larger nominal dimensions and treated to a minimum of 0.60 pcf) (C18), Lumber and Plywood for Permanent Wood Foundations (C22), Round Poles and Posts Used in Building Construction(C23), Sawn Timber Used To Support Residential and Commercial Structures(C24), Sawn Crossarms (C25), Structural Glued Laminated Members and Laminations Before Gluing (C28), Structural Composite Lumber (C33), and Shakes and Shingles (C34); and in accordance with the respective cited standard (noted parenthetically) of the 2002 edition of the American Wood-Preservers' Association Standards: Lumber, Timbers and Plywood for Cooling Towers (C30). Forest products treated with this product may only be sold or distributed for uses within the AWPA Commodity Standards under which the treatment occurred, except where otherwise provided above.

Revised Language Manufacturing Use Product (MUP)

This product may only be used (1) for formulation of the following end-use wood preservative products: Ammoniacal copper zinc arsenate (ACZA) or chromated copper arsenate (CCA) labeled in accordance with the Directions for Use shown below, or (2) by persons other than the registrant, in combination with one or more other products to make: ACZA wood preservative; or CCA wood preservative that is used in accordance with the Directions for Use shown below.

This product may only be used for preservative treatment of the following categories of forest products and in accordance with the respective cited standard (noted parenthetically) of the 2001 edition of the American Wood-Preservers' Association (AWPA) Standards: Lumber and Timber for Salt Water Use Only (C2), Piles (C3), Poles (C4), Plywood(C9), Wood for Highway Construction (C14), Round, Half Round and Quarter Round Fence Posts (C16), Poles, Piles and Posts Used as Structural Members on Farms, and Plywood Used on Farms (C16), Wood for Marine Construction (C18), Lumber and Plywood for Permanent Wood Foundations(C22), Round Poles and Posts Used in Building Construction (C23), Sawn Timber Used To Support Residential and Commercial Structures (C24), Sawn Crossarms (C25), Structural Glued Laminated Members and Laminations Before Gluing (C28), Structural Composite Lumber (C33), and Shakes and Shingles (C34); and in accordance with the respective cited standard (noted parenthetically) of the 2002 edition of the American Wood-Preservers' Association Standards: Lumber, Timbers and Plywood for Cooling Towers (C30). Forest products treated with this product may only be sold or distributed for uses within the AWPA Commodity Standards under which the treatment occurred.

Effective December 31, 2004, this product may only be used for preservative treatment of the following categories of forest products and in accordance with the respective cited standard (noted parenthetically) of the 2001 edition of the American Wood-Preservers' Association (AWPA) Standards: Lumber and Timber for Salt Water Use (also includes brackish water) Only (C2), Piles (C3), Poles (C4), Plywood(C9), Wood for Highway Construction (C14), Round, Half Round and Quarter Round Fence Posts (C16), Poles, Piles and Posts Used as Structural Members on Farms, and Plywood Used on Farms (C16), Wood for Marine Construction for Salt Water Use (also includes brackish water)(immersion and/or subject to saltwater (or brackish water) splash [''subject to saltwater (or brackish water) splash'' means any member of a marine structure which is positioned above mean high tide, but is subject to frequent wetting from wave action], [Pilings (sheet, round and square), Timbers, and Plywood; Walers, Framing, Stringers and Cross Bracing (2″ x 8″ and/or 3″ x 6″ and larger nominal dimensions and treated to a minimum of 0.60 pcf) (C18), Lumber and Plywood for Permanent Wood Foundations (C22), Round Poles and Posts Used in Building Construction(C23), Sawn Timber Used To Support Residential and Commercial Structures(C24), Sawn Crossarms (C25), Structural Glue Laminated Members and Laminations Before Gluing (C28), Structural Composite Lumber (C33), and Shakes and Shingles (C34); and in accordance with the respective cited standard (noted parenthetically) of the 2002 edition of the American Wood-Preservers' Association Standards: Lumber, Timbers and Plywood for Cooling Towers (C30). Forest products treated with this product may only be sold or distributed for uses within the AWPA Commodity Standards under which the treatment occurred, except where otherwise provided above.

Furthermore, any distribution, sale, or use of existing stocks of the products identified in Table 2 of Unit II. in a manner inconsistent with any of the Provisions for Disposition of Existing Stocks set forth below in Unit VI. will be considered a violation of FIFRA.

V. What is the Agency's 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 canceled or amended to terminate one or more uses. FIFRA further provides that, before acting on the request, EPA must publish a notice of receipt of any such request in the **Federal Register**. Thereafter, following the public comment period, the Administrator may approve such a request.

VI. Provisions for Disposition of Existing Stocks

Existing stocks are those stocks of registered pesticide products which are currently in the United States and which were packaged, labeled, and released for shipment prior to the effective date of the cancellation action. The cancellation order issued in this Notice includes the following existing stocks provisions.

The registrants of affected CCA products requested that the voluntary use terminations become effective December 31, 2004, with no provisions for existing stocks. Consequently, the Agency is not allowing for any existing stocks provisions for those affected products in the hands of the registrant on or after the effective date of the use terminations. Any sale, distribution, or use of those affected products on or after the effective date of this cancellation order is prohibited. This refers to CCA product labels that bear the C18 Marine Use, ''members out of water and not subject to saltwater [or brackish water] splash and not in soil use,'' and which do not bear labeling consistent with that set forth in Unit IV. above. Sale, distribution or use of the stocks in the channels of trade by persons other than the registrant may continue until depleted, provided any sale, distribution or use is in accordance with the existing label of that product.

List of Subjects

Environmental protection, Pesticides and pests, Chromated Copper Arsenate, CCA, and Treated Wood.

Dated: August 25, 2005.

Frank Sanders,

Acting Director, Antimicrobials Division, Office of Pesticide Programs.

[FR Doc. 05–17530 Filed 9–6–05; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPP–2005–0215; FRL–7731–1]

Terbacil; 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–2005–0215, must be received on or before October 7, 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: Sidney Jackson, Registration Division (7505C), Office of Pesticide Programs,

Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7610; e-mail address: *jackson.sidney@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. 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–2005–0215. 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–2005–0215. 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–2005–0215. 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–2005–0215.

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–2005–0215. 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: August 19, 2005.

Lois Rossi,

Director, Registration Division, Office of Pesticide Programs.

Summary of Petition

The petitioner summary of the pesticide petition is printed below as required by FFDCA section 408(d)(3). The summary of the petition was prepared by the petitioner and represents the view of the petitioner. The petition summary announces the availability of a description of the analytical methods available to EPA for the detection and measurement of the pesticide chemical residues or an explanation of why no such method is needed.

Interregional Research Project Number 4 (IR-4)

PP 3E6640

EPA has received a pesticide petition (PP 3E6640) from Interregional Research Project Number 4 (IR-4) on behalf of DuPont Crop Protection, P.O. Box 30, Newark, Delaware 19714-0030, proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR part 180 by establishing a tolerance for residues of the herbicide, terbacil (3-tert-butyl-5-chloro-6-methyluracil) and its metabolites [3-tert-butyl-5-chloro-6-hydroxymethyluracil], [6-chloro-2,3-dihydro-7-hydroxymethyl 3,3-dimethyl-5H-oxazolo(3,2-a) pyrimidin-5-one], and [6-chloro-2,3-dihydro-3,3,7-trimethyl-5H-oxazolo(3,2-a) pyrimidin-5-one] in or on the raw agricultural commodity watermelon at 1.0 parts per million (ppm). EPA has determined that the petition contains data or information regarding the elements set forth in section 408(d)(2) of the FFDCA; however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the petition. Additional data may be needed before EPA rules on the petition. This notice includes a summary of the petition that was prepared by DuPont Crop Protection.

A. Residue Chemistry

1. *Plant metabolism*. The metabolism and chemical nature of residues of terbacil in plants and animals are adequately understood. The fate of terbacil has been extensively studied using radioactive tracers in plant and animal metabolism/nature of the residue studies.

2. *Analytical method*. There is a practical analytical method utilizing microcoulometric gas chromatography with thermionic or nitrogen

phosphorous detection available for enforcement with a limit of detection that allows monitoring food with residues at or above tolerance levels. The limit of detection for the method determined by the lowest standard of 0.5 nanogram per microliter (ng/µl) was 0.05 ppm.

3. *Magnitude of residues*. Crop field trial residue data from a 69– to 94–day preharvest interval (PHI) study show that the proposed tolerance in or on watermelon at 1.0 ppm will not be exceeded when DuPont Sinbar (trade name) herbicide is used as directed.

B. Toxicological Profile

1. *Acute toxicity*. Terbacil technical has been placed in EPA Toxicity Category III for acute oral toxicity (rat lethal dose (LD_{50}) 934 milligram/kilogram (mg/kg) in female rats; 1,255 mg/kg in male rats); Category IV for acute inhalation lethal concentration (LC_{50}) >4.4 milligrams per liter (mg/L) in rats); Category IV for acute dermal (rabbit LD_{50} >5,000 mg/kg); and Category III for primary eye irritation (mild conjunctival effects clearing in 72 hours in rabbits). Although a primary dermal irritation study is not available on terbacil technical, the Agency indicated to the Registrant that if no dermal irritation was observed in a 21–day sub-chronic dermal study, then the requirements for the primary dermal irritation study would be satisfied. No dermal irritation was reported in that study. A dermal sensitization test on terbacil in guinea pigs showed no dermal sensitization.

2. *Genotoxicity*. Terbacil technical was tested and found negative in a Chinese hamster ovary (CHO) Hypoxanthine guanine phophoribosyl transferase (HGPRT) gene mutation assay when tested up to cytotoxic levels, with and without S-9 activation (cytotoxicity >3.0 micromolar (mM) without activation; >2.75 mM with activation). Terbacil technical was also negative for unscheduled DNA synthesis when tested up to cytotoxic levels (5 mM) in the rat. It was also negative for clastogenicity in a chromosomal aberration study in rat bone marrow cells, at doses up to 500 mg/kg.

3. *Reproductive and developmental toxicity*. Terbacil was tested in male and female rats at control and dietary levels of 50 or 250 ppm (equivalent to 2.5 or 12.5 mg/kg/day, over three generations. The first litter of each generation was discarded, and the second litter bred to produce the next generation. No reproductive effects were seen at the highest dose tested. Therefore, the no observed adverse effect level (NOAEL) for reproductive toxicity was equal to or greater than 250 ppm (12.5 mg/kg/day).

Terbacil has been tested in rats and rabbits for its potential to produce developmental toxicity. Rats were fed 0, 250, 1,250 or 5,000 ppm (equivalent to 0, 12.5, 62.5, or 250 mg/kg/day) of terbacil in the diet from days 6 through 15 of gestation. The developmental NOAEL was 250 ppm (12.5 mg/kg/day); the developmental LOAEL of 1,250 ppm (62.5 mg/kg/day) was based upon significantly decreased numbers of live fetuses per litter, apparently due to fetal loss occurring before or near the time of implantation. The maternal NOAEL was 250 ppm (12.5 mg/kg/day), based on decreased body weight at 1,250 ppm (62.5 mg/kg/day). Teratogenicity in pregnant rats was not demonstrated.

Rabbits were given doses of terbacil of 0, 30, 200, or 600 mg/kg/day by gavage, on gestation days 7 through 19. The maternal NOAEL was 200 mg/kg/day, based on maternal deaths (5 died and 2 were sacrificed in extremis) at the LOAEL of 600 mg/kg/day. The developmental NOAEL was also 200 mg/kg/day based on decreased live fetal weights in the high dose group. Teratogenicity in pregnant rabbits was not demonstrated.

4. *Subchronic toxicity.* Subchronic oral toxicity was tested in a 90–day feeding study in rats. A NOAEL of 100 ppm (equivalent to 5 mg/kg/day) and a LOAEL of 500 ppm, equivalent to 25 mg/kg/day highest dose tested (HDT) were established, based on increased absolute and relative liver weights, vacuolization and hypertrophy of hepatocytes. The data requirement for subchronic oral toxicity in a nonrodent was satisfied by a 2–year feeding study in beagle dogs, in which a NOAEL of 50 ppm (equivalent to 1.25 mg/kg/day) and a LOAEL of 250 ppm (equivalent to 7.2 mg/kg/day) were established, based on increased thyroid to body weight ratios, slight increase in liver weights, and elevated alkaline phosphatase levels.

Subchronic dermal toxicity was tested in a 21–day study in rabbits. Terbacil (80% active ingredient (a.i.)) was applied to prepared skin of male and female rabbits at 5,000 mg/kg/day, 5 hours/day, 5 days/week. No systemic toxicity was observed; mild scaling and staining were reported at the test sites.

5. *Chronic toxicity*. Terbacil 80% a.i. was administered to beagle dogs (4/sex/group) in the diet for 2 years, at doses of 50, 250, or 2,500/10,000 ppm (equivalent to 1.25, 6.25, 62.5/250 mg/kg/day). The NOAEL was 50 ppm (1.25 mg/kg/day) and the LOAEL was 250 ppm (6.25 mg/kg/day) based on increased thyroid to body weight ratios, slight increase in liver weights, and elevated alkaline phosphatase levels. Relative liver weights were also increased at 2,500 and 10,000 ppm in dogs sacrificed at 1 year and 2 years, respectively.

A 2–year rat study was conducted using terbacil 97.4% a.i. administered to male and female rats at dietary levels of 0, 25, 1,500, or 7,500 ppm (approximate doses for males of 0,0.9, 58, and 308 mg/kg/day and for females of 0, 1.4, 83/484 mg/kg/day). The systemic NOAEL is 25 ppm and the LOAEL is 1,500 ppm based on liver weight and centrilobular hypertrophy. The study was conducted at adequate dosages as demonstrated by the decrement in body weight gain in both sexes. There was no evidence of increased tumor incidence in the treated animals when compared to the controls.

Terbacil has been tested in a chronic 2–year feeding/oncogenicity study in mice at doses of 0, 50, 1,250, or 5,000/7,500 ppm (equivalent to 7, 179, 714/1,071 mg/kg/day). The increase in dose occurred after week 54. A systemic NOAEL of 50 ppm is based on the LOAEL of 1,250 ppm that resulted in mild hypertrophy of the centrilobular hepatocytes and decreased pituitary weights in males. Pituitary weight was also decreased in high-dose females. There was an increased incidence of lung neoplasms (adenomas and adenocarcinomas) in all treated male mice, which was not dose-related; in addition, these tumors were within the range of similar tumors observed in historical control mice.

6. *Animal metabolism*. Radiolabeled terbacil was tested in rats in single doses of 6.5 or 500 mg/kg; 97-103% of radioactivity was recovered within 5 days: 70-86% in urine, and 28% in feces. The major metabolites were glucuronide, sulfate, and N-acetylcysteine conjugates. The primary metabolic pathway is hydroxylation of the 6-methyl group to form the alcohol, which is conjugated to form the glucuronide (35% of the dose) and the sulfate derivatives (11%). Terbacil is also metabolized to the 5-hydroxy intermediate, which is further conjugated to form a sulfate derivative (17%).

7. *Metabolite toxicology*. The parent molecule is the only moiety of toxicological significance appropriate for regulation in plant and animal commodities.

8. *Endocrine disruption*. No observed effects reported.

C. Aggregate Exposure

1. *Dietary exposure*—i. *Food.* Tolerances have been established for the residues of terbacil in or on a variety of agricultural commodities. For purposes

of assessing dietary exposure, chronic and acute dietary assessments have been conducted using all existing and pending tolerances for terbacil. To estimate acute dietary risk, the endpoint selected was based on a rat development toxicity study in which the maternal and fetal NOAEL were 12.5 mg/kg/day. The reference dose (RfD) for systemic toxicity was determined for terbacil as 0.013 mg/kg/day, by the Agency's RfD committee in 1986. The RfD was calculated from a 2–year feeding study in dogs in which the NOAEL was 1.25 mg/kg/day (based on increased relative liver weights and increased serum alkaline phosphatase, seen at 7.25 mg/kg/day), and an uncertainty factor of 100. The RfD of 0.013 mg/kg/day was reaffirmed by the Agency's RfD Committee on September 1, 1994.

A Tier 1 (screening) assessment was conducted by DuPont; tolerance values, indicated below, were used in the assessment with no adjustments for processing or usage. (Alfalfa feed commodities are not included in the assessment because they are not consumed by humans.)

Commodity	Tolerance (ppm)
Apple	0.3
Asparagus	0.4
Blueberry	0.2
Caneberry Crop Subgroup 13B	0.2
Peach	0.2
Peppermint	2.0
Spearmint	2.0
Strawberry	0.1
Sugarcane	0.4
Watermelon	1.0 (proposed)

The chronic risk values were calculated with a chronic reference dose (cRfD) of 0.013 mg/kg body weight (bwt)/day. The chronic dietary exposure for the U.S. population was 0.000725 mg/kg bwt/day (5.6% of the cRfD). The most sensitive subpopulation was children 1-6 years old with a chronic dietary exposure of 0.002991 mg/kg bwt/day (23.0% of the cRfD).

The acute risk values were calculated with an acute reference dose (aRfD) of 0.125 mg/kg bwt/day. The acute dietary exposure (at the 95th percentile) for the U.S. population was 0.003071 mg/kg bwt/day (2.5% of aRfD). The most sensitive subpopulation was children 1-2 years old with an acute dietary exposure (at the 95th percentile) of 0.015641 mg/kg bwt/day(12.5% aRfD).

These results of Tier 1 (screening) assessments support the registrant's view that there is reasonable certainty of no harm from the use of this product as labeled/proposed.

Terbacil is classified as a Group E carcinogen—no evidence of carcinogenicity in either rats or mice. Therefore, a carcinogenicity risk analysis for humans is not required.

ii. *Drinking water.* Other potential dietary sources of exposure of the general population to pesticides are residues in drinking water.

For acute drinking water risk, the Drinking Water Levels of Concern (DWLOCs) were calculated using an aRfD (acute) endpoint of 0.125 mg/kg and compared to surface water or ground water EEC (estimated environmental concentration) values of 0.154 ppm and 0.125 ppm, respectively. The DWLOC values are as follows:

Population Subgroups	DWLOC Values (ppm)
U.S. Population	4.3
Non-Nursing Infants	1.1
Children 1-6 Years	1.1
Children 7-12 Years	1.2
Females 13+ Nursing	3.6
Males 13-19 Years	4.3
Seniors 55+	4.3

For chronic drinking water risk, the DWLOCs were calculated using a cRfD (chronic) endpoint of 0.013 mg/kg and compared to surface water or ground water EEC values of 0.105 ppm and 0.0089 ppm, respectively. The DWLOC values are as follows:

Population Subgroups	DWLOC Values (ppm)
U.S. Population	0.43
Non-Nursing Infants	0.10
Children 1-6 years	0.10
Children 7-12 Years	0.12
Females 13+ Nursing	0.36
Males 13-19 years	0.43
Seniors 55+	0.44

The estimated environmental concentrations are within acceptable ranges. Because of the conservative nature of the screening level dietary assessments performed, and the fact that actual ground water monitoring data, although limited, are not showing large amounts of terbacil present, DuPont does not believe that drinking water sources of terbacil are of concern.

2. *Non-dietary exposure.* Terbacil is not registered for any use that could result in non-occupational, non-dietary exposure to the general population. Alfalfa feed commodities were not included in the assessment because they are not consumed by humans.

D. Cumulative Effects

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency considers ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' 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 the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

In assessing the potential risk from cumulative effects of terbacil and other chemical substances, the Agency has considered structural similarities that exist between terbacil and other substituted uracil compounds such as bromacil and lenacil.

A comparison of the available toxicological database for terbacil and bromacil revealed no clear common mode of toxicity for these chemicals. The toxicology database for lenacil was not considered because there are currently no registered uses of lenacil. A summary of the most prominent clinical

signs from terbacil and bromacil follows.

The following clinical signs were observed in the terbacil toxicology database: Decrease in body weight, increase in liver weights, vacuolization and hypertrophy of hepatocytes, hypertrophy of centrilobular hepatocytes in males, decreased pituitary weights in males and females, increase in thyroid/body weight ratio, and elevated alkaline phosphatase.

The following clinical signs were observed in the bromacil toxicology database: Decreased body weight, focal atrophy of seminiferous tubules (testicular abnormalities), hydronephrosis, suggestive histological evidence for antithyroid activity (cystic follicles in the thyroid and enlargement of centrilobular cells of the liver), and a positive trend in thyroid tumors for male rats (basis of C classification for carcinogenicity).

Based on these data, DuPont concludes that there is no clear common mode of toxicity (thyroid or liver) between terbacil and bromacil. With both chemicals, there is marginal evidence of liver effects (principally enlargement of centrilobular cells). Enlargement of liver cells is not a specific enough effect to be considered a common mode of toxicity. The thyroid effects observed with bromacil were cystic follicles. Terbacil induced an increase in relative thyroid weights but no increase in absolute thyroid weights. An increase in relative weight without a corresponding increase in absolute weight has very little meaning, especially without any supporting histological or hormonal evidence. This conclusion was based on the marginal liver effects noted in the databases, and the absence of thyroid effects in the terbacil database (with the exception of increases in relative thyroid weights).

DuPont has no information indicating that any other chemical has a common mode of toxicity with terbacil and, therefore concludes that an aggregate risk assessment will indicate risks resulting only from terbacil.

E. Safety Determination

1. *U.S. population*. EPA has determined that the established tolerances for terbacil meet the safety standards under the FQPA amendments to section 408(b)(2)(D) for the general population. In reaching this determination, EPA has considered available information on aggregate exposures (both acute and chronic) from non-occupational sources, food and drinking water, as well as the possibility of cumulative effects from terbacil and other chemicals with similar mechanism of toxicity.

Since there are no residential or lawn uses of terbacil, no dermal or inhalation exposure is expected in and around the home.

In assessing acute dietary risk from food, the endpoint selected was developmental toxicity. Because the endpoint of concern is a developmental effect, the only sub-population of concern is females of child-bearing age (i.e., females, 13+ years old).

The acute risk values were calculated by DuPont with an aRfD of 0.125 mg/kg bwt/day. The acute dietary exposure (at the 95th percentile) for the U.S. population was 0.003071 mg/kg bwt/day (2.5% of aRfD). The most sensitive subpopulation was children 1-2 years old with an acute dietary exposure (at the 95th percentile) of 0.015641 mg/kg bwt/day (12.5% aRfD).

The chronic risk values were calculated by DuPont with a cRfD of 0.013 mg/kg bwt/day. The chronic dietary exposure for the U.S. population was 0.000725 mg/kg bwt/day (5.6% of the cRfD). The most sensitive subpopulation was children 1-6 years old with a chronic dietary exposure of 0.002991 mg/kg bwt/day (23.0% of the cRfD).

In evaluating the potential for cumulative effects, EPA compared terbacil with other structurally similar substituted uracil compounds, such as bromacil and lenacil, and then with other compounds producing similar effects. A comparison of the available toxicological database for terbacil and bromacil revealed no clear common mode of toxicity for the chemicals. The toxicology database for lenacil was not considered because there are currently no registered uses of lenacil. Based on the available data, the Agency has determined that there is no clear common mode of toxicity between terbacil and bromacil.

2. *Infants and children*. EPA has determined that the established tolerances for terbacil meet the safety standard under the FQPA amendment to section 408(b)(2)(C) for infants and children. The safety determination for infants and children considers the factors noted above for the general population, but also takes into account the possibility of increased dietary exposure due to the specific consumption patterns of infants and children, as well as the possibility of increased susceptibility to the toxic effects of terbacil residues in this population subgroup.

In determining whether or not infants and children are particularly susceptible to toxic effects from terbacil residues, EPA considered the completeness of the database for developmental and reproductive effects, the nature of the effects observed, and other information.

Based on current data requirements, terbacil has a complete database for developmental and reproductive toxicity. Because the developmental NOAELs were the same as those for maternal toxicity, and the NOAEL for systemic (parental) toxicity was higher than the NOAEL for reproductive toxicity, DuPont believes that these data do not suggest an increased pre- or post-natal sensitivity of children and infants to terbacil exposure. Therefore, DuPont concludes that the available toxicology data do not support an uncertainty factor of 1,000 as specified in FQPA and that the present uncertainty factor of 100 is adequate to ensure the protection of infants and children from exposure to terbacil.

It is estimated by DuPont that terbacil exposure from the chronic diet is as follows: All infants less than 1 year—18% of the cRfD; Nursing infants—9.7% of the cRfD; Non-nursing infants—21.2% of the cRfD; Children 1-6 years—23% of the cRfD.

F. International Tolerances

There are no established Codex maximum residue levels (MRL's) or international tolerances for terbacil on watermelon.

[FR Doc. 05–17529 Filed 9–6–05; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[OPPT–2005–0045; FRL–7735–9]

Certain New Chemicals; Receipt and Status Information

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: Section 5 of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture (defined by statute to include import) a new chemical (i.e., a chemical not on the TSCA Inventory) to notify EPA and comply with the statutory provisions pertaining to the manufacture of new chemicals. Under sections 5(d)(2) and 5(d)(3) of TSCA, EPA is required to publish a notice of receipt of a premanufacture notice (PMN) or an application for a test marketing exemption (TME), and to publish periodic status reports on the chemicals under review and the receipt of notices of commencement to manufacture those chemicals. This status report, which