unnecessary or contrary to the public interest, an agency may issue a rule without providing notice and an opportunity for public comment. EPA has determined that there is good cause for making today's rule final without prior proposal and opportunity for comment because EPA merely is correcting the effective date of the promulgated rule to be consistent with the congressional review requirements of the Congressional Review Act as a matter of law and has no discretion in this matter. Thus, notice and public procedure are unnecessary. The Agency finds that this constitutes good cause under 5 U.S.C. 553(b)(B). Moreover, since today's action does not create any new regulatory requirements and affected parties have known of the underlying rule since July 24, 1998, EPA finds that good cause exists to provide for an immediate effective date pursuant to 5 U.S.C. 553(d)(3) and 808(2).

II. Administrative Requirements

Under Executive Order 12866 (58 FR 51735, October 4, 1993), this action is not a ''significant regulatory action'' and is therefore not subject to review by the Office of Management and Budget. In addition, this action does not impose any enforceable duty, contain any unfunded mandate, or impose any significant or unique impact on small governments as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). This rule also does not require prior consultation with State, local, and tribal government officials as specified by Executive Order 12875 (58 FR 58093, October 28, 1993) or Executive Order 13084 (63 FR 27655 (May 10, 1998), or involve special consideration of environmental justice related issues as required by Executive Order 12898 (59 FR 7629, February 16, 1994). Because this action is not subject to notice-and-comment requirements under the Administrative Procedure Act or any other statute, it is not subject to the regulatory flexibility provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). This rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because EPA interprets E.O. 13045 as applying only to those regulatory actions that are based on health or safety risks, such that the analysis required under section 5–501 of the Order has the potential to influence the regulation. This rule is not subject to E.O. 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

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. Section 808 allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice and public procedure is impracticable, unnecessary or contrary to the public interest. This determination must be supported by a brief statement. 5 U.S.C. 808(2). As stated previously, EPA has made such a good cause finding, including the reasons therefor, and established an effective date of June 21, 1999. 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 the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

This action only amends the effective date of the underlying rule; it does not amend any substantive requirements contained in the rule. Accordingly, to the extent it is available, judicial review is limited to the amended effective date. Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of the action must be filed in the United States Court of Appeals for the appropriate circuit by August 20, 1999.

Dated: June 14, 1999.

Carol M. Browner,

Administrator.

[FR Doc. 99–15542 Filed 6–18–99; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–300872; FRL–6083–9]

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 the biochemical hydrogen peroxide on all food commodities when applied/used as an algaecide, fungicide, and bactericide at the rate of ≤ 1% hydrogen peroxide per application on growing crops (all food commodities) and postharvest potatoes. Biosafe Systems submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996 requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of hydrogen peroxide.

DATES: This regulation is effective June 21, 1999. Objections and requests for hearings must be received by EPA on or before August 20, 1999.

ADDRESSES: Written objections and hearing requests, identified by the docket control number [OPP–300872], 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–300872], 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, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA.

A copy of objections and hearing requests filed with the Hearing Clerk may be submitted electronically by sending electronic mail (e-mail) to: opp-docket@epa.gov. Copies of electronic objections and hearing requests must be submitted as an ASCII file avoiding 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 5.1/6.1 or ASCII file format. All copies of electronic objections and hearing requests must be identified by the docket control number [OPP–300872]. No Confidential Business Information (CBI) should be submitted through e-mail. Copies of electronic objections and hearing requests on this rule may be filed online at many Federal Depository Libraries.

FOR FURTHER INFORMATION CONTACT: By mail: Anne Ball, c/o Product Manager (PM) 90, Biopesticides and Pollution Prevention Division (7511C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

Office location, telephone number, and e-mail address: 9th fl., Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, 703–308–8717; e-mail address: ball.anne@epa.gov.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 23, 1998 (63 FR 50901) (FRL–6028–4), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a(e), as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104–170) announcing the filing of a pesticide tolerance petition by Biosafe Systems, at that date at 45 E. Woodthrush Trail, East Medford, NJ 08055, at present at 80 Commerce St., Glastonbury, CT 06033. The notice included a summary of the petition prepared by the petitioner Biosafe Systems, the registrant. There were no comments received in response to the notice of filing. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of hydrogen peroxide. By this final rule, EPA is granting the petition. EPA is amending the existing exemption for hydrogen peroxide in accordance with the petition. Based on this action, EPA considers the existing exemption to be reassessed.

I. Risk Assessment and Statutory Findings

New section 408(c)(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(c)(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....'' Additionally, section 408(b)(2)(D) requires that 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.''

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.

II. 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.

Hydrogen peroxide at a concentration of 27.17% has a pH of 1.05 at which concentration EPA assumes a toxicity category I for skin and eye irritation. Biosafe has submitted toxicology information from open literature for aqueous solutions containing 6% hydrogen peroxide and for aqueous solutions containing 50% hydrogen peroxide. The concentrate (27.17% hydrogen peroxide) will be diluted with water at the rate of 1:50 or 1:100 or 1:300 and thus, the concentration of hydrogen peroxide in the product at the time of application will range from 0.09% to 0.54%. The information from open literature demonstrated that solutions containing 6% hydrogen peroxide have an acute oral $LD_{50} \geq 5,000$ milligram/kilogram (mg/kg) in rats (toxicity category III), an acute dermal $LD_{50} \geq 10,000$ mg/kg in rabbits (toxicity category IV), and an inhalation LC_{50} of 4 milligram/liter (mg/l) (toxicity category IV). The 6% hydrogen peroxide solutions are mild irritants to rabbit skin and cause severe irreversible corneal injury in half of the exposed rabbits (toxicity category I). Toxicology information from open literature demonstrated that solutions which contained 50% hydrogen peroxide have an acute oral $LD_{50} \leq 500$ mg/kg in rats (toxicity category II), and an acute dermal $LD_{50} \leq 1,000$ mg/kg in rabbits(toxicity category II). No deaths resulted after an 8–hour exposure of rats to saturated vapors of 90% hydrogen peroxide, LC_{50} = 4 mg/l (2,000 ppm). Solutions which contain 50% hydrogen peroxide also are extremely irritating (corrosive) to rabbit eyes (toxicity category I).

EPA has concluded that for food use at an application rate of ≤ 1% hydrogen peroxide no apparent acute toxicity and subchronic toxicity end points exist to suggest a significant toxicity. An RfD (chronic toxicity) for hydrogen peroxide has not been estimated because of its short half-life in the environment and lack of any residues of toxicological concern. For similar reasons, an additional safety factor was not judged necessary to protect the safety of infants and children. Additionally, hydrogen peroxide is listed by the Food and Drug Administration as Generally Recognized As Safe (GRAS). Additionally hydrogen peroxide is used to treat food at a maximum level of 0.05% in milk used in cheesemaking, 0.04% in whey, 0.15% in starch and corn syrup, and 1.25% in emulsifiers containing fatty acid esters as bleaching agents (21 CFR 184.1366). As a GRAS substance hydrogen peroxide may be used in washing or to assist in the lye peeling of fruits and vegetables (21 CFR 173.315).

III. Aggregate Exposures

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

A. Dietary Exposure

1. *Food*. For the proposed uses the concentrate of hydrogen peroxide will be diluted with water at the rate of 1:50, 1:100 or 1:300 corresponding to a low concentration of hydrogen peroxide in the product at the time of application (0.09–0.54%). The solution, having a low concentration of hydrogen peroxide, reacts on contact with the surface on which it is sprayed and degrades rapidly to oxygen and water. Therefore residues in or on treated food commodities of the algaecide/fungicide/bactericide hydrogen peroxide are expected to be negligible. Additional sources of the GRAS substance hydrogen peroxide in concentrations range from 0.04% to 1.25% in various foods as cited above (21 CFR 184.1366).

2. *Drinking water exposure*. At the proposed application rates, the use of hydrogen peroxide as an algaecide, fungicide, and bactericide to treat food commodities could result in a minimal transfer of residues to potential drinking water sources. This is due to the low application rate and the rapid chemical degradation of hydrogen peroxide into oxygen and water neither of which is of toxicological concern.

B. Other Non-Occupational Exposure

There may be minimal amounts of non-dietary exposure to hydrogen peroxide in homes through the infrequent and short topical use of the substance in treating minor skin injuries and in its use in oral mouthwashes. Exposure is expected to be minimal also because of the rapid chemical degradation of hydrogen peroxide into oxygen and water.

IV. Cumulative Effects

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

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

Because hydrogen peroxide is of low toxicity, 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 food commodities for hydrogen peroxide when applied at ≤ 1% will not pose a dietary risk under reasonably foreseeable circumstances. Further, the EPA Office of Water has stated that it has seen no new data that contradict the assessment previously given, which is that low concentrations of hydrogen peroxide do not typically persist in drinking water at levels that pose a health risk. Accordingly, EPA concludes that there is a reasonable certainty of no harm to consumers, including infants and children, from aggregate exposure to hydrogen peroxide.

VI. Other Considerations

A. Endocrine Disruptors

There is no evidence to suggest that hydrogen peroxide in the proposed concentrations will adversely affect the endocrine system.

B. Analytical Method(s)

An analytical method for the detection of residues of hydrogen peroxide is not applicable to this tolerance exemption because of the low concentration of hydrogen peroxide in the product at the time of application at the time of application (≤ 1%) and its rapid degradation to water and oxygen on contact with crops.

C. Codex Maximum Residue Level

There are no Codex Maximum Residue Levels (MRLs) established for residues of hydrogen peroxide.

VII. Objections and Hearing Requests

The new FFDCA 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) and 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 governs 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 August 20, 1999, 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 under the ''ADDRESSES'' section (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). 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 tolerance objection fee waivers, contact James Tompkins, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location, telephone number, and e-mail address: Rm. 239, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, (703) 305–5697, tompkins.jim@epa.gov. Requests for waiver of tolerance objection fees should be sent to James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

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). 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). 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.

VIII. Public Record and Electronic Submissions

EPA has established a record for this regulation under docket control number [OPP–300872] (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.

Objections and hearing requests may be sent by e-mail directly to EPA at:

opp-docket@epa.gov

E-mailed objections and hearing requests must be submitted as an ASCII file avoiding the use of special characters and any form of encryption.

The official record for this regulation, as well as the public version, as described in this unit 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 record which will also

include all comments submitted directly in writing. The official record is the paper record maintained at the Virginia address in ''ADDRESSES'' at the beginning of this document.

IX. Regulatory Assessment Requirements

A. Certain Acts and Executive Orders

This final rule establishes an exemption from the tolerance requirement under section 408(d) of the FFDCA 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 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 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 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.

B. Executive Order 12875

Under Executive Order 12875, entitled *Enhancing the Intergovernmental Partnership* (58 FR 58093, October 28, 1993), EPA may not issue a regulation that is not required by statute and that creates a mandate upon a State, local or tribal government, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by those governments. If the mandate is unfunded, EPA must provide to OMB a description of the extent of EPA's prior consultation with representatives of affected State, local, and tribal governments, the nature of their concerns, copies of any written communications from the governments, and a statement supporting the need to issue the regulation. In addition, Executive Order 12875 requires EPA to develop an effective process permitting elected officials and other representatives of State, local, and tribal governments ''to provide meaningful and timely input in the development of regulatory proposals containing significant unfunded mandates.''

Today's rule does not create an unfunded Federal mandate on State, local, or tribal governments. The rule does not impose any enforceable duties on these entities. Accordingly, the requirements of section 1(a) of Executive Order 12875 do not apply to this rule.

C. Executive Order 13084

Under Executive Order 13084, entitled *Consultation and Coordination with Indian Tribal Governments* (63 FR 27655, May 19, 1998), EPA may not issue a regulation that is not required by statute, that significantly or uniquely affects the communities of Indian tribal governments, and that imposes substantial direct compliance costs on those communities, unless the Federal government provides the funds necessary to pay the direct compliance costs incurred by the tribal governments. If the mandate is unfunded, EPA must provide OMB, in a separately identified section of the preamble to the rule, a description of the extent of EPA's prior consultation with representatives of affected tribal governments, a summary of the nature of their concerns, and a statement supporting the need to issue the regulation. In addition, Executive Order 13084 requires EPA to develop an effective process permitting elected officials and other representatives of Indian tribal governments ''to provide meaningful and timely input in the development of regulatory policies on matters that significantly or uniquely affect their communities.''

Today's rule does not significantly or uniquely affect the communities of Indian tribal governments. This action does not involve or impose any requirements that affect Indian tribes. Accordingly, the requirements of section 3(b) of Executive Order 13084 do not apply to this rule.

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 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 the rule in the **Federal Register**. This 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: June 3, 1999.

Kathleen D. Knox,

Acting Director, Biopesticides and Pollution Prevention 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.

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 ≤ 1% hydrogen peroxide per application on growing crops and postharvest potatoes when applied as an algaecide, fungicide and bactericide.

[FR Doc. 99–15718 Filed 6–18–99; 8:45 am]

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