PART 180—[AMENDED]

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

Authority: 21 U.S.C. 346a and 371.

2. Section 180.495 is amended as follows:

a. By adding a heading to paragraph (a).

b. In paragraph (b) by adding a heading and alphabetically adding the following commodities.

c. Paragraphs (c) and (d) are added and reserved with headings.

§ 180.495 Spinosad; tolerances for residues.

(a) *General.* [Reserved]

(b) *Section 18 emergency exemptions.*

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Commodity	Parts per million	Expiration/Revocation Date
Brassica (Cole) Leafy Vegetables Crop Group (5)	10.0	9/30/98
* * *	* * * *	
Fruiting Vegetables (except Cucurbits) Crop Group (8)	0.25	9/30/98
Leafy Vegetables (except Brassica vegetables) Crop Group (4)	10.0	9/30/98
Tomato paste	0.50	9/30/98

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 97–27727 Filed 10–21–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300548; FRL–5742–5]

RIN 2070–AB78

Pyrithiobac Sodium Salt; Time-Limited Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation extends the time-limited tolerance for residues of the herbicide pyrithiobac sodium salt (sodium 2-chloro-6-[(4,6-dimethoxypyrimidin-2-yl)thio]benzoate) in or on cottonseed at 0.02 parts per million (ppm). E.I. du Pont de Nemours & Co., Inc., requested this tolerance under the Federal Food, Drug and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1966 (Pub. L. 104–170). The tolerance will expire on September 30, 1999.

DATES: This regulation is effective October 22, 1997. Objections and requests for hearings must be received by EPA on or before December 22, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300548], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300548], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300548]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: James A. Tompkins, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, e-mail: tompkins.james@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of July 11, 1997 (62 FR 37241)(FRL–5728–7), EPA, issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide petition (PP 4F4391) for tolerance by E.I. du Pont de Nemours & Co., Inc., Barley Mill Plaza, P.O. Box 80038, Wilmington, DE 19880–0038. This notice included a summary of the petition prepared by du Pont. There were two comments received in response to the notice of filing from cotton growers urging the extension of the time limited tolerance.

The petition requested that 40 CFR 180.487 be amended by extending the time-limited tolerance for residues of the herbicide pyrithiobac sodium salt (sodium 2-chloro-6-[(4,6-dimethoxypyrimidin-2-yl)thio]benzoate) in or on cottonseed at 0.02 ppm. This tolerance will expire on September 30, 1999.

In the **Federal Register** of October 25, 1995 (60 FR 54607)(FRL–4982–8), EPA established a time limited tolerance for residues of the herbicide pyrithiobac sodium in or on cottonseed at 0.02 ppm. The time limited tolerance will expire on September 30, 1997.

I. Risk Assessment and Statutory Findings

New 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. First, EPA determines the toxicity of pesticides based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health. An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted. Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100 percent or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same rationale as the 100-fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute'', ''short-term'', ''intermediate term'', and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1–day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1-7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of FQPA, this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated. High-end exposures from all three sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization. Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1–7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses). Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children. The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level

and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent of crop treated estimates are derived from Federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant subpopulation group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups, to pesticide residues. For this pesticide, the most highly exposed population subgroup (children 1 to 6) was not regionally based.

II. 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 pyrithiobac sodium and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of pyrithiobac sodium on cottonseed at 0.02 ppm. EPA's assessment of the dietary 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 salt are discussed below.

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

2. A 90–day rat feeding study with a No Observed Effect Level (NOEL) of 50 ppm (3.25 mg/kg/day for males and 4.14 mg/kg/day for females) and a Lowest Observed Effect Level (LOEL) 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 B-oxidation in males.

3. A 90–day mouse feeding study with a NOEL of 500 ppm (83.1 mg/kg/day for males and 112 mg/kg/day for females) and a LOEL 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 NOEL of 5,000 ppm (165 mg/kg/day) and a LOEL 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 NOEL of 50 mg/kg/day and a dermal irritation LOEL of 500 mg/kg/day based on increased incidence of erythema and edema, and with a systemic dermal NOEL of 500 mg/kg/day and a Systemic Dermal LOEL of 1,200 mg/kg/day based on body weight gain inhibition.

6. A 90–day rat neurotoxicity screening battery with a systemic NOEL of 7,000 ppm (466 mg/kg/day for males and 588 mg/kg/day for females) and a systemic LOEL of 20,000 ppm (1376 mg/kg/day for males and 1,609 mg/kg/day for females), based on decreased hind grip strength and increased foot spay in males, and a neurotoxicity NOEL of 20,000 ppm [Highest Dose Tested (HDT)].

7. A 78–week dietary carcinogenicity study in mice with a NOEL of 1,500 ppm 217 mg/kg/day (males) and 319 mg/kg/day (females) and a LOEL 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 and 1,500 dose groups (but not at the high dose of 5,000 ppm) with the controls. The carcinogenic effects observed are discussed below.

8. A 24–month rat chronic feeding/carcinogenicity study with a systemic NOEL of 1,500 ppm (58.7 mg/kg/day for males and 278 mg/kg/day for females) and a systemic LOEL of 5,000 ppm (200 mg/kg/day for males and 918 mg/kg/day for females) based on decreases in body weight, body weight gains and food efficiency in females, increased incidence of eye lesions in males and females, 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 B-oxidation in males and an increased incidence of inflammatory and degenerative lesions in the kidney in females. There was evidence of carcinogenicity based on a 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 feeding study with a NOEL of 5,000 ppm (143 mg/kg/day for males and 166 mg/kg/day for females) and a LOEL of 20,000 ppm (580 mg/kg/day for males and 647 mg/kg/day for females) based on decreases in body weight gain and increased liver weight.

10. A two generation reproduction study in rats with a maternal NOEL of 1,500 ppm (103 mg/kg/day) and a maternal LOEL of 7,500 ppm (508 mg/kg/day ppm), based on decreased body weight/gain and food efficacy. The Reproductive and Offspring NOEL is 7,500 ppm (508 mg/kg/day) and the reproductive and offspring LOEL is 20,000 ppm (1,551 mg/kg/day), based on decreased pup body weight.

11. A developmental toxicity study in rabbits with a maternal and developmental NOEL of 300 mg/kg and a Maternal LOEL of 1,000 mg/kg based on deaths, decreased body weight gain and feed consumption, increased incidence of clinical signs, and an increase in abortions and a developmental LOEL of 1,000 mg/kg, based on decreased fetal body weight gain.

12. A developmental toxicity study in rats with a maternal NOEL 200 mg/kg and a maternal LOEL of 600 mg/kg due to increased incidence of peritoneal staining. The developmental NOEL is 600 mg/kg and the developmental LOEL 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 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 doing regimens, with a corresponding lower amount being eliminated in the feces compared to the males.

B. Toxicological Endpoints

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

3. *Chronic toxicity*. EPA has established the RfD for pyrithiobac sodium at 0.587 milligrams/kilogram/day (mg/kg/day). This RfD is based on the systemic NOEL 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*. The Health Effects Division Carcinogenicity Peer Review Committee 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** in 1986 (51 FR 33992, September 24, 1986) 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 1.05×10^{-3} $(mg/kg/day)^{-1}$ in human equivalents based on male kidney tumors.

B. Exposures and Risks

1. *From food and feed uses.* Time limited tolerances have been established (40 CFR 180.487) for the residues of pyrithiobac sodium in or on the raw agricultural commodity cottonseed at 0.02 ppm until September 30, 1997. Processing studies for cotton have shown that pyrithiobac sodium does not concentrate in cottonseed processed commodities. Risk assessments were conducted by EPA to assess dietary exposures and risks from herbicide pyrithiobac sodium salt (sodium 2-chloro-6-[(4,6-dimethoxypyrimidin-2-yl)thio]benzoate) as follows:

Based on the assumption that 100% of the crop is treated with pyrithiobac sodium, the upper bound limit of the dietary carcinogenic risk is calculated in the range of one incidence in a billion (1.0×10^{-9}).

Using the NOEL of 58.7 mg/kg/day from the most sensitive species in the rat chronic feeding study with a 100-fold safety factor, the Reference Dose (RfD) for systemic effects is 0.58 mg/kg/day. The theoretical maximum residue contribution (TMRC) from the established and proposed tolerances is 0.000001 mg/kg/day and utilizes less than 1 percent of the RfD for the overall U.S. population. For exposure of the most highly exposed subgroup in the population, children 1 through 6 years old, the TMRC is 0.000001 mg/kg/day which is still less than 1 percent of the RfD.

2. *From drinking water.* Pyrithiobac sodium concentration in surface water has been estimated by using the Generic Expected Environmental Concentrations (GENEEC) model. The worst case exposure estimate for surface water is 7.76 parts per billion (ppb) and for ground water is 0.778 ppb. Based on the estimated exposures to pyrithiobac sodium from drinking water, the percentage of the RfD utilized for children (1 through 6 years old) would be 0.1% of the RfD. The exposure for the general U.S. population would be less than 0.1% of the RfD.

The worst case estimate for cancer risk from the estimated residues of pyrithiobac sodium in drinking water is 2.3×10^{-7} .

3. *From non-dietary exposure.* There are no non-food uses of pyrithiobac sodium currently registered under the FIFRA, as amended. No non-dietary exposures are expected for the general population.

4. *Cumulative exposure to substances with 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.'' The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning common mechanism of toxicity in a meaningful way. EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

EPA does not have, at this time, available data to determine whether pyrithiobac sodium salt 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.

C. Aggregate Risks and Determination of Safety for U.S. Population

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

2. *Chronic risk.* Using the exposure assumptions described above, EPA has concluded that aggregate exposure to pyrithiobac sodium from food and drinking water will utilize less than 0.1% of the RfD for the U.S. population. For the major identifiable subgroup with the highest aggregate exposure, children (1 through 6 years old), the aggregate exposure to pyrithiobac sodium from food and drinking water will utilize less than 0.2% of the RfD. 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.

D. Aggregate Cancer Risk for U.S. Population

Based on the upper bound potency factor (Q_1*) of 1.05×10^{-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 2.3×10^{-7}.

E. Aggregate Risks and Determination of Safety for Infants and Children

1. *Safety factor for infants and children*—a. *In general.* In assessing the potential for additional sensitivity of infants and children to residues of pyrithiobac sodium, EPA considered data from developmental toxicity studies in the rat and rabbit and a two-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from pesticide exposure during prenatal development to one or both parents. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

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- and post-natal toxicity and the completeness of the database 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. EPA believes that reliable data support using the standard MOE and uncertainty factor (usually 100 for combined inter- and intra-species variability)) and not the additional tenfold MOE/uncertainty factor when EPA has a complete data base under existing guidelines and when the severity of the effect in infants or children or the potency or unusual toxic properties of a compound do not raise concerns regarding the adequacy of the standard MOE/safety factor.

b. *Developmental and Reproductive toxicity studies.* The pre- and post-natal toxicology data base for pyrithiobac sodium is complete with respect to current toxicological data requirements. The results of these studies indicate that infants and children are not more sensitive to exposure, based on the results of the oral rat and rabbit developmental toxicity studies and the two-generation reproductive toxicity study in rats. Therefore, EPA concludes an additional tenfold safety factor is not necessary.

2. *Chronic risk.* Using the conservative exposure assumptions described above, EPA has concluded that aggregate exposure to pyrithiobac sodium from food and drinking water will utilize less than 0.2% of the RfD for infants and children. 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. EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to pyrithiobac sodium residues.

III. Other Considerations

A. Metabolism In Plants and Animals

The metabolism of pyrithiobac sodium in plants and animals is adequately understood for purposes of this tolerance.

B. Analytical Enforcement Methodology

An adequate analytical method, High Pressure Liquid Chromatography - Ultra Violet (HPLC-UV) with column switching, is available for enforcement purposes. Because of the long lead time from establishing these tolerances to publication of the enforcement methodology in the Pesticide Analytical Manual, Vol. II, the analytical methodology is being made available in the interim to anyone interested in pesticide enforcement when requested from: Calvin Furlow, Public Information and Records Integrity Branch, Information Resources and Records Service (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Room 1130A, CM#2, 1921 Jefferson Davis Highway, Arlington, VA 22202, (703–305–5937).

C. Magnitude of Residues

The nature of the residue in plants is adequately understood for the purposes of this time-limited tolerance.

D. International Residue Limits

There are no Codex Alimentarius Commission (Codex) Maximum Residue Levels (MRLs) for pyrithiobac sodium.

IV. Conclusion

The analysis for pyrithiobac sodium using tolerance level residues for all population subgroups examined by EPA shows the use on cotton will not cause exposure at which the Agency believes there is an appreciable risk. Based on the information cited above, EPA has determined that the extension of the time limited tolerance for residues of pyrithiobac sodium in cottonseed at 0.02 ppm until September 30, 1999 by amending 40 CFR 180.487 will be safe; therefore, the tolerances are extended as set forth below.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use

those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by December 22, 1997, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is 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 in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as Confidential Business Information (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.

VI. Public Docket

EPA has established a record for this rulemaking under docket control number [OPP–300548] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The public record is located in Room 1132 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Highway, Arlington, VA.

Electronic comments may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

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). 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) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or special considerations as required by Executive Order 12898, entitled Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations (59 FR 7629, February 16, 1994), or require OMB review in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these 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. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

VIII. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted 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 General Accounting Office prior to publication of this rule in today's **Federal Register**. This 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: October 1, 1997.

Daniel M. Barolo,

Director, 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. 346a and 371.

2. By revising § 180.487 to read as follows:

§ 180.487 Pyrithiobac sodium; tolerances for residues.

(a) *General.* (1) Time-limited tolerances are established for residues of the herbicide, pyrithiobac-sodium, sodium 2-chloro-6-[(4,6-dimethoxypyrimidin-2-yl)thio]benzoate, in or on the food commodities in the table in paragraph (a)(2). The tolerance will expire on the date specified in the table.

(2) Residues in these commodities not in excess of the established tolerance resulting from the use described in the following table remaining after expiration of the time-limited tolerance

will not be considered to be actionable if the herbicide is applied during the term of and in accordance with the provisions of paragraph (a) of this section.

Commodity	Parts per million	Expiration/ revocation date
Cottonseed	0.02	Sept. 30, 1999

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 97–27843 Filed 10–21–97; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 180 and 186

[OPP–300563; FRL–5748–9]

RIN 2070–AB78

Cyromazine; Pesticide Tolerances for Emergency Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes time-limited tolerances for the combined residues of cyromazine and its metabolite melamine in or on the meat, fat, and meat byproducts of turkeys. This action is in response to EPA's granting of an emergency exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act authorizing use of the pesticide on turkeys. This regulation establishes a maximum permissible level for residues of cyromazine and its metabolite melamine in this food commodity pursuant to section 408(l)(6) of the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996. These tolerances will expire and are revoked on October 1, 1998.

DATES: This regulation is effective October 22, 1997. Objections and requests for hearings must be received by EPA on or before December 22, 1997.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300563], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300563], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300563]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Andrew Ertman, Registration Division 7505C, Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 308-9367, e-mail: ertman.andrew@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: EPA, on its own initiative, pursuant to section 408(e) and (l)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) and (l)(6), is establishing tolerances for combined residues of the insecticide (larvicide) cyromazine and its metabolite melamine, in or on meat, fat, and meat byproducts of turkeys at 0.05 part per million (ppm). These tolerances will expire and are revoked on October 1, 1998. EPA will publish a document in the **Federal Register** to remove the revoked tolerances from the Code of Federal Regulations.

I. Background and Statutory Authority

The Food Quality Protection Act of 1996 (FQPA) (Pub. L. 104–170) was signed into law August 3, 1996. FQPA amends both the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 301 *et seq*., and the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 *et seq* . The FQPA amendments went into effect immediately. Among other things, FQPA amends FFDCA to bring all EPA pesticide tolerance-setting activities under a new section 408 with a new safety standard and new procedures. These activities are described below and discussed in greater detail in the final rule establishing the time-limited tolerance associated with the emergency exemption for use of propiconazole on sorghum (61 FR 58135, November 13, 1996)(FRL–5572–9).

New 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. . . .''

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that ''emergency conditions exist which require such exemption.'' This provision was not amended by FQPA. EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

Section 408(l)(6) of the FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under section 18 of FIFRA. Such tolerances can be established without providing notice or period for public comment.