Thus, Executive Order 13175 does not apply to this rule.

IX. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 17, 2002.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 374.

2. Section 180.507 is amended by alphabetically adding the following commodity to the table in paragraph (b) to read as follows:

§ 180.507 Azoxystrobin; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/revocation date
* *	* * *	
Safflower	1.0	6/30/05
* *	* * *	

* * * * *

[FR Doc. 02–21679 Filed 8–27–02; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0140; FRL–7192–1]

Thiophanate-methyl; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of thiophanate-methyl and its metabolite (methyl 2-benzimidazoyl carbamate (MBC)) in or on grapes, pears, potatoes, canola and pistachios. Cerexagri, Inc. and the Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective August 28, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0140, must be received on or before October 28, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION.** To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0140 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Mary L. Waller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 308–9354; e-mail address: waller.mary@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS Codes	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at http://www.epa.gov/opptsfrs/home/guidelin.htm.

2. *In person.* The Agency has established an official record for this action under docket ID number OPP–2002–0140. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential

Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305–5805.

II. Background and Statutory Findings

In the **Federal Register** of August 8, 1997 (62 FR 42788) (FRL–5237–6), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide petition (PP 5F4550) by Cerexagri, Inc., 2000 Market Street, Philadelphia, PA 19103. This notice included a summary of the petition prepared by Cerexagri, Inc., the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.371 be amended by establishing tolerances for residues of the fungicide thiophanate-methyl in or on grapes at 5.0 part per million (ppm), and in or on pears at 7.0 ppm.

In the **Federal Register** of March 28, 2002 (67 FR 14944) (FRL–6829–1), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104–170), announcing the filing of pesticide petitions (PP 2E6355, 2E6367, and 2E6368) by the Interregional Research Project Number 4 (IR-4), 681 U.S. Highway #1 South, North Brunswick, NJ, 08902–3390. This notice included a summary of the petition prepared by IR-4. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.371 be amended by establishing tolerances for combined residues of the fungicide thiophanate-methyl, (dimethyl [(1,2-phenylene)-bis(iminocarbonothioyl)] bis(carbamate), its oxygen analogue dimethyl-4,4-o-phenylenebis(allophonate), and its benzimidazole-containing metabolites (calculated as thiophanate-methyl), in or on potatoes at 0.05 ppm (PP 2E6367), on pistachios at 0.2 ppm (PP 2E6355), and on canola at 0.1 ppm (PP 2E6368).

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL–5754–7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for tolerances for residues of thiophanate-methyl and its metabolite MBC, expressed as thiophanate-methyl on grapes at 5.0 ppm, on pears at 3.0 ppm, on pistachios at 0.1 ppm, on potatoes at 0.1 ppm, and on canola at 0.1 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by thiophanate-methyl are discussed in Table 1 below. In addition, the nature of the toxic effects caused by carbendazim or MBC are discussed in Table 2 below. MBC which is also a pesticide is the primary metabolite and the metabolite of concern for thiophanate-methyl. The tables also include the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY OF THIOPHANATE-METHYL

Guideline No.	Study Type	Results
870.3100	90–Day oral toxicity in rodents	NOAEL = 15.7 milligrams/kilograms/day (mg/kg/day) LOAEL = 155.0 mg/kg/day, based on anemia, increased serum cholesterol and calcium (males), increased liver and thyroid weights, increased kidney (males) weight and increased incidence of thyroid hyperplasia/hypertrophy, liver swelling and lipofuscin deposition, and glomerulonephrosis (males) were observed
870.3150	90–Day oral toxicity in dogs	NOAEL = 50 mg/kg/day LOAEL = 200 mg/kg/day, based on thin/dehydrated appearance, tarry stools, decreased body weight/weight gain, decreased food consumption, slight anemia, increased serum cholesterol, decreased serum T3/T4 (females), increased liver and thyroid weights, thyroid follicular cell hypertrophy and hyperplasia, hypoplasia/atrophy of the prostate, thymic involution/atrophy (males) and depletion of spleen lymphoid cells

TABLE 1.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY OF THIOPHANATE-METHYL—Continued

Guideline No.	Study Type	Results
870.3200	21–Day dermal toxicity in rabbits	Systemic toxicity NOAEL = 100 mg/kg/day Systemic toxicity LOAEL = 300 mg/kg/day, based on decreased food consumption in females Slight dermal irritation was observed at all dose levels
870.3465	14–Day inhalation toxicity in rodents	NOAEL = 0.00514 mg/Liter (L) LOAEL = 0.0151 mg/L, based on increased incidence of alveolar macrophages, pneumonocyte hyperplasia of the lung and nonsuppurative alveolitis
870.3700	Developmental toxicity in rodents	Maternal NOAEL = 300 mg/kg/day Maternal LOAEL = 1,000 mg/kg/day based on decreased body weight gain Developmental NOAEL ≥ 1,000 mg/kg/day LOAEL > 1,000 mg/kg/day
870.3700	Developmental toxicity in rodents	Maternal NOAEL = 18 mg/kg/day Maternal LOAEL = 85 mg/kg/day based on decreased food consumption Developmental NOAEL ≥ 163 mg/kg/day (HDT) Developmental LOAEL none established
870.3700	Developmental toxicity in rabbits	Maternal NOAEL = 6 mg/kg/day Maternal LOAEL = 20 mg/kg/day, based on transiently decreased body weight gain, increased abortion/total litter loss Developmental NOAEL ≥ 20 mg/kg/day Developmental LOAEL - none established
870.3700	Developmental toxicity in rabbits	Maternal NOAEL = 10 mg/kg/day Maternal LOAEL = 20 mg/kg/day, based on decreased body weight gain and food consumption Developmental NOAEL = 20 mg/kg/day Developmental LOAEL = 40 mg/kg/day, based on increased supernumerary ribs and decreased fetal weight
870.3800	Reproduction and fertility effects	Parental systemic NOAEL < 13.7 mg/kg/day Parental systemic LOAEL = 13.7 mg/kg/day based on hepatocellular hypertrophy and thyroid hypertrophy/hyperplasia Reproductive NOAEL ≥ 138.9 mg/kg/day Reproductive LOAEL > 138.9 mg/kg/day Offspring NOAEL = 13.7 mg/kg/day Offspring LOAEL = 43.3 mg/kg/day based on slightly reduced body weights of the F2b offspring during lactation
870.3800	Reproduction and fertility effects	Parental systemic/reproductive NOAEL ≥ 32 mg/kg/day Parental/systemic/reproductive LOAEL > 32 mg/kg/day Offspring NOAEL = 8 mg/kg/day Offspring LOAEL = 32 mg/kg/day based on slightly decreased mean litter weights
870.4100	Chronic toxicity dogs	NOAEL = 8 mg/kg/day LOAEL = 40 mg/kg/day based on decreased body weight/weight gain, markedly increased serum TSH (1 male) and decreased T4 (males), increased serum cholesterol (males), increased abs/rel thyroid weights (both sexes) and thyroid follicular cell hypertrophy (females)
870.4100	Chronic toxicity dogs	NOAEL = 23.7 mg/kg/day LOAEL = 123.3 mg/kg/day based on hepatocellular hypertrophy in females
870.4100	Chronic toxicity in rodents	NOAEL = 5.75 mg/kg/day LOAEL = 24.3 mg/kg/day based on decreased body weight and body weight gain in both sexes and increased incidence of thyroid and testicular microscopic effects in males
870.4100 870.4200	Chronic toxicity/Carcinogenicity in rodents	NOAEL = 8.8 mg/kg/day LOAEL = 54.4 mg/kg/day based on decreased body weight/weight gain (males; marginal in females), decreased food efficiency (males; marginal in females), sporadic effects on circulating T3/T4 and TSH, increased serum cholesterol and creatinine, decreased serum cholinesterase in females, increased liver, thyroid and kidney weights, liver hypertrophy and lipofuscin accumulation, thyroid hypertrophy and hyperplasia and lipofuscin accumulation in the kidney

TABLE 2.—SUBCHRONIC, CHRONIC, AND OTHER TOXICITY OF MBC

Guideline No.	Study Type	Results
870.3150	90–Day oral toxicity in dogs	NOAEL = 11.3 mg/kg/day (F), 14.4 mg/kg/day (M) LOAEL = 35 mg/kg/day (F), 40.7 mg/kg/day (M) based on histopathology changes in liver 1/4 males and 1/4 females) and testes (¼ males) and increased alkaline phosphatase, cholesterol and serum glutamate pyruvate transaminase (SGPT). Liver effects included hepatic cirrhosis (hepatic cell necrosis, tubular collapse, and increased fibrous connective tissue around triads)
870.3700	Developmental toxicity in rodents	Maternal NOAEL = 20 mg/kg/day Maternal LOAEL = 90 mg/kg/day based on increased absolute liver weight Developmental NOAEL = 10 mg/kg/day Developmental LOAEL = 20 mg/kg/day based on decreased fetal body weight and increases in skeletal variations and a threshold for malformations
870.3700	Developmental toxicity in nonrodents	Maternal NOAEL = 20 mg/kg/day Maternal LOAEL = 125 mg/kg/day based on abortions and decreased body weight Developmental NOAEL = 10 mg/kg/day Developmental LOAEL = 20 mg/kg/day based on decreased implantations and litter size, and increased resorptions. Malformations (fused ribs, and malformed cervical vertebrae) were noted at 125 mg/kg/day)
870.3800	Reproduction and fertility effects	Reproductive NOAEL = 25 mg/kg/day Reproductive LOAEL = 250 mg/kg/day based on toxic signs of decrased pup weight noted at weaning
870.4100	Chronic toxicity in dogs	NOAEL = 2.5 mg/kg/day LOAEL = 12.5 mg/kg/day based on swollen, vacuolated hepatic cells, hepatic cirrhosis and chronic hepatitis and biochemical alterations indicative of liver damage (i.e., increased cholesterol, total protein, serum glutamate pyruvate transaminase (SGPT) and alkaline phosphatase levels, and decreased A/G ratio)
870.4100	Chronic toxicity in dogs	NOAEL = 6.43 mg/kg/day (200 ppm) LOAEL = 16.54 mg/kg/day (500 ppm) based on possible transient increase in cholesterol (males and females) consistent
870.4100 870.4200	Chronic toxicity/Carcinogenicity in rodents	NOAEL = 25 mg/kg/day LOAEL = 250 mg/kg/day based on statistically significant decreases in red blood cell parameters (hematocrit, hemoglobin an red blood cells) in females and histological lesions in the liver (cholangiohepatitis and pericholangitis) in males and females. No evidence of carcinogenicity
870.4200	Carcinogenicity in rodents	NOAEL (non-cancer systemic) = 75 mg/kg/day LOAEL (non-cancer systemic) = 225 mg/kg/day based on liver toxicity (hepatocellular necrosis and swelling), body weight decrease and lymphoid depletion. In both sexes, there was an increased incidence of liver tumors In males, hepatocellular carcinomas were noted at 225 mg/kg/day, while females exhibited carcinomas and adenomas at all dose levels
870.4200	Carcinogenicity in mice	NOAEL (non-cancer systemic) = 34.4–41.9 mg/kg/day LOAEL (non-cancer systemic) = 522–648 mg/kg/day based on increases the incidences of hepatic cell hypertrophy, clear cell foci and hepatocellular necrosis. No increased incidence of carcinogenicity was noted
870.4200	Carcinogenicity in mice	NOAEL = 45 mg/kg/day LOAEL = 750 mg/kg/day based on hepatic alterations which included increased relative liver weights in both sexes, increased number of foci of cellular alterations in the liver in females, neoplastic nodules in females and hepatoblastomas in males
NA	Single dose (gavage) rat study	NOAEL: none observed LOAEL: 50 mg/kg/day based on premature release of immature germ cells 2 days post exposure, and atrophy of a few seminiferous tubules and significant decrease in seminiferous tubule diameter 70 days post exposure

B. Toxicological Endpoints

The dose at which the NOAEL from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the LOAEL is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

The Agency used a toxic equivalency factor (TEF) approach to sum exposure

and risk estimates from TM and MBC plus other metabolites of concern as MBC equivalents. A TEF approach was used because both TM and MBC share common toxicological effects (i.e., developmental and liver effects, and liver tumors), and because individuals may be exposed to both compounds simultaneously on food commodities, in drinking water and on treated lawns. Using the TEF approach, all thiophanate-methyl dietary exposure estimates were adjusted upwards to account for differences in acute population adjusted doses (aPADs) and chronic population adjusted doses (cPADs) between thiophanate-methyl and MBC.

The Population Adjusted Dose (PAD) is the adjusted Reference Dose (RfD) reflecting the retention or reduction of the FQPA safety factor for all populations. The PAD is the RfD which is derived from an exposure level at which there are no statistically or biologically significant increases in the frequency or severity of adverse effects between the exposed population and its appropriate control, along with the application of uncertainty factors. The percent of the PAD is calculated as the ratio of the exposure value to the PAD (exposure/PAD x 100 = % PAD). A non-cancer TEF is derived based on a ratio of the MBC PAD to the TM PAD.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The aPAD or cPAD is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a ''point of departure'' is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure (MOE_{cancer}= point of departure/exposures) is calculated. A summary of the toxicological endpoints for thiophanate-methyl used for human risk assessment is shown in the following Table 3. Table 4 summarizes the toxicological endpoints for MBC.

TABLE 3.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR THIOPHANATE-METHYL FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and/or Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary, females 13–50 years	NOAEL = 20 mg/kg/day UF = 100 Acute RfD = 0.2 mg/kg/day	FQPA SF = 3 aPAD = acute RfD FQPA SF = 0.067 mg/kg/day	1997 Rabbit developmental study LOAEL = 40 mg/kg/day based on supernumerary ribs in fetuses of exposed dams and decreased fetal weight
Acute dietary, General population	NOAEL = 40 mg/kg/day UF = 100 Acute RfD = 0.4 mg/kg/day	FQPA SF = 3 aPAD = acute RfD FQPA SF = 0.13 mg/kg/day	Chronic oral toxicity dog study LOAEL = 200 mg/kg/day based on tremors 2–4 hours post-dosing in 7 of 8 dogs
Chronic dietary	NOAEL = 8 mg/kg/day UF = 100 Chronic RfD = 0.08 mg/kg/day	FQPA SF = 3 cPAD = chronic RfD FQPA SF = 0.027 mg/kg/day	Chronic oral toxicity dog study LOAEL = 40 mg/kg/day based on thyroid effects and decreased body weight
Short- and intermediate-term - Incidental ingestion	Oral NOAEL = 10 mg/kg/day	LOC for MOE = 300 for all residential populations	1997 Rabbit developmental study LOAEL = 20 mg/kg/day based on decreased maternal body weight and food consumption
Short- and intermediate term - dermal	Dermal NOAEL = 100	LOC for MOE = 300 for all residential populations	21–day rabbit dermal toxicity study LOAEL = 300 mg/kg/day based on decreased body weight (28%) and food consumption (15%)
Short- and intermediate term - inhalation**	Oral NOAEL = 10 mg/kg/day (inhalation absorption rate = 100% relative to oral absorption)	LOC for MOE = 300 for all residential populations	1997 Rabbit developmental study LOAEL = 20 mg/kg/day based on decreased maternal body weight and food consumption

TABLE 3.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR THIOPHANATE-METHYL FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and/or Level of Concern for Risk Assessment	Study and Toxicological Effects
Long-term dermal and inhalation**	NOAEL = 8 mg/kg/day (dermal absorption rate = 7% relative to oral absorption; inhalation absorption rate = 100% relative to oral absorption)	LOC for MOE = 300 for all residential populations	Chronic oral toxicity dog study LOAEL = 40 mg/kg/day based on thyroid effects and decreased body weight
Cancer**	Q1* = 1.16 x 10^{-2} (mg/kg/day)$^{-1}$ (dermal absorption rate = 7% relative to oral absorption; inhalation absorption rate = 100% relative to oral absorption)	Q1* = 1.16 x 10^{-2} (mg/kg/day)$^{-1}$	78–Week mouse study based on male mouse liver adenoma and/or carcinoma and/or hepatoblastoma combined tumor rates

* The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.

**Since an oral value was selected, 7% dermal absorption factor and 100% inhalation absorption factor (equivalent to oral absorption) should be used for route-to-route extrapolation.

TABLE 4.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR MBC FOR USE IN HUMAN RISK ASSESSMENT

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and/or Level of Concern for Risk Assessment	Study and Toxicological Effects
Acute dietary, females 13–50 years	NOAEL = 10 mg/kg/day UF = 100 Acute RfD = 0.1 mg/kg/day	FQPA SF = 10 aPAD = acute RfD FQPA SF = 0.01 mg/kg/day	Rat developmental study with MBC LOAEL = 20 mg/kg/day based on decreased fetal body weight and increases in skeletal variations and a threshold for malformations in fetuses of exposed dams
Acute dietary, General population, including infants and children	LOAEL = 50 mg/kg/day UF = 300 acute RfD = 0.17 mg/kg/day	FQPA SF = 10 for infants and children FQPA SF = 1 general population aPAD = acute RfD FQPA SF = 0.017 mg/kg/day (infants and children) = 0.17 (general population)	Single dose rat study LOAEL = 50 mg/kg/day based on adverse testicular effects including sloughing (premature release) of immature germ cells 2 days post exposure, atrophy of a few seminiferous tubules in one testicle, significant decrease in seminiferous tubule diameter, and slight abnormal growth of the efferent ductules at 70 days post exposure
Chronic dietary	NOAEL = 2.5 mg/kg/day UF = 100 Chronic RfD = 0.025 mg/kg/day	FQPA SF = 10 for children and females 13–50 yrs FQPA SF = 1 general population cPAD = chronic RfD ÷FQPA SF = 0.0025 mg/kg/day (children and females) = 0.025 (general pop.)	2–year dog study with MBC LOAEL = 12.5 mg/kg/day based on histopathological lesions of the liver characterized as swollen, vacuolated hepatic cells, hepatic cirrhosis and chronic hepatitis in both sexes
Short-term incidental ingestion	Oral NOAEL = 10 mg/kg/day	LOC for MOE = 1,000 for all residential populations	1997 Rabbit developmental study with thiophanate-methyl LOAEL = 20 mg/kg/day based on decreased maternal body weight and food consumption
Intermediate - term Incidental ingestion	Oral NOAEL = 11 mg/kg/day (rounded to 10 mg/kg/day)	LOC for MOE = 1,000 for all residential populations	90–day dog feeding study with MBC LOAEL = 35 mg/kg/day based on adverse liver effects.
Short- and intermediate term dermal**	Oral NOAEL = 10 mg/kg/day (dermal absorption rate = 3.5% relative to oral absorption)	LOC for MOE = 1,000 for children and females (residential)	Rat developmental study with MBC LOAEL = 20 mg/kg/day based on decreased fetal body weight and increases in skeletal variations and a threshold for malformations in fetuses of exposed dams

TABLE 4.—SUMMARY OF TOXICOLOGICAL DOSE AND ENDPOINTS FOR MBC FOR USE IN HUMAN RISK ASSESSMENT—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and/or Level of Concern for Risk Assessment	Study and Toxicological Effects
Long-term dermal**	Oral NOAEL = 2.5 mg/kg/day (dermal absorption rate = 3.5% relative to oral absorption)	LOC for MOE = 1,000 for children and females (residential)	2–year dog study with MBC LOAEL = 12.5 mg/kg/day based on histopathological lesions of the liver characterized as swollen, vacuolated hepatic cells, hepatic cirrhosis and chronic hepatitis in both sexes of dogs
Short-, intermediate- and long term inhalation	Inhalation NOAEL = 0.96 (10 mg/m^3)	LOC for MOE = 1,000 for children and females (residential)	90–day rat inhalation study with benomyl LOAEL = 4.8 mg/kg/day (50 mg/m^3) based on Olfactory degeneration in the nasal cavity
Cancer**	Q1* = 2.39 x 10^{-3} (mg/kg/day)$^{-1}$ (dermal absorption rate = 3.5% relative to oral absorption; inhalation absorption rate = 100% relative to oral absorption)	Q1* = 2.39 x 10^{-3} (mg/kg/day)$^{-1}$	2–Year mouse study with MBC based on hepatocellular (adenoma and/or carcinoma) tumors in female CD–1 mice

* The reference to the FQPA Safety Factor refers to any additional safety factor retained due to concerns unique to the FQPA.
**Since an oral value was selected, 7% dermal absorption factor and 100% inhalation absorption factor (equivalent to oral absorption) should be used for route-to-route extrapolation.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* Tolerances have been established (40 CFR 180.371) for the residues of thiophanate methyl (dimethyl [(1,2- phenylene)-bis(iminocarbonothioyl)] bis[carbamate]), its oxygen analogue dimethyl-4,4-o-phenylene bis (allophonate), and its benzimidazole-containing metabolites (calculated as thiophanate-methyl) in or on the following crops and commodities: Almonds, apples, apricots, beans, celery, cherries, cucumbers, melons, nectarines, onions, pecans, peaches, peanuts, plums, potatoes (seed pieces), prunes, pumpkins, soybeans, squash, strawberries, sugar beets, wheat, eggs, and the meat, meat-by-products, fat and liver of cattle, goats, hogs, horses, and sheep. Emergency exemptions have been established for the use of thiophanate-methyl on citrus and blueberries. The Agency is modifying the tolerance expression so that the residues to be regulated in plant and animal commodities for purposes of tolerance enforcement will consist of the residues of thiophanate-methyl and its metabolite (methyl 2-benzimidazolyl carbamate (MBC)), expressed as thiophanate-methyl.

Exposure from the use of benomyl, another pesticide which degrades under environmental conditions to MBC was not included in this assessment because the only basic registrant of benomyl requested voluntary cancellation of all benomyl-containing products in April 2001. Product cancellations were effective in early 2001 with sales and distribution of benomyl containing products ending by December 31, 2001. However, the Agency conducted a dietary assessment using USDA Pesticide Data Program (PDP) monitoring data for benomyl, measured as MBC to estimate residues of thiophanate-methyl because MBC is a common metabolite of both benomyl and thiophanate-methyl. PDP data were available for apples, bananas, beans, cucurbits, peaches and strawberries. The PDP analytical method employs a hydrolysis step that converts any benomyl present to MBC. MBC is then quantitated and corrected for molecular weight, and results are measured as the sum of benomyl and MBC. Therefore, using MBC data to estimate thiophanate-methyl residues may be a conservative approach in that it may overestimate thiophanate-methyl residues. Risk assessments were conducted by EPA to assess dietary exposures from thiophanate-methyl and MBC in food as follows:

i. *Acute exposure.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1 day or single exposure. The Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: Maximum percent crop treated (PCT) estimates and anticipated residue estimates were used. The estimate of acute dietary exposure to thiophanate-methyl for the most highly exposed population subgroup of concern, (infants <1 year) is 25% of the aPAD at the 99.9th percentile and the estimate for the general U.S. population is 10% of the aPAD at the 99.9th percentile. The estimate of acute dietary exposure to MBC + other metabolites from thiophanate-methyl for the most highly exposed population subgroup of concern, (infants <1 year) is 89% of the aPAD at the 99.9th percentile and the estimate for the general U.S. population is 4% of the aPAD at the 99.9th percentile.

In addition, acute dietary risk estimates for thiophanate-methyl and MBC and other metabolites of concern were added together for females (13–50 years) to account for the total acute dietary risk estimate for developmental effects. Addition of acute dietary risk estimates is appropriate since both chemicals have aPADs that are based on developmental effects for females, and because individuals may consume both residues simultaneously on a given food commodity. The estimate of total acute dietary exposure to thiophanate-methyl and MBC for the only population subgroup of concern, (females 13–50 years) is 51% of the aPAD.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the DEEM® analysis evaluated the

individual food consumption as reported by respondents in the USDA 1989–1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: Average residues from field trial data and average PCT estimates were used. The chronic dietary exposure estimates for thiophanate-methyl are as follows: children (1–6 years) is 2.3% of the cPAD; infants (<1 year) is 1.6% of the cPAD; children (7–12 years) is 1.3% of the cPAD; general U.S. population is 0.8% of the cPAD; females (13–50 years) and males (13–19 years) is 0.6% of the cPAD. The chronic dietary exposure estimates for MBC and other metabolites from thiophanate-methyl are as follows: children (1–6 years) is 26% of the cPAD; children (7–12 years) is 16% of the cPAD; infants (<1 year) is 12% of the cPAD; females (13–50) is 8% of the cPAD; general U.S. population and males (13–19 years) is 1% of the cPAD. The total chronic dietary exposure estimates for thiophanate-methyl and MBC are as follows: Children (1–6 years) is 28% of the cPAD; children (7–12 years) is 17% of the cPAD; infants (<1 year) is 13% of the cPAD; females (13–50 years) is 8.5% of the cPAD; general U.S. population is 1.7% of the cPAD; and males (13–19 years) is 1.6% of the cPAD.

iii. *Cancer*. Cancer risk estimates included existing uses, new uses, and 1 year of citrus use under an emergency exemption amortized over 70 years. The lifetime cancer risk estimate from thiophanate-methyl using benomyl/MBC PDP data is 7.6×10^{-7}. The lifetime cancer risk estimate from MBC and other metabolites from thiophanate-methyl is 9.3×10^{-8}. The total lifetime thiophanate-methyl and MBC dietary cancer risk estimate is 8.5×10^{-7}. It is appropriate to add the cancer risk estimates from TM and MBC because both chemicals cause mouse liver tumors, and because both chemicals may be found concurrently on food items treated with thiophanate-methyl.

iv. *Anticipated residue and PCT information*. Section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide chemicals that have been measured in food. If EPA relies on such information, EPA must require that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. Following the initial data submission, EPA is authorized to require similar data on a time frame it deems appropriate. As required by section 408(b)(2)(E), EPA will issue a Data Call-In for information relating to anticipated residues to be submitted no later than 5 years from the date of issuance of these tolerances.

Section 408(b)(2)(F) states that the Agency may use data on the actual percent of food treated for assessing chronic dietary risk only if the Agency can make the following findings: Condition 1, that the data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide residue; condition 2, that the exposure estimate does not underestimate exposure for any significant subpopulation group; and condition 3, if data are available on pesticide use and food consumption in a particular area, the exposure estimate does not understate exposure for the population in such area. In addition, the Agency must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The Agency used PCT information for almonds, apples, apricots, beans (succulent or dried), green beans, bananas, blueberries, canola, celery, cherries, citrus, cucurbits (cantaloupe, cucumbers, melons, pumpkins, squash, watermelons), garlic, grapes, nectarines, onions (bulb and green), peaches, peanuts, pears, pecans, pistachios, plums/prunes, potatoes, soybeans, strawberries, sugar beets, and wheat. In addition, when PCT estimates indicated no thiophanate-methyl use, a default minimum assumption of 1% crop treated was applied. Where residues were nondetectable, one-half the limit of quantitation was assumed for treated commodities.

The Agency believes that the three conditions listed above have been met. With respect to Condition 1, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA uses a weighted average PCT for chronic dietary exposure estimates. This weighted average PCT figure is derived by averaging State-level data for a period of up to 10 years, and weighting for the more robust and recent data. A weighted average of the PCT reasonably represents a person's dietary exposure over a lifetime, and is unlikely to underestimate exposure to an individual because of the fact that pesticide use patterns (both regionally and nationally) tend to change continuously over time, such that an individual is unlikely to be exposed to more than the average PCT over a lifetime. For acute dietary exposure estimates, EPA uses an estimated maximum PCT. The exposure estimates resulting from this approach reasonably represent the highest levels to which an individual could be exposed, and are unlikely to underestimate an individual's acute dietary exposure. The Agency is reasonably certain that the percentage of the food treated is not likely to be an underestimated. As to Conditions 2 and 3, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows the Agency to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available information on the regional consumption of food to which thiophanate-methyl may be applied in a particular area.

2. *Dietary exposure from drinking water*. Available environmental fate data suggest that thiophanate-methyl rapidly degrades to MBC following application to ornamentals, turf and agricultural crops. MBC has a low potential to leach to ground water in measurable quantities from most typical uses based on its high soil organic carbon partition coefficient (Koc) of 2,100 L/kg. Available data indicate that the primary metabolite of thiophanate-methyl, MBC, is less mobile and significantly more persistent in many soils, especially under anaerobic conditions. The MBC aerobic soil half-life is 320 days, while the aerobic and anaerobic aquatic metabolism half lives are 61 and 743 days, respectively. The Agency concludes that MBC will probably not reach ground water to any significant concentration due to its high Koc.

The Agency currently lacks sufficient monitoring data to complete a quantitative drinking water exposure analysis and risk assessment for thiophanate-methyl and MBC. Therefore, the Agency is presently relying on water-quality models to estimate environmental concentrations (EECs) of pesticides in ground and surface water in order to estimate drinking water exposures to thiophanate-methyl and MBC. None of these models include consideration of

the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

EPA does not use these model estimates to quantify risk. Currently, EPA uses a drinking water level of comparison (DWLOC) as a surrogate to capture risk associated with exposure to pesticides in drinking water. A DWLOC represents the concentration of a pesticide in drinking water that would be acceptable as an upper limit in light of total aggregate exposure to that pesticide from food, water, and residential uses (if any). A DWLOC will vary depending on the residue level in foods, the toxicity endpoint and the drinking water consumption patterns and body weights for specific population subgroups. The calculated DWLOC is compared to the model estimate (EEC), and if the model estimates are below the DWLOC, the risks are not considered to be of concern.

For estimating ground water concentrations of thiophanate-methyl and MBC, EPA used the Screening Concentration in Ground Water (SCI-GROW) model. The SCI-GROW is based on scaled ground water concentration from ground water monitoring studies, and environmental fate properties (aerobic soil half-lives and organic carbon partitioning coefficients-Koc's). SCI-GROW provides a screening concentration which is an estimate of likely ground water concentrations if the pesticide were used at the maximum allowed label rate in areas with ground water vulnerable to contamination. In most cases, a majority of the pesticide use area will have ground water that is less vulnerable to contamination than the areas used to derive the SCI-GROW estimate. Using SCI-GROW, the acute and chronic ground water EEC for thiophanate-methyl ranged from 0.033 part per billion (ppb) to 0.006 ppb, and the acute and chronic EEC for MBC ranged from 0.51 ppb to 3.0 ppb.

For estimating surface water concentrations of thiophanate-methyl and MBC, EPA used a Tier II model, Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS). PRZM (3.12)/EXAMS (2.97.5) modeling uses an index reservoir and a percent crop area (PCA) adjustment to estimate concentrations in surface water used as a source of drinking water. The index reservoir represents a watershed that is more vulnerable than most watersheds used as drinking water sources. The index reservoir is used as a standard watershed that is combined with local soils, weather, and cropping practices to represent a vulnerable watershed for each crop that could support a drinking water supply. If a community derives its drinking water from a large river, the estimated exposure would likely be higher than the actual exposure. Conversely, a community that derives its drinking water from smaller bodies of water with minimal outflow would likely get higher drinking water exposure than estimated using the index reservoir. Areas with a more humid climate that use a similar reservoir and cropping patterns would likely get more pesticides in their drinking water than predicted levels.

A single steady flow was used to represent the flow through the reservoir. Discharge from the reservoir also removes chemicals so this assumption will underestimate removal of the pesticide from the reservoir during wet periods and overestimate removal during dry periods. This assumption can both underestimate or overestimate the concentration of pesticide in the reservoir depending upon the annual precipitation pattern at the site. The index reservoir scenario uses the characteristic of a single soil to represent all soils in the basin. Soils can vary substantially across even small areas, thus, this variation is not reflected in these simulations.

The index reservoir scenario does not consider tile drainage. Areas that are prone to substantial runoff are often tiled drained. This assumption may underestimate exposure, particularly on a chronic basis. However, the watershed used to model the EECs for thiophanate-methyl and MBC had no documented tile drainage. Additionally, PRZM/EXAMS is unable to easily model spring and fall turnover which would result in complete mixing of a chemical through the water column during these events. Because of this inability, the watershed used was simulated without stratification. However, there is data that suggests that the watershed used does stratify in the deepest parts of the lake at least in some years, thereby adding to the conservativeness of the estimate.

The EEC's for thiophanate-methyl and MBC were estimated based on the new maximum agricultural application rate which was the proposed new use on pears (2.8 pound active ingredient/Acre/season (lb./a.i./acre)). The previous existing maximum label rate was reduced by half as a result of risk mitigation. The EEC's using the new maximum rate are as follows: The acute or peak (1 in 10 years) EEC for thiophanate-methyl is 8.2 ppb and 23.5 ppb for MBC; the non-cancer chronic (1 in 10 years) EEC for thiophanate-methyl is 0.70 ppb and 14.0 ppb for MBC; and the cancer chronic (mean 36–year annual concentration) EEC is 0.5 ppb for thiophanate-methyl and 11.5 ppb for MBC.

As a result of risk mitigation, the maximum nonagricultural application rate (tees and greens of golf courses - 8.16 lb. a.i./acre) was also substantially reduced. Using the mitigated rate (tees and greens of golf courses - 8.16 lb. a.i./acre), the EEC's for thiophanate-methyl and MBC are as follows: The acute EEC for thiophanate-methyl is 22.7 ppb and 25 ppb for MBC; the non-cancer chronic EEC for thiophanate-methyl is 0.92 ppb and 8.8 ppb for MBC; and the cancer chronic EEC is 0.41 ppb and is 6.0 ppb for MBC.

Since the chronic and cancer endpoints are based on the same adverse effect, the thiophanate-methyl and MBC EECs are added together. The total thiophanate-methyl plus MBC chronic EEC is 9.72 ppb and the cancer EEC is 6.39 ppb.

3. *From non-dietary exposure*. The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Thiophanate-methyl is currently registered for use on the following residential non-dietary sites: Lawns and home orchards. MBC is registered for use as an in-can paint preservative which can be used in residential settings and as a fungicide applied as a tree injection. The risk assessment was conducted using the following residential exposure assumptions: Potential residential or nonoccupational post-application exposure to adults and children may occur as a result of residential application or professional lawn care operator application of thiophanate-methyl products to home lawns and golf courses.

As a result of risk mitigation, application rates for nonagricultural uses have been reduced, the use of thiophanate-methyl by residents will be limited to granular products for broadcast turf treatment and liquid treatments for ornamentals, and application using a belly grinder or by hand will be removed from pesticide labels. In addition, the Agency has negotiated a reduction in the rate of MBC used as an in-can paint preservative. The following exposure

and risk estimates are based on the mitigated rates and label revisions negotiated by the Agency.

i. *Chronic exposure and risk*. The Agency estimated cancer risks based on the number of years a person typically works in a home garden (50 years) and lifetime (70 years) which are also the population defaults used by the Agency. Therefore, cancer risks are based on 50 applications in a lifetime. A cancer risk assessment is considered appropriate because thiophanate-methyl has been assessed as a carcinogen using a model for carcinogenesis that assumes any exposure at any point in time may result in carcinogenic effects. These estimated risk do not exceed the Agency's level of concern.

Lifetime cancer risk estimates for applying thiophanate-methyl products once per year for 50 years (i.e., 50 times in a lifetime) range from 4.7×10^{-9} to 2.8×10^{-8} for ornamental treatment using a backpack sprayer and a ready to use hose-end sprayer, respectively. Cancer risk estimates for the other application methods are between these ranges.

Lifetime cancer risk estimates for post-application exposure to thiophanate-methyl ranged from 1.3×10^{-7} to 1.3×10^{-9} for adults. Cancer risk estimates were not calculated for children as the exposure scenario was not applicable.

ii. *Short- and intermediate-term exposure and risk*. All residential exposures are considered to be short-term (1–30 days) for residential handlers during the application of thiophanate-methyl products to turf and ornamentals. Intermediate- and long-term exposures of residential applicators were not anticipated based on the use pattern of thiophanate-methyl and information from the registrant. Considering toxicological criteria and potential for exposure, the Agency conducted dermal and inhalation exposure assessments. The Agency only assessed exposure to thiophanate-methyl because MBC risk from treated turf are considered to be negligible relative to thiophanate-methyl risks (i.e., at least 10 fold lower) based on chemical-specific turf transferable residue data.

Residential application of thiophanate-methyl products to lawns and ornamentals at the new maximum rate resulted in short-term risk estimates that are below the Agency's level of concern (i.e., total MOE <300). The inhalation MOE ranged from 140,000 to 620,000. The dermal MOE ranged from 1,900 to 37,000. Total dermal and inhalation MOEs range from 1,900 to 35,000.

Short-term risk estimates for residential/recreational post-application dermal exposure to adults resulted in estimates below the Agency's level of concern. The dermal MOE for adults ranged from 1,700 to 49,000. Short-term risk estimates for children (1–6 years) are as follows: MOE of 73,000 for incidental soil ingestion; MOE of 1,000 for contact with treated turf; MOE of 990 for object to mouth exposure; MOE of 250 for hand to mouth exposure; and MOE of 31 for incidental granular ingestion. The MOEs below 300 exceed the Agency's level of concern. However, the Agency believes that the exposure is significantly lower than that estimated in this assessment because the scenarios used to determine risk estimates are conservative and are considered as a screening level for risk. Both the adult and toddler transfer coefficients are upper percentile exposure duration values. Where study data were used, the risk estimates were better refined, and hence, less conservative. The dermal exposure estimates related to lawn skin contact which were based on study data were more refined than the estimates of incidental ingestion of thiophanate-methyl residues which were based on standard defaults from Agency standard operating procedures for residential exposure assessments. The registrant is undertaking a study to refine the oral exposures. If these data do not confirm that the Agency's estimates were overestimates, the registrant has agreed to cancel the use on turf in residential areas.

Inhalation exposures are thought to be negligible in outdoor post-application scenarios relative to dermal and oral exposures because of the low vapor pressure of thiophanate-methyl (1.3×10^{-5} milimeter mercury (mmHg)) and MBC (1×10^{-7} mmHg) and because the uses (and primary exposures) are outdoors allowing for significant dilution. As such, inhalation exposures were not considered in the post-application exposure assessment.

4. *Cumulative exposure to substances with a common mechanism of toxicity*. 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.''

EPA does not have, at this time, available data to determine whether thiophanate-methyl and MBC have a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, thiophanate-methyl and MBC do not appear to produce a toxic metabolite produced by other substances. For the purposes of these tolerances action, EPA has not assumed that thiophanate-methyl and MBC have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *In general*. FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

2. *Prenatal and postnatal sensitivity of thiophanate-methyl*. In assessing the potential for additional sensitivity of infants and children to residues of thiophanate-methyl and MBC, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2–generation reproduction study in the rat. The Agency determined that the FQPA safety factor should be retained at 3X for assessing the risk posed by thiophanate-methyl for the following reasons:

(i). The toxicity data base is incomplete (acute and subchronic neurotoxicity studies are required due to evidence of neurotoxicity) and the requirement for a developmental neurotoxicity study has been reserved.

(ii). The Agency evaluated the new 1997 prenatal developmental toxicity study in rabbits and classified this study as acceptable for assessment of susceptibility.

(iii). The Agency determined that the prenatal developmental toxicity study in the rat was acceptable for assessment of susceptibility.

(iv). The Agency concluded that the available data provided no indication of increased susceptibility for *in utero* exposure in the developmental studies

in rats and rabbits or following prenatal/postnatal exposure in the multi-generation reproduction studies in rats.

(v). The dietary (food and drinking water) and non-dietary exposure assessments will not underestimate the potential exposures for infants and children from the use of thiophanate-methyl.

3. *Prenatal and postnatal sensitivity of MBC.* The Agency determined that the FQPA Safety factor should be retained at 10X for assessing the risk posed by MBC for the following reasons:

(i). Evidence of increased susceptibility following *in utero* exposure to MBC in the prenatal developmental toxicity in rats and rabbits.

(ii). The need for developmental neurotoxicity study in rats for carbendazim.

4. *Conclusion*. Based on the developmental and reproductive data on thiophanate-methyl and MBC, EPA determined that an additional 3X safety factor for thiophanate-methyl and that an additional 10X safety factor for MBC for the protection of infants and children (as required by FQPA) should be retained.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water (e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure)). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by EPA are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: Acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and ground water are less than the calculated DWLOCs, EPA concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which EPA has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because EPA considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, EPA will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk*. The thiophanate-methyl acute dietary risk estimate uses 10% of the aPAD for the general U.S. population and 25% of the aPAD for the most highly exposed population subgroup of concern, infants, (<1 year). For MBC, the acute dietary risk estimate uses 4% of the aPAD for the general U.S. population and 89% of the aPAD for the population subgroup of concern, infants, (<1 year). The total thiophanate-methyl plus MBC acute dietary risk estimate for the only population subgroup of concern, females (13–50 years) uses 51% of the aPAD. The DWLOC based on simultaneous dietary exposure to both MBC and thiophanate-methyl which was converted to MBC equivalents resulted in the following DWLOCs: Infants (<1 year) 18 ppb; children (1–6 years) 57 ppb; females (13–50 years) 150 – 170 ppb; and general U.S. population 5,700 ppb. The lowest DWLOC for the population subgroup, infants (<1 year) does not exceed the EEC for ground water (0.033 ppb); however, the DWLOC does exceed the EEC for surface water (25 ppb). Although the EEC is exceeded, the DWLOC is greatly inflated as 50% of the aPAD percentage is consumed by citrus which is a 1–year registration only. When citrus is removed from the DWLOC estimation, the DWLOC becomes 94 ppb which is well above the EEC of 25 ppb. The DWLOC is significantly lowered by the addition of citrus because field trial data was used which results in an overly conservative estimation.

Another indication that the addition of citrus based on field trial data results in an over estimation is the fact that benomyl PDP data available for citrus indicated that there were zero hits out of 689 Florida samples of orange juice. These data were not used to refine the DWLOC estimation as the benomyl application rate is somewhat lower than the thiophanate-methyl rate approved in this year's emergency exemption for thiophanate-methyl. However, the Agency believes that while most growers used the benomyl rate as the emeregency exemption was approved later in the use season and thus fewer applications than were authorized were actually used. Furthermore, if the higher rate were used, the impact would be lessened by the fact that juice is a blended commodity. Therefore, although the DWLOC is exceeded, the acute dietary risk from food and water does not exceed the Agency's level of concern.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to thiophanate-methyl and MBC will utilize the following percentages of the RfD for the U.S. population: Thiophanate-methyl - 0.7%; MBC - 1.0% and total thiophanate-methyl plus MBC - 1.7%. The major identifiable subgroup with the highest aggregate exposure is children (1–6 years), and EPA has concluded that aggregate dietary exposure to thiophanate-methyl and MBC wil utilize the following percentages of the RfD: thiophate-methyl - 2.3%; MBC - 26% and total thiophanate-methyl plus MBC - 28%. EPA generally has no concern for exposures below 100% of the RfD because the RfD represents the level at or below which daily aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. The aggregate chronic DWLOCs are as follows: 858 ppb for the general U.S. population; 69 ppb for females (13–50 years); 22 ppb for infants (<1 year); and 18 ppb for children (1–6 years). The aggregate surface water EEC for thiophanate-methyl is 0.7 ppb; 14 ppb for MBC and 14.7 ppb for thiophanate-methyl plus MBC. Therefore, the chronic aggregate risk to not exceed the Agency's level of concern.

3. *Short-term risk*. Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Thiophanate-methyl and MBC are currently registered for use that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic food and water and short-term exposures for thiophanate-methyl and MBC.

All residential exposures are considered to be short-term. The MOE's (converted to MBC equivalents) for

aggregate short-term exposure to thiophanate-methyl are as follows: Oral exposure of children (1–6 years) is 670; dermal exposure of children (1–6 years) is 1,000; and dermal exposure of females (13–50 years) is 1,315. The MOEs for aggregrate exposure to MBC from the use of MBC as an in-can paint preservative are 670 for dermal exposure and 770 for exposure via inhalation. The MOEs (converted to MBC equivalents) for the total thiophanate-methyl and MBC aggregate exposure are as follows: 630 for oral and dermal exposure of children (1–6 years); 770 for exposure via inhalation for females (13–50 years); and 620 for oral and dermal exposure for females (13–50 years). Although the MOEs below 1,000 exceed the Agency's level of concern, when considering the conservative method of exposure estimation previously discussed, and the negotiated risk mitigation whereby the registrant has agreed to conduct hand-press studies to help refine this assessment, the risks do not exceed the Agency's level of concern.

4. *Aggregate cancer risk for U.S. population*. The total thiophanate-methyl and MBC dietary cancer risk is 8.5×10^{-7} for existing and new uses. The cancer risk from non-occupational residential exposure is 3.7×10^{-7}. The aggregate cancer risk is 1.2×10^{-6}. This risk estimate includes cancer risk from both thiophanate-methyl and MBC on food including all pending uses and section 18 uses, thiophanate-methyl exposure from treating ornamentals, thiophanate-methyl exposure from performing post-application lawn activities, and exposure from applying paint containing MBC. This is considered to be a high-end risk scenario since it is not expected that someone would treat ornamentals, perform high exposure post-application activities, and apply paint containing MBC every year for 70 years. Therefore, this estimate is considered to be a conservative estimate. Additionally, the cancer risk estimate based on the highest EEC (thiophanate-methyl plus MBC EEC) is 9.6×10^{-7}. This is also a very high-end risk estimate as it is based on the maximum rate being applied every season for 70 years. Thus, food plus water (assuming that the modeled surface water EEC is equivalent to concentrations in finished drinking water) plus non-occupational residential cancer risk is 2.2×10^{-6} which is still within the range considered as negligible. In addition, the cancer risk estimates using benomyl/MBC PDP monitoring data to estimate thiophanate-methyl residues are below 1×10^{-6} for thiophanate-methyl existing uses, new uses, and the amortized section 18 use on citrus. Therefore, the risks do not exceed the Agency's level of concern.

5. *Determination of safety*. Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to thiophanate-methyl and MBC residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology high pressure liquid chromatography/ultra violet (HPLC/UV) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PRRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5229; e-mail address: furlow.calvin@epa.gov.

B. International Residue Limits

The Codex Alimentarius Commission has established maximum residue limits (MRLs) for thiophanate-methyl residues in/on various plant and animal commodities. Codex MRLs for thiophanate-methyl are currently expressed as MBC. The Codex MRL residue definition and the U.S. tolerance definition are currently incompatible and will remain incompatible even after the U.S. tolerance definition is revised, as the revised tolerance definition will include both thiophanate-methyl and MBC.

C. Conditions

A 30–day plant back interval is required for crops without labeled uses of thiophanate-methyl. Registrations for the use on canola will be restricted to use in Minnesota, Montana and North Dakota (East of Interstate 15).

V. Conclusion

Therefore, the tolerances are established for residues of thiophanate-methyl and its metabolite (methyl 2–benzimidazoyl carbamate (MBC)), expressed as thiophanate-methyl in or on grapes at 5.0 ppm, on pears at 3.0 ppm, on pistachios at 0.1 ppm, on potatoes at 0.1 ppm, and on canola (restricted to use in Minnesota, Montana and North Dakota (East of Interstate 15)) at 0.1 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2002–0140 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk on or before October 28, 2002.

1. *Filing the request*. Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your written request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall # 2, 1921 Jefferson Davis Hwy., Arlington, VA. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the

Office of the Hearing Clerk is (703) 603–0061.

2. *Tolerance fee payment*. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket ID number OPP–2002–0140, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism*(64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 3, 2002.

Debra Edwards,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 374.

2. Section 180.371 is amended as follows:

i. By alphabetically adding entries for the commodities ''grape,'' ''pear,'' and ''pistachio'' and revising the entry for ''potatoes, seed treatment'' to read ''potato'' to the table in paragraph (a) as set forth below.

ii. By adding text and a table to paragraph (c):

§ 180.371 Thiophanate-methyl; tolerances for residues.

(a) *General.* Thiophanate-methyl and its metabolite (methyl 2-benzimidazoyl carbamate (MBC)), expressed as thiophanate-methyl

Commodity	Parts per million
* * *	* *
Grape	5.0
* * *	* *
Pear	3.0
* * *	* *
Pistachio	0.1
* * *	* *
Potato	0.1
* * *	* *

* * * * *

(c) *Tolerances with regional registrations.* Tolerances with regional registration, as defined in § 180.1(n), are established for the residues of thiophanate-methyl and its metabolite (methyl 2-benzimidazolyl carbamate (MBC)), expressed as thiophanate-methyl in or on the following raw agricultural commodity:

Commodity	Parts per million
Canola	0.1

* * * * *

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0215; FRL–7195–7]

Pyriproxyfen; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for the residues of pyriproxyfen in or on acerola at 0.10 part per million (ppm), bushberry subgroup at 1.0 ppm, feijoa at 0.10 ppm, fruit, stone, group at 1.0 ppm, guava at 0.10 ppm, jaboticaba at 0.10 ppm, juneberry at 1.0 ppm, lingonberry at 1.0 ppm, longan at 0.30 ppm, lychee at 0.30 ppm, passionfruit at 0.10 ppm, pulasan at 0.30 ppm, rambutan at 0.30 ppm, salal at 1.0 ppm, spanish lime at 0.30 ppm, starfruit at 0.10 ppm, and wax jambu at 0.10 ppm. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective August 28, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0215, must be received on or before October 28, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0215 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Shaja R. Brothers, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: (703) 308–3194; e-mail address: brothers.shaja@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

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 the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations,'' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the**Federal Register** listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/