to waive the 180–day comment period and is providing a 30–day public comment period before taking action on the requested amendments to delete uses. Because of risk concerns posed by certain uses of diazinon, EPA intends to grant the requested amendments to delete uses at the close of the comment period for this announcement, unless the Agency receives any substantive comment within the comment period that would merit its further review of these requests.

III. Proposed Existing Stocks Provisions

EPA received requests for voluntary cancellation of the diazinon registrations identified in Table 1 and requests for amendments to terminate certain uses of the diazinon registrations identified in Table 2. Pursuant to section 6(f) of FIFRA, EPA intends to grant these requests by issuing a cancellation order at the end of the 30–day comment period unless the Agency receives any substantive comment within the comment period that would merit its further review of these requests. In the event that EPA issues a cancellation order, EPA intends to include in that order the existing stocks provisions set forth in this section. For purposes of that cancellation order, the term ''existing stocks'' will be defined, pursuant to EPA's existing stocks policy (June 26, 1991, 56 FR 29362) (FRL–3846–4), as those stocks of a registered pesticide product which are currently in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the cancellation or amendment. Any distribution, sale, or use of existing stocks after the effective date of the cancellation order that the Agency intends to issue that is not consistent with the terms of that order will be considered a violation of section 12(a)(2)(K) and/or 12(a)(1)(A) of FIFRA.

EPA Intends that the Cancellation Order Includes the Following Existing Stocks Provisions

1. *Distribution or sale of products bearing instructions for use on agricultural crops.* The distribution or sale of existing stocks by the registrant of any product listed in Table 2 that bears instructions for use on the agricultural crops identified in List 1 will not be lawful under FIFRA 1 year after the effective date of the cancellation order. Persons other than the registrant may continue to sell or distribute the existing stocks of any product listed in Table 2 that bears instructions for any of the agricultural uses identified in List 1 after the effective date of the cancellation order.

2. *Distribution or sale of products bearing instructions for use on outdoor non-agricultural sites.* The distribution or sale of existing stocks by the registrant of any product listed in Table 1 or 2 that bears instructions for use on outdoor non-agricultural sites will not be lawful under FIFRA 1 year after the effective date of the cancellation order. Persons other than the registrant may continue to sell or distribute the existing stocks of any product listed in Table 1 or 2 that bears instructions for use on outdoor non-agricultural sites after the effective date of the cancellation order.

3. *Distribution or sale of products bearing instructions for use on indoor sites.* The distribution or sale of existing stocks by the registrant of any product listed in Table 1 or 2 that bears instructions for use at or on any indoor sites (except mushroom houses), shall not be lawful under FIFRA as of the effective date of the cancellation order.

4. *Retail and other distribution or sale of existing stock of products for indoor use.* The retail sale of existing stocks by any person other than the registrants of products listed in Table 1 or 2 bearing instructions for any indoor uses except mushroom houses will not be lawful under FIFRA after December 31, 2002.

5. *Use of existing stocks.* EPA intends to permit the use of existing stocks of products listed in Table 1 or 2 until such stocks are exhausted, provided such use is in accordance with the existing labeling of that product.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: July 19, 2001.

Lois Rossi,

Director, Special Review and Reregistration Division, Office ofPesticide Programs.

[FR Doc. 01–19174 Filed 7–31–01; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[PF–1032; FRL–6789–2]

Notice of Filing a Pesticide Petition to Establish a Tolerance fora 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 control number PF–1032, must be received on or before August 31, 2001.

ADDRESSES: Comments may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit I.C. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1032 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Fungicide Branch, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–7740; e-mail address: giles-parker.cynthia@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

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

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this

document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/.

2. *In person.* The Agency has established an official record for this action under docket control number PF–1032. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

C. How and to Whom Do I Submit Comments?

You may submit comments through the mail, in person, or electronically. To ensure proper receipt by EPA, it is imperative that you identify docket control number PF–1032 in the subject line on the first page of your response.

1. *By mail.* Submit your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

2. *In person or by courier.* Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Information Resources and Services Division (7502C), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA. The PIRIB is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

3. *Electronically.* You may submit your comments electronically by e-mail to: opp-docket@epa.gov, or you can submit a computer disk as described above. Do not submit any information electronically that you consider to be CBI. Avoid the use of special characters and any form of encryption. Electronic submissions will be accepted in Wordperfect 6.1/8.0 or ASCII file format. All comments in electronic form must be identified by docket control number PF–1032. Electronic comments may also be filed online at many Federal Depository Libraries.

D. How Should I Handle CBI That I Want to Submit to the Agency?

Do not submit any information electronically that you consider to be CBI. You may claim information that you submit to EPA in response to this document as CBI by marking any part or all of that information as 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 version of the official record. Information not marked confidential will be included in the public version of the official record without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person identified 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 control 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 Comestic Act (FFDCA), 21 U.S.C. 346a. EPA has determined that this petition contains data or information regarding the elements set forth in 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: July 13, 2001.

James Jones,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by section 408(d)(3) of the FFDCA. The summary of the petition was prepared by the petitioner and represents the view of the petitioners. EPA is publishing the petition summary verbatim without editing it in any way. 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. duPont de Nemours

PP7E4847

EPA has received a pesticide petition (PP7E4847) from E.I. duPont de Nemours and Company (Dupont, P.O. Box 80038, Wilmington, DE 19880–0038 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of famoxadone in or on the raw agricultural commodity grapes at 2.0 parts per million and raisins at 4 parts per million (ppm). EPA has determined that the 4 ppm 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 supports 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 famoxadone is adequately understood in three distinct crops to support these tolerances: Tomatoes, potatoes and grapes. These studies showed no significant metabolites (all < 10%TRR) in the raw agricultural commodities (tubers,tomato fruit, grape berries). The only significant residue in any of the studies was the parent compound, famoxadone, occurring primarily as surface residues (grape berries and tomato fruit). No residues were detected in potato tubers. Thus, the proposed tolerance expression is for the parent compound, famoxadone (DPX–JE874) only.

2. *Analytical method.* An analytical enforcement method is available for determining famoxadone plant residues in or on grapes, raisins, potatoes, cucurbit vegetables (cucumbers, melons and squash), fruiting vegetables (tomatoes, peppers), and head lettuce using gas-liquidchromatography (GC) with nitrogen phosphorus detection (NPD). The method is applicable to high and medium moisture, oily and non-oily crops and related matrices. The limit of quantitation is 0.02 ppm. The limit of quantitation allows monitoring of crops with famoxadone residues at or above the levels proposed in these tolerances.

3. *Magnitude of residues — grapes and raisins.* Results from magnitude of residue and residue decline studies conducted on grapes in major European producing and exporting regions support the grape tolerance of 2.0 ppm. The mean residue value was 0.61 ppm +/− 0.38 ppm with a range of 0.07 to 2.14 ppm.

No residues were detected in juice or wine fractions upon processing or fermentation of grapes treated with exaggerated rates of famoxadone. The limit of quantitation was 0.02 ppm. Residues did concentrate by a factor of 1.9X in raisins, thus supporting a tolerance of4.0 ppm.

B. Toxicological Profile

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

Study Type	Species	Results	Toixcity Category
Oral LD_{50}	Rat	> 5,000 mg/kg	Category IV
Dermal LD_{50}	Rabbit	>2,000 mg/kg	Category III
Inhalation LC_{50}	Rat	>5.3 mg/L	Category IV
Eye irritation	Rabbit	Transient redness; clear by 72 hours	Category III
Dermal irritation	Rabbit	Minimal irritation at 72 hours	Category IV
Dermal sensitization	Guinea pig	Not a sensitizer	

In an acute neurotoxicity test, famoxadone was not neurotoxic to rats. The NOAEL was 1,000 milligams/kilogram (mg/kg) in males, based on systemic toxicity at 2,000 mg/kg. The NOAEL in females was 2,000 mg/kg, the highest dose tested (HDT).

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

Bacterial genemutation	*Salmonella* and *E. Coli*	Negative
Mammalian gene mutation *in vitro*	CHO/HGPRT	Negative
Mammalian chromosome aberrations *in vitro*	CHO	Positive without activation Negative with activation
Mammalian chromosome aberrations *in vivo*	Mouse micronucleus	Negative
Unscheduled DNA synthesis *in vitro*	Primary rat hepatocytes	Negative
Unscheduled DNA synthesis *in vivo*	Primary rat hepatocytes	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 famoxadone.

In a 2–generation rat reproduction study, the NOAEL for both adults and offspring was 200 ppm (11.3–17.5 mg/kg/day depending on gender and generation) based on clinical signs, decreased body weights, effects on nutritional parameters, and liver toxicity in adults and decreased weight of pups. Effects on pups occurred only at a maternal effect level and may have been due to altered growth and nutrition in the dams. There were no effects on reproduction (mating, fertility, and reproductive organs) up to and including the highest concentration tested, 800 ppm (44.7–71.8 mg/kg/day).

In studies conducted to evaluate developmental toxicity potential, famoxadone was neither teratogenic nor uniquely toxic to the conceptus. In a rat developmental toxicity study, the maternal NOAEL was 250 mg/kg/day based on decreased weight gain and food consumption at 500 mg/kg/day. The fetal NOAEL was 1,000 mg/kg/day, the HDT. In rabbits, NOAEL for compound-related systemic toxicity was 1,000 mg/kg/day. There were no developmental effects at any dose level. Several rabbits had weight loss, decreased food consumption, clinical signs, fecal impactions and subsequent abortion at 1,000 mg/kg/day. These effects were considered due to the physical properties of the dosing solution rather than systemic toxicity. Often fecal impaction preceded abortions.

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 90–day feeding study in rats, the NOAEL was considered to be 200 ppm (13 and 17 mg/kg/day) based on mild hepatotoxicity and mild regenerative hemolytic anemia in both sexes and decreased body weight in females at 800 ppm (52 and 66 mg/kg/day, in males and females respectively) and higher. An effect on weight gain in female rats at 17 mg/kg/day was considered spurious since it was not duplicated in any other rat studies including those of thesame or longer duration.

In a subchronic neurotoxicity study in rats, there was no evidence of neurotoxicity up to and including the highest concentration tested, 800 ppm (46.9 and 59.3 mg/kg/day for males and females, respectively). The NOAEL for systemic toxicity was 200 ppm (11.7 and 14.4 mg/kg/day in males and females, respectively) based on body weight and nutritional effectsat 800 ppm.

In mice, the subchronic NOAEL was 350 ppm (62.4 and 79.4 mg/kg/day in males and females, respectively), based on hepatotoxicity and mild anemic effects at higher concentrations.

In a 90–day feeding study in dogs, the NOAEL was 40 ppm (1.3 mg/kg/day) in males. In females, 40 ppm (1.4 mg/kg/day) was a marginal effect level for lens lesions. At 300 ppm, lens lesions were observed in males and females upon ophthalmologic exam and confirmed by histopathology. These lesions were not considered relevant to human health and to acute risk assessment, since they did not occur in a 1–year primate study. Excluding lens lesions, the NOAEL was 300 ppm (10.0 and 10.1 mg/kg/day in males and females, respectively), based upon effects on body weight and food consumption, hemolytic anemia, and hyperkalemia with associated clinical signs at 1000/600 ppm (23.8/21.2 and 23.3/20.1 mg/kg/day in males and females, respectively). The test concentration was lowered to 600 ppm after 5.3 weeks because of the signs related to hyperkalemia.

Famoxadone was tested in 28–day feeding studies in rats and mice, designed to evaluate immunotoxicity. The NOAEL in rats was 200 ppm (14 and 16 mg/kg/day in males and females, respectively) based on decreased body weight, body weight gain, food consumption, food efficiency, and increased spleen weights at 800 ppm (55 and 57 mg/kg/day for male and females, respectively). There was no effect in response to sheep red blood cell (SRBC) challenge at any concentration tested. In mice, the NOAEL was 2,000 ppm (327 and 417 mg/kg/day in males and females, respectively) based onincreased spleen weights and a minimal decrease in humoral response to SRBC. Famoxadone is not considered immunotoxic in rats and produced equivocal evidence of immunotoxicity in mice.

In a 28–day repeated dose dermal study, the NOAEL for male rates was 250 mg/kg/day based on changes in liver enzymes at 500 mg/kg/day. The NOAEL for female rats was 1,000 mg/kg/day, the HDT.

5. *Chronic toxicity*. Chronic studies with famoxadone were conducted on rats, mice, dogs and monkeys 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. Famoxadone was not oncogenic.

Famoxadone was not oncogenic in rats. The chronic NOAEL was 200 ppm (8.4 and 10.7 mg/kg/day in males and females, respectively) based on hepatotoxicity and anemia in both sexes and decreased body weight, body weight gain, and food efficiency in females at 400 ppm (16.8 and 23.0 mg/kg/day in males and females, respectively).

In mice, the chronic NOAEL was 700 ppm (95.6 and 130 mg/kg/day for males and females, respectively) based on hepatotoxicity in males and females and amyloidosis in females at 2,000 ppm (274 and 392 mg/kg/day in males and females, respectively). Famoxadone was not oncogenic in mice.

In a 1–year feeding study in dogs, the only effect observed was lens lesions at 300 ppm (8.8 and 9.3 mg/kg/day for males and females). The NOAEL for these lesions was 40 ppm (1.2 mg/kg/day in both sexes). Use of this NOAEL is considered very conservative since these lesions are not considered appropriate to human risk assessment based on the absence of this effect in a primate study.

In a 1–year gavage study, the NOAEL in cynomolgus monkeys was 100 mg/kg/day in both males and female based on slight hemolytic anemia in both sexes at the 1,000 mg/kg/day dose level. There were no other effects observed at any level.

6. *Animal metabolism*. Famoxadone was rapidly eliminated in the rat, primarily by fecal excretion and to a lesser extent in the urine. Absorption and metabolism of famoxadone was limited. There was no accumulation in organs or tissues. Parent famoxadone was the major component recovered. Hydroxylated parent compound and sulfated cleavage products were also recovered to a much lesser extent.

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

8. *Endocrine disruption*. Chronic, lifespan, and multigenerational bioassays in mammals and acute andsubchronic 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 famoxadone is negligible.

C. Aggregate Exposure

1. *Dietary exposure*. Famoxadone is a new fungicide with proposed uses on the commercial crops: Fruiting vegetables (tomatoes and peppers), cucurbit vegetables (cucumbers, melons and squash), head lettuce, potatoes and imported grapes. There are no residential uses for the famoxadone-containing fungicide.

i. *Food*. The chronic RfD of 0.012 mg/kg/day is based on a NOAEL of 1.2 mg/kg/day for lens lesions from a 1–year dog feeding study and an uncertainty factor of 100. This is considered highly conservative because these lesions were not produced in a chronic monkey study. The acute NOAEL of 10.0 mg/kg bw/day is based upon body weight effects occurring early in a 90–day dog study. Since body weight is not actually an acute effect, the acute NOAEL selected is highly conservative and it is likely that the actual acute NOAEL is much higher than 10.0 mg/kg/day.

a. *Chronic dietary exposure assessment*. Chronic dietary exposure, resulting from all of the proposed uses of famoxadone, cucurbit vegetables, fruiting vegetables, head lettuce, potatoes, and imported grapes, is well within acceptable limits for all sectors of the population. The Chronic Module of the Dietary Exposure Evaluation Model (DEEM, Novigen Sciences, Inc., 1998 Version 6.4 (chronic) and 6.54 (acute)) was used to conduct the assessment with the anticipated reference dose (RfD) of 0.012 mg/kg/day. The analysis employed overall-mean field-trial values and conservatively assumed that 30% of the crops on the proposed label plus imported grapes would be treated with famoxadone.

For the general U.S. population, the estimated chronic dietary exposure to famoxadone is 0.000335 mg/kg/day, and utilizes 2.8% of the chronic RfD. The exposure for the potentially most highly exposed subgroup in the population, children 1–6 years, is 0.000487 mg/kg/day or 4.1% of the chronic RfD. The table below lists the results of this analysis, which indicate large margins of exposure for each population subgroup and very low probability of effects resulting from chronic exposure to famoxadone. Since the RfDs are well below 100%, the chronic dietary safety of famoxadone clearly meets the FQPA standard of reasonable certainty of no harm.

RESULTS OF CHRONIC DIETARY EXPOSURE ESTIMATE

Population Group	Maximum Dietary Exposure (mg/kg/day)	% RfD
U.S. Population	0.000335	2.8
Non-Nursing Infants (<1 year)	0.000111	0.9
Children (1–6 years)	0.000487	4.1
Children (7–12 years)	0.000391	3.3
Females (13+ years)	0.000430	3.6

b. *Acute dietary exposure*. The acute dietary exposure to famoxadone (99th percentile) is 0.001848 mg/kg/day, or 1.85% acute RfD for the overall U.S. population. The exposure (99th percentile) of the most highly exposed subgroup in the population, children 1–6 years, is 0.002559 mg/kg/day or 2.56% aRfD. The results of this analysis are given in the table below. All of the results are extremely reassuring, because they are based on several very conservative assumptions. Foods that were considered in exposure estimates were cucurbit vegetables, fruiting vegetables, head lettuce, imported grapes, and potatoes. Since the% aRfDs are well below 100%, the acute dietary safety of famoxadone clearly meets the FQPA standard of reasonable certainty of no harm.

RESULTS OF ACUTE DIETARY EXPOSURE ESTIMATE

Population group	99TH Percentile of expsure		99.9TH Percentile of expsure	
	Exposure (mg/kg/day)	% RfD	Exposure (mg/kg/day)	% RfD
U.S. Population	0.001848	1.85	0.006128	6.13
Non-Nursing (<1 year)	0.000949	0.95	0.003667	3.67
Children (1–6 years)	0.002559	2.56	0.008944	8.94
Children (7–12 years)	0.002002	2.00	0.007364	7.36
Females (13–50 years)	0.001843	1.84	0.006072	6.07

ii. *Drinking water*. Famoxadone is highly unlikely to contaminate groundwater resources due to its immobility in soil, low water solubility, high soil sorption, moderate soil half-life, and resulting low ground and surface water exposure. Both acute and chronic drinking water exposure analyses were calculated using EPA screening models (SCI-GROW for groundwater and GENEEC for surface water). Results indicate that a reasonable certainty exists that famoxadone residues will not contribute significantly to the aggregate acute and chronic human risk. The predicted concentration for famoxadone in groundwater under worst case conditions was 0.0097 parts per billion (ppb). The predicted peak concentration for famoxadone in surface water in a small non-flowing pond, directly adjacent to treated fields (aerial application at the maximum rate), was 2.49 ppb. The 56–day average concentration predicted for the same pond scenario was 0.05 ppb. The EPA uses drinking water levels of comparison (DWLOCS) as a surrogate measure to capture risk associated with exposure to pesticides in drinking water. The DWLOC is the concentration of a pesticide in drinking water that would be acceptable as an upper limit in light of total aggregate exposure to that pesticide from food, water and residential uses. A DWLOC will vary depending on the residue level in foods, the toxicity endpoint, drinking water consumption patterns, and body weights for specific subpopulations. The chronic DWLOCs are 0.41 ppm for the U.S. population and 0.12 ppm for the most exposed population subgroup, children (1–6 years). The DWLOCs are substantially higher than the GENEEC 56–day estimated environmental concentration of 0.05 ppb for famoxadone in surface water or the Sci-Grow estimate of 0.0097 ppb famoxadone in ground water. Therefore, since the estimated famoxadone concentrations are well below the chronic DWLOCs, the chronic dietary safety of famoxadone residues from drinking water clearly meets the FQPA standard of reasonable certainty of no harm. Using the appropriate inputs, the acute DWLOCs are 3.3 parts per million (ppm) for the U.S. population, and 0.91 ppm for the most exposed population subgroup, children (1–6 years). The estimated maximum concentration of famoxadone in surface water (2.49 ppb, derived from GENEEC) or in groundwater (0.0097 ppb, derived from Sci-Grow) is much lower than the acute DWLOC. Since the estimated famoxadone concentrations in ground and surface water are well below acute DWLOCs, the acute dietary safety of famoxadone residues from drinking water clearly meets the FQPA standard of reasonable certainty of no harm.

2. *Non-dietary exposure*. Famoxadone products are not labeled for residential non-food uses, thereby eliminating the potential for residential exposure. Non-occupational, non-dietary exposure for famoxadone 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 famoxadone should be cumulative with those of any other chemical. Famoxadone is a member of a new class of fungicides that acts by inhibition of mitochondrial respiration. Famoxadone's biochemical mode of action on fungi and toxicological profile in animals appear to be unique. Given the distinct chemical, biological and toxicological profile, famoxadone's 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. Ample margins of safety have been demonstrated for both situations. For the U.S. population, the chronic dietary exposure to famoxadone from all proposed uses is 0.000335 mg/kg/day, which utilizes 2.8% of the RfD for the overall U.S. population, assuming 30% of the crops are treated. The acute dietary exposure to the U.S. population is 0.001848 mg/kg/day (99th percentile) or 1.85% of the aRFD (99th percentile). At the 99th percentile, the acute dietary exposure for the U.S. population is 0.006128 mg/kg/day or 6.13% of the aRfD.

Using only PHED data levels A and B (those with a high level of confidence), the margin of exposures (MOEs) for occupational exposure are 2,665 to 5,329 for mixer/loaders, 34,418 for aerial applicators, and 1,096 for ground applicators. For flaggers, the MOE is 13,500. Based on the completeness and reliability of the toxicity data and the conservative exposure assessments, there is a reasonable certainty that no harm will result from the aggregate exposure of residues of famoxadone including all anticipated dietary

exposure and all other non-occupational exposures.

2. *Infants and children*. Chronic dietary exposure of the most highly exposed subgroup in the population, children 1–6, is 0.000487 mg/kg/day or 4.1% of the RfD. The acute dietary exposure of the most exposed subgroup, children 1–6, is 2.56% of the aRfD (99th percentile). For non-nursing infants (< 1 year), the acute dietary exposure is 0.95% RfD (99th percentile).

There are no residential uses of famoxadone and contamination of drinking water is extremely unlikely. Based on the completeness and reliability of the toxicity data, the lack of toxicological endpoints of special concern, the lack of any indication of greater sensitivity of children, and the conservative exposure assessment, there is a reasonable certainty that no harm will result to infants and children from the aggregate exposure to residues of famoxadone from all anticipated sources of dietary and non-occupational exposure. Accordingly, there is no need to apply an additional safety factor for infants and children.

F. International Tolerances

To date, no Codex, Canadian, or Mexican tolerances exist for famoxadone.

[FR Doc.01–19169 File7–31–01;8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–00723; FRL–6787–4]

Combined Chronic Toxicity/ Carcinogenicity Testing of Respirable Fibrous Particle Final Test Guideline; Notice of Availability

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of availability.

SUMMARY: EPA has established a unified library for test guidelines issued by the Office of Prevention, Pesticides and Toxic Substances (OPPTS) for use in testing chemical substances to develop data for submission to EPA under the Toxic Substances Control Act (TSCA), the Federal Food, Drug, and Cosmetic Act (FFDCA), or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). These test guidelines represent an Agency effort that began in 1991 to harmonize the test guidelines within OPPTS, as well as to harmonize the OPPTS test guidelines with those of the Organization for Economic Cooperation and Development (OECD). The process for developing and amending these test guidelines includes public participation and the extensive involvement of the scientific community, including peer review by the Scientific Advisory Panel (SAP) and the Scientific Advisory Board (SAB) and other expert scientific organizations. With this notice, EPA is announcing the availability of the final test guideline for OPPTS 870.8355 Combined Chronic Toxicity/ Carcinogenicity Testing of Respirable Fibrous Particles.

FOR FURTHER INFORMATION CONTACT: Barbara Cunningham, Director, Office of Program Management and Evaluation, Office of Pollution Prevention and Toxics (7401), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (202) 554–1404; e-mail address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Does this Action Apply to Me?

This action is directed to the public in general. Although this action may be of particular interest to those persons who are or may be required to conduct testing of chemical substances under TSCA, FFDCA, or FIFRA, 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 under **FOR FURTHER INFORMATION CONTACT**.

II. How Can I Get Additional Information, Including Copies of this Document or Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. You may also obtain copies of test guidelines from the EPA Internet Home Page at http://www.epa.gov/opptsfrs/home/guidelin.htm.

2. *In person*. The Agency has established an official record for this final guideline under docket control number OPP–00723. The official record consists of the documents specifically referenced in this action, any public comments received during an applicable comment period, and other information related to this action, including any information claimed as confidential business information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period, is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm.119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

III. What Action is EPA Taking?

EPA is announcing the availability of the final test guideline for OPPTS 870.8355 Combined Chronic Toxicity/ Carcinogenicity Testing of Respirable Fibrous Particles.

EPA recognizes that the current health effects test guidelines for chronic inhalation toxicity and/or carcinogenicity studies on chemicals are not specific enough for the testing of fibrous substances. These guidelines have to be modified to take into account testing issues which are unique to fibrous particles. Although a number of test systems and/or protocols have been utilized by the scientific community for evaluating the fibrogenic and carcinogenic potential of fibrous particles, there has been considerable debate about the scientific validity and utility of available test methods. Thus, there is a need for EPA to develop a standardized health effects test guideline for fibrous substances that can be used by EPA in future rulemaking, negotiated enforceable consent agreements, or voluntary action to obtain the necessary toxicologic information for risk assessment purposes.

The objective of this combined chronic toxicity/carcinogenicity testing of respirable fibrous particles is to determine the effects of a fibrous substance identified to be of potential health concern in at least a rodent species following prolonged and repeated inhalation exposure. The application of this guideline should generate data which identify the majority of chronic toxic and carcinogenic effects and determine dose-response relationships.

EPA recognizes concerns have been expressed about data development using animal models. While no comments were received from the animal advocacy