than 12,000 based on a NOEL of 3 mg/kg/day from the developmental toxicity study. The acute dietary exposure to kasugamycin for this group is less than 1% of the reference dose (RfD) which was defined as the NOEL from the developmental study in rabbits including an uncertainty factor of 100 (NOEL = 3 mg/kg/day, RfD = 0.03 mg/kg/day).

ii. Chronic dietary exposure to kasugamycin residues of females age 13–49 was less than 0.1% of the chronic RfD. The RfD was defined as the NOEL from the developmental study in rabbits including an uncertainty factor of 100 (NOEL = 3 mg/kg/day, RfD = 0.03 mg/kg/day).

These values are based on tolerance level residues and 100% imported crops treated with kasugamycin. These can be considered conservative values.

D. Cumulative Effects

Section 408(b)(2)(D)(v) of FFDCA requires that the Agency must consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' Available information in this context includes not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanism of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way for most registered pesticides. However, the mode of action of kasugamycin differs substantially from those of other aminoglycoside antibiotics. Because kasugamycin acts at a different point in protein syntheses than that affected by other aminoglycoside antibiotics, cross-resistance between kasugamycin and other similar antibiotics is extremely unlikely. In addition, kasugamycin is active only against phytopathogenic fungi and bacteria. Because kasugamycin is not effective against common human or animal pathogens, it has never been employed as a human or veterinary-use antibiotic. For the same reason, there is essentially no possibility that use of kasugamycin as a plant protection agent can give rise to antibiotic resistance in human or animal pathogens.

E. Safety Determination

1. *U.S. population.* Using the conservative assumptions of tolerance level residues and 100% of imported crops treated with kasugamycin, based on the completeness and reliability of the toxicity data, it is concluded that dietary exposure to proposed uses of kasugamycin will utilize less than 0.1% of the chronic RfD and less than 1% of the acute RfD for the females of childbearing age population group, the most sensitive group, and is likely to be much less, as more realistic data and models are developed. The MOE from the dietary exposure for the same group is higher than 12,000 and is likely to be higher, as more realistic data and models are developed. The Agency has no cause for concern if total acute residue contribution is less than 100% of the acute RfD, because the RfD represents the level at or below which daily exposure over a lifetime will not pose appreciable risk to human health. Therefore, there is a reasonable certainty that no harm will occur to the U.S. population from dietary exposure to residues of kasugamycin.

2. *Infants and children.* The toxicological database for evaluating pre- and post-natal toxicity for kasugamycin is complete with respect to current data requirements. There are no special pre- and post-natal toxicity for infants and children, based on the results of the rat and rabbit developmental toxicity studies or the 2-generation reproductive toxicity study in rats. In all cases there were no developmental and offspring toxicity effects at the maternal toxicity level. Using the conservative assumption described in Unit E.1., based on the completeness and reliability of the toxicity data, it is concluded that the exposure to the proposed uses of kasugamycin on imported crops will utilize at most 1.0% of the acute or chronic RfD. Therefore, there is a reasonable certainty that no harm will occur to infants and children from exposure to residues of kasugamycin.

F. International Tolerances

CODEX Maximum Residue Limits (MRLs) have not been established for kasugamycin in either tomato or peppers, and a joint meeting on pesticide residues (JMPR) review of kasugamycin residue data is not scheduled. Spain has established an MRL for kasugamycin in tomato, at 0.05 ppm. There are no existing MRLs for kasugamycin in pepper.

[FR Doc. 05–6848 Filed 4–7–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0074; FRL–7703–8]

Iprovalicarb; 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 identification (ID) number OPP–2005–0074, must be received on or before May 9, 2005.

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: Mary Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 308–9354; e-mail address: *waller.mary@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. 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. 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. 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 ID number OPP–2005–0074. 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, 1801 S. Bell St., 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–2005–0074. 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–2005–0074. 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–2005–0074.

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, 1801 S. Bell St., Arlington, VA, Attention: Docket ID Number OPP–2005–0074. 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 28, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view 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.

Bayer CropScience AG

PP 3E6578

EPA has received a pesticide petition (3E6578) from Bayer CropScience AG; 2 T.W. Alexander Drive; Research Triangle Park, NC 27709 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 180.581 by establishing a tolerance for residues of iprovalicarb in or on the raw agricultural commodity tomato at 1.0 parts per million (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 metabolism of iprovalicarb was investigated in grapes, potatoes and tomatoes, and the metabolic pathway is similar in the three crops. The rate of degradation on plants is quite low, and the parent compound was always the major component, with quantitatively relevant metabolites formed only in potatoes. The metabolites observed in the potato were also observed in the rat. Therefore, iprovalicarb is the only residue of concern. Plant metabolism proceeds along three pathways:

i. Hydroxylation/glycosylation of parent at the 4-methyl group on the phenyl ring, followed by further conjugations.

ii. Cleavage of the amide group between the L-valine and *p*-methyl-phenethylamine moieties.

iii. Hydroxylation/glycosylation of parent at the phenyl-ring 3 position.

2. *Analytical method*. Iprovalicarb residues are quantified by reversed phase HPLC with Electrospray MS/MS-detection. The instrument response was linear over the range of 0.0005 to 0.26 ppm. For the analysis of iprovalicarb residues in tomatoes, the limit of quantification and the limit of detection were determined to be 0.02 ppm and 0.005 ppm, respectively. Iprovalicarb residue recoveries ranged from 81% to 98% for tomato samples fortified at 0.017 ppm and from 80% to 90% for tomato sampled fortified at 0.166 ppm.

3. *Magnitude of residues*. Twenty residues trials were conducted that are representative of tomatoes grown in countries that export tomato commodities to the United States. The maximum iprovalicarb residue in/on whole, unwashed tomatoes grown for exportation to the United States was 0.41 ppm. The average iprovalicarb residue in/on whole, unwashed tomatoes grown for exportation to the United States as fresh tomatoes and processed tomatoes was 0.12 ppm and 0.07 ppm, respectively. Washing of whole tomatoes reduces iprovalicarb residues by 56%. Iprovalicarb residues were reduced by 88%, 73% and 71% via processing of fresh, unwashed tomatoes to peeled fruit, juice and puree, respectively. The iprovalicarb residue concentration factor for tomato paste is 1.38. The theoretical maximum iprovalicarb residue in tomato paste is 0.56 ppm, (0.41 ppm x 1.38 = 0.56 ppm). Since tomato paste is a blended commodity and the average residue in/on tomatoes grown for export to the United States as processed tomatoes is

0.07 ppm, the anticipated iprovalicarb residue in tomato paste is only 0.10 ppm. (0.07 ppm x 1.38 = 0.10 ppm).

B. Toxicological Profile

OPPTS Harmonized Guideline 870.1100, Acute oral toxicity, LD_{50} 5,000 milligram/kilogram/body weight (mg/kg/bwt) is the only entry that did not appear in Table 1 of the final rule of August 22, 2002.

1. *Acute toxicity*. See Table 1 of the final rule published in the **Federal Register** of August 22, 2002 (67 FR 54351) (FRL–7194–3).

2. *Genotoxicity*. See Table 1 of the final rule published in the **Federal Register** of August 22, 2002 (67 FR 54351).

3. *Reproductive and developmental toxicity*. See Table 1 of the final rule published in the **Federal Register** of August 22, 2002 (67 FR 54351).

4. *Subchronic toxicity*. See Table 1 of the final rule published in the **Federal Register** of August 22, 2002 (67 FR 54351).

5.*Chronic toxicity*. See Table 1 of the final rule published in the **Federal Register** of August 22, 2002 (67 FR 54351).

6. *Animal metabolism*. See Table 1 of the final rule published in the **Federal Register** of August 22, 2002 (67 FR 54351).

7. *Metabolite toxicology*. The toxicity of *p*-methyl-phenethylamine, a rat, plant and soil metabolite, was investigated in two studies:

i. The acute oral LD_{50} in Wistar rats was determined to be in the range of 300 to 500 mg/kg/bwt.

ii. No mutagenic activity was observed in the Salmonella/microsome test. *p*-Methyl-phenethylamine was found at concentrations of <0.2% and has been determined to not be toxicologically significant.

8. *Endocrine disruption*. No endocrine disruption potential was observed in the 2–generation reproduction study, developmental toxicity studies, subchronic feeding studies, and chronic feeding studies.

C. Aggregate Exposure

1. *Dietary exposure*. There are no registered uses of iprovalicarb in the United States, and no registrations are pending. Dietary exposure to iprovalicarb in the United States is limited to residues in/on imported grape commodities and the proposed imported tomato commodities.

i. *Food*. Exposure to iprovalicarb residues in food is limited to imported grape and tomato commodities. U.S. consumption of fresh grapes, grape juice, raisins and wine that is from imported sources is estimated to be 35%, 43.3%, 7%, and 15%, respectively. The percent U.S. consumption of tomato commodities potentially treated with iprovalicarb that is from imported sources is estimated to be 13.4% for fresh tomatoes and 2.9% for processed tomatoes.

ii. *Drinking water*. Iprovalicarb is not registered for use in the United States. Therefore, there is no exposure to iprovalicarb through drinking water in the United States.

2. *Non-dietary exposure*. Iprovalicarb is not registered for use in the United States. Therefore, there is no non-dietary exposure to iprovalicarb in the United States.

D. Cumulative Effects

Iprovalicarb is a member of a new class of chemistry and does not have a mode of action that is common with other registered pesticides. Therefore, there are no cumulative effects.

E. Safety Determination

1. *U.S. population*. Iprovalicarb has low acute toxicity, so no acute safety determination is needed. EPA has previously determined that the chronic Population Adjusted Dose for iprovalicarb is 0.026 mg/kg/bwt/day and the uncertainty factor is 100. Based upon average residues in/on imported tomato commodities, and assuming that 100% of the tomato commodities that are imported from countries in which iprovalicarb is potentially used have been treated with iprovalicarb, the estimated chronic dietary risk based upon exposure of 50% of the reference population was estimated using CARES verison 1.3 to be 0.1% of the cPAD. The excess lifetime cancer risk was estimated using CARES version 1.3 to be 1.64×10^{-8}.

2. *Infants and children*. The population subgroup with the maximum estimated dietary exposure is children age 1 to 2 years old. For this subgroup, and using the same assumptions as listed for the U.S. population, the estimated chronic dietary risk is 0.5% of the cPAD.

F. International Tolerances

Currently, there is no CODEX maximum residue level (MRL) for iprovalicarb residues in/on tomatoes. Italy is the only country for which there currently is a registration for the use of iprovalicarb on tomatoes and for which the additional active ingredient included in the formulation for resistance management purposes also has a U.S. tolerance. Italy has established an MRL of 1.0 ppm for iprovalicarb residues in/on tomatoes.

[FR Doc. 05–7042 Filed 4–7–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0089; FRL–7706–8]

Flumioxazin; 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 identification (ID) number OPP–2005–0089, must be received on or before May 9, 2005.

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: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460–0001; telephone number: (703) 305–6224; e-mail address: *miller.joanne@epamail.epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you an agricultural producer, food manufacturer, or pesticide manufacturer. 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. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining