INFORMATION CONTACT. These electronic submissions will be accepted in WordPerfect or ASCII file format. Avoid the use of special characters and any form of encryption. Do not submit any disk or CD ROM through the mail. Disks and CD ROMs risk being destroyed when handled as Federal Government mail.

2. *Telephone or fax*. Telephone or fax your request to participate in the meeting to the person listed under **FOR FURTHER INFORMATION CONTACT**.

3. *By hand delivery or courier*. Deliver your comments to: OPPT Document Control Office (DCO) in EPA East Bldg., Rm. 6428, 1201 Constitution Ave., Washington, DC. Attention: Docket ID Number OPPT–2005–0012. The DCO is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the DCO is (202) 564–8930.

II. Background

In 1996, through enactment of FQPA, which amended the FFDCA, Congress directed EPA to develop a screening program, using appropriate validated test systems and other scientifically relevant information, to determine whether certain substances may have hormonal effects in humans. In 1996, EPA chartered a scientific advisory committee, the Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), under the authority of FACA, to advise it on establishing a program to carry out Congress' directive. EDSTAC recommended a multi-step approach including a series of screens (Tier 1 screens) and tests (Tier 2 tests) for determining whether a chemical substance may have an effect similar to that produced by naturally occurring hormones. EPA adopted almost all of EDSTAC's recommendations in the program that it developed, the Endocrine Disruptor Screening Program (EDSP), to carry out Congress' directive.

EPA is in the process of developing and validating the screens and tests that EDSTAC recommended for inclusion in the EDSP. In carrying out this validation exercise, EPA is working closely with, and adhering to the principles of the Interagency Coordinating Committee for the Validation of Alternate Methods (ICCVAM). EPA also is working closely with the Organization for Economic Cooperation and Development's (OECD) Endocrine Testing and Assessment Task Force to validate and harmonize endocrine screening tests of international interest.

Finally, to ensure that EPA has the best and most up-to-date advice available regarding the validation of the screens and tests in the EDSP, EPA chartered the Endocrine Disruptor Methods Validation Subcommmittee (EDMVS) of the National Advisory Council for Environmental Policy and Technology (NACEPT). The EDMVS convened nine meetings between October 2001 and December 2003. In 2003, NACEPT recommended EDMVS become an Agency level 1 FACA Committee due to the complexity of the recommendations. The EDMVAC was chartered in 2004. The EDMVAC provides independent advice and counsel to the Agency on scientific and technical issues related to validation of the EDSP Tier 1 screens and Tier 2 tests, including advice on methods for reducing animal use, refining procedures involving animals to make them less stressful, and replacing animals where scientifically appropriate. EDMVAC and previous EDMVS meeting information and corresponding docket numbers are available electronically, from the EPA Internet Home Page at *http://www.epa.gov/scipoly/oscpendo/*. You may also go to the EPA Docket at *http://www.epa.gov/edocket/*, and follow the online instructions for submitting materials.

III. Meeting Objectives for the April 26–28, 2005 Meeting

The objectives for the April 26–28, 2005 meeting (docket ID number OPPT–2005–0012) are to introduce the newly established EDMVAC Committee, review and discuss: Steroidogenesis (Tier 1 Assay), Uterotrophic (Tier 1 Assay, OECD), EPA Fish Screen Multi-Chemical Studies (Tier 1 Assay), OECD Fish Screen Phase 1B (Tier 1 Assay), Amphibian Metamorphosis Phase 1 Report and Phase 2 Draft Plan (Tier 1 Assay, OECD).

A list of the EDMVAC members and meeting materials are available at *http://www.epa.gov/scipoly/oscpendo/* and in the public docket.

List of Subjects

Environmental protection, Endocrine disruptors, Hazardous substances, Health, Safety.

Dated: April 1, 2005.

Clifford Gabriel,

Director, Office of Science Coordination and Policy.

[FR Doc. 05–7043 Filed 4–7–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0017; FRL–7704–2]

Kasugamycin; 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–2005–0017, 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 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–2005–0017. 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.1. 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–2005–0017. 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–2005–0017. 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–2005–0017.

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–2005–0017. 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 pesticide 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 pesticide 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 (PP) 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.

Arvesta Corporation as agent for Hokko Chemical Industry Co., Ltd.

PP 3E6579

EPA has received pesticide petition 3E6579 from Arvesta Corporation, 100 First St., Suite 1700, San Francisco, CA 94105 as agent for Hokko Chemical Industry Co. Ltd. 4–20, Nihonbashi Hongokucho 4 Chome, Chuo-Ku, Tokyo 103–8341, Japan, 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 kasugamycin, 1L-1,3,4/2,5,6-1-deoxy-2,3,4,5,6-pentahydroxy-cyclohexyl-2-amino-2,3,4,6-tetradeoxy-4-(α-iminoglycino)-α-D-arabino-hexopyranoside, in or on the raw agricultural commodity fruiting vegetables (Crop Group 8) at 0.04 parts per million (ppm), tomato juice at 0.06 ppm, tomato puree at 0.06 ppm, and tomato paste at 0.25 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 supports granting of the petition. Additional data may be needed before EPA rules on the petition.

A. Residue Chemistry

1. *Plant metabolism.* The nature of residues of kasugamycin in tomato was investigated using ^{14}C radiolabeled kasugamycin. Parent kasugamycin was the primary component in both fruit and foliage. The main metabolite in fruit, present at a maximum level of 0.01 ppm, was identified as kasugamycinic acid, resulting from the conversion of the iminomethyl function to a carboxylic acid. Additional investigation of extracts from foliage indicated the presence of:

i. 2-N-acetyl kasugamycin, formed by acylation of the primary amine.

ii. Kasuganobiosamine, formed by loss of the carboxylic acid function of kasugamycinic acid.

iii. Conjugates of kasugamycin and kasugamycinic acid.

However, of the minor metabolites found in the foliage, only the conjugates were observed in tomato fruit.

2. *Analytical method.* A practical analytical method for detecting and measuring levels of kasugamycin has been developed and validated in all appropriate agricultural commodities. This analytical method is suitable for monitoring of food with residues at the levels proposed for the tolerances. The limit of quantitation (LOQ) for this method is 0.04 ppm. An independent laboratory validation of the residue analytical method was successful.

3. *Magnitude of residues.* The number of field residue trials required for an import tolerance is based on the percent of total consumed crop commodity attributed to imports from countries where the product is or is intended to be registered for use on the crop. The number of trials may be reduced if a crop group tolerance is requested. Using this consideration, EPA determined that the residue field program should consist of three trials on bell pepper, three trials on non-bell pepper, and eight trials on tomato. Field residue trials in support of this import tolerance were conducted at sites representative of locations in which the product will be used on the intended crops with applications at the

maximum use rate for each crop. As a result of the field trials, the tolerance proposed for the fresh fruiting vegetables is 0.04 ppm. A tomato processing study was not conducted. However, using the detectable levels of kasugamycin residues in the tomato fruits, the expected levels of residues in tomato juice, tomato puree, and tomato paste were calculated using the maximum theoretical concentration factors from the harmonized test guideline OPPTS 860.1520 of 1.4, 1.4, and 5.5, respectively. As a result of these calculations, the following tolerances are proposed for tomato processing commodities: 0.06 ppm (tomato juice), 0.06 ppm (tomato puree), and 0.25 ppm (tomato paste).

B. Toxicological Profile

A full battery of toxicology testing including studies of acute, subchronic, chronic, oncogenicity, developmental, reproductive, and genotoxicity effects is available for kasugamycin. The acute oral toxicity, the only acute testing required for import tolerances, is low. Subchronic and chronic studies exhibit no-observed-effects-level (NOEL) values from a low 5 milligram/kilogram/day (mg/kg/day) (2–year chronic toxicity in dogs) to 135 mg/kg/day (13–week feeding study with mice). Kasugamycin is not oncogenic and weight-of-evidence indicates it is not genotoxic. There are no concerns of developmental or reproductive effects. The lowest chronic NOEL of 3 mg/kg/day is taken from the rabbit maternal toxicity in the developmental study.

1. *Acute toxicity*. The acute oral toxicity for kasugamycin (the only study required for import tolerances establishment) is very low. The acute oral Lethal Dose to 50% (LD_{50}) is greater than 5,000 mg/kg, which will gives kasugamycin a Toxicity Category IV.

2. *Genotoxicty*. Kasugamycin was negative in the following assays: Bacterial reverse mutation, Chinese hamster ovary (CHO), chromosomal aberration (*in vitro*), mammalian erythrocyte micronucleus, unscheduled DNA synthesis, *in vitro* mammalian cell gene mutation. Overall, it is unlikely that kasugamycin presents a genetic hazard.

3. *Reproductive and developmental toxicity*. Developmental effects of kasugamycin were studied in rats and rabbits and multi-generational effects on reproduction were studied in rats.

i. *Rat developmental*. In the developmental toxicity study conducted with rats the maternal NOEL is 40 mg/kg/day based on reduced body weight gain and food consumption. There were no developmental effects and the developmental NOEL is 1,000 mg/kg/day the highest dose tested.

ii. *Rabbit developmental*. In the developmental toxicity study conducted with rabbits the maternal NOEL is 3 mg/kg/day based on reduced body weight gain and food consumption, two abortions and one total litter loss. There were no developmental effects and the developmental NOEL is 10 mg/kg/day the highest dose tested.

iii. *Reproduction*. In the rat reproduction study the parental NOEL is 10 mg/kg/day based on decrease body weight. The reproductive NOEL is 50 mg/kg/day (based on increase length of time required for mating).

4. *Subchronic toxicity*. Subchronic toxicity studies have been conducted with kasugamycin in the rat, mouse, and dog.

i. *Rats*. Kasugamycin technical was tested in rats in a 13–week feeding study. Observations were altered blood biochemistry, elevated absolute and relative cecum weights, and increased relative kidney weights. Both males and females at the high dose increased their water consumption compared to controls. In addition, males in the 6,000 ppm group had an increase in eosinophilic bodies in the proximal tubule cells of the kidney and the females had an increase in foam cell aggregation in the lungs. Foam cells generally contained lipid droplets and may be derived from macrophage. The NOEL is 300 ppm (17.53 mg/kg/day in males and 22.33 mg/kg/day in females)

ii. *Mice*. A 13–week feeding study in mice was conducted. Effects included ulceration and inflammation of the anus, altered hematological, and clinical chemistry. Females in the 10,000 ppm group had a diffuse basophilia and hyperplasia of the epithelium of the proximal tubule of the kidney. Dilatation of the seminiferous tubules of males was observed in the high-dose group and sometimes associated with degeneration of the seminiferous epithelium. The NOEL is 1,000 ppm (135.4 mg/kg/day in males and 170.9 mg/kg/day in females).

iii. *Dog*. A 13–week oral toxicity study was conducted in beagle dogs. Effects included decreased food consumption and body weight gain, discolored feces, tongue lesions, swollen mouth, and excessive salivation. The NOEL is 300 ppm (10.59 mg/kg/day in males and 11.44 mg/kg/day in females).

5. *Chronic toxicity*. Kasugamycin has been tested in chronic studies with dogs, rats, and mice.

i. *Rats*. In a 24–month combined chronic/oncogenicity study in rats findings were increased cecum weights and kidney weights, increased brown pigment deposition in the kidney proximal tubules and an increased incidence of foam cell aggregation in the lungs. No significant increase in neoplastic lesions. The NOEL is 300 ppm (10.59 mg/kg/day in males and 11.44 mg/kg/day in females).

ii. *Mice*. Kasugamycin was administered in diet to mice for 78 weeks. Observations were lower absolute and relative spleen weights for males at 1,500 ppm. The NOEL is 300 ppm (34.94 mg/kg/day in males and 42.49 mg/kg/day in females)

iii. *Dog*. Kasugamycin was administered for 52 weeks to dogs. The administration of 3,000 ppm kasugamycin was associated with minimally higher urea nitrogen and creatinine, lower urine volume, and higher urine specific gravity. The NOEL is 1,000 ppm.

iv. *Carcinogenicity*. Kasugamycin did not produce carcinogenicity in adequately designed chronic studies with rats or mice. Arvesta Corporation anticipates that the cancer classification of kasugamycin will be ''E'' (no evidence of carcinogenicity for humans).

6. *Animal metabolism*. Following administration to the rodent, the majority of kasugamycin is excreted into the feces, a small amount was eliminated in the urine, and less than 0.1% of the radioactivity was retained in the carcass. Kasugamycin is not excreted in the bile and enterohepatic circulation of kasugamycin does not occur. There were no apparent sex related differences.

7. *Metabolite toxicology*. No metabolites of significant expected toxicity were identified in the animal metabolism study.

8. *Endocrine disruption*. Data from the subchronic studies indicate that there is no expected endocrine disruption effects.

C. Aggregate Exposure

1. *Dietary exposure*. Acute and chronic dietary analyses were conducted to estimate exposure to potential kasugamycin residues in or on the following crops: Fruiting vegetables using CARES software developed by CropLife and DietRisk™ TSG's software. Kasugamycin is not used in the United States so there is no need for water exposure analysis. In calculating the exposure the following assumptions were made: Tolerance level of residues, and 100% imported crops treated with kasugamycin.

2. *Food*—i. The acute dietary margin of exposure (MOE) estimates for kasugamycin residues in food at 99.9th percentile of females age 13–49 is higher

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**.