

there is no additional concern for toxicity of metabolites.

3. *Endocrine disruption.* Fludioxonil does not belong to a class of chemicals known for having adverse effects on the endocrine system. No estrogenic effects have been observed in the various short- and long-term studies conducted with various mammalian species.

C. Aggregate Exposure

1. *Dietary exposure.* The dietary exposure evaluation was made using the Dietary Exposure Evaluation Model (DEEM[®], version 7.76) from Novigen Sciences, Inc. DEEM[®] default processing factors were used along with USDA's Continuing Survey of Food Intake by Individuals (CSFII) with the 1994–96 consumption database and the Supplemental CSFII children's survey (1998) consumption database. DEEM[®] inputs for all currently registered uses, pending uses, and proposed uses. Secondary residues in animal commodities were not considered in this evaluation since calculations showed that residue transfers from fed items to livestock and milk were minimal and resulted in negligible exposures.

i. *Food.* This chronic assessment utilized established tolerance values for the current uses and proposed tolerance values for the added proposed uses. This assessment assumes 100% crop treated for all commodities except strawberries and bulb vegetables. For strawberries and bulb vegetables, projected percent crop treated values of 50% and 28%, respectively, were calculated as a percent of base acres divided by the total planted acres.

ii. *Drinking water.* Estimated Environmental Concentrations (EEC's) of fludioxonil in drinking water were determined for the highest use rate of fludioxonil, which is turfgrass. SCI-GROW (Version 2.1) was used to determine acute and chronic estimated environmental concentrations in ground water. FIRST (Version 1.0) was used to determine acute and chronic estimated environmental concentrations in surface water.

Based on model outputs, the estimated environmental concentrations of fludioxonil are 0.0553 parts per billion (ppb) for acute and chronic exposure to ground water and 70 ppb and 33 ppb for acute and chronic exposure, respectively, to surface water.

2. *Non-dietary exposure.* There is a potential residential post-application exposure to adults and children entering residential areas treated with fludioxonil. Since the Agency did not select a short-term endpoint for dermal exposure, only intermediate-term

dermal exposures were considered. Based on the residential use pattern, no long-term post-application residential exposure is expected.

D. Cumulative Effects

EPA does not have, at this time, available data to determine whether fludioxonil has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, fludioxonil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that fludioxonil has a common mechanism of toxicity with other substances.

E. Safety Determination

1. *U.S. population.* The chronic dietary exposure analysis showed that exposure from the established tolerances and proposed new tolerances for the general U.S. population would be 8% of the RfD. Chronic exposures to the U.S. population resulted in a margin of exposure (MOE) of 1445. The benchmark MOE for this assessment is 100. Therefore, results from the %RfD based risk analysis showed acceptable safety margins with respect to chronic exposures incurred by the dietary consumption of fludioxonil-treated commodities.

2. *Infants and children.* The chronic reference dose (RfD) for fludioxonil is 0.03 milligrams/kilograms (mg/kg) body weight/day and is based on a one year dog study with a no observed adverse effect level (NOAEL) of 3.3 mg/kg body weight/day and a safety factor of 100X. No additional FQPA safety factor was applied. The chronic dietary exposure analysis showed that exposure from the established tolerances and proposed new tolerances for Non-Nursing Infants <1 years old (the subgroup with the highest exposure) would be 34% of the RfD. The most sensitive subpopulation in the chronic assessment was non-nursing infants (<1 year old) with a MOE of 329. The benchmark MOE for this assessment is 100. Therefore, the estimates of dietary exposure clearly indicate adequate safety margins for the overall U.S. population.

Chronic Drinking Water Levels of Comparison (DWLOC) were calculated based on a chronic RfD of 0.03 mg/kg/day. For the chronic assessment, the non-nursing infant subpopulation generated the lowest chronic DWLOC of approximately 200 ppb. This gave a corresponding MOE value of 1,000. The

chronic DWLOC of 200 ppb is considerably higher than the chronic EEC of 33 ppb and the MOE far exceeds the benchmark MOE of 100.

F. International Tolerances

There are no Codex Maximum Residue Levels established for fludioxonil.

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BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2002–0015; FRL–6833–7]

Notice of Filing Pesticide Petitions to Establish a Tolerance for Certain Pesticide Chemicals in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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

DATES: Comments, identified by docket control number OPP–2002–0015, must be received on or before May 31, 2002.

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 OPP–2002–0015 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–7610; e-mail address: jackson.sidney@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	Crop production

Categories	NAICS codes	Examples of potentially affected entities
	112 311	Animal production Food manufacturing
	32532	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" 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 OPP-2002-0015. 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.

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 OPP-2002-0015 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 Hwy., 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 OPP-2002-0015. 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 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 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 pesticide petitions as follows proposing the establishment and/or amendment of regulations for residues of certain pesticide chemicals 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 these petitions contain 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: April 15, 2002.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Summaries of Petitions

Petitioner summaries of the pesticide petitions are printed below as required by section 408(d)(3) of the FFDCA. The summaries of the petitions were prepared by the petitioners and

represent the views of the petitioners. EPA is publishing the petition summaries verbatim without editing them 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.

Interregional Research Project Number 4 (IR-4)

PP 1E6304, 2E6357, 2E6364, 2E6373

EPA has received pesticide petitions 1E6304, 2E6357, 2E6364 and 2E6373, from the Interregional Research Project Number 4 (IR-4), 681 U.S. Highway #1 South, North Brunswick, NJ 08902-3390 proposing, pursuant to section 408(d) of the FFDCFA, 21 U.S.C. 346a(d), to amend 40 CFR 180.532 by establishing tolerances for residues of cyprodinil, [4-cyclopropyl-6-methyl-N-phenyl-2-pyrimidinamine], in or on the following raw agricultural commodities (RACs):

1. PP 1E6304 proposes a tolerance for caneberry subgroup at 10.0 parts per million (ppm).
2. PP 2E6357 proposes a tolerance for bushberry subgroup, lingonberry, juneberry, and salal, at 3.0 ppm.
3. PP 2E6364 proposes a tolerance for watercress at 20 ppm.
4. PP 2E6373 proposes a tolerance for pistachio at 0.07 ppm.

Additional data may be needed before EPA rules on the petitions. Syngenta Crop Protection, Inc., Greenboro, NC 27409, is the manufacturer of the chemical pesticide, cyprodinil. Syngenta prepared and submitted the following summary of information, data, and arguments in support of the pesticide petitions. This summary does not necessarily reflect the findings of EPA.

A. Residue Chemistry

1. *Plant metabolism.* The metabolism of cyprodinil is adequately understood for the purpose of the proposed tolerances.

2. *Analytical method.* Syngenta has developed and validated analytical methodology for enforcement purposes. This method (Syngenta Crop Protection Method AG-631B) has passed an Agency petition method validation for several commodities and is currently the enforcement method for cyprodinil. An extensive data base of the method validation data using this method on various crop commodities is available.

3. *Magnitude of residues.* Complete residue data for caneberry subgroup, bushberry subgroup, lingonberry, juneberry, salal, pistachio, and

watercress have been submitted. The requested tolerances are adequately supported.

B. Toxicological Profile

An assessment of toxic effects caused by cyprodinil is discussed in Unit III. A. and Unit III. B. of the **Federal Register** dated June 22, 2001 (66 FR 33478).

1. *Animal metabolism.* The metabolism of cyprodinil in rats is adequately understood.

2. *Metabolite toxicology.* The residues of concern for tolerance setting purposes is the parent compound. Based on structural similarities to genotoxic nucleotide analogs, there was concern that the pyrimidine metabolites (CGA-249287, NOA-422054) may be more toxic than the parent compound. However, EPA's review indicates similar results in an acute oral and mutagenicity studies with both the parent compound and the CGA-249287 metabolite. EPA concluded that the toxicity of the CGA-249287 and NOA-422054 metabolites is no greater than that of the parent, conditional on submission and review of confirmatory data of an acute oral toxicity study and bacterial reverse mutation assay for the NOA-422054 metabolite. Although the metabolites CGA-232449 and CGA-263208 were determined to be of potential toxicological concern, they are not expected to be more toxic than cyprodinil *per se*.

3. *Endocrine disruption.* Cyprodinil does not belong to a class of chemicals known or suspected of having adverse effects on the endocrine system. Developmental toxicity studies in rats and rabbits and a reproduction study in rats gave no indication that cyprodinil might have any effects on endocrine function related to development and reproduction. The chronic studies also showed no evidence of a long-term effect related to the endocrine system.

C. Aggregate Exposure

1. *Dietary exposure.* Permanent tolerances have been established (40 CFR 180.532(a)) for the residues of cyprodinil, in or on a variety of RACs. Tolerances are established on grape at 2.0 ppm, grape, raisin at 3.0 ppm; onion, dry bulb at 0.6 ppm, onion green at 4.0 ppm; stone fruit group at 2.0 ppm, pome fruit group at 0.1 ppm, apple, wet pomace at 0.15 ppm; almond nutmeat at 0.02 ppm and almond hulls at 0.05 ppm. Time-limited tolerances under section 18 of Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (emergency exemption) have been established under 180.532(b) for caneberry subgroup at 10.0 ppm, and strawberry at 5.0 ppm. Tolerances

values proposed in this submission are: Caneberry subgroup (10.0 ppm); pistachio (0.07 ppm); watercress (20 ppm); bushberry subgroup (3.0 ppm), lingonberry (3.0 ppm), juneberry (3.0 ppm) and salal (3.0 ppm).

a. *Food.* The dietary exposure evaluation was made using the dietary exposure evaluation model (DEEMtm, version 7.76) from Novigen Sciences, Inc. DEEM default processing factors were used along with United States Department of Agriculture (USDA) continuing survey of food intake by individuals (CSFII) with the 1994-1996 consumption data base and the supplemental CSFII children's survey (1998) consumption data base. DEEM inputs for all currently registered uses, and proposed uses listed above. Secondary residues in animal commodities were not considered in this evaluation since calculations showed that residue transfers from feed items to livestock and milk were minimal and resulted in negligible exposures.

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. EPA has not conducted an acute dietary risk assessment since no toxicological endpoint of concern was identified during the review of the available data.

ii. *Chronic exposure.* This chronic assessment utilized established tolerance values for the current uses and proposed tolerance values for the added proposed uses. This assessment assumes 100% crop treated for all commodities. The chronic population adjusted dose (cPAD) for cyprodinil is 0.03 milligram/kilogram (mg/kg) body weight/day (bwt/day) and is based on a chronic rat study with a no observed adverse effect level (NOAEL) of 2.7 mg/kg bwt/day and a uncertainty factor (UF) of 100X. No additional Food Quality Protection Act (FQPA) safety factor was applied. For the purpose of aggregate assessment, the exposure values were expressed in terms of margin of exposure (MOE) which was calculated by dividing the NOAEL by the exposure for each population subgroup. The benchmark MOE for this assessment is 100. Results from the cPAD based risk analysis showed that there were acceptable safety margins with respect to chronic exposures incurred by the dietary consumption of cyprodinil-treated commodities. Chronic exposures to the U.S. population (48 states, all seasons) resulted in a MOE of 1,274 (7.1% of the total cPAD of 0.03 mg/kg bwt/day). The most sensitive subpopulation in the

chronic assessment was children (1 to 6 years) with a MOE of 354 (25.5% of the cPAD). The results of the chronic dietary risk assessment are presented in Table 1.

b. *Drinking water exposure.* Estimated environmental concentrations (EEC's) of cyprodinil in drinking water were determined for the highest use rate of cyprodinil, which is almond. Screening concentration in ground water (SCI-GROW) (Version 2.1) was used to determine acute and chronic EECs in ground water. First (Version 1.0) was used to determine acute and chronic EECs in surface water. Based on model outputs, the EECs of cyprodinil are 0.0056 parts per billion (ppb) for acute

and chronic exposure to ground water and 35 ppb and 1 ppb for acute and chronic exposure, respectively, to surface water. Chronic drinking water levels of comparison (DWLOC) were calculated based on a cPAD of 0.03 mg/kg/day. For the chronic assessment, children (1 to 6 years) subpopulation generated the lowest chronic DWLOC of approximately 224 ppb. This gave a corresponding MOE value of 27,000. The chronic DWLOC of 224 ppb is considerably higher than the chronic EEC of 1 ppb and the MOE far exceeds the benchmark MOE of 100. The results for the U.S. population and the most sensitive subpopulation are presented in Table 1.

2. *Non-dietary exposure.* Cyprodinil is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

3. *Chronic aggregate exposure.* Using the total MOE equation for the determination of aggregate exposure (food and drinking water only), resulted in an aggregate MOE_T of 342 for the most sensitive subpopulation, children (1 to 6 years). Table 1 summarizes the aggregate chronic exposure (food and drinking water only) for cyprodinil.

TABLE 1.—CYPRODINIL CHRONIC AGGREGATE EXPOSURES

Population Sub-group	Drinking Water MOE _{A, B, C}	Drinking Water % cPAD ^D	Food MOE _{A, B, C}	Food % cPAD ^D	MOE _T ^{C, E}
U.S. population	94,5	0,1	1,274	7,1	1,229
Children (1 to 6 years)	27	0,33	354	25,5	342

^AMOE= NOAEL/Exposure

^BNOAEL= 3.3 mg/kg body weight/day

^CBenchmark MOE = 100

^DcPAD = 0.03 mg/kg body weight/day

^EMOE_T = 1/((1/MOE_{food})+(1/MOE_{d.water}))

D. Cumulative Effects

Cumulative exposure to substances with a common mechanism of toxicity. Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." EPA does not have, at this time, available data to determine whether cyprodinil has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, cyprodinil does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that cyprodinil has a common mechanism of toxicity with other substances.

E. Safety Determination

1. *U.S. population.* The chronic dietary exposure analysis showed that exposure from the proposed new tolerances for the general U.S. population would be 7.1% of the cPAD.

2. *Infants and children.* The chronic dietary exposure analysis showed that exposure from the proposed new tolerances for children 1 to 6 years old (the subgroup with the highest exposure) would be 25.5% of the cPAD. Therefore, the estimates of dietary exposure clearly indicate adequate safety margins for the overall U.S. population.

F. International Tolerances

There are no Codex maximum residue level's established for cyprodinil.

[FR Doc. 02-10632 Filed 4-30-02; 8:45 am]

BILLING CODE 6560-50-S

ENVIRONMENTAL PROTECTION AGENCY

[OPP-2002-0029; FRL-6834-7]

Notice of Filing Pesticide Petitions to Establish a Tolerance for Certain Pesticide Chemicals in or on Food

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces the initial filing of pesticide petitions proposing the establishment of regulations for residues of certain

pesticide chemicals in or on various food commodities.

DATES: Comments, identified by docket control number OPP-2002-0029, must be received on or before May 31, 2002.

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 OPP-2002-0029 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: Sidney Jackson, Registration Division (7505C, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-7610; e-mail address: jackson.sidney@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: