Dated: February 4, 2003.

Craig E. Bone,

Captain, Coast Guard Captain of the Port, New York.

[FR Doc. 03–3980 Filed 2–18–03; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0273; FRL–7278–7]

Pelargonic Acid (Nonanoic 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 the pelargonic 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. requested this tolerance under the Federal Food, Drug, and Cosmetic Act (FFDCA), as amended by the Food Quality Protection Act of 1996 (FQPA).

DATES: This regulation is effective February 19, 2003. Objections and requests for hearings, identified by docket ID number OPP–2002–0273, must be received on or before April 21, 2003.

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 VI. 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–2002–0273. 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/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.

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 0F6193) 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 180.1159 be amended by establishing an exemption from the requirement of a tolerance for residues of nonanoic acid. Nonanoic acid is a component of a proposed product KX-6116 in which this active ingredient is present at 6.49% in the formulation. The proposed sanitizer formulation is applied to food contact surfaces such as equipment, pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment in restaurants, food service operations, dairies, breweries, wineries, and 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 an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the

variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by pelargonic acid (nonanoic acid) are discussed in this unit.

A. Acute Toxicity

As a result of a number of acute toxicity studies, technical pelargonic acid is placed in the following Toxicity Categories: Primary eye irritation (Toxicity Category II), primary eye irritation (Toxicity Category II), acute oral toxicity (Toxicity Category IV), acute dermal and inhalation toxicity (Toxicity Category III). Sensitization test results showed that pelargonic acid cannot be considered a dermal sensitizer.

B. Subchronic and Chronic Toxicity

In an oral toxicity study (conducted for 14-days), no systemic toxicity was observed with either sex even at the highest dose tested, 20,000 parts per million (ppm) (1,834 milligrams/kilogram/day (mg/kg/day)). In addition, pelargonic acid showed no adverse effects on survival, clinical signs, body weight gain, food consumption, hematology, clinical chemistry or gross pathology. For each dose, three animals per sex were tested. However, the study did not report organ weights and histopathology. This was considered a deficiency in this study. Nevertheless, the Agency determined that because no toxic effects were observed at a very high level of ~ 2,000 mg/kg, a 90–day oral study was not necessary.

A 28–day dermal toxicity study conducted on rabbits was submitted to the Agency under TSCA section 8(e). Five male and five female New Zealand white rabbits were dermally treated with pelargonic acid present in mineral oil. In all, 10 applications were made (5 per week) at a dose level of 500 mg/kg/day. A 2–week recovery period was allowed for selected rabbits. During the first and second week of treatment, slight body weight loss and decreased food consumption were observed. One female rabbit showed ocular discharge and hypoactivity during the second week of treatment. All rabbits dermally treated with pelargonic acid by day 14 showed signs of severe erythema and moderate edema. Dermal reactions consisting of moderate desquamation, moderate fissuring, eschar, exfoliation and necrosis were also observed at day 14. By day 29, all dermal reactions had reversed. It was evident that at the treatment level of 500 mg/kg/day of pelargonic acid, significant dermal signs of toxicity were observed but no significant systemic reaction.

A supplemental study on chronic toxicity/carcinogenicity in mice was conducted for 80 weeks. A dose of 50 mg of pelargonic acid was dermally applied to each mouse twice/day for 80 weeks. Histopathology showed no non-neoplastic or neoplastic lesions on skins and internal organs of mice. The Agency concluded that this study although not exactly conducted according to guideline, adequately assesses the chronic toxicity and the carcinogenic potential of pelargonic acid via the dermal route.

C. Developmental Toxicity

A development toxicity was conducted on a group of 22 pregnant Crl:COBS CD(SD)BR rats. These rats were treated with pelargonic acid in corn oil at a dose of 1,500 mg/kg on gestation days 6 through 15 (both days inclusive). Maternal body weight was not significantly affected during the treatment. Only 1 out of 22 animals showed signs of clinical toxicity. No significant histopathology signs were observed in the maternal animals. Pelargonic acid treatment did not have any significant effect on cesarean section observations. Four fetuses in one litter showed a higher incidence of cleft palate compared to the control mean. For maternal toxicity, the Agency has determined the no observed adverse effect level (NOAEL) to be greater than 1,500 mg/kg/day. Because fetal effects were observed at 1,500 mg/kg/day, the NOAEL for developmental toxicity was not determined. The Agency has determined that this dose is in excess of the Agency's limit dose for toxic effects. The type and level of exposure expected from the use of this chemical is much lower than the dose level shown in the study.

D. Mutagenicity/Carcinogenicity

Ames Test (Salmonella/reverse mutation assay) showed pelargonic acid to be non-mutgenic. Similarly, *in vivo* cytogenetics study using micronucleus assay gave a negative result. In a mouse lymphoma forward mutation study, pelargonic acid appears to induce a weak mutagenic response at or higher than 50 milligrams/milliliter (mg/mL) level. This was observed in the presence of increasing toxicity, and may be an indication of gross chromosomal changes or damage and not actual mutational changes within the thymidine kinese gene locus.

As described above, a summary of the results of a dermal carcinogenicity study in mice with pelargonic acid was submitted. Fifty mice were treated twice-weekly with 50 mg doses of undiluted pelargonic acid for 80 weeks. No evidence of severe dermal or systemic toxicity was seen. Histopathology revealed no tumors of the skin or the internal organs

E. Exposure Assessment

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). The Agency has considered available information on the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue of pelargonic acid (nonanoic acid) and to other related substances. In these considerations, the Agency has included dietary exposure under the tolerance exemption and all other tolerances or exemptions in effect for pelargonic acid's chemical residue and exposure from non-occupational sources. The Food and Drug Administration has cleared pelargonic acid as a synthetic food flavoring agent (21 CFR 172.515), as an adjuvant, production aid and sanitizer to be used in contact with food (21 CFR 178.1010(b)) and in washing or to assist in lye peeling of fruits and vegetables (up to 1%) (21 CFR 173.315). Pelargonic acid is also exempt from the requirement of a tolerance when used in or on all food commodities, as a plant regulator on plants, seeds, or cuttings after harvest in accordance with GAP. It is also exempt from a tolerance when used as a herbicide on all plant food commodities provided that allocations are not made directly to the food commodity except when used as a harvest aid or dessicant to any root or tuber vegetable, bulb, or cotton (40 CFR 180.1159). Applications of the proposed end-use products containing pelargonic acid will not directly contact edible portions of food commodities.

1. *Food*. For the proposed sanitizer uses, a worst case dietary exposure estimate has been calculated, assuming that all food consumed by an adult or child has contacted a sanitized surface using pelargonic acid, that a 1 mg/cm^2 sanitizer residue remains on the surface, and that 100% of the residue (170 ppm) is transferred to the food from the surface. Using these assumptions, in which all food contacts 4,000 cm^2 of sanitized non-porous food-contact surfaces a worst case dietary exposure of 680 µg/day is calculated. For a 70 kg adult this becomes 9.7 µg/kg/day and for

a 15 kg child, exposure is calculated as 45 µg/kg/day.

2. *Drinking water exposure*. KX-6116 as a sanitizer contains pelargonic acid as its active component and low concentrations of pelargonic acid could be expected to be introduced into drinking water. However, exposure through drinking water is expected to be low and not of significance.

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

4. *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 Unit VII. EPA concluded that pelargonic acid is sufficiently non-toxic that EPA can determine that it does not share a common mechanism of toxicity with other substances.

F. Safety Factor for 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 III.G., EPA concluded that pelargonic 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.

G. Determination of Safety

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

1. Fatty acids such as pelargonic acid are processed by known metabolic pathways within the body and contribute to normal physiological function.

2. Pelargonic acid is naturally present at levels up to 224 parts per billion (ppb) in apples, 385 ppm in the skin of grapes, and 143 ppm in grape pulp. It is present in a number of other foods as well. An average serving of grapes containing 385 ppm of pelargonic acid in the grape skins would result in exposure to pelargonic acid to an average consumer of 164 µg/kg/day. In comparison, a worst case estimate of dietary exposure to pelargonic acid as a result of its use as sanitizer is 9.7 µg/kg/day for a 70 kg adult and 45 µg/kg/day for a 15 kg child.

3. The Food and Drug Administration has cleared pelargonic acid as a synthetic food flavoring agent (21 CFR 172.515), as an adjuvant, production aid and sanitizer to be used in contact with food (21 CFR 178.1010(b)) and in washing or to assist in lye peeling of fruits and vegetables (up to 1%) (21 CFR 173.315). Pelargonic acid is also exempt from the requirement of a tolerance when used in or on all food commodities, as a plant regulator on plants, seeds, or cuttings after harvest in accordance with Good Agricultural Practices (GAP). It is also exempt from a tolerance when used as a herbicide on all plant food commodities provided that allocations are not made directly to the food commodity except when used as a harvest aid or dessicant to any root or tuber vegetable, bulb, or cotton (40 CFR 180.1159).

4. Dietary toxicity testing evidenced adverse reactions only at doses that were at or above limit doses. Dermal toxicity testing showed no significant systemic reaction.

5. The estimated exposures to pelargonic 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. 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.

IV. 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 pelargonic 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 Ave., NW., Washington, DC 20460–0001. Office location and telephone number: 1921 Jefferson Davis Highway, 3rd Floor, Arlington, VA 22202, (703) 308–8253.

B. Existing Tolerances

1. *40 CFR 180.1159*. Pelargonic acid is exempted from the requirement of a tolerance on all food commodities when used as a plant regulator on plants, seeds, or cuttings and all food commodities after harvest in accordance with GAP or as a herbicide when applications are not made directly to the food commodity except when used as a harvest aid or dessicant to: any root and tuber vegetables, bulb vegetable or cotton. When pelargonic acid is used as a harvest aid or dessicant, application must be made no later than 24 hours prior to harvest.

2. *21 CFR 178.1010(c)(37)*. Pelargonic acid is permitted in food contact sanitizing solutions at a level up to 90 ppm.

3. *21 CFR 172.515*. Pelargonic acid may be safely used as synthetic food flavoring substances and adjuvants in food in the minimum quantity required to reproduce the intended effect.

4. *21 CFR 173.315*. Pelargonic acid may be used in an aliphatic acid mixture for washing or to assist in the peeling of fruits and vegetables. The aliphatic acid mixture may be used at a level not to exceed 1% in the lye peeling solution.

C. International Tolerances

No codex maximum residue levels have been established for the pelargonic acid.

V. Conclusion

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. The sanitizer shall be applied by immersion, coarse spay, or circulation technique as appropriate to the equipment or utensil. No potable

water rinse is required following the use of the sanitizer.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA, 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–2002–0273 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, 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–2002–0273, 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).

VII. Statutory and Executive Order Reviews

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.

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.

[FR Doc. 03–3842 Filed 2–18–03; 8:45 am]
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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)