Section XII. OTAQ Program Contact

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Margo Tsirigotis Oge,
Director, Office of Transportation and Air Quality.
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EBM 6900–50–P

ENVIRONMENTAL PROTECTION AGENCY


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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

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

DATES: Comments, identified by docket ID number OPP–2003–0119, must be received on or before May 21, 2003.

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

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

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

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

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

C. How and to Whom Do I Submit Comments?

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

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

i. EPA Dockets. Your use of EPA’s electronic public docket to submit comments to EPA electronically is EPA’s preferred method for receiving comments. Go directly to EPA Dockets at http://www.epa.gov/edocket, and follow the online instructions for submitting comments. Once in the system, select “search,” and then key in docket ID number OPP–2003–00119. The system is an “anonymous access” system, which means EPA will not...
know your identity, e-mail address, or other contact information unless you provide it in the body of your comment. ii. E-mail. Comments may be sent by e-mail to opp-docket@epa.gov. Attention: Docket ID number OPP–2003–0119. In contrast to EPA’s electronic public docket, EPA’s e-mail system is not an “anonymous access” system. If you send an e-mail comment directly to the docket without going through EPA’s electronic public docket, EPA’s e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA’s e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA’s electronic public docket.

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


3. By hand delivery or courier. Deliver your comments to: Public Information and Records Integrity Branch (PIRIB), Office of Pesticide Programs (OPP), Environmental Protection Agency, Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, Attention: Docket ID number OPP–2003–0119. Such deliveries are only accepted during the docket’s normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

Do not submit information that you consider to be CBI electronically through EPA’s electronic public docket or by e-mail. You may claim information that you submit to EPA as CBI by marking any part or all of that information as CBI (if you submit CBI on disk or CD ROM, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. In addition to one complete version of the comment that includes any information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket and EPA’s electronic public docket. If you submit the copy that does not contain CBI on disk or CD ROM, mark the outside of the disk or CD ROM clearly that it does not contain CBI. Information not marked as CBI will be included in the public docket and EPA’s electronic public docket without prior notice. If you have any questions about CBI or the procedures for claiming CBI, please consult the person listed under FOR FURTHER INFORMATION CONTACT.

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

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

1. Explain your views as clearly as possible.
2. Describe any assumptions that you used.
3. Provide copies of any technical information and/or data you used that support your views.
4. If you estimate potential burden or costs, explain how you arrived at the estimate that you provide.
5. Provide specific examples to illustrate your concerns.
6. Make sure to submit your comments by the deadline in this notice.
7. To ensure proper receipt by EPA, be sure to identify the docket ID number assigned to this action in the subject line on the first page of your response. You may also provide the name, date, and Federal Register citation.

II. What Action is the Agency Taking?

EPA has received a pesticide petition (2E6447, 2E6461, 2E6485, 3E6529, 3E6530) from Interregional Research Project Number (IR-4), 681 U.S. Highway #1 South, North Brunswick, NJ 08902 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 tolerances for residues of cyprodinil in or on the following raw agricultural commodities:

1. PP 2E6447 proposes the establishment of a tolerance for lychee, longan, rambutan, pulasan, and Spanish lime at 2.0 parts per million (ppm).
2. PP 2E6461 proposes the establishment of a tolerance for carrot at 0.5 ppm.
3. PP 2E6485 proposes the establishment of a tolerance for Brassica, head and stem subgroup 5A at 2.0 ppm, Brassica, leafy greens subgroup 5B at 10.0 ppm, and turnip, greens at 10.0 ppm.
4. PP 3E6529 proposes the establishment of a tolerance for herb subgroup 19A at 10 ppm.
5. PP 2E6530 proposes the establishment of a tolerance for almond, hulls at 8.0 ppm.

EPA has determined that the petition contains data or information regarding the elements set forth in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the petition. Additional data may be needed before EPA rules on the petition.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.
Syngenta Crop Protection, Inc., Greensboro, NC 27409.

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 method validation data using this method on various crop commodities is available.

3. Magnitude of residues. Complete residue data to support the requested tolerances for almond, hulls, Brassica, head and stem (Subgroup 5A), Brassica, leafy greens (Subgroup 5B), turnip, greens, herbs (Subgroup 19A), and lychee, longan, rambutan, pulasan, and Spanish lime have been submitted. The requested tolerances are adequately supported.

B. Toxicological Profile


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 acute oral and mutagenic 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, there 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. A Tier III acute and chronic dietary exposure evaluation was made using the Dietary Exposure Evaluation Model (DEEM™), version 7.76 from exponent. All consumption data for these assessments were taken from the USDA’s Continuing Survey of Food Intake by Individuals (CSFII) with the 1994–96 consumption data base and the Supplemental CSFII children’s survey (1998) consumption data base. These exposure assessments included all registered uses and pending uses on watercress, bushberries, caneberrys, juneberries, ligonberries, pistachios, and salal. i. Food—a. 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. b. Chronic exposure. Percent of crop treated values were estimated based upon economic, pest and competitive pressures. The values used in these assessments were: (Almonds, pome fruits, stone fruits and grapes), 100%; onions 9%; strawberries 42%; watercress, 95%; berries, 13%; pistachios, herbs, 80%; cucumbers 5A and 5B, carrots, turnip, greens, lychee, longan and Spanish lime, 10%. ii. Drinking water. Estimated Environmental Concentrations (EECs) of cyprodinil in drinking water were determined by EPA. EPA groundwater model Screening Concentration in Groundwater (SCI-GROW) was used to determine acute and chronic estimated environmental concentrations in ground water and the Agency’s surface water model, EPA’s pesticide root zone model/exposure analysis modeling system (PRZM/EXAMS) was used to determine acute and chronic EECs estimated environmental concentrations in surface water. Based on the model outputs, the EEC cyprodinil are 0.04 parts per billion (ppb) for acute and chronic exposure to ground water and 32 ppb and 6 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 cyprodinil. Since the Agency did not select a short-term endpoint for dermal exposure, only intermediate dermal exposures were considered. Based on the residential use pattern, no long-term post-application residential exposure is expected.

D. Cumulative Effects

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. For the purposes of this tolerance action, EPA has not assumed that cyprodinil has a common mechanism of toxicity with other substances.

E. Safety Determination

The acute dietary exposure analysis (food only) showed that exposure from all established and proposed cyprodinil uses would be 7.48% of the chronic reference dose (cRfD) for the most sensitive subpopulation, children 1–2 years old. EPA has determined that reliable data support using the standard margin of exposure (MOE) and uncertainty factor (100 for combined interspecies and intraspecies variability) for cyprodinil and that an additional safety factor of 10 is not necessary to be protective of infants and children.

Acute Drinking Water Levels of Comparison (DWLOC) were calculated based on an acute populated adjusted dose (aPAD) of 1.5 milligrams/kilogram/day. For the acute assessment, the females (13–50 years) subpopulation generated an acute DWLOC of approximately 44,600 ppb. The acute EEC of 32 ppb is considerably less than 44,600 ppb. For the chronic assessment, the children 1–2 years old subpopulation generated the lowest chronic DWLOC of approximately 280 ppb. Thus, the chronic DWLOC of 280 ppb is considerably higher than the chronic EEC of 6 ppb.

Syngenta has considered the potential aggregate exposure from food, water and non-occupational exposure routes and concluded that aggregate exposure is not expected to exceed 100% of the chronic reference dose and that there is a reasonable certainty that no harm will result to infants and children from the aggregate exposure to cyprodinil.
I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. As such, the Agency has not attempted to describe the specific entities that this action may apply to. Although others may be affected, this action applies directly to the submitter of the premanufacture notices addressed in the action. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under FOR FURTHER INFORMATION CONTACT.

B. How Can I Get Copies of This Document and Other Related Information?

1. Docket. EPA has established an official public docket for this action under docket identification (ID) number OPPT–2003–0019. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the EPA Docket Center, Rm. B102-Reading Room, EPA West, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566–1744 and the telephone number for the OPPT Docket, which is located in EPA Docket Center, is (202) 566–0280.

2. Electronic access. You may access this Federal Register document electronically through the EPA Internet under the “Federal Register” listings at http://www.epa.gov/fedrgstr/.

An electronic version of the public docket is available through EPA’s electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at http://www.epa.gov/edocket/ to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA’s electronic public docket.

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