intended to restate its commitment to cost share with Task Force I or to make an offer to cost share with Task Force II. In any case, Prochimie's letter at most shows that Prochimie made an offer to cost share, which was an option it emphasized that it had not selected. Prochimie did not provide any evidence that it had selected the option of offer to pay or that any such offer had been accepted. In order to support the option Prochimie selected to address the data requirements, it must provide evidence that any such offer had been accepted. Prochimie did not do that. Although Prochimie paid Task Force II for the use of several specific studies which are not involved in this Notice, those payments do not provide any evidence that a cost share agreement has been reached with respect to any other studies required by the 1991 DCI for nonresidential turf use that Task Force II submitted or has committed to submit. In fact, Mr. Rockwell, the chairman of Task Force II, stated in an affidavit dated May 2, 2000, that ''No written offer-to-pay or any offer to jointly develop any data as required by and identified in the 1991 DCI has ever been received by Thiram Task Force II. . .from Prochimie.'' Since Task Force II does not believe that it has ever received an offer to cost share from Prochimie, it is unlikely that a cost share agreement has been reached between Prochimie and Task Force II. Without adequate proof of such an agreement, Prochimie may not claim an ownership interest in Task Force II's data for which Prochimie has not paid and hence may not claim that such data satisfies Prochimie's obligations. Consequently, the Agency considers that Prochimie is in noncompliance with certain data requirements for nonresidential turf use imposed by the 1991 DCI irrespective of Task Force II's actions to address those data requirements. Those data requirements are identified in Appendix II to this Notice and are as follows: EPA Guideline Nos. 71–4(b), 83–4, 85–1, and 122–2.

Moreover, prior to its dissolution, Task Force I failed to satisfy certain 1984 DCI data requirements for nonresidential turf use that were also imposed by the 1991 DCI. Because Prochimie was a member of Task Force I and has not independently submitted data or otherwise addressed these requirements, Prochimie is in noncompliance with these requirements. These data requirements are identified in Appendix II to this Notice and are as follows: EPA Guideline Nos. 161–1, 161–2, 162–1, 163–1, and 164–1.

In a letter dated December 21, 1998, EPA informed Prochimie that the data required under the 1991 DCI were long overdue and that Prochimie had satisfied only those data requirements that had been satisfied by Task Force I prior to its dissolution. In a letter dated January 12, 1999, Prochimie informed EPA that ''Prochimie cost shared/co-owned several studies submitted by Task Force II.'' However, Prochimie did not provide the evidence required by the 1991 DCI that Prochimie and Task Force II have agreed to cost share in the development of any other data required by the 1991 DCI for nonresidential turf use. Prochimie's letter also restated Prochimie's commitment to satisfy certain data requirements that neither Task Forces committed to fulfill. However, Prochimie did not submit any studies or proof required by the 1991 DCI of a cost share agreement with any party obligated to satisfy these data requirements.

In a letter dated June 29, 1999, Prochimie requested data waivers (or determination of nonapplicability or no need for additional data) for, among others, the following data requirements: Guideline Nos. 82–2, 83–4, 122–2, 161–1, 161–2, 163–1, and 164–1, and 165–4. After careful consideration of Prochimie's requests, EPA denied the request for waiver of the above mentioned data requirements in letters dated May 21, 2001 and August 31, 2001.

In a letter dated August 31, 2001, EPA informed Prochimie of its failure to demonstrate that it had taken appropriate steps to secure data required by the 1991 DCI. In an attachment to the letter, EPA identified all of the data requirements for nonresidential turf use under the 1991 DCI and the names of the parties who submitted studies for those requirements. As shown in that attachment, UCB Chemicals Corporation, Inc. (''UCB''), not Task Force I or II, satisfied a number of data requirements under the 1991 DCI for nonresidential turf use. The letter notified Prochimie of the Agency's intent to issue a Notice of Intent to Suspend Prochimie's technical thiram registration unless, within 30 calendar days of its receipt of the letter, EPA received from Prochimie certain required data or proof of an agreement or offer to cost share with UCB. In its October 4, 2001 response, Prochimie did not provide any of the data/information that the Agency required, but instead requested a re–evaluation of the Agency's determination not to waive certain environmental fate studies, clarification of applicable existing data, and a determination of data requirements applicable to the nonresidential turf use.

To date, Prochimie has failed to take appropriate steps to secure certain data required by the 1991 DCI applicable to nonresidential turf use and remains in noncompliance with those data requirements, which are set forth in Appendix II to this Notice. Accordingly, the Agency is issuing this Notice of Intent to Suspend.

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

The Agency's authority for taking this action is section 6(f)(2) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq.*

List of Subjects

Environmental protection.

Dated: February 4, 2003.

Richard Colbert,

Director, Agriculture Division, Office of Compliance, Office of Enforcement and Compliance Assurance.

[FR Doc. 03–4776 Filed 2–27–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0006; FRL–7288–9]

Cymoxanil; Notice of Filing a Pesticide Petition to Establish a Tolerance for a Certain Pesticide Chemical in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of a pesticide petition proposing the establishment of regulations for residues of a certain pesticide chemical in or on various food commodities.

DATES: Comments, identified by docket ID number OPP–2003–0006, must be received on or before March 31, 2003.

ADDRESSES: Comments may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit I. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Mary L. Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9354; e-mail address: waller.mary@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 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. To determine whether you or your business may be affected by this action, you should carefully examine the applicability provisions in OPP–2003–0006. 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 an official public docket for this action under docket ID number OPP–2003–0006. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although, a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open 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/.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA dockets. You may use EPA dockets at http://www.epa.gov/edocket/ to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or on paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically*. If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also, include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. 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.

i. *EPA dockets*. Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA dockets at http://www.epa.gov/edocket, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2003–0006. The system is an ''anonymous access'' system, which means EPA will not know your identity, e-mail address, or other contact information unless you provide it in the body of your comment.

ii. *E-mail*. Comments may be sent by e-mail to opp-docket@epa.gov, Attention: Docket ID number OPP–2003–0006. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

iii. *Disk or CD ROM*. You may submit comments on a disk or CD ROM that you mail to the mailing address identified in Unit I.C.2. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption.

2. *By mail*. Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington,

DC 20460–0001, Attention: Docket ID number OPP–2003–0006.

3. *By hand delivery or courier*. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID number OPP–2003–0006. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA's electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA's electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA's electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

E. What Should I Consider as I Prepare My Comments for EPA?

You may find the following suggestions helpful for preparing your comments:

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

3. Provide copies of any technical information and/or data you used that support your views.

4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.

5. Provide specific examples to illustrate your concerns.

6. Make sure to submit your comments by the deadline in this notice.

7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and **Federal Register** citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition as follows proposing the establishment and/or amendment of regulations for residues of a certain pesticide chemical in or on various food commodities under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time, or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: February 10, 2003.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by E. I. du Pont de Nemours and Company and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues, or an explanation of why no such method is needed.

E. I. du Pont de Nemours and Company

PP 0F6072

EPA has received a pesticide petition (0F6072) from E. I. du Pont de Nemours and Company, DuPont Agricultural Products, Barley Mill Plaza, Wilmington, DE 19880–0038 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR 180.503 by establishing tolerances for residues of the fungicide, cymoxanil; 2-cyano-N-(ethylamino)carbonyl l-2-(methoxyimino)acetamide in or on the raw agricultural commodities cucurbit vegetables at 0.05 parts per million (ppm), fruiting vegetables at 0.2 ppm, and head lettuce at 4.0 ppm. EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism*. The plant metabolism of cymoxanil is adequately understood in three diverse crops: potatoes, tomatoes, and lettuce. The results of these plant metabolism studies indicate that cymoxanil degrades extensively to primarily the amino acid glycine, with subsequent re-incorporation into other naturally-occurring products, such as glucose.

2. *Analytical method*. An analytical enforcement method is available for determining these plant residues by high performance level chromotography (HPLC) with ultraviolet (UV) detection. The limit of quantitation allows monitoring of crops with cymoxanil residues at or above the levels proposed in these tolerances.

3. *Magnitude of residues—i. Cucurbit vegetables.* The magnitude and decline of residues of cymoxanil was determined on cucumber, cantaloupe and summer squash, the representative commodities for the cucurbit vegetable crop group as follows:

- *Cucumber*. DPX-KP481 50DF, containing 25% cymoxanil and 25% famoxadone, was applied as a water dispersible granule to six test sites in Florida, Georgia, Minnesota, Ohio, Virginia, and Texas. DPX-KP481 50DF was applied as seven broadcast applications at the maximum rate of 0.1875 lb cymoxanil acre for a maximum seasonal use rate of 1.31 lb cymoxanil/acre. Applications were made approximately 5 days apart. The target pre-harvest interval (PHI) was 3 days. Residues of cymoxanil were less than 0.05 ppm.
- *Cantaloupe.* DPX-KP481 50DF, containing 25% cymoxanil and 25% famoxadone, was applied as a water dispersible granule to six test sites in Florida, Georgia, Minnesota, Ohio, Virginia, and Texas. DPX-KP481 50DF was applied as seven broadcast applications at the maximum rate of 0.1875 lb cymoxanil/acre for a maximum seasonal use rate of 1.31 lb cymoxanil/acre. Applications were made approximately 5 days apart. The target PHI was 3 days. Residues of cymoxanil were less than 0.05 ppm.
- *Summer squash*. DPX-KP481 50DF, containing 25% cymoxanil and

25% famoxadone, was applied as a water dispersible granule to five test sites in Florida, Pennsylvania, Minnesota, North Carolina and California. DPX-KP481 50DF was applied as seven broadcast applications at the maximum rate of 0.1875 lb cymoxanil/acre for a maximum seasonal use rate of 1.31 lb cymoxanil/acre. Applications were made approximately 5 days apart. The target PHI was 3 days. Residues of cymoxanil were less than 0.05 ppm.

ii. *Fruiting vegetables*. The magnitude and decline of residues of cymoxanil was determined on tomato and pepper, the representative commodities for the fruiting vegetable crop group as follows:

- *Pepper*. Bell and non-bell DPX-KP481 50DF, containing 25% cymoxanil and 25% famoxadone, was applied as a water dispersible granule to nine test sites in Georgia, Florida, Ohio, Texas, Arizona, California, and New Mexico. DPX-KP481 50DF was applied as nine broadcast applications at a maximum seasonal use rate of 1.12 lb cymoxanil/acre. Applications were made approximately 5 days apart. The target PHI was 3 days. Residues of cymoxanil at the target PHI of 3 days ranged from less than 0.05–0.12 ppm in peppers (bell and non-bell).
- *Tomato*. DPX-KP481 50DF, containing 25% cymoxanil and 25% famoxadone was applied as a water dispersible granule to 12 test sites in Florida, Maryland, Pennsylvania, California and Indiana. DPX-KP481 50DF was applied as nine broadcast applications at a maximum seasonal use rate of 1.12 lb cymoxanil/acre. Applications were made approximately 5 days apart. The target PHI was 3 days. Residues of cymoxanil at the target PHI of 3 days were less than 0.05 ppm in tomatoes.
- *Tomato, process fractions*. DPX-KP481 50DF, containing 25% cymoxanil and 25% famoxadone, was applied as a water dispersible granule to one site in California to determine the magnitude of residue in tomato and the extent to which the residue concentrated in tomato processed fractions. DPX-KP481 50DF was applied in nine broadcast applications at 1X and 5X the proposed maximum rate of 1.12 lb cymoxanil/acre. Applications were made approximately 5 days apart. The target PHI was 3 days. When applied at 5X the maximum use rate residues did not concentrate in tomato washed, unwashed, paste or puree.

iii. *Head lettuce*. DPX-KP481 50DF, containing 25% cymoxanil and 25% famoxadone, was applied as a water dispersible granule to eight test sites in Arizona, California, Florida, New York, and New Mexico. DPX-KP481 50DF was applied as seven broadcast applications at the maximum rate of 0.1875 lb cymoxanil/acre for a maximum seasonal use rate of 1.31 lb cymoxanil/acre. Applications were made approximately 5 days apart. The target PHI was 3 days. Residues of cymoxanil in head lettuce ranged from less than 0.05–2.8 ppm (wrapper leaves attached) and less than 0.05–1.1 ppm (wrapper leaves removed).

B. Toxicological Profile

1. *Acute toxicity*. A battery of acute toxicity tests on technical cymoxanil places it in the following Toxicity Categories:

TABLE 1.—ACUTE TOXICITY RESULTS ON TECHNICAL CYMOXANIL

Oral LD_{50}	Rat	960 mg/kg	Category III
Dermal LD_{50}	Rabbit	>2,000 mg/kg	Category III
Inhalation LC_{50}	Rat	> 5.06 mg/L	Category IV
Eye irritation	Rabbit	Slight irritant	Category IV
Dermal irritation	Rabbit	Not an irritant	Category IV
Dermal sensitization	Guinea pig	Not a sensitizer	

An acute neurotoxicity study was not required with cymoxanil and no acute neurotoxicity has been observed in short-term or subchronic studies.

2. *Genotoxicty*. Cymoxanil was tested in a battery of assays to evaluate genotoxicity and chromosome aberrations with the following results. Based on the weight-of-evidence, cymoxanil is not considered to be genotoxic or clastogenic.

TABLE 2.—GENOTOXICITY AND CHROMOSOME ABERRATIONS ASSAY RESULTS

Bacterial gene mutation	*Salmonella typhimurium*	Negative
Mammalian gene mutation *in vitro*	CHO/HGPRT	Negative
Mammalian chromosome aberrations *in vitro*	CHO	Positive
Mammalian chromosome aberrations *in vitro*	Mouse micronucleus	Negative
Unscheduled DNA synthesis *in vitro*	Primary rat hepatocytes	Negative
Unscheduled DNA synthesis *in vitro*	Primary rat hepatocytes and Spermatocytes	Negative

3. *Reproductive and developmental toxicity*. The results of a series of studies indicated that there were no reproductive, developmental, or teratogenic hazards associated with cymoxanil.

In a 2-generation cymoxanil rat reproduction study, the no observed effect level (NOEL) for both parents and offspring was approximately 7 milligrams/kilogram/day (mg/kg/day), based on decreased body weight, weight gain and food consumption in adults and decreased pup weight in offspring at 32 mg/kg/day. There were no reproductive or fertility effects. Since offspring effects occurred only in the presence of maternal toxicity, it is considered a secondary effect to the health effects on the dam.

With cymoxanil, developmental studies conducted in rats demonstrated a NOEL of 10 mg/kg/day and a lowest observed effect level (LOEL) of 25 mg/kg/day for both adult and developmental effects. Maternal effects in rats included decreased weight, weight gain, and food consumption. Developmental effects were increases in fetal variations, which were the result of generalized delays in ossification, and overall malformations, although malformations detected were not dose-related. In rabbits, several developmental toxicity studies were conducted with cymoxanil. Based on the weight-of-evidence of all three studies, EPA considered there was no unique sensitivity of perinatal animals to the effects of cymoxanil, nor any anomalies of the fetal nervous system at maternally toxic doses up to and including 32 mg/kg/day (Cymoxanil Agency Risk Assessment, February 18, 1998).

4. *Subchronic toxicity.* Subchronic (90–day) feeding studies were conducted with rats, mice, and dogs. In addition, the following subchronic feeding studies were conducted: A 90–day in rats to evaluate neurotoxicity and 28–day feeding studies in rats and mice to evaluate immunotoxicity. A 28–day dermal study was conducted in rats.

In a subchronic toxicity/neurotoxicity study in rats with cymoxanil, the NOEL of 47.6 mg/kg/day in males was based on decreased body weights and minimal to mild testicular and epididymal effects at higher concentrations. In females, the NOEL of 59.9 mg/kg/day was based on effects on body weight, weight gain, and food efficiency at higher levels.

The subchronic NOEL for male mice administered cymoxanil was 8.25 mg/kg/day based on body weight and weight gain effects at 82.4 mg/kg/day and above. The NOEL for females was 121 mg/kg/day based on increases in spleen and liver weights at 433 mg/kg/day and above.

For cymoxanil, dogs were the most sensitive species in subchronic studies. Reduced body weight gain and/or food consumption was observed at 3 mg/kg/day or greater in females and 5 mg/kg/day and above in males. Both sexes had red blood cells (RBC) changes decreased RBC counts, hemaglobin (Hb), and/or hematocrit (Hct) and increased incidence of ketonuria at the intermediate and high concentration, and changes in serum chemistry (decreases in various electrolytes and proteins) at the high dose. Males had testicular and epididymal effects at the highest concentration, 11 mg/kg/day (raised from 5 mg/kg/day at week 3); this was considered to be retardation of development due to markedly reduced body weight in this group. The NOEL for males was 3 mg/kg/day. There was no NOEL in female dogs in the 90–day study. Although, a NOEL was not established in the dog subchronic study, 3 mg/kg/day was found to be a NOEL in a subsequent chronic study in dogs.

Subchronic 28–day studies were conducted in rats and mice to evaluate the immunotoxicity potential of cymoxanil. Cymoxanil was not immunotoxic up to and including the highest dose tested which was 1,600 ppm in rats (108 and 117 mg/kg/day in males and females, respectively), 1,200 ppm (218 mg/kg/day) in male mice, and 2,400 ppm (552 mg/kg/day) in female mice.

Cymoxanil was applied to the skin of rats 6–hours/day for 28 days at doses of 0, 50, 500, and 1,000 mg/kg/day. There were no effects at any dose tested. The 28–day dermal NOEL was 1,000 mg/kg/day, the highest dose tested.

5. *Chronic toxicity*. Chronic studies with cymoxanil were conducted on rats, mice, and dogs to determine oncogenic potential and/or chronic toxicity of the compound. Effects generally similar to those observed in the 90–day studies were seen in the chronic studies. Cymoxanil was not oncogenic.

The chronic NOEL for cymoxanil in male rats was 4.08 mg/kg/day based on decreased body weight, weight gain, food efficiency, and non-neoplastic lesions in several organs including lung inflammation, spermatid degeneration, and retinal atrophy at 30.3 mg/kg/day or higher. In addition, male rats in the two highest groups displayed increased aggressiveness and hyperreactivity consistent with the compromised general health status (i.e. systemic toxicity) of those groups. In females, the NOEL of 5.36 mg/kg/day was based on decreased body weight, weight gain, food efficiency, and non-neoplastic lesions in several organs including lungs, liver, intestines, mesenteric lymph nodes, sciatic nerve, and retina at 38.4 mg/kg/day or higher. Retinal atrophy and sciatic lesions are common spontaneous lesions associated with aging. These effects observed in cymoxanil test animals were considered aging-related effects. Spermatid degeneration occurs spontaneously in rats. While the incidence was increased in cymoxanil-treated rats, most were mild or minimal and none were more than moderate. Thus, the effects are considered a mild exacerbation of a spontaneously occurring lesion.

In mice, the chronic NOELs for cymoxanil were 4.19 and 5.83 mg/kg/day for males and females, respectively, based on changes in organ weights, gastrointestinal effects in females and liver, testes and epididymal effects in males at the LOEL. Similar to the rat, the testicular effects were considered an exacerbation of a spontaneous lesion, that occurred in one-quarter of the control mice. The LOELs were 42.0 and 58.1 mg/kg/day for males and females, respectively.

The chronic cymoxanil NOEL for male dogs was 3.0 mg/kg/day based on a temporary decrease in body weight and food consumption, and lower RBC count, hemoglobin, and hematocrit at 5.7 mg/kg/day. In female dogs the only finding was a transient effect on body weight, food consumption, and food efficiency at the highest dose tested, 3.1 mg/kg/day, only during the first week of the study. EPA considered the NOEL in females to be 3.1 mg/kg (Cymoxanil Agency Risk Assessment, February 18, 1998).

6. *Animal metabolism*. When administered by gavage to rats, cymoxanil was readily absorbed and eliminated. Absorption reached maximum concentrations in whole blood within 4 hours post-dosing. A rapid and almost complete elimination was observed in the urine and feces. The majority of radioactivity was recovered within 96 hours, mainly in urine but also in feces. Radioactivity in the tissues and carcass was less than 1%. In the urine and feces, the majority of the radioactivity was free and/or conjugated glycine. 2-Cyano-2-methoxyimino-acetic acid was also found in low levels in the urine and trace levels in the feces. Intact cymoxanil was less than 1% in feces and not detected in the urine. The metabolite profile in urine and feces was similar between sexes, among dose groups, and between dosing regimens (single vs. multiple).

7. *Metabolite toxicology*. There are no metabolites of toxicological significance to mammals.

8. *Endocrine disruption*. Chronic, lifespan, and multi-generational bioassays in mammals and acute and subchronic studies on aquatic organisms and wildlife did not reveal endocrine effects. Any endocrine-related effects would have been detected in this definitive array of required tests. The probability of any such effect due to agricultural uses of cymoxanil is negligible.

C. Aggregate Exposure

1. *Dietary exposure.* Cymoxanil is a fungicide currently registered in the United States for use on potatoes. In addition, tolerances have been for cymoxanil on imported tomatoes and grapes. This tolerance petition proposes the following new uses in the United States: Cucurbit vegetables, fruiting vegetables and head lettuce. There are no residential uses.

i. *Food—a. Chronic dietary exposure assessment.* The chronic RfD of 0.041 mg/kg/day is based on a NOEL of 4.08 mg/kg/day from the 1 year rat feeding study and an uncertainty factor of 100. The acute NOEL of 4.0 mg/kg/day is based upon maternal clinical signs and weight effects at higher levels in a rat developmental study.

Chronic dietary cymoxanil exposure risks resulting from the proposed use of DPX-KP481 50DF on cucurbits, fruiting vegetables, head lettuce, potatoes and imported grapes were estimated using the Dietary Exposure Evaluation Model (DEEM, Novigen Sciences, Inc., 1999 Version 6.74). The analysis conservatively assumed that 30% of the crops on the proposed label would be treated with DPX-KP481 50DF and used field trial residue data. The chronic dietary risk estimate for cymoxanil shows that an adequate margin of safety exists for all population subgroups and that no effects would result from dietary exposure to cymoxanil.

The following table presents the analysis which indicate large margins of safety for each population subgroup and very low probability of effects resulting from chronic exposure to cymoxanil in DPX-KP481 50DF. No sensitive subpopulations were identified. For the general populations and all subpopulations 0.2% or less of the chronic RfD used.

TABLE 3.—RESULTS OF CHRONIC DIETARY ANALYSIS WITH CYMOXANIL

Population Group	Maximum Dietary Exposure (mg/kg/day)	% RfD
U.S. population	0.000063	0.2
Non-nursing infants (<1 yr.)	0.000016	<0.1
Children (1–6 yr.)	0.000074	0.2
Children (7–12 yr.)	0.000068	0.2
Females (13+)	0.000074	0.2

b. *Acute dietary exposure*. Results of the Tier 3 acute dietary exposure analysis show that an adequate margin of safety exists for all population subgroups and that no acute effects would result from dietary exposure to cymoxanil. The analysis conservatively assumed that 30% of the crops on the proposed label would be treated with DPX-KP481 50DF and used field trial residue data.

The results of the acute dietary exposure analysis for cymoxanil are given in the table below. The percentages of acute reference dose (aRFD) for cymoxanil were calculated based on an acute NOEL of 4 mg/kg/day from the rabbit developmental study based on maternal clinical signs and weight effects at the higher levels and an uncertainty factor of 100. The results of the acute dietary exposure analysis for cymoxanil indicate that the predicted exposures, expressed as a percentage of the aRFD are well below 100%, showing cymoxanil clearly meets the Food Quality Protection Act (FQPA) standard of reasonable certainty of no harm and presents much lower acute dietary risk than many of its competitors. At the 99.9th percentile, the percentage of the aRFD was 4.47% for the general population and 5.72% for the most sensitive subpopulation, nursing females.

TABLE 4.—RESULTS OF ACUTE DIETARY ANALYSIS WITH CYMOXANIL

Population Group	99th Percentile of Exposure		99th Percentile of Exposure	
	Exposure (mg/kg/day)	%aRfD	Exposure (mg/kg/day)	%aRfD
U.S. population	0.000475	1.19	0.001789	4.47
Non-nursing infants (<1 yr.)	0.000184	0.46	0.000599	1.50
Children (1–6 yr.)	0.000576	1.44	0.002096	5.24
Children (7–12 yr.)	0.000485	1.21	0.001936	4.84
Females (13+ nursing)	0.000635	1.59	0.002287	5.72

ii. *Drinking water*. Surface water exposure was estimated using the Generic Expected Environmental Concentration (GENEEC) model. Ground water exposure was estimated using SCI-GROW. These are screening level

models used for determining upper bound concentrations of pesticides in surface water and ground water.

The acute drinking water levels of concern (DWLOCs) are 1.3 parts per million (ppm) for the U.S. population, and 0.38 ppm for the most exposed population subgroup, children (1–6 years). The estimated maximum concentration of cymoxanil in surface water (8.15 ppb) derived from GENEEC is much lower than the acute DWLOC. Therefore, one can conclude with reasonable certainty that residues of cymoxanil in drinking water will not contribute significantly to the aggregate acute human health risk.

The chronic DWLOCs are 1.4 ppm for the U.S. population and 0.4 ppm for the most sensitive subgroup, children (1–6 years). The DWLOCs are substantially higher than the GENEEC 56–day estimated environmental concentration of 0.37 ppb for cymoxanil in surface water. Therefore, one can conclude with reasonable certainty that residues of cymoxanil in drinking water do not contribute significantly to the aggregate chronic human health risk.

2. *Non-dietary exposure*. Cymoxanil products are not labeled for residential non-food uses, thereby eliminating the potential for residential exposure. Non-occupational, non-dietary exposure for cymoxanil has not been estimated because the proposed products are limited to commercial crop production. Therefore, the potential for non-occupational exposure is insignificant.

D. Cumulative Effects

EPA's consideration of a common mechanism of toxicity is not necessary at this time because there is no indication that toxic effects of cymoxanil should be cumulative with those of any other chemical compounds or with each other. Cymoxanil is a unique cyanoacetamide and is chemically unrelated to any other commercial plant disease control agent. Its biochemical mode of action on fungi appears to be unique; it is theorized to act through inhibition of multiple cellular processes, but a definitive mechanism has not been completely elucidated. Similarly, the mechanism of action underlying observed toxicological effects in mammals is not fully characterized and there is no reliable information to suggest that cymoxanil has a mechanism of toxicity in common with any other compound.

Given the distinct chemical and toxicological profile of cymoxanil, its low acute toxicity, absence of genotoxic, oncogenic, developmental, or reproductive effects, and low exposure potential, the expression of cumulative human health effects with any other natural or synthetic pesticide is not anticipated.

E. Safety Determination

1. *U.S. population*. Dietary and occupational exposure will be the major routes of exposure to the U.S. population for cymoxanil, and ample margins of safety have been demonstrated for both.

For cymoxanil, assuming 30% crop treated and residues estimated based on field trial results, the chronic dietary exposure for the overall U.S. population is estimated to be 0.000063 mg/kg/day, using 0.2 percent of the RfD. For acute dietary exposure, the estimated exposure is 0.000475 and 0.001789 at the 99th and 99.9th percentiles, which will utilize 1.19 and 4.47%, respectively, of the RfD for the overall U.S. population. The ground application margin of exposure (MOE) was 7,814 for mixers/loaders and 1,430 for applicators. The aerial application MOE was 3,907 for mixers/loaders and 38,763 for applicators. The MOE for flaggers was 10,916. Based on the completeness and reliability of the toxicity data and the conservative exposure assessments, there is reasonable certainty that no harm will result from the aggregate exposure of residues of cymoxanil including all anticipated dietary exposure and all other non-occupational exposures.

2. *Infants and children*. Chronic dietary exposure of cymoxanil for the most highly exposed children's subpopulations are: 0.000074 mg/kg/day for children 1–6 years and 0.000068 mg/kg/day for children 7–12 years, representing 0.2% of the chronic reference dose (cRfD) for each subpopulation. Exposure for all infant subpopulations was negligible. For acute dietary exposure of cymoxanil, the %RfD for children 1–6 years is 1.44 at the 99th percentile and 5.24 at the 99.9th percentile. For non-nursing infants (>1 yr.), the %RfD is 0.46 at the 99th percentile and 1.50 at the 99.9th percentile. There are no residential uses of cymoxanil; it is extremely unlikely that drinking water will be contaminated. Based on the completeness and reliability of the toxicity data base, the lack of toxicological endpoints of special concern, the lack of any indication that children are more sensitive than adults to cymoxanil, and the conservative exposure assessment, there is a reasonable certainty that no harm will result to infants and children from the aggregate exposure of residues of cymoxanil, including all anticipated dietary exposure and all other non-occupational exposures. Accordingly, there is no need to apply an additional safety factor for infants and children.

F. International Tolerances

To date, no international tolerances exist for cymoxanil.

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FEDERAL EMERGENCY MANAGEMENT AGENCY

[FEMA–1445–DR]

Alaska; Amendment No. 3 to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster declaration for the State of Alaska, (FEMA–1445-DR), dated December 4, 2002, and related determinations.

EFFECTIVE DATE: February 12, 2003.

FOR FURTHER INFORMATION CONTACT: Magda Ruiz, Response and Recovery Directorate, Federal Emergency Management Agency, Washington, DC 20472, (202) 646–2705 or *Magda.Ruiz@fema.gov*.

SUPPLEMENTARY INFORMATION: The notice of a major disaster declaration for the State of Alaska is hereby amended to include the following areas among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of December 4, 2002:

Kodiak Island Borough for Public Assistance (already designated for Individual Assistance).

Alaska Railroad right-of-way between Milepost 79 and Milepost 102 along the Turnagain Arm and state highway Milepost 4 Power Creek Road highway in the Cordova area for Public Assistance.

(The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 83.537, Community Disaster Loans; 83.538, Cora Brown Fund Program; 83.539, Crisis Counseling; 83.540, Disaster Legal Services Program; 83.541, Disaster Unemployment Assistance (DUA); 83.556, Fire Management Assistance; 83.558, Individual and Household Housing; 83.559, Individual and Household Disaster Housing Operations; 83.560 Individual and Household Program—Other Needs, 83.544, Public Assistance Grants; 83.548, Hazard Mitigation Grant Program.)

Joe M. Allbaugh,

Director.

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