physically appear as illustrated in § 1200.2, with no alterations.

(e) Only use the official seal for the time period designated in the approval letter (example: for the duration of a conference or exhibit).

Subpart D—Penalties for Misuse of NARA Seals

§ 1200.16 Will I be penalized for misusing the official seals?

(a) If you falsely make, forge, counterfeit, mutilate, or alter official seals, replicas, reproductions or embossing seals, or knowingly use or possess with fraudulent intent any altered seal, you are subject to penalties under 18 U.S.C. 506.

(b) If you use the official seals, replicas, reproductions, or embossing seals in a manner inconsistent with the provisions of this part, you are subject to penalties under 18 U.S.C. 1017 and to other provisions of law as applicable.

Dated: November 26, 2002.

John W. Carlin,

Archivist of the United States.

[FR Doc. 02–30766 Filed 12–3–02; 8:45 am]

BILLING CODE 7515–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0005; FRL–7279–5]

Pyrithiobac Sodium (sodium 2-chloro-6-[(4,6-dimethoxypyrimidin-2-yl)thio]benzoate); Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of pyrithiobac sodium (sodium 2-chloro-6-[(4,6-dimethoxypyrimidin-2-yl)thio]benzoate) in or on cotton, undelinted seed and cotton gin byproducts. DuPont Agricultural Products, Wilmington, DE requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) of 1996.

DATES: This regulation is effective December 4, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0005, must be received on or before February 3, 2003.

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–2002–0005 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Tompkins, Product Manager (PM) 25, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305–5697; e-mail address: *tompkins.jim@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be 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. *Docket*. EPA has established an official public docket for this action under docket identification (ID) number OPP–2002–0005. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305–5805.

2. *Electronic access*. You may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr/*. A frequently updated electronic version of 40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/4 0cfr180_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*.

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.

II. Background and Statutory Findings

In the **Federal Register** of September 24, 1997 (62 FR 49979) (FRL–5745–8), EPA issued a notice pursuant to section 408 of the FFDCA, 21 U.S.C. 346a, as amended by the FQPA of 1996 (Public Law 104–170), announcing the filing of a pesticide petition PP 4F4391 by DuPont Agricultural Products, Wilmington, DE. This notice included a summary of the petition prepared by DuPont Agricultural Products, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.487 be amended by establishing a tolerance for residues of the herbicide pyrithiobac sodium, (sodium 2-chloro-6-[(4,6-dimethoxypyrimidin-2-yl)thio]benzoate), in or on cotton, undelinted seed at 0.02 parts per million (ppm) and cotton gin byproducts at 0.1 ppm. The Registrant subsequently amended the petition by

increasing the tolerance request for cotton gin byproducts to 0.15 ppm.

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) of the FFDCA 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) of the FFDCA 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 November 26, 1997, (62 FR 62961) (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 a tolerance for residues of pyrithiobac sodium on cotton, undelinted seed at 0.02 ppm and cotton gin byproducts at 0.15 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 pyrithiobac sodium are discussed below. This discussion refers to the no observed effect level (NOEL) and the lowest observed effect level (LOEL) from the toxicity studies reviewed rather than the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) because the toxicity studies for pyrithiobac sodium were reviewed prior to adoption in 1998 of the NOAEL/LOAEL terminology by EPA's Office of Pesticide Programs (OPP) and its Health Effects Division (HED). At the time of the switch to the revised terminology, HED noted that the new terminology was unlikely to have any substantive effect on its hazard evaluations: ''In a practical sense, the terms NOEL and NOAEL have been used interchangeably in OPP. As a general rule, OPP would consider as appropriate for hazard identification and risk assessment only those effects which are adverse or potentially adverse. This inclusion of the term NOAEL should not change any of our hazard endpoints for regulation but add to the quality of the risk assessment.'' HED Standard Operating Procedure (SOP) 98.3

1. A rat acute oral study with a LD_{50} of 3,300 milligrams/kilogram (mg/kg) for males and a LD_{50} of 3,200 mg/kg for females.

2. A 90–day rat feeding study with a NOAEL of 50 parts per million (ppm) (3.25 mg/kg/day for males and 4.14 mg/kg/day for females) and a LOAEL of 500 ppm (31.8 mg/kg/day for males and 40.5 mg/kg/day for females based on decrease body weight gains and increased rate of hepatic beta-oxidation in males.

3. A 90–day mouse feeding study with a NOAEL of 500 ppm (83.1 mg/kg/day for males and 112 mg/kg/day for females) and a LOAEL of 1,500 ppm (263 mg/kg/day for males and 384 mg/kg/day for females) based on increased liver weight and an increased incidence of hepatocellular hypertrophy in males and decreased neutrophil count in females.

4. A 3–month dog feeding study with a NOAEL of 5,000 ppm (165 mg/kg/day) and a LOAEL of 20,000 ppm (626 mg/kg/day), based on decrease red blood cell count, hemoglobin, and hematocrit in females and increased liver weight in both sexes.

5. A 21–day rat dermal study with a Dermal Irritation NOAEL of 50 mg/kg/day and, a Dermal Irritation LOAEL of 500 mg/kg/day based on increased incidence of erythema and edema, and with a Systemic Dermal NOAEL of 500 mg/kg/day and a Systemic Dermal LOAEL of 1,200 mg/kg/day based on body weight gain inhibition.

6. A 90–day rat neurotoxicity screening battery with a Systemic NOAEL of 7,000 ppm (466 mg/kg/day for males and 588 mg/kg/day for females) and a Systemic LOAEL of 20,000 ppm (1,376 mg/kg/day for males and 1,609 mg/kg/day for females), based on deceased hind grip strength and increased foot spay in males, and a Neurotoxicity NOAEL of 20,000 ppm highest dose tested (HDT).

7. A 78–week dietary carcinogenicity study in mice with a NOAEL of 1,500 ppm 217 mg/kg/day (males) and 319 mg/kg/day (females) and a LOAEL of 5,000 ppm 745 mg/kg/day (males) and 1,101 mg/kg/day (females) based on decreased body weight gain in both sexes, treatment related increase in the incidence of foci/focus of hepatocellular alternation in males, and increased incidence of glomerulonephropathy (murine) in both sexes, and an increased incidence of infarct in the kidney and keratopathy of the eyes. There was evidence of carcinogenicity based on significant differences in the pair-wise comparisons of hepatocellular adenomas and combined adenoma/carcinoma in the 150 ppm and 1,500 ppm dose groups (but not at the high dose of 5,000 ppm) with the controls. The carcinogenic effects observed are discussed below.

8. A 23–month rat chronic toxicity/carcinogenicity study with a Systemic NOAEL of 1,500 ppm (58.7 mg/kg/day) for males and 5,000 ppm (278 mg/kg/day) for females, and with a Systemic LOAEL of 5,000 ppm (200 mg/kg/day) for males and 15,000 ppm (918 mg/kg/day) for females, based on deceased body weight, body weight gain and food efficiency for females, the increased incidence of eye lesions in both sexes, mild changes in hematology and urinalysis in both sexes, clinical signs suggestive of urinary tract dysfunction in males and females, increased incidence of focal cystic degeneration in the liver in males, increased rate of hepatic peroxisomal beta-oxidation in males and an increased incidence of inflammatory and degenerative lesions in the kidney in females. There was evidence of carcinogenicity based on significant dose-related increasing trend in kidney tubular combined adenoma/carcinoma in male rats and a significant dose related increasing trend in kidney tubular bilateral and/or unilateral adenomas in females. The carcinogenic effects observed are discussed further below.

9. A 1–year dog chronic toxicity study with a NOAEL of 5,000 ppm (143 mg/kg/day for males and 166 mg/kg/day for females) and a LOAEL of 20,000 ppm (580 mg/kg/day for males and 647 mg/kg/day for females) based on decreases in body weight gain, increase thyroid

and liver weights, and microscopic findings in the liver and kidneys.

10. A 2-generation reproduction study in rats with a NOAEL for maternal toxicity of 1,500 ppm (103 mg/kg/day) and a maternal LOAEL of 7,500 ppm (508 mg/kg/day), based on decreased body weight, body weight gain and food efficiency. The NOAEL for paternal toxicity is 1,500 ppm (86 mg/kg/day), while the LOAEL is 7,500 ppm (439 mg/kg/day), based on decreased body weight, body weight gain and food efficiency. The NOAEL for reproductive effects can be set at 7,500 ppm (508 mg/kg/day), the LOAEL at 20,000 ppm (1,551 mg/kg/day), based on decreased pup body weight. The NOAEL for effects on offspring is 7,500 ppm (508 mg/kg/day), and the LOAEL at 20,000 ppm (1,551 mg/kg/day), based on decreased pup body weight.

11. A 13–day dosing (gestation days 7–19) developmental toxicity study in rabbits with a maternal NOAEL of 300 mg/kg and a maternal LOAEL of 1,000 mg/kg based on deaths, decreased body weight gain and feed consumption, and an increase in early resorptions. There is developmental toxicity observed at 1,000 mg/kg based on decreased fetal body weights.

12. A 10–day dosing (gestation days 7–16) developmental toxicity study in rats wth a maternal NOAEL of 200 mg/kg and maternal LOAEL of 600 mg/kg due to increased incidence of peritoneal staining. The developmental NOAEL is 600 mg/kg and the developmental LOAEL is 1,800 mg/kg based on the increased incidence of skeletal variations.

13. No evidence of gene mutation was observed in a test for induction of forward mutations at the hypoxanthine guanine phophoribosyl transferase (HGPRT) locus in Chinese hamster ovary cells. No evidence was observed for inducing reverse gene mutation in two independent assays with *Salmonella typhimurium* with and without mammalian metabolic activation. Pyrithiobac sodium was negative for the induction of micronuclei in the bone marrow cells of mice, and negative for induction of unscheduled DNA synthesis in rat primary hepatocytes. Pyrithiobac sodium was positive for inducing chromosome aberrations assay in human lymphocytes.

14. A rat metabolism study showed that radio labeled pyrithiobac sodium is excreted in urine and feces with >90% being eliminated within 48 hours. A sex difference was observed in the excretion and biotransformation. Females excreted a greater amount of the radiolabel in the urine than males following all regimens, with a corresponding lower amount being eliminated in the feces compared to the males.

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 at which effects of concern are identified 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 intra species differences.

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 acute or chronic Population Adjusted Dose (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) = NOEL/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 pyrithiobac sodium used for human risk assessment is as follows:

1. *Acute toxicity*. EPA has concluded that no endpoint exists to suggest any evidence of significant toxicity from 1–day or single-event exposure.

2. *Short-term and intermediate-term toxicity*. EPA has concluded that available evidence does not indicate any evidence of significant toxicity from short-term and intermediate-term exposure.

3. *Chronic toxicity*. EPA has established the RfD for pyrithiobac sodium at 0.587 mg/kg/day. This RfD is based on the systemic NOAEL of 58.7 mg/kg/day for males in the rat chronic feeding study with a 100-fold safety factor to account for interspecies extrapolation and intraspecies variability.

4. *Carcinogenicity*. EPA has concluded that the available data provide limited evidence of the carcinogenicity of pyrithiobac sodium in mice and rats and has classified pyrithiobac sodium as a Group C (possible human carcinogen with limited evidence of carcinogenicity in animals) in accordance with Agency guidelines, published in the **Federal Register** of (September 24, 1986, 51 FR 33992) and recommended that for the purpose of risk characterization a low dose extrapolation model should be applied to the experimental animal tumor data for quantification for human risk (Q^{1*}). This decision was based on liver adenomas, carcinomas and combined adenoma/carcinomas in the male mouse and rare kidney tubular adenomas, carcinomas and combined adenoma/carcinomas in male rats. The unit risk, Q^{1*} (mg/kg/day)-1, of pyrithiobac sodium is 1.05 x 10–3 (mg/kg/day)-1 in human equivalents based on male kidney tumors.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses*. Permanent tolerances have been requested to replace the time limited tolerance in/on cottonseed 40 CFR 180.487 at 0.02 ppm, and a new tolerance for the residues of pyrithiobac sodium, in or on cotton gin byproducts at 0.1 ppm. The requested tolerance for cotton gin byproducts has been amended to 0.15 ppm based on the results of the submitted field residue trials, and cottonseed was changed to cotton, undelinted seed. Processing studies for cotton have shown that

pyrithiobac sodium does not concentrate in cottonseed processed food/feed commodities. No requested tolerances were necessary for meat, milk, and eggs because detectible residues are not expected in these commodities from this use on cotton. Risk assessments were conducted by EPA to assess dietary exposures from pyrithiobac sodium 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. EPA has concluded that no endpoint exists to suggest any evidence of significant toxicity from one-day or single-event exposure; therefore, an acute exposure assessment is not applicable.

ii. *Chronic exposure*. In conducting this chronic dietary risk assessment the Dietary Exposure Evaluation Model (DEEM™ analysis evaluated the individual food consumption as reported by respondents in the Department of Argiculture (USDA) 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. EPA assumed that all commodities for which tolerances exist and all cotton food commodities had pyrithiobac sodium residues at the appropriate tolerance level.

iii. *Cancer*. The cancer exposure assessment relied upon the same data and assumptions as the chronic exposure assessment.

iv. *Anticipated residue and percent crop treated (PCT) information*. Tolerance level residues and treatment of 100% of the crop was assumed. Anticipated residues and PCT information was not used.

2. *Dietary exposure from drinking water*. The Agency lacks sufficient monitoring exposure data to complete a comprehensive dietary exposure analysis and risk assessment for pyrithiobac sodium in drinking water. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling taking into account data on the physical characteristics of pyrithiobac sodium.

The Agency uses the GENEEC or the PRZM/EXAMS to estimate pesticide concentrations in surface water and SCI-GROW, which predicts pesticide concentrations in ground water. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop (PC) area factor as an adjustment to account for the maximum PC coverage within a watershed or drainage basin.

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.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a %RfD or %PAD. Instead drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to pyrithiobac sodium they are further discussed in the aggregate risk sections in Unit E.

Based on the GENEEC and SCI-GROW models the EECs of pyrithiobac sodium for chronic exposures are estimated to be 7.76 parts per billion (ppb) for surface water and 0.778 ppb for ground water.

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).

Pyrithiobac sodium is not registered for use on any sites that would result in residential exposure.

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 consider ''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 pyrithiobac sodium has 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, pyrithiobac sodium does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that pyrithiobac sodium has 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 (November 26, 1997, 62 FR 62961).

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 pre-natal and post-natal 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. *Pre-natal and post-natal sensitivity*. In a preliminary review, EPA concluded that data do not indicate that there is a significant potential for reproductive or developmental effects from pyrithiobac sodium as tested.

3. *Conclusion*. There is a complete toxicity data base for pyrithiobac sodium and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures. Pyrithiobac sodium has not been formally reviewed by the Agency regarding the need to retain the additional 10X safety factor for the protection of infants and children. Thus, despite the completeness of the database and the lack of any indication of significant potential for reproductive or developmental effects, EPA has retained the additional 10X safety factor until a full review can be completed. Retention of the additional safety factor yields a

cPAD for pyrithiobac sodium of 0.0587 mg/kg/day.

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 Office of Water 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 OPP 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.

Pyrithiobac sodium is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water.

1. *Acute risk*. EPA has concluded that no endpoint exists to suggest any evidence of significant toxicity from acute exposures from the use of pyrithiobac sodium on cotton.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to pyrithiobac sodium from food and water will utilize less than 0.2% of the cPAD for the U.S. population, and less than 0.2% of the cPAD for children 1 to 6 years at greatest exposure to both food and water. There are no residential uses for pyrithiobac sodium that result in chronic residential exposure to pyrithiobac sodium. EPA generally has no concern for exposures below 100% of the cPAD because the cPAD represents the level at or below which aggregate dietary exposure over a lifetime will not pose appreciable risks to human health. Due to the low exposure for the U.S. population (less than 0.2%) and for children 1 to 6 years (less than 0.2%) for both food and water, the calculated DWLOC is approximately equal to the cPAD.

3. *Short-term risk*. EPA has concluded that no endpoint exists to suggest any evidence of significant toxicity from short-term exposures from the use of pyrithiobac sodium on cotton.

4. *Intermediate-term risk*. EPA has concluded that no endpoint exists to suggest any evidence of significant toxicity from intermediate-term exposures from the use of pyrithiobac sodium on cotton.

5. *Aggregate cancer risk for U.S. population*. Based on the upper bound potency factor (Q*1) of 1.05 x 10–3 (mg/kg/day)-1, the aggregate upper bound lifetime cancer risk from the use of pyrithiobac sodium on cotton from worst case estimates of residues in food and drinking water is 2.3 x 10–7.

6. *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 pyrithiobac sodium residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology high performance liquid chromotography using ultra-violent detection (HPLC-UV) with column switching) is available to enforce the tolerance expression. The method may be requested from: Paul Golden, U.S. Environmental Protection Agency, Office of Pesticide Programs, BEAD, ACB, Environmental Science Center, 701 Mapes Road Fort Meade, MD 20755–5350; Telephone (410) 305–2960.

B. International Residue Limits

There are no established Codex maximum residue levels (MRLs) for pyrithiobac sodium on cottonseed. An established Mexican tolerance for pyrithiobac sodium on cottonseed is identical to the U.S. tolerance. Compatibility of tolerance levels is not an issue at this time.

C. Conditions

There are no conditions. Adequate residue data has been submitted to support the tolerances established in this **Federal Register** Notice.

V. Conclusion

Therefore, the tolerance is established for residues of pyrithiobac sodium, (sodium 2-chloro-6-[(4,6-dimethoxypyrimidin-2-yl)thio]benzoate), in or on cotton, undelinted seed at 0.02 ppm and cotton gin byproducts at 0.15 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–2002–0005 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 February 3, 2003.

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 (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. 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 (202) 260–4865.

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–2002–0005, 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 andIndian 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: November 8, 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 180.487 paragraph (a) is revised to read as follows:

§ 180.487 Pyrithiobac sodium; tolerances for residues.

(a) *General*. Tolerances are established for residues of the herbicide, pyrithiobac sodium, (sodium 2-chloro-6-[(4,6-dimethoxypyrimidin-2-yl)thio]benzoate), resulting from the application of the pesticide chemical in or on the following foods/feeds:

Commodity	Parts per million
Cotton gin byproducts	0.15
Cotton, undelinted seed	0.02

* * * * *

[FR Doc. 02–30472 Filed 12–3–02; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[I.D. 112702C]

Notification of U.S. Fish Quotas and an Effort Allocation in the Northwest Atlantic Fisheries Organization (NAFO) Regulatory Area

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notification of U.S. fish quotas and an effort allocation.

SUMMARY: NMFS announces that fish quotas and an effort allocation are available for harvest by U.S. fishermen in the NAFO Regulatory Area. This action is necessary to make available to U.S. fishermen a fishing privilege on an equitable basis.

DATES: All fish quotas and the effort allocation are effective January 1, 2003, through December 31, 2003. Expressions of interest regarding U.S. fish quota allocations for all species except 3L shrimp will be accepted throughout 2003. Expressions of interest regarding the U.S. 3L shrimp quota allocation and the 3M shrimp effort allocation will be accepted through January 3, 2004.

ADDRESSES: Expressions of interest regarding the U.S. effort allocation and quota allocations should be made in writing to Patrick E. Moran in the NMFS Office of Sustainable Fisheries, at 1315 East-West Highway, Silver Spring, MD 20910 (phone: 301–713–2276, fax: 301–713–2313, e-mail: pat.moran@noaa.gov).

Information relating to NAFO fish quotas, NAFO Conservation and Enforcement Measures, and the High Seas Fishing Compliance Act (HSFCA) Permit is available from Jennifer L. Anderson at the NMFS Northeast Regional Office at One Blackburn Drive, Gloucester, Massachusetts 01930 (phone: 978–281–9226, fax: 978–281–9394, e-mail: jennifer.anderson@noaa.gov) and from NAFO on the World Wide Web at http://www.nafo.ca.

FOR FURTHER INFORMATION CONTACT: Patrick E. Moran, 301–713–2276.

SUPPLEMENTARY INFORMATION:

Background

NAFO has established and maintains conservation measures in its Regulatory Area that include one effort limitation fishery as well as fisheries with total allowable catches (TACs) and member nation quota allocations. The principal species managed are cod, flounder, redfish, American plaice, halibut, capelin, shrimp, and squid. At the 2002 NAFO Annual Meeting, the United States received fish quota allocations for three NAFO stocks and an effort allocation for one NAFO stock to be fished during 2003. The species, location, and allocation (in metric tons or effort) of these U.S. fishing opportunities are as follows:

(1) Redfish NAFO Division 3M 69 mt

(2) Squid NAFO Subareas 3 & 4 453 mt

(3) Shrimp NAFO Division 3L 67 mt

(4) Shrimp NAFO Division 3M 1 vessel/100 days

Additionally, U.S. vessels may fish any portion of the 7,500 mt TAC of oceanic redfish in NAFO Subarea 2 and Divisions 1F and 3K. This opportunity is available only to members of NAFO that are not members of the North East Atlantic Fisheries Commission, on a first-come, first-served basis. Allocations are also available to U.S.