(c) *Regulations.* (1) Entry into or movement within these zones, including below the surface of the water, during times in which high interest vessels are present and the zones are enforced is prohibited unless authorized by the COTP Providence or authorized representative.

(2) The general regulations covering safety and security zones in §§ 165.23 and 165.33, respectively, of this part apply.

(3) All persons and vessels shall comply with the instructions of the COTP, and the designated on-scene U.S. Coast Guard personnel. On-scene Coast Guard patrol personnel include commissioned, warrant, and petty officers of the Coast Guard on board Coast Guard, Coast Guard Auxiliary, local, state, and federal law enforcement vessels.

Dated: August 19, 2002.

Mary E. Landry,

Captain, Coast Guard, Captain of the Port, Providence, Rhode Island.

[FR Doc. 02–22339 Filed 8–30–02; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP–2002–0217; FRL–7196–6]

Lactic acid, ethyl ester and Lactic acid, n-butyl ester; Exemptions from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes two exemptions from the requirement of a tolerance for residues of lactic acid, ethyl ester and lactic acid, n-butyl ester when used in pesticide formulations. PURAC America, Inc. submitted two petitions to EPA under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996, requesting these exemptions from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of lactic acid, ethyl ester and lactic acid, n-butyl ester.

DATES: This regulation is effective September 3, 2002. Objections and requests for hearings, identified by docket ID number OPP–2002–0217, must be received on or before November 4, 2002.

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 ID number OPP–2002–0217 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Kathryn Boyle, Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: 703–305–6304; e-mail address: boyle.kathryn@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Categories	NAICS codes	Examples of potentially affected entities
Industry	111 112 311 32532	Crop production Animal production Food manufacturing Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically*. You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at http://www.epa.gov/. To access this document, on the Home Page select ''Laws and Regulations, '' ''Regulations and Proposed Rules,'' and then look up the entry for this document under the ''**Federal Register**—Environmental Documents.'' You can also go directly to the **Federal Register** listings at http://www.epa.gov/fedrgstr/. A frequently updated electronic version of 40 CFR part 180 is available at http://www.access.gpo.gov/nara/cfr/cfrhtml_00/Title_40/40cfr180_00.html, a beta site currently under development.

2. *In person*. The Agency has established an official record for this action under docket control number OPP–2002–0217. 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 April 12, 2000 (65 FR 19759) (FRL–6498–8), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, as amended by the Food Quality Protection Act (FQPA) (Public Law 104–170), announcing the filing of pesticide tolerance petitions (PP 5E4510 and 5E4515) by PURAC America, Inc., Barclay Boulevard, Lincolnshire Corporate Center, Lincolnshire, IL 60069. This notice included a summary of the petitions prepared by the petitioner PURAC. There were no comments received in response to the notice of filing.

The petitions requested that 40 CFR 180.1001(c) and (e) be amended by establishing an exemption from the requirement of a tolerance for residues of ethyl lactate (CAS Reg. No. 97–64–3), also known as lactic acid, ethyl ester, and butyl lactate (CAS Reg. No. 138–22–7), also known as lactic acid, n-butyl ester.

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. Human Health Assessment

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 lactic acid, ethyl ester and lactic acid, n-butyl ester are discussed in this unit.

A. Toxicological Profile (Agency-Reviewed Studies) for Lactic Acid, Ethyl Ester (Ethyl Lactate)

1. *Acute oral toxicity in the rat.* Groups of five young adult outbred rats/sex were given a single oral dose of 2,000 milligrams/kilogram (mg/kg). All animals survived the 14–day observation period. No significant treatment-related effects on body weight were observed during the study, and gross necropsies of animals sacrificed after 14 days revealed no observable abnormalities. The lethal dose (LD_{50}) is greater than 2,000 mg/kg (males; females).

2. *Dermal developmental toxicity in the rat.* Lactic acid, ethyl ester was administered percutaneously to 25 rats/dose at dose levels of 0 (sham), 517, 1,551, or 3,619 mg/kg/day for 6 hours/day on days 6–15 of gestation. No systemic toxicity was noted at any dose level. Body weights, body weight gains, feed consumption, mortality, clinical signs of toxicity, and cesarean section parameters were unaffected by treatment. There were no treatment-related effects found on caesarean section examinations of the dams or external, visceral, or skeletal examinations of the fetuses. Both the maternal and developmental no observed adverse effect level (NOAEL) was 3,619 mg/kg/day, the highest dose tested. The lowest observed adverse effect level (LOAEL) was not determined, but would be greater than 3,619 mg/kg/day.

3. *Inhalation studies.* Three inhalation studies using lactic acid, ethyl ester were also submitted. However, the Agency was not able to use this information since the aerodynamic particle sizes (the mass median aerodynamic diameter (MMAD) and distribution of measurements) and the time required to reach equilibrium of the generated aerosols were not provided.

B. Toxicological Profile (Agency-Reviewed Studies) for Lactic Acid, n-Butyl Ester (Butyl Lactate)

1. *Acute oral toxicity in the rat.* Groups of five young adult outbred rats/sex were given a single oral dose of 2,000 mg/kg. All animals survived the 14–day observation period. No treatment-related effect on body weight was observed during the study and gross necropsies of animals sacrificed after 14 days revealed no observable abnormalities. The LD_{50} is greater than 2,000 mg/kg (males; females)

2. *Acute inhalation toxicity in the rat.* Groups of five young adult outbred rats/sex were given a whole body exposure to n-butyl-S-(-)- lactate vapor at 5.14 milligrams/liter (mg/L) (greater than 2X limit concentration) for 4 hours. All animals survived the 4–hour exposure period and 14–day observation periods. Moderately decreased breathing frequencies, wet fur (nose/head), were observed in 10/10 animals during and just following exposure. Effects subsided from all animals by day 1. No treatment-related effects on body weight were observed during the study, and gross necropsy after 14 days revealed no abnormalities. The lethal concentration (LC_{50}) is greater than 5.14 mg/L.

C. Structure Activity Relationship Assessment

For lactic acid, ethyl ester and lactic acid, n-butyl ester], toxicity was assessed, in part, by a process called structure-activity relationship (SAR). In this process, the chemical's structural similarity to other chemicals (for which data are available) is used to determine toxicity. For human health, this process, can be used to assess absorption and metabolism, mutagenicity, carcinogenicity, developmental and reproductive effects, neurotoxicity, systemic effects, immunotoxicity, and sensitization and irritation. This is a qualitative assessment using terms such as good, not likely, poor, moderate, or high.

For lactic acid, ethyl ester and lactic acid, n-butyl ester the SAR assessment determined that the chemical was not structurally related to any known carcinogens or developmental/reproductive toxicants. The following human exposures were examined as part of the analysis: inhalation, dermal, exposures to the eyes, and drinking water. For both chemicals, absorption is expected to be good (well-absorbed) for all routes based on analog data. It was noted that ester hydrolysis would be expected to release the corresponding alcohol. Both chemicals would be expected to be irritating to mucous membranes, and there is the possibility of irritation to the lungs and eyes. For both lactic acid, ethyl ester and lactic acid, n-butyl ester, the overall rating for human health is low concern.

The SAR did note a concern for solvent neurotoxicity, i.e., neurotoxic effects that can occur due to high and/or prolonged dermal and inhalation exposures to organic solvents. According to the SAR, the greatest concerns for both ethyl and butyl lactate, based on their structural chemistry and chemical class, are concerns for possible solvent neurotoxicity and irritation to mucous membranes, lungs and eyes. It should be noted that the inclusion of the phrase concerns for solvent-type neurotoxicity in the SAR assessment does not necessarily indicate chemical-specific concerns. By including this statement those performing the assessment are acknowledging that the chemical is a member of a class of chemicals that can exhibit solvent neurotoxicity.

D. Findings of the FAO/WHO Expert Committee on Food Additives

Ethyl lactate has been examined at several meetings of the (United Nations Food and Agriculture Organization/World Health Organization) FAO/WHO Joint Expert Committee on Food Additives (JECFA). At the last meeting, the absorption and metabolism of ethyl lactate was extensively studied. There has long been evidence that in mammals simple esters such as ethyl lactate readily undergo hydrolysis, yielding the

alcohol and acid from which the ester was formed. In the case of ethyl lactate, this would be ethyl alcohol (ethanol) and lactic acid. The human metabolism of ethanol is well understood: it is oxidized to carbon dioxide and water. The metabolism of lactic acid is also understood: it is an intermediate in human metabolism of glucose. The Committee determined that recent *in vivo* and *in vitro* studies indicated that ethyl-L-lactate was hydrolysed to ethyl alcohol and lactic acid mainly prior to absorption. Based on this understanding of the metabolism of ethyl lactate, the Committee also determined that it was not necessary to specify an estimate of acceptable daily intake.

E. Conclusions

The SAR assessments did not identify any concerns for carcinogenicity or developmental toxicity for either of these lactate esters. In fact, both lactic acid, ethyl ester and lactic acid, n-butyl ester were judged to be of low concern. The only concerns identified were for possible solvent neurotoxicity and irritation to mucous membranes, lungs and eyes. These identified concerns are for the dermal and inhalation exposure routes and are addressed through the use of protective equipment such as gloves and respirators, not through establishment of tolerance exemptions.

The lactic acid, ethyl ester dermal developmental toxicity study indicates low toxicity to both the mother and the developing fetus. Both the developmental and maternal NOAELs (3,619 mg/kg/day) are the highest dose tested. Given the structural similarities of the two chemicals, the Agency believes that the developmental toxicity study can be bridged to lactic acid, n-butyl ester.

The JECFA monograph deemed lactic acid, ethyl ester to be of such low concern that the acceptable daily intake is not specified. A consideration in this decision was the understanding that hydrolysis would occur in the human body thus yielding ethanol and lactic acid. The same hydrolysis would occur for lactic acid, n-butyl ester but would yield butanol and lactic acid. Butanol is also metabolized in the human body butanol is oxidized to butyraldehyde, which is oxidized to butyric acid, which is then metabolized via the fatty acid and tricarboxylic acid pathways. Thus, the human body has a known pathway to metabolize lactic acid, ethyl ester and lactic acid, n-butyl ester, and their metabolites.

IV. 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).

For lactic acid, ethyl ester and lactic acid, n-butyl ester a qualitative assessment for all pathways of human exposure (food, drinking water, and residential) is appropriate given the SARs which judged lactic acid, ethyl ester and lactic acid, n-butyl ester to be of low concern and the body's ability to metabolize lactic acid, ethyl ester and lactic acid, n-butyl ester, and their metabolites.

V. Cumulative Effects

Section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider available information concerning the cumulative effects of a particular pesticide's residues and other substances that have a common mechanism of toxicity. Lactic acid, ethyl ester and lactic acid, n-butyl ester are structurally related; however, both are lower toxicity chemicals; therefore, the resultant risks separately and/or combined should also be low. EPA does not have, at this time, available data to determine whether lactic acid, ethyl ester and lactic acid, n-butyl ester have a common mechanism of toxicity with other substances or how to include these pesticide chemicals in a cumulative risk assessment.

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

Based on the available date, the SAR assessment indicating low concern, and information on the metabolism of lactic acid, ethyl ester and lactic acid, n-butyl ester, EPA concludes that lactic acid, ethyl ester and lactic acid, n-butyl ester do not pose a dietary risk under reasonably foreseeable circumstances. Accordingly, EPA finds that there is a reasonable certainty that no harm will result to the general population, and to infants and children from aggregate exposure to lactic acid, ethyl ester and lactic acid, n-butyl ester. For both lactic acid, ethyl ester and lactic acid, n-butyl ester, due to the expected low oral toxicity, a safety factor analysis has not been used to assess the risk. For the same reasons and especially considering the developmental toxicity NOAEL, the additional tenfold safety factor for the protection of infants and children is unnecessary.

VII. Other Considerations

A. Endocrine Disruptors

FQPA requires EPA to develop a screening program to determine whether certain substances, including all pesticide chemicals (both inert and active ingredients), 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 to develop a screening and testing program as well as a priority setting scheme. As the Agency proceeds with implementation of this program, further testing of products containing lactic acid, ethyl ester and lactic acid, n-butyl ester for endocrine effects may be required.

B. Analytical Method(s)

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. Existing Tolerances

There are no existing tolerances or tolerance exemptions for ethyl and butyl lactate.

D. International Tolerances

The Agency is not aware of any country requiring a tolerance for lactic acid, ethyl ester and lactic acid, n-butyl ester nor have any CODEX Maximum Residue Levels (MRLs) been established for any food crops at this time.

E. List 4A Classification

It has been determined that lactic acid, ethyl ester and lactic acid, n-butyl ester are to be classified as List 4A inert ingredients. Thus, the tolerance exemptions will be established in 40 CFR 180.950 instead of 40 CFR 180.1001(c) and (e) as requested by the petitioner PURAC.

VIII. Conclusions

Based on the information in the record, summarized in this preamble, EPA concludes that there is a reasonable certainty of no harm from aggregate exposure to residues of lactic acid, ethyl ester and lactic acid, n-butyl ester. Accordingly, EPA finds that exempting lactic acid, ethyl ester and lactic acid, n-butyl ester from the requirement of a tolerance will be safe.

IX. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA

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

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

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP–2002–0217 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 November 4, 2002.

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 ID number OPP–2002–0217, 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 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

X. Regulatory Assessment Requirements

This final rule establishes an exemption from the tolerance requirement under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, this rule is not subject to Executive Order 13211, *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, or impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104–4). Nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); or OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113, section 12(d) (15 U.S.C. 272 note). Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not

require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure ''meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.'' ''Policies that have federalism implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.'' This final rule directly regulates growers, food processors, food handlers, and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). For these same reasons, the Agency has determined that this rule does not have any ''tribal implications'' as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure ''meaningful and timely input by tribal officials in the development of regulatory policies that have tribal implications.'' ''Policies that have tribal implications'' is defined in the Executive Order to include regulations that have ''substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and the Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.'' This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

XI. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a ''major rule '' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 19, 2002.

Debra Edwards,

Acting Director, Registration 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), 346(a) and 374.

2. Section 180.950 is amended by adding and reserving paragraph (d) and adding a new paragraph (e) to read as follows:

§ 180.950 Tolerance exemptions for minimal risk active and inert ingredients.

* * * * *

(d) [Reserved]

(e) *Specific chemical substances.* Residues resulting from the use of the following substances as either an inert or an active ingredient in a pesticide chemical formulation, including antimicrobial pesticide chemicals, are exempted from the requirement of a tolerance under FFDCA section 408, if such use is in accordance with good agricultural or manufacturing practices.

Chemical	CAS No.
Lactic acid, n-butyl ester	138-22-7
Lactic acid, ethyl ester	197–64–3

[FR Doc. 02–22369 Filed 8–30–02; 8:45 am]

BILLING CODE 6560–50–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 020306047–2047–01; I.D. 082302A]

Fisheries of the Northeastern United States; Summer Flounder, Scup, and Black Sea Bass Fisheries; Adjustment to the 2002 Black Sea Bass Total Allowable Landings (TAL)

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notification of restoration to the 2002 black sea bass TAL.

SUMMARY: NMFS restores 10,000 lb (4,534 kg) of unused research set-aside to the 2002 black sea bass TAL, and makes corresponding adjustments to the 2002 black sea bass recreational harvest limit and the 2002 Quarter 4 commercial quota. This action complies with Framework Adjustment 1 to Summer Flounder, Scup, and Black Sea Bass Fishery Management Plan (FMP), which implemented procedures for setting aside up to 3 percent of the annual TAL to fund research activities for the summer flounder, scup, and black sea bass fisheries. Framework Adjustment 1 also specified that, if a research proposal is disapproved by NMFS or the NOAA Grants Office, the research set-aside for that proposal would be reallocated (i.e., added back) into the TAL. On June 21, 2002, NMFS disapproved a research project for which 10,000 lb (4,534 kg) of the black sea bass TAL had been set-aside. The intent of this action is to restore 10,000 lb (4,536 kg) to the overall 2002 black sea bass TAL.

DATES: Effective September 3, 2002.

FOR FURTHER INFORMATION CONTACT: Richard A. Pearson, Fishery Policy Analyst, (978) 281–9279.

SUPPLEMENTARY INFORMATION:

Background

NMFS published a final rule in the **Federal Register** on August 10, 2001 (66 FR 42156), implementing Framework Adjustment 1 to the FMP. Framework Adjustment 1 implemented procedures for setting aside up to 3 percent of the annual TAL to fund research activities for the summer flounder, scup, and black sea bass fisheries. Framework Adjustment 1 also specified that, if a proposal is disapproved by NMFS or the NOAA Grants Office, the research set-