

instructions for any indoor uses except mushroom houses will not be lawful under FIFRA after December 31, 2002.

4. *Use of existing stocks.* EPA intends to permit the use of existing stocks of products listed in Table 2 or 3 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: December 29, 2000.

**Linda S. Propst,**

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

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## ENVIRONMENTAL PROTECTION AGENCY

[PF-988; FRL-6760-8]

### Notice of Filing a Pesticide Petition to Establish 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 control number PF-988, must be received on or before February 9, 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-988 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Cynthia L. Giles-Parker, 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-988. 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-988 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](mailto: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-988. 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 Cosmetic 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: December 26, 2000.

**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 petitioner. 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 and Company (DuPont)**

*PP OF6070*

EPA has received a pesticide petition (PP OF6070) from E. I. DuPont de Nemours and Company (DuPont), 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 part 180 by establishing a tolerance for residues of the fungicide famoxadone in or on the raw agricultural commodities (RACs) potatoes at 0.05 parts per million (ppm), cucurbit vegetable crop group (cucumbers, melons, and squash) at 0.7 ppm, fruiting vegetable crop group (tomatoes and peppers) at 1.0 ppm, and head lettuce at 15 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 famoxadone is adequately understood in 3 distinct crops to support these tolerances: tomatoes, potatoes, and grapes. These studies showed no significant metabolites all (< 10% total radioactive residue (TRR)) in the RACs (tubers, tomato fruit, and 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 potatoes, cucurbit vegetables (cucumbers, melons, and squash), fruiting vegetables (tomatoes, peppers), and head lettuce using gas-liquid chromatography (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 (LOQ) is 0.02 ppm.

The analytical enforcement for use on tomato processed fractions and also the RAC, tomato, utilizes column switching liquid chromatography with ultraviolet (UV) detection. The LOQ is 0.02 ppm.

The LOQ in each method allows monitoring of crops with famoxadone residues at or above the levels proposed in these tolerances.

3. *Magnitude of residues—i. Cucurbit vegetables.* The magnitude and decline of residues of famoxadone were determined on cucumber, cantaloupe, and summer squash, the representative commodities for the cucurbit vegetable crop group. Seventeen field trials were conducted in 1997 and 1998.

DPX-KP481 50DF, containing 25% cymoxanil and 25% famoxadone, was applied as 7 broadcast applications, each at the maximum rate of 3 oz famoxadone/Acre, for a maximum seasonal use rate of 21 oz famoxadone/Acre. Applications were made approximately 5 days apart.

The target pre-harvest interval (PHI) was 3 days.

- Residues of famoxadone in cucumbers from 6 test sites ranged from <0.02 to 0.19 ppm.

- Residues of famoxadone in cantaloupe from 6 test sites ranged from 0.11 to 0.46 ppm.

- Residues of famoxadone in summer squash from 5 test sites ranges from <0.02 to 0.37 ppm.

ii. *Fruiting vegetables.* The magnitude and decline of famoxadone residues were determined on tomatoes, and peppers (bell and non-bell), the representative commodities for the fruiting vegetable crop group. Twenty-one residue trials were conducted in 1996 and 1997.

DPX-KP481 50DF, containing 25% cymoxanil and 25% famoxadone, was applied as nine broadcast applications at a maximum seasonal use rate of 18 oz famoxadone/Acre. Applications were made approximately 5 days apart. The target PHI was 3 days. Residues of famoxadone on peppers (bell and non-bell) from 9 test sites ranged from 0.10–

0.70 ppm. Residues of famoxadone on tomatoes from 12 test sites ranged from 0.06–0.48 ppm.

DPX-KP481 50DF, containing 25% cymoxanil and 25% famoxadone, was applied to 1 site in California to determine the magnitude of residue in tomato and the extent of potential residue concentration in tomato processed fractions. DPX-KP481 50DF was applied in 9 broadcast applications at 2 oz famoxadone/Acre (1X) and 10 oz famoxadone/Acre (5X). Applications were made approximately 5 days apart. The target PHI was 3 days. When applied at 5X the maximum seasonal use rate, famoxadone residues decreased with washing and did not concentrate in puree, with respect to the unwashed raw agricultural commodity (RAC). Famoxadone residues concentrated in tomato paste derived from tomato, treated at the 5X rate by a factor of 1.3. The 1.3 concentration factor does not warrant a special tolerance for paste. At the 1X rate, the proposed tomato tolerance for the RAC, 0.7 ppm, is adequate to cover this level of concentration in the paste. A separate tolerance for paste does not need to be established.

iii. *Head lettuce*. Residue trials for head lettuce were conducted at 8 sites in 1997 and 1998. DPX-KP481 50DF, containing 25% cymoxanil and 25% famoxadone, was applied as 7 broadcast applications, each at the maximum rate of 3 oz famoxadone /Acre, for a maximum seasonal use rate of 21 oz famoxadone /Acre. Applications were made approximately 5 days apart. The target PHI was 3 days. Residues of famoxadone on head lettuce ranged from 0.64 to 14 ppm (with wrapper leaves) and 0.024 to 3.1 ppm (wrapper leaves removed).

iv. *Potato*. Residue trials for famoxadone were conducted at 16 sites in 1997. DPX-KP481 50DF, containing 25% cymoxanil and 25% famoxadone, was applied as 6 broadcast applications, each at 3 oz famoxadone/Acre, for a maximum seasonal use rate of 18 oz famoxadone/Acre. Applications were made approximately 5 days apart. The target PHI was 14 days. No quantifiable residues of famoxadone were seen in any potato sample above the LOQ (0.02 ppm).

DPX-KP481 50DF, containing 25% cymoxanil and 25% famoxadone, was applied to 1 test site in Washington to determine the magnitude of residue in

potato and the extent of potential residue concentration in potato processed fractions. DPX-KP481 50DF was applied 6 times as a broadcast spray, each at 15 oz famoxadone/Acre, for a total seasonal application rate of 90 oz ai/Acre (5X). When applied under these conditions, no quantifiable famoxadone residues were detected in unwashed or washed potatoes/culls, chips, or granule fractions. Thus no concentration occurred in these fractions. At the 5X rate, quantifiable residues were detected in wet potato peels at 0.033–0.035 ppm. The concentration factor was 1.12 (based on LOQ of 0.02 ppm). When adjusting the residues in wet peels from the seasonal 5X to the 1X rate (18 oz famoxadone/Acre), residues in peels are less than the LOQ. Therefore, the negligible residues in the peels (less than 2X the LOQ) are covered by the proposed tolerance for the RAC, 0.05 ppm, and no separate tolerance for potato peels need be established.

#### B. Toxicological Profile

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

#### TOXICITY CATEGORIES

Acute toxicities	Test animals	Tolerances	Categories
Oral LD <sub>50</sub>	Rat	>5,000 milligrams/kilograms (mg/kg)	Category IV
Dermal LD <sub>50</sub>	Rabbit	>2,000 mg/kg	Category III
Inhalation LC <sub>50</sub>	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 no observed adverse effect level (NOAEL) was 1,000 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.

<i>Bacterial gene mutation</i>	<i>Salmonella</i> and <i>E. Coli</i>	Negative
<i>Mammalian gene mutation in vitro</i>	CHO/HGPRT	Negative
<i>Mammalian chromosome aberrations in vitro</i>	chinese hampter ovary (CHO)	Positive without activation negative with activation
<i>Mammalian chromosome aberrations in vivo</i>	Mouse micronucleus	Negative
<i>Unscheduled DNA synthesis in vitro</i>	Primary rat hepatocytes	Negative
<i>Unscheduled DNA synthesis in vivo</i>	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 (bwt), 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, 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 bwt 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 the same 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 bwt and nutritional effects at 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 1,000/600 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 bwt, bwt gain, food consumption, food efficiency, and increased spleen weights at 800 ppm (55 and 57 mg/kg/day for males and females, respectively). There was no effect in response to anti-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 on increased 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 rats 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 bwt, bwt 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 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 famoxadone is negligible.

### C. Aggregate 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, and potatoes. There are no residential uses for the famoxadone-containing fungicide.

1. *Dietary exposure.* The chronic reference dose (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 bwt/day is based upon bwt effects occurring early in a 90-day dog study. Since bwt 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.

i. *Food—a. Chronic dietary exposure assessment.* Chronic dietary exposure, resulting from the proposed use of famoxadone on 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 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 food quality protection act (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 (99<sup>th</sup> percentile) is 0.001848 mg/kg/day, or 1.85% acute RfD for the overall U.S. population. The exposure (99<sup>th</sup> percentile) of the most highly exposed subgroup in the population, children 1–

6 years, is 0.002559 mg/kg/day or 2.56% RfD. 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 percent RfDs 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	99 <sup>th</sup> Percentile of Exposure		99.9 <sup>th</sup> Percentile of Exposure	
	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 ground water 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 concentration in ground water ((SCI-GROW) for ground water and generic expected environmental concentration (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 ground water 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 concern (DWLOC) 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 GENECC 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 ground water (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 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 (99<sup>th</sup> percentile) or 1.85% of the RfD (99<sup>th</sup> percentile). At the 99.9<sup>th</sup> percentile, the acute dietary exposure

for the U.S. population is 0.006128 mg/kg/day or 6.13% of the RfD.

Using only pesticide handlers exposure data base (PHED) data levels A and B (those with a high level of confidence), the margin of exposure (MOE) 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 RfD (99<sup>th</sup> percentile). For non-nursing infants (<1-year), the acute dietary exposure is 0.95% RfD (99<sup>th</sup> 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.

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#### ENVIRONMENTAL PROTECTION AGENCY

[FRL–6932–1]

#### Woody Wilson Battery Superfund Site; Notice of Proposed Settlement

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

**ACTION:** Notice of proposed settlement.

**SUMMARY:** The United States Environmental Protection Agency is proposing to enter into a settlement

with Woodrow Wilson, Jr. and Woodrow Wilson, Sr. pursuant to 122(h) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended, regarding the Woody Wilson Battery Superfund Site located in Ashley Heights, Hoke County, North Carolina. EPA will consider public comments on the proposed settlement for thirty (30) days. EPA may withdraw from or modify the proposed settlement should such comments disclose facts or considerations which indicate the proposed settlement is inappropriate, improper or inadequate. Copies of the proposed settlement are available from: Ms. Paula V. Batchelor, U.S. EPA, Region 4 (WMD–CPSB), Sam Nunn Atlanta Federal Center 61 Forsyth Street, SW., Atlanta, Georgia 30303, (404) 562–8887.

Written comments may be submitted to Ms. Batchelor within thirty (30) calendar days of the date of this publication.

Dated: December 7, 2000.

**Franklin E. Hill,**

Chief, CERCLA Program Services Branch, Waste Management Division.

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#### ENVIRONMENTAL PROTECTION AGENCY

[PB–402404A–MI; FRL–6751–5]

#### Lead-Based Paint Activities in Target Housing and Child-Occupied Facilities; State of Michigan Approval of Lead-Based Paint Activities Program

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

**ACTION:** Notice.

**SUMMARY:** On November 1, 1999, the State of Michigan, through the Michigan Department of Community Health, submitted an application for EPA approval to administer and enforce training and certification requirements, training program accreditation requirements, and work practice standards for lead-based paint activities in target housing and child-occupied facilities under section 402 of the Toxic Substances Control Act (TSCA). Michigan provided a self-certification letter stating that its program is at least as protective of human health and the environment as the Federal program and it has the legal authority and ability to implement the appropriate elements necessary to receive EPA approval. In the **Federal Register** of April 20, 2000 (FRL–6494–6), EPA published a notice announcing receipt of the State's