

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, or on the distribution of power and responsibilities between the Federal government and Indian tribes." This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

### VIII. Submission to Congress and the Comptroller General

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

#### List of Subjects in 40 CFR Part 180

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

Dated: December 8, 2001.

**Peter Caulkins,**

*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 371.

2. Section 180.551 is amended by alphabetically adding commodities to

the table in paragraph (a) to read as follows:

#### § 180.551 Fluthiacet-methyl; tolerances for residues.

(a) *General.* \* \* \*

Commodity	Parts per million
Corn, field, forage	0.050
Corn, field, grain	0.010
Corn, field, stover	0.050
Corn, pop, grain	0.010
Corn, pop, stover	0.050
Corn, sweet, forage	0.050
Corn, sweet, (K + CWHR)	0.010
Corn, sweet, stover	0.050
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### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[OPP-301196; FRL-6811-6]

RIN 2070-AB78

#### Sodium thiosulfate; Exemption from the Requirement of a Tolerance

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of sodium thiosulfate when used as an inert ingredient (dechlorinator) in or on growing crops, or when applied to raw agricultural commodities after harvest. Eden Bioscience submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996 requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of sodium thiosulfate.

**DATES:** This regulation is effective December 21, 2001. Objections and requests for hearings, identified by docket control number OPP-301196, must be received by EPA on or before February 19, 2002.

**ADDRESSES:** Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections

and hearing requests must identify docket control number OPP-301196 in the subject line on the first page of your response.

**FOR FURTHER INFORMATION CONTACT:** By mail: Kathryn Boyle, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-6304; and e-mail address: boyle.kathryn@epa.gov.

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

##### A. Does this Action Apply to Me?

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

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

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

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

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

part 180 is available at [http://www.access.gpo.gov/nara/cfr/cfrhtml\\_00/Title\\_40/40cfr180\\_00.html](http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html), a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301196. 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 September 6, 2000 (65 FR 54015) (FRL-6738-4), 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 (FQPA) (Public Law 104-170) announcing the filing of a pesticide petition (PP 0E6177) by Eden Bioscience, 11816 Creek Parkway North, Bothell, Washington, 98011-8205. This notice included a summary prepared by the petitioner. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.1001(c) be amended by establishing an exemption from the requirement of a tolerance for residues of sodium thiosulfate pentahydrate (CAS Reg. No. 10102-17-7). The petition requested only the use of sodium thiosulfate pentahydrate; however, sodium thiosulfate is also available in an anhydrous form. The two chemical substances differ only in the attachment of the water molecules. The petition specified that sodium thiosulfate should be used at a concentration of 1 to 6% of the formulated product.

The sodium thiosulfate will be used as a pretreatment for the water in tank mixes to remove chlorine or other reactant species, thus functioning as a dechlorinator or reducing agent. When mixed with chlorine-containing water,

sodium thiosulfate reacts with the chlorine according to the equation  $\text{Na}_2\text{S}_2\text{O}_3 + 4\text{Cl}_2 + 5\text{H}_2\text{O} \rightarrow 2\text{NaHSO}_4 + 8\text{HCl}$ . Sodium thiosulfate also reacts with hydrochloric acid (produced in the previous reaction) to form breakdown products such as sulfur, salt and water:  $\text{Na}_2\text{S}_2\text{O}_3 + 2\text{HCl} \rightarrow 2\text{NaCl} + \text{H}_2\text{O} + \text{S} + \text{SO}_2$ .

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish an exemption from the requirement for 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. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

## III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term "inert" is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

## IV. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information 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 sodium thiosulfate are discussed in this unit. The information submitted in support of this petition included portions of the Food and Drug Administration (FDA) generally recognized as safe (GRAS) determination ("Evaluation of the Health Aspects of Sodium Thiosulfate as a Food Ingredient"), articles from open literature, and an acute oral toxicity study.

### A. Medical Uses

There are medical uses of sodium thiosulfate. It has been used as an antidote for acute cyanide poisoning (intravenous injection), and is an ingredient in various dermally-applied lotion formulations used to treat acne and ringworm.

### B. GRAS Determination

Sodium thiosulfate pentahydrate has been classified as GRAS by the FDA when used as a formulation aid or reducing agent in alcoholic beverages (not to exceed 0.00005%) and table salt (not to exceed 0.1%). A GRAS determination means general recognition of safety by experts qualified by scientific training and experience to evaluate the safety of the substance for the specified use pattern. As noted by the limitations stated above, sodium thiosulfate has a very limited use pattern. EPA will use the information evaluated as part of the FDA GRAS determination to inform the Agency's decision.

In its 1975 Evaluation, FDA reported the following information on the sodium thiosulfate absorption and metabolism: Sodium thiosulfate is a normal constituent of human body fluids and is excreted in the urine of man and higher animals. Quantitative studies have demonstrated the consistent presence of 2 to 17 milligrams (mg) of thiosulfate sulfur in 24-hour urine specimens of healthy young adults. Variations in excretion of thiosulfate are related to the extent of protein metabolism, activity of the intestinal flora, and the sulfur-amino

acid content of the diet. The sulfur-containing amino acids of dietary protein are the source of the endogenous thiosulfate pool. Orally administered thiosulfate that is absorbed from the gastrointestinal tract is excreted in the urine unchanged or after oxidation to sulfate. From 5 to 70% of an oral dose of sodium thiosulfate is considered to be absorbed from the gastrointestinal tract of man and the remainder to be excreted in the feces.

According to the Evaluation, sodium thiosulfate was found to cause no mutagenic effects.

The Evaluation also included a summary of the results of developmental studies on rats, mice, and hamsters. It was determined there was no effect on nidation, maternal or fetal survival, or fetal development.

#### *C. Open Literature Articles*

Three of the articles from open literature were reviewed to determine if the articles could supply information to the Agency on the genotoxicity of sodium thiosulfate. There is no indication of any mutagenic activity associated with exposure to sodium thiosulfate.

#### *D. Acute Oral Toxicity Study*

An acute oral toxicity study in the rat performed with sodium thiosulfate pentahydrate was submitted. The study was classified as acceptable, toxicity category IV. The LD<sub>50</sub> is greater than 5,050 milligrams/kilograms (mg/kg) (males and females combined).

#### *E. Developmental Toxicity*

As part of the information submitted in support of the petition, the petitioner submitted the final reports for the rat, mouse, and hamster developmental studies that were discussed in the FDA Evaluation (dated 1972), as well as the final report for a rabbit developmental toxicity study (dated 1974). These studies were performed using the anhydrous form of sodium thiosulfate. Due to the passage of almost 30 years, as well as the changes in laboratory techniques that have occurred during this time, the data tables in the reports were reviewed to determine if any additional information were contained in the tables.

1. *Mouse.* Animals were tested at the following dose levels: Negative control, positive control, 5.5, 25.5, 118 or 550 mg/kg/day over a 10-day period from day 6 through day 15 of gestation. There was no indication of any effect on maternal or fetal survival, or in incidences of visceral or skeletal abnormalities. The male/female ratio of the fetuses were calculated to be,

respectively, 1.08, 0.93, 0.74, 0.90, 0.88, or 0.68. The ratios at the lowest and highest dose levels are lower than the other ratios.

2. *Rat.* Animals were tested at the following dose levels: Negative control, positive control, 4.0, 19.0, 86.0, or 400 mg/kg/day over a 10-day period from day 6 through day 15 of gestation. There was no indication of any effect on maternal or fetal survival, or in incidences of visceral or skeletal abnormalities. The male/female ratio of the fetuses were calculated to be, respectively, 0.84, 0.78, 0.84, 0.98, 0.92, or 0.73. There is an indication of skewing (a lowering) in these ratios at the highest dose level and in the positive control.

3. *Hamster.* Animals were tested at the following dose levels: negative control, positive control, 4.0, 19.0, 86.0, or 400 mg/kg/day over a 5-day period from day 6 through day 10 of gestation. There was no indication of any effect on maternal or fetal survival, or in incidences of visceral or skeletal abnormalities. The male/female ratio of the fetuses were calculated to be, respectively, 0.52, 0.54, 0.59, 0.47, 0.40, or 0.53. These ratios (including those from the controls) are very unusual.

4. *Rabbit.* The results of the rabbit developmental study were not considered in the FDA Evaluation. Animals were tested over a 13-day period from day 6 through day 18 of gestation. There was no indication of any effect on maternal or fetal survival, or in incidences of visceral or skeletal abnormalities at the highest dose level of 580 mg/kg/day. There was no indication of any effect on the male/female ratio of the fetuses since the ratio ranged from 1.13 to 1.26.

#### *F. Information from the Internet*

To ascertain whether additional information on sodium thiosulfate were available, the Agency also searched the Tox Net website at the National Library of Medicine (<http://www.toxnet.nlm.nih.gov>). This website contained only information on sodium thiosulfate anhydrous (CAS. Reg. No. 7772-98-7). The Tox Net website classified sodium thiosulfate as moderately toxic, and generally supported the information presented in the petition. The excerpts and summaries indicated that sodium thiosulfate is not mutagenic. No internet information indicated concerns for carcinogenicity or developmental/reproductive toxicity. One study which investigated the ability of sodium thiosulfate to cross the placenta in sheep, concluded that maternally-administered sodium thiosulfate (50

mg/kg) does not increase fetal plasma thiosulfate concentrations. No information on sodium thiosulfate was available on the National Toxicology Program website, the Agency for Toxic Substances and Disease Registry website, or the Agency's Integrated Risk Information System website. The TSCATs database (<http://esc.syrres.com/efdb/TSCATS.htm>) did not contain any summaries of any developmental or reproductive studies conducted with sodium thiosulfate.

#### *G. Toxicity of Sodium Thiosulfate*

Overall, sodium thiosulfate presents as a chemical with slight to moderate toxicity. It is Category IV for acute oral toxicity (the lowest classification), and there are no indications of mutagenicity. The available developmental data indicates no effect on maternal or fetal survival or increase in incidences of visceral or skeletal abnormalities. The sex ratios (the male/female ratio of the fetuses) should cluster close to 1, indicating equal numbers of males and females. This is evident in the range of ratios in the rabbit study. However, the Agency's re-evaluation of the summary data for the rat and mouse developmental data (two out of four species) suggest the possibility that various doses of sodium thiosulfate may be associated with an apparent skewing (a lowering) of the sex ratio. However, it was also most unusual that this skewing occurred not only for certain dose levels, but also for a positive control. The sex ratios for the hamster are very unusual. Therefore, there is an uncertainty as to what these ratios mean. But, there is the possibility of technician error in sex identification. In the three studies included in the FDA Evaluation (rat, mice, and hamster), the description of the studies included the following: All fetuses were examined grossly for the presence of external congenital abnormalities. One-third of the fetuses of each litter underwent detailed visceral examinations employing 10X magnification. "The remaining two-thirds were cleared and examined for skeletal defects." Thus, there was no chance to correct any mis-sexing. The rabbit study, in which there was no effect on the male/female ratio of the fetuses, was performed in a different manner: "All fetuses underwent a detailed gross examination for the presence of external congenital abnormalities." All were examined for visceral abnormalities. "All fetuses were then cleared and examined for skeletal defects." Thus, the examination of all fetuses apparently allowed for greater accuracy in sexing.

## V. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

EPA establishes exemptions from the requirement of a tolerance only in those cases where the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

### A. Dietary Exposure

For the purposes of assessing potential exposure under this exemption, EPA considered that sodium thiosulfate could be present in all raw and processed agricultural commodities and drinking water, and that non-occupational non-dietary exposure was possible.

1. *Food.* Protein, which is composed of various amino acids, is required for human survival. Sodium thiosulfate is produced in the human body during the metabolism of sulfur-containing amino acids. There is an effective self-regulating mechanism to rid the body of excess sodium thiosulfate through excretion in the urine. As previously stated, sodium thiosulfate is considered to be GRAS for a very specific use pattern. In the 1975 Evaluation, it was estimated that the per capita consumption of sodium thiosulfate was 12 micrograms ( $\mu\text{g}$ ) per day. Considering the use of sodium thiosulfate in pesticide products, as a dechlorinator when mixed with certain proteins such as harpin protein, and given the reactive nature (as a reducing agent) of sodium thiosulfate, this use pattern should not significantly increase the amount of

sodium thiosulfate in the food supply above those amounts permitted by FDA.

2. *Drinking water exposure.* Thiosulfate can be produced naturally by the reaction of elemental sulfur with sulfite ion in boiling water. Therefore, thiosulfate occurs naturally in such environments as hot springs, geysers, and marine hydrothermal vents. It can also occur in nature as the result of the biological or chemical oxidation of sulfide, and thus can be found in freshwater and marine sediments, and salt marshes.

Considering that thiosulfate can be metabolized by sulfate-reducing bacteria, and given its ability to react with chlorine (to act as a reducing agent), sodium thiosulfate is unlikely to occur in drinking water.

### B. Other Non-Occupational Exposure

The medicinal uses of sodium thiosulfate are also regulated by FDA. There are other industrial uses of sodium thiosulfate which include use as a photographic fixing agent. Sodium thiosulfate is also used to remove chlorine from water used in aquariums.

### C. Exposure Estimates

As previously stated, it was estimated that the per capita consumption of sodium thiosulfate was 12  $\mu\text{g}$  per day. This was based on the amount of sodium thiosulfate used by the food industry and assuming a population of 210 million. (The Agency acknowledges that this exposure estimate is almost 30 years old.) If this were converted to mg/kg/day using a 60 kg (female) body weight, then the exposure could be estimated as 0.0002 mg/kg/day. The highest dose levels in each of the developmental toxicity studies (mouse, rat, hamster, and rabbit) were respectively 550, 400, 400, and 580 mg/kg/day. No effects were noted at these levels. The Agency has not attempted to use a safety factor analysis for sodium thiosulfate; however, the 0.0002 mg/kg/day is orders of magnitude lower than the highest dose levels from any of the developmental toxicity studies. Thus, the reported uses of sodium thiosulfate, its use as a GRAS substance and its use as an inert ingredient (a dechlorinator) should result in human exposure far below any dose level that could possibly produce an adverse effect.

## VI. Cumulative Effects

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

residues and "other substances that have a common mechanism of toxicity." Sodium thiosulfate is produced in the human body during the metabolism of sulfur-containing amino acids. There is an effective self-regulating mechanism (excretion) to rid the body of excess sodium thiosulfate, so cumulative effects are unlikely as a result of exposure to sodium thiosulfate and a substance sharing a common mechanism of toxicity, assuming such a substance exists. The Agency has not made any conclusions as to whether or not sodium thiosulfate shares a common mechanism of toxicity with any other chemicals, since cumulative effects for sodium thiosulfate and other substances are unlikely.

## VII. Determination of Safety for U.S. Population

Based on the low-moderate toxicity of sodium thiosulfate and the low potential for exposure from the EPA regulated uses of sodium thiosulfate, as well as the FDA GRAS uses, the Agency has determined that aggregate exposure to sodium thiosulfate under reasonably foreseeable circumstances will pose no appreciable risks to human health. Accordingly, EPA concludes that there is a reasonable certainty of no harm to the U.S. population from aggregate exposure to residues of sodium thiosulfate and that a tolerance is not necessary.

## VIII. Determination of Safety for Infants and Children

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 concludes that a different margin of safety will be safe for infants and children. Due to the expected low toxicity of sodium thiosulfate, EPA has not used a safety factor analysis to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary. The Agency has determined that there is a reasonable certainty of no harm to infants and children from aggregate exposure to residues of sodium thiosulfate and that a tolerance is not necessary.

## IX. Other Considerations

### A. Endocrine Disruptors

FQPA requires EPA to develop a screening program to determine whether certain substances, including all pesticide chemicals (both inert and active ingredients), "may have an effect in humans that is similar to an effect

produced by a naturally occurring estrogen, or such other endocrine effect." EPA has been working with interested stakeholders to develop a screening and testing program as well as a priority setting scheme. As the Agency proceeds with implementation of this program, further testing of products containing sodium thiosulfate for endocrine effects may be required.

#### B. Analytical Method(s)

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

#### C. Existing Exemptions

There are no existing exemptions for sodium thiosulfate anhydrous or sodium thiosulfate pentahydrate.

#### D. International Tolerances

The Agency is not aware of any country requiring a tolerance for sodium thiosulfate anhydrous or sodium thiosulfate pentahydrate nor have any CODEX Maximum Residue Levels (MRLs) been established for any food crops at this time.

### X. Conclusions

Based on the information in this preamble, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of sodium thiosulfate anhydrous or sodium thiosulfate pentahydrate. Accordingly, EPA finds that exempting sodium thiosulfate anhydrous or sodium thiosulfate pentahydrate from the requirement of a tolerance will be safe.

### XI. 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-301196 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 19, 2002.

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

Mail your written request to: Office of the Hearing Clerk (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](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, 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 VIII.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-301196, 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](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 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).

### XII. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance

requirement 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 exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States,

or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any “tribal implications” as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure “meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.” “Policies that have tribal implications” is defined in the Executive Order to include regulations that have “substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes.” This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal

government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

### XIII. 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: December 6, 2001.

**Peter Caulkins,**

*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 371.

2. In § 180.1001, the table in paragraph (c) is amended by adding alphabetically the following inert ingredient to read as follows:

#### § 180.1001 Exemptions from the requirement of a tolerance.

\* \* \* \* \*

(c) \* \* \*

Inert ingredients	Limits	Uses
* * *	* * *	
Sodium thiosulfate anhydrous (CAS Reg. No. 7772-98-7 or sodium thiosulfate pentahydrate, CAS Reg. No. 10102-17-7)	Not to exceed 6% of the formulated product	Dechlorinator, reducing agent
* * *	* * *	

\* \* \* \* \*

[FR Doc. 01-31496 Filed 12-20-01; 8:45 am]

BILLING CODE 6560-50-S

**FEDERAL COMMUNICATIONS COMMISSION****47 CFR Part 36****Federal-State Joint Board on Universal Service****AGENCY:** Federal Communications Commission.**ACTION:** Correcting amendment.

**SUMMARY:** This document contains corrections to the final regulations in the *Fourteenth Report and Order*, which were published in the **Federal Register** of Tuesday, June 5, 2001, 66 FR 30080. Specifically, this correction revises the language in section 36.605(c)(3)(ii) to make it clear.

**DATES:** Effective January 22, 2002.

**FOR FURTHER INFORMATION CONTACT:** Greg Guice, Attorney, Common Carrier Bureau, Accounting Policy Division, (202) 418-0095.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's *Twenty-Third Order on Reconsideration* in CC Docket No. 96-45 released on July 11, 2001. The full text of this document is available for public inspection during regular business hours in the FCC Reference Center, Room CY-A257, 445 Twelfth Street, S.W., Washington, D.C., 20554.

**I. Introduction**

1. In this document, the Commission makes a correction to section 36.605(c)(3)(ii) of its rules adopted in the *Fourteenth Report and Order*, 66 FR 30080, June 5, 2001. The correction concerns the calculation of safety net additive support in the years following qualification for such support and is necessary to make the rule consistent with the text of the underlying order. Specifically, this correction revises the language in section 36.605(c)(3)(ii) to make it clear that rural telephone companies receive the lesser of either: (1) the sum of capped support and the safety net additive support in each year or (2) uncapped support in each year when the cap is not triggered.

**Need for Correction**

As published, the final regulations contain errors which may prove to be misleading and need to be clarified.

**List of Subjects in 47 CFR Part 36**

Communications common carriers, Telephone.

Federal Communications Commission.

**Magalie Roman Salas,**  
*Secretary.*

Accordingly, 47 CFR part 36 is corrected by making the following correcting amendment:

**PART 36—JURISDICTIONAL SEPARATIONS**

1. The authority citation for part 36 continues to read as follows:

**Authority:** 47 U.S.C. §§ 151-154, 201-205, 218-220, 254, 303(r), 403, 405, and 410.

2. Section 36.605(c)(3)(ii) is revised to read as follows:

**§ 36.605 Calculation of safety net additive.**

\* \* \* \* \*

(c) \* \* \*

(3) \* \* \*

(ii) Continue to pay safety net additive support in any of the four succeeding years in which the total carrier loop expense adjustment is limited by the provisions of § 36.603. Safety net additive support in the succeeding four years shall be the lesser of:

(A) The sum of capped support and the safety net additive support received in the qualifying year;

or

(B) The rural telephone company's uncapped support.

\* \* \* \* \*

[FR Doc. 01-31364 Filed 12-20-01; 8:45 am]

BILLING CODE 6712-01-P

**FEDERAL COMMUNICATIONS COMMISSION****47 CFR Part 54****[CC Docket No. 96-45; FCC 01-321]****Federal-State Joint Board on Universal Service; Petition for Reconsideration Filed by the United States Telecom Association****AGENCY:** Federal Communications Commission.**ACTION:** Final rule, denial.

**SUMMARY:** In this document, the Commission denies the request of the United States Telecom Association to reconsider portions of the *Contribution Interval Order* modifying the methodology used to assess contributions that carriers make to the federal universal service support mechanisms.

**FOR FURTHER INFORMATION CONTACT:** Richard D. Smith, Attorney, Common Carrier Bureau, Accounting Policy Division, (202) 418-7400.

**SUPPLEMENTARY INFORMATION:** This is a summary of the Commission's Order on

Reconsideration in CC Docket No. 96-45 released on November 6, 2001. The full text of this document is available for public inspection during regular business hours in the FCC Reference Center, Room CY-A257, 445 Twelfth Street, S.W., Washington, D.C., 20554.

**I. Introduction**

1. In this Order on Reconsideration, we deny the request of the United States Telecom Association (USTA) to reconsider portions of the *Contribution Interval Order*, 66 FR 16145, March 23, 2001, modifying the methodology used to assess contributions that carriers make to the federal universal service support mechanisms. Specifically, we deny USTA's request to reconsider the imposition of additional filing requirements and the method of calculating contributions from carriers that either under-report or over-report quarterly revenue. In so doing, we affirm our prior conclusion that the provision of sufficient and competitively neutral funding for the universal service support mechanisms depends on the timely submission of accurate revenue information from contributors.

**II. Discussion**

2. We deny the request of USTA to reconsider portions of the *Contribution Interval Order*. We find that USTA has raised no new issues or facts to persuade us to reconsider the decisions made in the *Contribution Interval Order*. Specifically, we conclude that the accurate submission of quarterly revenue data is essential to ensure that sufficient contributions are made to the federal universal service support mechanisms on a competitively neutral basis. The Commission carefully considered the implications of imposing additional reporting requirements on carriers in the *Contribution Interval Order* and concluded that such requirements were necessary. In addition, we conclude that the method adopted by the Commission of calculating contributions from carriers that under-report or over-report revenues provides an appropriate incentive for carriers to accurately report quarterly revenues to USAC.

3. *Reporting Requirements.* We deny USTA's request to reconsider the Commission's decision to increase carriers' reporting requirements. USTA's petition raises no new arguments that would convince us to reconsider the conclusion that the benefits of substantially reducing the contribution interval outweigh any increased