

decision. The applicant may appeal to the Regional Director, Alaska Region, within 180 days. The appeal must substantiate the basis of the applicant's disagreement with the Superintendent's determination. The Regional Director (or his representative) will meet with the applicant to discuss the appeal within 30 days of receiving the appeal. Within 15 days of receipt of written materials and the meeting, if requested, the Regional Director will affirm, reverse, or modify the Superintendent's determination and explain the reasons for the decision in writing. A copy of the decision will be forwarded promptly to the applicant and will be the final agency action.

(9) *How often will commercial fishing lifetime access permit be renewed?* The superintendent will renew lifetime access permit at 5-year intervals for the lifetime of a permittee who continues to hold a valid State limited entry commercial fishing permit, and for halibut an International Pacific Halibut Commission quota share, and is otherwise eligible to participate in the fishery under federal and State law.

(10) *What other closures and restrictions apply to commercial fishermen and commercial fishing vessels?*

The following are prohibited:

(i) Commercial fishing in the waters of Geikie, Tarr, Johns Hopkins and Reid Inlets.

(ii) Commercial fishing in the waters of the west arm of Glacier Bay north of 58°50'N latitude, except commercial fishermen who have been authorized by the superintendent to troll for salmon may troll for king salmon during the period October 1 through April 30, in compliance with state commercial fishing regulations.

(iii) Commercial fishing in the east arm of Glacier Bay, north of an imaginary line running from Point Caroline through the southern point of Garforth Island and extending to the east side of Muir Inlet, except commercial fishermen who have been authorized by the superintendent to troll for salmon may troll for king salmon south of 58°50'N latitude during the period October 1 through April 30, in compliance with state commercial fishing regulations.

(b) \* \* \*

(5) [Reserved]

(6) [Reserved]

\* \* \* \* \*

**Donald J. Barry,**

*Assistant Secretary for Fish and Wildlife and Parks.*

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[OPP-300935; FRL-6386-5]

RIN 2070-AB78

**Pyriithiobac 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 pyriithiobac 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 and Co., Inc., requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1966. The tolerance will expire on September 30, 2001.

**DATES:** This regulation is effective October 20, 1999. Objections and requests for hearings, identified by docket control number OPP-300935, must be received by EPA on or before December 20, 1999.

**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 control number OPP-300935 in the subject line on the first page of your response.

**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) 308-5697, e-mail: tompkins.james@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:

Cat-egories	NAICS	Examples of Potentially Affected Entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under "FOR FURTHER INFORMATION CONTACT."

*B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?*

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at <http://www.epa.gov/>. To access this document, on the Home Page select "Laws and Regulations" and then look up the entry for this document under the "Federal Register--Environmental Documents." You can also go directly to the **Federal Register** listings at <http://www.epa.gov/fedrgstr/>.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-300935. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

## II. Background and Statutory Findings

In the **Federal Register** of July 14, 1999 (64 FR 37972) (FRL-6085-5), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) announcing the filing of a pesticide petition (PP 4F4391) for a 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, 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 extending the time-limited tolerance for residues of the herbicide pyriithiobac 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, 2001.

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 pyriithiobac sodium in or on cottonseed at 0.02 ppm. The time limited tolerance expired on September 30, 1997. In the **Federal Register** of October 22, 1997 (62 FR 54778) (FRL-5742-5), EPA established a time-limited tolerance for residues of the herbicide pyriithiobac sodium in or on cottonseed at 0.02 ppm. This time-limited tolerance expires on September 30, 1999.

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

EPA performs a number of analyses to determine the risks from aggregate

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

## III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a time-limited tolerance for residues of pyriithiobac 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 pyriithiobac sodium are discussed in this unit.

1. A rat acute oral study with a LD<sub>50</sub> of 3,300 milligrams/kilogram (mg/kg) for males and a LD<sub>50</sub> 3,200 mg/kg for females.

2. A 90-day rat feeding study with a no observed adverse effect level (NOAEL) of 50 ppm (3.25 mg/kg/day for males and 4.14 mg/kg/day for females) and a lowest observed adverse effect level (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 B-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 decreased 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 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 NOAEL of 1,500 ppm (58.7 mg/kg/day for males and 278 mg/kg/day for females) and a systemic LOAEL 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 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 and increased liver weight.

10. A 2-generation reproduction study in rats with a maternal NOAEL of 1,500 ppm (103 mg/kg/day) and a maternal LOAEL of 7,500 ppm (508 mg/kg/day ppm), based on decreased body weight/gain and food efficacy. The reproductive and offspring NOAEL is 7,500 ppm (508 mg/kg/day) and the reproductive and offspring LOAEL 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 NOAEL of 300 mg/kg and a maternal LOAEL 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 LOAEL of 1,000 mg/kg, based on decreased fetal body weight gain.

12. A developmental toxicity study in rats with a maternal NOAEL 200 mg/kg and a 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 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. Pyriithiobac 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. Pyriithiobac sodium was positive for inducing chromosome aberrations assay in human lymphocytes.

14. A rat metabolism study showed that radio labeled pyriithiobac 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 dosing 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 one-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 Reference Dose (RfD) for pyriithiobac sodium at 0.587 milligrams/kilogram/day (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.* The Health Effects Division Carcinogenicity Peer Review Committee has concluded that the available data provide limited evidence of the carcinogenicity of pyriithiobac sodium in mice and rats and has classified pyriithiobac 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 (Q1\*). 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, Q1\* (mg/kg/day)<sup>-1</sup>, of pyriithiobac sodium is 1.05 x 10<sup>-3</sup> (mg/kg/day)<sup>-1</sup> in human equivalents based on male kidney tumors.

#### C. Exposures and Risks

1. *From food and feed uses.* Tolerances have been established (40 CFR 180.487) for the residues of pyriithiobac sodium in or on the raw agricultural commodity cottonseed at 0.02 ppm until September 30, 1999. Processing studies for cotton have shown that pyriithiobac sodium does not concentrate in cottonseed processed commodities. Risk assessments were conducted by EPA to assess dietary exposures and risks from herbicide pyriithiobac sodium salt (sodium 2-chloro-6-[(4,6-dimethoxypyrimidin-2-yl)thio]benzoate) as follows:

Based on assumption that 100% of the crop is treated with pyriithiobac sodium, the upper bound limit of the carcinogenic risk from food is calculated in the range of 1 incidence in a billion (1.0 x 10<sup>-9</sup>).

Using the NOAEL of 58.7 mg/kg/day from the most sensitive species in the rat chronic feeding study with a 100-fold safety factor, the 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% of the RfD for the overall U. S. population. For exposure of the most highly exposed subgroup in the population, children aged 1-6 years, the TMRC is 0.000001 mg/kg/day which is still less than 1% of the RfD.

2. *From drinking water.* Pyriithiobac 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 pyriithiobac sodium from drinking water, the percentage of the RfD utilized for children (1-6) 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 pyriithiobac sodium in drinking water is 2.3 x 10<sup>-7</sup>.

3. *From non-dietary exposure.* There are no non-food uses of pyriithiobac sodium currently registered under the Federal Insecticide, Fungicide and Rodenticide Act, as amended. No non-dietary exposures are expected for the general population.

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 pyriithiobac 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, pyriithiobac sodium salt 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 pyriithiobac sodium salt 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 (62 FR 62961, November 26, 1997).

#### *D. Aggregate Risks and Determination of Safety for U.S. Population*

1. *Acute, short- 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 pyriithiobac sodium on cotton.

2. *Chronic risk.* Using the TMRC exposure assumptions described in this unit, EPA has concluded that aggregate exposure to pyriithiobac sodium from food and water will utilize less than 0.1% of the RfD for the U.S. population. The major identifiable subgroup with the highest aggregate exposure is children (1-6 years), the aggregate exposure to pyriithiobac 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.

3. *Aggregate cancer risk for U.S. population.* Based on the upper bound potency factor (Q1\*) of  $1.05 \times 10^{-3}$  (mg/kg/day)<sup>-1</sup>, the aggregate upper bound lifetime cancer risk from the use of pyriithiobac sodium on cotton from worst case estimates of residues in food and drinking water is  $2.3 \times 10^{-7}$ .

4. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result from aggregate exposure to residues.

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

1. *Safety factor for infants and children— i. In general.* In assessing the potential for additional sensitivity of infants and children to residues of pyriithiobac sodium, EPA considered data from developmental toxicity studies in the rat and rabbit and a 2-generation reproduction study in the rat. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure gestation. 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 prenatal and postnatal toxicity and the completeness of the data base 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 margin of exposure (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 uncertainty factor (usually 100 for combined interspecies and intraspecies 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.

ii. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicology data base for pyriithiobac 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 2-generation reproductive toxicity study in rats.

iii. *Conclusion.* There is a complete toxicity data base for pyriithiobac sodium and exposure data are complete or are estimated based on data that reasonably accounts for potential exposures.

2. *Chronic risk.* Using the exposure assumptions described in this unit, EPA has concluded that aggregate exposure to pyriithiobac sodium for children and infants 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.

3. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to residues.

## **IV. Other Considerations**

### *A. Metabolism in Plants and Animals*

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

### *B. Analytical Enforcement Methodology*

Adequate enforcement methodology (High Pressure Liquid Chromatography-Ultra Violet (HPLC-UV) with column switching) is available to enforce the tolerance expression. The method may be requested from: Calvin Furlow, PIRIB, IRSD (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460; telephone number: (703) 305-5229; e-mail address: furlow.calvin@epa.gov.

### *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 pyriithiobac sodium.

### *E. Rotational Crop Restrictions*

No tolerances for inadvertent residues of pyriithiobac sodium are required in rotational crops.

## **V. Conclusion**

Therefore, the time-limited tolerance for residues of pyriithiobac sodium in cottonseed at 0.02 ppm is extended until September 30, 2001.

## **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 control number OPP-300935 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 December 20, 1999.

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, 401 M St., SW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. M3708, 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](mailto: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, 401 M St., SW., 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, 401 M St., SW., 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 control number OPP-300935, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., 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](mailto: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 file format 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 section 408(d) of the FFDCA 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) (Public Law 104-4). Nor does it require prior consultation with State, local, and tribal government officials as specified by Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993) and Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), or special consideration of environmental justice related issues 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 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). 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 12612, entitled *Federalism* (52 FR 41685, October 30, 1987). This action 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 the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a(b)(4). 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). In addition, 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.

**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 rule in the **Federal Register**. This 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: October 5, 1999.

**James Jones,**

*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), (346a) and 371.

2. In § 180.487, by revising paragraph (a) to read as follows:

**§ 180.487 Pyriithiobac sodium; tolerances for residues.**

(a) *General.* Time-limited tolerances to expire on September 30, 2001 are established for residues of the herbicide, pyriithiobac-sodium, sodium 2-chloro-6-[(4,6-dimethoxypyrimidin-2-yl)thio]benzoate, in or on the following raw agricultural commodities:

Commodity	Parts per million	Expiration/Revocation Date
Cottonseed .....	0.02	9/30/01

\* \* \* \* \*

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Parts 261, 262, and 268**

[FRL-6458-8]

RIN 2050-AE05

**Land Disposal Restrictions Phase IV: Final Rule Promulgating Treatment Standards for Metal Wastes and Mineral Processing Wastes; Mineral Processing Secondary Materials and Bevill Exclusion Issues; Treatment Standards for Hazardous Soils, and Exclusion of Recycled Wood Preserving Wastewaters**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule; technical correction.

**SUMMARY:** On May 11, 1999, the Agency published technical amendments correcting the Land Disposal Restrictions (LDR) Phase IV final rule. In today's rule, we are correcting two minor typographical errors and one omission in the May 11th rule. Also, we are correcting three other errors in the LDR Phase IV final rule that came to our attention after the May 11th technical amendments were promulgated.

**EFFECTIVE DATE:** This rule is effective on October 20, 1999.

**ADDRESSES:** The public may obtain a copy of this technical correction at the RCRA information Center (RIC), located at Crystal Gateway One, 1235 Jefferson Davis Highway, First Floor, Arlington, Virginia.

**FOR FURTHER INFORMATION CONTACT:** For general information contact the RCRA Hotline at (800) 424-9346 (toll free) or (703) 920-9810 in the Washington, DC metropolitan area. For information on this rule contact Peggy Vyas (5302W), Office of Solid Waste, 401 M Street, SW, Washington, DC 20460, (703) 308-5477, e-mail address is "vyas.peggy@epamail.epa.gov".

**SUPPLEMENTARY INFORMATION:**

**I. Reasons and Basis for Today's Action**

The Agency recently published five rules all related to various aspects of the final Phase IV Land Disposal Restrictions (LDR) rule. These are: the May 12, 1997 LDR final rule (the so-called "Mini" Phase IV Rule, 62 FR 25998), the May 26, 1998 LDR Phase IV final rule (63 FR 28556), the August 31, 1998 administrative stay regarding certain zinc micronutrient fertilizers (63 FR 46332), the September 4, 1998 emergency revisions to the treatment standards for carbamate production wastes (63 FR 172), and the September

24, 1998 revisions to the treatment standards for spent aluminum potliners (63 FR 51254).

On May 11, 1999, the Agency published technical amendments correcting and clarifying certain aspects of all of these rules (64 FR 25408). The May 11th rule contained two minor typographical errors and one omission that we are correcting along with three other errors in the original May 26, 1998 LDR Phase IV final rule that have recently come to our attention.

**II. Corrections to the May 11, 1999 Technical Amendments**

**A. Arsenic Treatment Standard in K088**

In the September 24, 1998 (63 FR 51254) revision of the treatment standards for spent potliners from primary aluminum reduction (K088), the Agency inadvertently omitted the treatment standard adopted for fluoride wastewaters from the entry for K088 in the table of treatment standards in § 268.40. The May 11, 1999 technical amendments restored the fluoride wastewater treatment standard. However, in doing so, EPA inadvertently printed an incorrect measurement unit for the K088 treatment standard for arsenic (a standard which in fact required no correction at all).

The treatment standard for the nonwastewater form of arsenic in K088 (as revised on September 24, 1998) is 26.1 mg/kg, which is to be measured by the total amount of arsenic in the treatment residue. In the May 11, 1999 rule, the treatment standard was incorrectly given as 26.1 mg/l TCLP (a more conventional leaching test not using acid digestion). Today's rule removes the erroneous reference to "mg/l TCLP" for the nonwastewater arsenic standard for the K088 entry in the § 268.40 table.

**B. Carbamate Treatment Standards**

In the September 4, 1998 (63 FR 172) revision of the treatment standards for listed hazardous wastes from carbamate production, the Agency added a paragraph (i) to § 268.40, which inadvertently replaced the existing paragraph (i). The May 11, 1999 technical correction failed to properly reinstate the old paragraph. Today's rule reinserts paragraph § 268.40(i) from the September 4, 1998 rule and redesignates it as § 268.40(j).

**C. Citation Within § 262.34(a)(4)**

Part 262.34 contains the requirements for accumulating hazardous waste prior to treatment. In the May 11, 1999 technical correction, the Agency