs 44167901, 40913301, AND 41091601)

Location	Single Application Rate, lb ai/A	No. of Applications	Seasonal Application Rate, lb ai/A	Pre-harvest Interval, days	Residues Found, ppm	
					Mancozeb	ETU
CA	1.6 + 2.4	5	11.2	0	<0.05	<0.01
CA	1.6 + 2.4	5	11.2	0	<0.05	<0.01
WI	1.6	7	11.2	3	<0.02	<0.01
FL	1.6	7	11.2	3	0.03	<0.01
FL	1.6	7	11.2	3	0.03	<0.01
PA	1.6	7	11.2	3	<0.02	<0.01
PA	1.6	7	11.2	3	<0.02	<0.01
MO	1.6	7	11.2	3	0.02	<0.01
MO	1.6	7	11.2	3	<0.02	<0.01
MO	1.6	7	11.2	3	0.1	<0.01
MO	1.6	7	11.2	3	0.03	<0.01
NY	1.6	7	11.2	3	<0.02	<0.01
MN	1.6	7	11.2	4	<0.02	<0.01
MN	1.6	7	11.2	4	<0.02	<0.01
CA	1.6 + 2.4	5	11.2	5	<0.05	0.01
CA	1.6	5	11.2	5	<0.05	0.02
CA	1.6	7	11.2	14	<0.02	0.02
CA	1.6	7	11.2	14	0.02	<0.01
WA	1.6	7	11.2	14	<0.02	<0.01
CA	1.6	7	11.2	14	<0.02	0.02
UT	1.6	7	11.2	14	<0.02	<0.01
UT	1.6	7	11.2	14	<0.02	<0.01
ID	1.6	7	11.2	14	<0.02	<0.01
ID	1.6	7	11.2	14	<0.02	<0.01
CA	1.6 + 2.4	5	11.2	15	<0.05	0.03
CA	1.6 + 2.4	5	11.2	15	<0.05	0.02

2. *Maneb*. In response to EPA's requests for data in the late 1980s and early 1990s, one registrant, Elf Atochem North America, Inc. submitted data in 1994 pertaining to the magnitude of maneb residues in or on potatoes. The data were determined to be insufficient to fulfill the total field trial requirement, because "field trials were not conducted in states where a 3-day PHI is allowed." However, they did indicate that residues of maneb and ETU from maneb will not exceed the established tolerance of 0.1 ppm in or on potatoes harvested 1 day following the last of eight foliar applications of the dry flowable

formulation for a total seasonal rate of 12.8 lb active ingredient/Acre (ai/A) because the combined residues of maneb and its metabolite ETU were nondetectable (<0.06 to <0.08 ppm) in or on potatoes (Refs. 13, 14 and 5).

Available field trial data for maneb and ETU in or on potatoes were among the data used in conjunction with MBS from 1989–1990 to assess acute and chronic dietary (food) risk in the 2005 maneb RED. In the 2005 RED, EPA determined that the overall aggregate risk from residues of maneb and ETU on food was determined to be below the Agency's levels-of-concern. The

reduction in PHI to 3 days will not change this determination.

3. *Metiram*. The Task Force did not provide new evidence to support a 3-day PHI for use of metiram on potatoes because such data had previously been submitted to the Agency in 1988. This earlier data involved field trials performed in 1987 in seven states to measure the magnitude of metiram and ETU residues on potatoes. The review of these studies shows that "(t)he 80% WP metiram formulation was foliarly applied 10 times (with a 5- to 21-day retreatment interval), to potato plants at 1.6 lb ai/A/application (1x) using

ground equipment. Individual residues of metiram and ETU were <0.10 ppm (nondetectable) and <0.01 (nondetectable) to 0.02 ppm, respectively, in or on treated potato tuber samples harvested immediately (0-day) following the last of the above treatment schedule. The maximum residues of metiram in or on potato tubers following treatments at 1x were <0.10 ppm which is below the established tolerance of 0.5 ppm" (Ref. 10). The tolerance was later reassessed and set at 0.2 ppm, which met the FFDCA safety finding as well allowing the Agency to harmonize the tolerance with the Codex maximum residue limit (MRL) for EBDCs in or on potatoes.

Since residues of metiram measured in or on potatoes were below the tolerance level for potatoes harvested immediately after the final treatment, potatoes harvested 3 days after treatment should have residues that are lower and also below the tolerance level. As was stated in the maneb discussion, overall risk from residues of metiram and ETU on food was determined to be below the Agency's levels of concern, and would be expected to remain so if a 3-day PHI for potatoes were established nationwide (Ref. 10).

C. Revision of the Cancer Endpoint for ETU

The Task Force notes in its 2003 petition that the Q1*¹¹ for ETU has changed since the 1992 NOIC. If there is evidence, such as tumor formation, and the pesticide is classified as a carcinogen, a quantitative assessment is conducted using a Q1* (non-threshold) or a Margin of Exposure (threshold) approach. The Agency evaluated the risk from ETU in the NOIC using a Q1* of 0.11 milligrams/kilogram/day (mg/kg/day)⁻¹. The Agency subsequently recalculated the ETU Q1* in 1995, resulting in a Q1* of 0.06 mg/kg/day⁻¹. As a result of this new assessment endpoint, the Task Force suggests that the reduction in the PHI for use of EBDCs on potatoes would be even less likely to result in exceedances of the Agency's levels of concern. In its reregistration decisions for the EBDCs, using the lower Q1*, EPA found that the level of concern for cancer risk was not exceeded.

The reduction of the Q1* for ETU was significant new evidence that allowed the Agency to make a safety finding for the reregistration of EBDC fungicides. It

is important to note that the field trial data alone indicate that residues of ETU on potatoes from application of EBDCs would not be significantly different for PHIs of 3 and 14 days. Therefore, the reduction of the Q1* for ETU is a less compelling argument for reducing the PHI to 3 days as exposure levels show that there are no risks of concern.

VI. Risk-Benefit Assessment

A. Significance of Substantial New Evidence

When the Agency issued the cancellation order for EBDC fungicides in 1992, it allowed a shorter, 3-day PHI for EBDCs on potatoes in nine states in which late blight disease occurred. The Agency was made aware soon thereafter that late blight disease was also present in four states not identified in the cancellation order, and the 3-day PHI was extended to those states to afford the same protection against late season onset of late blight disease through amendments to the cancellation order. The evidence presented by the Task Force that late blight has since spread to almost all potato-growing states, when combined with the scientific finding that the resulting exposures would still meet the "reasonable certainty of no harm" standard set forth in section 408 of the FFDCA, is a compelling justification for extending the 3-day PHI to all states in which EBDCs could be applied to potatoes.

It is important to keep in mind that there are also residue data for mancozeb and maneb on potatoes submitted since the cancellation order that support the nationwide adoption of the 3-day PHI. As shown above, the mancozeb field trial data indicate that mancozeb and ETU residues from the use of mancozeb on potatoes were insignificant, and that the concentrations of mancozeb and ETU residues reflecting a 3-day PHI were not significantly different than those reflecting a 14-day PHI. Similarly, maneb field trial data submitted since the cancellation order indicate that ETU residues were undetectable for treated potatoes after both 1-day and 7-day PHIs. These data, in conjunction with previously submitted metiram data showing no ETU residues on potatoes harvested the day of treatment, indicate that adoption of a 3-day PHI nationwide will not meaningfully increase exposure to ETU in or on potatoes.

Although the requirements for additional field trials for use of maneb on potatoes are still outstanding because geographic representation was inadequate, the Agency believes it unlikely that the residues resulting from a 3-day PHI in other regions would be

sufficiently different to be of concern, based on similar data for mancozeb on potatoes. In modifying the Cancellation Order to change the 14-day PHI from the use of EBDCs on potatoes to 3 days nationwide, the Agency would condition the registration with a requirement that the registrants provide the confirmatory data to fulfill the field trial data requirement (OPP guideline 171-4(k); OPPTS guideline 860.1500).

As described above, the reduction of the Q1* for ETU was also "substantial new evidence" but a less compelling argument for modifying the cancellation order because the exposure levels to ETU were not of concern.

B. Alternative Control Measures

As stated earlier, EBDCs are needed to control the nationwide spread of late blight, because the alternative products that are registered to address late blight are not adequate (Ref. 2).

VII. Subpart D Determination

Under 40 CFR 164.131(a), the Administrator is to provide a hearing to modify a prior final cancellation decision only if it is determined that certain criteria have been met. Having concluded that the EBDC Task Force has presented substantial new evidence concerning the request to provide for a 3-day PHI nationwide which was not available when the final cancellation order went into effect, the Administrator must now determine whether that evidence "may materially affect" that order. The Administrator has concluded that the new information materially affects whether the cancellation order should be modified because this information allows the Agency to find that a nationwide 3-day PHI meets the FIFRA standard for registration. Thus, the first criterion in 40 CFR 164.131(a) has been met.

Information provided by the Task Force on the late blight spread nationwide could not have "through the exercise of due diligence" been obtained before the 14-day restriction was in place as late blight had not yet spread nationwide. When information existed concerning the spread of late blight nationwide and the need for additional tools to combat it, the Task Force submitted the newly obtained information. Therefore, the second criterion in 40 CFR 164.131(a) has also been met.

Based on the above analysis and because the Agency believes it is appropriate under this circumstance to modify the cancellation order to allow a 3-day PHI, the Administrator has decided to issue this notice under

¹¹ The Q1*, or cancer slope factor, is an upper bound estimate of the increased cancer risk from a lifetime exposure to an agent. Upper bound in this context is a plausible upper limit to the true probability.

subpart D to provide an opportunity for a hearing.

Since EPA issued its NOIC in 1992, substantial new evidence has been presented to the Agency that supports amendment of the cancellation order to allow all states to have a 3-day PHI for potatoes. The new information focuses on the need for the EBDCs to combat the late blight problem in the United States. For example, metalaxyl-resistant strains of late blight were reported in at least 32 states, which means that resistant strains are currently present in virtually all potato producing states. Additionally, since the pest problem can spread long distances via airborne spores and virtually all states that produce planting stock (seed-potatoes) have documented the presence of metalaxyl-resistant strains; all production states have a high probability of encountering metalaxyl-resistant late blight strains in any given year. Based on the information reviewed, a 3-day PHI is likely to reduce the number of tubers that become infected just prior to harvest and will therefore increase the number of tubers that can be stored.

Pursuant to 40 CFR 164.131(c), the Administrator is specifying those issues of fact and law to be adjudicated in the hearing convened pursuant to this notice. Because the purpose of such a hearing is only to consider whether to modify certain aspects of the Administrator's prior cancellation decision and because a prompt conclusion to the hearing is a requisite of meaningful relief for the applicant, the evidentiary presentation in the hearing shall be strictly confined to the issues of fact and law which the Administrator has determined are presented by the Task Force submission.

1. *Issues of fact.* The issues of fact to be adjudicated are:

- i. What is the current status (nationwide) of late blight on potatoes?
- ii. Has the occurrence of late blight changed since the initial cancellation order issued in 1992?
- iii. Are EBDCs necessary to respond to late blight?
- iv. What are the dietary risks associated with EBDC use on potatoes?

2. *Issues of law.* The issues of law to be adjudicated are:

- i. Has substantial new evidence been presented pertaining to the request to reduce the nationwide PHI on potatoes to 3 days?
- ii. If it is substantial new evidence, could the applicant, through due diligence, have discovered this information prior to issuance of the cancellation order?

iii. Does the 3-day PHI meet the FIFRA 2(bb) standard?

The sole objective of this hearing is to determine whether or not the order canceling all sale, distribution, and use of pesticide products containing EBDCs that do not comply with the current label restriction on the PHI for potatoes should be modified to permit a nationwide 3-day PHI.

B. Hearing Requests

The applicant and the Agency shall automatically be parties in the hearing. Any other person or party who seeks to participate in the hearing must submit a written hearing request describing the interest of that person or party in the proceeding and the nature and purpose of the participation sought. All requests for a hearing must be received by the Office of the Hearing Clerk within 30 calendar days from the date of publication of this Notice in the **Federal Register**. Such requests must include an identification of the requestor's interest in the proceeding, the hearing issues the requestor wishes to participate in, and the requestor's position with respect to such issue(s). Requests for a hearing must be submitted to: Office of Hearing Clerk, U.S. EPA, 1200 Pennsylvania Ave, N.W., Washington, D.C. 20460. Requests may be hand delivered to the Office of the Hearing Clerk at: 1099 14th St., NW., Suite 350, Washington, DC.

C. Scheduling

As required by 40 CFR 164.131(c), the Administrator is specifying a schedule for this hearing. In recognition of the narrow scope of the proceeding, the Administrator is establishing the following schedule. However, if no other interested party requests a hearing, the Agency intends to file a motion pursuant to 40 CFR 164.60 requesting that the Administrative Law Judge issue an accelerated decision pursuant to 40 CFR 164.91(a)(8) in favor of modifying the cancellation order as requested.

The Chief Administrative Law Judge shall appoint an Administrative Law Judge to preside at this proceeding within 20 calendar days from date of publication of this Notice in the **Federal Register**. The hearing shall commence in Washington, DC as soon thereafter as practicable but in no event later than 40 calendar days from the date of publication of this Notice in the **Federal Register**. The presiding Administrative Law Judge shall transmit recommended findings of fact and conclusions of law and the hearing record to the Administrator within 70 calendar days from the date of publication of this Notice in the **Federal Register**. The

parties shall submit any objections to the recommended findings of fact and conclusions of law to the Administrator within 10 business days after issuance, and the Administrator will enter a final order as soon thereafter as practicable.

D. Separation of Functions

EPA's Rules of Practice forbid anyone who may take part in deciding this case at any stage of the proceeding, from discussing the merits of the proceeding ex parte with any party or with any person who has been connected with the preparation or presentation of the proceeding as an advocate or in any investigative or expert capacity, or with any of his or her representatives (40 CFR 164.7).

Accordingly, the following EPA offices, and the staffs thereof, are designated as the judicial staff of EPA in any administrative hearing on this issue: the Office of Administrative Law Judges, the Environmental Appeals Board, the Deputy Administrator, and the members of the staff in the immediate office of the Deputy Administrator, and the Administrator and the members of staff in the immediate office of the Administrator. The following offices are designated as the trial staff in any proceeding which may arise under this Notice: The Office of General Counsel, the Assistant Administrator for the Office of Prevention, Pesticides, and Toxic Substances and immediate staff, the Office of Pesticide Programs, and the Office of Compliance Monitoring. None of the persons designated as the judicial staff may have any ex parte communications with the trial staff or any other interested person not employed by EPA on the merits of any of the issues involved in this proceeding, without fully complying with the applicable regulations.

IX. References

1. USEPA, 1992. Ethylene Bisdithiocarbamate (EBDCs); Notice of Intent to Cancel and Conclusion of Special Review [57 FR 7484].
2. USEPA, 2005e. Reregistration Eligibility Decision (RED) for Mancozeb.
3. USEPA, 2005d. Reregistration Eligibility Decision (RED) for Maneb.
4. USEPA, 2005c. Reregistration Eligibility Decision (RED) for Metiram.
5. USEPA, 1998. Maneb (014505) and Mancozeb (014504) on Onions and Potatoes: Reregistration. Memo from Susan Hummel to R. B. Perfetti, January 6, 1998.
6. USEPA, 2003. Reregistration of Mancozeb: Request to Reduce Pre-Harvest Interval for Potatoes and Waive Processing Study. Memo from C.

Olinger to Tawanda Spears, September 7, 2003.

7. USEPA, 2005a. Assessment of the EBDC/ETU Task Forces Request to Reduce the EBDC Fungicides PHI on Potatoes from 14 to 3 Days. Memo from R. Mitchell and T. Kiely to Tawanda Spears, April 7, 2005.

8. USEPA, 1995. New York State Department of Environmental Conservation Emergency Exemption Requests For The Use of Dimethomorph and Cymoxanil Package Mixtures With Mancozeb (Acrobat M2, Curzate M-8) For Control of Potato Late Blight (95-NY-06, 95-N&Y-07). Memo from J. Hogue and R. Mitchell to L. Pemberton.

9. EBDC/ETU Task Force, 2003. Re: Amendments to the Registrations of Products Containing Ethylene Bidisthiocarbamates ("EBDCs") as an Active Ingredient to Change the Preharvest Interval ("PHI") for Potatoes. Memo from Edward Ruckert to James Jones, August 25, 2003.

10. USEPA, 2005b. Metiram (Chemical ID No. 014601, Case No. 0644) Revised Residue Chemistry Chapter for the Reregistration Eligibility Decision (RED) Document. Memo from C. Olinger to Tawanda Spears, June 23, 2005.

11. Bookbinder, M. (1988) Metiram and Ethylene Thiourea: Magnitude of the Residue in Potatoes Treated by Ground Equipment in Colorado, Idaho, Maine, Michigan, North Dakota, Oregon, and Wisconsin, 1987. Unpublished study prepared by Enviro-Bio-Tech, Ltd. 223 p.

12. USEPA, 2001. Reregistration of Mancozeb: Potato Crop Field Trial and Corn Processing Studies. Memo from C. Olinger to Anne Overstreet, March 15, 2001.

13. USEPA, 1988. Reregistration Standard for Maneb. November 10, 1988.

14. USEPA, 1996. Maneb (014505) and Mancozeb (014504) on Onions and Potatoes: Reregistration. Memo from S. Hummel to K. Boyle, September 6, 1996.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: July 2, 2007.

Peter Caulkins,

Acting Director, Special Review and Reregistration Division, Office of Pesticide Programs

[FR Doc. E7-13471 Filed 7-10-07; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPP-2007-0395; FRL-8136-1]

Notice of Filing of Pesticide Petition for Residues of Silver as Component of Food Contact Surface Sanitizing Solution

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the amendment of regulations at 40 CFR 180.190(a) for residues of antimicrobial pesticide formulation containing silver compounds applied to food contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils.

DATES: Comments must be received on or before August 10, 2007.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2007-0395 and pesticide petition number (PP 7F7178), 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 Building), 2777 S. Crystal Drive, 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 telephone number is (703) 305-5805.

Instructions: Direct your comments to docket ID number EPA-HQ-OPP-2007-0395. 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 or e-mail. The Federal 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, your e-mail address will be automatically captured and included as part of the comment that is placed in the docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the docket index. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, 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 telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Marshall Swindell, PM 33, Antimicrobials Division (7510P), Office of Pesticide Programs, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-6341, e-mail address: swindell.marshall@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

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