ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–301071; FRL–6748–5]

RIN 2070–AB78

Hydrogen Peroxide; 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 Hydrogen Peroxide, in or on all raw and processed food commodities when used in sanitizing solutions containing a diluted end-use concentration of hydrogen peroxide up to 1,100 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, (FFDCA) as amended by the Food Quality Protection Act (FQPA) of 1996 requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of hydrogen peroxide. This final rule reinserts, and amends the hydrogen peroxide exemption that was deleted from the July 1, 1998 edition of 40 CFR; incorporates the currently published hydrogen peroxide exemption, unchanged and adds the subject hydrogen peroxide exemption. This final rule is being published with a companion final rule titled ''Peroxyacetic Acid; 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–301071, 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–301071 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; and 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	Examples of Potentially Affected Entities
Industry	111	Crop production
.....	112	Animal production
.....	311	Food manufacturing
.....	32532	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–301071. 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 FFDCA, 21 U.S.C. 346a, as amended by the FQPA (Public Law 104–170) announcing the filing of a pesticide tolerance petition by Ecolab, Inc. This notice included a summary of the petition prepared by the petitioner Ecolab, Inc. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR 180.1197 be amended by establishing an exemption from the requirement of a tolerance for residues of hydrogen peroxide.

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 hydrogen peroxide are discussed in this unit.

Ecolab, Inc., has requested a waiver of all toxicology testing requirements for hydrogen peroxide. This includes waivers for all acute, 90–day subchronic, chronic, oncogenicity, developmental, reproductive, mutagenicity, neurotoxicity and metabolism requirements for hydrogen peroxide. The Agency has reviewed the data waivers requested and concurs that no additional generic toxicology testing will be needed for hydrogen peroxide for the following reasons:

1. Hydrogen peroxide 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 hydrogen peroxide to exist as itself, along with detoxifying enzymes found in cells (eg., catalase, glutathione peroxidase), makes it very difficult to find any residues of hydrogen peroxide in or on foods (at proposed use levels), by conventional analytical methods.

The proposed food contact applications also utilize very low concentrations of hydrogen peroxide. Therefore, food residues are expected to be short-lived, based on half-lives for hydrogen peroxide as short as a few minutes under certain conditions. Residues are not of toxicological concern because hydrogen peroxide decomposes rapidly into oxygen and water. The Agency has no toxicological concern with oxygen and water.

2. There are acceptable acute generic data referenced in the Reregistration Eligibility Document for Peroxy Compounds (December 1993, Case 4072). Hydrogen peroxide 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 are expected to result in a lack of any residues of toxicological concern.

3. A waiver was granted for all the remaining toxicology testing requirements because of the reasons given above, and because there is an extensive data base assembled by the Agency's Office of Water. Although the Office of Water's data does show toxicological effects in experimental animals, these effects occur only at high doses that are not expected from the proposed uses of hydrogen peroxide. In addition, the rapid decomposition of hydrogen peroxide into oxygen and water, which are not of toxicological concern, mitigates any concern for residues.

Therefore, the lack of any residues of toxicological concern and the existence of toxicological effects only at high dose levels in experimental animals minimizes any concern for exposure to the very low doses that may be present as a result of the proposed uses.

The Agency also recognizes that commercially available 3% hydrogen peroxide solutions have been used for many years for personal and medical uses. The use directions for some of these products state that these 3% solutions can be used as a sanitizing mouthwash. Other food contact and medicinal uses for hydrogen peroxide include applications for wines and liquors (artificial aging), dentifrices, sanitary lotions, and pharmaceutical preparations.

The long use history of hydrogen peroxide and weight of empirical evidence and experimental data has led the Food and Drug Administration (FDA) to put hydrogen peroxide on the Generally Recognized As Safe (GRAS) list when used on food processing equipment, utensils, and food contact articles (21 CFR part 178). Potential symptoms of acute over exposure to medium or high concentrations of hydrogen peroxide include irritation of eyes, nose and throat, corneal ulceration, erythema, vesicles on skin, and bleaching of hair.

IV. Aggregate Exposures

A. Dietary Exposure

1. *Food*. For the proposed sanitizer uses, the 11.2% (by weight) concentrate of hydrogen peroxide 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 concentration range of hydrogen peroxide in the sanitizer product at the time of application of 29 to 202 parts per million (ppm). The sanitizer solution, having a low concentration of hydrogen peroxide, reacts on contact with the surface on which it is applied and degrades rapidly into oxygen and water which pose no toxicological concern. Therefore, residues of hydrogen peroxide resulting from its use in sanitizer solutions even up to 1,100 ppm are expected to be negligible on all raw and processed food commodities. The difference between the 202 ppm maximum end use concentration, and the 1,100 ppm exemption concentration requested by Ecolab, is warranted to overcome any degradation of hydrogen peroxide during transport and non-use periods, and to provide flexibility for changes in formulation.

Additional dietary sources of the GRAS substance hydrogen peroxide are not expected to be significant and range in concentration from 0.04 to 1.25% in the FDA food contact approvals cited below:

Under 21 CFR 184.1366, hydrogen peroxide is GRAS when used on milk intended for use in cheese making (maximum treatment level of 0.05%), whey, during preparation of modified whey by electrodialysis methods (maximum treatment level of 0.04%), dried eggs, dried egg whites, and dried egg yolks, tripe, beef feet, herring, wine, starch (maximum treatment level of 0.15%), instant tea, corn syrup (maximum treatment level of 0.15%), colored cheese whey (maximum treatment level of 0.05%), wine vinegar, and emulsifiers containing fatty acid esters (maximum treatment level of 1.25%).

Hydrogen peroxide presently has the following additional EPA and FDA clearances:

Under 40 CFR 180.1197 as a direct application at 120 ppm to fruits, vegetables, tree nuts, cereal grains, herbs and spices.

Under 21 CFR 172.892 for modification of food starch to be added to human food items.

Under 21 CFR 178.1005 for sterilization of polymeric food surfaces. Sanitizing solution is not to contain more than 35% hydrogen peroxide.

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 550 ppm nor more than 1,100 ppm hydrogen peroxide (21 CFR 178.1010(c)(25)).

Under 21 CFR 184.136 as GRAS when hydrogen peroxide meets Food Chemical Codex specifications, to treat certain foods as a antimicrobial, bleaching agent, oxidizing and reducing agent. Residual hydrogen peroxide must be removed during processing of food.

Under 21 CFR 173.315(a)(2) for use in washing or to assist in the lye peeling of fruits and vegetables that are not raw agricultural commodities. Used in combination with acetic acid. Not to exceed 59 ppm in wash water.

Under 21 CFR 178.1010(c)(33) for sanitizing solutions used on food processing equipment and dairy processing equipment. Sanitizing solutions may contain not less than 300 ppm nor more than 465 ppm of hydrogen peroxide.

2. *Drinking water exposure*. Use of hydrogen peroxide for indoor food equipment sanitization uses is not expected to result in the transfer of any residues to potential drinking water sources. Therefore, no risk assessment is warranted.

B. Other Non-Occupational Exposure

Hydrogen peroxide is currently registered by EPA for a wide variety of uses. These includes use as a water additive for control of spoilage microorganisms on raw and processed food commodities; use as an algaecide, fungicide and bactericide on growing crops and post harvest potatoes; use on agricultural premises and equipment, food handling/storage establishments premises and equipment; use on commercial, institutional and industrial premises and equipment; use on residential, public access premises, medical premises and equipment; use for materials preservation; and for industrial processes and water systems.

Hydrogen peroxide is also approved for a variety of medicinal uses including sanitization of scrapes, cuts, and burns to human and animal skin, and as a human oral sanitizing mouthwash. It is also used by medical doctors for general cleansing and sanitization of surgical areas of the body after operations. Hydrogen peroxide use in homes is medicinal and exposures are expected to be infrequent and at extremely short topical duration.

The Agency does not know of all approved or actual uses for hydrogen peroxide. However, non-dietary exposures are not expected to pose any quantifiable added risk because of a lack of any significant residues of toxicological concern.

V. Cumulative Effects

The FQPA (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 hydrogen peroxide, its low toxicity, and rapid degradation, EPA does not believe that there are any concerns regarding the potential for cumulative effects of hydrogen peroxide with other substances due to a common mechanism of action.

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

Because hydrogen peroxide is of low toxicity, and the proposed uses employ low concentrations of hydrogen peroxide, and hydrogen peroxide degrades rapidly following application, EPA concludes that this exemption from the requirement of a tolerance in or on all raw and processed food commodities, when hydrogen peroxide is used in diluted sanitizing solutions up to 1,100 ppm, poses no dietary risk to the U.S. population including infants and children, under reasonably forseeable circumstances. Further, EPA finds that there is a reasonable certainty of no harm from aggregate exposure to hydrogen peroxide and thus that the exemption for hydrogen peroxide 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 one day or single exposure. No acute exposure and risk assessment is applicable because no acute toxicological effects of concern or exposure are anticipated with the proposed food contact uses for hydrogen peroxide. This is due to the lack of any residues of toxicological concern as a result of the automatic and rapid decomposition of hydrogen peroxide into oxygen and water. Use of hydrogen peroxide 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 hydrogen peroxide 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 hydrogen peroxide. This is due to the lack of any residues of toxicological concern as a result of the automatic and rapid decomposition of hydrogen peroxide into oxygen and water. Use of hydrogen peroxide 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*. Available data suggest that hydrogen peroxide can act as a promoter of carcinogenisis at relatively high doses (in excess of 600 milligrams/kilograms (mg/kg)) after chronic administration in drinking water to experimental animals. Epidemiological reports indicate that the major effect from accidental ingestion of high doses of hydrogen peroxide in humans (ie., 1,000 mg/kg) is acute and severe clinical toxicity, which in a few cases resulted in death.

Based on the proposed use concentrations for hydrogen peroxide, and data indicating negligible residues on food, exposure to hydrogen peroxide 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 further by the rapid decomposition of hydrogen peroxide into oxygen and water, which are not of toxicological concern, and the existence of specific enzymes (ie., catalase and glutathione peroxidases) for breakdown of hydrogen peroxide.

Therefore, the Agency concludes that the cancer risk for the U.S. population from aggregate exposure to hydrogen peroxide 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 hydrogen peroxide, 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 data base, 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 margin of exposure (MOE) analysis or through using uncertainty (safety) factors (UF) 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 UF/MOE is designed to account for interspecies extrapolation and intraspecies variability.

In the case of the proposed food contact uses for hydrogen peroxide, because of the lack of any 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 hydrogen peroxide. For the same reason, an additional safety factor to protect infants and children is unnecessary. Additionally, based on the following, no increased susceptibility to infants or children is expected to occur.

i. Three older studies on the developmental and reproductive effects of hydrogen peroxide 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 mg/kg).

ii. Hydrogen peroxide 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 and metals accelerates dissociation. The proposed food contact applications utilize very low concentrations of hydrogen peroxide (i.e ppm). Food residues are expected to be short-lived and are not expected to accumulate. This is because hydrogen peroxide dissociates rapidly in air into oxygen and water. The Agency has no toxicological concern with 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, and because there is an extensive data base assembled by the Agency's Office of Water showing toxicological effects in experimental animals only at high concentrations, which are not expected with the proposed use patterns.

iv. The Agency also recognizes that commercially available 3% hydrogen peroxide solutions have been used for many years for personal and medical uses. The use directions for some of these products state that these solutions can be used as a sanitizing mouthwash. The long use history of hydrogen peroxide and weight of empirical and experimental data has led the FDA to put it on the GRAS list when used on food processing equipment, utensils, and food contact articles (21 CFR part 178).

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

VII. Other Considerations

A. Endocrine Disruptors

The 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 hydrogen peroxide 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 for residues in food is being granted for hydrogen peroxide, an enforcement analytical method is not needed. However, an analytical method (designated QATM 202 by Ecolab, Inc., a redoxtitration 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, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., 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 180.1197, an exemption from the requirement of a tolerance is established for residues of hydrogen peroxide in or on all food commodities at the rate of less than or equal to 1% hydrogen peroxide per application on growing crops and post harvest potatoes, when applied as an algaecide, fungicide, and bactericide.

D. International Tolerances

There are no Codex Alimentarius (Codex) Commission Maximum Residue Levels for Hydrogen Peroxide.

VIII. 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–301071 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–301071, 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).

IX. 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).

X. 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 180.1197, is revised to read as follows:

§ 180.1197 Hydrogen Peroxide; exemption from the requirement of a tolerance.

(a) An exemption from the requirement of a tolerance is established for residues of hydrogen peroxide in or on raw agricultural commodities, in processed commodities, when such residues result from the use of hydrogen peroxide as an antimicrobial treatment in solutions containing a diluted end-use concentration of hydrogen peroxide up to 120 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 hydrogen peroxide in or on all food commodities at the rate of less than or equal to 1% hydrogen peroxide per application on growing crops and post harvest potatoes when applied as an algaecide, fungicide and bactericide.

(c) An exemption from the requirement of a tolerance is established for residues of hydrogen peroxide, in or on all raw and processed food commodities when used in sanitizing solutions containing a diluted end-use concentration of hydrogen peroxide up to 1,100 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. 00–30680 Filed 11–30–00; 8:45 am]
BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–6910–4]

National Priorities List for Uncontrolled Hazardous Waste Sites

AGENCY: Environmental Protection Agency.

ACTION: Final rule.

SUMMARY: The Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (''CERCLA'' or ''the Act''), as amended, requires that the National Oil and Hazardous Substances Pollution Contingency Plan (''NCP'') include a list of national priorities among the known releases or threatened releases of hazardous substances, pollutants, or contaminants throughout the United States. The National Priorities List (''NPL'') constitutes this list. The NPL is intended primarily to guide the Environmental Protection Agency (''EPA'' or ''the Agency'') in determining which sites warrant further investigation to assess the nature and extent of public health and environmental risks associated with the site and to determine what CERCLA-financed remedial action(s), if any, may be appropriate. This rule adds 8 new sites to the NPL; 7 sites to the General Superfund Section of the NPL and one site to the Federal Facilities Section.

EFFECTIVE DATE: The effective date for this amendment to the NCP shall be January 2, 2001.

ADDRESSES: For addresses for the Headquarters and Regional dockets, as well as further details on what these dockets contain, see Section II, ''Availability of Information to the Public'' in the ''Supplementary Information'' portion of this preamble.

FOR FURTHER INFORMATION CONTACT: Yolanda Singer, phone (703) 603–8835, State, Tribal and Site Identification Center; Office of Emergency and Remedial Response (mail code 5204G); U.S. Environmental Protection Agency; 1200 Pennsylvania Avenue NW., Washington, DC 20460; or the Superfund Hotline, phone (800) 424–9346 or (703) 412–9810 in the Washington, DC, metropolitan area.

SUPPLEMENTARY INFORMATION:

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