the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27).

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is 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 in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

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.

VI. Public Docket

EPA has established a record for this rulemaking under docket control number [OPP–300654] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Electronic comment may be sent directly to EPA at:

opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VII. 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) (Pub. L. 104-4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or 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 in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these 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. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

VIII. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted 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 General Accounting Office prior to publication of this rule in today's **Federal Register**. This 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: April 30, 1998.

Frank Sanders,

Director, Antimicrobials 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. 346a and 371.

2. Section 180.1196 is added to read as follows:

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

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, tree nuts, cereal grains, herbs, and spices.

[FR Doc. 98–12036 Filed 5–5–98; 8:45 am]

BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300655; FRL–5789–4]

RIN 2070–AB78

Hydrogen Peroxide; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes an exemption from the requirement of a

tolerance for residues of the antimicrobial pesticide hydrogen peroxide up to 120 ppm, in or on raw agricultural commodities, in processed commodities, when such residues result from the use of hydrogen peroxide as an antimicrobial agent on fruits, tree nuts, cereal grains, herbs, and spices. Ecolab, Inc. requested this exemption under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996 (Pub. L. 104-170).

DATES: This regulation is effective May 6, 1998. Objections and requests for hearings must be received by EPA on or before July 6, 1998.

ADDRESSES: Written objections and hearing requests, identified by the docket control number, [OPP–300655], must be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. Fees accompanying objections and hearing requests shall be labeled ''Tolerance Petition Fees'' and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251. A copy of any objections and hearing requests filed with the Hearing Clerk identified by the docket control number, [OPP–300655], must also be submitted to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring a copy of objections and hearing requests to Rm. 119, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may also be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epamail.epa.gov. Copies of objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption. Copies of objections and hearing requests will also be accepted on disks in WordPerfect 5.1/6.1 file format or ASCII file format. All copies of objections and hearing requests in electronic form must be identified by the docket control number [OPP–300655]. No Confidential Business Information (CBI) should be submitted through e-mail. Electronic copies of objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Marshall Swindell, Product Manager 33, Antimicrobials Division 7510W, Office of Pesticide Programs, Environmental Protection Agency, 401M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: 2800 Crystal Drive, 6th Floor, Arlington, VA, 22202, 703-308-6341, e-mail: swindell.marshall@epamail.epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 14, 1998 (63 FR 2235) (FRL–5759–7), EPA, issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e) announcing the filing of a pesticide petition (PP) 7F4834 for tolerance by Ecolab, Inc., 370 Wabasha Street, St. Paul, MN 55102. This notice included a summary of the petition prepared by Ecolab, Inc., the registrant. There were no comments received in response to the notice of filing.

Subsequently, the proposed tolerance exemption was amended to delete meat, meat by-products, poultry, milk, and eggs. This was done because at the low proposed use concentrations, no residues of toxicological concern are expected on any animal feeds that may be exposed to hydrogen peroxide. Therefore, no residues of toxicological concern are anticipated either in animals that may consume these feeds, or in associated animal by-products.

In addition, the proposed tolerance exemption was amended to include a maximum residue limit of 120 ppm for hydrogen peroxide. This limitation was added because of Agency concerns that a high use concentration could result in measurable residues of hydrogen peroxide. Residue data will be needed to increase or remove this limitation.

I. Risk Assessment and Statutory Findings

New section 408(b)(2)(A)(i) of the FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance or exemption from the requirement of a 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 based primarily on toxicological studies using laboratory animals. These studies address many adverse health effects, including (but not limited to) reproductive effects, developmental toxicity, toxicity to the nervous system, and carcinogenicity. Second, EPA examines exposure to the pesticide through the diet (e.g., food and drinking water) and through exposures that occur as a result of pesticide use in residential settings.

A. Toxicity

1. *Threshold and non-threshold effects.* For many animal studies, a dose response relationship can be determined, which provides a dose that causes adverse effects (threshold effects) and doses causing no observed effects (the ''no-observed effect level'' or ''NOEL'').

Once a study has been evaluated and the observed effects have been determined to be threshold effects, EPA generally divides the NOEL from the study with the lowest NOEL by an uncertainty factor (usually 100 or more) to determine the Reference Dose (RfD). The RfD is a level at or below which daily aggregate exposure over a lifetime will not pose appreciable risks to human health.

An uncertainty factor (sometimes called a ''safety factor'') of 100 is commonly used since it is assumed that people may be up to 10 times more sensitive to pesticides than the test animals, and that one person or subgroup of the population (such as infants and children) could be up to 10 times more sensitive to a pesticide than another. In addition, EPA assesses the potential risks to infants and children based on the weight of the evidence of the toxicology studies and determines whether an additional uncertainty factor is warranted.

Thus, an aggregate daily exposure to a pesticide residue at or below the RfD (expressed as 100% or less of the RfD) is generally considered acceptable by EPA. EPA generally uses the RfD to evaluate the chronic risks posed by pesticide exposure. For shorter term risks, EPA calculates a margin of exposure (MOE) by dividing the estimated human exposure into the NOEL from the appropriate animal study. Commonly, EPA finds MOEs lower than 100 to be unacceptable. This 100-fold MOE is based on the same

rationale as the 100-fold uncertainty factor.

Lifetime feeding studies in two species of laboratory animals are conducted to screen pesticides for cancer effects. When evidence of increased cancer is noted in these studies, the Agency conducts a weight of the evidence review of all relevant toxicological data including short-term and mutagenicity studies and structure activity relationship. Once a pesticide has been classified as a potential human carcinogen, different types of risk assessments (e.g., linear low dose extrapolations or MOE calculation based on the appropriate NOEL) will be carried out based on the nature of the carcinogenic response and the Agency's knowledge of its mode of action.

2. *Differences in toxic effect due to exposure duration.* The toxicological effects of a pesticide can vary with different exposure durations. EPA considers the entire toxicity data base, and based on the effects seen for different durations and routes of exposure, determines which risk assessments should be done to assure that the public is adequately protected from any pesticide exposure scenario. Both short and long durations of exposure are always considered. Typically, risk assessments include ''acute,'' ''short-term,'' ''intermediate term,'' and ''chronic'' risks. These assessments are defined by the Agency as follows.

Acute risk, by the Agency's definition, results from 1-day consumption of food and water, and reflects toxicity which could be expressed following a single oral exposure to the pesticide residues. High end exposure to food and water residues are typically assumed.

Short-term risk results from exposure to the pesticide for a period of 1-7 days, and therefore overlaps with the acute risk assessment. Historically, this risk assessment was intended to address primarily dermal and inhalation exposure which could result, for example, from residential pesticide applications. However, since enaction of the Food Quality Protection Act of 1996 (FQPA), this assessment has been expanded to include both dietary and non-dietary sources of exposure, and will typically consider exposure from food, water, and residential uses when reliable data are available. In this assessment, risks from average food and water exposure, and high-end residential exposure, are aggregated.

High-end exposures from all three sources are not typically added because of the very low probability of this occurring in most cases, and because the other conservative assumptions built into the assessment assure adequate protection of public health. However, for cases in which high-end exposure can reasonably be expected from multiple sources (e.g. frequent and widespread homeowner use in a specific geographical area), multiple high-end risks will be aggregated and presented as part of the comprehensive risk assessment/characterization.

Since the toxicological endpoint considered in this assessment reflects exposure over a period of at least 7 days, an additional degree of conservatism is built into the assessment; i.e., the risk assessment nominally covers 1-7 days exposure, and the toxicological endpoint/NOEL is selected to be adequate for at least 7 days of exposure. (Toxicity results at lower levels when the dosing duration is increased.)

Intermediate-term risk results from exposure for 7 days to several months. This assessment is handled in a manner similar to the short-term risk assessment.

Chronic risk assessment describes risk which could result from several months to a lifetime of exposure. For this assessment, risks are aggregated considering average exposure from all sources for representative population subgroups including infants and children.

B. Aggregate Exposure

In examining aggregate exposure, FFDCA section 408 requires that EPA take into account available and reliable information concerning exposure from the pesticide residue in the food in question, residues in other foods for which there are tolerances, residues in groundwater or surface water that is consumed as drinking water, and other non-occupational exposures through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

Dietary exposure to residues of a pesticide in a food commodity are estimated by multiplying the average daily consumption of the food forms of that commodity by the tolerance level or the anticipated pesticide residue level. The Theoretical Maximum Residue Contribution (TMRC) is an estimate of the level of residues consumed daily if each food item contained pesticide residues equal to the tolerance. In evaluating food exposures, EPA takes into account varying consumption patterns of major identifiable subgroups of consumers, including infants and children.

The TMRC is a ''worst case'' estimate since it is based on the assumptions that food contains pesticide residues at the tolerance level and that 100% of the crop is treated by pesticides that have established tolerances. If the TMRC exceeds the RfD or poses a lifetime cancer risk that is greater than approximately one in a million, EPA attempts to derive a more accurate exposure estimate for the pesticide by evaluating additional types of information (anticipated residue data and/or percent of crop treated data) which show, generally, that pesticide residues in most foods when they are eaten are well below established tolerances.

Percent of crop treated estimates are derived from federal and private market survey data. Typically, a range of estimates are supplied and the upper end of this range is assumed for the exposure assessment. By using this upper end estimate of percent of crop treated, the Agency is reasonably certain that exposure is not understated for any significant sub-population group. Further, regional consumption information is taken into account through EPA's computer-based model for evaluating the exposure of significant sub-populations including several regional groups, to pesticide residues. For hydrogen peroxide, based on the lack of any residues of toxicological concern, it is unlikely that significant exposure through the proposed use would occur to any sub-population although sensitive sub-populations may exist (eg.,catalase deficient individuals).

II. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action, EPA has sufficient data to assess the hazards of hydrogen peroxide and to make a determination on aggregate exposure, consistent with section 408(b)(2), for an exemption of a requirement for a tolerance for residues of hydrogen peroxide up to 120 ppm, in or on raw agricultural commodities, in processed commodities, when such residues result from the use of hydrogen peroxide as an antimicrobial agent on fruits, tree nuts, cereal grains, herbs, and spices. EPA's assessment of the dietary exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies 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 (H_2O_2) are discussed below.

Ecolab, Inc. has requested a waiver of all toxicology testing requirements for hydrogen peroxide. This includes waivers for all acute, 90-day sub-chronic, chronic, oncogenicity, developmental, reproductive, mutagenicity, neurotoxicity and metabolism requirements for hydrogen peroxide. Ecolab's rationale for waivers in each of these areas is similar, and are summarized by the following four arguments:

1. Available data at the Agency are sufficient to estimate the potential human health hazard of the end use product.

2. Hydrogen peroxide is generally recognized as safe (GRAS) according to the Food and Drug Administration (21 CFR part 178) when used on food-processing equipment, utensils, and food contact articles.

3. Based on the chemical reactivity of this compound and its unstable nature, conduct of long term or metabolism studies would be extremely difficult and unreliable.

4. The published Reregistration Eligibility Document for Peroxy Compounds (Case 4072, December, 1993), has waived all further toxicology testing requirements for peroxy compounds.

The Agency has reviewed the data waivers requested and concurs that no 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 (i.e., 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 about 4 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 only at high concentrations, the Agency is not concerned because of the rapid decomposition of hydrogen peroxide into oxygen and water.

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), dentrifices, sanitary lotions, and pharmaceutical preparations.

The long use history of hydrogen peroxide and weight of empirical evidence and experimental data has led the FDA to put hydrogen peroxide on the GRAS list when used on food processing equipment, utensils, and food contact articles (21 CFR 178). Potential symptoms of acute overexposure 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.

The following is a summary of the existing generic data base for acute, subchronic, chronic, mutagenic, developmental, reproductive, and carcinogenic effects of hydrogen peroxide in mammalian test animals. These data show that significant toxicological effects of hydrogen peroxide in mammalian test systems are measurable only at high doses. The proposed food contact use patterns are not expected to result in residues of toxicological concern due to the rapid decomposition of hydrogen peroxide into oxygen and water. The following generic acute toxicology data for hydrogen peroxide were cited in the 1993 RED for hydrogen peroxide. The subchronic, chronic, carcinogenicity, developmental, and reproductive toxicology, along with the mutagenicity data are summarized from the Office of Water data base.

1. *Acute studies*— i. A study on mice showed an acute oral LD_{50} of 2,000 milligrams/kilogram (mg/kg).

ii. A study on rats showed an acute dermal LD_{50} of 4,060 mg/kg.

iii. A study on mice showed an acute inhalation LC_{50} of 227 ul/L.

iv. An eye irritation study on rabbits produced severe irritation.

v. A dermal irritation study on rabbits showed hydrogen peroxide was corrosive.

2. *Subchronic exposure*— i. Weanling Osborne-Mendel rats were exposed to a 0.45% (560 mg/kg/day) aqueous solution of hydrogen peroxide in drinking water for 3 weeks. When corrected for differences observed in water intake between control and treated rats, there were no significant differences observed in absolute and relative organ weights of the kidney, spleen, heart, or testes. A NOEL of 560 mg/kg/day was determined, although a lowest-observed-effect level (LOEL) was not.

ii. Young male Holtzman rats were administered doses of 0, 500, 1,000, or 1,500 mg/kg/day hydrogen peroxide in water for 8 weeks. Increased mortality was noted at the high dose. Increased incidence of dental caries and pathological changes in the periodontium were also noted at the mid and high dose. A LOEL of 500 mg/kg/day was determined, but a NOEL was not established.

iii. Male and female C57BL/6N, DBA/2N, and BALB/cAnN mice were given hydrogen peroxide at 0, 0.1, or 0.4% in drinking water for 30 or 60 days. Equivalent doses (assuming water intake of 150 ml/kg/day) were 0, 150, or 600 mg/kg/day. The high dose resulted in erosion of the glandular stomach in 29% of mice treated for 30 days and in 40% of mice treated for 60 days. Duodenal lesions, but no frank nodules, were also observed at the high dose. A LOEL of 600 mg/kg/day was determined, but due to the lack of data reported at the 150 mg/kg/day dose, a NOEL could not be definitively assigned.

3. *Chronic exposure*— i. Wistar rats were administered 30 or 60 mg/kg/day hydrogen peroxide for 100 days by oral intubation. After 100 days, decreases in plasma protein, hematocrit, and plasma catalase were observed. Administration

of the same dose levels in feed had no effects. A NOEL of 30 mg/kg/day could be determined from this study.

ii. Three-week old mice (strain not specified) were administered 0.15% hydrogen peroxide in drinking water for 35 weeks, presumed equivalent to 150 mg/kg/day. Degenerative changes in the liver and kidney, as well as inflammation, irregularity and slight necrosis of the stomach wall were observed. The LOEL was determined to be 150 mg/kg/day in this study, but a NOEL was not identified.

iii. Male and female C57BL/6N mice were administered 0, 0.1, or 0.4% hydrogen peroxide in drinking water for up to 700 days. Doses of 0, 150, and 600 mg/kg/day were calculated based on assumed intake of 150 mL/kg/day water. The gastrointestinal tract was examined over the course of the study through serial sacrifice at time points between 90-700 days. Gastric lesions consisting of erosion and hyperplastic nodules were detected in the stomach and duodenum after 1-2 years exposure. The LOEL was determined to be 150 mg/kg/day from this study.

4. *Carcinogenicity*— i. Gastric carcinogenesis was investigated in male Wistar rats. Twenty-one rats received the initiator MNNG in drinking water for 8 weeks at 100 mg/L, while uninitiated rats (10 animals) received plain drinking water. After 8 weeks, both groups received 1% hydrogen peroxide in drinking water from week 8 through week 40. Two other groups (30 and 10 rats, respectively) were chosen as initiated and uninitiated controls. Surviving rats were sacrificed and necropsied at 40 weeks. Erosion and ulceration along the limiting ridge of the fundic mucosa was observed. Initiated rats showed an increased incidence of adenomatous hyperplasia in this stomach area. There were no adenocarcinomas induced in the stomach or duodenum. Papillomas of the forestomach were induced by hydrogen peroxide alone.

ii. Three month old Syrian hamsters were administered either: twice weekly applications of 30% hydrogen peroxide in the left buccal pouch, twice weekly buccal application of 0.25% 9,10 dimethyl-1,2-benzanthracene with either 30% or 3% hydrogen peroxide (hydrogen peroxide applied on a different day than the DMBA), or DMBA only. Buccal pouches were examined for tumor development at 19 and 22 weeks after sacrifice. No epidermoid carcinomas were observed after 22 weeks of treatment with hydrogen peroxide alone. All three groups receiving DMBA treatment did develop tumors. The tumors in the group receiving the 30% hydrogen peroxide and DMBA were reported to be more anaplastic with deeper penetration of tissue. It was concluded that hydrogen peroxide may augment oral carcinogenesis induced by DMBA.

iii. Male and female weanling C57Bl/6J mice were administered 0, 0.1, or 0.4% hydrogen peroxide in drinking water for up to 108 weeks. Erosion of the glandular stomach was observed in 20% and 42% of dosed mice at the 0.1% and 0.4% dose levels, respectively, compared to 4% in controls. Duodenal nodules were observed in treated mice and were classified into hyperplasia, adenoma, and carcinoma. Hyperplasia was significantly increased at the 0.1% and 0.4% dose levels (40% and 62% of treated mice respectively), as was the incidence of duodenal carcinoma, observed in 5 of 99 high dose animals, 1 of 101 low dose animals, and absent in controls.

iv. Various strains of mice (C57Bl/6N, DBA/2N, BALB/c) were exposed to 0.4% hydrogen peroxide in drinking water over their lifetime. Appearance of duodenal lesions (plaques and nodules) was noted in all strains after 90 days of treatment. Temporary withdraw of hydrogen peroxide produced apparent reversibility in C57BL/6N mice only after 30 days of no treatment. After 150 days of treatment, C57BL/6N mice appeared to have an increased incidence of duodenal lesions relative to the other two strains. After 420-740 days of treatment, the incidence of duodenal carcinoma was 0, 1%, and 5% in control, low, and high dose, respectively. This study did not present concurrent control data, and used varying numbers of mice for examination at the various time points. Therefore, results from this study are considered equivocal.

v. Strains of mice differing in catalase activities of the duodenum, blood, and liver (in order of decreasing activity: C3H/HeN, B6C3F1, C57BL/6N, C3H/C) were given a solution of 0.4% hydrogen peroxide in drinking water for approximately 6 months. The duodenum was examined for the incidence and total lesions in each strain. Approximately 18-22 mice per strain were examined. The data suggested that the number of duodenal lesions per mouse and total incidence was inversely correlated wi th catalase activity.

vi. Recent experimental evidence (Upham, et al., Carcinogenesis 18(1): 37-42, 1997) has implicated hydrogen peroxide in the inhibition of gap junctional intercellular communication in rat liver epithelial cells (a significant step in production of tumors). These recent data lend support to the above studies in the implication of high levels of hydrogen peroxide as a promotor of tumorigenesis. The International Agency for Research in Cancer (IARC) has designated hydrogen peroxide as not classifiable as to carcinogenicity, based on the data noted above.

5. *Developmental and reproductive toxicity*. Three older studies on the developmental and reproductive effects of hydrogen peroxide are available. These data indicate no apparent developmental or reproductive effects observed from administration of hydrogen peroxide at concentrations up to 1% (1000 mg/kg).

6. *Mutagenicity*— i. In a standard plate incorporation assay, hydrogen peroxide (concentrations not stated) was weakly mutagenic to strains TA98, TA97, and TA1537 for frame shift mutations and to strain TA102 for oxidative mutations, but was not mutagenic to strains TA100 and TA1538.

ii. Using isolated hepatocytes from Female Fischer rats, hydrogen peroxide was incubated at concentrations from 0.01 to 1.0mM for 1 hour at 37 degrees Celsius. Overt cytotoxicity was observed at 1mM. A concentration dependent increase in single strand DNA breaks was observed at all other exposure levels. No double strand DNA breaks or DNA cross-links were observed.

iii. In a human bronchial epithelial cell system, nucleic acid synthesis was observed to be significantly decreased after exposure to hydrogen peroxide at 1.2mM for six hours followed by a cell growth period of 7-9 days. At 100 m, single strand DNA breaks and DNA-protein cross links were observed, with single strand breaks predominating. DNA strand breakage has also been observed in other test systems (hamster V79 cells and bovine pulmonary artery and aortic endothelial cells).

iv. Cell killing and DNA damage were examined in Chinese hamster fibroblast cells (V79-379A). After incubation of cells with 1-100 mM hydrogen peroxide at ice cold temperatures for 10 or 20 minutes, single strand breaks were observed at 1 mM hydrogen peroxide. Double strand breaks and cell killing were observed at higher (10mM) concentrations of hydrogen peroxide.

B. Toxicological Endpoints

1. *Acute toxicity*. The Agency has concluded that for the proposed food contact uses, no apparent toxicity endpoint exists to suggest any evidence of significant toxicity from a one-day or single-event exposure.

2. *Short - and intermediate - term toxicity*. The Agency has concluded that

for the proposed food contact uses, no apparent toxicity endpoint exists to suggest any evidence of significant toxicity from short and intermediate term exposure.

3. *Chronic toxicity.* A RfD for hydrogen peroxide has not been established because of its short half life and lack of any residues of toxicological concern. As discussed in the December 1993 Reregistration Eligibility Document for Peroxy Compounds, and in this final rule, under the proposed and existing dietary related use patterns (i.e., raw and processed agricultural commodities, food processing equipment in breweries, wineries, and beverage plants), there is expected to be a lack of any residues of toxicological concern.

4. *Carcinogenicity.* 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 hydrogen peroxide rapidly breaks down into oxygen and water. Because of this rapid decomposition, the Agency does not expect residues of the parent compound on the treated comodities.

Based on the proposed use concentrations for hydrogen peroxide, and data indicating a lack of residues of concern 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 by the rapid decomposition of hydrogen peroxide into oxygen and water, 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 hydrogen peroxide.

C. Exposures and Risks

1. *From food and feed uses.* An exemption from the requirement of a tolerance is being established (40 CFR 180.1197) for the residues of hydrogen peroxide) up to 120 ppm, in or on a variety of (raw agricultural commodities, in processed commodities, when such residues result from the use of hydrogen peroxide as an antimicrobial agent on fruits, tree nuts, cereal grains, herbs, and spices.

There are no existing food or feed use tolerances or exemptions from the requirement of a tolerance in title 40 of the CFR for hydrogen peroxide. The following 21 CFR tolerances and/or exemptions from tolerances are noted:

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%).

Under 21 CFR 178.1010, hydrogen peroxide is approved for use as a sanitizing solution for use on food processing equipment and utensils, and on dairy processing equipment. It is also approved for use in sterilizing polymeric food-contact surfaces.

Under 21 CFR 173.315, hydrogen peroxide is approved for use in washing or to assist in the lye peeling of fruits and vegetables.

Risk assessments were conducted by EPA to assess dietary exposures and risks from hydrogen peroxide as follows:

i. *Acute exposure and risk.* 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 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.

ii. *Chronic exposure and risk.* 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.

2. *From drinking water.* Although the proposed food contact uses for hydrogen peroxide acid may result in transfer of minor amounts of residues to potential drinking water sources, no risk assessment is warranted because of: (i) the rapid degradation of hydrogen peroxide into oxygen, and water, and (ii) these degradates are not of toxicological concern. Information from the EPA Office of Water also indicates that when used for potable water disinfection, no residues of hydrogen peroxyide acid are present by the time the water is pumped through a distribution system.

3. *From non-dietary exposure.* Hydrogen peroxide 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.

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.

4. *Cumulative exposure to substances with common mechanism of toxicity.* 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.''

The Agency believes that ''available information'' in this context might include not only toxicity, chemistry, and exposure data, but also scientific policies and methodologies for understanding common mechanisms of toxicity and conducting cumulative risk assessments. For most pesticides, although the Agency has some information in its files that may turn out to be helpful in eventually determining whether a pesticide shares a common mechanism of toxicity with any other substances, EPA does not at this time have the methodologies to resolve the complex scientific issues concerning

common mechanism of toxicity in a meaningful way.

EPA has begun a pilot process to study this issue further through the examination of particular classes of pesticides. The Agency hopes that the results of this pilot process will increase the Agency's scientific understanding of this question such that EPA will be able to develop and apply scientific principles for better determining which chemicals have a common mechanism of toxicity and evaluating the cumulative effects of such chemicals. The Agency anticipates, however, that even as its understanding of the science of common mechanisms increases, decisions on specific classes of chemicals will be heavily dependent on chemical specific data, much of which may not be presently available.

Although at present the Agency does not know how to apply the information in its files concerning common mechanism issues to most risk assessments, there are pesticides as to which the common mechanism issues can be resolved. These pesticides include pesticides that are toxicologically dissimilar to existing chemical substances (in which case the Agency can conclude that it is unlikely that a pesticide shares a common mechanism of activity with other substances) and pesticides that produce a common toxic metabolite (in which case common mechanism of activity will be assumed).

The Agency does not at this time have data specifically either to support, or to refute a common mechanism of toxicity for peroxy compounds (i.e., hydrogen peroxide, peroxyacetic acid). The Agency believes that based on the known common 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. Although a common mechanism of toxicity may or may not be inferred, the Agency's concerns for cumulative risk is mitigated by the lack of residues of the parent compound (hydrogen peroxide) at proposed use levels, and by the rapid decomposition of the parent compound into products which are not of toxicological concern (i.e., oxygen and water). As data become available, the Agency may require further studies on the peroxy compounds to determine whether a cumulative risk assessment is warranted.

EPA does not have, at this time, available data to determine whether hydrogen peroxide has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, hydrogen peroxide does not appear to produce toxic metabolites. For the purposes of this exemption from the requirement of a tolerance, EPA has not assumed that hydrogen peroxide has a common mechanism of toxicity with other substances.

D. Aggregate Risks and Determination of Safety for U.S. Population

1. *Acute, short- and intermediate-term risk.* The Agency has concluded that no endpoint exists to suggest any evidence of significant toxicity from acute, short term or intermediate term exposures from the proposed food contact uses of hydrogen peroxide. Short- and intermediate-term aggregate exposure takes into account chronic dietary food and water (considered to be a background exposure level) plus indoor and outdoor residential exposure.

The Agency concludes that there is a reasonable certainty of no harm for acute, short term, and intermediate risk from aggregate exposure to hydrogen peroxide under the proposed use concentrations.

2. *Chronic risk.* Residues of hydrogen peroxide are expected to dissociate rapidly on the surface of materials which it contacts. Therefore, the chronic risk from dietary exposure is expected to be negligible. No chronic exposure and risk assessment is required 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 in air into oxygen and water.

The Agency concludes that there is a reasonable certainty of no harm for chronic risk from aggregate exposure to hydrogen peroxide under the proposed use concentrations.

E. Aggregate Cancer Risk for U.S. Population

Available data suggest that hydrogen peroxide acts as a promoter of carcinogenisis at relatively high doses (in excess of 600 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 (i.e., 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 (i.e., catalase and glutathione peroxidases) for breakdown of hydrogen peroxide.

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.

F. Aggregate Risks and Determination of Safety for Infants and Children

Safety factor 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 pre-and post-natal 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 NOEL 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 hydrogen peroxide, because of the lack of any residues of toxicological concern, a NOEL 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 conditions, no increased susceptibility to infants or children is expected to occur.

1. 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).

2. Hydrogen peroxide is highly reactive and short lived because of the inherent instability of the peroxide bond (i.e., 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.

3. 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.

4. 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 Generally Recognized As Safe (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 (i.e., 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.

III. Other Considerations

A. Endocrine Disruption

EPA is required to 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...'' The Agency is currently working with interested stakeholders, including other government agencies, public interest groups, industry and research scientists in developing a screening and testing program and a priority setting scheme to implement this program. Congress has allowed three years from the passage of the FQPA (August, 1999) to implement this program. At that time, the EPA may require further testing of this active ingredient and end use products for endocrine disrupter effects. There is no current evidence to suggest that hydrogen peroxide acts in a manner similar to any known hormone or that it acts as an endocrine disrupter.

B. Analytical Enforcement Methodology

Because an exemption from the requirement of a tolerance is being granted for hydrogen peroxide, an enforcement analytical method is not needed. However, an adequate analytical method (designated QATM 202 by Ecolab, Inc., a redox titration procedure) is available in the interim. Because of the long lead time from establishing a tolerance or exemption of the requirement of a tolerance to publication of the enforcement methodology in the Pesticide Analytical Manual., Volume II, the analytical method is being made available to anyone interested in pesticide enforcement when requested from Norm Cook, Antimicrobials Division (7510W), Office of Pesticide Programs, US Environmental Protection Agency, 401 M Street, SW., Washington, DC 20460. Office location and telephone number: 2800 Crystal Drive, 6th Floor, Arlington, VA 22202, 703-308-6411.

C. Magnitude of Residues

Residues of hydrogen peroxide are short lived on treated crops and are not expected to bioaccumulate in livestock and/or poultry that consume treated feedstuffs. Because of the lack of any residues of toxicological concern, the Agency has waived this data requirement.

D. International Residue Limits

There are no Codex Alimentarius Commission (Codex) Maximum Residue Levels (MRLs) for hydrogen peroxide.

IV. Conclusion

Therefore, the exemption from the requirement of a tolerance is established for residues of hydrogen peroxide up to 120 ppm in or on raw agricultural commodities, in processed commodities, when such residues result from the use of hydrogen peroxide as an antimicrobial agent on fruits, tree nuts, cereal grains, herbs, and spices.

It should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the exemption from the requirement of a tolerance for hydrogen peroxide, if new relevant adverse effects information comes to the Agency's attention.

V. Objections and Hearing Requests

The new FFDCA section 408(g) provides essentially the same process for persons to ''object'' to a tolerance regulation issued by EPA under new section 408(e) and (l)(6) as was provided in the old section 408 and in section 409. However, the period for filing objections is 60 days, rather than 30 days. EPA currently has procedural regulations which govern the submission of objections and hearing requests. These regulations will require some modification to reflect the new law. However, until those modifications can be made, EPA will continue to use those procedural regulations with appropriate adjustments to reflect the new law.

Any person may, by July 6, 1998, file written objections to any aspect of this regulation and may also request a hearing on those objections. Objections and hearing requests must be filed with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25).

Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issues on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the requestor (40 CFR 178.27).

A request for a hearing will be granted if the Administrator determines that the

material submitted shows the following: There is 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 in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

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.

VI. Public Docket

EPA has established a record for this rulemaking under docket control number [OPP–300655] (including any comments and data submitted electronically). A public version of this record, including printed, paper versions of electronic comments, which does not include any information claimed as CBI, is available for inspection from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

The public record is located in Room 119 of the Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

Electronic comments may be sent directly to EPA at:
opp-docket@epamail.epa.gov.

Electronic comments must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this rulemaking, as well as the public version, as described above will be kept in paper form. Accordingly, EPA will transfer any copies of objections and hearing requests received electronically into printed, paper form as they are received and will place the paper copies in the official rulemaking record which will also include all comments submitted directly in writing. The official rulemaking record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

VII. Regulatory Assessment Requirements

This final rule establishes an exemption from the requirement of a tolerance 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) (Pub. L. 104–4). Nor does it require any prior consultation as specified by Executive Order 12875, entitled Enhancing the Intergovernmental Partnership (58 FR 58093, October 28, 1993), or 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 in accordance with Executive Order 13045, entitled Protection of Children from Environmental Health Risks and Safety Risks (62 FR 19885, April 23, 1997).

In addition, since these 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. Nevertheless, the Agency has previously assessed whether establishing tolerances, exemptions from tolerances, raising tolerance levels or expanding exemptions might adversely impact small entities and concluded, as a generic matter, that there is no adverse economic impact. The factual basis for the Agency's generic certification for tolerance actions published on May 4, 1981 (46 FR 24950) and was provided to the Chief Counsel for Advocacy of the Small Business Administration.

VIII. Submission to Congress and the General Accounting Office

Under 5 U.S.C. 801(a)(1)(A), as added by the Small Business Regulatory Enforcement Fairness Act of 1996, the Agency has submitted 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 General Accounting Office prior to publication of this rule in today's **Federal Register**. This 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: April 30, 1998.

Frank Sanders,

Director, Antimicrobials 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. 346a and 371.

2. Section 180.1197 is added to read as follows:

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

An exemption from the requirement of a tolerance is established for residues of hydrogen peroxide up to 120 ppm in or on raw agricultural commodities, in processed commodities, when such residues result from the use of hydrogen peroxide as an antimicrobial agent on fruits, tree nuts, cereal grains, herbs, and spices.

[FR Doc. 98–12037 Filed 5–5–98; 8:45 am]
BILLING CODE 6560–50–F

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 261 and 279

[FRL–5969–4]

Hazardous Waste Management System; Identification and Listing of Hazardous Waste; Recycled Used Oil Management Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: Today's direct final rule eliminates errors and clarifies ambiguities in the used oil management standards. Specifically, this rule clarifies when used oil contaminated with polychlorinated biphenyls (PCBs) is regulated under the used oil management standards and when it is not, that the requirements applicable to releases of used oil apply in States that