

II. Background

A. What Action is the Agency Taking?

EPA has reassessed the uses of procymidone, and on July 7, 2005, reached a tolerance reassessment decision for this pesticide. Procymidone is a fungicide used to treat wine grapes outside of the United States. A tolerance of 5 parts per million for wine grapes has been established, with no U.S. registrations, to permit the import of wine produced from procymidone treated grapes. Currently, procymidone exposures to the U.S. general population exist only through drinking imported wine made from procymidone treated grapes. Since there are no registered uses of procymidone in the U.S., no occupational, residential, or drinking water exposures are expected. EPA has not made a common mechanism of toxicity finding and therefore, has not assumed that procymidone has a common mechanism of toxicity with other substances for the purposes of this tolerance action.

The Agency is now issuing for comment the resulting Report on Food Quality Protection Act (FQPA) Tolerance Reassessment Progress and Risk Management Decision for procymidone, known as a TRED, as well as related risk assessments and technical support documents. EPA developed the procymidone TRED through a modified, streamlined version of its public process for making tolerance reassessment and reregistration eligibility decisions. Through these programs, the Agency is ensuring that pesticides meet current standards under the Federal Food, Drug, and Cosmetic Act (FFDCA) and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended by FQPA. EPA must review tolerances and tolerance exemptions that were in effect when the FQPA was enacted, to ensure that these existing pesticide residue limits for food and feed commodities meet the safety standard established by the new law. Tolerances are considered reassessed once the safety finding has been made or a revocation occurs. EPA has reviewed and made the requisite safety finding for the procymidone tolerance included in this notice.

EPA is applying the principles of public participation to all pesticides undergoing reregistration and tolerance reassessment. The Agency's Pesticide Tolerance Reassessment and Reregistration; Public Participation Process, published in the **Federal Register** of May 14, 2004 (69 FR 26819) (FRL-7357-9), explains that in conducting these programs, the Agency

is tailoring its public participation process to be commensurate with the level of risk, extent of use, complexity of issues, and degree of public concern associated with each pesticide. EPA can expeditiously reach decisions for pesticides like procymidone, which pose no risk concerns and require no risk mitigation. Once EPA assesses uses and risks for such pesticides, the Agency may go directly to a decision and prepare a document summarizing its findings, such as the procymidone TRED.

The tolerance reassessment program is being conducted under Congressionally mandated time frames, and EPA recognizes the need both to make timely decisions and to involve the public in finding ways to effectively mitigate pesticide risks. Procymidone, however, poses no risks that require mitigation. The Agency therefore is issuing the procymidone TRED, its risk assessments, and related support documents simultaneously for public comment. The comment period is intended to provide an opportunity for public input and a mechanism for initiating any necessary amendments to the TRED. All comments should be submitted using the methods in Unit I. of the **SUPPLEMENTARY INFORMATION**, and must be received by EPA on or before the closing date. These comments will become part of the Agency Docket for procymidone. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

EPA will carefully consider all comments received by the closing date and will provide a Response to Comments Memorandum in the Docket and electronic EDOCKET. If any comment significantly affects the document, EPA also will publish an amendment to the TRED in the **Federal Register**. In the absence of substantive comments requiring changes, the decisions reflected in the TRED will be implemented as presented.

B. What is the Agency's Authority for Taking this Action?

Section 408(q) of the FFDCA, 21 U.S.C. 346a(q), requires EPA to review tolerances and exemptions for pesticide residues in effect as of August 2, 1996, to determine whether the tolerance or exemption meets the requirements of section 408(b)(2) or (c)(2) of FFDCA. This review is to be completed by August 3, 2006.

List of Subjects

Environmental protection, Pesticides and pests.

Dated: August 15, 2005.

Debra Edwards,

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

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ENVIRONMENTAL PROTECTION AGENCY

[OPP-2005-0206; FRL-7726-3]

Fipronil; 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-2005-0206, must be received on or before September 23, 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: 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 are 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-2005-0206. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets. Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public

docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing in EPA's electronic public docket as EPA receives them and without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. When EPA identifies a comment containing copyrighted material, EPA will provide a reference to that material in the version of the comment that is placed in EPA's electronic public docket. The entire printed comment, including the copyrighted material, will be available in the public docket.

Public comments submitted on computer disks that are mailed or delivered to the docket will be transferred to EPA's electronic public docket. Public comments that are mailed or delivered to the docket will be scanned and placed in EPA's electronic public docket. Where practical, physical objects will be photographed, and the photograph will be placed in EPA's electronic public docket along with a brief description written by the docket staff.

C. How and to Whom Do I Submit Comments?

You may submit comments electronically, by mail, or through hand delivery/courier. To ensure proper receipt by EPA, identify the appropriate docket ID number in the subject line on the first page of your comment. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments. If you wish to submit CBI or information that is otherwise protected by statute, please follow the instructions in Unit I.D. Do not use EPA Dockets or e-mail to submit CBI or information protected by statute.

1. *Electronically.* If you submit an electronic comment as prescribed in this unit, EPA recommends that you include your name, mailing address, and an e-mail address or other contact information in the body of your comment. Also include this contact information on the outside of any disk or CD ROM you submit, and in any cover letter accompanying the disk or CD ROM. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. EPA's policy is that EPA will not edit your comment, and any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

i. *EPA Dockets.* Your use of EPA's electronic public docket to submit comments to EPA electronically is EPA's preferred method for receiving comments. Go directly to EPA Dockets at <http://www.epa.gov/edocket/>, and follow the online instructions for submitting comments. Once in the system, select "search," and then key in docket ID number OPP-2005-0206. 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-2005-0206. 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-2005-0206.

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-2005-0206. 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 15, 2005.

Donald R. Stubbs,

Acting 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.

BASF Corporation

5F6948 and 2E6490

EPA has received a pesticide petition (5F6948) from BASF Corporation, P.O. Box 13528, Research Triangle Park, NC 27709 proposing, pursuant to section 408(d) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C.

346a(d), to amend 40 CFR 180.517 by establishing a tolerance for residues of mixture comprising fipronil, 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(1R,S)-(trifluoromethyl)sulfinyl]-1H-pyrazole-3-carbonitrile and its metabolites 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl) sulfonyl]-1H-pyrazole-3-carbonitrile and 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)thio]-1H-pyrazole-3-carbonitrile and its photodegrade 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(1R,S)-(trifluoromethyl)-1H-pyrazole-3-carbonitrile in or on the raw agricultural commodity corm vegetables (crop group 1-C at 0.04 parts per million (ppm), and indirect and inadvertent residues on wheat, grain at 0.005 and wheat, forage at 0.02 ppm and wheat, hay and straw at 0.03 ppm. EPA has received a pesticide petition 2E6490 from The Interregional Research Project No. 4 (IR-4), Technology Centre of New Jersey, Rutgers, the State University of New Jersey, 681 U.S. Highway 1 South, North Brunswick, NJ 08902-3390 proposing, pursuant to section 408(d) of the FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR 180.517 by establishing a tolerance for residues of mixture comprising fipronil, 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(1R,S)-trifluoromethyl)sulfinyl]-1H-pyrazole-3-carbonitrile and its metabolites 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl) sulfonyl]-1H-pyrazole-3-carbonitrile and 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)thio]-H-pyrazole-3-carbonitrile and its photodegrade 5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(1R,S)-(trifluoromethyl)-1H-pyrazole-3-carbonitrile in or on the raw agricultural commodities onion (dry bulb), garlic, shallot (dry bulb) at 0.02 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.

A. Residue Chemistry

1. *Plant metabolism.* The metabolism of fipronil is adequately understood. Adequate data on the nature of the residues in both plant and animals, including identification of major

metabolites and degradates of fipronil, are available. In plants and animal the metabolism of fipronil proceeds via oxidation of the sulfoxide to yield sulfone and hydrolysis of nitrile to yield the amide. Fipronil and its sulfone and amide constitute greater than 75% of the identified residues in all studies. A limited amount of reduction of sulfoxide to yield the sulfide occurs in some cases. Further transformation of primary metabolites affords minor amounts of carboxylic acid, the amide and the 4-protopyrazole.

2. *Analytical method.* Validated analytical methods are available for detecting and measuring levels of fipronil and its metabolites in onion, dry bulb, potato (corn vegetables) and

its processing fractions and wheat grain, forage, hay, and straw. The Method utilizes Capillary Gas Chromatography equipped with a Ni electron capture detector. The Limit of Quantitation (LOQ) for all potato matrices is 0.003 ppm for all analytes. The LOQ for onion is 0.005 for all analytes.

3. *Magnitude of residues.* Field trials were carried out in order to determine the magnitude of residue in potato. Field trials were conducted in the required regions. Field trials were carried out using the maximum label rate of 0.1 lbs active ingredient (a.i.) per acre applied in furrow followed by four sequential foliar applications at 0.05 lbs a.i. per acre. The results demonstrate that any residue present would originate

from the in-furrow not the foliar applications. In addition a processing study was conducted on potatoes. Onion field trials were conducted in the required regions. The application was by seed treatment at 25 grams of active ingredient/kilogram (g a.i./Kg) of seed. Twelve field trials were conducted where wheat was planted following application to primary crops. Applications rates were 0.13 lbs a.i. per acre in-furrow for six corn trials and 0.2 lbs a.i. per acre foliar for six cotton trials.

B. Toxicological Profile

1. *Acute toxicity.* For technical fipronil:

Oral LD ₅₀	Rat	LD ₅₀ = 97 mg/kg b.w.	category II/(moderately toxic)
Dermal LD ₅₀	Rat	LD ₅₀ >2,000 mg/kg b.w. (HDT)	category III (slightly toxic)
Dermal LD ₅₀	Rabbit	LD ₅₀ = 354 mg/kg b.w.	category II(moderately toxic)
Inhalation LC ₅₀	Rat	LC ₅₀ = 0.39 mg/L	category II(moderately toxic)
Eye Irritation	Rabbit	slight irritation	category III
Skin Irritation	Rabbit	slight irritation	category IV
Skin Sensitization (Maximization Test)	Guinea pig	Not sensitizing	
Acute Neurotoxicity	Rat	NOAEL = 2.5 mg/kg/day (for general toxicity)	

2. *Genotoxicity.* Fipronil was negative in both *in vitro* and *in vivo* assays conducted to investigate gene mutations, DNA damage, and chromosomal aberrations.

3. *Reproductive and developmental toxicity.* The developmental toxicity NOELs in the rat and rabbit were 20 mg/kg/day (HDT) and 1 mg/kg/day (HDT), respectively. Maternal toxicity was observed in the rat at the HDT as evidenced by decreased body weight gain and food efficiency. In the rabbit, the maternal toxicity NOAEL was less than 0.1 mg/kg/day, based on reduced body weight gain and food efficiency at all dose levels tested. In a two-generation rat study, the NOEL for parental (systemic) toxicity was 3 ppm (0.26 mg/kg/day for both sexes combined), based on increased weight of the thyroid glands and liver in males and females, decreased weight of the pituitary gland in females, and an increased incidence of follicular epithelial hypertrophy in females at 30 ppm. The NOEL for reproductive toxicity was 30 ppm (2.64 mg/kg/day for both sexes combined), based on clinical signs of toxicity in pups, decreased litter size, decreased pup body weights,

decreased mating, decreased fertility index, reduced pre- and postnatal survival, and delays in physical development at 300 ppm (26.03 and 28.40 mg/kg/day for males and females, respectively).

In a developmental neurotoxicity study in the rat, the NOAEL for maternal toxicity was 10 ppm (0.91 mg/kg/day), based on decreased body weights and body weight gain at 200 ppm (HDT; 15 mg/kg/day). Considerable maternal toxicity at the HDT prevented adequate neurotoxicity evaluation of pups at this dose level. There was no evidence of neurotoxicity at 10 ppm (0.91 mg/kg/day), which was the NOAEL for developmental neurotoxicity. The NOAEL for general developmental toxicity was 0.5 ppm (0.05 mg/kg/day), based on systemic effects consisting of decreases in pup weights during lactation and increases in time of preputial separation in males at 10 ppm.

4. *Subchronic toxicity.* The NOAEL for systemic toxicity in rat was 5 ppm (0.35 mg/kg/day for both sexes combined), based on alterations in serum protein values and increased weight of the liver and thyroid at 30

ppm (1.93 and 2.28 mg/kg/day for males and females, respectively). The NOAELs in the dog were 2 and 0.5 mg/kg/day for male and female, respectively, based on clinical signs of toxicity in males at 10 mg/kg/day and clinical signs of toxicity and decreased body weight gain in females at 2 mg/kg/day. The NOAEL for mice was 10 ppm (1.27 and 1.72 mg/kg/day for males and females, respectively), based on a possible decreased body weight gain at 25 ppm (3.2 and 4.53 mg/kg/day for males and females, respectively). A repeated dose dermal study in the rabbit had a systemic NOAEL of 5 mg/kg/day, based on decreased body weight gain and food consumption at 10 mg/kg/day, and a dermal irritation NOEL of 10.0 mg/kg/day (HDT).

In a subchronic neurotoxicity study in rats, the NOEL was 5 ppm (0.301 and 0.351 mg/kg/day for males and females, respectively), based on results of the functional observational battery (FOB) at 150 ppm (8.89 and 10.8 mg/kg/day for males and females, respectively).

5. *Chronic toxicity.* The NOAEL for systemic toxicity in a 1-year feeding study in the dog was 0.3 mg/kg/day in females and 1 mg/kg/day in males,

based on clinical signs of neurotoxicity at 1 and 2 mg/kg/day in females and males, respectively. The NOAEL for systemic toxicity in mice was 0.5 ppm (0.06 mg/kg/day) based on decreased body weight gain, decreased food conversion efficiency in males, increased liver weights, and liver histopathology at 10 ppm (1.3 mg/kg/day). Fipronil was not carcinogenic when administered to mice at dose levels up to 60 ppm. The NOAEL in a 2-year dietary study in the rat was 0.5 ppm (0.019 and 0.025 mg/kg/day for males and females, respectively) based on clinical signs of toxicity and alterations in clinical chemistry and thyroid parameters at 1.5 ppm (0.059 and 0.078 mg/kg/day for males and females, respectively). The EPA's Health Effects Division Carcinogenicity Peer Review Committee classified fipronil in Group C - Possible Human Carcinogen, based on thyroid tumors observed in rats at 300 ppm (HDT). Mechanistic data indicate that these tumors are related to a disruption in the thyroid-pituitary status and are specific to the rat. In addition, there was no apparent concern for mutagenic activity. Thus, it was recommended that RfD methodology, i.e. non-linear or threshold, be used for the estimation of human risk.

6. *Animal metabolism.* The metabolism of fipronil is adequately understood. Adequate data on the nature of residues in both plants and animals, including identification of major metabolites and degradates of fipronil, are available. In plants and animals the metabolism of fipronil proceeds via oxidation of the sulfoxide to yield sulfone and hydrolysis of nitrile to yield the amide. Fipronil and its sulfone and amide constitute greater than 75% of the identified residues in all studies. A limited amount of reduction of sulfoxide to yield the sulfide occurs in some cases. Further transformation of the primary metabolites affords minor amounts of the carboxylic acid, the amide and the 4-protiopyrazole.

7. *Metabolite toxicology.* MB46513 photodegrade acute oral toxicity:

Oral LD ₅₀	Rat LD ₅₀ = 16 mg/kg b.w.	category I (highly toxic)
Dermal LD ₅₀	Rabbit LD ₅₀ > 2,000 mg/kg b.w. (HDT)	category III (slightly toxic)

i. *Acute neurotoxicity.* The NOEL was 2 mg/kg, based on decreases in body weight gain and food consumption in

males and females during the week following treatment, decreases in locomotor activity, hind-limb splay and rectal temperature 6-hour post dosing in males and females, and decreases in the proportion of males with an immediate righting reflex on days 7 and 14, at 12 mg/kg/day.

In a rat developmental toxicity study, the NOEL was 1 mg/kg/day, based on the slight increase in fetal and litter incidence of reduced ossification of several bones at 2.5 mg/kg/day.

ii. *Subchronic toxicity.* The NOAEL in the rat was 3 ppm (0.18 and 0.21 mg/kg/day in males and females, respectively), based on clinical signs of toxicity in both sexes and decreased body weight and body weight gain in males at 10 ppm. The NOEL for the mouse was 0.5 ppm (0.08 mg/kg/day), based on the aggressive and irritable behavior with increased motor activity in males at 2 ppm. The NOEL for the dog was 9.5 ppm (0.29 mg/kg/day), based on behavioral changes in females at 35 ppm (1.05 mg/kg/day).

The rat chronic/carcinogenicity study was negative for carcinogenicity. The LOAEL for females was 0.5 ppm (0.032 mg/kg/day), based on clinical signs of toxicity. There was no NOEL established. For males, the NOAEL was 2 ppm (0.098 mg/kg/day), based on clinical signs of toxicity, and stomach and lung histopathology at 10 ppm (0.497 mg/kg/day). No thyroid effects are observed in any of the rat, mouse or dog studies with MB46513, supporting the conclusion that there is no concern for cancer due to exposure to MB46513.

8. *Endocrine disruption.* Data from the reproduction/ developmental toxicity and short- and long-term repeated dose toxicity studies with fipronil in the rat, rabbit, mouse, or dog, do not suggest any endocrine disruption activity. This information is based on the absence of any treatment-related effects from the histopathological examination of reproductive organs as well as the absence of possible effects on fertility, reproductive performance, or any other aspect of reproductive function, or on growth and development of the offspring. Evidence of offspring toxicity was observed only in the presence of significant parental toxicity. Fipronil disrupts the thyroid-pituitary axis. However, mechanistic studies have demonstrated that fipronil decreases thyroid hormone levels in long-term studies via increased clearance, rather than a direct effect on the thyroid.

Concerns related to long-term exposure of fipronil are addressed in human risk estimates, as the chronic RfD (0.0002 mg/kg/day) is based on endpoints that

include thyroid hormone related effects in rats.

C. Aggregate Exposure

1. *Dietary exposure.* An assessment was conducted to determine the acute and chronic exposure of all population sub-groups to residues of fipronil. Tolerance values have previously been established and are listed in 40 CFR 180.517.

This analysis included all crops with established tolerance values and the proposed new crops of white potato, sweet potato, onion bulb, garlic, shallot bulb and the inadvertent residue tolerance on wheat grain. The dietary exposure assessment for crops with established tolerances was conducted by the U.S. Environmental Protection Agency in 2001 (PP# 7F04832. Fipronil in/on Cotton. HED Risk Assessment. Barcode D248827; PC Code 129121; Case 288765 ; submission S547814). Using these dietary exposure values is conservative because the registration for fipronil on cotton was withdrawn, and the dietary exposure assessment conducted by HED included all currently registered uses and the proposed cotton use. Using the HED exposure values is conservative (overestimates actual exposure) because the cotton use and all requested modifications to existing tolerances were included in the dietary exposure assessment.

The dietary exposure assessment for white potato, sweet potato, onion bulb, garlic, and shallot bulb were conducted using tolerance level residues, default processing factors, and 100% crop treated factors. These assumptions are conservative because it assumes all commodities will be at tolerance level and 100% of the crop has been treated with fipronil. The dietary exposure assessment for the inadvertent residues in wheat grain was conducted using tolerance level residues, default processing factors, and a 7% crop treatment factor. The U.S. EPA used a 7% crop treatment factor for corn in the dietary exposure assessment. The tolerance for wheat grain is from inadvertent residues that would occur when wheat is planted following a fipronil treatment of corn. Therefore, the 7% crop treatment factor applies to wheat inadvertent residues.

The dietary exposure assessments were conducted using the Dietary Exposure Evaluation Model software with Food Commodity Intake Database (DEEM-FCID).

i. *Food—*a. *Acute dietary exposure assessment.* The acute population adjusted dose (aPAD) used was 0.025 mg/kg bw/day. Using the exposure

assumptions discussed above, the maximum fipronil acute dietary exposure from food is 11% aPAD. The results of the acute dietary assessment are presented in Table 1.

TABLE 1.—COMBINATION OF THE ACUTE DEEM™ DIETARY ANALYSIS AT 95TH PERCENTILE FOR FIPRONIL CONDUCTED BY THE US EPA FOR EXISTING USES AND BASF FOR THE USE ON WHITE AND SWEET POTATOES

Subgroups	Exposure (mg/kg bw/day)	% aPAD ^a
U.S. Population	0.001495	6
All Infants (<1 year old)	0.002502	10
Children (1–6 years old)	0.002859	11
Children (7–12 years old)	0.001814	7
Females (13–50 years old)	0.0009342	4
Males (13–19 years old)	0.001332	5
Males (20+ years old)	0.000962	4
Seniors (55+ years old)	0.0007642	3

^a The aPAD = 0.025 mg/kg bw/day.

b. *Chronic dietary exposure assessment.* The chronic population adjusted dose (cPAD) used was 0.0002 mg/kg bw/day. Using the exposure assumptions discussed above, the maximum fipronil chronic dietary

exposure from food is 56% cPAD. The results of the chronic dietary assessment are presented in Table 2.

TABLE 2.—COMBINATION OF THE CHRONIC DEEM™ DIETARY ANALYSIS FOR FIPRONIL CONDUCTED BY THE U.S. EPA FOR EXISTING USES AND BASF FOR THE USE ON WHITE AND SWEET POTATOES

Subgroups	Exposure (mg/kg bw/day)	% cPAD ^a
U.S. Population	0.0000546	27
All Infants (< 1 year old)	0.0000685	34
Children (1–6 years old)	0.0001114	56
Children (7–12 years old)	0.0000738	37
Females (13–50 years old)	0.0000420	21
Males (13–19 years old)	0.0000619	31
Males (20+ years old)	0.0000494	25
Seniors (55+ years old)	0.0000425	21

^a The cPAD = 0.0002 mg/kg bw/day.

ii. *Drinking water.* The drinking water values used for comparison to the DWLOC (Drinking Water Level of Comparison) can be calculated from model estimates or actual monitoring data. When modeling was conducted, the currently registered corn use resulted in the highest predicted estimated water concentrations. If monitoring data is available it can be used instead of model predictions. A drinking water monitoring study for fipronil and relevant metabolites in surface water from the corn growing regions has been conducted (MRID 45526101). Therefore, these actual

measured drinking water values will be used in the drinking water assessment. The ground water values model by the EPA when the cotton use was examined will also be used for comparison. Based on the tier I screening model SCI-GROW (screening concentration in ground water), the acute ground water value will not exceed 0.061 ppb (0.032 µg/L for fipronil, 0.012 µg/L for MB46136, 0.016 µg/L for MB46513, and 0.001 µg/L for MB45950). This value of 0.061 ppb is also used for chronic ground water comparisons.

In the drinking water monitoring study, water samples were collected from 12 municipal water treatment facilities. The water treatment facilities were selected based on the source of water and the previously documented use of fipronil in the watershed area. Raw and finished water samples were collected at each water treatment site. The samples were collected on regular intervals between April and August. The water samples were analyzed for fipronil and metabolites: MB45950, MB46136, and MB46513. The LOQ for the method was 10 parts per trillion (ppt) and the LOD was 4 ppt. No residues were detected in any of the finished water samples and no confirmed fipronil-related residues were found in any of the raw samples. This study showed that the use of fipronil in corn production does not pose a risk to surface drinking water.

a. *Acute aggregate exposure and risk (food and water).* The acute dietary risk associated with the existing fipronil uses and the proposed use of white and sweet potatoes does not exceed a level of concern. The estimated exposure at the 95th percentile uses ≤ 11% of the aPAD (Table 1). The surface water and ground water estimated concentrations were used to compare to the DWLOC. The estimated water concentrations are less than the calculated DWLOC (Table 3). Therefore, it can be concluded with reasonable certainty that residues of fipronil and metabolites in drinking water do not contribute significantly to the acute aggregate human health risk.

TABLE 3.—ACUTE AGGREGATE EXPOSURE FOR THE USE OF FIPRONIL ON WHITE POTATOES, SWEET POTATOES, AND ALL EXISTING USES

Population Subgroup	aPAD mg/kg/day	Dietary Exposure ¹ , mg/kg/day	Allowable Drinking Water Exposure ² , mg/kg/day	DWLOC, ppb	Surface Water ³ , ppb	Ground Water EEC, ppb
U.S. Population	0.025	0.001495	0.023505	823	0.04	0.061
All Infants (< 1 year old)	0.025	0.002502	0.022498	225	0.04	0.061

TABLE 3.—ACUTE AGGREGATE EXPOSURE FOR THE USE OF FIPRONIL ON WHITE POTATOES, SWEET POTATOES, AND ALL EXISTING USES—Continued

Population Subgroup	aPAD mg/kg/day	Dietary Exposure ¹ , mg/kg/day	Allowable Drinking Water Exposure ² , mg/kg/day	DWLOC, ppb	Surface Water ³ , ppb	Ground Water EEC, ppb
Children (1-6 years old)	0.025	0.002859	0.022141	221	0.04	0.061
Children (7-12 years old)	0.025	0.001814	0.023186	232	0.04	0.061
Females (13-50 years old)	0.025	0.0009342	0.024066	722	0.04	0.061
Males (13-19 years old)	0.025	0.001332	0.023668	828	0.04	0.061
Males (20+ years old)	0.025	0.000962	0.024038	841	0.04	0.061
Seniors (55+ years old)	0.025	0.0007642	0.024236	848	0.04	0.061

¹ The dietary exposure values are from Table 1.

² Allowable Drinking Water Exposure (mg/kg/day) = aPAD (mg/kg/day) - Acute Dietary Exposure (mg/kg/day).

³ The surface water concentration is the sum of the LOQ for fipronil, and metabolites: MB45950, MB46136, and MB46513 (0.04 µg/L = 0.01 + 0.01 + 0.01).

b. *Short- and intermediate-term aggregate exposure and risk (food, water and residential exposure).* Short- and intermediate-term aggregate exposure takes into account residential exposure plus chronic exposure from food and water. Aggregation of systemic oral, dermal and inhalation exposure from the residential use is not appropriate due to differences in the toxicity endpoints observed between oral (neurotoxicity and alterations in clinical chemistry and thyroid parameters), dermal (decrease in body weight gain and food consumption) and inhalation (developmental effects including decreases in pup weights during lactation and increases in time of preputial separation) routes. Also, there is no significant post-application exposure to adults. However, post-

application exposure to children is included in the exposure assessment.

Post-application exposure of children can occur from three scenarios: (1) Incidental ingestion of fipronil pellets or granules; (2) incidental ingestion of soil (hand to mouth) from fipronil treated residential areas; and (3) incidental ingestion (hand to mouth) of fipronil from treated pets. EPA's OPP Health Effects Division believes that exposure from scenario 1 is episodic and is only a one time occurrence and episodic exposure is not aggregated with food and water. Exposure from scenario #3 (3×10^{-5} mg/kg/day) is greater than scenario #2 (1.2×10^{-6} mg/kg/day) and therefore this exposure will be aggregated with food and water exposure.

The short- and intermediate-term exposure risk assessment was only

determined for the most highly exposed subpopulation which is children 1-6 years old (Table 4). The target MOE for short- and intermediate- term exposure risk assessment is 300 and therefore, the maximum allowable exposure is 0.00033 mg/kg bw/day (LOAEL, 0.1/300 safety factor). The short- and intermediate term MOE for children 1-6 years of age is 707 which is greater than 300. Also, the calculated DWLOC is greater than the predicted chronic surface and ground water concentrations. Therefore, taking into account all registered uses and the white and sweet potato uses, it can be concluded with reasonable certainty that residues of fipronil and metabolites in drinking water will not result in short- and intermediate-term aggregate human health risks.

TABLE 4.—SHORT- AND INTERMEDIATE-TERM AGGREGATE EXPOSURE AND DWLOC CALCULATIONS FOR CHILDREN 1–6 YEARS OLD FOR THE USE OF FIPRONIL ON WHITE POTATOES, SWEET POTATOES, AND ALL EXISTING USES

Max Exposure ¹ , mg/kg/day	Chronic Food Exposure ² , mg/kg/day	Residential Exposure ³ , mg/kg/day	Short-and Intermediate-Term Aggregate MOE (food and Residential) ⁴	Maximum Water Exposure, mg/kg/day ⁵	DWLOC, ppb	Surface Water ⁶ , ppb	Ground Water EEC, ppb
0.00033	0.0001114	0.00003	707	0.0001886	1.886	0.04	0.061

¹ Maximum Exposure (mg/kg/day) = LOAEL / Target MOE (0.1 / 300).

² Chronic food exposure for children 1–6 years of age is from Table 2.

³ Residential exposure is for incidental ingestion (hand to mouth) of fipronil from treated pets.

⁴ Aggregator MOE = [LOAEL/(chronic food exposure + residential exposure)].

⁵ Maximum water exposure (mg/kg/day) = Target maximum exposure - (Food exposure and Residential exposure).

⁶ The surface water concentration is the sum of the LOQ for fipronil, and metabolites: MB45950, MB46136, and MB46513 (0.04 µg/L = 0.01 + 0.01 + 0.01).

c. *Chronic aggregate exposure and risk (food and water).* The chronic dietary risk associated with the existing

fipronil uses and the proposed use of white and sweet potatoes does not exceed a level of concern. The estimated

exposures for all subpopulations are ≤ 56% of the cPAD (Table 2). The surface water and ground water estimated

concentrations were used to compare to the DWLOC. The estimated water concentrations are less than the

calculated DWLOC (Table 5). Therefore, it can be concluded with reasonable certainty that residues of fipronil and

metabolites in drinking water do not contribute significantly to the chronic aggregate human health risk.

TABLE 5.—CHRONIC AGGREGATE EXPOSURE FOR THE USE OF FIPRONIL ON WHITE POTATOES, SWEET POTATOES, AND ALL EXISTING USES

Population Subgroup	cPAD,mg/kg/day	Dietary Exposure ¹ , mg/kg/day	Allowable Drinking Water Exposure ² , mg/kg/day	DWLOC, ppb	Surface Water ³ , ppb	Ground Water EEC, ppb
U.S. Population	0.0002	0.0000546	0.0001454	5.09	0.04	0.061
All Infants (< 1 year old)	0.0002	0.0000685	0.0001315	1.32	0.04	0.061
Children (1–6 years old)	0.0002	0.0001114	0.0000886	0.89	0.04	0.061
Children (7–12 years old)	0.0002	0.0000738	0.0001262	1.26	0.04	0.061
Females (13–50 years old)	0.0002	0.0000420	0.0001580	4.74	0.04	0.061
Males (13–19 years old)	0.0002	0.0000619	0.0001381	4.83	0.04	0.061
Males (20+ years old)	0.0002	0.0000494	0.0001506	5.27	0.04	0.061
Seniors (55+ years old)	0.0002	0.0000425	0.0001575	5.51	0.04	0.061

¹ The dietary exposure values are from Table 2.

² Allowable Drinking Water Exposure (mg/kg/day) = aPAD (mg/kg/day) - Acute Dietary Exposure (mg/kg/day).

³ The surface water concentration is the sum of the LOQ for fipronil, and metabolites: MB45950, MB46136, and MB46513 (0.04 µg/L = 0.01 + 0.01 + 0.01 + 0.01)]

2. *Non-dietary exposure.* The residential exposure for fipronil products was assessed by the U.S. EPA in the cotton risk evaluation in 2001.

i. *Pet products.* The residential exposure for the Frontline® pet products was assessed. The residential exposure for the Frontline® pet products was determined based on the following submitted studies: (1) Dermal and Inhalation Exposure of Commercial Pet Groomers During the Application of Frontline® Spray Treatment (MRID #44433302), (2) Dermal Exposure of Commercial Pet Groomers During the Application of Frontline® and Top Spot® (MRID 44433303), and four studies examining the dislodgeable residues of fipronil following the spray and spot treatment application to dogs and cats (MRID 4443330–09). Based on these studies, HED determined the dermal and inhalation exposure for residential applicators were 3.0×10^{-3} mg/kg bw/day and 1.78×10^{-6} mg/kg bw/day, respectively. The non-dietary, oral (hand to mouth) was estimated to be no greater than 3.0×10^{-5} mg/kg bw/day. The post-application dermal exposure for toddlers was estimated to be 1.0×10^{-3} mg/kg bw/day. The MOEs for all exposure scenarios evaluated were greater than 1500.

ii. *Fire ant products.* The applicator exposure was determine using the "Draft Standard Operating Procedures for Residential Exposure" (December 18, 1997). The greatest homeowner

applicator exposure was calculated from the application of the granular product with a drop spreader. The average daily dose for dermal and inhalation exposure were 6.0×10^{-4} mg/kg bw/day and 1.3×10^{-6} mg/kg bw/day, respectively. The MOEs for all exposure scenarios were $\geq 8,000$.

Post-application from the fire ant granular products can occur from dermal exposure and ingestion of granules from treated soil and/or ingestion of treated soil by children. Based on a submitted dislodgeable foliar residue study (MRID 44506901), HED concluded that fipronil cannot be dislodged from treated turf and post-application exposure from turf will not occur. HED calculated exposure to children from the ingestion of granules in the treated area to be 2.8×10^{-3} mg/kg bw/day which resulted in a MOE of 890. The post-application exposure to children from ingestion of treated soil was calculated to be 1.2×10^{-6} mg/kg bw/day which resulted in a MOE of 83,000.

HED concluded that there are no risk concerns for fipronil from the residential uses.

D. Cumulative Effects

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider available information concerning the cumulative effects of a particular pesticide's residues and other

substances that have a common mechanism of toxicity.

The EPA is currently developing methodology to perform cumulative risk assessments. At this time, there are no available data to determine whether fipronil has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment.

E. Safety Determination

1. *U.S. population.* Based on this risk assessment, BASF concludes that there is a reasonable certainty that no harm will result to the general population from the aggregate exposure to fipronil.

2. *Infants and children.* Based on this risk assessment, BASF concludes that there is a reasonable certainty that no harm will result to infants or children from the aggregate exposure to fipronil residues.

F. International Tolerances

The following maximum residue levels (MRLs) have been established by the Codex Alimentarius Commission (CODEX) for fipronil residues on the following plant commodities: banana, 0.005 mg/kg; barley 0.002 mg/kg; cabbage, head, 0.02 mg/kg; flowerhead brassicas, 0.02 mg/kg; maize 0.01 mg/kg; maize fodder 0.1 mg/kg; maize forage 0.1; oats, 0.002 mg/kg; potato 0.02 mg/kg; rice 0.01 mg/kg; rice, straw and fodder, dry, 0.2 mg/kg; rye 0.002 mg/kg; sugar beet 0.2 mg/kg; sugar beet leaves

or tops, 0.2 mg/kg; sunflower seed, 0.002 mg/kg; triticale, 0.002 mg/kg; wheat 0.002 mg/kg.

The following maximum residue levels (MRLs) have been established by the Codex Alimentarius Commission (CODEX) for fipronil residues on the following animal commodities: cattle, kidney 0.02 mg/kg; cattle liver 0.1 mg/kg; cattle meat 0.05 mg/kg; eggs 0.02 mg/kg; poultry meat 0.01 mg/kg; poultry, edible offal, 0.02 mg/kg.

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ENVIRONMENTAL PROTECTION AGENCY

[OPP-2005-0212; FRL-7728-3]

Emamectin; 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-2005-0212, must be received on or before September 23, 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: Thomas Harris, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-9423; e-mail address: harris.thomas@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 code 111)
- Animal production (NAICS code 112)

- Food manufacturing (NAICS code 311)
- Pesticide manufacturing (NAICS code 32532)

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be 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-2005-0212. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although, a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1801 S. Bell St., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr/>.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

Certain types of information will not be placed in the EPA Dockets.

Information claimed as CBI and other information whose disclosure is restricted by statute, which is not included in the official public docket, will not be available for public viewing in EPA's electronic public docket. EPA's policy is that copyrighted material will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. To the extent feasible, publicly available docket materials will be made available in EPA's electronic public docket. When a document is selected from the index list in EPA Dockets, the system will identify whether the document is available for viewing in EPA's electronic public docket. Although, not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B. EPA intends to work towards providing electronic access to all of the publicly available docket materials through EPA's electronic public docket.

For public commenters, it is important to note that EPA's policy is that public comments, whether submitted electronically or on 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