

Populations (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, 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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(m)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR

67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

**VII. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: June 30, 2008.

**Lois Rossi,**

*Direction, 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. Section 180.438 is amended by:

■ i. Alphabetically adding okra and pistachios to the table in paragraph (a)(2).

■ ii. Revising paragraph (a)(3).

The amendments read as follows:

**§ 180.438 Lambda-cyhalothrin and an isomer gamma-cyhalothrin; tolerances for residues.**

- (a) \* \* \* \* \*
- (2) \* \* \*

| Commodity       | Parts per million |
|-----------------|-------------------|
| * * * * *       | *                 |
| Okra .....      | 0.20              |
| * * * * *       | *                 |
| Pistachio ..... | 0.05              |
| * * * * *       | *                 |

(3) A tolerance of 0.01 part per million is established for residues of the insecticide lambda-cyhalothrin and an isomer gamma-cyhalothrin in or on all food commodities (other than those already covered by a higher tolerance as a result of use on growing crops) in food-handling establishments where food products are held, processed, or prepared.

\* \* \* \* \*

[FR Doc. E8-15518 Filed 7-8-08; 8:45 am]

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2007-0571; FRL-8372-2]

**Ammonium Soap Salts of Higher Fatty Acids (C<sub>8</sub>-C<sub>18</sub> saturated; C<sub>8</sub>-C<sub>12</sub> unsaturated); 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 the ammonium soap salts of higher fatty acids (C<sub>8</sub>-C<sub>18</sub> saturated; C<sub>8</sub>-C<sub>12</sub> unsaturated) in or on all food commodities when applied for the suppression and control of a wide variety of grasses and weeds. Falcon Lab, LLC submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by

the Food Quality Protection Act of 1996 (FQPA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of ammonium soap salts of higher fatty acids (C<sub>8</sub>-C<sub>18</sub> saturated; C<sub>8</sub>-C<sub>12</sub> unsaturated).

**DATES:** This regulation is effective July 9, 2008. Objections and requests for hearings must be received on or before September 8, 2008, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2007-0571. To access the electronic docket, go to <http://www.regulations.gov>, select “Advanced Search,” then “Docket Search.” Insert the docket ID number where indicated and select the “Submit” button. Follow

the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in regulations.gov. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

**FOR FURTHER INFORMATION CONTACT:** Raderrio Wilkins, Biopesticides and Pollution Prevention Division (7511P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-1259; e-mail address: [wilkins.raderrio@epa.gov](mailto:wilkins.raderrio@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. General Information

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

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

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

###### B. How Can I Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at <http://www.regulations.gov>, you may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgstr>. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at <http://www.gpoaccess.gov/ecfr>.

###### C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2007-0571 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 as required by 40 CFR part 178 on or before September 8, 2008.

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA-HQ-OPP-2007-0571, by one of the following methods:

• **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the on-line instructions for submitting comments.

• **Mail:** Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

• **Delivery:** OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305-5805.

##### II. Background and Statutory Findings

In the **Federal Register** of August 8, 2007 (72 FR 44521) (FRL-8139-7), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP 7F7186) by Falcon Lab, LLC, 1103 Norbee Drive, Wilmington, DE 19803. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of ammonium soap salts of higher fatty acids (C<sub>8</sub>-C<sub>18</sub> saturated and C<sub>8</sub>-C<sub>12</sub> unsaturated). This notice failed to include a summary of the petition prepared by the petitioner Falcon Lab, LLC, nor was a summary of the petition provided in the docket for this action. Therefore, EPA republished notice of receipt of this petition in the **Federal Register** of April 16, 2008 (73 FR 20631) (FRL-8360-1), and posted the summary of the petition in the docket for this action. There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of 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 exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which require 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...." Additionally, section 408(b)(2)(D) of FFDCA requires that 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 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. 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.

Ammonium soap salts of fatty acids are one class of salts of fatty acids. Soaps are mineral salts of naturally occurring fatty acids. The fatty acids are a significant part of the normal daily diet, for they occur in dietary lipids which usually constitute about 90 grams in a day's diet. As discussed in this Unit, as part of the reregistration process, the Agency has already conducted a risk assessment for soap salts of fatty acids for their potential effects to human health and the environment and determined that all registered pesticide products containing the active ingredient Soap Salts are not likely to cause unreasonable adverse effects in people or the environment and were eligible for reregistration.

The Agency issued a Reregistration Eligibility Document (RED) in September 1992 for potassium salts of fatty acids (C<sub>12</sub>-C<sub>18</sub> saturated and C<sub>18</sub> unsaturated, including potassium laureate, potassium myristate, potassium oleate, and potassium ricinoleate (CAS No. 10124-65-9) and ammonium salts of fatty acids (C<sub>8</sub>-C<sub>18</sub> saturated and C<sub>18</sub> unsaturated, including ammonium oleate (CAS No. 84776-33-0)). While the RED does not specifically identify the active ingredient ammonium nonanoate (also called pelargonic acid) by name, the Agency believes the conclusions of the RED are applicable to ammonium nonanoate because the RED defines the soap salts of fatty acids that were assessed to be (C<sub>8</sub>-C<sub>18</sub>) and ammonium nonanoate (pelargonic acid) is an ammonium salt of C<sub>9</sub> fatty acid. All soap salts with fatty acids having aliphatic carbon chains lengths in the range between C<sub>8</sub> and C<sub>18</sub> saturated and C<sub>8</sub>-C<sub>12</sub> unsaturated are virtually identical in regard to chemistry and toxicology.

In support of the RED, the Agency conducted a risk assessment for soap salts for their potential effects (if any) to

human health. The Agency determined that soap salts of fatty acids are metabolized, forming simple compounds that serve as energy sources and structural compounds used in all living cells, and have low acute toxicity by the oral route of exposure. The RED notes that soap salts of potassium salts of coco fatty acid and sodium salts of caprylic acid, when administered to lab animals at high doses cause reproductive and mutagenic effects. However, based on the low toxicity of ammonium nonanoate and data/information reviewed in support of the tolerance exemption for pelargonic acid (ammonium nonanoate acid) which demonstrated that pelargonic acid did not cause developmental or mutagenic effects, the Agency believes that there would likely not be any reproductive or mutagenic effects for this active ingredient when used in the manner as described in this rule. Further the pesticidal concentration of ammonium nonanoate will be exceedingly lower in comparison to those high doses which were administered in the studies using potassium salts of coco fatty acids.

The active ingredient ammonium soap salts of fatty acids, is used as a contact, non-selective, broad spectrum, foliar-applied herbicides. This active ingredient was federally registered in 2006 as a non-food use pesticide for the suppression and control of a wide variety of undesirable grasses and weeds. In addition, ammonium salts of fatty acids have been registered for other non-food uses, including repelling rabbits and deer from forage and grain crops, vegetables and field crops, in orchards, and on nursery stock, ornamentals, flower, lawns, turfs, vines, shrubs and trees.

As part of this rulemaking, EPA reviewed the Soap Salts of Fatty Acid RED, the Pelargonic Acid Tolerance Exemption (40 CFR 180.1159), the data and/or information submitted by the petitioner and has concluded that ammonium nonanoate, a C<sub>9</sub> ammonium salt fatty acid (also called pelargonic acid) and other ammonium soap salts of higher fatty acids (C<sub>8</sub>-C<sub>18</sub> saturated; C<sub>8</sub>-C<sub>12</sub> unsaturated) do not pose an unreasonable adverse effect to the environment, when used in accordance with approved labeling. While this pesticide is not intended to be sprayed directly on food or feed crops, the Agency has determined that there may be a potential for exposure from residues of ammonium soap salts on food and feed as a result of unintentional spray or drift.

In lieu of submitting new Tier I toxicity studies for ammonium nonanoate, the registrant relied on data

previously submitted in support of the Soap Salts Registration Eligibility Document (RED). The RED concluded that fatty acids such as oleic acids and related C<sub>12</sub>-C<sub>18</sub> fatty acids are generally considered to be low toxicity by the oral route of exposure and gives a category IV for both oral and dermal route of exposure. This conclusion can be extended to all ammonium salts of fatty acids (C<sub>8</sub>-C<sub>18</sub> saturated; C<sub>8</sub>-C<sub>12</sub> unsaturated) because of the virtual identical chemistry and toxicology of these fatty acids.

In addition to relying on the RED, the petitioner submitted requests for waiver of additional studies in support of its petition for a tolerance exemption.

1. *Acute inhalation toxicity:* Ammonium salts of fatty acids do not form aerosol particulates, have a vapor pressure near that of water and do not readily vaporize. "In a study in which 10 rats were exposed for 8 hours to saturated vapors of mixed isomers of decanoic acid (C<sub>10</sub>) no deaths were observed." MRID 43843503 reported that the LC<sub>50</sub> was > 1.244 milligrams/liter (mg/L) for nonanoic acid (C<sub>9</sub>).

2. *Subchronic oral toxicity:* MRID 43843507 reported that no significant effects were demonstrated in a 14-day range finding study in rats given nonanoic acid at doses up to 1,834 mg/kilogram (kg)/day. "The agency concluded that a 90-day oral toxicity study was not necessary for a dietary risk assessment" of nonanoic acid due to the following:

- i. Lack of effects at extremely high doses in the range finding study;
- ii. Nature of nonanoic acid (a fatty acid) and its ubiquity in nature;
- iii. The results from acute mammalian toxicology studies; and
- iv. The unlikelihood of prolonged human exposure via the oral route due to the proposed use patterns.

Dietary exposure would be minimized via plant metabolism of ammonium nonanoic acid through oxidative pathways common for fatty acids. The same rationale can be applied to ammonium salts of fatty acids because they share a chemical identity with ammonium nonanoic acid.

3. *Teratogenicity:* MRID 43843508, a developmental toxicity study of nonanoic acid (C<sub>9</sub> fatty acid), reported that the treatment had no adverse effects on clinical signs, body weight, or food/water consumption. No fetal toxicity was observed. The mean number of viable fetuses, early or late resorptions, implantation sites, corpora lutea, pre- and post-implantation losses, sex ratios and fetal body weight were comparable to those of the control group. The no observed adverse effect level (NOAEL)

for maternal and developmental toxicity was 1,500 mg/kg/day and the lowest observed adverse effect level (LOAEL) was > 1,500 mg/kg/day. The developmental toxicity study for ammonium nonanoic acid showed no effects at dose levels above the limit dose (1,000 mg/kg/day). Therefore, the tier 1 data requirement for food use for this biochemical pesticide is satisfied. The same rationale can be applied to ammonium salts of fatty acids because they share a chemical identity with ammonium nonanoic acid.

4. *Immune response*: This study is conditionally required when there is a requirement for a sub-chronic oral, dermal, or inhalation study, depending on the most likely routes of exposure. The registrant requested waivers based on the factors given for the waiver request of the 90-day oral toxicity study.

#### IV. Aggregate Exposures

In examining aggregate exposure, section 408 of FFDCA 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).

Aggregate exposure to ammonium salts may occur via oral and dermal routes. Since the acute oral toxicity of soap salts is low (Toxicity Category IV), the risks anticipated from oral exposures are considered minimal. The acute dermal toxicity is also low (Toxicity Category IV). Longer dermal exposures can produce mild to moderate irritation, but soap salts are not skin sensitizers. As a result, the anticipated risks from dermal exposure are considered minimal. Since the inhalation route is not a likely exposure pathway the anticipated risk from inhalation exposure are also considered minimal.

##### A. Dietary Exposure

1. *Food*. Pesticides containing ammonium soap salts of fatty acids are likely to be used as contact, non-selective, broad spectrum, foliar-applied herbicides or as repellents. As such they are likely not to be applied directly to any food plants. Moreover, ammonium salts of fatty acids are expected to be rapidly metabolized by soil microorganisms, with a half-life of perhaps less than one day, therefore residues of ammonium salts of fatty acids when used in accordance with approved labeling will not persist in the

environment. The lack of direct application to food plants coupled with the rapid metabolization of ammonium salts when used as pesticides will result in low exposures to ammonium soap salts of fatty acids. However, if the exposures to ammonium soap salts to humans from food commodities that have been indirectly sprayed with residues of ammonium salts occur, the Agency does not expect exposures to be unsafe due the low acute toxicity and likely low exposure of these soap salts.

2. *Drinking water exposure*. No significant exposure to drinking water is expected from an accumulation of soap salts in the aquatic environment when it is used in accordance with approved labeling. Ammonium salts of fatty acids are not to be applied directly to water.

##### B. Other Non-Occupational Exposure

Non-occupational dermal exposure to ammonium salts of fatty acids will be expected since the use of this pesticide will be in the residential settings. However, the Agency believes that any hazard related to exposure to residential users from this pesticide will likely be insignificant. This belief is based on the fact that the toxicity data demonstrated no toxic endpoints upon which to base a risk characterization at or below 1,000 mg/kg of body weight/day (the limit dose).

Non-occupational inhalation exposure is not expected because ammonium salts of fatty acids do not form aerosol particulates, have a vapor pressure near that of water, and do not readily vaporize.

#### V. Cumulative Effects

Section 408(b)(2)(D)(v) of the FFDCA requires the Agency to consider the cumulative effect of exposure to residues that have a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. Except for ocular exposure, ammonium nonanoate is of low toxicity, and it is not anticipated that there would be cumulative effects from common mechanisms of toxicity.

Studies of fatty acids and fatty acid salts previously submitted to the Agency, indicate that the half-life of fatty acids is less than one (1) day (MRID 00157476). As can be expected, there is very rapid microbial degradation of fatty acids in soil. Fatty acids and their salts are excellent substrates for microbial growth, serving both as carbon sources and energy sources. The active ingredient cannot totally dissipate from soil, because there is a natural content of fatty acids in soil resulting from plant metabolism and by

formation of microbial organisms. Fatty acids constitute a significant portion of the normal daily diet of mammals (including humans, birds, and invertebrates since they are found in large amounts in the form of lipids in all living tissues (including seeds). Microbial metabolism of fatty acids has the effect of either converting the degradates to CO<sup>2</sup> and ester (if used as an energy source) or converting the carbon content of the fatty acid to any of the thousands of naturally occurring organic substances produced by the soil microflora (if used as a carbon source). Based on these known facts of the role of fatty acids in the environment and in food and feed, there should be no concern for cumulative effects of ammonium salts of fatty acids used as pesticides.

#### VI. Determination of Safety for U.S. Population, Infants and Children

There is a reasonable certainty that no harm to the U.S. population, including infants and children, will result from aggregate exposure to residues of ammonium salts of fatty acids (C<sub>8</sub>-C<sub>18</sub> saturated; C<sub>8</sub>-C<sub>12</sub> unsaturated) due to their use as a pesticide. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. As discussed in Unit III, ammonium salts of fatty acids (C<sub>8</sub>-C<sub>18</sub> saturated; C<sub>8</sub>-C<sub>12</sub> unsaturated) have low toxicity. Moreover, many soap salts of fatty acids are part of the human diet and pesticide exposures are not expected to exceed the levels of naturally occurring fatty acids in commonly eaten foods. Accordingly, exempting ammonium salts of fatty acids (C<sub>8</sub>-C<sub>18</sub> saturated; C<sub>8</sub>-C<sub>12</sub> unsaturated) from the requirement of a tolerance is considered safe.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of exposure MOE (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 exposure (safety) will be safe for infants and children. Margins of exposure are often referred to as uncertainty or safety factors. In this instance, based on all available information, the Agency concludes that ammonium salts of fatty acids are practically non-toxic to mammals including infants and children. Because there are no threshold effects of concern to infants, children, and adults when ammonium salt is used as labeled, the provision requiring an additional margin of safety does not apply. Further, the provisions of consumption patterns, special susceptibility, and cumulative

effects do not apply. As a result, EPA has not used a MOE approach to assess the safety of ammonium salts of fatty acids (C<sub>8</sub>-C<sub>18</sub> saturated; C<sub>8</sub>-C<sub>12</sub> unsaturated).

## VII. Other Considerations

### A. Endocrine Disruptors

EPA is required under the FFDCA, as amended by FQPA, to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally-occurring estrogen, or other such endocrine effects as the Administrator may designate". Ammonium salts of fatty acids (C<sub>8</sub>-C<sub>18</sub> saturated; C<sub>8</sub>-C<sub>12</sub> unsaturated) are not known endocrine disruptors nor are they related to any class of known endocrine disruptors.

### B. Analytical Method(s)

There have been no analytical procedures conducted to ascertain residuals of ammonium salts of fatty acids (C<sub>8</sub>-C<sub>18</sub> saturated; C<sub>8</sub>-C<sub>12</sub> unsaturated) on food crops that have been exposed to pesticides containing such ammonium salts of fatty acids. Naturally occurring fatty acids constitute a significant part of the normal daily diet and are of low toxicity when taken orally and pose no known health risks. Further, based on data and/or information already reviewed by the Agency in support of the reregistration of soap salts of fatty acids, the residues of these salts of fatty acids from pesticide use are not likely to exceed and are likely to be indistinguishable from levels of naturally occurring fatty acids in commonly eaten foods.

### C. Codex Maximum Residue Level

There are currently no established Codex, Canadian, or Mexican MRLs for ammonium salts of fatty acids in/on plants or livestock commodities. Therefore, no compatibility issues exist with regard to the proposed U.S. exemption from the requirement of a tolerance.

## VIII. Conclusions

There is currently no tolerance or tolerance exemption for ammonium salts of fatty acids. A proposed rule was published on May 1, 1996 (61 FR 19233) (FRL-5362-9), to exempt ammonium oleate and related C<sub>8</sub>-C<sub>18</sub> fatty acids ammonium salts from the requirement of a tolerance for residues in or on all raw agricultural commodities when used in accordance with good agricultural practice; however, the proposed rule was never finalized by

the Agency. This action will formalize food use approval for ammonium salts of fatty acids as stated in the 1992 RED: Soap Salts, by exempting ammonium salts of higher fatty acids from the requirement of a tolerance.

The Agency has determined that there is a reasonable certainty that no harm will result to the U.S. population, including infants and children from aggregate exposures to residues of ammonium salts of fatty acids (C<sub>8</sub>-C<sub>18</sub> saturated; C<sub>8</sub>-C<sub>12</sub> unsaturated). This conclusion is based on the demonstrated, very low acute oral and dermal toxicity of these ammonium salts and because the Agency anticipates that actual exposures in food will be low due to the uses of ammonium soap salts of fatty acids.

## IX. Statutory and Executive Order Reviews

This final rule establishes a tolerance under section 408(d) of 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). Because this final rule has been exempted from review under Executive Order 12866, this final 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) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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.*, 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).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, 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.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such,

the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not 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).

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).

## X. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report 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: June 30, 2008.

**Debra Edwards,**

*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. 321(q), 346a and 371.

■ 2. Section 180.1284 is added to subpart D to read as follows:

**§ 180.1284 Ammonium salts of higher fatty acids (C<sub>8</sub>-C<sub>18</sub> saturated; C<sub>8</sub>-C<sub>12</sub> unsaturated); exemption from the requirement of a tolerance.**

This regulation establishes an exemption from the requirement of a tolerance for residues of the ammonium salts of higher fatty acids C<sub>8</sub>-C<sub>18</sub> saturated; C<sub>8</sub>-C<sub>12</sub> unsaturated on in or on all food commodities when applied for the suppression and control of a wide variety of grasses and weeds.

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**BILLING CODE** 6560-50-S

**FEDERAL COMMUNICATIONS COMMISSION**

**47 CFR Part 73**

[MB Docket Nos. 06-121, 02-277, 04-228, MM Docket Nos. 01-235, 01-317, 00-244, 99-360; FCC 07-216]

**2006 Quadrennial Regulatory Review—Review of the Commission's Broadcast Ownership Rules and Other Rules Adopted Pursuant to Section 202 of the Telecommunications Act of 1996**

**AGENCY:** Federal Communications Commission.

**ACTION:** Final rule; announcement of effective date.

**SUMMARY:** This document announces the effective date of the rule change to section 73.3555(d) of the Commission's rules, which was published in the *Federal Register* on February 21, 2008.

The rule relates to the cross-ownership of broadcast stations and newspapers within a designated market area.

**DATES:** The final rule published on February 21, 2008 (73 FR 9481), modifying 47 CFR 73.3555(d), is effective July 9, 2008.

**FOR FURTHER INFORMATION CONTACT:** For additional information on this proceeding, contact Mania Baghdadi, *Mania.Baghdadi@fcc.gov*, 202-418-2330, of the Media Bureau, Industry Analysis Division.

**SUPPLEMENTARY INFORMATION:** In a Report and Order and Order on Reconsideration released on February 4, 2008, FCC 07-216, and published in the *Federal Register* on February 21, 2008, 73 FR 9481, the Federal Communications Commission adopted a new rule which contains information collection requirements subject to the Paperwork Reduction Act. The Report and Order and Order on Reconsideration stated that the rule change requiring OMB approval would become effective immediately upon announcement in the *Federal Register* of OMB approval. On June 23, 2008, the Office of Management and Budget (OMB) approved the information collection requirements contained in 47 CFR 73.3555(d). These information collections are assigned OMB Control Nos. 3060-0031 and 3060-0110. This publication satisfies the statement that the Commission would publish a document announcing the effective date of the rule change requiring OMB approval.

Under 5 CFR part 1320, an agency may not conduct or sponsor a collection of information unless it displays a current, valid OMB Control Number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act that does not display a valid OMB Control Number. The foregoing notice is required by the Paperwork Reduction Act of 1995, Public Law 104-13, October 1, 1995, 44 U.S.C. 3507. Broadcast licensees are reminded that, as enumerated in paragraph 78 of the Report and Order and Order on Reconsideration, licensees with a pending waiver request that involves an existing station combination consisting of more than one newspaper and/or more than one broadcast station will have 90 days after the changes to 47 CFR 73.3555(d) become effective to either amend their renewal or waiver requests or file a request for a permanent waiver. Entities that have been granted a temporary waiver of the newspaper/broadcast cross-ownership rule pending the completion of this rulemaking will have 90 days after the changes to 47 CFR 73.3555(d) become effective to either amend their renewal or waiver requests or file a request for a permanent waiver. See 73 FR at 9483, 9487.

Federal Communications Commission.

**William F. Caton,**  
*Deputy Secretary.*

[FR Doc. E8-15594 Filed 7-8-08; 8:45 am]

**BILLING CODE** 6712-01-P