Imazethapyr tolerant canola, cotton, and CDC triffid flax. There are no residential uses for any tribenuron methyl containing herbicides.

Based on data and information submitted by DuPont, EPA previously determined that the establishment of tolerances of tribenuron methyl on the following raw agricultural commodities would protect the public health, including the health of infants and children:

| Wheat | Barley | Grass | Oats |
|---|---|---|---|
| Grain | Grain | Forage | Grain |
| Straw | Straw | Hay | Straw |

Establishment of new tolerances for tribenuron methyl on imazethapyr tolerant canola seed at 0.02 ppm, cotton seed at 0.02 ppm, cotton gin trash at 0.02 ppm, and CDC triffid flax at 0.02 ppm, will not adversely impact public health.

Using the conservative exposure assumptions described in this unit, and based on the most sensitive chronic NOEL of 0.79 mg/kg/day and an RfD of 0.008 mg/kg/day, the aggregate dietary exposure will utilize 2.7% of the RfD for the U.S. population. Generally, exposure below 100% of the RfD are of no concern because the RfD represents the level at or below which daily dietary exposure over a lifetime will not pose risk to human health. We therefore conclude that there is reasonable certainty that no harm will result from aggregate exposure to tribenuron methyl residues.

2. *Infants and children.* Chronic dietary exposure of the most highly exposed subgroup in the population, children 1 to 6, is 0.000213 mg/kg/day or 2.7% of the chronic RfD. The acute dietary exposure of the most exposed subgroup, children 1 to 6, is 0.24% of the acute RfD (95$^{th}$ percentile). For non-nursing infants (<1–year), the acute dietary exposure is 0.15% acute RfD (95$^{th}$ percentile).

There are no residential uses of tribenuron methyl and contamination of drinking water is extremely unlikely. Based on the completeness and reliability of the toxicity data, the lack of toxicological endpoints of special concern, the lack of any indication of greater sensitivity of children, and the conservative exposure assessment, there is a reasonable certainty that no harm will result to infants and children from the aggregate exposure to residues of tribenuron methyl from all anticipated sources of dietary and non-occupational exposure. Accordingly, there is no need to apply an additional safety factor for infants and children.

*F. International Tolerances*

The maximum residue level (MRL) in Canada for tribenuron methyl on canola is 0.1 ppm. No Mexican or Codex MRLs exist for tribenuron methyl on canola. There are no Canadian, Mexican or Codex MRLs for tribenuron methyl on cotton and flax.

[FR Doc. 04–15208 Filed 7–6–04; 8:45 am]

**BILLING CODE 6560–50–S**

## ENVIRONMENTAL PROTECTION AGENCY

**[OPP–2004–0132; FRL–7362–5]**

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

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

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

**DATES:** Comments, identified by docket ID number OPP–2004–0132, must be received on or before August 6, 2004.

**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:** Ann Sibold, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–6502; e-mail address: *sibold.ann@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

### I. General Information

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you [grow brassica crops or mustard greens or consume them] Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111)
- Other vegetable (except potato) Farming (NAICS 111219)
- Farming (NAICS code 112 )
- Food manufacturing (NAICS 311)
- Fruit and vegetable preserving and specialty food manufacturing (NAICS code 3114)
- Pesticide manufacturing (NAICS code 32532)
- Entomological; services, agrecultural; insect control for crops (NAICS code 115112)
- Agricultural production or harvesting crews (NAICS code 115115)

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–2004–0132. 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–2004–0132. 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–2004–0132. 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–2004–0132.

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–2004–0132. 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: June 21, 2004.

**Lois Rossi,**

*Director, Registration Division, Office of PesticidePrograms.*

**Summary of Petition**

The petitioner's summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by ISK Biosciences Corporation, 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.

**ISK Biosciences Corporation**

*PP 4F6832P*

EPA has received a pesticide petition PP 4F6832 from ISK Biosciences Corporation, 7470 Auburn Road, Suite A, Concord, Ohio, 44077, 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 the combined residues of the insecticide flonicamid (N-(cyanomethyl)-4-trifluoromethyl)-3-pridinecarboxamide (CA) or N-cyanomethyl-4-trifluoromethylnicotinamide (IUPAC) and its metabolites, TFNA [4-trifluoromethylnicotinic acid, TFNA-AM (4-trifluoromethylnicotinamide) and TFNG N-(4-trifluoromethylnicotinoyl)-glycine) in or on the raw agricultural commodities: Brassica, head and stem, subgroup 5-A, at 1.5 parts per million (ppm), and mustard greens at 11 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.* Wheat, potato and peach metabolism studies were conducted using $14_{C}$-pyridyl-flonicamid. The metabolic profile was similar for all three matrices. The major metabolites for the various crops were: TFNA in peach, TFNA and TFNG in potato and TFNG in wheat. The metabolism of flonicamid in plants shows the main pathway of metabolism involves hydrolysis of -CN and $CONH_2$ functional groups in the molecule. The metabolism of flonicamid in plants is well understood.

2. *Analytical method.* Analytical methodology has been developed to determine the residues of flonicamid and its three major plant metabolites, TFNA, TFNG, and TFNA-AM in various crops. The residue analytical method for the majority of crops includes an initial extraction with acetonitrile (ACN)/deionized (DI) water, followed by a liquid-liquid partition with ethyl acetate. The residue method for wheat straw is similar, except that a $C_{18}$ solid phase extraction (SPE) is added prior to the liquid-liquid partition. The final sample solution is quantitated using a liquid chromatograph (LC) equipped with a reverse phase column and a triple quadruple mass spectrometer (MS/MS).

3. *Magnitude of residues.* Residue data were collected on mustard greens and the Brassica leafy vegetables, head and stem subgroup during field trials. Maximum total residues for head and stem Brassica (total of 12 field trials) ranged from 0.590 ppm (broccoli) to 1.281 ppm (cabbage). Maximum total residues for mustard greens (total of 6 field trials) ranged from 2.115 ppm to 10.113 ppm.

*B. Toxicological Profile*

1. *Acute toxicity.* A battery of acute toxicity studies was conducted which placed flonicamid technical in Toxicity Category III for oral $LD_{50}$, Category IV for dermal $LD_{50}$, inhalation $LC_{50}$, dermal irritation, and eye irritation. Flonicamid technical is not a dermal sensitizer. In an acute neurotoxicity study, the no observed adverse effect levels (NOAELs) for neurotoxicity were 600 milligrams/kilogram (mg/kg) in males and 1,000 mg/kg in female highest doses tested (HDT). The systemic NOAELs were 600 mg/kg in males and 300 mg/kg in females.

2. *Genotoxicty.* Flonicamid technical did not cause mutations in the bacterial reverse mutation or mouse lymphoma tests with or without metabolic activation, chromosome damage in the mouse micronucleus or cytogenetics tests with and without metabolic activation, an increase in DNA damage in the comet assay or in an *in vivo* rat unscheduled DNA synthesis (UDS) study. Based on the weight of evidence, it is concluded, that flonicamid technical is not genotoxic.

3. *Reproductive and developmental toxicity* A developmental toxicity study in rats resulted in the maternal and developmental no observed effect levels (NOELs) of 100 mg/kg/day. The maternal lowest observed effect level (LOEL) was 500 mg/kg/day based on the treatment-related effects observed on the liver and kidney of the dams in the highest dose group. The developmental LOEL was 500 mg/kg/day based on the increases in placental weights and incidences of fetal skeletal variations seen only at maternally toxic doses of 500 mg/kg/day.

In the rabbit developmental toxicity study, the maternal and developmental NOELs were 7.5 mg/kg/day and 25 mg/kg/day HDT, respectively. The maternal LOEL was 25 mg/kg/day based on

decreased body weights and food consumption. No adverse effects on the fetuses were observed at the highest dose.

In the multigeneration rat reproduction study, the NOAEL was 300 ppm for both parental animals (13.5-32.8 and 16.3-67.0 mg/kg/day, respectively, for males and females) and their offspring. The effects at the highest dose of 1,800 ppm included the following: Increased kidney weights and gross and histopathological alterations in the kidney. Findings noted in the top dose females included delayed vaginal opening and increased liver, kidney and spleen weights in the F1 generation and reduced ovary and adrenal weights in the parental generation and decreased uterine weights in the F1 female weanlings. There was an increase in the follicle stimulating hormone (FSH) and luteinizing hormone (LH) levels in F1 females tested for these endpoints. These findings did not affect the reproductive performance or survival of offspring in the study.

4. *Subchronic toxicity.* The no observed adverse effect level (NOAEL) for flonicamid technical in the rat 28–day dermal toxicity study was 1,000 mg/kg/day, which was the highest dose tested.

In a 90–day rat feeding study the NOAEL was established at 200 ppm (12.11 mg/kg/day) for males and 1,000 ppm (72.3 mg/kg/day) for females. The NOAELs were based on effects on hematology, triglycerides, and pathology in the liver and kidney.

In a 13–week mouse study, the NOAEL was 100 ppm (15.25 mg/kg/day in males and 20.1 mg/kg/day in females). The LOAEL is 1,000 ppm (153.9 mg/kg/day in males and 191.5 mg/kg/day in females) based on hematology effects and changes in glucose, creatinine, bilirubin, sodium, chloride and potassium levels, increased liver and spleen weights and histopathology findings in the bone marrow, spleen and kidney.

In a subchronic toxicity study in dogs with capsule administration, the NOAEL was 20 mg/kg/day based on findings of severe toxicity at a dose exceeding the maximum tolerated dose; symptoms included collapse, prostration and convulsions leading to early sacrifice at the LOAEL of 50 mg/kg/day.

In a subchronic neurotoxicity study in rats, the NOAEL for dietary administration was 1,000 ppm (67 mg/kg/day in males and 81 mg/kg/ day in females) for systemic toxicity based on body weight and food consumption effects. The NOAEL for neurotoxicity was 10,000 ppm (625 and 722 mg/kg/day in males and females, respectively highest dose tested.

5. *Chronic toxicity*. In the chronic dog study with administration via using capsules, the NOEL was 8 mg/kg/day. The LOAEL was 20 mg/kg/day based on reduced body weights in females and effects on the circulating red blood cells.

In a rat 24–month combined chronic and oncogenicity study, flonicamid technical was not carcinogenic in rats. The NOAEL was 200 ppm (7.32 mg/kg/day) for males and 1,000 ppm (44.1 mg/kg/day) for females. The LOAEL was 1,000 ppm for males and 5,000 ppm for females based on histopathology in the kidney, hematology effects, hepatic effects including changes in biochemical parameters, increased organ weights, and histopathological changes. Atrophy of striated muscle fibers, cataract and retinal atrophy observed in the high dose females were considered to be due to acceleration of spontaneous age-related lesions.

In the 18–month mouse study, effects were observed in the lung, liver, spleen and bone marrow at 250 ppm or higher. Findings included centrilobular hepatocellular hypertrophy, extramedullary hematopoiesis and pigment deposition in the spleen and decreased cellularity (hypocellularity) in the bone marrow. There were statistically significant increases in the incidence of alveolar/bronchiolar adenomas in both sexes of treated groups with hyperplasia/hypertrophy of epithelial cells in terminal bronchioles. There was a statistically significant increase in the incidence of alveolar/bronchiolar carcinomas in males at 750 ppm and 2,250 ppm and in females at 2,250 ppm only. These effects in the lungs of mice were not life threatening as most of effects were observed at the terminal sacrifice and there was no effect of treatment on mortality in the study. A no observed adverse effect level (NOAEL) could not be determined from the dose levels administered. Mechanism-of-action studies have indicated that the lung effects are unique to the mouse and are not likely to translate to other species including the rat. A second 18–month mouse study was conducted in CD-1 mice at dose levels ranging from 10 to 250 ppm to establish a NOAEL for hyperplasia/hypertrophy of epithelial cells in terminal bronchioles and for the incidence of alveolar/bronchiolar adenomas and carcinomas in both sexes. There was a statistically significant increase in the incidence of alveolar/bronchiolar adenomas in males at 250 ppm. In females, there was no statistically significant increase in the incidence of pulmonary neoplastic lesions at any dose level. The incidence of hyperplasia/hypertrophy of epithelial cells lining the terminal bronchioles of the lungs was statistically increased at 250 ppm in both sexes. There were no treatment-related increases in neoplastic or non-neoplastic lesions at dose levels of 80 ppm or lower in either sex. The NOAEL was 80 ppm, equivalent to 10.0 and 11.8 mg/kg body weight/day for males and females, respectively. This study confirmed a threshold for these effects at 80 ppm, which had been indicated in studies on the mechanism. Mechanism-of-action studies have indicated that the lung effects are unique to the mouse and are not likely to translate to other species including the rat. Flonicamid technical was not carcinogenic in the rat.

6. *Animal metabolism.* Rat, goat and poultry metabolism studies were conducted using $^{14}C$-pyridyl-flonicamid. The majority of the dose was rapidly excreted. Flonicamid was a major component of rat urine 48 hours after dosing. TFNA-AM was the major metabolite found in rats (urine), goats (milk and tissues) and in laying hens (tissues and eggs). TFNG was found between 8%–24% of the total radioactive residue (TRR) in the livers of rats sacrificed at intervals between 0.5–6 hours after dosing. The liver samples at these time intervals had $^{14}C$-residues of 2.3%–4.6% of the dose. TFNA was not a major component in animal tissues. The metabolism of flonicamid in animals shows the main pathway of metabolism involves hydrolysis of -CN and -$CONH_2$ functional groups in the molecule, identical to plant metabolism. The main metabolic reactions were hydrolysis of cyano to the amide function and ring hydroxylation. In rats flonicamid was further metabolized by several routes, including nitrile hydrolysis, amide hydrolysis, N-oxidation, and hydroxylation of the pyridine ring, leading to multiple metabolites. The metabolism of flonicamid in animals is well understood.

7. *Metabolite toxicology.* The main metabolites of flonicamid were examined in acute oral toxicity studies in rats and bacterial reverse mutation tests. All the metabolites were less toxic than flonicamid and not mutagenic.

8. *Endocrine disruption.* No special studies investigating potential estrogenic or other endocrine effects of flonicamid have been conducted. Some suggestions of possible endocrine effects were reported at the highest dose tested (1,800 ppm) in the multi-generation reproduction study which showed increased FSH and LH levels, a delay in the time to vaginal opening in the F1

generation, and reduced ovary and adrenal weights in the parental generation. However, there were no effects on reproductive performance or survival of the offspring in the study. At levels that are expected to be found in the environment, flonicamid will not cause any endocrine-related effects.

*C. Aggregate Exposure*

1. *Dietary exposure.* Potential dietary exposures from food were estimated using the proposed tolerances for all crops using the Dietary Exposure Evaluation Model (DEEM-FCID™) and percent crop treated of 100%. The following raw agricultural commodities were included: Head and stem Brassica, mustard greens, leaf lettuce, head lettuce, celery, spinach, cotton, potatoes, fruiting vegetables, cucurbits, stone fruits, pome fruits and resulting secondary residues in meat, milk, poultry and eggs.

a. *Food.* Acute dietary exposure was compared to the acute population adjusted dose (aPAD) of 3.0 mg/kg/day based on the NOEL of 300 mg/kg from the acute neurotoxicity study in rats and a 100–fold uncertainty factor. The U.S. population exposure is 0.31% of the aPAD and the most highly exposed subpopulation is children 1–2 years of age with 0.93% of the aPAD 95$^{th}$ percentile.

Based on the available data, an appropriate chronic population adjusted dose (cPAD) is 0.073 mg/kg/day based on the NOEL of 7.32 mg/kg/day from the chronic toxicity study in rats and a 100–fold uncertainty factor. The U.S. population exposure is 3.6% of the cPAD and the most highly exposed subpopulation exposure is children 1–2 years of age with 12.2% of the cPAD.

b. *Drinking water.* A drinking water level of comparison (DWLOC) was calculated by subtracting the chronic/acute food exposures calculated using DEEM™ from the cPAD/aPAD to obtain the acceptable chronic/acute exposure to flonicamid in drinking water. The estimated average and maximum concentration of flonicamid in surface water is 1.07 parts per billion (ppb) and 7.33 ppb, respectively. These are both well below the lowest chronic (641 ppb) and acute (29,720 ppb) DWLOC values for flonicamid. Therefore, taking into account all proposed uses, it can be concluded, with reasonable certainty that residues of flonicamid in food and drinking water will not result in unacceptable levels of human health risk.

2. *Non-dietary exposure.* There are currently no residential uses of flonicamid registered or pending action that need to be added to the total risk from exposure.

*D. Cumulative Effects.*

In consideration of potential cumulative effects of flonicamid and other substances that may have a common mechanism of toxicity, to our knowledge there are currently no available data or other reliable information indicating that any toxic effects produced by flonicamid would be cumulative with those of other chemical compounds; thus, only the potential risks of flonicamid have been considered in this assessment of its aggregate exposure. If ISK Biosciences Corporation learns of any other compound with the same mechanism of toxicity they will submit information for the EPA to consider concerning potential cumulative effects of flonicamid consistent with the schedule established by EPA in the **Federal Register** of August 4, 1997 (62 FR 42020), and other EPA publications pursuant to the Food Quality Protection Act.

*E. Safety Determination*

1. *U.S. population.* Using conservative exposure assessment analyses, the acute dietary exposure estimates are well below the aPAD of 3 mg/kg bwt/day for all population subgroups. In addition, the chronic dietary exposure estimates for the various population groups are well below the cPAD of 0.073 mg/kg bwt/day. Based on this information, ISK Biosciences Corporation concludes, that there is reasonable certainty that no harm will result from acute or chronic exposure to flonicamid.

2. *Infants and children.* Based on the available developmental and reproductive data on flonicamid, ISK Biosciences Corporation concludes, that reliable data support use of the standard 100-fold uncertainty factor, and that an additional uncertainty factor is not needed to protect the safety of infants and children under the Food Quality Protection Act (FQPA). Although, the reproduction study indicated signs of toxicity to some reproductive organs/systems at the high dose of 1,800 ppm in the diet, other signs of toxicity such as effects on the kidney accompanied these; there were no effects observed at a dose level of 300 ppm. There were no effects on reproduction or survival at any dose level. Since acute and chronic aggregate exposure assessments are well below the aPAD and cPAD respectively, there is reasonable certainty that no harm will result to infants and children from aggregate exposure to flonicamid residues.

*F. International Tolerances*

There are no Canadian or Mexican residue limits or Codex MRLs for the insecticide flonicamid and its metabolites TFNA, TFNA-AM and TFNG.

[FR Doc. 04–15206 Filed 7–6–04; 8:45 am]

**BILLING CODE 6560–50–S**

## ENVIRONMENTAL PROTECTION AGENCY

**[OPP–2004–0181; FRL–7364–7]**

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

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Notice.

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

**DATES:** Comments, identified by docket ID number OPP–2004–0181, must be received on or before August 6, 2004.

**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:** James A. Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5697; e-mail address: *tompkins.jim@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 code 111)
- Animal production (NAICS code 112)
- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be