Users of these products who desire continued use should contact the applicable registrant before January 3, 2005, to discuss withdrawal of the application for amendment. This 180–day period will also permit interested members of the public to intercede with registrants prior to the Agency's approval of the deletion.

Table 2 of this unit includes the names and addresses of record for all registrants of the products in Table 1 of this unit.

TABLE 2.—REGISTRANTS REQUESTING AMENDMENTS TO DELETE USES IN CERTAIN PESTICIDE REGISTRATIONS

EPA Company No.	Company Name and Address
7501	Gustafson, LLC 1400 Preston Road, Suite 400, Plano, TX 75093
62719	Dow Agrosciences, LLC 9330 Zionsville Road, Indianapolis, IN 46268

IV. What is the Agency Authority for Taking this Action?

Section 6(f)(1) of FIFRA provides that a registrant of a pesticide product may at any time request that any of its pesticide registrations be amended to delete one or more uses. The Act further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, the Administrator may approve such a request.

V. Procedures for Withdrawal of Request

Registrants who choose to withdraw a request for use deletion must submit the withdrawal in writing to Katie Hall using the instructions listed under **FOR FURTHER INFORMATION CONTACT**. The Agency will consider written withdrawal requests postmarked no later than January 3, 2005.

VI. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products which are currently labeled in the United States and which have been packaged, labeled, and released for shipment prior to the effective date of the cancellation action.

The Agency intends to authorize the registrants to sell or distribute product under the previously approved labeling through December 31, 2004, after approval of the revision, unless other restrictions have been imposed, as in special review actions. Stocks in the hands of dealers and distributors other than the registrants could be sold or distributed until December 31, 2005. The Agency anticipates that use of the products proposed for cancellation will end December 31, 2006. Any future tolerance modifications would be calculated from the December 31, 2006, date. EPA will issue a **Federal Register** notice with the cancellation order and final existing stock provisions.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: June 18, 2004.

Debra Edwards,

Director, Special Review and Reregistration Division, Office of Pesticide Programs.

[FR Doc. 04–15209 Filed 7–6–04; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2004–0180; FRL–7364–8]

Tribenuron 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 identification (ID) number OPP–2004–0180, 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 are a 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–2004–0180. 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 South 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 EPA's 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–2004–0180. 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–2004–0180. 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–2004–0180.

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 South Bell St., Arlington, VA, Attention: Docket ID Number OPP–2004–0180. 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 pesticide petition.

List of Subjects

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

Dated: June 22, 2004.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner's 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.

E. I. du Pont de Nemours and Company

PP 0F6135

EPA has received a pesticide petition (0F6135) from E. I. du Pont de Nemours and Company, DuPont Agricultural Products, Barley Mill Plaza, Wilmington, DE 19880–0038 proposing, pursuant to FFDCA section 408(d), 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of tribenuron methyl (methyl 2-[[[[(4-methoxy-6-methyl-1,3,5- triazin-2-yl)methylamino] carbonyl]amino]sulfonyl]benzoate) in or on the raw agricultural commodity imazethapyr tolerant canola at 0.02 parts per million (ppm), cotton seed at 0.02 ppm, cotton gin trash at 0.02 ppm, and Crop Development Center (CDC) triffid flax at 0.02 ppm. EPA has determined that the 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 pesticide petition.

A. Residue Chemistry

1. *Plant metabolism*. The qualitative nature of the residues of tribenuron methyl is adequately understood. Tribenuron methyl is rapidly metabolized in wheat plants with a half-life of less than 4 days. A major metabolic reaction was *N*-demethylation of tribenuron methyl to form metsulfuron methyl. Metsulfuron methyl was further metabolized, primarily through rapid hydroxylation of the phenyl ring, followed by conjugation with glucose. Hydrolysis of the sulfonylurea bridge of tribenuron methyl to release sulfonamide and triazine amine was also observed. The sulfonamide may be further metabolized to hydroxylated sulfonamide or cyclized to saccharin. The presence of α-hydroxy triazine amine, *N*-demethyl triazine amine, and *O*-demethyl *N*-demethyl triazine amine demonstrated that the released triazine moiety of tribenuron methyl was also extensively degraded in wheat. Metabolism studies were conducted with radioactive ^{14}C-tribenuron methyl on wheat under field conditions. Wheat plants were treated with 72–75 gram (g) active ingredient (a.i.)/health advisory (ha) of ^{14}C-phenyl and ^{14}C-triazine labeled tribenuron methyl at the tillering stage. Samples were harvested 0, 4, 8, 14, 21, 28, and 63 days after treatment. Total ^{14}C-residue levels in the foliage declined rapidly from 5.5 ppm at time of application to 0.55 ppm in the mature straw and 0.05 ppm in the grain (^{14}C-phenyl), and from 4.2 ppm to 0.37 ppm in the mature straw and 0.01 ppm in the grain (^{14}C-triazine). Analysis of the wheat foliage and straw extracts by high performance liquid chromotography (HPLC) and threshold level ceiling (TLC) revealed that tribenuron methyl was rapidly and extensively metabolized. Metabolites were identified based on chromatography with authentic standards. The major metabolites were the glucose conjugate of hydroxylated metsulfuron methyl, hydroxylated saccharin, the glucose conjugate of hydroxylated saccharin, saccharin, triazine amine, *O*-demethyl triazine amine, and *O*-hydroxy triazine amine.

A metabolism study was conducted with ^{14}C-tribenuron methyl on acetolactate synthase (ALS)-tolerant canola. ^{14}C-tribenuron methyl was applied at 25 g/ha as a topical spray treatment at 2 true leaf stage to bolting. Whole canola plants were harvested at 0, 2 days, 35 days, and at maturity, 78 days after treatment. Total reactive residue (TRR) in canola foliage, when expressed as tribenuron methyl equivalents, declined from, on average, 0.26 ppm at day 0 to 0.04 ppm at day 35. TRR in immature 35–day canola seed pods was not higher than 0.04 ppm, and was 0.02 ppm in 78–day seed samples. ^{14}C-tribenuron methyl accounted for greater than 81% of the radioactive residue in the 0 to 2–day foliage samples. Other minor components were polar metabolites or conjugates, each less than 10% of the TRR. No single component in the polar metabolites exceeded 0.01 ppm. In the 35–day foliage samples, ^{14}C-tribenuron methyl accounted for only about 11–25.5% of the TRR which is less than 0.01 ppm. The average half life for ^{14}C-tribenuron methyl was 15 days. Several metabolic processes in the foliage are involved. They include a hydrolytic cleavage of tribenuron methyl as well as *N*-demethylation of tribenuron methyl. Other demethylation and hydroxylation processes continued up to final harvest. The results of the study suggest that the tribenuron methyl metabolic process in canola follows a typical plant metabolism pattern, and no accumulation of tribenuron methyl is anticipated in canola when it is used in accordance with the proposed labels.

A metabolism study was conducted to determine the nature and magnitude of the residues of tribenuron methyl in

cotton plants after treatment with 2-^{14}C-tribenuron methyl. Soil treatments were applied at 0.3 ounce a.i./acre as a direct spray in an aqueous suspension containing inert dry-flowable (DF) formulation ingredients. The application was performed immediately after planting to provide the data for the shortest anticipated time between application and planting. No terminal residues at or above 0.01 ppm were observed in any triazine-label treated fractions of mature cotton after treatment with tribenuron methyl. No detectable residues were found in the undelinted seed and very low residues of 0.028 ppm were observed in the gin trash after treatment. Tribenuron methyl and its known metabolites are not expected to be present in the terminal residues in gin trash or undelinted seed, when applied according to the proposed label.

A confined crop rotation study with ^{14}C-phenyl tribenuron methyl was conducted using cabbage, red beets, sorghum, soybeans, and wheat planted in pots of sandy loam soil 30 and 120 days following a single application of ^{14}C-phenyl-labeled tribenuron methyl. For the 30–day aging period, samples from both treated and control crops were taken at 28, 49, and 67 days after planting with additional samples taken from the sorghum and soybeans plantings at 90 and 115 days. At maturity, all remaining plants were harvested and subdivided into edible and nonedible portions. Harvest dates, in days after planting were: 90 days (cabbage), 115 days (beets and wheat), and 168 days (sorghum and soybeans). Samples from all crops from the 120–day aging study were taken at 28, 48, 69, and 90 days (maturity for beets, cabbage, and wheat,) and 120 days and 169 days (maturity for sorghum and soybeans). Tribenuron methyl dissipated rapidly in the soil with none of the intact material detected after the 30–day aging period. The major radiolabeled residue extracted from the soil was saccharin which remained in the soil at very low levels throughout the study. Some accumulation of total radioactive residues was apparent in the mature sorghum foliage, soybean, and wheat due to the dehydrated nature of samples harvested. The major residue in the plants was identified as saccharin.

A confined crop rotation study with ^{14}C-triazine tribenuron methyl was conducted using cabbage, red beets, and sorghum. Sandy loam soil was treated at 32 g a.i./ha ^{14}C-phenyl tribenuron methyl in the greenhouse. Rotational crops were sown 30 and 120 days post-treatment. Tribenuron methyl degraded rapidly in the soil with no detectable intact material present 30 days post-treatment. The major radiolabeled metabolite was the triazine amine. No significant accumulation (less than 0.01 ppm) of radiolabeled materials from the soil were observed in the mature crops of cabbage foliage. Some accumulation of the radioactivity was observed in the mature beet foliage in the 30–day study (0.029 ppm) and the 120–day study (0.011 ppm). Major metabolites were *N*-demethyl triazine amine and *O*-hydroxy triazine amine. Accumulation of radioactivity was observed in the mature sorghum straw due to the dehydrated nature of this plant tissue at harvest. Levels of radiolabeled materials detected were 0.108 and 0.057 ppm in the 30–day and 120–day studies. The major metabolites were highly polar materials. Tribenuron methyl rapidly decomposes in soil to the triazine amine, which is then degraded, not accumulated, in plants.

Based on the absence of detectable residue in food commodities (barley and oat grain) and on the expected low residue levels of individual substances in feed items (straw) under normal conditions, and the Residue Chemistry Test Guidelines (OPPTS 860.1300(c)(2)(D)(ii) which states that; one metabolism study will be required for each of the crop groups defined in 40 CFR 180.34(f) except for herbs and spices, a plant metabolism study in barley and oat was not required. Additionally, based on the results of three metabolism studies on dissimilar crops having similar metabolic routes (canola, cotton, and wheat), an additional metabolism study for flax is not required.

2. *Analytical method.* There is an analytical method for determination of residues of tribenuron methyl in barley, wheat grain, straw, and wheat grain forage samples. The method is based on extraction of tribenuron methyl from crops with acetonitrile, and cleanup on a silica cartridge. Final determination is by normal phase liquid chromatography using a photoconductivity detector. Recoveries for grain, straw, and green forage samples fortified between 0.01 and 0.10 ppm averaged 88% with a standard deviation of 14%. The lower level of quantitation (LOQ) for grain and green forage is 0.01 ppm and for straw it is 0.02 ppm.

Another analytical method for determination of tribenuron methyl in wheat grain and straw uses 2 HPLC with ultra-violet (UV) detection at 254 nanometer (nm). The method provides a means to quantitate tribenuron methyl in these matrices at levels as low as 0.05 ppm based on a 5–gram sample.

An analytical method to detect tribenuron methyl at a level of 0.02 ppm or above in grass seed, straw, and seed screenings consists of using gel permeation chromatography and solid-phase extraction. Purified column eluent is taken to dryness, dissolved in ethyl acetate, and analyzed by capillary gas chromatography using a mass spectral detector. In fortification recovery trials, an average recovery of 87.6% with a standard deviation of 21% was obtained for 18 grass seed samples over a fortification range of 0.02 to 0.06 ppm. Tribenuron methyl residues in canola and flax samples were determined by an analytical method based on the use of liquid chromatography with eluent and column switching with photometric detection at 258 nm at levels as low as 0.02 ppm LOQ using a 5–gram sample.

Residues in cotton seed and gin trash were determined based on the use of column-switching liquid chromatography with detection via positive ion electrospray mass spectroscopy. The LOQ was determined to be 20 nanograms (ng)/g and the LOD was estimated to be 6 ng/g, based on a 5–gram sample.

3. *Magnitude of residues*—i. *Wheat, barley, grain, and straw.* A study was conducted to determine the extent of residues of tribenuron methyl in wheat when applied at the maximum use rate (0.25 ounce a.i./acre) 40 days before maturity. Samples of mature wheat, grain, and straw were taken from treated and control plots at pre-harvest intervals (PHI) ranging from 25 to 40 days after the test substance was applied. A 2–step HPLC method was used to determine tribenuron methyl at levels as low as 0.0075 ppm in wheat grain based on a 20–gram sample, and 0.014 ppm in wheat straw based on a 10–gram sample. No grain or straw samples showed quantifiable or detectable residues of tribenuron methyl.

A study was conducted to determine the extent of residues of tribenuron methyl in barley when applied at the maximum use rate (0.25 ounce a.i./acre) 40 days before maturity. Samples of mature barley grain and straw were taken from each plot at PHI ranging from 24 to 43 days after the test substance was applied. A 2–step HPLC method was used to determine tribenuron methyl at levels as low as 0.0066 ppm in barley grain based on a 20–gram sample, and 0.013 ppm in barley straw based on a 10–gram sample. One grain sample showed a detectable residue (0.0064 ppm) of tribenuron methyl, which is below the established grain tolerance of 0.05 ppm. A straw sample from one of the sites

contained tribenuron methyl at 0.034 ppm, which is below the established straw tolerance of 0.10 ppm. The remaining grain and straw samples showed no detectable or quantifiable residues of tribenuron methyl.

The results of the analyses of grain and straw from wheat and barley show that no residues were found in either grain or straw from plants treated at or below the maximum recommended application rate (0.25 ounce a.i./acre). The PHI ranged from 42–140 days (0.020 ppm–0.050 ppm LOQ). A small percentage of plants treated at higher rates showed some residues in straw.

ii. *Forage, grass, and hay*. Established plots of bluegrass, tall fescue, and perennial ryegrass grown for production of grass seed were each treated with 0.25 ounce a. i./acre and 0.50 ounce a.i./acre of ''express'' herbicide (formulated as a 75 DF water-dispersible granule). A total of 4 test sites were included in the study—2 for bluegrass and 1 each for tall fescue and perennial ryegrass. Sampling PHI ranged from 56 to 85 days. Reliable detected residues of tribenuron methyl (0.016 ppm or above) were not found in any crop fraction from any test site, with one exception of a residue level of 0.004 ppm for the 0.25 ounce a.i./acre treatment, and 0.006 ppm for the 0.50 ounce a.i./acre treatment. An attempt to reconfirm this result by reextracting a second screening waste sample failed to confirm the presence of these tribenuron methyl residues.

iii. *Grain, oat, and straw*. A study was conducted to determine the extent of residues of tribenuron methyl in oats when applied at 1 to 2 times the maximum use rate approximately 40 days before harvest. Samples of mature oat grain and straw were taken from both treated and control plots at PHI ranging from 39 to 57 days after the application of the test substance. A 2–step HPLC method was used to detect tribenuron methyl residues in oat grain at levels as low as 0.0055 ppm based on a 20–gram sample and in oat straw at levels as low as 0.018 ppm based on a 10 gram sample. Residues of tribenuron methyl in oat grain from oats treated at 1x and 2x were below the quantitation level of 0.013 ppm and 0.01 ppm, respectively. The residues of tribenuron methyl in oat straw were below the quantitation level of 0.018 ppm and 0.04 ppm respectively and also below reported detection level of 0.009 ppm and 0.018 ppm, respectively, in oat straw from oats treated at 1x and 2x rates.

iv. *Canola and flax*. Magnitude of residue studies were conducted on seed fractions of canola varieties containing the Smart™ trait and CDC triffid flax. The post-emergent broadcast application of Refine Extra® herbicide at a use rate of 15 to 30 g a.i./ha (representing 5 to 10 g a.i./ha of tribenuron methyl) which represents 1 to 2 times the proposed use rate for Refine Extra® herbicide on these canola and flax varieties. The study included treatment of 15 sites for canola containing the Smart™ trait and 11 sites for CDC triffid flax. No tribenuron methyl residues were found above the LOQ of 0.02 ppm in any seed samples treated with the test substance at a use rate of 15 to 30 g a.i./ha Refine Extra® herbicide.

v. *Cotton seed and gin trash*. Magnitude of residue studies were also conducted to determine residues of tribenuron methyl in cotton seed and cotton gin trash at 9 test sites. The study consisted of 3 treatments:

- One broadcast application at 0.45 ounce a.i./acre, applied approximately 14 days prior to planting.
- One broadcast application at 0.45 ounce a.i./acre, applied pre-plant, on the day of planting.
- One broadcast application at 2.25 ounce a.i./acre, applied pre-plant, the day of planting.

The anticipated target PHI was approximately 120 days after the last application of the test substance; actual PHIs ranged from 123 to 196 days. The experimentally determined LOQ was 20 parts per billion (ppb) for both analytes. The LOD was estimated to be 6 ppb. No tribenuron methyl residues were found above the LOQ of 0.02 ppm in any cotton seed and cotton gin trash samples treated with the test substance.

B. Toxicological Profile

1. *Acute toxicity*. Based on EPA criteria, technical tribenuron methyl is in acute toxicity category IV for oral and inhalation routes of exposure, and for skin irritation. Tribenuron methyl is in acute toxicity category III for the dermal route of exposure, and for eye irritation. It is not a skin sensitizer.

Acute oral toxicity in rats	Lethal dose $(LD)_{50}$ >5,000 milligrams/kilogram (mg/kg)
Acute dermal toxicity in rabbits	LD_{50} >2,000 mg/kg
Acute inhalation toxicity in rats	Lethal concentration $(LC)_{50}$ >5.0 mg/Liter (L)
Primary eye irritation in rabbits	Moderate effects reversed within 3 days
Primary dermal irritation in rabbits	Slight skin irritant
Dermal sensitization	Non-sensitizer

2. *Genotoxicity*. Technical tribenuron methyl has shown no genotoxic or mutagenic activity in the following *in vitro* and *in vivo* tests:

In vitro mutagenicity Ames Assay	Negative
In vitro mutagenicity chinese hampster ovary/hypoxanthine guanine phophoribosyl transferase (CHO/HGPRT) Assay	Negative
In vitro unscheduled deoxyribonucleic acid (DNA) synthesis	Negative
In vivo Cytogenetic	Negative
In vivo micronuclei induction (mouse)	Negative

Tribenuron methyl was negative for mutagenicity in an *in vitro* bacterial gene mutation assay using *Salmonella typhimurium* and in an *in vitro* mammalian cell gene mutation assay using chinese hampster ovary (CHO) cells. In cultured primary rat hepatocytes *in vitro*, thifensulfuron methyl was negative for the induction of unscheduled DNA synthesis.

In a test measuring clastogenic damage *in vivo*, tribenuron methyl was negative for the induction of chromosome aberrations in male and female rat bone marrow cells. A study measuring chromosome damage *in vivo* was conducted. The study included the evaluation of micronuclei in bone marrow polychromatic erythrocytes of male and female mice. The result was negative when exposures were conducted at 5,000 mg/kg body weight.

3. *Reproductive and developmental toxicity*. On long-term dietary administration, tribenuron methyl did not affect the reproduction or lactation performance of rats. Developmental studies in the rat and rabbit by gavage administration indicated that tribenuron methyl did not present a unique toxic risk to the fetus. Embryo-fetal and maternal NOAELs were equivalent in all cases.

There were no effects in reproduction or lactation in rats in a 1–generation reproduction study with rats fed for 90 days with diets that contained 0; 100; 1,750; or 5,000 ppm a.i. The no observed effect level (NOEL) was 100 ppm (7 mg/kg/day for males and 8 mg/

kg/day for females) based on lower mean dam and pup body weights for the intermediate and high dose groups.

There were no effects on fertility observed in a 2–generation reproduction study, in rats fed for at least 90 days with diets that contained 0, 25, 250, or 1,000 ppm a.i. The NOEL was 25 ppm based on lower body weights for the dams and offspring at 250 and 1,000 ppm. There were no differences attributed to administration of tribenuron methyl in the number of litters produced or other indices of reproductive performance. No compound-related effects on male fertility were noted. No effect on the number of pups born or pup survival were observed in any tribenuron methyl treated group.

In a study to evaluate developmental toxicity potential in rats, tribenuron methyl did not produce birth defects after administering via oral intubation to pregnant rats dosage levels of 0, 20, 125, and 500 mg/kg/day. The NOEL for this study was 20 mg/kg/day for both maternal and developmental toxicity. This was based on maternal effects at the 125 and 500 mg/kg/day. The effects included decreased body weight gain and food consumption and an increased incidence of excess salivation. Fetal effects included decreased body weights and increased number of resorptions (only at (hightest dose tested HDT)). In the rabbit developmental toxicity study, rabbits were fed dosage levels of 0, 5, 20, and 80 mg/kg/day. The NOEL for maternal and developmental toxicity was 20 mg/kg/day. This was based on maternal effects which included decreased feed consumption and an increased incidence of abortions (at the HDT). Fetal effects included slightly reduced body weights at 80 mg/kg/day.

4. *Subchronic toxicity*. The most sensitive species to subchronic exposure of tribenuron methyl was the rat. In the rat study, rats were fed dosage levels of 0; 100; 1,750; or 5,000 ppm tribenuron methyl for 90 days. The findings show that the NOEL for tribenuron methyl was 100 ppm for both male and female rats (90–day dietary). This concentration is equivalent to 7 and 9 mg/kg/day in male and female rats, respectively. The NOEL was based on the decreased body weight and decreased feed consumption noted in the 1,750 and 5,000 ppm groups. The NOEL for the 90–day mouse feeding study was 500 ppm (70 mg/kg/day for males and 90 mg/kg/day for females) based on liver and spleen effects at 1,250; 2,500; and 5,000 ppm at 4 weeks. An increase in liver weights at 2,500 ppm was noted with no histologic effects at any level. The NOEL for subchronic (90–day dietary) exposure in dogs was 500 ppm (15.1 mg/kg/day for male and 14.9 mg/kg/day for female dogs). This was based on lower mean body weights of male dogs fed the 2,500 ppm diet. A specific target organ was not identified in any of the species studied.

5. *Chronic toxicity*. The NOEL for chronic (18–month dietary) exposure in mice was 200 ppm (equivalent to 25 and 31 mg/kg/day in male and female mice, respectively). This was based on lower body weights for mice in the high-dose group (1,500 ppm). There were no neoplastic or other histopathological effects associated with this compound and no target organ was identified. Additionally, no evidence of tribenuron methyl induced oncogenicity was observed in the mouse.

The NOEL for chronic (2–year dietary) exposure in rats was 25 ppm (0.95 and 1.2 mg/kg/day for male and female rats, respectively). Lower body weights, which paralleled lower food consumption and organ weight effects, were observed in the 250 and 1,250 ppm groups. There were no clinical or histopathological effects associated with these organ weight effects. The incidence of mammary adenocarcinomas was greater than controls for female rats in the 1,250 ppm group. This effect was only observed in this high-dose group and under conditions of significant physiological stress (body weights for female rats were 42% lower than the controls).

In a 1–year feeding study in dogs, the NOEL was determined by DuPont to be 250 ppm (8.16 and 8.18 mg/kg/day for male and female dogs, respectively). This was based on slightly lower body weights and increased serum creatinine concentrations for dogs in the high-dose group (1,500 ppm). Upon review by EPA, the NOEL was set at 25 ppm (0.79 mg/kg/day). There were no neoplastic or other histopathological effects associated with compound administration.

6. *Animal metabolism*. Metabolism of tribenuron methyl was evaluated in rats using both phenyl and triazine labeling. Tribenuron methyl was extensively and rapidly converted to polar metabolites and primarily excreted in the urine and feces. Urinary excretion accounted for 2 to 4 times the amount of radiolabel excreted via feces in all groups. Essentially all of the tribenuron methyl and its metabolites were excreted in the urine and feces of the rat within 96 hours after dosing. Levels of radiolabeled residues in tissues were correspondingly higher in those groups with slower elimination kinetics, but no evidence of bioconcentration was seen. None of the dosed label was expired as carbon dioxide or volatile metabolites.

The average excretion half-life values for male and female rats in the low-dose group (20 mg/kg) were approximately the same (26–33 hours) and independent of dietary preconditioning. The average excretion half-lives for male and female rates in the high-dose groups (1,700; 1,800; and 2,000 mg/kg) were approximately 51–54 hours (males) and 68–96 hours (females). These results indicate that the metabolism of tribenuron methyl in male and female rats is qualitatively similar; however, female rats metabolize and excrete this product much slower than male rats at the high doses. The low residual radioactivity in the rat indicated that tribenuron methyl does not covalently bind to tissue macromolecules. Based on these data, the body burden of this compound is not expected to increase significantly upon repeated, long-term administration.

The major metabolites of tribenuron methyl are those expected from the enzymatic hydroxylation and dealkylation activities of the hepatic microsomal mixed function oxidase system. The major urinary metabolites were identified as metsulfuron methyl and saccharin (phenyl labeled groups) and metsulfuron methyl and *O*-demethyl triazine amine (triazine labeled groups); no evidence of glucuronide or sulfate conjugation was seen.

Results from a metabolism study with 2 radioactive forms of tribenuron methyl (^{14}C-triazine and ^{14}C-phenyl) in lactating goats show that most of the dosed radioactivity was recovered in the urine (61–71%) and feces (15–20%). In the urine, intact tribenuron methyl and metsulfuron methyl accounted for 17–23% and 20–22% of the administered dose, respectively. The third major component in phenyl-dosed goat urine was saccharin (23.5% of the dose); the third major metabolite in the triazine-dosed goat urine was *O*-demethyl *N*-demethyl triazine amine (10.9%). The highest levels of residues observed in the milk were 0.09 ppm (tribenuron methyl equivalents) from the triazine-dosed goat, and 0.006 ppm from the phenyl-dosed goat. Recoveries of the administered dose were 82.2% for the goat given the triazine label, and 86.8% for the goat dosed with the phenyl label. Throughout the dosing phase, the goats did not display any signs of toxicity, and there was no effect on milk production.

There were no significant levels of unique plant metabolites of thifensulfuron methyl found in food or feed products at crop maturity. Hence,

toxicity testing of other degradation products of thifensulfuron methyl is not needed.

7. *Metabolite toxicology*. There is no evidence that the metabolites of tribenuron methyl as identified in either the plant or animal metabolism studies are of any toxicological significance.

8. *Endocrine disruption*. In a previous 2–year feeding study, female rats fed, 1,250 ppm tribenuron methyl had an approximately 3–fold increase in mammary adenocarcinoma incidence when compared to control. This concentration of tribenuron methyl exceeded the maximum tolerated dose, producing a 43% decrease in body weight. In contrast, an 18–month feeding study demonstrated that tribenuron methyl was not oncogenic in mice. Because tribenuron methyl is also negative in five short-term tests for genotoxicity, a non-genotoxic mechanism was investigated. A study was designed to investigate whether tribenuron methyl can alter the hormonal system of female rats, which would support a non-genotoxic mechanism for the tribenuron methyl-induced mammary adenocarcinoma. The integrity of the endocrine system was assessed by monitoring the estrous cycle, measuring serum hormone levels, characterizing the estrogen and progesterone receptors from the uterus and mammary gland, and weighing reproductive organs.

The data from this study indicate that the endocrine system may have been affected at a relatively high dose, 5,000 ppm. These data further suggest that the hormonal effects served to enhance the growth of preinitiated mammary cells in this susceptible rat strain. Such hormone-mediated effects are considered to have a threshold below which growth of mammary tissue will not be affected. Adequate margins of safety protect humans from these threshold effects.

C. Aggregate Exposure

1. *Dietary exposure*. The chronic reference dose (RfD) of 0.008 mg/kg/day is based on the NOEL of 0.79 mg/kg/day from a 1–year dog feeding study and a 100X safety factor (SF). The acute RfD of 0.20 mg/kg/day is based the NOEL of 20 mg/kg/day from the rabbit and rat developmental studies and a 100X safety factor.

i. *Food*. Chronic dietary exposure assessment. Chronic dietary exposure, resulting from the proposed use of tribenuron methyl on barley, canola, cotton, flax, grass, oats, and wheat, is well within the acceptable limits for all sectors of the population, as predicted by the chronic module of the Dietary Exposure Evaluation Model ((DEEM), Novigen Sciences, Inc., 1999 Version 6.74). The percentage or proportion of a crop that is treated can have a significant effect on the exposure profile. In this case, it was assumed for the crop that 100% was treated with tribenuron methyl. Based on a comparison with the use profile for most other herbicides, this is an extremely conservative estimate. The predicted chronic exposure for the U.S. population subgroup was 0.000094 mg/kg body weight/day (bwt/day). The population subgroup with the highest predicted level of chronic exposure was the children 1 to 6 years subgroup with an exposure of 0.000213 mg/kg bwt/day. Based on a chronic NOEL of 0.79 mg/kg bwt/day and a 100–fold (SF), the chronic RfD would be 0.008 mg/kg bwt/day. For the U.S. population, the predicted exposure is equivalent to 1.2% of the chronic RfD. For the population subgroup with the highest level of exposure (children 1 to 6 years), the exposure would be equivalent to 2.7% of the chronic RfD. Because the predicted exposures, expressed as percentages of the chronic RfD, are well below 100%, there is reasonable certainty that no chronic effects would result from dietary exposure to tribenuron methyl.

ii. *Acute dietary exposure*. The predicted acute exposure for the U.S. population subgroup was 0.000262 mg/kg bwt/day (95^{th} percentile). The population subgroup with the highest predicted level of acute exposure was the children 1 to 6 years subgroup with an exposure of 0.000475 mg/kg bwt/day (95^{th} percentile). Based on an acute NOEL of 20 mg/kg bwt/day and a 100–fold SF, the acute RfD would be 0.20 mg/kg bwt/day. For the U.S. population the predicted exposure (at the 95^{th} percentile) is equivalent to 0.13% of the acute RfD. For the population subgroup with the highest level of exposure (children 1 to 6 years), the exposure (at the 95^{th} percentile) would be 0.24% of the acute RfD. Because the predicted exposures, expressed as percentages of the acute RfD, are well below 100%, there is reasonable certainty that no acute effects would result from dietary exposure to tribenuron methyl.

iii. *Drinking water*. Surface water exposure was estimated using the Generic Expected Environmental Concentration (GENEEC) model. Ground water exposures were estimated using screening concentration in ground water (SCI-GROW).

EPA uses drinking water levels of comparisons (DWLOCs) as a surrogate measure to capture risk associated with exposure to pesticides in drinking water. A DWLOC is the concentration of a pesticide in drinking water that would be acceptable as an upper limit in light of total aggregate exposure to that pesticide from food, water, and residential uses. A DWLOC will vary depending on the residue level in foods, the toxicity endpoint and with drinking water consumption patterns and body weights for specific subpopulations.

The acute DWLOCs are 7 ppm for the U.S. population and 2 ppm for the subpopulation with the highest exposure (children 1 to 6 years). The estimated maximum concentration of tribenuron methyl in surface water 0.7 ppb are derived from GENEEC is much lower than the acute DWLOCs. Therefore, one can conclude with reasonable certainty that residues of tribenuron methyl in drinking water do not contribute significantly to the aggregate acute human health risk.

The chronic DWLOCs are 0.3 ppm for the U.S. population and 0.01 ppm for the subpopulation with the highest exposure (children 1 to 6 years). These DWLOC values are substantially higher than the GENEEC 56–day estimated environmental concentration of 0.3 ppb for tribenuron methyl in surface water. Therefore, one can conclude with reasonable certainty that residues of tribenuron methyl in drinking water do not contribute significantly to the aggregate chronic human health risk.

2. *Non-dietary exposure*. Tribenuron methyl is not registered for any use which could result in non-occupational or non-dietary exposure to the general population.

D. Cumulative Effects

Tribenuron methyl belongs to the sulfonylurea class of crop protection chemicals. Other structurally similar compounds in this class are registered herbicides. However, the herbicidal activity of sulfonylureas is due to the inhibition of ALS, an enzyme found only in plants. This enzyme is part of the biosynthesis pathway leading to the formation of branched chain amino acids. Animals lack ALS and this biosynthetic pathway. This lack of ALS contributes to the relatively low toxicity of sulfonylurea herbicides in animals. There is no reliable information that would indicate or suggest that thifensulfuron methyl has any toxic effects on mammals that would be cumulative with those of any other chemical.

E. Safety Determination

1. *U.S. population*. Tribenuron methyl is the active ingredient in two DuPont herbicides with new proposed uses on the following commercial crops:

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 (95th percentile). For non-nursing infants (<1–year), the acute dietary exposure is 0.15% acute RfD (95th 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