

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 FFDC 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 FFDC 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.

#### 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 recordkeeping requirements.

Dated: January 21, 2003.

**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 374.

2. Section 180.1159 is amended by adding paragraph (c) to read as follows:

#### § 180.1159 Pelargonic acid; exemption from the requirement of a tolerance.

\* \* \* \* \*

(c) An exemption from the requirement of a tolerance is established for residues of pelargonic acid in or on all raw agricultural commodities and in processed commodities, when such residues result from the use of pelargonic acid as an antimicrobial treatment in solutions containing a diluted end-use concentration of pelargonic acid up to 170 ppm per application on food contact surfaces such as equipment, pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment in restaurants, food service operations, dairies,

breweries, wineries, beverage and food processing plants.

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#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[OPP-2002-0272; FRL-7278-6]

#### Decanoic Acid; Exemption from the Requirement of a Pesticide Tolerance

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of decanoic acid (capric acid) in or on all foods when applied/used as a component of a food contact surface sanitizing solution in food handling establishments. Eco Lab Inc. 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 decanoic acid.

**DATES:** This regulation is effective February 19, 2003. Objections and requests for hearings, identified by docket ID number OPP-2002-0272, must be received on or before April 21, 2003.

**ADDRESSES:** Written objections and hearing requests may be submitted electronically, by mail, or through hand delivery/courier. Follow the detailed instructions as provided in Unit X. of the **SUPPLEMENTARY INFORMATION**.

**FOR FURTHER INFORMATION CONTACT:** Adam Heyward, Antimicrobials Division (7510C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-6422; e-mail address: heyward.adam@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:

- Crop production (NAIC code 111)
- Animal production (NAIC code

112)

- Food manufacturing (NAIC code 311)
- Pesticide manufacturing (NAIC code 32532)

#### *B. How Can I Get Copies of This Document and Other Related Information?*

1. *Docket.* EPA has established an official public docket for this action under docket identification (ID) number OPP-2002-0272. The official public docket consists of the documents specifically referenced in this action, any public comments received, and other information related to this action. Although a part of the official docket, the public docket does not include Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. The official public docket is the collection of materials that is available for public viewing at the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA. This docket facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The docket telephone number is (703) 305-5805.

2. *Electronic access.* You may access this **Federal Register** document electronically through the EPA Internet under the "**Federal Register**" listings at <http://www.epa.gov/fedrgrstr/>. 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.

An electronic version of the public docket is available through EPA's electronic public docket and comment system, EPA Dockets. You may use EPA Dockets at <http://www.epa.gov/edocket/> to submit or view public comments, access the index listing of the contents of the official public docket, and to access those documents in the public docket that are available electronically. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the docket facility identified in Unit I.B.1. Once in the system, select "search," then key in the appropriate docket ID number.

## **II. Background and Statutory Findings**

In the **Federal Register** of December 7, 2001 (66 FR 63534) (FRL-6737-9), EPA issued a notice pursuant to section 408 of FFDCA, 21 U.S.C. 346a, as amended by FQPA (Public Law 104-170), announcing the filing of a pesticide petition (PP 0F6194) by Eco Lab Inc., 370 N. Wabasha Street, St. Paul, MN

55102. That notice included a summary of the petition prepared by Eco Lab Inc., the registrant. 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 is established for residues of decanoic acid in or on all raw agricultural commodities and in processed commodities, when such residues result from the use of decanoic acid as an antimicrobial treatment in solutions containing a diluted end-use concentration of decanoic acid up to 170 parts per million (ppm) per application on food contact surfaces such as equipment, pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment in restaurants, food service operations, dairies, breweries, wineries, beverage and food processing plants. The sanitizer is applied by immersion, coarse spray, or circulation technique as appropriate to the equipment. The solution, once applied is allowed to drain and dry and there is no potable water rinse.

Section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of the 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. Section 408(b)(2)(C) of the FFDCA 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 assesses the hazards of the pesticide through examination and review of available toxicology data. Second, EPA examines the potential route(s) and duration(s) of exposure to the pesticide through food, drinking water, and through other exposures that can occur as a result of pesticide use in residential settings.

## **III. Aggregate Risk Assessment and Determination of Safety**

Consistent with section 408(b)(2)(D) of the FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2) of the FFDCA, for an exemption from the requirement of a tolerance for residues of decanoic acid on all food up to 170 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

### *A. Toxicological Profile*

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available toxicology data from the open scientific literature as well as the data submitted in support of this action and has considered its validity, completeness and reliability and the relationship to human risk. EPA has also considered available information on potential differences in sensitivity to the toxicity of the pesticide in major identifiable subgroups of consumers, including infants and children. The natures of the toxic effects caused by decanoic acid (capric acid) are discussed in this unit.

### *B. Acute Toxicity*

The acute oral toxicity of decanoic acid is low lethal dose (LD)<sub>50</sub> >10 grams/kilograms (g/kg) as is the acute dermal toxicity (LD<sub>50</sub> > 5 g/kg). Decanoic Acid is a moderate to severe skin irritant when applied undiluted to intact or abraded rabbit skin for 24 hours. Decanoic acid is also a severe eye irritant when applied as a 5% solution.

### *C. Subchronic Toxicity*

As reported in Patty's Industrial Hygiene and Toxicology, 4th ed., rats fed capric acid at 10% in the diet for 150 days showed no adverse effects from treatment. In another study, rats administered approximately 4 g decanoic acid /kg/day for 6 weeks showed reduced body weight gain and increased plasma triglyceride levels. In a longer term study in which rats were fed 2.5 g/kg/day decanoic acid for 47 weeks, no adverse toxicological effects were noted. Dogs administered 4.4 g/kg/day decanoic acid for 102 days showed no adverse effects of treatment.

### *D. Developmental and Reproductive Effects*

In a study by Hendrich *et al.* (JAOCS, Vol. 70, no. 8, August 1993, pages 797-802), the potential reproductive effects of decanoic acid were examined in

CBA/2 and C57B1/6 mice. Groups of mice received diets containing either 17.2% beef tallow and 3.5% corn oil or 8.6% crude *Cuphea* oil and 3.5% corn oil. *Cuphea* oil is composed of 76% decanoic acid, 4.8% octanoic acid, 2.5% dodecanoic acid, 2.2% myristate, 3.4% palmitate, 0.7% stearate, 3.3% oleate, and 5.5% linoleate. Parental animals were fed for various times due to the short supply of *Cuphea* oil. C57B1/6 mice were fed for either 10 months, 8 months, or 5 months (F1, F2, and F3 generations), while the CBA/2 mice were fed for 11–12 months, 9–11 months, and 6–8 months (F1, F2, and F3 generations). Body weights, food intake, liver weights, and total serum cholesterol were analyzed as well as the number of pups born and surviving to weaning. Histopathology was performed on liver, left kidney, spleen, heart, lung, and one testis. The histopathology appears to have been done only on parental mice. Feeding of *Cuphea* oil containing decanoic acid to successive generations of two strains of mice had no effect on reproduction in either strain of mouse. In the F1 generation of the CBA/2 strain, the reported number of pups per female was decreased in the *Cuphea*-fed mice vs. the mice fed the basal diet without the *Cuphea* oil. However, this effect was not observed in any other generation of the CBA/2 strain or in any generation of the C57B1/6 strain and is therefore not interpreted as a treatment-related effect. Body weight in C57B1/6 and CBA/2 mice was reduced approximately 10% after 13 weeks of treatment but this effect was not observed in successive generations. Food intake was not consistently affected by treatment. Serum cholesterol was significantly increased in C57B1/6 mice after 3 months of treatment, and the increase was also observed after 5 and 12 months. Fatty vacuolization was observed in the liver of most mice after treatment. CBA/2 mice tended to accumulate fat as large vacuoles in periportal hepatocytes with smaller vacuoles in centrilobular hepatocytes. C57B1/6 mice had a more diffuse fatty change with large vacuoles in centrilobular areas.

#### E. Carcinogenicity/Mutagenicity

There are no published studies on carcinogenicity of decanoic acid, but available mutagenicity data indicate that decanoic acid is negative for mutagenic effects.

#### F. Physiological Effects

Decanoic acid was observed to enhance the permeability of the blood-brain in Wistar rats to several hydrophilic compounds when

administered into the carotid artery (Ohnishi *et al.*, J. Pharm. Pharmacol. 51: 1015–1018, 1998).

#### IV. Aggregate Exposures

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

##### A. Dietary Exposure

1. *Food; existing tolerances and other clearances.* The Food and Drug Administration (FDA) has established a food additive clearance for decanoic acid at levels up to 234 ppm in sanitizing solutions (21 CFR 178.1010(c)(22), (30), (31), (34)), and has also cleared this chemical for direct addition to food for human consumption without limits.

Decanoic acid is also permitted for use in food as a lubricant, binder and as a defoaming agent as a component in the manufacture of other food-grade components, without limits, provided it meets the criteria as set forth in 21 CFR 172.860.

Worst case dietary exposures for the sanitizer use of decanoic acid have been calculated assuming that all food consumed by an adult or child has contacted a 4,000 cm<sup>2</sup> sanitized surface using decanoic acid, that a 1 milligram/centimeter (mg/cm)<sup>2</sup> sanitizer residue remains on the surface, and that 100% of the residue (28 ppm) is transferred to the food from the surface. Using these assumptions a worst case dietary exposure of 113 µg/day is calculated. For a 70 kg adult this becomes 1.6 µg/kg/day, and for a 15 kg child, intake is calculated as 7.5 µg/kg/day.

2. *Drinking water exposure.* The use of decanoic acid as a component of KX-6116 food surface sanitizer could result in the introduction of very low concentrations of decanoic acid into drinking water. However, this exposure through drinking water is expected to be minimal.

##### B. Non-Occupational Exposure

Based on the intended use of decanoic acid in food handling establishments, exposure to decanoic acid as a component of KX-6116 sanitizer through non-occupational sources is not likely to occur.

#### V. Cumulative Effects

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider available information

concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. Based on the information discussed in Section VII below, EPA concluded that decanoic acid is sufficiently non-toxic that EPA can determine that it does not share a common mechanism of toxicity with other substances.

#### VI. Additional Safety Factor for the Protection of Infants and Children

Section 408 of the FFDCA 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 on toxicity and exposure unless EPA determines that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a MOE analysis or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

Based on the considerations discussed in Unit VII. of this document, EPA concluded that decanoic acid was sufficiently non-toxic that a margin of safety analysis was not appropriate. For the same reason, EPA has not applied an additional margin of safety for the protection of infants and children.

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

Based on the following considerations, EPA concludes that decanoic acid is unlikely to pose a risk under all reasonable exposure scenarios:

1. The fatty acids as a group including decanoic acid have a safe history of use as natural components of many foods, as direct food additives, and as cosmetic ingredients. Furthermore, fatty acids are processed by known metabolic pathways within the body and contribute to normal physiological function.

2. The Joint FAO/WHO Expert Committee on Food Additives did not establish a specific allowable daily intake (ADI) for decanoic acid (i.e. Reference dose (RfD)) based on the knowledge that the compound is already a component of the human diet, has a long history of use, and does not present with any significant toxicology concerns and therefore does not represent a health hazard.

3. The Food and Drug Administration has established a food additive clearance for decanoic acid at levels up to 234 ppm in sanitizing solutions (21 CFR 178.1010(c)(22), (30), (31), (34)),

and has also cleared this chemical for direct addition to food for human consumption without limits. Decanoic acid is also permitted for use in food as a lubricant, binder and as a defoaming agent as a component in the manufacture of other food-grade components, without limits, provided it meets the criteria as set forth in 21 CFR 172.860.

4. Evidence of adverse reactions to decanoic acid in dietary toxicity testing was observed only at doses that were at or above limit doses.

5. The estimated exposures to decanoic acid and other fatty acids from direct or indirect addition to food as well as sanitizer uses are well below the doses administered in animal studies that are required to elicit an adverse effect. For example, adverse effects in toxicity testing could only be achieved by doses in the range of several grams of decanoic acid per kilogram of body weight per day. A worst case dietary exposure for the sanitizer use estimated exposure for a 70 kg adult of 1.6 µg/kg/day, and for a 15kg child of 7.5 µg/kg/day.

Accordingly, EPA concludes that there is a reasonable certainty of no harm to the general population, including infants and children, from aggregate exposure to pelargonic acid.

## VIII. Other Considerations

### A. Analytical Method(s)

Because an exemption from the requirement of a tolerance without numerical limitation for residues in food is being granted for decanoic acid, an enforcement analytical method is not needed. However, an analytical method is available in cases of gross misuse. The analytical method is being made available to anyone interested in pesticide enforcement when requested, from Norm Cook, Antimicrobials Division (7510C), Office of Pesticide Programs, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, D.C. 20460. Office location and telephone number: 1921 Jefferson Davis Highway, 3rd Floor, Arlington, VA 22202, (703) 308-8253.

### B. International Tolerances

No codex maximum residue levels have been established for decanoic acid.

## IX. Conclusion

An exemption from the requirement of a tolerance is established for residues of decanoic acid in or on all raw agricultural commodities and in processed commodities, when such residues result from the use of decanoic

acid as an antimicrobial treatment in solutions containing a diluted end-use concentration of decanoic acid up to 170 ppm per application on food contact surfaces such as equipment, pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment in restaurants, food service operations, dairies, breweries, wineries, beverage and food processing plants. The sanitizer is applied by immersion, coarse spray, or circulation technique as appropriate to the equipment. The solution, once applied is allowed to drain and dry and there is no potable water rinse.

## 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, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) of the FFDCA 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) of FFDCA, as was provided in the old sections 408 and 409 of the FFDCA. 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-2002-0272 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 April 21, 2003.

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 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](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 20460-0001.

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 VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.1. Mail your copies, identified by docket ID number OPP-2002-0272, 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.1. 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. Statutory and Executive Order Reviews**

This final rule establishes an exemption from the requirement of a tolerance under section 408(d) of the FFDCFA 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 section 408(d) of the FFDCFA, 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. 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 section 408(n)(4) of the FFDCFA. 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.

#### **XII. 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: January 21, 2003.

**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 374.

2. Section 180.1223 is added to subpart D to read as follows:

#### **§ 180.1223 Decanoic acid; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance is established for residues of decanoic acid in or on all raw

agricultural commodities and in processed commodities, when such residues result from the use of decanoic acid as an antimicrobial treatment in solutions containing a diluted end-use concentration of decanoic acid (up to 170 ppm per application) on food contact surfaces such as equipment, pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment in restaurants, food service operations, dairies, breweries, wineries, beverage and food processing plants.

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## DEPARTMENT OF ENERGY

### 41 CFR Part 109-6

RIN 1991-AB61

#### Official Use of Government Passenger Carriers Between Residence and Place of Employment

**ACTION:** Final rule.

**AGENCY:** Office of Management, Budget and Evaluation, Department of Energy (DOE).

**SUMMARY:** The Department of Energy publishes a final rule to remove from the DOE Property Management Regulation (DOE-PMR) certain overly broad restrictions regarding the use of government passenger carriers between an employee's residence and place of employment, and to update references to the Federal Management Regulation.

**EFFECTIVE DATE:** This rule is effective February 19, 2003.

**FOR FURTHER INFORMATION CONTACT:** Stephen J. Michelsen, Director, Office of Resource Management, Office of Procurement and Assistance Management, Department of Energy, (202) 586-1368, 1000 Independence Avenue, SW., Washington, DC 20585.

**SUPPLEMENTARY INFORMATION:** The DOE-PMR at 41 CFR 109-6.4 sets forth rules that apply to the use of Government passenger carriers between a DOE employee's residence and place of employment. Section 109-6.402(b) restricts such use to the Secretary of Energy and persons "engaged in field work," as determined by the Secretary. DOE today is eliminating this restriction from the DOE-PMR because it prevents certain uses by employees of Government passenger carriers between residence and place of employment that are authorized by statute and the implementing Federal Management Regulation. Other uses authorized by 31 U.S.C. 1344 include, but are not limited to: use by an officer or employee with

regard to which the Secretary, has determined, that highly unusual circumstances present a clear and present danger, that an emergency exists, or that other compelling operational considerations make such transportation essential to the conduct of official business; use by a single principal deputy to the Secretary if the Secretary determines appropriate; and use, when approved by the Secretary, by officers or employees when essential for the safe and efficient performance of intelligence, counterintelligence, protective services, or criminal law enforcement duties. The rule being promulgated today harmonizes the DOE-PMR with the relevant statutory authority and allows Government vehicles to be used in the manner authorized by the statute. In addition, this rule updates DOE-PMR, 41 CFR 109-6.4, by replacing obsolete references to sections of the Federal Management Regulation which was revised in 2000 (65 FR 54966, September 12, 2000).

This rule is being promulgated as a final rule, without providing for a public comment period, or a 30 day effective date because it addresses a matter relating to agency management or personnel or to public property and therefore is not subject to the notice and comment requirements of the Administrative Procedures Act. *See* 5 U.S.C. 553(a).

#### Regulatory Review

##### A. Review Under Executive Order 12866

This final rule has been determined not to be a "significant regulatory action" under Executive Order 12866, "Regulatory Planning and Review," (58 FR 51735, October 4, 1993). Accordingly, this final rule is not subject to review under that Executive Order by the Office of Information and Regulatory Affairs of the Office of Management and Budget (OMB).

##### B. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Agency to assess the effects of Federal regulatory action on State, local, and tribal governments and the private sector. DOE has determined that today's regulatory action would not impose a Federal mandate on State, local, or tribal governments or on the private sector.

##### C. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, "Civil Justice

Reform," 61 FR 4729 (February 7, 1996), imposes on Executive agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction. With regard to the review required by section 3(a), section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive Agencies to review regulations in light of applicable standards in section 3(a) and 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this final rule meets the relevant standards of Executive Order 12988.

##### D. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act of 1980, Public Law 96-354, requires preparation of a regulatory flexibility analysis for any rule which is subject to notice and comment rulemaking requirements. As noted above, this rule addresses a matter relating to agency management or personnel or to public property and maybe is not subject to the notice and comment requirements of the Administrative Procedures Act.

##### E. Review Under Paperwork Reduction Act

No new information collection requirements subject to the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) are imposed by today's regulatory action.

##### F. Review Under the National Environmental Policy Act

This rule eliminates certain restrictions on the official use of government passenger carriers by DOE employees between residence and place of employment. Implementation of this rule will not result in environmental