b. *Chronic drinking water risk.* Chronic DWLOCs were calculated based on a cPAD of 0.0006 mg/kg/day. For the chronic assessment, the non-nursing infants subpopulation generated the lowest chronic DWLOC of approximately 5.5 ppb. EPA has determined that the surface water chronic EEC is 0.77 ppb and the ground water EEC is 1.9 ppb. Since the ground water value is greater than the surface water value, the ground water value will be used for comparison purposes and will protect for any concerns for surface water concentrations. Since the chronic DWLOC of 5.5 ppb is higher than the chronic EEC of 1.9 ppb, Syngenta believes that EPA should not have a concern for chronic risk to either surface or ground water.

c. *Lifetime drinking water risk.* Based on currently registered and proposed uses for thiamethoxam, Syngenta has determined a DWLOC of 2.0 ppb. At the currently registered maximum use rate of 0.125 lbs. a.i. per acre per growing season, EPA has used the SCI-GROW model to predict a ground water EEC of 1.9 ppb. Thus, the ground water EEC is below the lifetime DWLOC for the general population. The Agency used a screening level model designed to estimate pesticide concentrations in shallow ground water. A number of factors demonstrate that the actual lifetime exposure through drinking water will be less than the lifetime DWLOC. These reasons are as follows:

- Thiamethoxam is a systemic pesticide. EPA's Tier I ground water model assumes that all of the product that is applied to the crop is available for run off. Syngenta has submitted data to show that a percentage (15–25%) of the product is absorbed by the plant, resulting in that much less product available to leach into ground water. Although, data submitted is on only two crops (beans and cucumbers), it is likely that the total amount of thiamethoxam available for ground water leaching is less than the amount EPA uses as a model input.
- Although, the Agency model is based on aerobic soil half lives, EPA's lifetime risk assessment is for lifetime exposure. Data indicate the anaerobic aquatic half-life for thiamethoxam is shorter than the aerobic soil half-life and longer than the aerobic aquatic half-life. Although, EPA is unable to predict, with a high degree of certainty, what happens to thiamethoxam ground water over time, this does provide some support for the expectation that concentrations in ground water will decline between annual applications.
- Shallow ground water modeling is not the perfect model for representing all drinking water from ground water sources. It is likely to be an over estimate of most drinking water concentrations, which tend to originate from deeper sources. EPA's experience is that the model is reasonably accurate for shallow drinking water, but it is less accurate for estimating concentrations in drinking water from deeper sources.
- The Agency has established conditions of registration for the previous uses that include two prospective ground water studies and a retrospective monitoring study, so that the reasonable certainty of no harm finding will be sustained. Preliminary results have indicated no detections of thiamethoxam in ground water.
- The dietary food risk is based on residue data derived from the average of field trials, which were performed at a higher application rate than what was accepted by EPA. It is not unusual in the Agency's experience for field trial data to be an order of magnitude above actual monitoring. Since thiamethoxam has only recently been registered, actual monitoring data are not yet available. It is likely that the actual risk contribution from food will be much lower than current data indicate, which would result in a larger lifetime DWLOC. Syngenta expects that this refined lifetime DWLOC would be larger than the EECs for the proposed uses. Based on the previous points, Syngenta does not expect that the general population would be exposed to levels exceeding the lifetime DWLOC.

2. *Non-dietary exposure.* Thiamethoxam is not currently registered for use on any sites that would result in residential exposure.

D. Cumulative Effects

The potential for cumulative effects of thiamethoxam and other substances that have a common mechanism of toxicity has also been considered. Thiamethoxam belongs to a new pesticide chemical class known as the neonicotinoids. There is no reliable information to indicate that toxic effects produced by thiamethoxam would be cumulative with those of any other chemical including another pesticide. Therefore, Syngenta believes it is appropriate to consider only the potential risks of thiamethoxam in an aggregate risk assessment.

E. Safety Determination

Syngenta concludes, as described above, that there is reasonable certainty that no harm to the U.S. population will result from aggregate acute or chronic dietary exposure to thiamethoxam residues including the proposed commodities.

F. International Tolerances

There are no codex MRLs established for residues of thiamethoxam.

[FR Doc. 03–7803 Filed 4–1–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2003–0102; FRL–7299–6]

Fludioxonil; Notice of Filing Pesticide Petitions 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–2003–0102, must be received on or before May 2, 2003.

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

FOR FURTHER INFORMATION CONTACT: Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; 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 potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS 111)
- Animal production (NAICS 112)
- Food manufacturing (NAICS 311)
- Pesticide manufacturing (NAICS 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of

entities not listed in this unit could also be affected. 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 OPP–2003–0102. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

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

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

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

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

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

C. How and to Whom Do I Submit Comments?

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

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

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at *http://www.epa.gov/edocket*, and follow the online instructions for submitting comments. Once in the system, select ''search,'' and then key in docket ID number OPP–2003–0102. 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–2003–0102. In contrast to EPA's electronic public docket, EPA's e-mail system is not an ''anonymous access'' system. If you send an e-mail comment directly to the docket without going through EPA's electronic public docket, EPA's e-mail system automatically captures your e-mail address. E-mail addresses that are automatically captured by EPA's e-mail system are included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

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

2. *By mail.* Send your comments to: Public Information and Records Integrity Branch (PIRIB) (7502C), Office

of Pesticide Programs (OPP), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001, Attention: Docket ID number OPP–2003–0102.

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–2003–0102. Such deliveries are only accepted during the docket's normal hours of operation as identified in Unit I.B.1.

D. How Should I Submit CBI to the Agency?

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

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

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

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

1. Explain your views as clearly as possible.

2. Describe any assumptions that you used.

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

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

5. Provide specific examples to illustrate your concerns.

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

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

II. What Action is the Agency Taking?

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

List of Subjects

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

Dated: March 25, 2003.

Debra Edwards,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petitions

The petitioner's summary of the pesticide petitions is printed below as required by FFDCA section 408(d)(3). The summary of the petitions was prepared by the petitioner and represents the views of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed. The Interregional Research Project Number 4 (IR-4) prepared and submitted the pesticide petitions to EPA on behalf of Syngenta Crop Protection, Inc., the registrant.

Interregional Research Project Number 4

PP 2E6486, 2E6462, 3E6526, and 2E6448

EPA has received pesticide petitions 2E6486, 2E6462, 3E6526, and 2E6448, from the IR-4 Project, Center for Minor Crop Pest Management, Rutgers, The State University of New Jersey, 681 U.S. Highway #1 South, North Brunswick, NJ 08902–3390 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 180.516 by establishing tolerances for residues of fludioxonil, 4-(2,2-difluoro-1,3-benzodioxol-4-yl)-H-pyrrole-3-carbonitrile, in or on the following raw agricultural commodities:

1. *PP 2E6486* proposes tolerances as follows:

- Brassica, head and stem subgroup 5a at 1.5 parts per million (ppm).
- Brassica, leafy greens subgroup 5b at 9.0 ppm.
- Turnip, greens at 9.0 ppm.

2. *PP 2E6462* proposes a tolerance for carrot at 0.5 ppm.

3. *PP 3E6526* proposes a tolerance for herb subgroup 19a at 33.0 ppm.

4. *PP 2E6448* proposes a tolerance for the following:

- Longan at 2.0 ppm.
- Lychee at 2.0 ppm.
- Pulasan at 2.0 ppm.
- Rambutan at 2.0 ppm.
- Spanish lime at 2.0 ppm.

Pending PP 3E6526 proposes a tolerance for herb subgroup 19a at 33.0 ppm. A tolerance currently exist for fludioxonil on herbs and spices at 0.02 ppm (40 CFR 180.516). This notice proposes amending 40 CFR 180.516 as follows:

1. Delete existing herbs and spices tolerance of 0.02 ppm and establish a seperate herb subgroup 19a tolerance at 33.0 ppm.

2. Establish a seperate spice subgroup 19b tolerance at 0.02 ppm.

As the result of this proposed amendment, the pending herb subgroup 19a tolerance at 33.0 ppm precludes the need for the existing herbs tolerance of 0.02 ppm. Moreover, the existing spices tolerance of 0.02 ppm is changed to spice subgroup 19b at 0.02 ppm.

Additional data may be needed before EPA rules on the petitions. Syngenta Crop Protection, Inc., Greensboro, NC 27409 is the manufacturer of the chemical pesticide, fludioxinil. 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 fludioxonil 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-597B) has passed an Agency petition method validation for several commodities and is currently the enforcement method for fludioxonil. This method has also been forwarded to the Food and Drug Administration for inclusion into PAM II. An extensive data base of method validation data using this method on various crop commodities is available.

3. *Magnitude of residues*. Complete residue data for Brassica, head and stem (subgroup 5e.c.), Brassica leafy greens (subgroup 5e.c.), turnip, greens, herb (subgroup 19e.c.), and lychee, longan, rambutan, pulasan, and Spanish lime have been submitted. The requested tolerances are adequately supported by field research data.

B. Toxicological Profile

An assessment of toxic effects caused by fludioxonil is discussed in Unit III.A. and Unit III.B. of the **Federal Register** of August 2, 2002 (67 FR 50354) (FRL–7188–7).

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

2. *Metabolite toxicology*. The residues of concern for tolerance setting purposes is fludioxonil, the parent compound. Consequently, 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-term and long-term studies conducted with various mammalian species.

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. Empirically derived processing studies for apple juice (0.09X), apple pomace (6.77X), and grape juice (0.36X) were used in these assessments. The apple juice processing factor was used as a surrogate for pear juice and all other processing factors used DEEM™ defaults. All consumption data for these assessments were taken from the U.S. Department Agriculture (USDA) 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 uses proposed in this submission: Brassica, head and stem (subgroup 5e.c.), Brassica, leafy greens (subgroup 5e.c.), turnip, greens, carrot, herbs (subgroup 19e.c.), lychee, longan, and Spanish lime. Secondary residues in animal commodities were estimated based on theoretical worst-case, yet nutritionally adequate animal diets and transfer information from feeding studies.

i. *Food*. For the purposes of assessing the potential dietary exposure under the proposed tolerances, Syngenta Crop Protection has estimated aggregate exposure from all crops for which tolerances are established or proposed. These assessments utilized residue data from field trials where fludioxonil was applied at the maximum intended use rate and samples were harvested at the minimum pre-harvest interval (PHI) to obtain maximum residues. Percent of crop treated (PCT) values were estimated based upon economic, pest and competitive pressures. The values used in these assessments were: All seed treatment uses, 100%; apricots and pistachios, 10%; cherries, 16%; nectarines, 49%; onions, 9%; peaches, 22%; plums, 25%; other stone fruit, 20%; strawberries, 42%; watercress, 95%; berries, 13%; salal, 13%; herbs, 80%; crop group 5e.c. and 5e.c., carrots, and lychee, turnips and longan 10%.

ii. *Acute exposure*. An acute reference dose (aRfD) of 1.0 milligram/kilogram body weight (mg/kg/bwt) day for the females 13–50 years subpopulation only was based on a no observed adverse effect level (NOAEL) of 100 mg/kg/bwt day from a rat teratology study and an uncertainty factor of 100X. No additional FQPA safety factor was applied. For the purpose of aggregate risk assessment, the exposure value was expressed in terms of margin of exposure (MOE) which was calculated by dividing the NOAEL by the exposure for each population subgroup. In addition, exposure was expressed as a percent of the aRfD. Acute exposure to the females 13–50 years subpopulation resulted in a MOE of 9,933 (1.01%) of the aRfD of the 1.0 mg/kg bwt/day. Since the benchmark MOE for the assessment was 100 and since EPA generally has no concern for exposures below 100% of the RfD, Syngenta believes that there is a reasonable certainty that no harm will result from dietary (food) exposure to residues arising from the current and proposed uses for fludioxonil.

iii. *Chronic exposure*. The chronic reference dose (cRfD) for fludioxonil is 0.033 mg/kg bwt/day and is based on a 1–year study in dogs with a NOAEL of 3.3 mg/kg bwt/day and an Uncertainty Factor (UF) of 100X. No additional Food Quality Protection Act (FQPA) safety factor was applied. The fludioxonil Tier III chronic dietary exposure assessment was based upon residue field trial results. For the purpose of aggregate risk assessment, the exposure values were expressed in terms of MOE which was calculated by dividing the NOAEL by the exposure for each population subgroup. In addition, exposure was expressed as a percent of the RfD. Chronic exposure to the most exposed subpopulation (children 1 and 2 years old) resulted in a MOE of 2,668 (3.75%) of the cRfD of 0.033 mg/kg bwt/day. Since the benchmark MOE for this assessment was 100 and since EPA generally has no concern for exposures below 100% of the RfD, Syngenta believes that there is a reasonable certainty that no harm will result from dietary (food) exposure to residues arising from the current and proposed uses for fludioxonil.

iv. *Drinking water*. Another potential source of exposure of the general population to residues of fludioxonil are residues in drinking water. Fludioxonil rapidly degrades via photolysis on the soil surface and in water. The half-lives are 1 day and 10 days, respectively. This potential for rapid degradation reduces the potential for ground water or surface water exposure. Fludioxonil soil/solution partition coefficients vary from 991 to 2,440 indicating a relatively high affinity for binding to soil. Estimated Environmental Concentrations (EECs) of fludioxonil in drinking water were determined for the highest use rate of fludioxonil (turfgrass use). Sceening Concentration in Ground Water (SCI-GROW) (Version 2.2) was used to determine acute and chronic ECCs in ground water and FQPA Index Reservior Screening Tool (FIRST) (Version 1.0) was used to determine acute and chronic estimated environmental concentrations in surface water. Based on the model outputs, the ECCs of fludioxonil are 0.174 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. Acute Drinking Water Levels of Comparison (DWLOC) were calculated based on an acute Populated Adjusted Dose (aPAD) of 1 mg/kg/day. For the acute assessment, the females (13–50 years) subpopulation generated an acute DWLOC of approximately 30,000 ppb. Thus, the acute DWLOC of 30,000 ppb is considerably higher than the acute EEC of 70 ppb. Chronic DWLOC were calculated based on a cRfD of 0.033 mg/kg/day. For the chronic assessment, the children 1 and 2 years old subpopulation generated the lowest chronic DWLOC of approximately 320 ppb. Thus, the chronic DWLOC of 320 ppb is considerably higher than the chronic EEC of 33 ppb.

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

3. *Chronic aggregate exposure*. Based on the completeness and reliability of the toxicity data supporting these petitions, Syngenta believes that there is a reasonable certainty that no harm will result from aggregate exposure to residues arising from all current and proposed fludioxonil uses, including anticipated dietary exposure from food, water, and all other types of non-occupational exposures.

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 fludioxonil 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 fludioxonil has a common mechanism of toxicity with other substances.

E. Safety Determination

The chronic dietary exposure analysis (food only) showed that exposure from all established and proposed fludioxonil uses would be 3.75% of the cRfD for the most sensitive subpopulation, children 1 and 2 years old. Additionally, for females 13–50 years old, the acute dietary exposure analysis (food only) showed that exposure from all established and proposed fludioxonil uses would be 1.01% of the aPAD. EPA has determined that reliable data support using the standard MOE and uncertainty factor (100 for combined interspecies and intraspecies variability) for fludioxonil and that an additional safety factor of 10 is not necessary to be protective of infants and children.

Acute DWLOCs were calculated based on an aPAD of 1 mg/kg/day. For the acute assessment, the females (13–50 years) subpopulation generated an acute DWLOC of approximately 30,000 ppb. The acute EEC of 70 ppb is considerably less than 30,000 ppb. For the chronic assessment, the children 1 and 2 years old subpopulation generated the lowest chronic DWLOC of approximately 320 ppb. Thus, the chronic DWLOC of 320 ppb is considerably higher than the chronic EEC of 33 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 cRfD and that there is a reasonable certainty that no harm will result to infants and children from the aggregate exposure to fludioxonil.

F. International Tolerances

There are no Codex maximum residue levels established for fludioxonil.

[FR Doc. 03–7977 Filed 4–1–03; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2002–0352; FRL–7286–2]

Experimental Use Permit; Receipt of Application

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces receipt of an application 524–EUP–OA from Monsanto Company requesting an experimental use permit (EUP) for the *Bacillus thuringiensis* Cry3Bb1 protein and the genetic material necessary for its production (vector ZMIR39) in corn. The Agency has determined that the application may be of regional and national significance. Therefore, in accordance with 40 CFR 172.11(a), the Agency is soliciting comments on this application.

DATES: Comments, identified by docket ID number OPP–2002–0352, must be received on or before May 2, 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: Mike Mendelsohn, Biopesticides and Pollution Prevention Division (7511C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–8715; e-mail address: *mendelsohn.mike@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This action is directed to the public in general. This action may, however, be of interest to those persons who are interested in agricultural biotechnology or may be required to conduct testing of chemical substances under the Federal Food, Drug, and Cosmetic Act (FFDCA) or the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Since other entities may also be interested, 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 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 OPP–2002–0352. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

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

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at *http://www.epa.gov/edocket/* to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Once in the system, select ''search,'' then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is