the transitional provisions. Based on its review, the Postal Service has determined to adopt the proposed changes without revision. As of January 1, 2001, the DMM is revised to eliminate the transitional accommodation to mailers with stationery bearing obsolete ancillary service endorsements.

DMM F030.1.2 is revised to provide ancillary services only in accordance with the valid endorsements shown in DMM F010. Mail bearing obsolete, invalid, or conflicting ancillary service endorsements will no longer be considered acceptable for mailing and the Postal Service may refuse to accept this mail. If mail bearing invalid or conflicting endorsements is discovered in the mailstream it will be handled as unendorsed mail. In the case of Standard Mail (B), "treatment as unendorsed mail" effectively means that mail will be treated as if endorsed "Forwarding Service Requested." This provision recognizes that the general public (in contrast with business mailers) is unfamiliar with ancillary service endorsements and ensures that packages will be delivered or returned.

Comments Received

The Postal Service received two comments on the proposed rule. One comment was from an importer of material for domestic entry, and the other from an individual customer.

The importer was concerned that mail bearing invalid or conflicting ancillary service endorsements would not be accepted for mailing, potentially creating a disadvantage for the importer, relative to foreign postal administrations, who enter mail in accordance with international postal conventions. Mailers who import material for domestic entry to the United States Postal Service, for the services, benefits, and opportunities that arrangement presents, must comply with domestic mailing requirements. Exceptions based on the origin or particular qualities of matter that is mailed domestically are not permitted. Commercial mailers are expected to communicate applicable DMM requirements to their clients and ensure the mailability of material intended for domestic entry. International mail received from foreign postal administrations is subject to the provisions of the Universal Postal Convention. The provisions of this agreement are different than domestic procedures and requirements and are generally binding on the Postal Service, which is signatory to the Convention. Changes to international mailing conditions must generally be negotiated and require amendment of multilateral conventions and agreements. Modifications to the conditions for entry of international mail are not being considered at this time.

The individual customer comment concerned the lost value of stationery bearing obsolete or invalid endorsements and the treatment of items deposited in mail collection boxes which enter the mailstream and are therefore considered "accepted." The proposed rule was asserted to be "discriminatory," since improperly prepared mail that is presented to an employee could be refused, while mail deposited in a collection box can remain in the mailstream and be treated as unendorsed mail.

Mailers have had an extended period of time to adopt correct ancillary service endorsements. Residual stationery inventory can be used if obsolete endorsements are obliterated, minimizing any hardship. Otherwise, acceptance employees routinely reject improperly prepared mail or require customers to correct irregularities. The fact that improperly prepared items may enter the mailstream through unstaffed collection points reflects the practicalities of providing convenient and universal access to the postal network and is not discriminatory. The final rule simply requires the proper endorsement of mail for which an ancillary service is desired and terminates the transitional provisions for servicing invalid endorsements.

For the reasons discussed above, the Postal Service adopts the following amendments to the Domestic Mail Manual, which is incorporated by reference in the Code of Federal Regulations (see 39 CFS 111).

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Postal Service.

PART 111—[AMENDED]

1. The authority citation for 39 CFR part 111 continues to read as follows:

Authority: 5 U.S.C. 552(a); 39 U.S.C. 101, 401, 403, 404, 414, 3001–3011, 3201–3219, 3403–3406, 3621, 3626, 5001.

2. Revise the *Domestic Mail Manual* (DMM) as follows:

F Forwarding and Related Services

F000 Basic Services

* * * * *

F030 Address Correction, Address Change, FASTforward, and Return Services

1.0 ADDRESS CORRECTION SERVICE

* * * * *

1.2 Invalid Endorsement

Any obsolete ancillary service endorsement or similar sender endorsement not shown in F010 is considered invalid. Material bearing invalid or conflicting ancillary service endorsements will not be accepted for mailing. If discovered in the mailstream, mail bearing an invalid ancillary service endorsement or conflicting endorsements is treated as unendorsed mail. Exception: Standard Mail (B) pieces that are unendorsed, or that bear invalid or conflicting ancillary service endorsements and are undeliverable, will be treated as if endorsed "Forwarding Service Requested."

This change will be published in a future issue of the *Domestic Mail Manual*. An appropriate amendment to 39 CFR 111.3 to reflect these changes will be published.

Stanley F. Mires,

Chief Counsel, Legislative.

[FR Doc. 00–30581 Filed 11–30–00; 8:45 am]

BILLING CODE 7710–12–U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301068; FRL–6748–6]

RIN 2070–AB78

Peroxyacetic Acid; 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 peroxyacetic acid, in or on all raw and processed food commodities when used in sanitizing solutions containing a diluted end-use concentration of peroxyacetic acid up to 500 ppm, and applied to tableware, utensils, dishes, pipelines, tanks, vats, fillers, evaporators, pasteurizers, aseptic equipment, milking equipment, and other food processing equipment in food handling establishments including, but not limited to dairies, dairy barns, restaurants, food service operations, breweries, wineries, and beverage and food processing plants. Ecolab, Incorporated submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996 requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to

establish a maximum permissible level for residues of peroxyacetic acid. This final rule amends the current peroxyacetic acid exemption; and adds the subject peroxyacetic acid exemption. This final rule is being published with a companion final rule titled "Hydrogen Peroxide; Exemption From the Requirement of a Tolerance."

DATES: This regulation is effective December 1, 2000. Objections and requests for hearings, identified by docket control number OPP–301068, must be received by EPA on or before January 30, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VIII. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP–301068 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Marshall Swindell, Product Manager 33, Antimicrobial Division (7510C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703 308–6341; e-mail address: swindell.marshall@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/.

2. *In person.* The Agency has established an official record for this action under docket control number OPP–301068. 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 February 3, 1999 (64 FR 22) (FRL–5273–7), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act (FQPA) (Public Law 104–170) announcing the filing of a pesticide tolerance petition by, Ecolab, Incorporated. This notice included a summary of the petition prepared by the petitioner Ecolab, Incorporated. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.1196 be amended by establishing an exemption from the requirement of a tolerance for residues of peroxyacetic acid.

III. Risk Assessment

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.

IV. Toxicological Profile

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by peroxyacetic acid are discussed in this unit.

Ecolab, Inc. has requested a waiver of all toxicology testing requirements for peroxyacetic acid. This includes waivers for all acute, 90-day sub-chronic, chronic, oncogenicity, developmental, reproductive, mutagenicity, neurotoxicity and metabolism requirements for peroxyacetic acid. The Agency has reviewed the data waivers requested and concurs that no additional generic toxicology testing will be needed for

peroxyacetic acid for the following reasons.

1. Peroxyacetic acid is highly reactive and short lived because of the inherent instability of the peroxide bond (ie., the O-O bond). Agitation or contact with rough surfaces, sunlight, organics and metals accelerates decomposition. The instability of peroxyacetic acid to exist as itself, along with detoxifying enzymes found in cells (eg., catalase, glutathione peroxidase), makes it very difficult to find any residues of peroxyacetic acid in or on foods (at proposed use levels), by conventional analytical methods.

The proposed food contact applications also utilize very low concentrations of peroxyacetic acid. Therefore, food residues are expected to be short-lived, based on half-lives for peroxyacetic acid as short as a few minutes under certain conditions. The primary degradates are acetic acid, oxygen and water, and these degradates are not of toxicological concern.

2. There are acceptable acute generic data referenced in the Reregistration Eligibility Document (RED) for Peroxy Compounds (December 1993, Case 4072). Peroxyacetic acid was found to be corrosive and severely irritating to the eyes, skin, and mucous membranes but only when high concentrations were used. The proposed use patterns involve low concentrations and are expected to result in a lack of any residues of toxicological concern. The RED document waived all other non-acute toxicology data requirements for peroxyacetic acid.

3. No data exists for the subchronic, chronic, carcinogenicity, mutagenicity, developmental and reproductive toxicity of peroxyacetic acid. However, peroxyacetic acid shares similar chemical characteristics with hydrogen peroxide which has a more extensive toxicology data base. For example, peroxyacetic acid and hydrogen peroxide both decompose into two identical degradates that do not pose any toxicological concern. These two degradates are oxygen and water. Acetic acid is also a degradate of peroxyacetic acid and does not pose any toxicological concern.

Peroxyacetic acid and hydrogen peroxide also show similar chemical characteristics for corrosivity, pH, rapid peroxide bond dissociation, and production of oxygen molecules. Because of these similar chemical characteristics, and low expected exposures with the proposed uses, the dose-response toxicology relationships (i.e. adverse effects experienced only at very high doses) shown by the data for hydrogen peroxide, can also be expected with peroxyacetic acid. The remaining toxicology testing requirements for peroxyacetic acid were waived because of the similar chemical characteristics, similar expected dose-response relationships with hydrogen peroxide, low exposure levels under the proposed uses, and for the reasons given above.

V. Aggregate Exposures

A. Dietary Exposure

1. *Food.* For the proposed sanitizer uses, the 15.2% (by weight) concentrate of peroxyacetic acid will be diluted with potable water at the rate of 1 to 1.8 ounces of concentrated product per 1,024 ounces (8 gallons) of dilution water for food contact surfaces (eg., food packaging equipment), and for eating, drinking, and food preparation utensils. For low temperature (120 degrees F) tableware sanitization in warewashing machines, the dilution rate is 1 ounce of concentrated product per 3,840 ounces (30 gallons) of dilution water.

These dilution rates correspond to a low concentration range of peroxyacetic acid in the sanitizer product at the time of application of 40 to 274 ppm. The sanitizer solution, having a low concentration of peroxyacetic acid reacts on contact with the surface on which it is applied and degrades rapidly to acetic acid, oxygen and water which pose no toxicological concern. Therefore, residues of peroxyacetic acid resulting from its use in sanitizer solutions up to 500 ppm are expected to be negligible on all raw and processed food commodities. The difference between the 274 ppm maximum end use concentration, and the 500 ppm exemption concentration requested by Ecolab, is warranted to overcome any degradation of peroxyacetic acid during transport and non-use periods, and to provide flexibility for changes in formulation.

The following EPA and FDA tolerances and/or exemptions from tolerances for peroxyacetic acid are noted:

Under 40 CFR 180.1196 as a direct application at 100 ppm to fruits, vegetables, tree nuts, cereal grains, herbs and spices.

Under 21 CFR 178.1010(b)(30) for sanitizing solutions used on food-processing equipment and utensils and on other food contact articles. Sanitizing solutions may contain not less than 100 ppm nor more than 200 ppm peroxyacetic acid as per 21 CFR 178.1010(c)(25).

Under 21 CFR 178.1010(b)(38) for sanitizing solutions used on food processing equipment and dairy processing equipment. Sanitizing solutions may contain not less than 200 ppm nor more than 315 ppm as per 21 CFR 178.1010(c)(33).

Under 21 CFR 173.315(a)(2) in washing or to assist in lye peeling of fruits and vegetables that are not raw agricultural commodities. The concentration can not exceed 80 ppm in the wash water.

In 21 CFR 184.1005, the acetic acid degradate of peroxyacetic acid is Generally Recognized As Safe (GRAS) as a direct food additive substance when used in baked goods, cheeses, dairy product analogs, chewing gum, condiments, relishes, fats, oils, gravies, sauces, and meat products.

2. *Drinking Water Exposure.* The proposed indoor food contact uses for peroxyacetic acid are not expected to result in transfer of peroxyacetic acid to any potential drinking water sources. Therefore, no risk assessment is warranted.

B. Other Non-Occupational Exposure

Peroxyacetic acid is currently registered by EPA for a wide variety of uses including: agricultural premises and equipment; food handling/storage establishments premises and equipment; commercial, institutional and industrial premises and equipment; residential and public access premises; medical premises and equipment; materials preservation; and industrial processes and water systems. The Agency does not know of all approved or actual uses for peroxyacetic acid. However, non-dietary exposures are not expected to pose any quantifiable added risk because of the lack of any expected residues and degradates of toxicological concern. Minimal residues and degradates are expected due to previously discussed unique chemistry associated with peroxide bond chemistry.

VI. Cumulative Effects

The Food Quality Protection Act (1996) stipulates that when determining the safety of a pesticide chemical, EPA shall consider, among other things, available information concerning the cumulative effects to human health that may result from dietary, residential, or other non-occupational exposure to other substances that have a common mechanism of toxicity. The reason for consideration of other substances is due to the possibility that low-level exposures to multiple chemical substances that cause a common toxic effect by a common mechanism could lead to the same adverse health effect as would a higher level of exposure to any of the other substances individually. A person exposed to a pesticide at a level

that is considered safe may in fact experience harm if that person is also exposed to other substances that cause a common toxic effect by a mechanism common with that of the subject pesticide, even if the individual exposure levels to the other substances are also considered safe.

Because of the low use rates of peroxyacetic acid, its low toxicity and rapid degradation, EPA does not believe that there are any concerns regarding the potential for cumulative effects of peroxyacetic acid with other substances, due to a common mechanism of action. Peroxyacetic acid is not known to have a common toxic metabolite with other substances. Therefore, EPA has not assumed that peroxyacetic acid has a common mechanism of toxicity with other substances.

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

Peroxyacetic acid is of low toxicity, and the proposed uses employ low concentrations. Because of the low toxicity and rapid degradation of peroxyacetic acid following application, EPA concludes that this exemption from the requirement of a tolerance in or on all raw and processed food commodities, when peroxyacetic acid is used in diluted sanitizing solutions up to 500 ppm, will not pose a dietary risk to the U.S. population, infants, or children, under reasonably forseeable circumstances. Further, EPA finds that there is a reasonable certainty of no harm from aggregate exposure to peroxyacetic acid and thus that the exemption for peroxyacetic acid is safe. The Agency's human risk assessment findings are summarized below.

1. *Acute dietary risk assessment.* Acute dietary risk assessments are performed for a food-use pesticide if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. No acute exposure and risk assessment is applicable for peroxyacetic acid because no acute toxicological effects of concern are anticipated with the proposed food contact uses. This is due to the lack of any residues of toxicological concern because of the rapid decomposition of peroxyacetic acid into acetic acid, oxygen, and water. Use of peroxyacetic acid for indoor food equipment sanitization uses is not expected to result in the transfer of any residues to potential drinking water sources.

2. *Chronic dietary risk assessment.* Residues of peroxyacetic acid are not expected to remain on the surface of materials which it contacts. Therefore, the risk from dietary exposure is expected to be negligible. No chronic exposure and risk assessment is applicable because no chronic toxicological effects are anticipated with the proposed food contact uses for peroxyacetic acid. This is due to the lack of any residues of toxicological concern because of the rapid decomposition of peroxyacetic acid into acetic acid, oxygen, and water. Use of peroxyacetic acid for indoor food equipment sanitization uses is not expected to result in the transfer of any residues to potential drinking water sources.

3. *Aggregate cancer risk for U.S. population.* The Agency believes that based on the known chemistry of peroxy compounds, toxic effects occur as a result of species formed either during spontaneous decomposition or enzymatic conversion of the peroxy bond (i.e. O-O bond). These effects occur only after long term administration of high dose levels, where the parent compound is continually present. Available data show that peroxyacetic acid rapidly breaks down into oxygen, water, and acetic acid. Because of this rapid decomposition, the Agency does not expect residues of the parent compound when used as a sanitizer.

Based on the proposed use concentrations for peroxyacetic acid, and data indicating a lack of residues of concern on food, exposure to peroxyacetic acid under the proposed food contact use concentrations is not likely to result in any adverse clinical effects, including promotion of carcinogenisis. This conclusion is supported by the rapid decomposition of peroxyacetic acid into oxygen, water, and acetic acid, which are not of toxicological concern, and the existence of specific enzymes in the human body (i.e. catalase and glutathione peroxidase) which also can break down peroxyacetic acid.

The Agency concludes that cancer risk for the U.S. population from aggregate exposure to peroxyacetic acid is negligible under the proposed food contact use concentrations.

4. *Aggregate risks and determination of safety for infants and children.* In assessing the potential for additional sensitivity of infants and children to residues of peroxyacetic acid, EPA considered data from developmental and reproductive toxicity studies available from the scientific literature and summarized by the Office of Water. The developmental toxicity studies are designed to evaluate adverse effects on the developing organism resulting from maternal pesticide exposure during gestation. Reproduction studies provide information relating to effects from exposure to the pesticide on the reproductive capability of mating animals and data on systemic toxicity.

FFDCA section 408 provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database, 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. In either case, EPA generally defines the level of appreciable risk as exposure that is greater than 1/100 of the no observed adverse effect level (NOAEL) in the animal study appropriate to the particular risk assessment. This 100-fold uncertainty factor/margin of exposure is designed to account for inter-species extrapolation and intra-species variability.

In the case of the proposed food contact uses for peroxyacetic acid, because of the lack of any significant residues of toxicological concern, a NOAEL was not identified for risk assessment purposes, and the uncertainty (safety) factor approach was not used for assessing any risk level by peroxyacetic acid. For the same reason, an additional safety factor to protect infants and children is unnecessary. Additionally, based on the following information, no increased susceptibility to infants or children is expected to occur.

i. Three studies on the developmental and reproductive effects of hydrogen peroxide (and by similarity, peroxyacetic acid) are available. The data from these studies indicates that no apparent developmental or reproductive effects were observed from administration of hydrogen peroxide at concentrations up to 1% (1,000 milligrams/kilograms).

ii. Peroxyacetic acid is a highly reactive and short lived molecule because of the inherent instability of the peroxide bond (ie., the O-O bond). Agitation or contact with rough surfaces, sunlight, organics, and metals accelerates dissociation. The instability of peroxyacetic acid to exist as itself, along with natural detoxifying enzymes found in plant and animal cells (eg., catalase, glutathione peroxidase), makes it very difficult to find any residues of peroxyacetic acid in or on foods (at proposed use levels), by conventional analytical methods. The proposed food

contact applications utilize very low concentrations of peroxyacetic acid (ppm). Food residues are expected to be short-lived and are not expected to accumulate. This is because peroxyacetic acid dissociates rapidly into acetic acid, oxygen, and water. The Agency has no toxicological concern with acetic acid, oxygen, and water.

iii. A waiver was granted for all the remaining toxicology testing requirements because of the reasons given in items a and b above.

Therefore, because of the rapid decomposition of peroxyacetic acid residues into degradates that are of no toxicological concern (ie., oxygen, water, acetic acid), the Agency concludes that there is a reasonable certainty of no harm for infants and children from exposure to peroxyacetic acid under the proposed food contact use concentrations.

VIII. Other Considerations

A. Endocrine Disruptors

The Food Quality Protection Act (FQPA; 1996) requires that EPA develop a screening program to determine whether certain substances (including all pesticides and inerts) "may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen, or such other endocrine effect...." EPA has been working with interested stakeholders, including other government agencies, public interest groups, and industry and research scientists to develop a screening and testing program as well as a priority setting scheme to implement this program. The Agency's proposed Endocrine Disrupter Screening Program was published in the **Federal Register** on December 28, 1998 (63 FR 71541). As the Agency proceeds with implementation of this program, further testing of peroxyacetic acid for endocrine effects may be required. The currently available animal data suggest no significant endocrine effects from exposure to hydrogen peroxide.

B. Analytical Method(s)

Because an exemption from the requirement of a tolerance without numerical limitation on residue levels is being granted for peroxyacetic acid, an enforcement analytical method is not needed. However, an analytical method (designated QATM 202 by Ecolab, Inc., a redox titration procedure) 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, Environmental Protection Agency, 1200 Pennsylvania Avenue, N.W., Washington, DC 20460. Office location and telephone number: 1921 Jefferson Davis Highway, 3rd Floor, Arlington, VA 22202, 703 308–8253.

C. Existing Tolerances

In 40 CFR Part 180.1196, an exemption from the requirement of a tolerance is established for residues of peroxyacetic acid up to 100 ppm in or on raw agricultural commodities, in processed commodities, when such residues result from the use of peroxyacetic acid as an antimicrobial agent on fruits, vegetables, tree nuts, cereal grains, herbs, and spices.

D. International Tolerances

There are no Codex Alimentarius (Codex) Commission Maximum Residue Levels for peroxyacetic acid.

IX. Objections and Hearing Requests

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–301068 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 January 30, 2001.

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

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260–4865.

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

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

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VIII.A., you should also send a copy of your request to the PIRIB for its

inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP–301068, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: opp-docket@epa.gov. 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 file format 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).

X. 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). 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 prior consultation as specified by Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998); special considerations as required by Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or require 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).

XI. 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: November 9, 2000.

Frank Sanders,

Director, Antimicrobial Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), (346a) and 371.

2. Section 180.1196 is revised to read as follows:

§ 180.1196 Peroxyacetic acid; exemption from the requirement of a tolerance.

(a) An exemption from the requirement of a tolerance is established for residues of peroxyacetic acid in or on raw agricultural commodities, in processed commodities, when such residues result from the use of peroxyacetic acid as an antimicrobial treatment in solutions containing a diluted end use concentration of peroxyacetic acid up to 100 ppm per application on fruits, vegetables, tree nuts, cereal grains, herbs, and spices.

(b) An exemption from the requirement of a tolerance is established for residues of peroxyacetic acid, in or on all raw and processed food commodities when used in sanitizing solutions containing a diluted end-use concentration of peroxyacetic acid up to 500 ppm, and applied to tableware, utensils, dishes, pipelines, tanks, vats, fillers, evaporators, pasteurizers, aseptic equipment, milking equipment, and other food processing equipment in food handling establishments including, but not limited to dairies, dairy barns, restaurants, food service operations, breweries, wineries, and beverage and food processing plants.

[FR Doc. 00–30679 Filed 11–30–00; 8:45 am]
BILLING CODE 6560–50–S