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.

IX. 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: September 13, 2002.

Richard P. Keigwin, Jr.,

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 180.535 is amended by alphabetically adding the following commodities to the table in paragraph (b) to read as follows:

§ 180.535 Fluroxypyr 1-methylheptyl ester; tolerances for residues.

* * * * *

(b) * * *

Commodity	Parts per million	Expiration/revocation date
* * * * *		
Sorghum, grain, forage	2.0	12/31/05
Sorghum, grain, grain	0.035	12/31/05
Sorghum, grain, stover	4.0	12/31/05

* * * * *

[FR Doc. 02–24093 Filed 9–24–02; 8:45 am]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0016; FRL–7199–1

Sucrose Octanoate Esters; 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 certain sucrose octanoate esters on all food commodities when applied/used in accordance with good agricultural practices. AVA Chemical Ventures, L.L.C. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act (FQPA) 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 sucrose octanoate esters.

DATES: This regulation is effective September 25, 2002. Objections and requests for hearings, identified by docket identification (ID) number OPP–2002–0016, must be received on or before November 25, 2002.

ADDRESSES: Written objections and hearing requests may be submitted by mail, electronically, or in person. Please follow the detailed instructions for each method as provided in Unit IX. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket ID number OPP–2002–0016 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Denise Greenway, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington,

DC 20460–0001; telephone number: (703) 308–8263; e-mail address: *greenway.denise@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*, a beta site currently under development. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

2. *In person*. The Agency has established an official record for this action under docket ID number OPP–2002–0016. 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 9, 1999 (64 FR 49010) (FRL–6095–9), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a(d)(3), as amended by FQPA (Public Law 104–170), announcing the filing of a pesticide tolerance petition (PP 8E4926) by AVA Chemical Ventures, L.L.C., 65 Aviation Avenue (now at 80 Rochester Avenue, Suite 214), Portsmouth, NH 03801. This notice included a summary of the petition prepared by the petitioner AVA Chemical Ventures, L.L.C. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of sucrose fatty acid esters. EPA has determined that the designation ''sucrose fatty acid esters'' is too broad, in that it could include other compounds not intended by the registrant, and for which the Agency has not reviewed relevant data. The data and information submitted by the registrant in support of the petition cover an exemption from the requirement of a tolerance for sucrose octanoate esters, which have been identified as the specific type of sucrose fatty acid esters that act as the active ingredient (a.i.) in the petitioner's pending products. EPA's general policy is to establish a tolerance or exemption from the requirement of a tolerance for the actual a.i. contained in the registrant's products. Because the a.i. for which the registrant actually is petitioning is technically defined as sucrose octanoate esters [(α-D-glucopyranosyl-β-D-fructofuranosyl-octanoate), mono-, di-, and triesters of sucrose octanoate], all discussions in this rule and in the resulting tolerance exemption expression refer only to ''sucrose octanoate esters [(α-D-glucopyranosyl-β-D-fructofuranosyl-octanoate), mono-, di-, and triesters of sucrose octanoate].'' Hereinafter, EPA uses the terms ''sucrose octanoate esters'' and ''SOEs'' to mean sucrose octanoate esters [(α-D-glucopyranosyl-β-D-fructofuranosyl-octanoate), mono-, di-, and triesters of sucrose octanoate].

III. Statutory Authority

This exemption from the requirement of a tolerance is being issued under the authority of section 408(c) of FFDCA (21 U.S.C. 346a(c)). Under FFDCA section 408, EPA regulates pesticide chemical residues by establishing tolerances limiting the amounts of residues that may be present in or on food, or by establishing exemptions from the requirement of a tolerance for such residues. Food includes articles used for food or drink by humans or other animals. A food containing pesticide residues may not be moved in interstate commerce without an appropriate tolerance or an exemption from the requirement of a tolerance.

Section 408(c)(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(c)(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....'' FFDCA section 408(b)(2)(D) specifies other, general factors EPA must consider in establishing an exemption, including the consideration of the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' FFDCA section 408(c)(3) prohibits an exemption unless

there is either a practical method for detecting and measuring levels of pesticide chemical residue in or on food or EPA determines that there is no need for such a method and states the reason for such determination.

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.

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.

Sucrose octanoate esters are made from a caprylic fatty acid ester derived from an edible oil or fat, and sucrose. Sucrose is the primary product of photosynthesis (Reference 1) and therefore, common in food crops eaten regularly by humans and animals. Sucrose, also known as table sugar, has an exceedingly long history of human dietary exposure (Reference 1). The octanoate esters are made from octanoic acid (caprylic acid), a common fatty acid in plants, which is produced in small quantities in the human body and is marketed as a human dietary supplement (Reference 1). Sucrose octanoate esters derived from edible vegetable oils, edible tallow or hydrogenated edible tallow have been FDA-approved since 1983 (21 CFR 172.859) when used (as an additive for direct addition to food) as emulsifiers in certain processed foods and as post-harvest protective coatings for certain fruits. FDA expanded in 1995 the range of foods in which SOEs are permitted, to include use in emulsifiers, stabilizers, and texturizers in chewing gum, confections, and frostings; texturizers in surimi-based fabricated seafood products; and emulsifiers in coffee and tea beverages with added dairy ingredients and/or dairy product analogs (60 FR 44755). The applicant collected and summarized the toxicological data associated with the cited FDA food-use approvals and submitted this information in support of their tolerance exemption request (Reference 2). The Agency reviewed both the summaries and the underlying data.

Toxicity information/data submitted in support of this tolerance exemption are referenced below. New studies were contracted by the petitioner only for primary eye irritation and primary dermal irritation. Data waivers were requested and granted for all other toxicity data requirements. Publically available information/data were submitted, in lieu of studies, as part of the scientific justification necessary to support the data waiver requests (References 2, 3, and 4). In addition, the Agency has found additional relevant data from additional public sources including the National Toxicology Program which have been of value to the Agency's review of this petition (Reference 1). The submitted information/data, in combination, were found equivalent to what would normally be provided by guideline studies, and therefore would likely have been adequate to meet each toxicology requirement had they been submitted as such pursuant to 40 CFR 152.90(b)(4). More detailed analyses of these data and information can be found in specific Agency reviews of the studies and technical literature (References 1, 5, and 6).

1. *Primary eye irritation (OPPTS 870.2400, 152–13) MRIDs 446101–05 and 446101–06:* Following ocular instillation of 0.1 mL of undiluted manufacturing-use product into the eyes of rabbits, moderate to severe eye irritation and mild corneal opacity was observed in the treated eyes of all rabbits at 24 hours post-dosing, and persisted in 1 rabbit to 21 days post-dosing. Mild iritis was exhibited in 3 rabbits at 24 hours post-dosing, and persisted in 1 rabbit to 72 hours. Classification: Acceptable; Toxicity Category I for the manufacturing-use product. In a second primary eye irritation study, following ocular instillation of 0.1 mL of undiluted end-use product into the eyes of rabbits, moderate to severe eye irritation was observed in the treated eyes of all 6 rabbits at 72 hours post-dosing, was mild at 7 days, and cleared by 14 days. Mild corneal opacity was observed in all 6 rabbits at 24 hours, and persisted to 7 days in 1 rabbit, then cleared by 14 days post-dosing. Mild iritis persisted in 4 rabbits to 72 hours, then cleared. Classification: Acceptable; Toxicity Category II for the end-use product.

2. *Primary dermal irritation (OPPTS 870.2500, 152–14) MRIDs 446101–03 and 446101–04:* Following dermal application of 0.5 mL of undiluted manufacturing-use product to the skin of rabbits, 5 rabbits exhibited very slight erythema and one exhibited well-defined erythema at 1 hour post-treatment. Very slight erythema persisted on 4 rabbits to 24 hours, then cleared. No edema was observed on any rabbit. Classification: Acceptable; Toxicity Category IV for the manufacturing-use product. In a second primary dermal irritation study, following dermal application of 0.5 mL of undiluted end-use product to the skin of rabbits, very slight erythema was exhibited by 6 rabbits at 0.5 hour post-treatment and 5 rabbits exhibited very slight to slight edema. All symptoms cleared by 24 hours. Classification: Acceptable; Toxicity Category IV for the end-use product.

Data waivers were requested for the following studies. Although no acute toxicity studies were conducted by the registrant, acceptable information/data was submitted from the open technical literature to support the data waiver requests.

3. *Acute oral toxicity waiver (OPPTS 870.1100, 152–10) MRID 444158–03, and Amendment number 1:* Acute oral and dietary toxicity data, previously evaluated in three publications by the Food and Agriculture Organization (FAO) of the United Nations World Health Organization (WHO), were submitted in support of this data waiver request (References 2, and 3). The data contained in these reports demonstrated that SOEs had extremely low oral toxicity (in laboratory studies), even at concentrations substantially higher than are found in human food. Extremely high concentrations were needed to produce toxic symptoms in laboratory studies (LD_{50} <20,000 milligrams/kilogram (mg/kg)). Long-term and short-term dietary studies (100 days to 2.5 years), evaluated in the aforementioned FAO/WHO reports, demonstrated that dietary consumption at levels of up to 3% in the diets of rats, mice and dogs caused no substantial toxicological effects. An acceptable daily intake (ADI) of SOEs for humans was estimated to be up to 16 mg/kg body weight/day, which is equivalent to 1.28 kg of SOEs per day for a 176 lb person. In studies with rats and humans, it was demonstrated that SOEs were rapidly hydrolyzed and absorbed by the body. In addition, the National Toxicology Program lists the octanoic acid oral LD_{50} for rats as 10,080 mg/kg (Reference 1). The information/data described above supports waivers from the data requirements for acute oral toxicity studies. The Agency concludes that SOEs have extremely low toxicity. Classification: Acceptable; Toxicity Category IV for the manufacturing-use product and end-use product.

4. *Acute dermal toxicity waiver (OPPTS 870.1200, 152–11) MRID 444158–03 and Amendment number 1:* A data waiver was granted for this guideline study based on the strength of the supporting information/data submitted by the registrant. In addition, publically available sources list the octanoic acid dermal LD_{50} for rabbits as > 5,000 mg/kg (Reference 1). Classification: Acceptable; Toxicity Category IV for the manufacturing-use product and end-use product.

5. *Acute inhalation toxicity waiver (OPPTS 870.1300, 152–12) MRID 444158–03 and Amendment number 1:* A data waiver was granted for this guideline study based on the strength of the supporting information/data submitted by the registrant (References 2, 3, and 5). Classification: Acceptable; Toxicity Category IV for the manufacturing-use product and end-use product.

6. *Hypersensitivity study waiver (OPPTS 870.2600, 152–15) MRID 444158–04:* No hypersensitivity incidents (152.16) have been reported for laboratory workers regularly exposed to SOEs for up to 6 years. In addition, the registrant is obliged under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) section 6(a)(2) to notify the Agency in the event of such incidents. Classification: Acceptable.

7. *Genotoxicity and Mutagenicity waiver (OPPTS 870.5300, 870.5195; 152–17, and 152–19) MRID 444158–03 and Amendment number 1:* No guideline studies were submitted, but it was determined that none are required because acceptable information/data were submitted from the open technical literature to scientifically justify a waiver of the data requirements for genotoxicity and mutagenicity. This information/data demonstrate that SOEs are not genotoxic and/or mutagenic, nor is the a.i. structurally and/or chemically similar to known mutagens or known classes of mutagens (References. 2, 3, and 5). In addition, a study reported by the National Toxicology Program shows octanoic acid to be negative for genotoxicity/mutagenicity (Reference 1). Classification: Acceptable.

8. *Immune response and other Subdivision M toxicity data waivers (OPPTS 880.3800 through 870.4200, 152–18 through 152–29) MRID 444158–03 and Amendment number 1:* Due to the low toxicity of SOEs (as demonstrated in the cited open technical literature (References 2, 3, 4, 5, and 6), the Agency granted waivers from all other Subdivision M toxicity data requirements, including the 90–day feeding and teratogenicity studies. In addition, octanoic acid is considered a nonteratogenic compound even at the very high dose rate of 18.75 millimoles/kg (Reference 1).

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).

A. Dietary Exposure

1. *Food.* An ADI of SOEs for humans was estimated by FAO/WHO to be up to 16 mg/kg body weight/day, which is equivalent to 1.28 kg of SOEs per day for a 176 lb person (References. 2, 3, and 5). There are no reasonably foreseeable circumstances in which the residue levels of SOEs would ever approach this amount. Sucrose octanoate esters break down into their natural constituents (sugar and fatty acids) shortly after application. The foliar application rate for the product would be at a volume to volume rate of 0.32% to 0.40% (Reference 7) for the a.i.. Likewise the a.i. use rate when applied to honey bees would be 0.25%, and would range from 0.5% to 1.0% when treating mushroom growing media. In studies with rats and humans, it was demonstrated that SOEs were rapidly hydrolyzed and absorbed by the body (Reference 5). Because SOEs are the mono-, di- and tri-esters of sucrose with fatty acids and are derived from sucrose (sugar) and edible tallow or edible vegetable oils, there is a great likelihood of exposure in the normal human diet to SOEs and SOEs' components for most, if not all individuals, including infants and children. Sucrose octanoate esters are a sucrose fatty acid ester, and sucrose fatty acid esters are a normal part of the human diet. Thus SOEs may be considered a normal part of the human diet. To date, there have been no reports of any hypersensitivity incidents or reports of any known adverse reactions in humans resulting from exposure to SOEs, which have been FDA-approved food emulsifiers and post-harvest protective fruit coatings since 1983. Even if there is a significant increase in exposure to SOEs due to their use as a pesticide, the acute toxicity information and data available from the National Toxicology Program and submitted by the registrant demonstrating extremely low mammalian toxicity (Toxicity Category IV) indicate that risk associated with acute exposures by the oral, dermal and inhalation routes would be low to non-existent.

2. *Drinking water exposure.* No drinking water exposure is expected, as SOEs are not soluble in water, do not persist in the environment, and are biodegradable within approximately five days at approximately 20–27°C, in both aerobic and anaerobic conditions (Reference 5). Because SOEs have extremely low toxicity, have been approved for food use by FDA, and are present as direct food additives in many foods, should exposure through drinking water occur, no risk is anticipated.

B. Other Non-Occupational Exposure

The potential for non-dietary exposure to SOEs residues for the general population, including infants and children, is unlikely because potential use sites are commercial, agricultural, and large-scale horticultural. Sucrose octanoate esters' constituent sugars and fatty acids are normal parts of the human diet. Sucrose octanoate esters' toxicity has been determined to be extremely low (except via the ocular exposure route). Therefore, while there exists a great likelihood of prior exposure for most, if not all, individuals to both SOEs and SOEs' components, any increased exposure due to the proposed products would be negligible because the product would very likely be degraded to sugars and fatty acids and/or consumed by microorganisms before the general public would come in contact with treated plants or food products from treated plants.

VI. Cumulative Effects

The Agency has considered the cumulative effects of SOEs and other substances in relation to a common mechanism of toxicity. These considerations include the possible cumulative effects of such residues on infants and children. There is no indication of mammalian toxicity from the submitted information/data (except by the ocular route of exposure) for SOEs. Therefore, no adverse cumulative effects are expected.

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

1. *U.S. population.* There is a reasonable certainty that no harm will result from aggregate exposure to residues of SOEs to the U.S. population. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion based on the extremely low levels of mammalian toxicity associated with

SOEs (except for risk from ocular exposure, which will be mitigated via precautionary label language). Sucrose octanoate esters have extremely low toxicity (LD_{50} >20,000 mg/kg in laboratory studies of oral exposure), and it is unlikely that any toxic effects will result from exposure to SOEs via the oral, dermal or inhalation pathways when the products are used according to proposed label directions (Reference 5). The amount of SOEs applied to food crops is many orders of magnitude lower than the concentrations of SOEs needed to cause toxicological effects. Because the worst case scenario exposure is far below the level of any dietary toxicity known for SOEs or their components and degradates, EPA has determined that residues will not pose a dietary risk under reasonably foreseeable circumstances and that the setting of a tolerance exemption is appropriate.

2. *Infants and children.* FFDCA section 408 provides that EPA shall apply an additional ten-fold margin of exposure (safety) for infants and children in the case of threshold effects to account for pre-natal and post-natal toxicity and the completeness of the data base unless EPA determines that a different margin of exposure (safety) will be safe for infants and children. Margins of exposure (safety) are often referred to as uncertainty (safety) factors. In this instance, based on all the available information, the Agency concludes that SOEs are practically non-toxic to mammals, including infants and children (except via ocular exposure). Thus, there are no threshold effects of concern, and so 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 margin of exposure (safety) approach to assess the safety of SOEs.

VIII. 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.'' Following the recommendations of its Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC), EPA determined that there is no scientific basis for including, as part of the program, the androgen and thyroid hormone systems in addition to the estrogen hormone system. EPA also adopted EDSTAC's recommendation that the program include evaluations of potential effects in wildlife. For pesticide chemicals, EPA will use FIFRA and, to the extent that effects in wildlife may help determine whether a substance may have an effect in humans, FFDCA authority to require wildlife evaluations. As the science develops and resources allow, screening of additional hormone systems may be added to the Endocrine Disruptor Screening Program (EDSP). When the appropriate screening and/or testing protocols being considered under the Agency's EDSP have been developed, SOEs may be subjected to additional screening and/or testing to better characterize effects related to endocrine disruption.

Based on available data, no endocrine system-related effects have been identified with consumption of SOEs. It is an FDA-approved direct food additive comprised of sugars and fatty acids, having an ADI of 16 mg/kg body weight/day. To date, there is no evidence to suggest that SOEs affect the immune system, function in a manner similar to any known hormone, or that they act as an endocrine disruptor.

B. Analytical Method(s)

The Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation for the reasons stated above, including SOEs' low mammalian toxicity (except by ocular exposure). For the same reasons, the Agency has concluded that an analytical method is not required for enforcement purposes for SOEs.

C. Codex Maximum Residue Level

There are no Codex Maximum Residue Levels (MRLs) established for residues of SOEs.

IX. Conclusions

Based on the toxicology information/data submitted and publically available, there is a reasonable certainty that no harm will result from aggregate exposure of residues of SOEs to the U.S. population, including infants and children, under reasonably foreseeable circumstances, when the biochemical pesticide is used in accordance with good agricultural practices. This includes all anticipated dietary exposures and all other exposures for which there is reliable information. The Agency has arrived at this conclusion based on the information/data submitted and publically available data demonstrating no toxicity, except from ocular exposure. Potential risk from ocular exposure will be effectively addressed under FIFRA by mitigating precautionary label language. As a result, EPA establishes an exemption from the tolerance requirements pursuant to FFDCA 408(c) and (d) for residues of SOEs in or on all food commodities.

X. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to ''object'' to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number OPP–2002–0016 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 November 25, 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 (1900C), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001. You may also deliver your written request to the Office of the Hearing Clerk in Rm. 104, Crystal Mall # 2, 1921 Jefferson Davis Hwy., Arlington, VA. 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 (703) 603–0061.

2. *Tolerance fee payment*. If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it ''Tolerance Petition Fees.''

EPA is authorized to waive any fee requirement ''when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.'' For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305–5697, by e-mail at *tompkins.jim@epa.gov*, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

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 20460–0001.

3. *Copies for the Docket*. In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit IX.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket ID number OPP–2002–0016, 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 20460–0001. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

XI. References

1. *USEPA*. Brief summary of toxicity information to support registration/tolerance exemptions for sucrose octanoate. R. S. Jones to D. Greenway; August 8, 2002.

2. *Barrington, T., and C. L. Hartman*. Sucrose fatty acid esters-Safety data in support of petition proposing a temporary (sic) exemption from the requirement of a tolerance for use in all food commodities (MRID 444158–03); October 2, 1997.

3. *Barrington, T. and W. L. Biehn*. Sucrose fatty acid esters-safety data in support of petition proposing an exemption from the requirement of a tolerance for use in all food commodities, Amendment number 1 to MRID 444158–03; July 13, 1998.

4. *Barrington, A*. Waiver request; July 12, 2002.

5. *USEPA*. Science review in support of registration of sucrose octanoate esters. R.S. Jones to D. Greenway; February 14, 2000.

6. *USEPA*. Sucrose octanoate esters; A request for concurrence on a decision to waive the requirement for 90–day feeding (152–20) and teratogenicity (152–23) studies, based on the Registrant's correspondence of July 12, 2002. D. Greenway to R. S. Jones; August 7, 2002.

7. *Barrington, A*. Sucrose octanoate esters - per-acre application rates; July 12, 2002.

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: September 11, 2002.

James Jones,

Acting 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), 346(a) and 371.

2. Section 180.1222 is added to subpart D to read as follows:

§ 180.1222 Sucrose octanoate esters; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of sucrose octanoate esters [(α-D-glucopyranosyl-β-D-fructofuranosyl-octanoate), mono-, di-, and triesters of sucrose octanoate] in or on all food commodities when used in accordance with good agricultural practices.

[FR Doc. 02–24224 Filed 9–24–02; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0235; FRL–7198–4]

Clopyralid; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of clopyralid in or on certain raw agricultural commodities. Interregional Research Project Number 4 (IR-4) and Dow Agro Sciences LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective September 25, 2002. Objections and requests for hearings, identified by docket control number OPP–2002–0235, must be received on or before November 25, 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 VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–2002–0235 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. Miller, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW.,Washington, DC 20460; telephone number: 703 305–6224; and e-mail address: *miller.joanne@epamail.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